DRAFT RECOMMENDATIONS OF THE INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

FOR CONSULTATION AND ICRP INTERNAL USE ONLY

Comments on this updated draft are invited, through the consultation form at **www.icrp.org**, no later than **15 September 2006**.

The present updated draft was prepared taking account of the many helpful comments received during consultation on the first draft and on various documents underpinning the Recommendations (health risks; dosimetry; optimisation; representative person). In this second round of consultation the Commission calls attention, at the appropriate chapters in the draft, to issues where additional comments providing specific guidance would be particularly welcome.

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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 the biological and physical assumptions and concepts required updating, although they have proved robust in the main. 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, it has also become apparent that the radiological protection of non-human species should receive more emphasis than in the past. -Finally, there have been societal developments in that more transparency is expected in developing new recommendations that could be accepted globally.

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.

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.

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)

The work of the Commission was greatly aided by significant contributions from P. Burns, H. Menzel, and J. Cooper.

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 the 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 is financed mainly by voluntary contributions from international and national governmental bodies with an interest in radiological protection. Some additional funds accrue from royalties on the Commission's publications. Members' institutions also provide support by making in-kind contributions.

(4) The Commission works closely with its sister body, the International Commission on Radiation Units and Measurements, and has official relationships with the World Health Organization and the International Atomic Energy Agency. It also has important relationships with the International Labour Organization and other United Nations bodies, including the United Nations Scientific Committee on the Effects of Atomic Radiation and the United Nations Environment Programme. Other organisations with which it works include the European Commission of the European Union, the Nuclear Energy Agency of the Organization for Economic Co-operation and Development, the International Standards Organization, and the International Electro-technical Commission. The Commission also maintains contact with the professional radiological community through its strong links with the International Radiation Protection Association. The Commission also takes account of progress reported by major national organisations.

1.2. The development of the Commission's recommendations

(5) 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 annual individual dose of about 1000 millisievert (mSv). 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).

(6) The development of both the military and industrial uses of nuclear energy led the Commission in the early nineteen-fifties 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 introduced the optimisation principle. This was successively formulated as the recommendation to maintain exposure 'to the lowest possible level' (1954), '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). In 1990, the annual dose limits were further reduced to respectively 20 mSv per year on the average for workers and 1 mSv per year on the average for the public based on the revision of the risk for stochastic effects estimated from the Hiroshima –Nagasaki atomic bomb survivors (ICRP, 1991).

(7) The Commission's first report in the current series, subsequently numbered Publication 1 (1959), contained the recommendations approved in 1958. Subsequent general recommendations have appeared as Publication 6 (1964), Publication 9 (1966), and Publication 26 (1977). In 1977, 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. In 1990, the Commission produced new 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 Protection, rather than one of dose limitation (ICRP, 1991). The principles of justification, optimisation and individual dose limitation remained, but more stringent requirements were placed on the optimisation of protection from sources by restricting maximum doses by constraints so as to limit the inequity that is likely to result from inherent economic and societal judgements. Subsequent reports providing advice on more specialised topics have been published.

(8) Since *Publication 60,* there has been a series of publications that have provided additional guidance for the control of exposures from radiation sources (Table 1). 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 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).

Table 1. ICRP Policy Guidance issued since *Publication 60*.

Publication No. (Reference)	Publication Title
Publication 62 (ICRP, 1991c)	Radiological Protection in Biomedical Research
Publication 63 (ICRP, 1993a)	Principles for intervention for Protection of the Public in a Radiological Emergency
Publication 64 (ICRP, 1993b)	Protection from Potential Exposure: A Conceptual Framework
Publication 65 (ICRP, 1994a)	Protection against Radon-222 at Home and at Work
Publication 68 (ICRP, 1994b)	Dose Coefficients for Intakes of Radionuclides by Workers
Publication 73 (ICRP, 1996)	Radiological Protection and Safety in Medicine
Publication 75 (ICRP, 1997a)	General Principles for Radiation Protection of Workers
Publication 76 (ICRP, 1997b)	Protection from Potential Exposures: Application to Selected Radiation Sources
Publication 77 (ICRP, 1998a)	Radiological Protection Policy for the Disposal of Radioactive Waste
Publication 81 (ICRP, 2000a)	Radiation protection Recommendations as Applied to the Disposal of Long-lived Solid Radioactive Waste
Publication 82 (ICRP, 2000b)	Protection of the Public in Situations of Prolonged Radiation Exposure
Publication 84 (ICRP, 2000c)	Pregnancy and Medical Radiation
Publication 91 (ICRP, 2003b)	A Framework for Assessing the Impact of Ionising Radiation on Non-Human Species
Publication 94 (ICRP, 2004a)	Release of Patients after Therapy with Unsealed Radionuclides

(9) The Commission's 1990 system of protection, set out in Publication 60, was the result of developments over some 30 years. During this period, the system became increasingly complex as the Commission sought to reflect the many situations to which the system applied. This complexity involved the justification of practices, the optimisation of protection, including the use of source-related dose constraints, and of individual-related dose limits. It was also necessary to deal separately with (i) the prospective design of protection for practices that are subject to control with the objective of restricting any dose additional to background doses, and (ii) with the establishment of protective actions for emergency and existing exposure situations for which the only feasible controls are some kind of intervention to reduce the doses. These two distinct types of situations were termed simplistically as 'practices' and 'interventions'. The Commission also found it necessary to apply the recommendations in different ways to occupational, medical, and public exposures. All these categorisations created a complexity that has not always been easy to explain.

(10) In 1996, the relevant intergovernmental international organisations within the United Nations established the *International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources*

('BSS', IAEA 1996a), which follow the Commission's recommendations set out in *Publication 60* (1991b). 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 1984 and 1996, respectively.

(11) 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. The major features of the revised Recommendations are:

- Maintaining the Commission's three fundamental principles of radiological protection, namely justification, optimisation and dose limitation, and clarifying how they apply to radiation sources delivering exposure and to individuals receiving exposure. This includes establishing source-related principles that apply to all controllable exposure situations, which the revised recommendations now 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;
- Using the same conceptual approach for constraining doses in source-related protection, which should be applicable to all exposure situations, regardless of the type of source. The dose constraints would then quantify the most fundamental levels of protection for workers and the public from single sources in all situations;
- Complementing the limits and constraints with the requirement to optimise protection at a source;
- Bringing up to date the understanding of the biology and physics of radiation exposure, and consequently updating the radiation and tissue weighting factors in the dosimetric quantity effective dose; and;

- Including a policy approach for radiological protection of non-human species.

(12) 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. 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 changes to radiological protection regulations that are appropriately based on its previous Recommendations in ICRP 60 and subsequent policy guidance.

(13) The current recommendations reiterate the importance of optimisation in radiological protection and extend the successful experience in the implementation of this requirement for practices to other situations. 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). The system of protection now recommended by the Commission is to be seen as both an evolution of, and a further clarification of, the 1990 recommendations.

(14) The principles of justification, optimisation and limitation elaborated in Publication 60 still apply. They have been clarified as to their application to source - or individual-related protection and more emphasis is placed on source-related constraints and optimisation.

(15) These consolidated Recommendations are supported by a series of foundation documents and supporting documents termed 'building blocks', which elaborate on important aspects of the Commission's policy. The foundation documents address the following topics:

- 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*).

- Basis for dosimetric quantities used in radiological protection and their application (Annex B to these *Recommendations*).

Additional guidance is provided on the following topics:

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

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

- The concept and use of reference animals and plants for the purposes of radiological protection (*Publication YY*, ICRP, 200Y)

- Radiological protection in medical exposure of patients (*Publication ZZ*, ICRP, 200z).

- The scope of radiological protection: exemption and exclusion (*Publication WW*, ICRP, 200W)

(16) The system of protection of humans is based on the use of a) reference anatomical and physiological models of the human being, 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 anticipated 'dose per unit intake' of different radionuclides 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.

(17) 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 averaging over age groups and both genders. The dosimetric quantity recommended for radiological protection, effective dose, is also computed by age- and gender-averaging. 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.

(18) 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 (from all radiation sources), characterisation of the relevant biological processes (primarily through DNA damage) and risk characterisation involving reference values.

(19) 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. It 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.

(20) The Commission continues to believe that this is likely to be the case in general terms under 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 10.

(21) The Commission's recommendations cover exposures to sources, insofar as they are controllable (i.e., that actions can be taken to restrict exposures from the source). The advice of the Commission is aimed principally at the regulatory authorities and operators that have responsibility for establishing protection standards, as well as their specialist advisers. 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 is an advisory body that offers its recommendations to regulatory and advisory agencies, mainly by providing 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. The Commission hopes that its advice is of help to regulators and operators, to the professional staff whom they use as their advisers, and to individuals who make decisions about health protection associated with the use of ionising radiation.

(22) The Commission does not recommend gender-specific data for the purposes of radiological protection, and continues to present gender-averaged tissue weighting factors and numerical risk estimates. However, for the purposes of retrospective evaluation of radiation-related risks, such as in epidemiologic studies, it is appropriate to use gender-specific data and calculate gender-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 should not be used for epidemiological evaluations, nor should it be used for any specific investigation of human exposure. 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.

(23) These recommendations, as in previous reports, are confined to protection against ionising radiation. The Commission recognises the importance of adequate control over sources of non-ionising radiation. The International Commission on Non-ionizing Radiation Protection, ICNIRP, provides recommendations concerning such sources (ICNIRP, 2004).

(24) 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 medical exposure of patients. Chapter 7 deals with natural exposures and chapters 8 and 9 describe potential exposures and emergency exposures, respectively. Chapter 10 discusses protection of the environment. Chapter 11 deals with implementation of the Commission's recommendations.

2. THE AIMS AND SCOPE OF THE RECOMMENDATIONS

2.1. The aims of the Recommendations

(25)   The primary aim of the Commission 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.

(26)   This aim cannot be achieved solely on the basis of scientific knowledge on radiation exposure and its health effects. It also requires a paradigm, i.e., a model for protecting humans and the environment against radiation. Scientific data, such as those concerning health risks attributable to radiation exposure are a necessary condition, but societal and economic aspects of protection have to be considered. All 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. It is not the Commission's task to give advice on underlying ethical and economic policies, although it continues to strive to be aware of society's attitudes. 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.

(27)   While endeavours involving radiation exposure can be beneficial, the exposure itself must be treated with care rather than fear and its risks should be kept in perspective, both with the benefits of uses and with other individual and societal risks. The procedures currently available to restrict the exposures from ionising radiation are sufficient, if used properly, to ensure that the associated risks remain a minor component of the spectrum of risks to which people are subjected throughout life.

2.2. The structure of the system of protection

(28)   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 accidents. 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.

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

these effects occurring long after exposure. At low doses, of the order of those caused by natural background radiation, 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 hypothesis or LNT, is considered by the Commission to be the best approach to managing risk from radiation exposure.

(30) The probabilistic nature of stochastic effects makes 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 hypothesis 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:

Source related:
- **The principle of justification:** Any decision that alters the radiation exposure situation, e.g., by introducing a new radiation source or by reducing existing exposure, should do more good than harm, i.e., yield an individual or societal benefit that is higher than the detriment it causes.

- **The principle of optimisation of protection:** The level of protection should be the best under the prevailing circumstances, i.e., maximising the margin of good over harm. To avoid serious inequities resulting from the optimisation procedure, there should be restrictions on the doses or risks to individuals from a particular source (dose or risk constraints). Thus, optimisation involves keeping exposures as low as reasonably achievable taking into account economic and societal factors, as well as any inequity in the distribution of doses and benefits amongst those exposed.

Individual related:
- **The principle of limitation of maximum doses:** In planned situations, the total dose to any individual from all regulated sources should not exceed the appropriate limits specified by the Commission.

These principles are discussed in Chapter 5.

(31) In protecting individuals from the harmful effects of ionising radiation, it is the control of radiation doses that is important, no matter what the source. The Commission defines controllable dose as the dose or the sum of the doses to an individual from a particular source that can reasonably be controlled by whatever means. Such doses could be received at work, in medical practice and in the environment from the use of man-made sources of radionuclides, or could arise from elevated levels of natural radiation and radionuclides, including radon. The term covers doses that are being received e.g., from radon, and doses that are to be received in the future, e.g., from the introduction of new sources or following an actual or potential accident. Exposures from situations excluded from legislation because they are not amenable to control, are by definition uncontrollable exposures.

(32) The principal subdivisions 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 (certain 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;

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

- The implementation of the recommendations by users, operators and regulators of radiation sources, public health authorities, and employers, the workforce, and the public at large.

(33) In these Recommendations, the Commission uses the same conceptual approach in the source-related protection, regardless of the type of source. This means that optimisation of protection is always constrained by a level of dose where action is almost always warranted. This level of dose, or constraint, is aimed at not selecting in the process of optimisation any protection options that would involve individual doses above the selected constraint. Compliance with the constraint is not in itself considered sufficient within the system of protection. The principle of optimisation of protection applies in all circumstances, including those where the relevant constraint is already satisfied. The manner in which the principle is applied will, however, depend upon the specifics of the exposure situation under consideration. For example, in the case of planned situations, where exposure can be controlled to a greater or lesser extent at the source, the operator may be expected to keep application of the optimisation approach under continuous review during the operation of the practice and to report on this topic periodically to the regulator. In other circumstances, the review could take the form of a straightforward periodic check on whether the optimisation principle can be considered to be broadly satisfied. 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.

2.3. The scope of the recommendations

(34) The Commission's system of radiological protection applies to all radiation sources and 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).

(35) 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.*

(36) 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.

(37) The Commission has up till now distinguished between practices that added doses and interventions that reduced doses (ICRP, 1991). The principles of protection have been applied differently in the two situations. That distinction has been seen as artificial, and therefore, the Commission now characterises the possible situations where radiation exposure may occur as *planned, emergency*, and *existing exposure situations*); and with one set of principles for all these situations to which its recommendations apply (See section 5.4).

(38) The term '*practice'* has, however, become widely used in radiological protection. The Commission will continue to use this term to denote an endeavour that causes an increase in exposure to radiation or in the risk of exposure to radiation. An endeavour can be a business, trade, industry or any other productive enterprise; 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.

(39) The term '*intervention*' has also become widely used in radiological protection and has been incorporated into national and international standards to describe interventional situations. 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 these protective actions are the only options.

(40) 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. One option to more clearly communicate the concept 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.

2.4. Exclusion and exemption

(41) 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 endeavours making use of radiation, can or need to be regulated. There are two unique aspects of ionising radiation that complicate the assessment of what cannot or need not be regulated. Firstly, with current technologies, extremely low and trivial levels of radiation and radioactivity are detectable; secondly, the current radiological protection paradigm regarding radiation health effects assumes that there is no threshold below which the detrimental properties cannot be assigned to radiation. These features of detectability and detriment assumptions however are not sufficient reasons for including all exposures and all sources within the scope of regulatory control. To be consistent with the principle of optimisation, i.e., that radiation exposures should be as low as reasonably achievable considering economic and societal factors, account needs to be taken of both the *amenability* and *necessity* of controlling the exposure. As such, legislators and regulators should concentrate on situations where regulation brings about positive net benefits.

(42) 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 be controlled with regulatory instruments, and (ii) the exemption from radiological protection regulatory requirements of situations that are unwarranted to be

controlled because the associated risk is negligible under any conceivable circumstance. 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 provide the regulator with the authority to exempt situations from specified regulatory requirements, particularly from those of an administrative nature such as notification and authorisation. 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 release from specific regulatory obligations. Strictly, the term 'exemption' can only apply to personal entities, either physical or legal persons, as it relates to the waiving by the regulatory authority of requirements that would otherwise apply to a person as a legal obligation

(43) The Commission's position continues to be that, provided that every individual is afforded an acceptable level of protection, regulatory control should not be applied if it is unfeasible or the societal efforts needed for its application would be disproportionate to the saving in detriment it would be considered to achieve[1]. The protection provided by regulations that are not in accord with this recommendation would not be *optimised*. The Commission would consider such regulations unwarranted.

(44) 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.

(45) Certain practices and sources (that in principle are subject to radiological protection regulations) may be exempted from some requirements because their control is not warranted. The principles that should govern the process of exemption are the following:
- the individual risk attributable to the radiation exposure caused by an exempted practice or source must be insignificant (for man-made sources, this is judged to correspond to an annual dose of around 10 μSv);
- radiological protection, including the efforts for the regulatory control, must be optimised; and,
- the practice must be justified and its sources should be inherently safe.

