2005 RECOMMENDATIONS OF THE INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

SUMMARY OF THE RECOMMENDATIONS

(S1) This Summary indicates the Commission's aims and the way in which the recommendations may be applied. The necessary concepts are defined and explained in the main text following this Summary.

The Aim of the Recommendations

(S2) The fundamental aim of the Commission was set out as follows in the 1990 Recommendations.

> 'The primary aim of radiological protection is to provide an appropriate standard of protection for man without unduly limiting the beneficial actions giving rise to radiation exposure. This aim cannot be achieved on the basis of scientific concepts alone. 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, they are no different from those working in other fields concerned with the control of hazards.'

This statement still represents the Commission's position.

(S3) The Commission has concluded that its recommendations should be based on a simple, but widely applicable, general system of protection that will clarify its objectives and will provide a basis for the more formal systems needed by operating managements and regulators. It also recognises the need for stability in regulatory systems at a time when there is no major problem identified with the practical use of the present system of protection in normal situations. The use of the optimisation principle, together with the use of constraints and the current dose limits, has led to a general overall reduction in both occupational and public doses over the past decade. The Commission now strengthens its recommendations by quantifying constraints for all controllable sources in all situations.

The Principles of Protection

(S4) The system of protection now recommended by the Commission is to be seen as a natural evolution of, and as a further clarification of, the 1990 Recommendations. The 2005 Recommendations establish quantified restrictions on individual dose from specified sources in all situations within their scope. These restrictions should be applied to the exposure of actual or representative individuals. They provide a level of protection for individuals that should be considered as obligatory, and not maintaining these levels of protection should be regarded as a failure. The quantified restrictions are complemented by the requirement to optimise the level of protection achieved.

(S5) The most fundamental level of protection is the source-related restriction on individual dose called a *dose constraint*. It is used to provide a level of protection for the most exposed *individuals* within a class of exposure, in all situations within the scope of the recommendations, *from a single source*. Except for the exposure of patients, these constraints should be regarded as the basic levels of protection to be attained in all situations that are addressed by the Commission; normal situations, accidents and emergencies, and the case of controllable existing exposure. These constraints represent the level of dose where action to avert exposures and reduce doses is virtually certain to be justified.

(S6) In all situations the constraints are complemented by the requirement to optimise the level of protection achieved. This is because there is presumed to be some probability of health effects even at small increments of exposure to radiation above the natural background. The Commission therefore recommends that further, more stringent, measures should be considered for each individual source. This requirement for the optimisation of protection includes, but is more comprehensive than, the need to ensure that all exposures are as low as reasonably achievable, economic and social factors being taken into account, in the relevant situation. This requirement cannot be defined in general quantitative terms; it calls for judgement about each situation causing exposure of individuals and is the concern of the operating managements and the responsible national authorities.

(S7) Table S1 presents the Commission's recommended maximum values of dose constraints. In essence, four values are recommended according to the type of situation to be controlled. They should be considered as giving the upper restriction that is to be applied by the appropriate national authorities to determine the most applicable constraints for the situation under consideration. The Commission expects that the resulting national values of constraints normally will be lower than the maximum value recommended by the Commission, but probably not by as much as a factor of ten.

Table S1. Maximum dose constraints recommended for workers and members of the public from single dominant sources for all types of exposure situations that can be controlled.

Maximum constraint (effective dose, mSv in a year)	Situation to which it applies
100	In emergency situations, for workers, other than for saving life or preventing serious injury or preventing catastrophic circumstances, and for public evacuation and relocation; and for high levels of controllable existing exposures. There is neither individual nor societal benefit from levels of individual exposure above this constraint.
20	For situations where there is direct or indirect benefit for exposed individuals, who receive information and training, and monitoring or assessment. It applies into occupational exposure, for countermeasures such as sheltering, iodine prophylaxis in accidents, and for controllable existing exposures such as radon, and for comforters and carers to patients undergoing therapy with radionuclides.
1	For situations having societal benefit, but without individual direct benefit, and there is no information, no training, and no individual assessment for the exposed individuals in normal situations.
0.01	Minimum value of any constraint

(S8) The level of protection for an individual from all sources within a class of exposure, in normal situations only, is the *dose limit*. The Commission has recommended values of dose limits in its 1990 Recommendations, ICRP *Publication 60*, which have been adopted in international safety standards and in the national legislation of nearly all countries. The Commission continues to recommend the use of its 1990 dose limits, in normal situations only.

Optimisation of Protection

(S9) Optimisation of protection is a process that is an important component of a successful radiological protection programme. In application, it involves evaluating and, where practical to do so, incorporating measures that tend to lower radiation doses to members of the public and to workers. But conceptually it is broader, in that it entails consideration of the avoidance of accidents and other potential exposures. It incorporates a range of qualitative and quantitative approaches.

(S10) An important role of the concept of optimisation of protection is to foster a 'safety culture' and thereby to engender a state of thinking in everyone responsible for control of radiation exposures, such that they are continuously asking themselves the question, 'Have I done all that I reasonably can to reduce these doses?' Clearly, the answer to this question is a matter of judgement and necessitates co-operation between all parties involved and, as a minimum, the operating management and the regulatory agencies.

(S11) The involvement of *stakeholders*, a term which has been used by the Commission in *Publication 82* to mean those parties who have interests in and concern about a situation, is an important input to optimisation. While the extent of stakeholder involvement will vary from one situation to another in the decision-making process, it is a proven means to achieve the incorporation of values into decisions, the improvement of the substantive quality of decisions, the resolution of conflicts among competing interests, the building of trust in institutions as well as the education and information the workers and the public. Furthermore, involving all parties affected by the decision 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.

Exclusion of radiation sources

(S12) There are many sources for which the resulting levels of annual effective dose are very low, or for which the combination of dose and difficulty of applying control are such that the Commission considers that the sources can legitimately be *excluded* completely from the scope of its Recommendations. Since cosmic rays are ubiquitous and all materials are radioactive to a greater or lesser degree, the concept of exclusion is essential for the successful application of the system of protection. The Commission has concluded that the activity concentration values in Table S2 provide a definition of what is to be considered radioactive for practical radiological protection purposes, and therefore the levels at which materials are to be within the scope of its recommendations. It now recommends the figures in Table S2 as the basis of exclusion from the scope of its recommendations.

Table S2. Recommended Exclusion Levels

Nuclides	Exclusion activity concentration
Artificial a-emitters	0.01 Bq g^{-1}
Artificial ß/? emitters	0.1 Bq g^{-1}
Head of chain activity level†, ^{238}U, ^{232}Th	1.0 Bq g^{-1}
^{40}K	10 Bq g^{-1}

† For ^{238}U and ^{232}Th chains, this value also applies to any nuclide in a chain that is not in secular equilibrium excluding ^{222}Rn and daughters in air which in all situations are controlled separately.

The development of effective dose

(S13) The weighting factors in calculating effective dose are intended to take account of many types of radiation, many types of stochastic effects, and many tissues in the body. They are therefore only loosely based on a wide range of experimental data. It is unrealistic to expect them to apply accurately to any particular case. In recent recommendations, the Commission has deliberately selected broadly based values of these weighting factors.

(S14) The weighting factor for radiation quality is applied directly to the absorbed dose in a tissue or organ. This weighted tissue dose has been called both dose equivalent and equivalent dose at various times. There has been substantial confusion between these terms, particularly in translation from English into other languages. The Commission now avoids both of those terms and uses ***radiation weighted dose*** in a tissue or organ. The unit of radiation weighted dose is the joule per kilogram with the special name sievert (Sv). The Commission is considering a new special name for radiation weighted dose so as to avoid the use of the name 'sievert' for both radiation weighted dose and effective dose.

(S15) When, as is usual, more than one tissue is exposed, it is necessary to use the tissue weighting factor. The application of both the radiation and the tissue weighting factors to the tissue absorbed doses leads to the effective dose. The effective dose, as currently defined, will continue to be used by the Commission for protection purposes,

$$E = ?_{T}\ w_T\ ?_{R}\ w_R \bullet D_{T,R}$$

where E is the effective dose, w_R and w_T are the radiation and tissue weighting factors, and $D_{T,R}$ is the mean absorbed dose in tissue or organ T due to incident radiation R. The unit of effective dose is the joule per kilogram and called the sievert (Sv). Since the effective dose is derived from mean absorbed doses in tissues and organs of the human body, a dosimetric model must be specified or implied in any statement of the magnitude of the effective dose.

(S16) As in the 1990 Recommendations, radiation weighting factors are determined by the characteristics of the type and energy of the radiation incident on the body or, in the case of sources within the body, emitted by the source. The radiation weighting factors are then applied to the mean tissue dose in any specified part of the human body. The radiation weighting factors in Table S3 are essentially those suggested in *Publication 92* and are now recommended for general use in radiological protection. For neutrons a continuous curve is recommended shown in Figure S1. In order to reduce computational difficulties in evaluating effective dose the function in Figure S1 is given in Equation S1.

$$w_R = \begin{cases} 2.5 + 18.2 \exp[-(\ln E_n)^2/6] & \text{for } E_n < 1 \text{ MeV} \\ 5.0 + 17.0 \exp[-(\ln (2E_n))^2/6] & \text{for } E_n \geq 1 \text{ MeV.} \end{cases} \quad \ldots\ldots\ldots\ldots\ldots\ldots\text{(S1)}$$

where E_n is in MeV. The radiation weighting factor for neutrons is applied to the mean absorbed doses in the relevant tissues and organs. The dose is that from both the neutron induced charged particles and the secondary photons induced in the body.

(S17) The Commission has reviewed the epidemiological data that can be used to assess nominal risk factors for cancer and hereditary diseases. From these it has developed a new estimate of detriment resulting from radiation exposure which has been used to specify its recommended w_T values. The new values that apply for the tissue weighting factors are listed below in Table S4. The weighting factor for Remainder tissues is to be applied to dose averaged over the 14 specified organs and tissues that constitute the Remainder.

Table S3. Radiation weighting factors, w_R

Type and energy range	w_R
Photons	**1**
Electrons and muons	**1**
Protons	**2**
Alpha particles, fission fragments, heavy nuclei	**20**
Incident neutrons	**See Figure S1 and Equation S1**

Figure S1. Radiation weighting factor, w_R, for incident neutrons versus neutron energy. (A) Step function and (B) continuous function given in *Publication 60*, (C) function proposed in this report.

