PREFACE

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

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

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

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

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

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

(2001-2005)

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

Scientific Secretary: J. Valentin

(2005-2009)

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

Scientific Secretary: J. Valentin

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

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

EXECUTIVE SUMMARY

(to be completed)

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

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

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

1. INTRODUCTION

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

1.1. The history of the Commission

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

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

1.2. The development of the Commission's recommendations

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

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

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

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

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

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

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

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

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

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

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

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

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

- Low-dose extrapolation of radiation-related cancer risk (*Publication 99*, ICRP, 2006).
- Biological and epidemiological information on health risks attributable to ionising radiation: A summary of judgements for the purposes of radiological protection of humans (Annex A to these Recommendations).
- Quantities used in radiological protection (Annex B to these Recommendations).
- Optimisation of radiological protection (in *Publication 101*, ICRP, 2006).
- Assessing dose to the representative person (in *Publication 101*, ICRP, 2006).
- A framework for assessing the impact of ionising radiation on non-human species (*Publication 91*, ICRP, 2003)

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

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

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

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

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

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

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

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

1.2.1. The evolution of dose quantities and their units

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

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

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

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

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

1.3. Structure of the Recommendations

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

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

2. THE AIMS AND SCOPE OF THE RECOMMENDATIONS

2.1. The aims of the Recommendations

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

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

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

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

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

2.2. The structure of the system of protection

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

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

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

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

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

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

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

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

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

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

Source-related principles (apply in all situations):

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

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

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

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

Individual-related principle (applies in planned situations):

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

These principles are discussed in more detail in Chapter 5.

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

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

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

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

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

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

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

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

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

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

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

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

2.3. The scope of the Recommendations

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

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

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

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

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

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

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

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

2.4. Exclusion and exemption

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

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

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

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

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

3. BIOLOGICAL ASPECTS OF RADIOLOGICAL PROTECTION

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

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

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

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

3.1 The induction of tissue reactions (deterministic effects)

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

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

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

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

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

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

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

3.2.1 Risk of cancer

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

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

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

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

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

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