(46) The Commission considers that exemption should not be entirely linked to triviality of risk because it is a broader concept that refers to unwarranted control

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[1] In this context, 'societal efforts' includes all relevant efforts and expenditure of resources, both by the regulator and the regulated, together with any other burden borne by society or opportunity foregone in applying the radiological controls; and 'detriment' is a generic term meaning a composite of all measures of harm connected with the radiation exposure to be regulated.

due to any reason. Reasons for regulatory exemption includes, but are not limited to, triviality of risk. The criterion for deciding whether or not regulatory controls are warranted has multiple attributes and should be situation specific. It should not be determined only by a dose level but by also taking account of other factors involved in controlling exposure. It should not be surprising that different circumstances could lead to different dose levels below which regulatory control is considered unwarranted. National regulators should decide the criteria for exemption on a case-by-case basis and the dosimetric boundary of 10 μSv y^{-1} should be only one of the criteria used.

(47) Some generic exemption criteria have been established by intergovernmental organisations in order to promote international consistency. For example, international exemption levels have been adopted for apparatuses and devices that emit adventitious (or unintended) radiation of low energy (or low intensity) and for radioactivity in a variety of substances, such as radioactivity in commodities that are not consumed and in some foodstuffs (refs to FAO, WHO, IAEA). Detailed guidance on exclusion and exemptions is provided in the foundation document *The Scope of Radiological Protection Regulations* (ICRP, 2006).

3.   BIOLOGICAL ASPECTS OF RADIOLOGICAL PROTECTION

(48)   The 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 of cells at 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.

(49)   In *Publication 60* (ICRP, 1991b) the Commission classified the radiation effects that results 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 noted under 3.2.6, are not yet sufficiently well understood to assign to either of the generic categories. Since 1990 ICRP 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 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, 2006).

3.1.   The induction of tissue reactions

(50)   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.

(51)   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 (Dorr and Hendry, 2001). Examples of these radiation-induced tissue reactions are given in Annex A.

(52) Reviews of biological and clinical data have led to further development of ICRP judgements on the cellular and tissue mechanisms that underlie tissue reactions and the dose-thresholds that apply to major organs and tissues. However, for the purposes of radiological protection, in the absorbed dose range up to around 100 mGy (low LET or high LET) no tissues are judged to show radiosensitivity that is sufficient to allow the dose-threshold for clinically relevant functional impairment to be exceeded. 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.

(53) 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 5. However new data on the radiosensitivity of the eye are expected and the Commission will consider these data when they become available.

3.2. The induction of cancer and hereditary effects

3.2.1. Risk of cancer

(54) The accumulation of cellular and animal data relevant to radiation tumorigenesis have, 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/dose-rate effects. Of particular importance are the advances in understanding of the induction by radiation 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 the microdosimetric aspects of radiation-induced DNA damage have also contributed significantly to this understanding.

(55) 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 under 100 mSv it is scientifically reasonable to assume that the increase in the incidence of cancer or hereditary effects will rise in direct proportion to an increase in the absorbed dose in the relevant organs and tissues.

(56) 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, an hypothesis that is generally know as 'linear non-threshold' or LNT. This view accords with that given by UNSCEAR (2000) 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 assumption of the LNT hypothesis 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.

(57) However, the Commission emphasises that whilst the LNT hypothesis remains a scientifically plausible element in its practical system of radiological protection, biological information that would ambiguously verify the hypothesis is unlikely to be forthcoming (see also UNSCEAR 2000). 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. On this point, the Commission also emphasises that its estimates of nominal risk coefficients (Table 2 and Annex A) relate to contemporary human populations and depend upon current information on baseline disease rates, disease detriment and associated biological/clinical features. These factors are certain to change substantially over future generations and this adds to the implausibility of attempting to project the magnitude of radiation-associated disease far into the future.

(58) In arriving at its practical judgement on LNT, 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 (*Publication 99*; ICRP, 2006). The Commission recognises that these biological factors may be components of radiation cancer risk but that current uncertainties on their mechanisms and tumorigenic consequences are too great for the development of practical judgements on low dose risk. The Commission also notes that since the estimation of nominal cancer risk coefficients is based upon direct human epidemiological data, any contribution from these cellular phenomena would be included in that estimate. Uncertainty with regard to the role of these processes in cancer risk will remain until the demonstration of not only their relevance to cancer development in vivo but also knowledge of the dose-dependence of the cellular processes involved.

(59) 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.

(60)   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.

(61)   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.

(62)   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 direct 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).

(63) 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 abberations 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 value of 1.5 was chosen for use by the BEIR VII Committee. 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 recognised 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 also notes that a DDREF is considered for solid cancers and not leukaemia for which a linear-quadratic response, i.e. a lower risk per unit dose is seen at low doses compared to high.

(64)   In considering all the data noted above, and recognising the broad range of experimental animal data showing reduction in carcinogenic effectiveness and lifeshortening 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 2 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

(65) 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 and mouse genetic data, that the risk of heritable diseases tended to be overestimated in the past.

(66) 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. ICRP 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.

(67) 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 second generation risk of about 2000 cases per million 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 risk. This issue is discussed in detail in Annex A.

(68) The new estimate for genetic risks up to the second generation is around 0.2% per Gy (1 case in 500 live births per Gy). This value relates to continuous low dose-rate exposures over these two generations i.e. doses to the grandparental and parental generations. As a result, these new estimates of genetic risk will reduce the 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

(69) 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 gender-averaged nominal risk coefficients.

(70) The calculation of gender-averaged nominal risk coefficients for cancer involves the estimation of nominal risks for different organs and tissues, adjustment of these risks for lethality/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.

(71) 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 2, where they are compared with the estimate of detriment used in the 1990 Recommendations in *Publication 60* (ICRP, 1991b).

(72) 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 2**.** 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	7.3
Adult	4.1	4.8	0.1	0.8	4	5.6

[1]Values from Annex A.

(73) The present detriment-adjusted nominal risk coefficient for cancer shown in Table 2 has been computed in a different manner from that of *Publication 60*. The

present estimate is based upon lethality/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. In this respect it is notable that the nominal risk coefficient for fatal cancer in the whole population that may be projected from the cancer incidence data of Annex A is around 4% per Sv as compared with the *Publication 60* value of 5% per Sv.

(74)   An additional point relating to the lethality-adjusted cancer risk of Table 2 is that during the period that these recommendations are likely to apply, the survival rates for many cancers are expected to rise. In this respect the nominal risk coefficient given will tend to be an over-estimate of risks in the future.

(75)   In summary, the Commission considers that while the nominal risk estimates are now slightly smaller than in 1990, for practical purposes the risk is in the same order of magnitude as before. Thus, the approximate overall risk coefficient of about 0.00005 per mSv on which the current international radiation safety standards are based continues to be appropriate for purposes of radiological protection.

3.2.4. Radiation effects in the embryo and fetus

(76)   The risks of tissue reactions and malformation in the irradiated embryo and fetus have been reviewed recently 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 low LET.

(77)   The new data confirm embryonic sensitivity 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 and the data reviewed provide no reason to believe that there will be significant risks to health expressing after birth.

(78)   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 may be discounted.

(79)   The *Publication 90* (ICRP, 2003a) review of A-bomb 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 entirely 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 clinical significance. This judgement accords with that developed in *Publication 60* (ICRP, 1991b).

(80) *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. From the studies reviewed in *Publication 90* it is also concluded that it is not possible to develop a system of tissue weighting factors for the embryo/fetus for use in the estimation of in utero risks from internal radiations.

(81) Finally, the Commission recommends that in utero exposure should not be a specific protection case in prolonged exposure situations where the dose is well below about 100 mSv. This view relating to annual in utero doses of below 100 mSv was first expressed in *Publication 82* and is based upon the following judgements by the Commission: a) the low probability of excess cancer in the liveborn and the fact that the period of exposure of the embryo/fetus is only a small fraction of that of the general population, b) the absence of risk of induced malformation under 100 mSv, and c) the very low risk of effects on the developing brain during the short in utero period of sensitivity.

3.2.5. Genetic susceptibility to cancer

(82) 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/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.

(83) 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 far more variable expression of cancer following radiation exposure.

(84) 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.

(85) 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.

3.2.6. Non-cancer diseases after radiation

(86) 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 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/tissue mechanisms might underlie such a diverse set of non-cancer disorders.

(87) 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 under around 100 mSv.

4. DOSIMETRIC QUANTITIES

4.1. Introduction

(88) Radiological protection is concerned with controlling exposures to ionising radiation, so that the risk of radiation-induced cancer and hereditary disease (termed stochastic effects) is limited to acceptable levels and tissue reactions (sometimes also, but less precisely, termed deterministic effects) are prevented. For assessing doses from radiation exposures, special *dosimetric quantities* have been developed. The fundamental *protection quantities* adopted by ICRP are based on measures of the energy deposited to organs and tissues of the human body. For relating the measure of radiation exposure to radiation risk (detriment), it is also necessary to take into account variations in the response of organs and tissues of the body to radiations of different quality as well as the varying sensitivity of organs and tissues to ionising radiation. The underlying principle adopted by ICRP has been to use *absorbed dose* as the fundamental physical quantity of energy deposition, to average it over specified organs and tissues, and to apply suitably chosen weighting factors to the absorbed dose to take account of both the biological effectiveness of different radiations and the varying sensitivities of organs and tissues to the induction of cancer and hereditary disease.

(89) This scheme was first implemented by ICRP in *Publication 26* (ICRP, 1977) with the introduction of the protection quantities *dose equivalent*, for organs and tissues of the human body, and *effective dose equivalent.* 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 quantity 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.

(90) In practice the effective dose itself cannot be measured directly in body tissues. The protection system therefore includes *operational quantities* that can be measured and from which the effective dose can be assessed.

(91) The general acceptance of effective dose and the demonstration of its practicability 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

(92) 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 Annex A, or Chapter 3). 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 Annex B). The radiation weighting factors for radiations characterised by a high linear energy transfer, so called high-LET radiations (see below), are derived for stochastic effects at low doses.

(93) At high doses and especially in accident situations, radiation exposures may cause tissue reactions (sometimes termed deterministic effects). Such clinically observable damages occur above threshold doses. The extent of damage depends upon the absorbed dose and dose rate as well as radiation quality (Chapter 3). 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. As a consequence the quantities equivalent dose and effective dose should not be used in the quantification of radiation doses and in making decisions on the need for any treatment when radiation exposure could give rise to tissue reactions. In such situations, 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

(94) The procedure for dose assessment adopted by ICRP 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 are then summed to give the effective dose which is a quantity based on the internal and external exposure to radiation fields and the primary physical interactions in human tissues as well as on judgements about the biological reactions resulting in stochastic health effects (Annex B).

4.3.1. Absorbed dose

(95) In radiation biology, 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, $d\bar{\varepsilon}$, imparted by ionising radiation in a volume element and the mass, dm, of the matter in that volume, that is

$$D = \frac{d\bar{\varepsilon}}{dm}$$
(4.1)

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. In principle, 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. It implicitly takes account of the radiation field as well as all of its interactions with matter inside and outside the specified volume.

4.3.2. Averaging of dose

(96) When using the quantity absorbed dose in practical applications, doses are often 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 from 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 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.

(97) The averaging of absorbed dose is carried out over the volume 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 penetrability or range of the radiation incident on the body. Microdosimetric phenomena reduce the homogeneity of the dose distribution in the low dose range. 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 due to microdosimetric properties. In cases of extreme partial body exposure, tissue damage may occur even if the mean organ 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.

(98) 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, on the homogeneity of the activity distribution as well as on the anatomical structures (e.g., walled` organs like the urinary bladder, airways of the respiratory tract, and the highly heterogeneous mixture of bone mineral, inactive and active bone marrow). 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). Radionuclides may be distributed throughout body tissues (e.g. tritiated water, ^{40}K) or concentrated in only one or a few tissues (e.g. ^{131}I, ^{239}Pu).

4.3.3. Equivalent dose and radiation weighting factors

(99) The protection quantities are used to specify exposure limits for keeping the occurrence of stochastic health effects below acceptable 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, $D_{T,R}$, due to radiation of type R in the volume of a specified organ or tissue T. 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 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).

(100) In the early 1960s, radiation weighting in the definition of radiological protection quantities was related to the radiation quality as a function of LET 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.

(101) Since 1991 re-evaluation of the data (see Annexes A and B) has led to a revised set of w_R values adopted in these recommendations. 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 and are assigned fixed values for radiological protection purposes.

Table 3**.** 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 nuclei	20
Neutrons	A continuous function of neutron energy is recommended (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 source.

(102) ***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 adopted in these recommendations.

(103) **Photons.** Photons, electrons and muons are low-LET radiations with LET values of less than 10 keV/μm. Low-LET radiations have always been given a value of one in radiation weighting. This is reasonable and has been done mainly for practical reasons. There are good arguments (see Annex B) to continue with $w_R = 1$ for all low-LET radiations (Table 3). It 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 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).

(104) **Neutrons.** The radiation weighting factor for neutrons mainly 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).
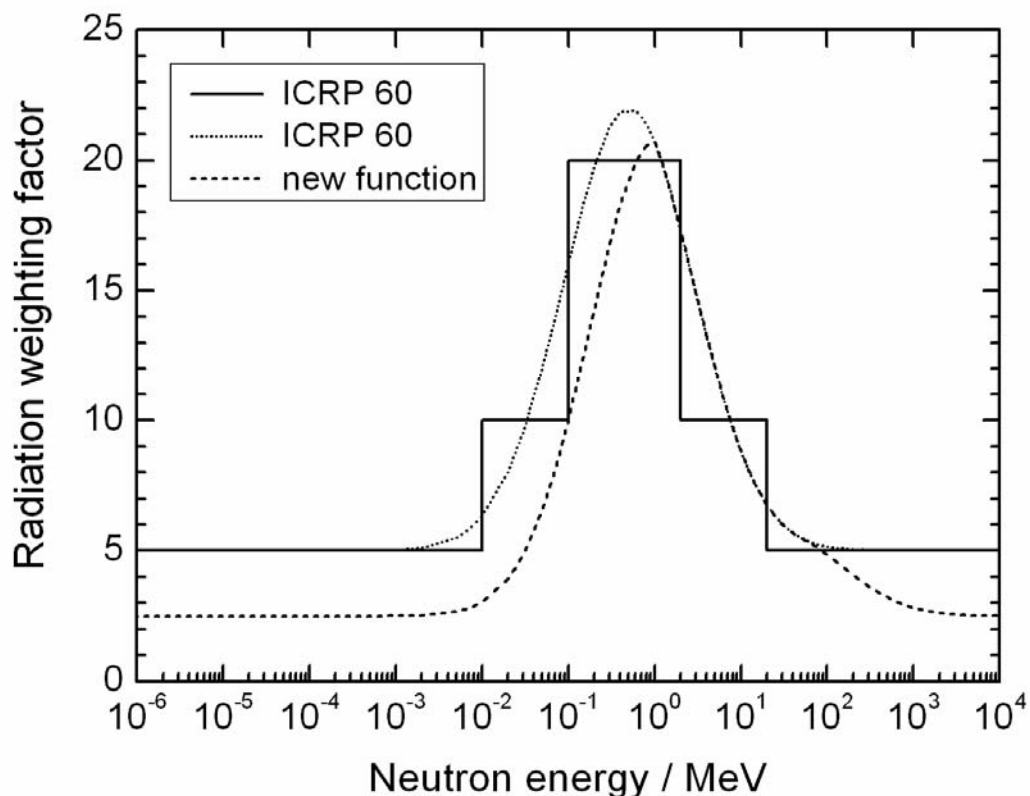
Fig. 1. Radiation weighting factor, w_R, for neutrons versus neutron energy. Step function and continuous function given in *Publication 60* (ICRP, 1991b) and the new function now recommended.

(105) In *Publication 60* (ICRP, 1991b) the radiation weighting factor for neutrons was given as a step function defining 5 energy regions with w_R values of 5, 10 and 20 (Fig. 1). It is now recommended that the radiation weighting factor for neutrons be given by a continuous function. It should be noted, however, that the use of a continuous function is based on the practical consideration that most neutron exposures involve a wide ranges 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 due to the increased contribution by protons. The following continuous function in neutron energy E_n (MeV) is recommended for the calculation of radiation weighting factors for neutrons:

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

This function (4.3) (Fig. 1) has been derived empirically and is consistent with existing biological and physical knowledge. At very high neutron energies the radiation weighting factor decreases and approaches 2 to be consistent with the w_R values for neutrons and protons (Annex B).