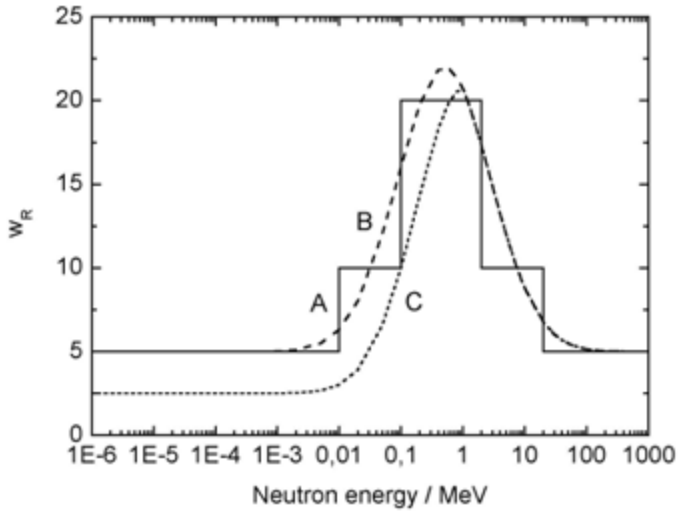


Table S4. Tissue weighting factors

Tissue	w_T	? w_T
Bone marrow, Breast, Colon, Lung, Stomach	**0.12**	0.60
Bladder, Oesophagus, Gonads, Liver, Thyroid	**0.05**	0.25
Bone surface, Brain, Kidneys, Salivary glands, Skin	**0.01**	0.05
Remainder Tissues*	**0.10**	0.10

***Remainder Tissues (14 in total)**

Adipose tissue, Adrenals, Connective tissue, Extrathoracic airways, Gall bladder, Heart wall, Lymphatic nodes, Muscle, Pancreas, Prostate, SI Wall, Spleen, Thymus, and Uterus/cervix.

The development of a framework for the protection of non-human species

(S18) The Commission's new framework for non-human species will be designed so that it is harmonized with its proposed approach for the protection of human beings. To achieve this, an agreed set of nomenclature, plus a set of reference dose models, data sets to relate exposure to dose, and interpretation of effects will be developed for a limited number of animal and plant types. This will also ensure that the protection of both humans and other organisms are protected on the same scientific basis, in terms of the relationships between exposures to ionising radiation and dose, and between dose and effects at the molecular, cellular, tissue and organ, and whole organism level.

(S19) The Commission recognises that a framework for radiological protection of the environment must be practical and, ideally, a set of ambient activity concentration levels would be the simplest tool. There is a need for international standards of discharges into the environment, and the Commission's common approach will provide a basis for the development of such standards. In order to demonstrate, transparently, the derivation of ambient activity concentration levels or standards, the reference-animal-and-plant approach will be helpful.

The Intended Use of the Recommendations

(S20) The Commission's advice has to be of a general and international nature. However, the Commission hopes that its advice will influence both regulatory agencies and management bodies, including their specialist advisors. It also hopes that its advice will continue to help in the provision of a consistent basis for national and regional regulatory policies and standards. The Commission recognises that these hopes will be fulfilled only if there is general acceptance of its judgements and policies by the managements of practices causing exposures to radiation, by regulatory agencies, and by governments. Its experience since its establishment in 1928 leads the Commission to conclude that this coherent acceptance exists.

(S21) The Commission aims to provide guidance to a wide range of organisations in a wide range of countries and regions. The Commission believes that these bodies have the responsibility to design their own procedures, which may require development of their own internal documents. The Commission's underlying hope is that it can encourage the widespread development of a radiological safety culture, which lies within the framework of its recommendations, and which then permeates all the operations involving exposure to ionising radiation. The starting point for this should be a programme of relevant education and training.

CONTENTS

1. INTRODUCTION

1.1. The History of the Commission

(1) 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 renames as now to reflect the widening of its scope to non-medical radiation. 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.

(2) 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 (CEC), the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD/NEA), the International Standards Organisation (ISO), the International Electro-technical Commission (IEC), and the International Radiation Protection Association (IRPA). It takes account of progress reported by major national organisations.

(3) The legal seat of the Commission is in England, where it is registered as a 'Charity', i.e. a non-profit-making organisation established for the benefit of the public.

1.2. The Development of the Commission's Recommendations

(4) The Commission issued its first report (in the name of ICXRP) in 1928. The first report in the current series, subsequently numbered *Publication 1* (ICRP, 1959), contained the recommendations approved in September 1958. Subsequent general recommendations have appeared as *Publication 6* (1964), *Publication 9* (1966), and *Publication 26* (1977). *Publication 26* was amended by an ICRP Statement in 1978 and further clarified and extended by Statements in later years (ICRP 1980, 1984a, 1984b, 1985c, and 1987). Reports providing advice on more specialised topics have appeared as intermediate and subsequent publication numbers.

(5) 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 dose constraints, and of individual dose limits. It was also necessary to deal separately with practices that were subject to control and with existing situations for which the only feasible controls were some kind of intervention to reduce the doses. The Commission also found it necessary to apply the recommendations in different ways to occupational, medical, and public exposures. This complexity is logical, but it has not always been easy to explain the variations between different applications.

(6) The Commission regularly examines the status of its recommendations and reviews the increasing knowledge of the effects of exposure to ionising radiation in order to decide whether new recommendations are needed. The Commission strives to make its system more coherent and comprehensible, while recognising the need for stability in international and national regulations, many of which have only fairly recently implemented the 1990 Recommendations. However, new scientific data have been produced since 1990 and there have been societal developments in that more openness or transparency is expected in

developing new recommendations and, in addition, there has been a move from the utilitarian approach of 'the greatest good for the greatest number', to one with more concern for the 'individual', all of which have inevitably led to some changes in the formulation of the recommendations.

(7) Since the 1990 Recommendations, there have been ten publications, listed in Table 1, that have provided additional guidance for the control of exposures from radiation sources. When the 1990 Recommendations are included, there are eleven reports that specify some 30 different numerical values for restrictions on individual dose for differing circumstances. Furthermore, these numerical values are justified in many different ways. In addition the Commission has developed policy guidance for protection of non-human species in *Publication 91* (ICRP, 2003b).

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

Publication 62 (ICRP, 1991c)	Radiological Protection in Biomedical Research
Publication 63 (ICRP, 1991d)	Principles for intervention for Protection of the Public in a Radiological Emergency
Publication 64 (ICRP, 1993a)	Protection from Potential Exposure: A Conceptual Framework
Publication 65 (ICRP, 1993b)	Protection against Radon-222 at Home and at Work
Publication 73 (ICRP, 1996a)	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, 1997c)	Radiological Protection Policy for the Disposal of Radioactive Waste
Publication 81 (ICRP, 1998b)	Radiation protection Recommendations as Applied to the Disposal of Long-lived Solid Radioactive Waste
Publication 82 (ICRP, 1999a)	Protection of the Public in Situations of Prolonged Radiation Exposure

(8) It is against this background that the Commission has concluded that the 2005 Recommendations should consolidate all the advice included in and developed since the 1990 Recommendations in *Publication 60*. The major features are: -

- Recommending dose constraints that quantify the most fundamental levels of protection for workers and the public from single sources in all situations.
- Maintaining the *Publication 60* limits for the combined dose from all regulated sources that represent the most that will be accepted in normal situations by regulatory authorities.
- Complementing the constraints and limits with the requirement for optimisation of protection from a source.
- Recognising where the responsibility for justifying the introduction of a new practice lies.
- Updating the weighting factors in the dosimetric quantity Effective Dose.

- Emphasizing that patient dose should be commensurate with the clinical benefit expected from a given justified diagnostic or therapeutic procedure.
- Including a policy for radiological protection of non-human species.

(9) Sources of ionising radiation have always been a natural and universal feature of the environment. Additional sources and increased doses from existing sources result from many human actions. Since ionising radiation is universal and is capable of damaging the health of living organisms, it is necessary to consider where, and how much, protection should be sought.

(10) The Commission wishes to emphasize its view that, while the use of ionising radiation for beneficial purposes can entail significant risks if not appropriately controlled, it needs to be treated with care rather than fear and its risks should be kept in perspective, both with the benefits of uses and with other risks. The procedures 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 exposed.

(11) Although the principal objective of the Commission has been, and remains, the achievement of radiological protection with respect to human exposure it has, nevertheless, long had regard to the potential impact on other species. The Commission expressed its view on this subject in 1977, and again in 1990, in a manner that was considered appropriate, and proportionate, at those times. However, interest in environmental protection has greatly increased since then, not only in relation to ionising radiation but in relation to all aspects of human activity. The Commission has therefore decided that this subject now needs to be considered explicitly, and in more detail, than has been the case in the past.

(12) The recommendations of the Commission, 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. Recommendations concerning such sources are provided by the International Commission on Non-Ionizing Radiation Protection, ICNIRP.

2. THE AIM AND SCOPE OF THE COMMISSION'S RECOMMENDATIONS

2.1. The aim of the recommendations

(13) The primary aim of the Commission is to contribute to the establishment and application of an appropriate level of protection for the human population and, where necessary, for other species without unduly limiting the desirable human actions and lifestyles that give rise to, or increase, radiation exposures.

(14) This aim cannot be achieved solely on the basis of scientific data, such as those concerning health risks, but must include consideration of social and economic aspects. 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, they are not different from those working in other fields concerned with the control of hazards. However, it is not the Commission's task to give advice on the underlying ethical and economic policies, although it must be always aware of changes in society's attitudes.

2.2. The scope of the recommendations

(15) It is self-evident that the Commission's recommendations can apply 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 by the Commission 'controllable sources' and are included in the scope of these recommendations.

(16) The term *'source'* is used by the Commission to indicate the cause of an exposure, not necessarily a physical source of radiation. For example, when radioactive materials are released to the environment as waste, both the installation as a whole and the discharged material can be regarded as sources, depending on the context. The term 'exposure' is used by the Commission to mean the process of being exposed to radiation or radioactive material. Exposure can then lead to a dose to some part of the exposed individual.

(17) The term *'practice'* has become widely used in radiological protection. The Commission uses it to mean those sources within the scope of the recommendations that correspond to any human activity deliberately introduced, or maintained, and which increases, or potentially increases, radiation exposure of individuals or the number of individuals exposed.

(18) Judgements on whether it would be justifiable to introduce or continue a particular practice involving exposure to ionising radiation are important. Alternatives to existing practices may develop over time, which would require that those practices that do exist should be periodically re-examined to ensure that they are still justified. The responsibility for judging the justification of a practice usually falls on governments or government agencies to ensure an overall benefit in the broadest sense to society and thus not to each individual. Governments make these decisions for strategic, economic, defence and other reasons and radiological protection considerations are recognised as being only one input that could influence the justification decisions. Therefore, while justification is a prerequisite of the complete system of radiological protection, the methods of ensuring justification are largely outside the scope of these Recommendations.

(19) 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 that should be justified, as is any other practice, although that justification lies more often with the profession rather than with government. In addition, however, a more detailed form of justification has to be applied to the procedures within the practice. 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. The methods of justification of medical procedures therefore remain part of the Commission's Recommendations and are discussed in Chapter 9.

(20) 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. The Commission then aims to apply its system of protection to practices that have been declared justified. However, the system may also be applied in situations where the practice has not been declared justified.

(21) The Commission intends its recommendations to be applied to all sources within the scope of its recommendations, not only in normal situations, which are everyday situations, but also in existing controllable exposure situations, and in emergencies, meaning unexpected situations requiring urgent action. An emergency may result from a sudden event or from slow deterioration, leading to the point where urgent action is required. The different types of situation require different treatment.