(106) ***Protons and pions.*** When considering exposure to protons, only external radiation sources are of importance in practical radiological protection. In 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 concern 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 considered to be sufficiently conservative for external proton radiation and is, therefore, recommended for general use. It replaces the value of 5 recommended in *Publication 60* (ICRP 1991b).

(107) 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.

(108) ***Alpha particles.*** Humans are predominantly 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 that provide information on the risk from incorporated alpha emitters. The distribution of radionuclides and the estimation of dose and its distribution in tissues and organs are complex and 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* and Annex B).

(109) Reviews of available human and animal data for alpha-emitting radionuclides 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.

(110) *Heavy ions and fission fragments.* 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. Due to the short ranges of heavy ions and fission fragments in organs and tissues have a strong influence on their biological effectiveness. A radiation weighting factor of 20 (see Table 3), which equals that for α-particles, is recommended as a conservative estimate (see Annex B).

(111) In external exposure, heavy ions are encountered in radiation fields at aviation at high altitudes and in space. 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 strongly along its track. The selection of a single w_R value of 20 for all types and energies of heavy charged particles is recommended as a conservative estimate, sufficient for the general application in radiological protection. For applications in space, where these particles contribute significantly to the total dose in the human body, a more accurate approach may have to be chosen based on the calculation of a mean quality factor in the human body (see Annex B).

4.3.4. Effective dose and tissue weighting factors

(112) The effective dose, E, is defined in Publication 60 (ICRP 1991) as

$$E = \sum_T w_T \sum_R w_R D_{T,R} \qquad (4.4)$$

where w_T is the tissue weighting factor for tissue, T and with $\Sigma\, w_T = 1$. The sum is performed over all organs and tissues of the human body considered to be sensitive to the induction of stochastic effects (see Annex A). 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 below). Care must be taken in ensuring that the quantity being used is clearly stated

(113) 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 based in part on the respective values of relative radiation detriment (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 to take account of the enhanced 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.

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

(114) The w_T for the remainder tissues (0.12) applies to the arithmetic mean dose of the 14 organs and tissues listed in the footnote to Table 4. The so-called splitting rule in the treatment of the remainder in *Publication 60* is no longer used and hence the effective dose is additive. The sum of the w_T values has to be 1 by definition. See explanations below and Annex B for further details.

Table 4. Recommended tissue weighting factors.

Tissue	w_T	$\sum w_T$
Bone-marrow, 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.

(115) The equivalent dose and effective dose include weighting factors which are based on radiobiological findings and physical properties of radiations. These factors are selected from a wide range of data and are judged to be satisfactory for practical use in radiological protection (see Annex B). Furthermore they represent mean values for humans averaged over both genders and all ages and thus do not take account of the characteristics of particular individuals.

(116) 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).

(117) The effective dose is calculated for a set of standard conditions (see Annex B). In previous recommendations, gender-invariant biokinetic models and computational phantoms have been used. Male and female computational phantoms have now been developed and recommended for use in future calculations of dose coefficients for external radiation fields and for the intake of radionuclides (see Annex B).

4.3.5. Gender averaging

(118) In operational and practical radiological protection, it is useful to determine one value of effective dose for both genders. Therefore, the tissue weighting factors of Table 4 are gender-averaged values and are valid for the breast, gonads, and other organs and tissues 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):

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

(119) Values of radiation detriment that underpin the selection of tissue weighting factors, w_T, are described in Chapter 3 (see also Annexes A and B). A particular issue in the calculation of effective dose is the assessment of the dose to 'remainder' tissues. The so-called 'splitting rule' in treatment of the remainder tissues in *Publication 60* (ICRP, 1991b) resulted in an effective dose lacking additivity, and is no longer applied.

(120) 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 into 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 4.2. The current remainder formulation specifies 12 tissues common to both genders and one gender-specific tissue in each gender (prostate in the male and uterus/cervix in the female) for a total of 13 tissues. The equivalent dose to the tissues of remainder of the male, H_T^M, and female, H_T^F, are computed as

$$H_{RT}^M = \sum_T^{13} H_T^M \text{ and } H_{RT}^F = \sum_T^{13} H_T^F . \tag{4.6}$$

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

4.4. Operational quantities

(121) The body-related protection quantities, equivalent dose and effective dose, are not measurable in practice. Hence operational quantities are used for the assessment of effective dose or mean doses in tissues or organs. These quantities aim to provide an estimate or upper limit 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. More details are given in Annex B.

(122) For the monitoring of external exposures, various operational dose equivalent quantities have been defined by ICRU. Different operational dose equivalent quantities have been defined for area and individual monitoring. A detailed description is given in Annex B. 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.

(123) The effective dose for external radiation exposure is calculated for standard conditions, for example mono-energetic radiations and standard irradiation geometries. In addition, the human body is defined by anthropomorphic voxel phantoms with clearly defined geometry and defined anatomical parameters (ICRP, 2002).

(124) The system of dose assessment for intakes of radionuclides relies on the calculation of the intake of a radionuclide 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 (doses per unit intake, Sv Bq$^{-1)}$ recommended by ICRP for a large number of radionuclides. Dose coefficients have been given for members of the public of various ages and for adults who are occupationally exposed (Annex B).

4.5. Assessment of radiation exposure

4.5.1. External radiation exposure

(125) Individual monitoring of external exposure is usually performed with personal dosimeters worn on the body and the operational quantity defined for this application takes this into account. For individual monitoring, the operational quantity is the personal dose equivalent, $H_P(d)$, which is the dose equivalent in 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 dosimeter is worn. For penetrating radiation a depth d = 10 mm, $H_P(10)$, and for weakly penetrating radiation a depth d = 0.07 mm, $H_P(0.07)$, is recommended. In special cases 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 no personal dosimeters are generally available that allow this to be measured.

(126) Previous calculations of dose coefficients have used various 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 has adopted computational phantoms of the adult male and female body that are based on medical tomographic images. The phantoms are made up of 3-dimensional volume 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 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.

4.5.2. Internal radiation exposure

(127) 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 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:

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

(128) 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 age 70 years.

(129) 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 genders. 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).

(130) For internal radiation exposure the procedure is similar to that described above for external exposure. The calculations of dose coefficients giving the committed effective dose for the intake of a specified radionuclide (Sv Bq^{-1}) use defined biokinetic and dosimetric models in conjunction with the mathematical phantoms. 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 new computational male and female models will be used to compute, for a series of sources, the fraction of the energy emitted within source region S that is absorbed in target region T. These approximations are considered to be adequate for the main tasks in radiological protection.

(131) Gender-averaged committed effective dose coefficients[2] for the intake of specified radionuclides will be calculated so that the committed effective dose coefficient $e(\tau)$ is given as:

$$e(\tau) = \sum_{T} w_{T} \left[\frac{h_{T}^{M}(\tau) + h_{T}^{F}(\tau)}{2} \right] \qquad (4.9)$$

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. The summation in Equation (1.9) extends over the committed equivalent dose coefficients for the remainder tissues in both the male and female.

4.5.3. Occupational exposure

(132) In monitoring occupational exposures to external radiation, individual dosimeters 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 homogeneous 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 appropriate and recommended dose coefficients (see Annex B).

(133) In practice the doses obtained from the assessment of exposures from external radiation and from intakes of radionuclides are combined for the assessment of the value of total effective dose for demonstrating compliance with dose limits and constraints. The effective dose, E, can be estimated in most situations of occupational exposure from the operational quantities 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 the committed effective dose from internal exposure 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. This might include the activity median aerodynamic diameter (*AMAD)* of the inhaled aerosol and the chemical form of the particulate matter to which the

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

specified radionuclide is attached. The radiation dose from radon and thoron and their decay products may also need to be taken into account in the overall dose assessment.

(134) If incorporation of radionuclides occurs through the skin or wounds, an associated effective dose would have to be included in the assessment.

4.5.4. Public exposure

(135) Public exposures can occur from natural radiation sources, which may be modified by human activities, from technical installations, or from combinations of such sources. 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 usually obtained by direct measurements 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 or environmental transport, e.g. from the release of radionuclides and transport through soil – plants – animals to humans) to assess doses from external radiation exposure or intakes of radionuclides (se Annex B).

4.5.5. Medical exposure of patients

(136) 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 some value for comparing doses from different diagnostic and therapeutic procedures and for comparing the use of similar technologies and procedures in different hospitals and countries as well as from 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.

(137) Medical exposures of patients to external radiation are commonly concerned with limited parts of the body only, and it is important that medical staff is 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. Care has to be taken in such situations so that no tissue reactions occur.

(138) 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.

4.5.6. Application of the effective dose

(139) The primary use of the effective dose is to provide an instrument for demonstrating compliance with dose limits in radiological protection. Effective dose should be used for assessing exposures and controlling possible stochastic effects in

the low dose range for regulatory purposes. 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.

(140) The main and primary use of reference values of effective dose is to provide a means of demonstrating compliance with dose limits. In this sense effective dose is used for regulatory purposes worldwide. In practical radiological protection applications, effective dose is used for the control of radiation exposures of workers and for dose records. This is appropriate as long as the effective dose is close to or below dose limits.

(141) 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.

(142) For retrospective assessments of occupational doses in specified individuals that may exceed dose limits, effective dose may provide an approximate or rough 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 it is attempted to estimate organ-specific risks for the specified individuals.

(143) Effective dose is a risk related 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, absorbed doses, not effective doses, are required for calculations of probability of causation of cancer in individuals.

(144) In cases of high doses that could give rise to tissue reactions the use of effective dose is completely inappropriate. 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).

4.5.7. Collective dose

(145) 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 by multiplying the number of exposed persons times

the average dose they received 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 intent of the collective quantities is to serve as an instrument in optimisation of radiological protection only the collective effective dose is retained in the present system.

(146) 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. In the case of low individual dose which are small fractions of the radiation dose received from natural sources and may involve wide geographical areas and/or long time scales, the use of collective dose for risk estimates is not a reasonable procedure as it both aggregates too much information for the decision making process and combines several sources of uncertainty. This topic is discussed in further detail in Section 5.8.7.

(147) Collective dose is mainly an instrument for optimisation, for comparing radiological technologies and protection procedures. Collective dose is not intended as a tool for epidemiologic risk assessment and it is therefore inappropriate to use it in risk projections based on epidemiological 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 dose were never intended and are an incorrect use of this radiological protection quantity.

(148) 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 $\mathrm{d}N/\mathrm{d}E$ denoted 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).

4.6. Uncertainties and judgements

(149) 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).

(150) Uncertainty refers to the level of confidence and precision 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 or precision of measurements and judgements will become less with decreasing doses and increasing complexity of the system. Variability refers to quantitative differences between different members of the population in question. All these aspects are included in the judgements.

(151) 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. Values for the uncertainties may need to be made for special cases, however, and approaches to their use have been described in a number of publications e.g., (EC/USNRC 1998, 2000; 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.

(152) 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. However, for prospective dose assessments and in particular for calculations of the effective dose in regulatory processes, the dosimetric models and parameter values that the Commission recommends for determining doses from quantitative information should be taken as reference models. These values have been fixed by convention and are therefore not subject to uncertainty. Equally the Commission considers that the dosimetric models and parameter values which are needed for the purpose of recommending dose limits or constraints 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.

(153) 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. Because of the prospective nature of radiological protection, the Commission does not recommend re-computation of existing values with the new models and parameters.

(154) In the retrospective assessment of doses that may approach or exceed limits, it may be appropriate, where possible; to consider uncertainties in assessed doses (see Annex B).

5. THE SYSTEM OF RADIOLOGICAL PROTECTION OF HUMANS

(155) 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.

(156) 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 dose and 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 selection 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.

(157) The first and fundamental simplification was used in the 1990 Recommendations and recognises that many individuals are exposed to several types of sources, which can in principle be controlled (ICRP, 1991). For example, most workers who are exposed to radiation sources as part of their work are also exposed to radon at work, to controllable environmental sources including radon at home, 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 was and is still reflected in the new recommendations by the separation of the exposure into three types: occupational exposure, medical exposure of patients, and public exposure (see section 5.3). The Commission continues to recommend that no attempt is made to add the exposures in different groups, even when a single individual is subject to exposure in several groups.

(158) The second simplification suggests that each source, or group of sources, can be often treated on its own (ICRP, 1991). 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 assessment'. However, each individual is exposed as a result of several sources, so a second form of assessment is needed. This starts from a single individual and considers all the sources causing exposures to that individual. This assessment is called 'individual-related' (see section 5.6)

(159) The system of protection now recommended by the Commission is to be seen as a further clarification of the 1990 Recommendations. Constraints contribute to the level of protection for an individual by applying criteria for protection of that individual from a single source. They are specified for planned situations and emergency situations as well as for the case of existing controllable exposure. This

use of constraints is not to be confused with the complementary requirement to optimise the level of protection.

5.1.   The definition of a single source

(160) The Commission uses the term 'source' to indicate sources of radiation, such as radiation generators and radionuclides (e.g. as sealed radioactive materials), and also, more generally, to indicate the cause of exposure to radiation or to radionuclides in radioactive substances, and not necessarily an individual physical source of radiation. For instance, if radioactive materials 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.

(161) In the application of constraints, the term 'single source' should be used in a broad sense, such as the x-ray equipment in a hospital, or the releases of radioactive materials from an installation. In general a source is an entity for which radiological protection can be optimised as an integral whole. Most situations will give rise to a predominant source of exposure for any single individual, or representative individual, making it possible to treat sources singly when considering actions. Provided that the operator and the regulator both apply the Commission's broad policies, the definition of a single source is straightforward. 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

(162) The Commission intends its recommendations to be applied to all sources in the following three types of exposure situations which address in total all conceivable circumstances:

- *planned situations* are 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.

- *emergency situations* are unexpected situations that occur during the operation of a practice, requiring urgent action. Emergency situations may arise from practices.

- *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 were operated outside the Commission's recommendations.

(163) It follows that 'practices' could be the origin of planned, emergency, and existing situations. Therefore, the three types of exposure situations replace the previous two categories 'practices' and 'interventions'. There are some small differences in application of the system of protection between these three types of situations.

5.3. Categories of exposure

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

5.3.1. Occupational exposure

(165) Occupational exposure is defined by the Commission as all radiation exposure of workers incurred as a result of their work, with the exception of excluded exposures and exposures from exempt practices or exempt sources. Both licensees and employers have 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.

(166) 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.

5.3.2. Public exposure

(167) Public exposure encompasses all exposures other than occupational and medical exposures of patients. Public exposure includes the fetus of a pregnant radiation worker or of a pregnant patient undergoing a radiological procedure. 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

(168) Radiation exposures of patients can occur in diagnostic, screening, or 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, and medical exposure of patients is therefore dealt with separately.

5.4. The identification of the exposed individuals

(169) It is necessary to deal separately with at least three categories of exposed individuals, namely workers (informed individuals), the public (general individuals), and patients. They essentially correspond to individuals whose exposures fall into

the three categories of exposure defined in section 5.3. One individual can be exposed occupationally, as a patient, or as a member of the public.

5.4.1. Workers

(170) A radiation 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.

(171) 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. Other workers, such as administrative and support staff, are more similar to the general public and are treated as such.

5.4.2. Patients, including their comforters and carers

(172) The application of the Commission's quantitative restrictions on dose are not recommended for individual patients because they 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.

(173) Some exposures have to be incurred in the care and support of patients. Members of the public supporting patients being treated by internal radioactive sources in hospital or at home require individual consideration. Relevant constraints should be higher than those for individuals in the general population. Further guidance on medical exposure for relatives, visitors and caregivers at home is provided in a forthcoming ICRP Committee 3 report on medical radiation, in *Publication 94* (ICRP, 2004a), and in Section 6.5.

5.4.3. Members of the public

(174) The Commission has specified dose limits for exposure to members of the public in planned situations. These can be used only as a basis for national policy. Dose limits cannot in principle be applied to operational control, because neither the operator nor the regulator has the information about the totality of sources contributing to the dose to be limited in planned situations. Therefore, an individual dose from a single source in planned situations has to be judged against the appropriate constraint.

(175) In general, especially for public exposure, each source will result in a distribution of doses over many individuals, so it will be necessary to use the concept of a representative individual to typify the most highly exposed individuals. The Commission has earlier used the concept of critical group, but following *Publication 101* (ICRP, 2006b), the Commission now recommends the use of the representative individual for the purpose of radiological protection.

(176) The representative individual, who may be hypothetical, receives a dose that is representative of the more highly exposed individuals in the population. It is important that the individual habits (e.g. consumption of foodstuffs, breathing rate,

location, usage of local resources) used to characterise the representative individual 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 individuals considered. Further details on characterising the representative individual are provided in *Publication 101* (ICRP, 2006b).

5.5. The exposure of women

(177) 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. However, if a woman has declared that she is pregnant, additional controls have to be considered to protect the 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 fetus broadly comparable to that provided for members of the general public. This should not be understood as an ethical position of the Commission on the status of the fetus. 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 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 dose to the fetus would exceed about 1 mSv during the remainder of the pregnancy. Additional guidance is given in Section 6.3.

(178) 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. 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 high accidental doses and high 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.

(179) The exposure of patients who may be pregnant is dealt with in the forthcoming ICRP Committee 3 report on medical exposures. For members of the public, the limit on effective dose means that the embryo/fetus is adequately protected and no further restrictions are recommended. These conclusions are also found in *Publication 90* (ICRP, 2003a).

(180) 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 offspring are similar to or less than those to the reference adult person, although there are a few exceptions where the dose to the offspring 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 exceptionally rare that the dose to the offspring can exceed that of the reference adult by a factor of up to about 3.
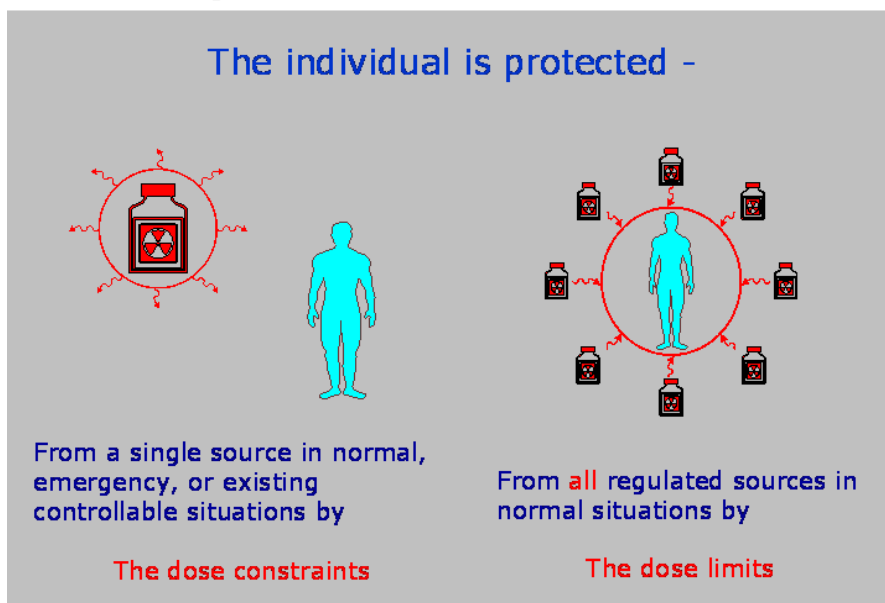
5.6. Levels of protection

(181) Even within a single type of exposure, 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 the sources causing substantial exposures to the individual. This approach is called *'individual-related'*.

(182) In the 1990 Recommendations, it was suggested that each source or group of sources within a type of exposure 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 single source to assure the protection of a group of individuals from that source. Protection from single sources is achieved by the use of constraints during the optimisation procedure (see section 5.8)

(183) When a level of protection is set for an individual from all regulated sources within a type of exposure in planned situations only, it is called a dose limit. 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 constraints for protection from a single source in all situations and the use, in planned situations only, of individual-related dose limits.

Fig. 2. Illustrating the difference between a dose limit and a dose constraint to protect members of the public or individual workers. *[Will be redrawn]*

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(184) The most fundamental level of protection, therefore, is the source-related restriction to the dose that individuals may incur, namely the *dose constraint*. For potential exposures, the corresponding concept is the *risk constraint* (see chapter 8). The dose constraint is used to provide a level of protection for the most highly exposed individuals from a single source within a class of exposure and within an exposure situation. The Commission recommends the use of quantitative dose constraints to protect the most highly exposed individuals from the relevant sources. Compliance with the relevant dose constraint is not in itself a sufficient condition to satisfy the Commission's recommendations; radiological protection must also be optimised (see section 5.8).

Many comments on the previous draft Recommendations indicated that the Principle of Justification had not been presented clearly enough. ICRP would now particularly appreciate comments indicating whether the present treatment of this topic is adequate in the present draft.

5.7. The principles of protection

(185) 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 equally 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 that the source-related principles apply to all controllable situations;

Source related:

- **The principle of justification:** Any decision that alters the radiation exposure situation, e.g., by introducing a new radiation source or by reducing existing exposure, should do more good than harm, i.e., yield an individual or societal benefit that is higher than the detriment it causes.

- **The principle of optimisation of protection:** Optimisation of protection should ensure the selection of the best protection option under the prevailing circumstances, i.e., maximising the margin of good over harm. To avoid serious inequities resulting from this optimisation procedure, there should be restrictions on the doses or risks to individuals from a particular source (dose or risk constraints). Thus, optimisation involves keeping exposures as low as reasonably achievable, taking into account economic and societal factors as well as any inequity in the distribution of doses and benefits amongst those exposed.

Individual related:

- **The principle of limitation of maximum doses:** In planned situations, the total dose to any individual from all the regulated sources should not exceed the appropriate limits specified by the Commission.

(186) Dose limits do not apply to medical exposure of patients, emergency situations, or to existing situations.

(187) For occupational exposure, dose limits apply to those situations which are determined by the regulator.

5.7.1. Justification in situations involving occupational and public exposure

(188) 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 they produce sufficient net benefit to the exposed individuals or to society to offset the radiation detriment caused. In this context, a planned situation is a generic type of practice, the essential features of which are not dependent on external factors such as the site on which it is carried out. Judgements on whether it would be justifiable to introduce or continue particular types of practice involving exposure to ionising radiation are important.

(189) 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 exposure situations and radiological emergencies. In these circumstances, the principle of justification is applied in making the decision as to whether to take action to avert further exposure. Any actions taken to reduce doses, which always have some disadvantages, should be justified in the sense that they should do more good than harm.

(190) In both approaches, the responsibility for judging the justification usually falls on governments or government agencies to ensure an overall benefit in the broadest sense to society and thus not to each individual. Radiological protection considerations will be important to a greater or lesser extent depending upon the circumstances.

5.7.2. Justification for medical exposure of patients

(191) Medical exposure of patients calls for a different and more detailed approach to the process of justification. The medical use of radiation is a practice (i.e. radiological practice) that should be justified, as is any other planned situation, although that justification lies more often with the profession than with government. In medicine, there are three levels of justification: (1) the use of radiation is accepted as being beneficial to the patient, and its justification is now taken for granted; (2) a specified procedure with a specified objective is defined and justified; and (3) the application of the procedure to an individual patient should be justified. 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 part of the Commission's Recommendations.

5.8. Optimisation of protection

(192) The principle of optimisation of protection and constraints 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.

(193) The principle of optimisation is defined by the Commission as the source related process to keep the magnitude of individual doses, the number of people exposed and the likelihood of occurring exposure where these are not certain to be received, as low as reasonably achievable below the appropriate dose constraints, economic and societal factors being taken into account.

(194) The Commission has provided guidance in *Publications 37, 55,* and *60* (ICRP, 1983, 1988, and 1991b) on how to apply the optimisation principle, and these recommendations remain valid. However, the way the principle of optimisation should be implemented is now viewed as a broader process reflecting the increasing role of individual equity, safety culture and stakeholder involvement (*Publications 77, 82*: ICRP, 1998, 1999). The Commission is aware that this approach reflects the way in which many operators are currently applying the principle of optimisation.

(195) The Commission has previously recommended in its system of protection for practices that the optimisation process should have restrictions on the doses to individuals, termed dose constraints, in order to reduce inequities inherent in the optimisation process. The Commission now recommends that this process of optimisation and constraints be applied in all three types of exposure situations, recognising that there will be differences in application between the three situations.

(196) The optimisation must be implemented through an on-going, cyclical 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;
- 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;
- 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 accidents and other potential exposures for planned situations.

(197) In all situations the process of optimisation and constraints is used in planning protective actions and in establishing the appropriate level of protection in the prevailing circumstances; the doses to be compared with the constraint are always 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. The Commission uses the term 'constraint' only for this prospective purpose. Constraints are used as integral part of the process of optimising prospectively radiological protection as discussed in Section 5.8.1 below. They are not intended as a form of retrospective dose limitation, even if they are considered in the feedback process. The optimisation processes should be interactive and iterative involving national authorities and operators.

Comments received on the topic of Dose Constraints showed that this tool had been treated somewhat inconsistently in the previous draft Recommendations. ICRP would now particularly appreciate comments indicating whether the present treatment of this topic is adequate in the present draft.

5.8.1. Constraints

(198) The most fundamental level of protection is the source-related restriction called a dose constraint, or risk constraint for potential exposures (see Chapter 8). Constraints apply in all situations being used prospectively as the starting point in the optimisation process. They are used to provide a level of protection for the most highly exposed individuals from a single source within a type of exposure. The intention of the optimisation process is to result in exposures that are below the relevant constraint. The Commission recommends the use of quantitative dose constraints to protect the most highly exposed individuals from all identified controllable sources.

(199) The concept of dose constraints was introduced in *Publication 60* as a means to ensure that the optimisation process did not create inequity, i.e., the possibility that some individuals in an optimised protection scheme may be subject to substantially 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 optimisation. The Commission calls these source-related dose constraints, previously called upper bounds. They form an integral part of the optimisation of protection. For potential exposures, the corresponding concept is the risk constraint' (para 121, ICRP, 1991).

(200) The dose constraint is related to one source under each particular circumstance, which can be either a planned situation, or an emergency situation, or a situation of existing exposure. Constraints for planned situations represent a basic level of protection for the planned operation of a practice. Such constraints will always be lower than the pertinent dose limit. During planning of the operation it will be ensured that the source concerned does not cause doses exceeding the constraint; optimisation of protection will establish a level of dose below the constraint.

(201) In emergency or existing controllable exposure situations, the constraint represents the level of dose or risk where action to reduce that dose or risk is almost always warranted in that particular situation. In some rare exceptional situations, such constraints could be higher than any dose limit (viz., if the actions needed to reduce doses below dose limits would entail more detriment than that associated with the averted dose). Thus, the chosen value for a constraint will depend upon the circumstances of the exposure under consideration; it must also be realised that the constraint does not represent the demarcation between 'safe' and 'dangerous' and does not reflect a step change in the associated health risk. It will usually be appropriate for dose constraints to be fixed at the national or local level taking account of the Commission's guidance.

5.8.2. Factors influencing the choice of source-related dose constraints

(202) In providing guidance on values for dose constraints, the Commission has assumed a linear relationship between radiation dose and risk of cancer or hereditary effects in exposed organs or tissues. 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. Epidemiological studies have shown a statistically significant excess of cancer deaths in populations exposed to doses in excess of around 100 mSv. For these reasons, the Commission considers that the maximum value for a constraint is 100 mSv incurred either acutely or in a year. There is no net individual or societal benefit that can compensate for higher levels of exposures, except in extreme situations such as the saving of life or the prevention of a serious catastrophe.

(203) The numerical criteria recommended by the Commission in *Publication 60* and subsequent publications can all be, with the exception of the limits, regarded as constraints. The values fall into three defined bands (see Table 4) 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 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).

(204) The first band, under 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 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 constraint, thus providing a rigorous level of protection.

(205) 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 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. In the event of an accident, countermeasures such as sheltering and iodine prophylaxis would fall within this band.

(206) 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. 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, but exposure situations involving abnormally high levels of natural background radiation may also be in this band. Consideration should be given to reducing doses. It follows that the higher the dose, the more effort should be devoted to dose reduction.

(207) In all cases the bands for dose constraints are specified in terms of projected incremental individual doses. The Commission's upper value for a constraint 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, however, one source will be dominant and the upper value could be applied to that source.

(208) The Commission's banding of constraints 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 that would be tolerated within the system of protection in the circumstances under consideration being expressed as dose per year. For emergency situations, the values refer to acute exposures, which would not be expected to be repeated.

(209) It should be emphasised that the set of values for constraints represents the fundamental levels for a source-related system of control of the exposures to the individual. Generally, there is a dominant source and the selection of the appropriate

constraint ensures the required level of protection. Additional restrictions are needed in the situation where one individual is exposed to several sources. The Commission still considers that the source-related principle of optimisation below the constraint is the most effective tool for protection, whatever the situation.

5.8.3. Selection of a dose constraint

(210) A necessary stage in applying the principle of optimisation of protection is the selection of an appropriate value for the dose constraint. 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 4 should enable the selection of the appropriate band for the constraint. 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 for occupational, medical and public exposure in the three exposure situations.

5.8.4. Dose constraints for occupational exposure

(211) The Commission continues to recommend that occupational exposure in planned situations is controlled by the procedures of optimisation below the constraint and the use of prescriptive limits. For many types of occupation in planned 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 occupation. The class of occupation should be specified in fairly broad terms, such as work in x-ray diagnostic departments, the routine operation of nuclear power plants, or the inspection and maintenance of nuclear installations. It will usually be appropriate for such dose constraints to be fixed at the national or local level. When using a dose constraint, a designer should specify the sources to which it is linked so as to avoid confusion with other sources to which the workforce might be concurrently exposed.

(212) The source-related dose constraint for occupational exposure in planned situations should be set for each source to ensure that the dose limit is not exceeded (see Section 5.9).

(213) The Commission recommends that occupationally exposed workers involved in an emergency situation should be subject to special conditions. While the general principles of optimisation still apply, exposure of emergency teams could be limited mainly by operational controls on their individual doses. Since the doses incurred could be higher than in planned situations, the Commission recommends that these doses should be treated separately from those incurred in planned situations. Furthermore, because emergencies involving significant exposures of emergency teams are rare, relaxation of the controls for planned situations could be permitted without compromising long term protection. The Commission's occupational dose guidelines for emergencies are summarised as follows:

- For first responders undertaking rescue operations that involve saving life, no dose restrictions are recommended in principle if, and only if, the benefit to others clearly outweighs the risk to the rescuer. Otherwise, for rescue operations involving the prevention of serious injury or the development of catastrophic conditions, every effort should be made to avoid serious tissue injuries by keeping doses below about 1000 mSv and, ideally, to avoid other tissue injuries by keeping doses below 100 mSv, the Commission's maximum value for a constraint.
- For first responders undertaking other immediate and urgent rescue actions to prevent injuries or large doses to many people, all reasonable efforts should be made to keep doses below 100 mSv.
- For actions taken by workers engaged in recovery operations, the doses received should be treated as part of normal occupational exposure and the normal occupational dose limits would apply. Recovery operations should be planned exposure situations.

(214) Protection of workers in existing exposure situations should follow the system for planned exposure situations.

5.8.5. Dose constraints in medical exposure of patients

(215) The exposure of patients is intentional and both benefit and risk are mainly to the patient. Medical exposure of patients is therefore dealt with separately. Some exposures have to be incurred in the care and support of patients. Members of the public supporting patients being treated by internal radioactive sources in hospital or at home require individual consideration. Relevant constraints should be higher than those for general individuals. Further guidance on medical exposure for relatives, visitors and caregivers at home is provided in the corresponding foundation document and in Section 6.5.

5.8.6. Dose constraints in public exposure

(216) In planned situations, the Commission continues to recommend that public exposure be controlled by the procedures of optimisation below the source-related dose 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 individual* should be used to represent the most highly exposed individuals. This concept replaces the critical group concept previously used by the Commission (see Section 5.4.3). The dose constraint should be applied to the dose to the representative individual from the source for which the protection is being optimised. Occasionally, the representative individual will receive doses from other sources subject to regulatory control. If the relevant exposures to the representative individual are likely to approach the dose limit for public exposure (see Section 5.9), the constraints applied to each source must be selected to account for any significant contribution from other relevant sources to the exposure of the representative individual. The constraints for members of the public in planned situations should be smaller than the public dose limit.