(22) Existing controllable exposure situations, whether natural or artificial, or those resulting from previous practices, as well as those from emergencies, usually involve sources that can be controlled only by action to modify the pathways of exposure. Whatever the origin, such sources already exist and justification is not relevant. These sources are therefore within the scope of the Commission's Recommendations, unless they have been excluded on other grounds.

(23) Apart from the situations that are outside the scope of the recommendations, the Commission has aimed to make its recommendations applicable as widely and as consistently as is possible. In particular, the Commission's recommendations cover exposures to both natural and artificial sources, insofar as they are controllable.

2.3. Exclusion and authorization of exposures

(24) There are many sources for which the resulting levels of annual effective dose are very low, or for which the combination of dose and difficulty of applying control are such that the Commission considers that the sources can legitimately be *excluded* completely from the scope of its Recommendations. Since all materials are radioactive to a greater or lesser degree, the concept of exclusion is essential for the successful application of the system of protection. In principle, it can be applied to both natural and artificial[1] sources of radiation although in practice it will largely be of use in the control of natural sources. The Commission considers that numerical criteria for exclusion would assist in the consistent application of the concept. Its recommendations are found in Chapter 8.

(25) Sources and exposures that are not excluded are within the scope of the system of protection. These sources and exposures should be subject to appropriate authorization by the relevant regulatory agency. The Commission recognises that there are also circumstances where sources are within the scope of the Recommendations, but where regulatory provisions may be unnecessary because additional protective actions are not needed. In such cases *exemption* may be granted through a regulatory decision.

(26) In order to avoid excessive regulatory procedures provisions can be made for granting exemptions in cases where it is clear that further controls are unnecessary. The regulatory act of assessing the situation and granting an exemption is, in itself, a form of authorization and the material that is exempted remains subject to the system of protection, although without further regulatory control.

[1] Because of the ubiquity of radiation, it is useful to deal separately with the primordial and man-made radiation and radioactive materials. These have been termed *'natural'* and *'artificial'* respectively, but the distinction is not precise. For example, some radionuclides that are primordial and therefore considered 'natural' can be produced artificially. Others that are produced by humans and therefore considered 'artificial' are in fact also produced in nature by incoming solar neutrons or natural fission processes such as that at Oklo, Africa.

(27) The Commission believes that the exemption of sources is an important regulatory instrument. It notes that the International Atomic Energy Agency and the Nuclear Energy Agency of the OECD issue advice on this subject to their Member States. Furthermore, a substantial amount of work has been undertaken on this topic within other international and regional, as well as national, organisations.

(28) The practical application of the concept requires derivation of exemption levels in terms of activity concentration. These levels should enable exemption of appropriate sources of exposure including wastes containing very low levels of activity. International agreement on a single set of radionuclide-specific levels for exemption would facilitate a consistent regulatory approach worldwide. Sources with activity concentration above exemption levels need not necessarily be subject to the full rigour of regulations. A graded approach to regulation based on assessed hazard would focus regulatory effort onto areas where most benefit would be obtained.

2.4. Waste disposal and remediation of sites

(29) Preferably neither waste disposal nor remediation of sites should be regarded as practices in their own right. They should be treated as parts of the practice that gave rise to the wastes and the contaminated sites. The recommendations in Chapters 6, 7, 8 and 10 should be applied. The Commission has already given advice for its general policy of waste disposal, for the disposal of long-lived solid waste, and for remediation of contaminated ground, in *Publications 77, 81* and *82* respectively. This advice continues to represent the Commission's views.

(30) However, this is not possible if the original practice is no longer in existence. If the waste disposal, or the remediation, cannot be treated as parts of a practice, they then have to be dealt with in isolation and should be treated as existing controllable exposure, see Chapter 6.

2.5. Features influencing the format of the recommendations

(31) Several features influence the ways in which the Commission's aims can be implemented. These include the nature and magnitude of the health effects due to exposures to radiation and the form of dosimetric quantities used to specify unequivocally any quantitative recommendations. The inevitable and ubiquitous exposures due to natural sources are also important. The existence of this natural background of radiation means that, in practice, the radiation risk factors required for use in protection are those applicable to increments of, or additions to, doses above 1 or 2 millisieverts in a year. This is because an absolute dose of 0.01 mSv cannot be received in isolation, but rather an additional 0.01 mSv above the natural background and it is the incremental risk of the exposure that is of interest for decision making. These features are discussed in Chapter 5, which sets out the Commission's general system of protection.

3. QUANTITIES USED IN RADIOLOGICAL PROTECTION

3.1. Introduction

(32) For the primary aim of establishing principles and systems of radiological protection, dosimetric quantities are needed in order to assess the radiation exposures of humans as well as other organisms in a quantitative way. Such quantification of radiation doses is necessary in order to achieve dose response relationships for radiation effects. These are the basis for risk estimation over wider dose ranges than are available from experimental and epidemiological studies, and especially in the important low dose range.

(33) The development of health effects caused by ionising radiation starts with the physical processes of energy absorption in biological tissue, which lead to ionisations with molecular changes which may occur in clusters, e.g. in the genetic information of cells, the DNA in the cell nucleus. The dosimetric quantities adopted by the Commission are based therefore on measures of the energy imparted to organs and tissues of the body. They can be related to quantitative estimates of health risks. Further description of the biological effects of exposure is given in Chapter 4. The protection system also includes operational quantities, defined by ICRU. These are used in measurements and practical applications for investigating situations involving external exposure and intakes of radionuclides.

(34) ICRP has developed specific dosimetric quantities for radiological protection that allow the extent of exposure to ionising radiation from both whole and partial body external irradiation and from intakes of radionuclides to be quantified. The assessed doses can then be compared with recommended quantitative restrictions on dose for individuals when occupationally exposed or when exposed in their capacity as members of the public.

(35) Ideally, for demonstrating compliance with the constraints, there would be one single dosimetric quantity specifying the 'amount' of radiation which is quantitatively related to the probability of an effect for all types of radiations, regardless of whether the radiation is incident on the body or emitted by radionuclides within the body. This is complicated by variations in the response of biological matter to radiations of different quality and by the varying sensitivity to radiation damage of the organs and tissues of the body. The Commission has introduced such a single quantity, the effective dose, as an approach to overcome some of these problems. This quantity can be used for regulations of important parts of health effects.

(36) The Commission's dosimetric quantities and nominal risk coefficients are intended for use in radiological protection, including the assessment of risks in general terms. Specific investigations, such as retrospective assessments of risks of stochastic effects in a known population of identified individuals, are best undertaken using specific data.

3.2. Summary of health effects caused by ionising radiation

(37) The relationship between radiation exposures and health effects is complex. The physical processes linking exposure and doses in human tissues involve energy transport at the molecular level. The biological links between this energy deposition and the resulting health effects involve molecular changes in cells. In *Publication 60* (ICRP, 1991), the Commission recognised that the gross (macroscopic) quantities used in radiological protection omitted consideration of the discontinuous nature of the physical and biological processes of ionisation. However, it concluded that their use was justified empirically by the observation that the gross quantities (with adjustments for different types of radiation) correlate reasonably well with the resulting biological effects. It further recognised that more use might eventually be made of other quantities based on the statistical distribution of events in a small volume of material, corresponding to the dimensions of biological entities such as the nucleus of the cell or its DNA. Meanwhile, for practical reasons, the Commission continues to use the macroscopic quantities.

(38) Radiological protection in the low dose range is primarily concerned with protection against radiation-induced cancer and hereditary disease. These diseases are termed stochastic effects, as they are probabilistic in nature and are believed to have their origins in damage in single cells. For protection purposes, it is assumed that these effects increase with increasing radiation dose, with no threshold, and that any increment of exposure above the natural background produces a linear increment of risk.

(39) The quantity *effective dose* has been introduced in order to limit the risk of stochastic effects. It has been intended that the risk of stochastic effects at exposures corresponding to the dose limits should be equal, regardless of the manner of irradiation – whether the body is uniformly or heterogeneously irradiated from external radiation or from intakes of radionuclides. This has been accomplished by first weighting the absorbed dose according to the biological effectiveness of the different radiation qualities with a *radiation weighting factor* w_R. The summation of the radiation weighted doses to the various tissues and organs of the human body, modified by *tissue weighting factors*, w_T, then gives the *effective dose*. The tissue weighting factors account for the varying radiation sensitivity of tissues to the induction of stochastic effects.

(40) At higher doses, associated mainly with accident situations, tissue reactions (formally called deterministic effects) including acute effects, and late effects such as cataracts of the lens of the eye, necrotic and fibrotic reactions in many tissues and organs, may occur if exposures exceed a threshold dose. This threshold varies with the dose rate, especially for exposures to low LET radiation. High LET radiation, from neutrons and alpha particles, causes more damage per unit of absorbed energy than low LET radiation. Values of Relative Biological Effectiveness (RBE) for tissue reactions for high-LET compared with low-LET radiations have been determined for different biological endpoints and different tissues or organs. In general the RBE values were found to be smaller than those for stochastic effects and to vary with the tissue damage described. The application of values of the radiation weighting factor, w_R, for assessing the tissue damage from high LET radiations would, therefore, result in an overestimate of the likely occurrence and severity of any tissue damage. When assessing radiation exposure for determining the potential for tissue damage, the average absorbed dose, weighted by an appropriate value of RBE for the biological end point of concern, should be used (see Section 3.6).

3.3. Absorbed dose in radiological protection

(41) A particular feature of ionising radiations is their discontinuous interaction with matter. The related probabilistic nature of energy depositions results in distributions of imparted energy on a cellular and molecular level that are very heterogeneous at low doses. Organs and tissues are made up of cells, which are considered the key target for radiation damage. Absorbed dose is the statistical mean of the distribution of energy imparted in small volumes divided by the mass of the corresponding volume. However, the smaller the average radiation dose to an organ or tissue, the fewer the number of cells that will be hit by an ionising track. The fluctuations of energy imparted in individual cells and sub-cellular structures are the subject of microdosimetry.

(42) The magnitude of the fluctuations depend on the value of the absorbed dose, on the size of the volume considered and these variations increase with increasing ionisation density (LET, linear energy transfer) of the radiation. At the low doses generally of concern in radiological protection, the fluctuation of energy imparted can be substantial between individual cells and within a single hit cell. This is the case particularly for densely ionising radiations such as alpha-particles and charged particles from neutron interactions.

3.3.1. The definition of absorbed dose

(43) In radiology, radiation biology, and radiological protection the absorbed dose, D, is the fundamental physical quantity. It is used for all types of ionising radiation and any irradiation geometry. Absorbed dose, D, is defined as the quotient of *mean* energy, $d\bar{e}$, imparted by ionising radiation in a volume element and the mass dm of the matter in that element. The SI unit is joule per kilogram, J kg^{-1}, and the special name is gray (Gy).

$$D = \frac{d\bar{e}}{dm}$$

(44) Absorbed dose is defined based on the expectation value of the stochastic quantity e, energy imparted, and therefore does not consider the random fluctuation of the interaction events. It is defined at any point in matter and, in principle, is a measurable quantity, i.e. it can be determined experimentally and by computation. The definition of absorbed dose has the scientific rigour required for a fundamental quantity. It takes implicitly account of the radiation field as well as of all of its interactions inside and outside the specified volume. It does not, however, consider the atomic structure of matter and the stochastic nature of the interactions.

(45) At a given absorbed dose, the actual value of energy imparted in a cell (the elementary unit of life) is given by the product of frequency of energy deposition events and the value of energy deposited in each event. At a given (low) absorbed dose, for less densely ionising radiations (photons, electrons) the energy imparted in each event is low and more cells experience energy deposition events than in the case of exposure by densely ionising radiation. As a consequence, also the fluctuation in the energy imparted among cells is therefore smaller.

(46) For densely ionising radiation (charged particles from neutrons and alpha-particles) and low doses of low LET radiation, the frequency of events in most cells is zero, in a few it is one and extremely exceptionally more than one. The value of energy imparted in most individual cells is then zero but in the hit cells it will exceed the mean value by orders of magnitude. These large differences in the energy deposition distribution in microscopic regions for different types (and energies) of radiation have been related to observed differences in biological effectiveness or radiation quality.

(47) In the definition of radiological protection quantities no attempts are made to specify these stochastic distributions at a microscopic level. Even the quality factor used in the definition of operational quantities is dependent on LET only which also is a non stochastic quantity. Instead a pragmatic and empirical approach has been adopted to take account of radiation quality differences - and therefore implicitly also of the differences in distributions of energy imparted in microscopic regions - by defining radiation weighting factors. The selection of these factors is mainly a judgement based on the results of radiobiological experiments.

3.3.2. Radiological protection quantities: Averaging of dose

(48) While absorbed dose is defined to give a specific value (averaged in time) at any point in matter, averaging of doses over larger tissue volumes is often performed when using the quantity absorbed dose in practical applications, as in radiological protection. It is especially assumed for stochastic effects at low doses that such a mean value can be correlated with the risk of a detriment to this tissue with sufficient accuracy. The averaging of absorbed dose and the summing of mean doses in different organs and tissues of the human body, as given in the definition of all the protection quantities, is only possible under the assumption of a linear

dose-response relationship with no threshold (LNT). All protection quantities rely on these hypotheses.

(49) Protection quantities are based on the averaging of absorbed dose over the volume of a specified organ or tissue. The extent to which the average absorbed dose in an organ is representative of the absorbed dose in all regions of the organ depends on a number of factors. For external radiation exposure, this depends on the degree of penetration of the radiation incident on the body. For penetrating radiation (photons, neutrons), the absorbed dose distribution within a specified organ may be sufficiently homogeneous and thus the average absorbed dose is a meaningful measure of the absorbed dose throughout the organ or tissue. For radiation with low penetration or limited range (low-energy photons, charged particles) as well as for widely distributed organs (e.g. bone marrow) exposed to non-uniform radiation flux, the absorbed dose distribution within the specified organ may be very heterogeneous.

(50) For radiations emitted by radionuclides residing within the organ or tissue, so-called internal emitters, the absorbed dose distribution in the organ depends on the penetration and range of the radiations and the homogeneity of the activity distribution within the organs or tissues. The absorbed dose distribution for radionuclides emitting alpha particles, soft beta particles, low-energy photons, and Auger electrons may be highly heterogeneous. This heterogeneity is especially significant if radionuclides emitting low-range radiation are deposited in particular parts of organs or tissues, e.g. plutonium on bone surface or radon daughters in bronchial mucosa and epithelia. In such situations the organ-averaged absorbed dose may not be a good dose quantity for estimating the stochastic damage. The applicability of the concept of average organ dose and effective dose may, therefore, need to be examined critically in such cases and sometimes empirical and pragmatic procedures must be applied. ICRP has developed dosimetric models for the lungs, the gastrointestinal tract and the skeleton that take account of the distribution of radionuclides and the location of sensitive cells in the calculation of average absorbed dose to these tissues.

3.3.3. Radiation weighted dose and effective dose

(51) The definition of the protection quantities is based on the mean absorbed dose, $D_{T,R}$, due to radiation of type R and averaged over the volume of a specified organ or tissue T. The protection quantity *radiation weighted dose* in an organ or tissue, H_T,[2] is then defined by equation (1). The unit of radiation weighted dose is J kg^{-1} and up until now has had the special name sievert (Sv). The Commission is considering a new name for the unit of radiation weighted dose so as to avoid the use of the name sievert both for radiation weighted dose and for effective dose.

$$H_T = \sum_R w_R D_{T,R} \qquad (1)$$

where $D_{T,R}$ is the average absorbed dose due to radiation of type R and w_R the corresponding radiation weighting factor. The sum is performed over all types of radiations involved. Values of w_R are based upon the relative biological effectiveness (RBE) of various radiations for stochastic effects, especially compared with the effects of x or γ rays at low doses.

(52) The effective dose, E, is defined as given in *Publication 60* (ICRP, 1991a) by

[2] The new name *radiation weighted dose* which replaces the former name *equivalent dose* for H_T is proposed in order to more clearly point to its definition and to avoid any further confusion with the term *dose equivalent* used in the definition of operational dose quantities.

$$E = \sum_{T} w_T \sum_{R} w_R D_{T,R} \qquad (2)$$

where w_T is the tissue weighting factor with $\Sigma\, w_T = 1$. The sum is performed over all organs and tissues of the human body considered in the definition of E. The unit of effective dose is J kg^{-1} with the special name sievert (Sv).

(53) The averaging of doses for defining quantities in radiation protection is a widely accepted approach. As one of the basic quantities in radiological protection, the radiation weighted dose will continue to play a central role in spite of the limitations in an average absorbed dose quantity as mentioned before. A set of w_R-values for various radiations was described in *Publication 60* (ICRP, 1991a). The only modifications recommended at present for the calculation of radiation weighted doses are some numerical adjustments to be introduced for the values of w_R for neutrons and protons.

(54) It must be stressed that effective dose is intended for use as a principal protection quantity for establishment of prospective radiation protection guidance. It should not be used to assess risks of stochastic effects in retrospective situations for exposures in identified individuals, nor should it be used in epidemiological evaluations of human exposure, because the Commission has made judgements on radiation risks in the derivation of *'detriment'* for the purpose of defining tissue weighting factors. Its main use is to enable external and internal irradiation to be added as a means to demonstrate compliance with the Commission's quantitative restrictions on dose, which are expressed in effective dose. In this sense effective dose is used for regulatory purposes worldwide.

(55) Effective dose is defined by doses in the human body and is in principle as well as in practice a non-measurable quantity. For estimating values of effective dose, conversion coefficients are generally applied which relate the effective dose of a person to other measurable quantities, e.g. air kerma or particle fluence in case of external exposure or activity concentrations etc. in case of internal exposure. In order to provide a practicable approach to the assessment of effective dose, in particular for occupational exposure to low doses, conversion coefficients are calculated for standard conditions (monoenergetic radiations, standard irradiation geometries, selected chemical compounds) in anthropomorphic phantoms with clearly defined geometry, including all organs specified in the definition of effective dose and all regions (including surfaces of bone mineral and airways, contents of walled organs, and volume of organs) where radionuclides might reside in the body.

3.4. Weighting Factors

(56) Some radiations are more damaging than x and ? rays and stochastic effects are more likely in some tissues than in others. It is in order to improve the correlation between dose quantities applied in radiation protection and the effects considered two types of weighting factors have been introduced, a radiation weighting factor, w_R, and a tissue weighting factor, w_T. These weighting factors are needed for the calculation of the effective dose.

(57) The weighting factors are intended to take account of most types of practically relevant radiation and of stochastic effects (radiation-induced cancer and hereditary diseases) in different tissues of the body. They are therefore broadly based on a wide range of experimental data and epidemiological studies. In *Publication 60* the Commission deliberately selected a general set of these weighting factors, sufficiently accurate and appropriate for the needs in radiation protection. It is unrealistic, however, to expect them to be applicable to precise estimate risks of any particular individual or health effect in particular cases when radiation exposures have occurred.

(58) The procedure of weighting, like that of averaging of doses, is relevant to radiological protection only if the dose-response relationship shows an increase in risk proportional to the dose. The weighting factors and the dosimetric quantities based on w_R and w_T therefore relate only to stochastic effects.

3.4.1. Radiation weighting factors

(59) The radiation weighting factor, w_R, has been defined for the protection quantities. It is a factor by which the mean absorbed dose in any tissue or organ is multiplied to account for the detriment by the different types of radiation relative to photon radiation. Values of w_R are taken to be independent of a specific tissue. Numerical values of w_R are specified in terms of type and energy of radiations either incident on the human body or emitted by radionuclides residing within the body. The same value of the radiation weighting factor, w_R, is applicable to all tissues and organs of a body independent of the fact that the actual radiation field in the body may vary between different tissues and organs due to attenuation and degradation of the primary radiation and the production of secondary radiations of different radiation quality in the body.

(60) The selection of radiation weighting factors, w_R, is based on the evaluation of the relative biological effectiveness (RBE) of the different radiations with respect to stochastic effects. The concept of RBE values characterising the different effectiveness of radiations is used in radiobiology. An RBE value is given by the ratio of the absorbed doses of two types of radiation producing the same specified biological effect (dose value of a reference radiation divided by the corresponding dose value of the radiation considered). RBE values usually depend on the effect investigated, on the tissue or cell type, as well as on the dose, the dose rate, and the dose fractionation scheme. For radiological protection, the RBE values at low doses and low dose rates are of particular interest.

(61) The evaluation of w_R values is based mainly on RBE data from in vivo investigations with animals. While in vitro investigations on cells can provide important contributions to the understanding of basic mechanisms regarding carcinogenesis, the RBE values obtained in such studies are less well correlated with carcinogenesis in humans. In many cases, however, there is not enough or sufficiently precise data available from in vivo investigations on cells. Then the $Q(L)$ function, which is mainly based on data from in vitro experiments, and the calculation of a mean Q value for the human body is additionally used for deriving radiation weighting factor values. This is especially the case for protons and heavy ions, partially also for neutrons (*Publication 92*; ICRP, 2003c).

Reference Radiation

(62) Obviously, the RBE values depend on the reference radiation chosen. Generally, low-LET radiation is taken as a reference and mostly ^{60}Co-gamma rays or medium to high energy x rays have been used. For all RBE data published, precise information on the reference radiation used is necessary. In *Publication 60* (ICRP, 1991a) the Commission has recommended a radiation weighting factor value of w_R=1 for all photons. This is consistent with the fact that no specific photon energy has been fixed as a reference and therefore an average of RBE data related to photons of different energies is applied. This does not, however, imply that there exist no differences in radiation quality with photon energy. In particular, in vitro experiments on cells show significant differences in radiation quality between e.g. ^{60}Co-gamma rays and low energy x rays.

Radiation weighting factors for photons, electrons, and muons

(63) Photons, electrons, and muons are generally low-LET radiations. In the past, low-LET radiations have always been given a value of one in radiation weighting. This has been done mainly for practical reasons and in consideration of the large uncertainties in estimating radiation risk factors which did not justify a more detailed description. In vitro investigations

of dicentrics in human lymphocytes and of mutations and transformations in other cell lines, e.g. in human and human-hamster hybrid cells, have shown that low energy x rays have a significantly larger RBE than ^{60}Co-gamma radiation. 20 keV x rays may be about 2 to 3 times as effective as conventional 200 kV x rays and these are about twice as effective as ^{60}Co-gamma rays. A much lower ratio has been observed in animal experiments while epidemiological data are not precise enough to see any differences.