(217) In the context of radioactive waste management, the Commission has previously recommended that the constraint for members of the public should have a value of no more than about 0.3 mSv in a year (*Publication 77*, ICRP; 1998a). In circumstances where there are planned discharges of long-lived radionuclides to the

environment, it will need to be verified that build up in the environment does not result in this constraint being exceeded. Where such verification is not possible, the Commission has recommended that it would be prudent to apply a constraint of the order of 0.1 mSv in a year to the prolonged component of the dose (*Publication 82*, ICRP; 2000b). The Commission continues with these recommendations.

(218) For emergency situations, the Commission recommends that optimisation of protection of the public should be performed if the individual public doses exceed a level for which some form of intervention with protective actions would be warranted under almost any circumstances. Selection of this level, now termed a constraint, is the responsibility of national authorities.

(219) Also for existing exposure situations, the Commission recommends that optimisation of protection of the public should be performed if the projected individual dose to the public exceeds a level for which some form of intervention with protective actions would be warranted under almost any circumstances in order to reduce the level of exposure as low as reasonably achievable below the constraint. It is the responsibility of national authorities to select this constraint, which should not exceed 100 mSv per year and typically should not exceed around 20 mSv per year.

(220) For both emergency and existing exposure situations, a wide range of alternative protective actions should be considered if individual doses are projected to be above the selected value for the relevant constraint, The intent should be to keep doses below the selected value of the constraint. Nevertheless, in exceptional circumstances compliance with a specific constraint may not represent the radiological optimum outcome. Such situations should be investigated on a case-by-case basis and could be considered in any a decision on revising the value for the constraint in question.

5.8.7. Application of optimisation and constraints

(221) The optimisation of protection is a forward-looking iterative process aimed at preventing exposures before they occur. 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.

(222) In the case of planned situations, the expected doses can be assessed in advance and protection can be planned accordingly. Consequently, the optimisation process should reject any protection options that would involve doses above the appropriate constraint.

(223) In emergency and existing exposure situations, where exposures are not planned, constraints should be viewed as a level of ambition and not as a mandatory level which must be achieved. In these situations, the process of selecting a constraint will of necessity take account of the practicability of reducing or

preventing the exposure including the scale, extent and cost of any consequential actions. Clearly, it would be a misapplication of radiological principles to select a value for a constraint, compliance with which would involve disproportionate resources.

(224) Constraints define a level above which action to reduce doses must almost always be taken. The requirement to optimise protection, however, applies in principle at all levels of dose or risk and is a continuing process. This means that the responsible agencies should periodically ask whether all that is reasonable has been done to reduce doses. The effort that is expended in answering this question in the case of an operating practice may well be more than, say, in the case of an existing exposure situation involving natural activity where the answer may be intuitively obvious.

(225) Nevertheless, the Commission recognises that responsible agencies need to focus their efforts on areas where benefits can be obtained and should not be required to address situations where regulatory efforts are either unwarranted or unfeasible. Guidance on the scope of regulating radiological protection is provided in Section 10.

(226) The best option is always specific to the exposure situation and represents the best level of protection that can be achieved under the 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. 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.

(227) The Commission wishes to emphasise that optimisation is not minimisation. It is the result of an evaluation, which carefully balances the detriment from the exposure (economic, human, social, political, etc.) and the resources available for the protection of individuals. Thus the best option is not necessarily the one with the lowest dose.

(228) In addition to the reduction of the magnitude of individual exposures, there is the additional expectation to reduce the number of exposed individuals. 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. Additional aspects to be considered in the comparison of protection options include the equity in the distribution of exposure among the concerned group of individuals. A particular issue is the one related to the comparison of the distribution of the exposures over long time periods and future populations.

(229) 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 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 doses can be calculated within the optimisation process.

(230) There are important limitations in the use of collective dose for risk assessment (see Sections 3.2.1 and 4.5.7). However, such calculations can be a useful tool for preliminary judgements to examine the feasibility of an epidemiological study in a specific situation, or the plausibility of attributing observed health effects to a source of exposure.

(231) 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, more weight could be given to moderate and high doses and to doses received in the near future. This is because of the increasing uncertainty of the relevance of very low doses and doses received in the remote 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.

(232) Within the system of radiological protection both the operators and the appropriate national authorities have responsibilities for applying the optimisation principle. The implementation of the process of optimisation of protection is the responsibility of the operating management, subject to the requirements of the authority. An active safety culture supports the successful application of optimisation by both the operational management and by the authority.

(233) All aspects of optimisation cannot be codified; optimisation is more an obligation of means than of results. Except in cases of regulatory violation, it is not the role of the 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.

Table 4. Framework for source-related dose constraints 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 – Acute or Annual (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.	Constraint 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. Dose constraint for radon in dwellings.
under 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.

5.9. Dose limits

(234) Dose limits apply in planned situations. In respect to the selection of dose limits, the Commission finds it useful to describe the acceptability of exposures (or risk) in three ways: unacceptable, tolerable, or acceptable. These degrees of acceptability are necessarily subjective and must be interpreted in relation to the nature of the planned activity and the type and source of the exposure under consideration. An unacceptable exposure is one that would not be acceptable to the regulator on any reasonable basis in planned exposure situations. Thus, unless the planned exposures can be reduced, the planned operation is unacceptable. For existing and emergency situations, there also exist dose levels that in most situations would be regarded as unacceptable, even though there may be exceptions, e.g., in the case of very high natural background radiation.

(235) A tolerable exposure is one that can reasonably be tolerated, although there may be room for optimisation of protection leading to lower exposures. An acceptable exposure is one that can be accepted without further improvement, i.e., protection has been optimised. In this framework, the dose limit represents a selected boundary in the region between unacceptable and tolerable for the situation to which the dose limit applies, namely for the control of sources in planned exposure situations. The dose constraint in each band represents the level of dose where action is almost always warranted.

(236) The Commission has concluded that the existing dose limits on effective dose that it recommended in *Publication 60* continue to provide an appropriate level of protection in planned situations (ICRP, 1991b). The reasons for this are twofold. Firstly, the Commission now emphasises the use of constraints on single sources, which are more restrictive than limits in planned situations. Secondly, 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 on Biological Effects). 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.

(237) 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 5 years (100 mSv in 5 years), with the further provision that the effective dose should not exceed 50 mSv in any single year.

(238) 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.

(239) 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.

(240) The recommended limits are summarised in Table 5. Dose limits do not apply in situations where the exposed individual is engaged in life saving actions or is attempting to prevent a catastrophic situation. The guidance given in section 11 would apply in such situations.

(241) In addition, 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 5. However new data on the radiosensitivity of the eye with regard to visual impairment are expected and the Commission will consider these data when they become available.

(242) 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 regulatory agencies and applied in the process of optimisation of protection.

Table 5. Recommended dose limits[1]

Type of limit	Occupational	Public
Effective dose	**20 mSv per year**, averaged over defined periods of 5 years and not exceeding 50 mSv in any single year	**1 mSv in a year**, or exceptionally more in a single year provided that the average over 5 years does not exceed 1 mSv per year
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. An additional limit is needed for localised exposures in order to prevent tissue reactions.

[3] Averaged over 1 cm^2 area of skin regardless of the area exposed (see also *Publication 59*, ICRP 1991a).

6.   MEDICAL EXPOSURE OF PATIENTS

(243) The exposure of patients is deliberate. Except in radiotherapy, it is not the aim to deliver a dose of radiation, but rather to use the radiation to provide diagnostic information or to conduct an 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.

(244) First and most important, 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. The recommendations provided in the previous chapters also apply to the exposures of workers in medical services and members of the public. For both these classes, some changes of emphasis have to be considered. The source-related dose constraints in Section 5.8, above, should apply to the workers and members of the public, but it should be recognised that some exposures have to be incurred in the care and support of patients. Members of the public may also be exposed in the course of caring for patients at home.

(245) Secondly, the patient has a special relationship with the medical and nursing staff. The system of protecting the staff from the source, e.g. shielding, should be designed to minimise any sense of isolation experienced by the patient. This is particularly relevant in nuclear medicine and brachytherapy, where the source is within the patient. Thirdly, radiotherapy aims to destroy the tumour tissue. Some functional damage to surrounding tissue and some risk of stochastic effects in adjacent non-target tissues are inevitable but should be minimised by the use of appropriate techniques and optimisation. Finally, hospitals and radiology installations have to be reasonably accessible to the public, whose exposure is thus more difficult to control than it is in industrial premises to which the public generally do not have access.

(246) The physicians involved in the processes that irradiate patients should always be trained in the principles of radiological protection. This is because of the deliberate nature of the exposures. Radiation exposures in medicine are not limited by any regulatory process, but are controlled by the physician, who therefore should be aware of the risks and benefits of the procedures involved.

6.1.   Justification of radiological procedures

(247) At the most fundamental level, the use of radiation in medicine is accepted as doing more good than harm to the patient. In addition, there are two levels of justification of a procedure in medicine. At the first level, a specified procedure with a specified objective is defined and justified, e.g., chest radiographs for patients showing relevant symptoms, or a group at risk to a condition that can be detected and treated. The aim of this generic 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 second 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.

(248) This procedure should be reviewed regularly to manage doses to patients to be commensurate with the medical objectives. In diagnosis, this means avoiding unnecessary exposures, while in therapy it requires delivery of the required dose to the volume to be treated, avoiding unnecessary exposure of healthy tissues.

6.1.1. The generic justification of a defined radiological procedure

(249) The generic justification of the radiological procedure is a matter for national professional bodies, sometimes in conjunction with national regulatory agencies. 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. The possibility of accidental 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.

6.1.2. The justification of a procedure for an individual patient

(250) For complex diagnostic procedures and for therapy, generic justification may not be sufficient. Individual justification by the radiological practitioner and the referring physician is then important and should take account of all the available information. This includes the details of the proposed procedure and of 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 criteria and patient categories in advance.

6.2. Optimisation of protection for patient doses in medical exposures

(251) The medical procedures causing patient exposures have to be justified and are usually for the direct benefit of the exposed individual and consequently somewhat less attention has been given to optimisation of protection in medical exposure of patients than in other applications of radiation sources. The optimisation of protection in patient exposures does not necessarily mean the reduction of doses to the patient. It is difficult to make a quantitative balance between loss of diagnostic information and reduction in dose to the patient.

(252) The Commission now uses the same conceptual approach in the source-related protection, irrespective of the type of source. This means that optimisation of protection is always constrained by a level of dose where action is almost always warranted. This level of dose, or constraint, is aimed at not selecting from the process of optimisation any protection options that would involve individual doses above the appropriate constraint. In the case of exposure from diagnostic 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.

(253) More discussion of its implementation is given in this section. 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.

6.2.1. Diagnostic reference levels

(254) Diagnostic reference levels apply to medical exposure of patients, not to occupational and public exposure. They 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. The values should be selected by professional medical bodies and reviewed at intervals that represent a compromise between the necessary stability and the long-term changes in the observed dose distributions. The selected values will be specific to a country or region.

(255) Diagnostic reference 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 (*Publication 73*, ICRP; 1996a). The diagnostic reference level should be expressed as a readily measurable patient-related quantity for the specified procedure. Additional guidance is given in the forthcoming ICRP Committee 3 'report on medical radiation and in Supporting Guidance 2 (ICRP, 2001).

(256) The levels are not intended to be used in a precise manner and a multiplicity of levels will reduce their usefulness. Reference levels for therapeutic procedures are not appropriate. The doses to the target tissues are chosen for each individual patient as part of the dose-planning procedures and must be large enough to be effective.

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

(258) In radiotherapy, optimisation involves not only delivering the prescribed dose to the tumour, but also planning the protection of tissues outside the target volume (*Publication 44*, ICRP; 1985).

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

6.3. Exposure of pregnant patients

(260) Prenatal doses from most correctly performed diagnostic procedures present no measurably increased risk of prenatal death, developmental damage including malformation, or impairment of mental development over the background incidence of these entities. Higher doses such as those involved in therapeutic procedures have the potential to result in developmental harm.

(261) 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 radiopharmaceuticals that are used in nuclear medicine can pose increased fetal risks. The Commission has given detailed guidance in *Publication 84 (*ICRP, 2000c*)*.

(262) It is important 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 careful treatment planning. Cancers in the pelvis can rarely be adequately treated during pregnancy without severe or lethal consequences for the fetus.

(263) Termination of pregnancy is an individual decision affected by many factors. Doses below 100 mGy to the developing organism should not be considered a reason for terminating a pregnancy. At fetal doses above this level, informed decisions should be made based upon individual circumstances, including the magnitude of the estimated embryonic/fetal dose.

(264) In many countries, radiation exposure of pregnant females in biomedical research is not specifically prohibited. However, their involvement in such research is very rare and should be discouraged.

6.4. The optimisation of protection for patient comforters and carers

(265) The exposures, other than occupational, of informed and consenting individuals helping to support and comfort patients, are connected with medical exposures. This definition includes the exposures of families and friends of patients discharged from a hospital.

(266) The exposure, other than occupational, of informed and consenting individuals helping to support and comfort patients, is a part of medical exposure. This definition includes the exposures of families and friends of patients discharged from hospital after diagnostic or therapeutic nuclear medicine procedures. Their exposure is different from that for public exposure, because the constraints on their exposures are not restricted by the dose limits. In *Publication 73* the Commission specified that dose in the region of a few mSv per episode is likely to be acceptable. This constraint is not to be used rigidly. For example, higher doses may well be appropriate for the parents of very sick children, if they are properly informed of the risks. However, the Commission (*Publication 94*) now also recommends that young children and infants, as well as visitors not engaged in direct care or comforting, should be treated as members of the public (i.e., be subject to a constraint).

6.4.1. Volunteers for research

(267) The use of volunteers in biomedical research makes a substantial contribution to medicine and to human radiobiology. Some of the research studies are of direct value in the investigation of disease; others provide information on the metabolism of pharmaceuticals and of radio-elements 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.

(268) 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 radiation protection advice.

6.4.2. Medico-legal exposures

(269) Insurance companies may also require individuals to receive medical exposures. In these cases, the public constraints are not appropriate and national authorities should use higher values similar to those for helpers and carers of a few mSv per episode.

6.5. Release of patients after therapy with unsealed radionuclides

(270) Unsealed radionuclides are radiopharmaceuticals that are injected, ingested or inhaled and have been used in the diagnosis and treatment of various diseases for many years. These may localise in body tissues until they decay or they may be eliminated through various pathways e.g., urine.

(271) Some public exposure may result from wastes discharged by nuclear medicine departments. The implications of such discharges to sewers and of airborne effluents should be assessed to ensure the relevant national constraints for public exposure are met. The adventitious or 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 for thyroid cancer (*Publications 73* and *94*). Further information and advice are available in the forthcoming ICRP Committee 3 document on medical exposures.

(272) Precautions for the public are rarely required after diagnostic nuclear medicine procedures but after some therapeutic procedures, doses to the public, patient's relatives and others may need to be limited. This mainly involves the frequently used radionuclide iodine-131, a high-energy gamma emitter.

(273) When releasing a patient treated with radioiodine, the exposure to other individuals needs to be controlled, although the risk of cancer induction from these patients treated with radioiodine is very low. However, the thyroid gland of persons

under the age of 15 is highly radiosensitive, so that particular care should be taken to avoid the contamination of infants, children and pregnant women. The risks from internal contamination of others are less significant than those from external exposure.

(274) 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. These recommendations advise a dose constraint of a few mSv per episode for caregivers and relatives, who should not be subject to the public dose limit. This dose constraint has often been inappropriately interpreted as a rigid annual dose limit.

(275) The Commission now recommends (*Publication 94*; ICRP, 2004a) that a dose constraint of a few mSv per episode should not apply to infants, young children and casual visitors. They should be subject to the public dose limit of 1 mSv/year.

(276) 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 public dose limits and dose constraints for other individuals should be observed. 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 and environmental factors.

7. EXPOSURE TO NATURAL SOURCES

(277) The Commission's system of radiological protection applies to all radiation sources and exposures including those of natural origin. Such sources are the dominant cause of exposure for the vast majority of people.

(278) Exposures to natural sources in the general environment are called existing exposures in the Commission's terminology. The recommended procedure of justification of an action to reduce the exposure followed by optimisation under a constraint is applied to the natural sources. The dose limits recommended by the Commission for planned situations do not apply to decisions on intervention in relation to natural sources.