(64) In internal dosimetry, a single w_R value for all photons and electrons emitted is a simplification in the determination of radiation weighted organ doses. Usually, complex models such as the alimentary tract model or the respiratory tract model are applied to calculate the distribution of radionuclides in the various organs and tissues of the body from ingestion or inhalation data and the corresponding organ doses. Often the parameters used in these models contain large uncertainties and many parameters can only be considered as rough estimates.

(65) In external exposure by photons with energies from 30 keV to 5MeV, a considerable part of the organ doses are from Compton-scattered photons in the body with an average energy significantly lower than that of the incident photons. In deep-lying organs this portion can amount to about 50 % of the total organ dose for 1 MeV photons. Therefore, for external photon radiations with different energies, the variation of the mean RBE averaged over the whole body is expected to be considerably smaller than the corresponding differences obtained from investigations of small cell probes.

(66) Low-energy photon radiation has been shown to have an RBE much higher than 1. However, it is strongly attenuated by the tissue close to the surface of the body and can be easily shielded. Hence, its contribution to the effective dose is mostly small. In radiation measurements, the operational dose quantities H^* are used to assess effective dose. For low energy photons, their values provide a very conservative estimate of E, up to a factor 6 or even higher for some directions of radiation incidence. For all these reasons it is a pragmatic decision to keep the w_R value for photons, electrons , and muons equal to 1.

(67) While there are good arguments for continuing to keep w_R for low-LET radiations equal to 1, it is important to state that this simplification is sufficient only for the intended applications of the quantity effective dose, e.g. for dose limitation, assessment, and controlling of doses, but not for the retrospective assessment of individual risks of stochastic effects from radiation exposures or for use in epidemiological evaluations. In those cases, more detailed information on appropriate RBE values should be considered.

Radiation weighting factors for neutrons

(68) The radiation quality of neutrons incident on the human body is strongly dependent on the neutron energy because of the variation of the secondary radiation produced by neutrons in the human body. In *Publication 60*, the radiation weighting factor for neutrons was given in two ways. A step function defining 5 neutron energy ranges was provided with w_R values of 5, 10, and 20, respectively. Furthermore, a continuous function was defined as an approximation for use in calculations. It is now recommended that in future only a continuous function is used for defining radiation weighting factors for neutrons.

(69) At neutron energies below about 1 MeV, the effect of the secondary photons produced in the human body is mainly responsible for the recommended decrease of the neutron weighting with decreasing energy. When RBE data obtained from investigations with small animals is used as the basis for the evaluation of a w_R value applied to human exposure situations , the higher dose contribution from secondary photons in the human body compared to species with smaller bodies has to be taken into account. These photons are mainly produced by the capture reactions of degraded neutrons in nuclei throughout the entire body. Their contribution to the total radiation weighted dose of an organ is strongly dependent on

the body size and on the position of the organ considered in the body. For external neutrons and whole body exposure, a mean value can be determined as an average over all tissues and organs of the human body.

(70) The calculation of the energy dependence of the radiation weighting can be based on the $Q(L)$ relationship defined in *Publication 60* (ICRP, 1991a) and the calculation of a human body averaged mean quality factor q_E. Then the relationship between q_E and a weighting factor may be defined by the function

$$w_R = 1.6\,(q_E - 1) + 1 \qquad (3)$$

This equation preserves a value of w_R of about 20 at incident neutron energies near 1MeV. Calculations of q_E have been performed considering the dose distribution in the human body and the weights w_T of the different organs and tissues by the equation

$$q_E = H_E / D_E = \sum_T w_T Q_T D_T \Big/ \sum_T w_T D_T \,. \qquad (4)$$

Due to the different w_T values of the organs and tissues not symmetrically distributed in the human body, the value of q_E depends on the directional incidence of the radiation on the body.

(71) A similar energy dependence of the radiation weighting can be obtained by other considerations. At first the mean absorbed dose contribution, f_γ, from secondary photons (low-LET component relative to the total dose) in the human body and the contribution from secondary charged particles (high-LET component) are calculated by:

$$f_{\text{low-LET}} = (\Sigma\, w_T D_T f_{\text{low-LET,T}}) / (\Sigma\, w_T D_T) \text{ and}$$
$$f_{\text{high-LET}} = 1 - f_{\text{low-LET}} \qquad (5)$$

where $f_{\text{low-LET,T}}$ is the relative absorbed dose contribution in the tissue or organ T. Secondly a 'mixture rule' is applied for the calculation of a body-averaged relative biological effectiveness using the equation:

$$\text{RBE}_{av} = \text{RBE}_{\text{high-LET}}\,(1 - f_{\text{low-LET}}) + \text{RBE}_{\text{low-LET}}\, f_{\text{low-LET}} \qquad (6)$$

where RBE_{av} is the resulting RBE properly averaged over the human body. This 'mixing rule' is applied in the neutron energy range from thermal neutrons up to 1 MeV. For the photon contribution a value of $\text{RBE}_{\text{low-LET}} = 1$ is taken and for the high-LET neutron component also a constant $\text{RBE}_{\text{high-LET}}$ is chosen which is consistent with experimental data on the induction of dicentrics. The selected value of $\text{RBE}_{\text{high-LET}} = 25$ from animal data results in an RBE_{av} value of about 20 in the human body for neutrons of 1 MeV. Depending on the exposure conditions chosen, the energy dependence of RBE_{av} is similar to that of q_E in the energy range from thermal up to 1 MeV neutrons.

(72) In view of all considerations, a simple function is recommended for the definition of the radiation weighting factor in the energy range below 1 MeV:

$$w_R = 2.5 + 18.2 \exp[-(\ln E_n)^2/6] \quad \text{for} \quad E_n < 1 \text{ MeV} \qquad (7)$$

Figure 1 shows that in the neutron energy range below 1 MeV the values of w_R are much less than those given in *Publication 60*. They are now fully considering the effect of secondary photons in the body and are better related to the mean quality factor q_E.

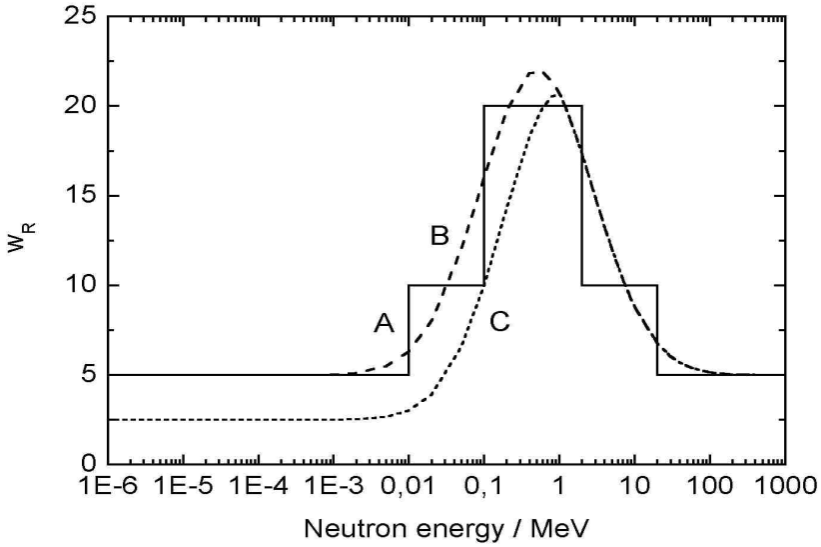
(73) The energy range above 1 MeV needs different considerations. All existing experimental data either on animals or on cells, however, show a strong decrease of RBE with increasing neutron energy. This is consistent with calculations based on the $Q(L)$ function (*Publication 92*; ICRP, 2003c). If, however, the strong correlation between q_E and w_R as defined in *Publication 92* would be applied, in the energy range between 5 and 150 MeV ths

would result in an increase of w_R for neutrons between 22% and 39% relative to the data of the continuous function as defined in *Publication 60*. Such an increase is not supported by any experimental data.

(74) It is therefore recommended to stay with the continuous function of *Publication 60* at neutron energies equal and above 1 MeV and to change this function at low energies only. Thus, in conclusion the following functions are recommended:

$$w_R = \begin{cases} 2.5 + 18.2 \exp[-(\ln E_n)^2/6] & \text{for } E_n < 1 \text{ MeV} \\ 5.0 + 17.0 \exp[-(\ln (2E_n))^2/6] & \text{for } E_n \geq 1 \text{ MeV}. \end{cases} \quad (8)$$

Figure 1. Radiation weighting factor, w_R, for incident neutrons versus neutron energy. (A) step function and (B) continuous function given in *Publication 60* (ICRP, 1991a), *(C) New function calculated on the basis of equations (8)*



Radiation weighting factor for protons

(75) Only external radiation sources have to be considered for proton exposure in practical radiological protection. In recent years proton radiation has received more attention due to an increased interest in dose assessment for air crew exposure and in space. Because of the small range of low energy protons (range of 4 MeV protons: 0.025 cm in tissue), mainly protons with energies above 10 MeV should be considered when choosing a value of the radiation weighting factor for protons. There are very few investigations on animals that give information on the RBE for high energy protons. Mostly RBE values between 1 and 2 are observed. The mean quality factor of 100 MeV protons stopping in tissue is calculated to be less than 1.2. At very high proton energies, near 1 GeV, secondary charged particles from nuclear reactions become more important and the mean quality factor increases up to about 1.8. Taking all considerations and available data into account, the radiation weighting factor for protons of all energies should have a value of 2 (*Publication 92*; ICRP, 2003c).

Radiation weighting factor for α-particles, fission fragments, and other heavy particles

(76) Humans are mainly exposed to α particles from internal emitters, e.g. from inhaled radon progeny or ingested α-emitting radionuclides like radium, thorium, and plutonium. There are a number of epidemiological studies that provide information on the risk for inhaled or intravenously injected α emitters. The distribution of radionuclides and the dosimetry in

the body and also the estimation of dose distributions in tissues and organs are very complex and are strongly based on the models used. The estimated doses are, therefore, associated with large uncertainties. For this reason most epidemiological studies cannot be used as the sole basis for an assessment of the RBE for α emitters. From calculations using the $Q(L)$ function, the mean quality factor of a 6 MeV alpha particle slowing down in tissue is estimated to be about 20.

(77) The Commission continues to recommend a value for w_R of 20 for α particles. It also continues to recommend a value of 20 for w_R in the case of heavy nuclei and fission fragments. Doses from fission fragments are important in internal dosimetry and regarding radiation weighting factors the situation is similar to that for α particles. Due to their short ranges the distribution of the actinides in the organs and tissues has a strong influence on their biological effectiveness. A radiation weighting factor of 20 as for α particles may be a rough conservative estimate.

(78) In external exposure, heavy ions and other types of radiation, e.g. pions, are mainly occurring in radiation fields near high energy accelerators, at aviation altitudes, and in space. For heavy ions, the data obtained by in vitro experiments clearly show an LET dependence of RBE. The RBE decreases with increasing LET for LET values above about 200 keV/µm. For heavy charged particles incident on a human body and stopped in the body, the radiation quality of the particle changes strongly along the track. As an average value, a constant weighting factor of 20 for all types and energies of heavy charged particles is chosen to be sufficient for the general application in radiological protection.

Summary of radiation weighting factors

(79) The new radiation weighting factors are summarised in Table 2.

Table 2. Radiation weighting factors

Type and energy range	Radiation weighting factor, w_R
Photons	**1**
Electrons	**1**
Protons	**2**
Alpha particles, fission fragments, heavy nuclei	**20**
Neutrons	**A continuous curve is recommended. See Figure 1 and equations (8)**

3.4.2. The selection of tissue weighting factors

(80) The Commission has previously made a policy decision that there should be only one single set of w_T values that are averaged over both genders and all ages. The Commission continues to maintain that policy in these Recommendations.

(81) The tissue weighting factors, as defined in *Publication 60*, are based on complex reasoning, much of which is often overlooked. For example, they were not based solely on the cancer fatality risk. It was intended to reflect the relative detriment from the exposure of single organs or tissues. The Commission now begins with cancer incidence data and takes account of the lethality rate, the years of life lost and of a weighted contribution from the non-fatal cancers and from hereditary disorders. The values of w_T are normalised to give a total of one. The grouping of tissues is complex and substantial rounding takes place. The Commission's new approach to the calculation of detriment is outlined in Annex A and has been used to derive a new set of tissue weights. The new values that apply for the tissue weighting factors are listed below in Table 3.

Table 3. Tissue weighting factors

Tissue	w_T	? w_T
Bone marrow, Breast, Colon, Lung, Stomach	**0.12**	0.60
Bladder, Oesophagus, Gonads, Liver, Thyroid	**0.05**	0.25
Bone surface, Brain, Kidneys, Salivary glands, Skin	**0.01**	0.05
Remainder Tissues* (Nominal w_T applied to the average dose to 14 tissues)	**0.10**	0.10

***Remainder Tissues (14 in total)**

Adipose tissue, Adrenals, Connective tissue, Extrathoracic airways, Gall bladder, Heart wall, Lymphatic nodes, Muscle, Pancreas, Prostate, SI Wall, Spleen, Thymus, and Uterus/cervix.

3.5. Practical application in radiological protection

(82) Radiological protection is concerned with controlling exposures to low radiation doses that give rise to stochastic effects and preventing exposures that could give rise to high radiation doses resulting in tissue damage (deterministic effects). These two types of effect are considered separately below.

3.5.1. Control of stochastic effects

(83) Both ICRP and ICRU define dosimetric quantities for use in radiological protection. ICRU has introduced quantities, collectively referred to as *Operational Quantities,* for area and individual monitoring of radiation from sources external to the body. For area monitoring, these quantities are *ambient dose equivalent* and *directional dose equivalent.* They are based on simple geometric models for the radiation field and the dose at a specific point in the ICRU sphere phantom (ICRU, 1980).

(84) The definitions of the operational quantities take account of the common situation in which the individual dose assessment is performed with dosemeters worn on the body. The *personal dose equivalent* is, therefore, defined by the dose at a specific depth in the body below the point where the dosemeter is worn. The protection quantity adopted by ICRP for the control of stochastic effects is the effective dose. This quantity is by its definition related to doses in the human body and generally is not measurable. A variety of conversion coefficients link the effective dose to measurable physical quantities, e.g. radiation fluences or air kerma characterising the external radiation fields in the workplace.

(85) In *Publication 74* (1996b), the two Commissions jointly concluded that, for external sources, the two approaches are well correlated and in most practical situations the values of the operational dose quantities provide an assessment of effective dose that is sufficiently accurate for radiological protection applications. This will also be the situation after the recommended changes of w_R for neutrons and protons. ICRP also provides dose coefficients for the activity intake of radionuclides by inhalation and ingestion, and the airborne activity concentration of noble gas radionuclides.

(86) The calculation of absorbed dose within the tissues and organs of the body at risk of stochastic effects, which underlies the determination of effective dose, is derived by ICRP specified age- and gender-specific models of the body, and models describing the fate of radionuclides within the body – including dependence on the physico-chemical form of the radionuclides. The absorbed doses are modified by radiation weighting factors and age- and

gender-average tissue weighting factors to derive the value of the effective dose. The effective dose is thus defined for a hypothetical reference individual and, unlike the operational quantities, includes parameters specific to the age and gender of the exposed individual (e.g., the anatomical parameters) and other parameters that are independent of the exposed individual (e.g., the radiation and tissue weighting factors). These details are not part of the formal definition of the effective dose and thus must be considered when interpreting values of the protection quantity.

(87) The annual effective dose recorded for a worker is to be assessed as the sum of the effective dose from external exposure in that year and the committed effective dose from intakes of radionuclides in that year. The committed effective dose is not measurable, but can be calculated using measurements of activity in samples during monitoring of the workplace and/or the workers, including measurements of airborne activity concentrations, daily urinary and faecal excretion of radionuclides, and activity retained within the body or in specific organs. For practical purposes, the effective dose, E, can in most situations be estimated from operational quantities using the following formula:

$$E = H_p(10) + \sum_j e_{j,inh}(50) \cdot I_{j,inh} + \sum_j e_{j,ing}(50) \cdot I_{j,ing}$$

where $H_P(10)$ is the personal dose equivalent resulting from exposures to the radiation fields, $e_{j,inh}(50)$ is the committed effective dose coefficient for activity intakes by inhalation of radionuclide j, $I_{j.\mathrm{inh}}$ is the activity intake of radionuclide j, by inhalation, $e_{j,ing}(50)$ is the committed effective dose coefficient for activity intakes of radionuclide j by ingestion, and $I_{j,\mathrm{ing}}$ is the activity intake of radionuclide j by ingestion. The commitment period of 50 years is a rounded value that relates to the life expectancy of a young person entering the workforce.

(88) Although dose records are for individuals the dose coefficients on which they are based are derived for reference individuals. If doses approach or exceed the dose constraints, then investigations may need to be undertaken to address workplace and individual specific characteristics in the dose assessment. The committed effective dose coefficients from the intake of a radionuclide are also used for prospective dose estimates of individual members of the public. In these cases a commitment period of 50 years is used for the adult and the effective dose to age 70 years for infants and children.

(89) ICRP has previously used age-specific computational models of the human anatomy based on a model defined by the Medical Internal Radiation Dose (MIRD) Committee. The MIRD computational model (or MIRD phantom; Snyder et al., 1978) is an analytical representation of the body and its organs that has been widely used in computational dosimetry during the past thirty years. The Commission has now adopted new computational models of adult male and female workers based on medical topographic images. The anatomy is described by voxels (3-dimensional volume elements), each identified as to the organ/tissue type within which it resides. The models, referred to as 'voxel phantoms', have been designed to approximate the organ masses assigned to the reference adult male and female in *Publication 89* (ICRP, 2001).

(90) The new models will be used to compute the average absorbed dose, $\overline{D}_{\mathrm{T}}$, in organ or tissue T from radiation fields external to the body and the relationship of the effective dose to the operational quantities specific to the radiation field. Conversion coefficients representing the effective dose per unit fluence or air kerma as a function of radiation energy will be defined for various irradiation geometries and will be applicable to external exposures at the workplace.

(91) In *Publication 60*, the operational quantity *Annual Limit on Intake* (*ALI*) was defined as that activity of a radionuclide which would commit the reference individual to receive a

committed effective dose corresponding to the annual dose limit for occupational exposure of 20 mSv. The Commission does not now give ALI values, as it considers that for compliance with dose limits it is the total dose from external radiation as well as from intakes of radionuclides that must be taken into account as indicated above. It is, however, noted that the ALI concept can be useful in various practical situations; e.g., in characterising the relative hazard of radiation sources to ensure that appropriate administrative controls are in place.

(92) In the assessment of committed effective doses from internal radionuclides, it is often useful to define as a further operational quantity the *Derived Air Concentration* (*DAC*). This is that activity concentration of a radionuclide in air which would lead to a committed effective dose equal to the occupational dose limit assuming a breathing rate of 1.2 $m^3 h^{-1}$ and an annual working time of 2,000 h.

(93) ICRP Committee 2 is considering how best to give advice for assessing radiation doses from intakes of radionuclides. Model-based conversion coefficients are to be derived for radionuclides relating the effective dose to measurement of the specific radionuclide activity content in the body, body organ(s), excreta samples, and in air. It is considered that the provision of these coefficients, based upon the most recent biokinetic and dosimetric models, will facilitate the interpretation of monitoring data. Possible options are the committed dose per unit contained activity (activity contained in a measured sample) or the contained activity that would correspond to the occupational dose limit (or to 1 mSv). Predicted values of contained activity at various times after a single or continuous intake will also be tabulated, as in past documents of the Commission. It is expected that a consultation document will be issued by Committee 2 early in 2005. This will discuss these problems together with information on the revision of dose coefficients for occupational exposure that will take into account the new tissue weighting factors and updated biokinetic data.

3.5.2. Control of tissue reactions

(94) Tissue reactions are the result of the loss of function of a significant number of cells in a tissue. The dosimetric situation causing this loss of function is complex. If the dose is approximately uniform over the tissue, the mean absorbed dose is an appropriate starting point. If the dose is far from uniform, the localised damage may not reduce the performance of the tissue, but the localised damage may be severe. The biological consequences of these situations depend heavily on the spatial and temporal distributions of absorbed dose. The only approach is to make qualitative judgements based on the distribution of absorbed dose in location and time. For this last purpose, estimates of the distribution of absorbed dose, possibly weighted by selected values of relative biological effectiveness (RBE), will be needed. The unit of the RBE-weighted absorbed dose is J kg^{-1} and the special name, proposed in *Publication 92* (ICRP, 2003c), is the gray-equivalent (Gy-Eq).

(95) Apart from some exposures of medical patients and some serious emergency situations, which have to be managed separately, the control of stochastic effects will avoid the occurrence of most, and probably all, tissue reactions.

4. BIOLOGICAL ASPECTS OF RADIOLOGICAL PROTECTION

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

- tissue reactions, and
- cancer development in exposed individuals and heritable disease in their offspring due to mutation of somatic and reproductive (germ) cells respectively.

In *Publication 60* (ICRP, 1991a), the Commission classified tissue reactions as deterministic effects and used the term stochastic effects for cancer and heritable disease. Since 1990 ICRP has reviewed many aspects of the biological effects of radiation. The views developed are summarised in this Chapter and in Annex A. A more detailed document is to be published as ICRP (2005), a Task Group report of ICRP Committee 1.

4.1. The induction of tissue reactions

(97) Tissue injury and its various organ-specific manifestations are commonly called tissue or organ reactions. 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.

(98) Early tissue reactions (days to weeks) to radiation after the threshold dose has been exceeded may be of the inflammatory type resulting from the release of cellular factors or they be reactions resulting from cell loss (*Publication 59*; ICRP, 1991b). 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 Table 4.