(279) In cases where action to reduce doses is recommended, the process of optimisation below a constraint should be followed. The Commission has previously provided guidance on selecting an action level for protection against radon (see section 8.4), as well as for protection against other natural sources (ICRP 65, ICRP 82). These action levels are effectively constraints i.e., levels of aspiration often set by national authorities and not a mandatory level which must be achieved. In circumstances where doses exceed the value of constraints, optimised protective actions should be taken to reduce doses. Below the relevant constraint, action may be undertaken if technically easy and not entailing excessive cost, to reach an optimised level of exposure. In contrast to action levels below which no action is required, the process of optimisation and constraints do not use any predetermined end point below which no action is warranted to reduce the dose further.

(280) In many cases it will be obvious that action to reduce exposures is not warranted. This conclusion will often be intuitive. Principles for exclusion and exemption of natural sources are that the individual risk from the source or practice is insignificant, radiological protection is optimised, or the sources are inherently safe and the practice is justifiable. This is further discussed in Section 2.2.

7.1. Type of exposure

(281) There are many sources of exposure to natural radiation and each can vary significantly with geography, geology and lifestyle. Natural radiation exposures are broadly grouped as cosmic radiation and terrestrial radionuclides, which can result in external exposures (both indoors and outdoors) or internal exposures due to inhalation or ingestion.

(282) The development of human society has changed and this change has resulted in increased exposure to radionuclides in the thorium and uranium decay

chains. Siting of dwellings in high background areas, house construction materials rich in some radionuclides in the thorium and uranium decay chains, developments in eating and drinking habits that include the use of man-made fertilisers and water from mineral sources, have all typically increased the prolonged exposure of people. The radioactive progeny of radon-222 cause widespread exposure in many dwellings, where they are often the predominant source of prolonged exposure. In recent years, industrial development has further increased natural exposures to radionuclides in the thorium and uranium decay chains. Some industries have modified human habitats, making available naturally occurring radioactive materials (usually termed NORMs). Industries producing NORMs include: extractive industries for energy production; use of phosphate rock; and mining and milling of mineral sands.

(283) Living in areas with high concentrations of primordial radionuclides is a common cause of typically elevated exposures. Many situations of typically elevated exposure are created by the presence of high concentrations of the gas radon in dwellings. Others, however, are caused by elevated concentrations of other natural radionuclides in the environment. The vast majority of the world population incur doses around the average global exposure of 2.4 mSv per year; more than about 98% of the population incur doses lower than about 5 mSv per year, and about 99% doses lower than 7 mSv per year. However, there are inhabited areas of the world where the annual doses from natural sources are much higher than 10 mSv (UNSCEAR 2000).

(284) Doses from cosmic radiation at ground level (0.4 mSv per year) vary within a small range for the overwhelming majority of the population. Two thirds of the population live below 500 m and only 2 % live above 3000 m. The dose at 2000 m is approximately 2.5 times that at sea level and at 3000 m 4.4 times (UNSCEAR 2000).

(285) External exposure rates from terrestrial radiations are generated by potassium, uranium and thorium in soils and in building materials. The worldwide average dose rate is estimated to be 0.5 mSv per year, with most countries within the range of 0.3 – 0.6 mGy per year (UNSCEAR 2000). Outdoor exposure to these radiations is not amenable to control without avoiding certain locations. Indoor exposures are sometimes elevated due to the use of building materials with high natural radioactive content or from using building materials that have had their radioactive content inadvertently enhanced due to human activity. These indoor exposures can generally be reduced.

(286) Doses from ingestion of naturally occurring radionuclides commonly vary within a range of about a factor of two. The overall contribution of ^{40}K is substantial but is fairly constant and is limited by the body's uptake of potassium and not by the amount of potassium in the diet. Intakes of radionuclides in the thorium and uranium decay series are more. The average dose to individuals from this source is approximately 0.3 mSv per year with two thirds of this coming from ^{40}K.

(287) Radon exposure is dependent not only on geography and geology but also on lifestyle and building construction practices. While there can be large variations within a country there are also large variations between countries. The mean indoor radon concentration has been estimated to be 40 Bq m^{-3} with the mean for several

countries below 20 Bq m^{-3} and others above 100 Bq m^{-3} (UNSCEAR 2000). Within a country much larger variations can occur with some homes over one hundred times the average level making radon the most commonly variable source of natural exposure

7.2. Industries involving exposures to naturally occurring radioactive material

(288) Many industrially processed ores are enriched in radionuclides in the thorium and uranium decay chains. The levels of these radionuclides are often further elevated in waste streams and by-products. Consequential exposure of members of the public and the workforce can often occur. New facilities for processing such materials, where radiological protection requirement can be considered during the design stage, are planned situations. The Commission's requirements for such situations should apply.

(289) For historical reasons, however, such industries have not always operated completely within the Commission's system of protection. Steps should be taken to bring these existing facilities within the Commission's system. A decision should be made on whether it is justified to reduce exposures. This decision should also consider whether continued operation of the facility is also justified. When optimising protection, the constraint for occupational exposure should comply with the corresponding occupational dose limit, because occupational exposures are relatively straightforward to control. There may, however, be a number of issues surrounding public exposure, particularly to the accumulated waste residues from historical operations. Application of a constraint that complies with the Commission's public dose limit, which is intended to be used in circumstances where radiological protection has been planned in advance, may lead to protective actions which are inappropriate for the health benefits obtained. The Commission considers that such public exposure situations may be considered as existing exposure situations with the value for the dose constraint being selected accordingly.

(290) In cases where regulation is considered necessary, a graded approach should be used, taking account of the potential risks to people. For example, where the risks due to radiation are low and where the source or practice is inherently safe, a notification by the operator or owner to the regulatory body that the practice exists might be sufficient.

7.3. Controllability of natural sources

(291) Exposure to natural radiation sources is ubiquitous and not all exposure situations can or need be formally regulated or controlled. It has been considered useful to deal separately with primordial radiation and radioactive substances and those defined as 'man-made'. Exposure to natural sources is the largest contributor to human exposure, and logically it could be supposed that the most stringent radiological protection measures would apply to these sources. In fact, natural radiation exposure has not been dealt with comprehensively in radiological protection standards. The situation is made more complex when the concentrations of radionuclides that are of natural origin are enhanced, often inadvertently, by human activity. The distinction between 'natural' and 'man-made' or 'artificial' radiation exposure has proved to be peculiar and unconstructive.

(292) Perceptions can be different and members of the public make a distinction between natural and man-made exposure and weigh highly those radiation risks attributable to technological sources, claiming stronger protection for those sources. This has resulted in a dichotomous scale of protection depending on the origin of the exposure. Public concerns have led the Commission's radiological protection recommendations to be focused on 'man-made' sources with only a few situations involving 'natural' sources being considered. This is also due in part to the fact that 'man-made' sources are more readily controllable than natural sources.

(293) The Commission recommends that the radiological protection systems should include natural sources of exposure in a coherent and consistent way taking into account the feasibility of control and the perceived demands of those affected.

(294) Many natural radiation sources are not amenable to control in that they are unavoidable or uncontrollable, at least without inordinate effort, or while theoretically controllable are not feasible to control. Examples of sources which should be excluded are cosmic rays at ground level, ^{40}K in the human body and unmodified concentrations of naturally occurring radionuclides in most materials, except food stuffs, drinking water and animal feed, below 1000Bq/kg for the heads of uranium and thorium series and 10,000 Bq/kg for ^{40}K. Due to the wide variations in residential radon concentrations between regions, exclusion levels should be set 40 Bqm^{-3}, i.e. the global mean indoor radon concentration The Commission recommends that such sources are excluded from the radiation protection system (see Chapter 10).

(295) Other sources that are feasible to control but deliver such small exposures that control is unjustified or unnecessary should be exempted from most of the requirements of the radiation protection system. National authorities should determine activity concentration or activity levels for exemption for any amount of non-edible material and for moderate amounts of non-edible material, for food and drinking water, and for material in the form of a sealed source with a dose rate less than 1μSv/h at a distance of 0.1m (see Section 2.2.).

7.4. Constraints for radon in dwellings and workplaces

(296) Recent pooled analyses of European and North American and Chinese residential case-control studies (Darby et al 2005, 2006; Krewski et al. 2005, 2006; Lubin et al. 2004) indicate a significant association between the risk of lung cancer and exposure to residential radon. On the basis of currently available information, the Commission believes that the measurement adjusted risk coefficients reported from the European pooling study (Darby et al 2005, 2006) currently provides a basis for estimating lifetime risks to people at home, i.e. an ERR per 100 Bq m^{-3} of 0.16 (95% CI: 0.05 - 0.31) after adjustment for smoking status. In the absence of other causes of death, absolute lung cancer risks by age 75 at usual radon concentrations of 0, 100, and 400 Bq/m3 would be about 0.4%, 0.5% and 0.7% respectively for lifelong non-smokers, and about 25 times greater (10%, 12% and 16%) for cigarette smokers.

(297) 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 on domestic exposure to radon, the Commission now recommends that the estimation of risk from domestic radon exposure be based on the results of pooled residential case control radon studies. The currently available epidemiological evidence indicates that risks other than lung cancer from exposure to radon (and decay products) are likely to be small.

(298) The Commission has issued specific constraints for radon-222 at home and at work. There are several reasons to treat radon in this separate manner. The exposure route differs from that of other natural sources, and there are dosimetric and epidemiological issues peculiar to radon. 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.

(299) Because most people exposed to radon will also be exposed to other sources of radiation, it is helpful to provide a conversion from radon exposure to effective dose. The Commission has not used a dosimetric approach for radon in this conversion, but a direct comparison of the detriment associated with a unit effective dose and a unit radon exposure. In terms of detriment, an exposure to radon progeny of 1 mJ h m^{-3} is equivalent to an effective dose of 1.4 mSv for workers or 1.1 mSv for members of the public (ICRP, 1994). The corresponding figures for 1 working level moth (WLM) are 5.1 mSv for workers and 3.9 mSv for members of the public. This difference is due to the different detriments per mSv for workers and members of the public. The conversions obtained in this way are called conversion conventions, and they are based on detriment, not on dosimetry.

(300) In *Publication 65*, the policy was based upon first setting a level of effective dose from radon-222 where action would certainly be warranted to reduce the exposure. This was an effective dose of 10 mSv per year. The effective dose was converted into a value of radon concentration, which was different between homes and workplaces largely because of the relative number of hours spent at each. National regulatory agencies were expected to apply the optimisation of protection to find a lower level at which to act. The optimisation presumption thus led to a suggested range, within which so-called *action levels* were expected to be set. The result of the optimisation was to set action levels above which action was required to reduce the dose. For practical application the Commission used activity concentrations, rather than dosimetric quantities, for these levels. For dwellings this range was a radon concentration of between 600 - 200 Bq m^{-3}, while the corresponding range for workplaces was 1500 - 500 Bq m^{-3}. The Commission, however, accepted that, where national considerations so indicated, an Action Level might be set below this suggested range. In particular, this may be the case where action levels are set for new buildings where radon remedial measures are far more cost effective than for existing buildings.

(301) The Commission reaffirms the basic principles for controlling radon exposure as set out in *Publication 65* (ICRP, 1994a). Even though the nominal risk per Sv has changed slightly, the Commission, for the sake of continuity and practicality, retains the relationship between the constraint of 10 mSv given in *Publication 65* and the recommended corresponding activity concentration. This means that the radon constraints remain at 1500 Bq m^{-3} for workplaces and 600 Bq m^{-3} for homes (Table 6).

Table 6. Constraints for Radon-222[†]

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

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

(302) It is the responsibility of the appropriate national authorities, as with other sources, to establish their own constraints and then to apply the process of optimisation of protection in their country. All reasonable efforts should be made to reduce radon-222 exposures at home and at work to below the constraints that are set. It is important that the action 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 constraints.

(303) It is now recognised that in some occupational exposure situations, particularly mines, radon 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 constraint for radon 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,.

(304) The problems posed by radon-220 (thoron) are much less widespread, and generally more tractable, than those posed by radon-222. For protection against thoron, it is usually sufficient to control the intake of the decay product, lead-212, which has a half-life of 10.6 hours. The current conversion convention suggested in Publication 65 (ICRP, 1994) is not applicable to thoron decay products.

(305) Once optimisation has resulted in concentration activities well below the constraints, no further action is required, apart from perhaps monitoring activity concentration sporadically to ensure that levels remain low.

8.   POTENTIAL EXPOSURES

(306) In the case of planned situations and existing situations, a certain level of exposure is reasonably expected to occur which can be compared against the appropriate constraint. Particularly in the case of planned situations, however, accidents and departures from planned operating procedures may occur that could give rise to higher exposures. Often, such events can be foreseen and their probability of occurrence estimated, but they cannot be predicted in detail. They are referred to as potential exposures. There is usually an interaction between potential exposures and the exposures arising from planned operations; for example, actions taken to reduce the exposure from planned operations may increase the probability of potential exposures. Thus, the storage of waste rather than its dispersal could reduce the planned exposures from discharges but would increase potential exposures.

(307) 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 may be useful to estimate risk by combining the estimated probability of occurrence with the health risk from the dose if it occurs. This quantity may 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, 1998).

8.1.   Different kinds of potential exposure

(308) 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.
- 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.
- 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.

(309) The initial treatment of potential exposures should form part of the protection applied to planned or existing situations. It should be recognised that the exposures, if they occur, 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).

(310) In case of major events with large-scale consequences, an assessment based on health effects as an immediate consequence of direct exposure to radiation only would be insufficient. In *Publication 96* (2005a), the Commission provides

some additional advice concerning radiological protection after events involving malicious intent. In case of exposures taking place far in the future, additional uncertainties are involved. 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.

8.2. Radiation safety and security

(311) The safety and security of radiation sources aim at preventing harm to health and property. The recommendations of the Commission presume that, as a precondition for adequate radiological protection, radiation sources are subject to proper security measures (ICRP, 1991). 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 requires that sources be kept secure so as to prevent theft or damage.

(312) 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 since long included aspects of security in its system of protection (ICRP, 1991). 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. Essential to safety are measures to ensure that control of radioactive material and access to radiation installations are not relinquished.

(313) When the Commission's current recommendations were developed, measures specifically to protect against terrorism or other malicious acts were not in focus. However, it has become evident that radiation safety must include also the potential for such scenarios (IAEA, 2001; 2003; in press).

(314) Secured sources can become, and have become, unsecured. Radiological accidents have occurred because of unintentional breaches in source security or because a discarded, or orphan, source was found. These events indicate what might occur if radioactive materials were 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 (see IAEA, 1988)..

8.3. Assessment of potential exposures

(315) 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 s0ome criterion of acceptability; and f)

optimisation of protection which may require several reiterations of the previous steps.

(316) 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).

(317) Conceptually, the simplest way of dealing with the potential exposure of individuals is 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 and the lifetime conditional probability of radiation-related death from the dose if it were to have been incurred. The resulting probability can then be compared to a risk constraint.

(318) 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, considering the uncertainties in estimations of the probability of an unsafe situation and the resulting dose, it will often be sufficient, at least for regulatory purposes, to use a generic risk constraint value based on generalisations about normal occupational exposures, rather than a more specific study of the particular operation. For occupational exposures, the Commission continues to recommend a generic risk constraint of $2\ 10^{-4}$. For potential exposures of the public, the Commission retains a risk constraint of 10^{-5}, as in the case of disposal of long-lived radioactive waste (ICRP 1998).

(319) The use of probability assessment is limited by the extent that unlikely events can be forecast. The estimates of annual probabilities of initiating events much less than 10^{-6} must be treated with doubt 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.

8.4. Optimisation of protection against potential exposures

(320) Conceptually, risks from planned exposures and from potential or unpredicted exposures can be equated, but simultaneous, formal optimisation of protection against both types of exposure would be difficult. The use of safety devices for protection against potential exposures includes an element of optimisation. Also, the generic occupational risk constraint recommended here corresponds to the health risk associated with occupational doses in an optimised operation.

(321) Optimisation of protection against potential exposures is primarily a matter of 'safety culture' and the use of sound engineering principles and experience. Optimal protection against potential exposures is not necessarily achieved at the same level of risk as optimal protection against planned exposure situations, because the costs of reducing risks due to such exposures and risks due to potential exposures may be quite different.

(322) Safety culture is an essential managerial principle for all individuals and organisations involved in radiological activities need to establish and maintain a

consistent and pervading approach to safety that governs all their actions. This principle was first defined in the context of nuclear safety and was then extended to radiation safety in general (IAEA, 1988; IAEA, 1996a).