Table 4. Types of Radiation-induced tissue reactions

	Example
Early reactions	
Inflammatory type	Erythematous skin reaction
Cell loss type	Mucositis, epidermal desquamation
Late reactions	
Generic type	Vascular occlusion leading to tissue necrosis
Consequential type	Mucosal ulceration leading to intestinal stricture

(99) Reviews of data on these effects 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 for the purposes of radiological protection, in the radiation dose range of a few mGy up to a few tens 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. Table 5 provides a summary of judgements from the Commission on dose-thresholds (~1% incidence) for radiation-induced tissue reactions and mortality together with their times of development.

Table 5: Projected threshold estimates of the acute absorbed doses for 1% incidences of morbidity and mortality involving adult human organs and tissues from whole-body ? exposures.

Effect	Organ/tissue	Time to develop effect	Absorbed dose (Gy)[e]
Morbidity:			*1% Incidence*
Temporary sterility Permanent sterility	Testes Testes	3-9 weeks 3 weeks	~0.1[a,b] <6[a,b]
Permanent sterility	Ovaries	< 1week	3[a,b]
Depression of blood-forming process	Bone marrow	3-7 days	0.5[a,b]
Main phase of skin reddening	Skin (large areas)	1-4 weeks	3-6[b]
Skin burns Temporary hair loss	Skin (large areas) Skin	2-3 weeks 2-3 weeks	5-10[b] <4[b]
Cataract (visual impairment)[f]	Eye	Several years	3[a,c]
Mortality:			
Bone marrow syndrome:			
- without medical care	Bone marrow	30-60 days	1[b]
- with good medical care	Bone marrow	30-60 days	2-3[b,d]
Gastro-intestinal syndrome:			
- without medical care	Small intestine	6-9 days	6[d]
- with conventional medical care	Small intestine	6-9 days	>6[b,c,d]
Pneumonitis	Lung	1-7 months	6[b,c,d]

[a]ICRP (1984c)

[b]UNSCEAR (1988)

[c]Edwards and Lloyd (1996)

[d]Scott and Hahn (1989), Scott (1993)

[e]Most values rounded to nearest Gy; ranges indicate area dependence for skin and differing medical support for bone marrow.

[f]Thresholds at lower doses are expected for lens opacities that are not associated with overt visual impairment.

4.2. The induction of cancer and hereditary effects

4.2.1. Risk of cancer

(100) The accumulation of cellular and animal data relevant to radiation tumorigenesis have, since 1990, greatly strengthened the view that DNA damage response processes in cells are of critical importance to the post-irradiation development of cancer. These mechanistic data on cellular response and animal tumorigenesis together with rapid 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 cancer risk at doses between a few mSv and a few tens of mSv; also to associated judgements on RBE/radiation weighting and 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 cancer-related gene/chromosomal mutations. Advances in the microdosimetric aspects of radiation-induced DNA damage have also contributed significantly to this understanding.

(101) Although there are recognised exceptions, for the purposes of radiological protection the Commission judges that the weight of evidence on fundamental cellular processes supports the view that in the low dose range up to a few tens of mSv, it is scientifically reasonable to assume that in general and for practical purposes cancer risk will rise in direct proportion to absorbed dose in organs and tissues. This view accords with that given by UNSCEAR (2000).

(102) In arriving at this practical judgement, 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. The Commission recognises that these biological processes 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 cancer risk. The Commission also recognises 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. Significant sources of uncertainty would therefore be dependent upon the demonstration of not only the relevance of these phenomena to cancer development in vivo but also knowledge of the dose-dependence of the cellular processes involved.

(103) 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 A-bomb Life Span Study (LSS). For cancer mortality the follow-up is 47 years (1950-1997); for cancer incidence the follow-up period is 41 years (1958-1998). These 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 2005 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.

(104) 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). 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 sites, e.g., lung, there are significant differences. 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.

(105) In principle, epidemiological data on protracted exposures may be informative on judgements on the dose and dose-rate effectiveness factor (DDREF) to be used in radiological protection. However, the statistical precision afforded by many of these studies is limited and for this reason the Commission reached a judgements on a suitable value for DDREF that is based on a combination of experimental data from quantitative cellular/animal studies and dose-response features of the LSS. From these data the Commission finds no good reasons to change its 1990 recommendations of a DDREF of 2. This risk reduction factor of 2 is to be applied to acute dose data in order to take account of the biologically expected decrease in cancer risk at low doses and low dose rates.

4.2.2. Risk of hereditary effects

(106) There are some post-1990 human and animal data on the quantitative aspects of radiation-induced germ cell mutation that impact on the Commission's judgement on the risk of induction of genetic disease expressing in future generations. There have also been substantial advances in the fundamental understanding of human genetic diseases and the process of germ line mutagenesis including that occurring after radiation. The Commission has re-appraised the methodology used in *Publication 60* (ICRP, 1991a) 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 (see UNSCEAR, 2001). Also, for the first time, a scientifically justified method for the estimation of risk of multifactorial disease has been included (*Publication 83*).

(107) 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. Also that direct data on spontaneous human mutation rates are used in conjunction with radiation-induced mutation rates derived from mouse studies (see UNSCEAR, 2001).

(108) 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). As a result, these new estimates of genetic risk by the Commission will tend to reduce the value of the tissue weighting factor for the gonads (see Annex A). This value relates to continuous low dose-rate exposures over these two generations i.e. doses to the grandparental and parental generations.

(109) The Commission has also given attention to somewhat contradictory data on the induction of mutations in certain repeated DNA sequences (frequently termed 'minisatellites') in mouse and human germ cells. On current knowledge these repeat sequence mutations are only rarely associated with heritable disease. For this reason, mutation rate data for minisatellites are not considered relevant to the estimation of the risk of heritable effects from radiation exposure.

4.2.3. Nominal probability coefficients for stochastic effects

(110) New data on the risks of radiation-induced cancer and hereditary effects have been used in risk modelling and disease detriment calculations in order to estimate nominal probability coefficients (see Annex A).

(111) On the basis of these calculations the Commission proposes nominal probability coefficients for lethality adjusted cancer risk as $6.2\ 10^{-2}\ Sv^{-1}$ for the whole population and $4.8\ 10^{-2}\ Sv^{-1}$ for adult workers aged 20-64. For hereditary effects, the lethality 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 6, where they are compared with the estimate of Detriment used in the 1990 Recommendations (ICRP, 1991a).

(112) In respect of Table 6 it is important to note that the detriment weighted nominal probability coefficient for cancer estimated here 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 (Annex A) 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 also notable that the nominal probability coefficient for fatal cancer in the whole population that may be projected from the cancer incidence data of Table A1.a of Annex A is 4.4% per Sv as compared with the *Publication 60* value of 5% per Sv.

(113) An additional point relating to the lethality adjusted cancer risk of Table 6 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.

Table 6: Nominal probability coefficients for stochastic effects (10^{-2} Sv^{-1})[1]

Exposed population	Lethality adjusted cancer risk	Lethality adjusted heritable effects	**Detriment**	Detriment Pub.60
Whole population	6.2	0.2	**6.5**	7.3
Adult workers	4.8	0.1	**4.9**	5.6

[1] Values from Tables A1.a and A1.b in Annex A.

4.2.4. Radiation effects in the embryo and fetus

(114) 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 up to a few tens of mGy low LET.

(115) The new data confirm embryonic sensitivity to the lethal effects of irradiation in the pre-implantation period of embryonic developments. At doses of a few tens of 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.

(116) In respect of the induction of malformations, the 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 in the range up to a few tens of mGy may be discounted.

(117) The 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 a non-threshold dose response cannot be excluded. However, even in

the absence of a true dose-threshold, any effects on IQ following in utero doses of a few tens of mGy would be undetectable and therefore of no practical significance. This judgement accords with that developed in *Publication 60*.

(118) *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. The Commission recognises that there are uncertainties on the risk of in-utero-induced solid cancers. However, the Commission suggests that it is reasonable to assume that life-time cancer risk following in utero exposure will be similar to that following irradiation in early childhood. From the studies reviewed in *Publication 90* it is 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. Finally, for the reasons given in *Publication 82* (ICRP; 1999a), the Commission suggests that in utero exposure should not be a specific protection case in common prolonged exposure situations where the prolonged dose is well below about 100 mSv.

4.2.5. Genetic susceptibility to cancer

(119) The issue of inter-individual genetic differences in susceptibility to radiation-induced cancer was noted in *Publication 60* and reviewed in *Publication 79* (ICRP, 1998a). 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 carriers of certain genes – the so called high penetrance genes which are 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 a high proportion of single gene, cancer prone disorders will show increased sensitivity to the tumorigenic effects of radiation.

(120) There is also a growing recognition and some data on variant genes of lower penetrance where gene-gene and gene-environment interactions determine a far more variable expression of cancer. Recently, good progress has been made in demonstrating experimentally the complex interactions that may underlie the expression of cancer-predisposing genes of lower penetrance; this work is, however, at a relatively early stage of development.

(121) On the basis of the data and judgements developed in *Publication 79* and further information reviewed in the UNSCEAR (2000 and 2001) 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.

(122) 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

4.2.6. Non-cancer diseases after radiation

(123) Since 1990 evidence has accumulated that the frequency of non-cancer diseases is increased in irradiated populations. The strongest evidence for the induction of these non-cancer effects at doses in the order of 1 Sv derives from the A-bomb LSS, and the most recent mortality analysis (Preston et al., 2003) 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 a threshold of around 0.5 Sv. It is unclear what forms of cellular/tissue mechanisms might underlie such a diverse set of non-cancer disorders, reported among the LSS data, although some association with sub-clinical inflammation (e.g. Hayashi et al., 2003) is possible.

(124) Additional evidence of the non-cancer effects of radiation, albeit at high doses, comes from studies of cancer patients receiving radiotherapy, e.g., Hancock et al (1993) studied 2232 patients treated for Hodgkin's disease and reported a three-fold risk of death due to heart disease after 30 Gy based on 88 deaths.

(125) Whilst recognising the potential importance of these observations on non-cancer diseases, the Commission judges that the data available at present do not allow for their inclusion in the estimation of detriment following radiation doses in the range up to a few tens of mSv.

5. THE GENERAL SYSTEM OF PROTECTION

5.1. The network of exposure s

(126) In dealing with many situations in radiological protection, 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 habits of the exposed individuals. For convenience, the environmental pathway is usually taken to include the link between the exposure and the doses. The available points of action have a substantial effect on the system of protection.

(127) Since there can be many sources, some individuals will be exposed to radiation from more than one of them. If natural sources are included, all individuals are exposed to ionising radiation through this network from at least a few sources. Fortunately, it is rarely necessary to consider treating this network as a single entity. Provided that doses are below the threshold for tissue reactions, the presumed proportional relationship between dose and stochastic effects makes it possible to deal independently with each part of the network and to select those parts that are important for radiological protection. Further, it is possible to subdivide these parts into groups that are relevant to various purposes.