(323) At nuclear installations, safety planning is usually well developed and potential exposures are usually taken into account in such planning. The Commission wishes to underscore the importance of, and feasibility of, similar planning at workplaces outside the nuclear fuel cycle. A structured approach is possible and desirable, even at quite small installations where specific expertise in safety matters is not always available within the organisation. It is important to ensure that radiological protection, safety and security of sources, and other health and environmental concerns are dealt with using an integrated approach. Some key attributes of safety culture are: personal dedication, safety thinking and an inherently questioning attitude.

8.5. Exposures with malicious intent

(324) There has been increasing concern internationally about the deliberate dispersion of radioactive material to cause panic and chaos, and this has raised the awareness regarding the security of radiation sources. It has also triggered a widespread request for professional advice on measures aimed at preventing radiological attacks and on protective measures in the case of such an event. Existing radiological emergency contingency plans have mainly focused on accident scenarios, rather than on radiological attacks designed to cause harm or fear.

(325) The preparation for and the response to a radiological attack should be aimed at protecting people against arbitrary and unpredictable radiation exposure situations. The Commission has issued guidance in its *Publication 96* (ICRP, 2005a) that provides advice on protecting rescuers and affected members of the public against radiation exposure in the aftermath of such an attack.

(326) In most postulated scenarios associated with a radiological attack, radiation doses incurred by the majority of exposed persons will probably be low, e.g. of the order of tens of mSv or less. While these low radiation doses have the potential to induce stochastic health effects, the probability of their occurrence is small. Conversely, a small number of people could be exposed to high radiation doses, e.g., of the order of thousands of mSv, and deterministic health effects are almost certain to occur.

(327) The response must essentially be to identify and characterise the emergency situation, to provide medical care for injured persons, to attempt to avoid further exposures, to gain control of the situation, to prevent the spread of radioactive materials, to provide accurate and timely information to the public, and to institute a process for returning to normality, while dealing with psychological issues, such as distress and misattribution and fear of illness, which will be a major concern. In the immediate response phase, exclusion distances used in relation to explosions are a good starting point for controlling the site for radiation levels, and typical precautions at medical facilities for infectious agents are sufficient as a starting point for handling persons that may be contaminated with radioactive material. Taking actions to avert exposures is much more effective than medical treatment after exposure has occurred.

(328) Responders undertaking recovery and restoration operations should be protected according to normal occupational radiological protection standards and should not exceed internationally accepted occupational dose limits. This limitation could be relaxed for informed volunteers undertaking urgent rescue actions following a radiological attack, and is not applicable for volunteered life-saving actions whenever the benefit to others clearly outweighs the rescuer's own risk. Female workers who may be pregnant or nursing an infant should not be employed as first responders undertaking life-saving or other urgent actions.

(329) Urgent actions in the rescue phase include: personal decontamination, sheltering, potassium iodine prophylaxis (if radioiodines are involved) and temporary evacuation. In the recovery phase, definitive relocation and resettlement may be needed in extreme cases. The recovery phase may require restoration and cleanup, the safe management of the radioactive waste remaining from these operations, management of corpses containing significant amounts of radioactive substances, and dealing with long-term prolonged exposure situations caused by remaining radioactive residues.

(330) The Commission's recommendations in this field should be seen as decision-aiding tool to help the competent authorities prepare for the aftermath of a radiological attack. The quantitative recommendations given above should be used at the planning stage as the basis for developing operational intervention levels. In order to prevent overreaction, it is essential that radiological protection decisions are proportional to the magnitude of the radiological attack.

8.6. Accidents in radiation therapy

(331) Accidental overdoses during radiotherapy often have devastating and sometimes fatal consequences. While a number of serious and fatal radiotherapy accidents are reported, it is likely that many more have occurred but were either not recognised or reported to regulatory authorities. Underdosage in radiotherapy also has serious and life-threatening consequences but is difficult to detect clinically and may only be manifest by poor tumour control.

(332) Radiotherapy accidents may happen as a consequence of different events and circumstances. Reported examples include:

- Vietnam (1992): An individual entered the irradiation room at an electron accelerator facility and unknowingly exposed his hands to the x-ray beam. One hand had to be amputated (IAEA, 1996b).
- Costa Rica (1996): Incorrect calibration of a cobalt-60 teletherapy unit following a source change which led to prolonged treatment times in 114 patients. 51 patients died within two years, 13 deaths were radiation related and 4 possibly related (IAEA, 1998).
- Thailand (2000): An abandoned cobalt-60 teletherapy head was partially dismantled, taken from unsecured storage and sold as scrap metal. Ten people received high doses and 3 died within two months of the accident (IAEA, 2002).
- Poland (2001): Following a drop in electrical power and then restoration of power, a medical linear accelerator delivered higher doses than expected due

to damage of a safety interlock system. 5 patients received severe radiation injuries (IAEA, 2004).

(333) Accident prevention in radiotherapy (external beam therapy and brachytherapy) should be an integral part of the design of equipment and premises and of the working procedures. It should not be considered an extra feature to be provided as an afterthought. A key focus of accident prevention has long been the use of multiple safeguards against the consequences of failures. This approach, now often called 'defense in depth', by analogy with military strategy, is aimed at preventing a single failure from having serious consequences. Some defenses are provided by the design of equipment, others by the working procedures. The Commission has given extensive advice on the prevention of accidents in *Publications 86*, *97*, and *98* (ICRP, 2000d, 2005b, 2005c).

9. EMERGENCY SITUATIONS AND EXISTING SITUATIONS

(334) Potential or unexpected exposures were discussed in Chapter 8, where it was emphasised that they need to be considered as a part of the assessment of planned situations. A potential exposure may become a real exposure and may call for intervention in the case of an emergency situation.

9.1. Types of emergency situations

(335) There are many types of conceivable accidents to be considered in the planning for emergency situations: those occurring at nuclear facilities (e.g., power reactors and other fuel cycle facilities involving criticality or chemical reactions and release of radioactive materials) and those occurring at radiological facilities or involving other radiation sources, such as from the medical, industrial and commercial use of radionuclides. Accidents in the transportation of radioactive materials may also lead to the release of radionuclides to the environment.

(336) No single accident type or sequence of events can be used as a basis for developing emergency response plans. In the case of nuclear facilities, the type of plant and its potential for release of different radionuclides will influence the emergency response plan developed specifically for that plant and its site. The off-site consequences of the range of predicted accident sequences can form a basis on which detailed emergency plans are prepared. Accidents at certain nuclear fuel cycle facilities may have as their main consequence the release of materials which are chemically toxic and for which the radiological contribution to the hazard is minimal. Response plans for radiological emergencies involving lost sources, or involving transport of radioactive materials, will need to have broad applicability because the site at which the accident may occur will not be known in advance.

(337) The first concern in the event of a radiological emergency situation is to keep the exposure to individuals from all pathways below the thresholds for serious deterministic health effects. In addition, the unacceptability of a high risk of stochastic health effects to individuals may be a significant factor in the decision making process. The countermeasures forming a programme of intervention in the case of an accident or an emergency situation always have some disadvantages, and they should be justified. Their form, scale and duration should then be optimised so as to maximise the net benefit.

(338) In emergency situations, the same approach of optimisation below a dose constraint should be applied. The dose constraint represents the level of dose where action is almost always warranted. Compliance with the constraint is not in itself considered sufficient, optimisation of protection is also required. The dose limits recommended by the Commission for planned situations do not apply to decisions on intervention in emergency situations. The use of these pre-determined dose limits as the basis for deciding on intervention might involve measures that would be out of all proportion to the benefit obtained, and would then be in conflict with the principle of justification. The Commission therefore recommends against the application of these dose limits in emergency situations for deciding on the need for, or scope of, intervention. Nevertheless, at some level of dose, approaching that which would cause tissue reactions, some kind of intervention will become almost mandatory. The Commission now considers this level to be 100 mSv either acute or in a year.

(339) In ICRP *Publications 60* and *63* (1991), the Commission set out general principles for planning intervention in the case of an accident. All accidents are different, as are the approaches of national organisations having responsibility for response to an emergency situation. The Commission's general guidelines need to be translated into appropriate emergency response plans by competent national authorities. The intervention levels given in those publications are now regarded as constraints.

9.2. Existing situations

(340) In some cases, existing radiation sources of natural origin cause exposures high enough to warrant radiological protection considerations (see Chapter 7). In other cases, it may be necessary to take radiological protection decisions concerning existing man-made sources of radiation (for instance, significant radioactive contamination may have been detected after a planned operation has ceased).

(341) The Commission pointed out in *Publication 82* (ICRP; 2000b) that members of the public (and sometimes their political representatives) may have personal and distinct views on the radiation risks attributable to artificial sources of prolonged exposure in relation to those due to natural sources. This usually results in differently perceived needs for response and a different scale of protection, depending on the origin of the exposure. The claim for protection is generally stronger when the source of exposure is a technological by-product rather than when it is considered to be of natural origin.

(342) Typically elevated prolonged exposures due to natural radiation sources are usually ignored by society, while relatively minor prolonged exposures to artificial long-lived radioactive residues are a cause of concern and sometimes prompt actions that are 'unnecessary' in a radiological protection sense. This reality of societal and political attributes, generally unrelated to radiological protection, usually influences the final decision on the level of protection against prolonged exposure. Therefore, while the Commission provides *decision-aiding* recommendations mainly based on scientific considerations on radiological protection, the outcome of its advice will be expected to serve as an input to a final (usually wider) *decision-making* process, which may include other societal concerns and considerations. The decision-making process may include the participation of relevant stakeholders rather than radiological protection specialists alone.

9.3. Projected, averted, and residual dose

(343) In many situations, actions to reduce exposure cannot be applied at the source and have to be applied to the pathways leading to a dose in humans. Doses to the population at risk should first be estimated for each exposure pathway without taking into account possible protective actions. These are called *projected doses*, which are the key concept for planning an intervention. The *averted dose* for each pathway is the dose saved by implementing a protective action. The duration of the exposure is an important consideration because protraction of the dose influences the threshold dose at which deterministic effects appear.

(344) If the interventions are fully effective, the averted dose is numerically equal to the projected dose. Intervention may not be fully effective, however, either because dose has already been received, or because the intervention itself may only partly reduce the total projected dose. The remaining dose from each pathway is called *residual dose*. The sum of residual doses from all pathways after implementation of protective actions should be kept under review because of the possibility of a significant risk of health effects.

9.4. Justification

(345) The decision maker should determine whether the protective action is justified from the viewpoint of those individuals who are the most at risk. After that, consideration should be given to justification of the action from society's point of view, because the costs and benefits will probably not be evenly distributed amongst the same people. The societal considerations may extend the protective action to cover an even larger group of affected people, or they may set limits to the practical or financial feasibility of the action (e.g. evacuation of a large city). In case the proposed protective action is not justified from the viewpoint of the individual, decision makers may still seek to reduce the collective dose and the detriment, and care should be taken not to do more harm than good in the process.

(346) Justification of an intervention should begin by considering the average projected dose to the exposed population to which the intervention would be applied (e.g. sheltering, evacuation, relocation). If the protective action is not justified, consideration should be given to whether there are subgroups of the population whose characteristics differ significantly from the average and for whom the protective action might be justified.

(347) The introduction of any particular protective action entails some risk to the individuals affected and some harm to society in terms of financial costs and of societal and economic disruption. Therefore, before introducing a protective action, it should be shown that it can produce a positive net benefit. Each protective action that has been implemented should be subject to periodic review to ensure that its continuation in its present form is justified. For emergency situations where the projected dose from a specific pathway or combination of pathways may approach thresholds for serious deterministic health effects, protective actions are almost always justified a priori.

9.5. Optimisation of protection

(348) Results of the optimisation process below the dose constraint will lead to *intervention levels*. The constraint represents the fundamental level of protection for the most exposed individuals and the level of dose or risk where action is almost always warranted. The intervention level represents the optimised, and thus the best, level of protection under the given planning circumstances. The chosen values of constraints and intervention levels will thus depend upon the circumstances. The quantities should be directly measurable, such as activity concentrations for food or exposure rates for ground contamination and generally can be related to the averted dose.

(349) The benefit of a particular protective action within a programme of intervention should be judged on the basis of the dose averted (achieved or

expected) by that specific protective action. Thus each protective action has to be considered on its own merits. For example, decisions about the control of specific foodstuffs are independent of decisions about other foodstuffs and of decisions about sheltering or evacuation. In addition, however, the doses that would be incurred via all the relevant pathways of exposure, some subject to protective actions and some not, should be assessed. If the total residual dose to some individuals is so high as to be unacceptable even in an emergency, the feasibility of additional protective actions influencing the major contributions to the total residual dose should be considered. Doses causing serious deterministic effects or a high probability of stochastic affects would call for such a review. For this purpose, a level of dose received by all pathways should be assessed at the planning stage.

(350) It is important that decision makers inform the public of all aspects of their decisions, otherwise the public may be misled and the radiological protection efforts may be mistrusted.

10. PROTECTION OF THE ENVIRONMENT

10.1. Introduction

(351) 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 radiation 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.

(352) 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. But 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.

(353) 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. 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 notes that its recommended weighting factors for man, and effective dose as defined for man, are not intended for non-human species and cannot be utilised for such purposes. 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.

(354) 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. 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 experienced 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.

10.2. Reference Animals and Plants

(355) 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.

(356) For human beings, it has been convenient to consider the effects of radiation as being of a non-stochastic (causing tissue damage) or of a stochastic nature. With regard to non-human species, however, not only is there a lack of data to classify radiation effects in such a way, but there is also no clear reason as to why or how such information could be useful in assuring that the objectives of protecting the environment had been achieved. Thus other ways of considering radiation effects are likely to prove to be more useful for non-human species, such as those that cause early mortality, or morbidity, or reduced reproductive success, irrespective of the stochastic or non-stochastic nature of the underlying causes.

(357) The Commission recognises that the development of such a Reference Animal and Plant approach cannot provide an assessment of the probability and severity of the potential effects of radiation on all types of organisms, but it should provide the basis for drawing some broad conclusions, and serve as a focus for more detailed investigations where warranted. And by the development of such a framework, the Commission will also be in a better position to provide more general advice with regard to those aspects or features of different environments that are likely to be of concern under different radiation exposure situations. But it also recognises that the framework it is now developing for non-human species needs to complement and not compromise the radiation protection system that has been developed for human beings, and that it also needs to complement those measures that are being developed for the protection of the environment from other potential hazards.

11. IMPLEMENTATION OF THE COMMISSION'S RECOMMENDATIONS

(358) This chapter is concerned principally with 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.

(359) The International Atomic Energy Agency and the Nuclear Energy Agency of OECD issue further advice on the infrastructure required for radiological protection to their member states (see, e.g., IAEA, 1996a; 2000 and NEA, 2005). Generic advice on organisation for health and safety at work is provided by the International Labour Organization.

11.1. The infrastructure for radiological protection and safety

(360) Because of the hazards associated with ionising radiation, and the fact that special instruments are needed to detect such radiation, 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), and the employees at such undertakings, and may include additional bodies and persons responsible for protection and safety.

(361) Members of the public are often stakeholders when decisions concerning radiological issues are to be taken, and have a legitimate interest in access to such decisions and information on how they were reached. However, responsibility for radiological protection cannot be transferred to individual members of the public. As an example, warning signs may be helpful for information purposes, but an operator cannot evade responsibility simply by posting warning signs.

(362) 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.

(363) 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.

(364) 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 regulatory agency, or some other designated body, will have to accept some of the responsibilities usually carried by the operating management.

(365) 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 regulatory agencies, 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.

(366) 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 regulatory agencies should be held accountable for the advice they give and any requirements they impose.

(367) 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 accident 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.

11.1.1. Decision-aiding and decision-making

(368) The Commission provides recommendations on radiological protection on the basis of scientific assessments of the health risks associated with exposure levels and relevant attributes of various exposure situations. However, it also recognises the importance of additional societal and political attributes, generally unrelated to radiological protection, which usually influence the final decision on situations of exposure to radiation and the level of protection to be provided against such exposures. Therefore, while the Commission's publications provide *decision-aiding* recommendations mainly based on scientific considerations on radiological protection, the outcome of its advice could also serve as an input to the final (usually wider) *decision-making* process which may include other societal concerns and considerations.

(369) The involvement of stakeholders, a term which has been used by the Commission in *Publication 82* (ICRP, 2000) to mean those persons or organisations who have interests in and concern about a situation, is an important decision-aiding input to decision-making on radiological protection issues, not least in the optimisation process. While the extent of stakeholder involvement will vary from one situation to another, it is a proven means to achieve the incorporation of values into the decision-making process, the improvement of the substantive quality of

decisions, the resolution of conflicts among competing interests, the building of shared understanding with both workers and the public as well as trust in institutions. Furthermore, involving all concerned parties reinforces the safety culture and introduces the necessary flexibility in the management of the radiological risk that is needed to achieve more effective and sustainable decisions.

11.1.2. Responsibility under prescriptive regulation regimes

(370) 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.

(371) It may be tempting to use such requirements in view of their purported short-term efficiency, especially where the operating management lacks detailed experience. Prescriptive requirements concerning the conduct of operations do, however, result in some de facto transfer of responsibility and accountability from the operator to the regulator. In the long run, they also reduce the operators' incentive for self-improvement. Therefore, it is usually better to adopt a regulatory regime that places a more explicit responsibility on the operator, and forces the operator to convince the regulator that adequate protection methods and standards are used and maintained.

(372) If in spite of this circumstances dictate the use of prescriptive requirements, their use 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.

11.1.3. External expertise and advice; delegation of authority

(373) 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.

(374) However, it must be clearly understood that 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.

(375) Similarly, a regulatory authority may be using consultants and advisory bodies in support of its activities. Again, 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.

(376) In some countries and legal systems, it is also possible theoretically for a regulatory agency to delegate authority concerning certain classes of simple decisions to an outside organisation, such as a professional body. Such delegation could lead to improved efficiency and economy in that the regulator can concentrate on 'difficult' cases. However, any such delegation will only be possible if the receiving organisation can stand up to the same scrutiny as the regulator. The organisation in question must be impartial, reliable, and consistent, and transparency must be ensured. There must also be a convincing system of auditing the practices of the organisation in question.

11.1.4. Mutual trust and accident reporting

(377) 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 (and, indeed, for satisfactory achievement of any kind of regulated safety and health at work and in the environment).

(378) An important task for a regulatory authority is to provide operating organisations with information aimed at the prevention of accidents. An accident and incident reporting routine with feedback to operators 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 regulator's trust in an operator. However, operating organisations also need to be able to trust the regulator. A primary requirement is that all operators are treated in a fair and equal manner. Furthermore, for an incident reporting system to work properly, operators must also trust regulators to regard safety improvements as more important than punishments. Realising this, some regulatory authorities use a graded approach, where punishments 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 more severe punishment.

11.2. Management requirements

(379) As pointed out in *Publication 60* (ICRP, 1991) and in several subsequent reports from the Commission, 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 a recognition that safety is a personal responsibility and is of major concern to the top management. Close links between the management and the representatives of the workforce have a major role to play.

(380) The details of the management structure and of the operating instructions will depend on the form and scale of the operating organisation, but their importance should be recognised even in small or informal organisations. 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.

(381) Attention should also be given to the layout of plant and equipment. In addition, the techniques for dealing with potential exposures include safety analysis to identify possible causes of accidents and the methods available to reduce their likelihood and severity, followed by the assessment of the reliability of all the principal systems affecting the probability of accidents. These systems include the plant and equipment, any software used in the equipment or in the operations, the operating and maintenance procedures, and the performance of the human operators. Much of the responsibility for these analyses should fall on the designer, but part of it should rest on the operating management.

(382) There should be plans for dealing with accidents. These plans should be subject to periodic review. All these reviews and assessments should lead to the preparation of written management requirements. Planning for the event of emergences 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. The hand-over should be a formal procedure. More details are given in Chapter 9.

(383) As stated in *Publication 75* (ICRP, 1997), 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. 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.

(384) 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 a 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.

11.2.1. Occupational services for protection and health

(385) One 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. The head of the protection service should have direct access to the senior operating management.

(386) The principal role of the occupational health service is the same as it is in any occupation. Physicians supervising the health of a force of radiation workers need to be familiar with the tasks and working conditions of the workforce. They then have to decide on the fitness of each worker for the intended tasks. The radiation component of the working environment will only very rarely have any significant influence on that decision. (An example of an exceptional situation might be the presence of radioactive dust in the working environment, which might disproportionally effect workers with skin or respiratory disorders, although the primary consideration in such a case would be to reduce the amount of dust). Furthermore, the radiation component of the working environment should have no influence on the administrative conditions of service of those occupationally exposed.

(387) The supervising physician, sometimes supported by specialists, may also be required to counsel workers in two special categories. The first is women who are, or may become, pregnant. They should be advised to inform the physician as soon as they think they may be pregnant, so that the management can be advised to arrange for any necessary change of duties or special protective provisions. The second group comprises any individuals who have been exposed substantially in excess of the dose limits or may have been involved in potentially dangerous situations. Only in exceptional conditions will clinical tests or treatment be indicated.

(388) The supervising physician needs information about the working conditions and the exposures of individual workers. Some of this information will come from installation records, and some from the protection service. Some of the data will be transferred to, and then form part of, the individual's medical record. Such records are usually regarded as medically confidential. It is important not to let confidentiality compromise the availability of the original data to the management and to non-medical professionals involved in protection.

11.3. The assessment of doses

(389) The basis of the Commission's recommendations is the restriction of doses and of the probability of incurring doses. The measurement or assessment of 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.

(390) General advice on dose monitoring practices is provided in *Publication 75* (ICRP, 1997). *Publication 78* (ICRP, 1998) gives advice on monitoring for internal contamination. The reports of the International Commission on Radiation Units and Measurements (ICRU) provide further detailed advice.

11.4. Compliance with the intended standard of protection

(391) 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.

(392) Regulatory agencies 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.

11.5. The classification of workplaces and working conditions

(393) One of the most important functions of management requirements is that of maintaining control over the sources of exposure and over the workers who are occupationally exposed. It is usually easy to specify the sources of occupational exposure. The specification has to be applied with common sense because man-made radionuclides are present in trace amounts in most materials. The control of sources is helped by requiring that the workplaces containing them be formally designated. The Commission uses two such designations: *controlled areas* and *supervised areas*.

(394) 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.

(395) The designation of controlled and supervised areas should be decided either at the design stage or locally by the operating management on the basis of operational experience and judgement. This judgement has to take account of the expected level and the likely variations of the doses and intakes, and the potential for accidents. Account should be taken both of the expected levels of exposure and of the likely variations in these exposures. In areas where there is no problem of contamination by unsealed radioactive materials, designated areas may sometimes be defined in terms of the dose rates at the boundary. The aim should be to ensure that anyone outside the designated areas will not need to be regarded as occupationally exposed. The dose limits recommended by the Commission are intended to apply to all workers, but the use of designated areas should enable the actual doses received outside the designated areas to be kept below the dose limits for public exposure.

GLOSSARY OF KEY TERMS AND CONCEPTS

[This Glossary will be re-checked and updated after public consultation]

α/β ratio: Dose at which the linear and quadratic components of cell killing are equal; a measure of the curvature of a cell survival curve, and a measure of sensitivity of a tissue or tumour to dose fractionate.

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.

Ambient Dose Equivalent, H*(10): The dose equivalent at a point in a radiation field that would be produced by the corresponding expanded and aligned field in the ICRU sphere at depth of 10 mm on the radius vector opposing the direction of thew aligned field. The unit of ambient dose equivalent is joule per kilogram (J kg^{-1}) and its special name is sievert (Sv).

Annual Limit on Intake (ALI): The activity of a radionuclide which taken into the body of a reference person alone results in a committed effective dose equal to the annual dose limit set by the ICRP for each year of occupational exposure.

Apoptosis: An active biochemical process of programmed cell death following radiation or other insults.

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.

Baseline rates: The annual disease incidence observed in a population in absence of exposure to the agent under study.

Becquerel (Bq): The special name for the SI unit of activity, 1 Bq = 1 s^{-1} ($\approx$ 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.

Biological Half-Life: The time required in the absence of further input for a biological system to eliminate, by natural processes, half the amount of a substance, (eg. radioactive material) that has entered it.

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

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 $\frac{\mathrm{d}N}{\mathrm{d}E}$ denoted 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 number of individuals who experiences these values of the effective dose, $N(E_1, E_2)$ is

$$N(E_1, E_2) = \int\limits_{E_1}^{E_2} \frac{\mathrm{d}N}{\mathrm{d}E}\, \mathrm{d}E$$

and the average value of effective dose $E(E_1,E_2)$ in the interval of individual doses between E_1 and E_2 and the time period Δ T is

$$E(E_1, E_2, \Delta T) = \frac{1}{N(E_1, E_2)} \int\limits_{E_1}^{E_2} E\; \frac{\mathrm{d}N}{\mathrm{d}E}\, \mathrm{d}E \quad .$$

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

Committed Effective Dose, E( ): The sum of the products of the committed organ or tissue equivalent doses and the appropriate organ or tissue weighting factors (w_T), where 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 Radiation-Weighted Dose, H_T( ): 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 is the integration time in years

Confidence limits: An interval giving the lowest and highest estimate of a parameter, that is statistically compatible with the data. For a 95% confidence interval, there is a 95% chance that the interval contains the parameter.

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.

Derived Air Concentration (DAC): Equals the ALI (of a radionuclide) divided by the volume of air inhaled by a reference person in a working year (ie. 2.4×10^3 m^3). The unit of DAC is Bq m^{-3}.

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".

Directional Dose Equivalent, H′(d,): The dose equivalent at a point in a radiation field that would be produced by the corresponding expanded field in the ICRU sphere at a depth, d, on a radius in a specified direction, . The unit of directional dose equivalent is joule per kilogram (J kg^{-1}) and its special name is sievert (Sv).

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}) and its special name is sievert (Sv).

Differentiation: The process whereby stem cells enter a pathway of proliferation during which daughter cells acquire specialised functions.

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 equivalent quantities
- ambient dose equivalent, H*(d): The dose equivalent that would be produced by the corresponding aligned and expanded field in the ICRU sphere at a depth d on the

radius opposing the direction of the aligned field, Used as a directly measurable proxy (i.e. substitute) for effective dose for use in monitoring of external exposure. The recommended value of d for strongly penetrating radiation is 10 mm.

- directional dose equivalent, H′(d,): The dose equivalent that would be produced by the corresponding expanded field in the ICRU sphere at a depth d on a radius in a specified direction. Used as a directly measurable proxy for equivalent dose in the skin for use in monitoring of external exposure, The recommended value of d for weakly penetrating radiation is 0.07 mm.

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 optimization 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 optimization. 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 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 $J \cdot h/m^3$).

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

Dose-threshold hypothesis: A given dose above background below which it is hypothesised that the risk of excess cancer and/or heritable disease is zero.

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

DMF: Dose modifying factor, ratio of doses with and without modifying agents, causing the same level of biological effect.

DNA damage signalling: Interacting biochemical processes which recognise and respond to DNA damage in cells eg. by causing arrest of the reproductive cell cycle.

DS02: A dose system developed in approximately 2002 for estimating gamma and neutron exposure under a large variety of situations and which allows the calculation of absorbed dose to specific organs for members of the Life Span Study. DS02 improved on the DS86 dose system.

DS86: A dose system developed in 1986 for estimating gamma and neutron exposure under a large variety of situations and which then allowed the calculation of absorbed dose to specific organs for members of the Life Span Study.

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

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

where H_T or $w_R D_{T,R}$ is the radiation-weighted dose in a tissue or organ, T, and w_T is the tissue weighting factor.

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

$$H_T = \sum_{R} w_{R} D_{T,R}$$

where $D_{T,R}$ 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).

Excess absolute risk: The rate of disease incidence or mortality in an exposed population minus the corresponding disease rate in an unexposed population. The excess absolute risk is often expressed as the additive excess per Gy or per Sv.

Excess relative risk: The rate of disease in an exposed population divided by the rate of disease in an unexposed population, minus 1.0. This is often expressed as the excess relative risk per Gy or per 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.

FSU: Functional sub-units of tissues eg. nephrons in kidney, alveoli in lung.

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

Growth factors: Molecules that act to control cell-reproduction and proliferation/differentiation of a population of cells.

Incidence (incidence rate): 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.

Kerma, K: The quotient of the sum of the kinetic energies, dE_{tr}, of all charged particles liberated by uncharged particles in a mass dm of material and the mass dm of that material.

$$K = \frac{dE_{tr}}{dm}$$

Kerma is defined as a non-stochastic quantity and dE_{tr} is, therefore, seen to be the expectation value of the sum of the kinetic energies. The SI unit for kerma is joule per kilogram (J kg^{-1}) and its special name is gray (Gy).

LD50: Dose that is lethal for half of the exposed individuals.

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.

Lifetime risk estimates: Several types of lifetime risk estimates can be used to calculate the risk over a lifetime that an individual will develop or die from a specific disease caused by an exposure: 1) the excess lifetime risk (ELR) which is the difference between the proportion of people who develop or die from the disease in an exposed population and the corresponding proportion in a similar population without the exposure; 2) the risk of exposure-induced death (REID) which is defined as the difference in a cause-specific death rate for exposed and unexposed populations of a given gender and age at exposure, as an additional cause of death introduced into a population, 3) loss of life expectancy (LLE) which describes the decrease in life expectancy due to the exposure of interest, and 4) lifetime attributable risk (LAR) is an approximation of the REID and describes excess deaths (or disease cases) over a follow-up period with population background rates determined by the experience of unexposed individuals. The LAR was used in this report to estimate lifetime risks.

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

Linear dose response: A statistical model that expresses the risk of an effect (e.g. disease or abnormality) as being proportional to dose.

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 hypothesis: 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).

Mean Absorbed Dose in a tissue or organ T, D_T: The absorbed dose D_T, averaged over the tissue or organ T, which is given by

$$D_T = \frac{\varepsilon_T}{m_T}$$

where ε_T is the mean total energy imparted in a tissue or organ T and m_T is the mass of that tissue or organ.

Mendelian diseases: Heritable diseases attributable to single gene mutations.

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

Multistage tumorigenesis: The stepwise acquisition of cellular properties that can lead to the development of tumour from a single (target) cell.

Mutation component (MC): A quantity that provides a measure of the relative change in disease frequency per unit relative change in mutation rate ie. a measure of responsiveness; MC values differ for different classes of heritable disease

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

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

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.

Particle Fluence, Φ: The fluence, Φ, is the quotient of dN by da, where dN is the number of particles incident on a small sphere of cross-sectional area da, thus

$$\phi = \frac{dN}{da}$$

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.

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

Potential recoverability correction factor (PRCF): A set of factors that take account of knowledge that different classes of germ line mutation will show differing degrees of recoverability in live born offspring ie. through differing capacities to allow completion of embryonic fetal development.

Progenitor cell: Undifferentiated cell capable of limited proliferation.

Projected dose: The dose that would be expected to be incurred if a specified countermeasure or set of countermeasures — or, in particular, no countermeasures were to be taken.

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 factor denoted w_R, it is 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.

Random error: Errors that vary in a non-reproducible way. These errors can be treated statistically by use of the laws of probability.

RBE: Relative Biological Effectiveness, ratio of absorbed dose of the reference low LET radiation and the high LET radiation that result in the same level of biological effect.

Reference individual: An idealized human with characteristics defined by the Commission for the purpose of radiological protection.

Reference Person: A person with the anatomical and physiological characteristics defined in the report of the ICRP Task Group on Reference Man (Publication 89; ICRP, 2001).

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).

Sensitivity analysis: Sensitivity analysis aims to quantify how the results from a model depend upon the different variables included in it.

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 ($J\ kg^{-1}$).

Specific Absorbed Fraction: The fraction of energy emitted as a specified radiation type in a source tissue which is absorbed in 1 kg of a target tissue.

Statistical power: The probability that an epidemiologic study will detect a given level of elevated risk with a specified degree of confidence.

Stem cell: Non-differentiated, pluripotent cell, capable of unlimited cell division.

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.

Systematic error: Errors that are reproducible and tend to bias a result in one direction. Their causes can be assigned, at least in principle, and they can have constant and variable components. Generally these errors cannot be treated statistically.

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.

Transport of risk: Taking a risk coefficient estimated for one population and applying it to another population with different characteristics. Also called transfer of risk.

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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

Two ICRP Committee 4 documents of particular relevance in this context, on the representative exposed person and on optimisation, were subjected to public consultation in 2005. Appropriately amended versions of these drafts can be viewed at www.icrp.org/Representative_person.pdf and www.icrp.org/Optimisation.pdf . A Main Commission draft document on the scope of radiological protection is subjected to public consultation until 19 June 2006 and can be viewed via www.icrp.org/draft_scope.asp .