(128) To make these selections, it is necessary to define for each selection the objectives, the organisations and individuals responsible for protection and the lines of responsibility, and the feasibility of obtaining the necessary information. This is still a complex procedure which has to be simplified at the expense of precision. The Commission has suggested two such simplifications.

(129) The first and fundamental simplification was used in the 1990 Recommendations (ICRP, 1991a) by the separation of the exposure into three classes: occupational exposure, which is the exposure incurred at work, and principally as a result of work; medical exposure, which is principally the exposure of persons as part of their diagnosis or treatment; and public exposure, which comprises all other exposures. No attempt was made to add the exposures in different classes, even when a single individual was subject to exposure in several classes. The Commission still continues to recommend these separations.

(130) Even within a single class, 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 include all the sources causing substantial exposures to the individual. This assessment is called '*individual-related*'.

(131) The second simplification, also used in the 1990 Recommendations, suggests that each source or group of sources within a class can sometimes 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*' assessment. The Commission now re-emphasises the primary importance of source-related assessments, since action can be taken for a single source to assure the protection of a class of individuals from that source.

5.2. The principles of protection

(132) The system of protection now recommended by the Commission is to be seen as a natural evolution of, and as a further clarification of, the 1990 Recommendations. The present 2005 Recommendations establish restrictions on individual dose from specified sources in all situations within their scope. These restrictions should be applied to the exposure of actual or representative individuals. They provide a level of protection for individuals that should be

considered as obligatory and not maintaining these levels of protection should be regarded as a failure. They are complemented by the requirement to optimize the level of protection achieved (See paragraph 128 and Chapter 7).

(133) The most fundamental level of protection is the source-related restriction called a **dose constraint**. It is used to provide a level of protection for the most exposed individuals from **a single source** within a class of exposure. The Commission recommends the use of quantitative dose constraints to protect the most exposed individuals from all identified controllable sources.

(134) When a level of protection is set for an individual from all sources within a class of exposure in normal situations only, it is called a **dose limit**. It is rarely possible to assess the total exposure of an individual from all the controllable sources. It is therefore necessary to make approximations to the dose to be compared with the quantitative limit. For occupational exposures, the approximations are more likely to be accurate since the operating management has access to the necessary information to identify and control the dose from all the relevant sources. The Commission has recommended values of dose limits in *Publication 60* (ICRP, 1991a) which have been adopted in international safety standards and in the national legislation of nearly all countries.

(135) Figure 2 illustrates the differences in concept between individual dose constraints for protection from a single source in all situations and the use, in normal situations only, of individual-related dose limits.

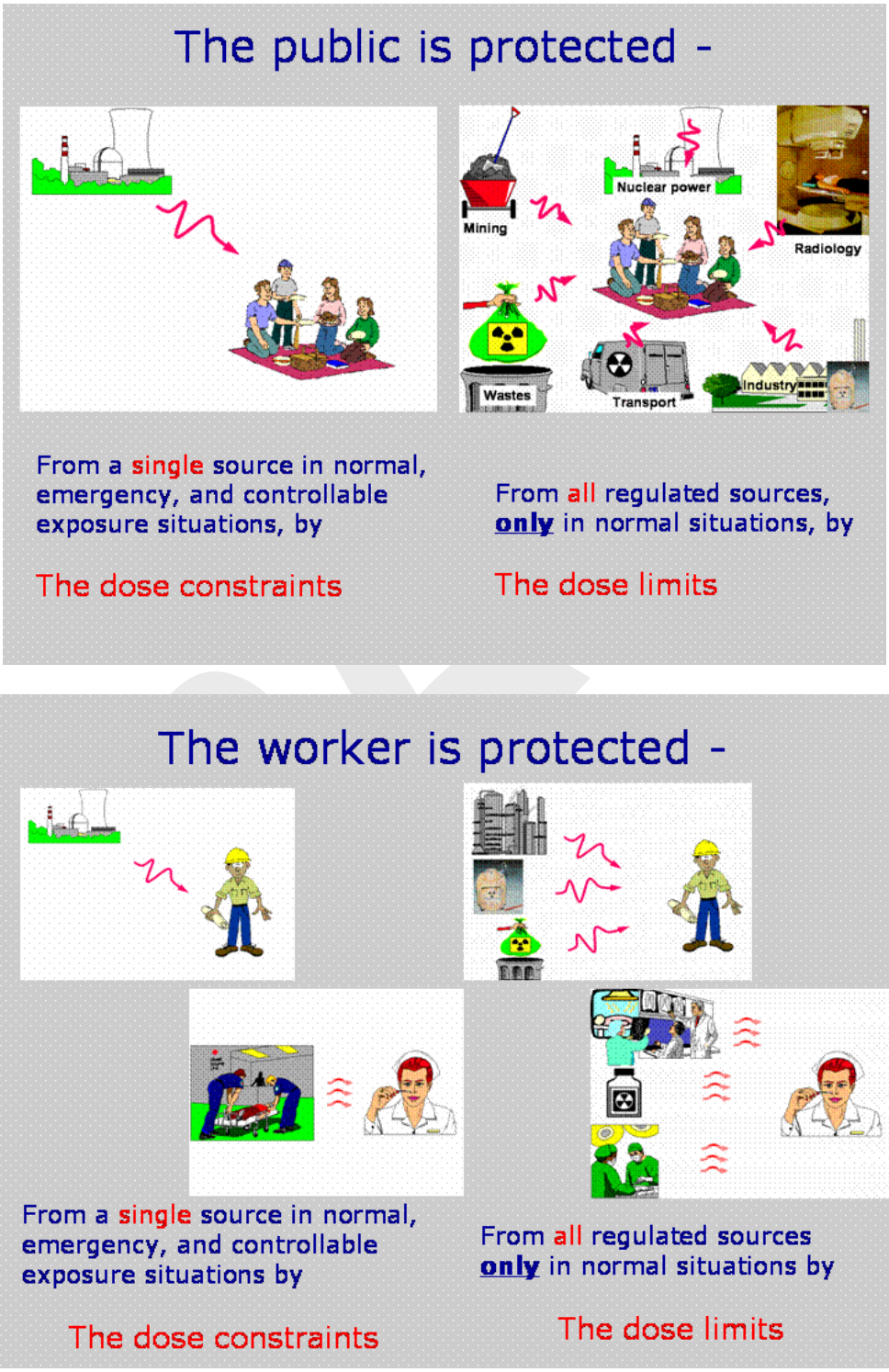
(136) The Commission now recommends maximum values of constraints to apply to all controllable sources. Constraints should also be set by Governments and their regulatory agencies, while in some cases managements may sometimes have sufficient power and information to set constraints for themselves. The Commission expects that, generally, the values of constraints implemented by regulatory agencies will be below its maximum recommended values.

(137) The dose constraint, or risk constraint for potential exposures, is related to one source under each particular circumstance which can be either a normal or an emergency situation, or one where there is an existing controllable exposure. 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 virtually certain to be warranted. It must be realised that the constraint does not represent the demarcation between 'safe' and 'dangerous'. Although it may be used as a regulatory tool, so that exceeding a mandatory constraint may be a statutory offence, it will not cause a step change in the associated health risk.

(138) The radiological principles which ensure the required levels of protection may be characterised by the use of quantitative primary dose constraints for all situations within the scope of the recommendations and, in normal situations only, the use of the dose limits. These are a necessary but not sufficient criterion for protection and therefore have to be complemented by the requirement to optimise protection to enhance the level of protection achieved.

(139) This complementary requirement of the Optimisation of Protection (See Chapter 7) cannot be defined in general quantitative terms; it requires judgement to be exercised about the best level of protection in each situation causing exposure of individuals and is the responsibility of the operating management, subject to the requirements of the competent national authorities. It includes the requirement that all exposures are to be as low as reasonably achievable, social and economic factors being taken into account, in the relevant situation.

FIGURE 2. Illustrating the difference between a dose limit and a dose constraint to protect members of the public or individual workers.



(140) The responsibility for optimisation rests with the operators, based on a policy established by the appropriate national authority. The operator is responsible for providing input to the optimisation that will establish the authority for the operation of licensed

practices, as well as for day-to-day optimisation. The operator's experience of optimisation is useful to the regulatory agencies. The results will, of necessity, be site and installation dependent and beyond the scope of the Commission.

5.3. Classes of exposure

(141) The Commission still recommends the separate control of occupational and public exposure. Medical diagnosis or treatment involves both of these and also the medical exposure of patients.

5.3.1. Occupational exposure

(142) Occupational exposure is defined by the Commission as the exposure incurred at work, and principally as a result of work.

(143) 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 the phrase 'occupational exposure (to radiation)' to exposures incurred at work as a result of situations that can reasonably be regarded as being the responsibility of the operating management.

(144) The sources involved in occupational exposure can usually be identified and constraints can be applied to each source. For each exposed individual or group of individuals, the sources will be controlled by one or a small number of employers at one or a small number of locations of work. The total dose to each exposed individual, or to a representative individual, can then be assessed. The Commission's dose limits can be applied to the total assessed dose.

5.3.2. Public exposure

(145) Public exposure is incurred as a result of a range of controllable sources. Dose limits for public exposure 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 normal situations. The only feasible approach is to select a single source, or a small group of sources, and to estimate the exposure to the most exposed individual or the most highly exposed group of individuals (the critical group). For normal situations, it is unlikely that the total exposure from the defined controlled sources can be judged against the dose limit. This is because the selected sources are only a part of the whole group of likely sources. Therefore, an individual dose from single source during normal situations has to be judged against the constraint.

5.3.3. Medical exposure

(146) Radiation exposures in medicine are predominantly medical exposures of the individuals undergoing diagnosis, screening, or therapy. But there are also exposures of the staff, and near-by members of the public, and individuals, other than staff, helping in the support and comfort of a patient. This is discussed in Chapter 9.

(147) There are several features of medical practice that require an approach to radiological protection which differs from that in other practices. The application of these recommendations to the medical uses of radiation therefore requires separate guidance. In the first place, the exposure of a patient is for the benefit of that patient and the exposure is usually voluntary. 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 guide interventional

radiology. Nevertheless, the dose cannot be reduced indefinitely without loss of diagnostic information.

(148) The application of the Commission's quantitative restrictions on dose are not recommended for individual patients 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 quantitative restrictions do 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 constraints in Chapter 6 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. This is dealt with in Chapter 9.

5.4. The application to operational and regulatory systems

(149) The Commission's advice has to be of a general and international nature. The Commission cannot provide direct regulatory or managerial texts. However, the Commission hopes that its advice will influence both regulatory agencies and management bodies, including their specialist advisors. It also hopes that its advice will continue to help in the provision of a consistent basis for national and regional regulatory policies and standards. The Commission recognises that these hopes will be fulfilled only if its judgements and policies continue to be accepted by the managements of practices causing exposures to radiation, by regulatory agencies, and by governments, as they have been since its establishment in 1928.

(150) The Commission aims to provide guidance to a wide range of organisations in a wide range of countries and regions. Those responsible for operational and regulatory requirements should judge their requirements against all the recommendations of the Commission. The Commission hopes that these requirements are broadly consistent with the Commission's guidance. The Commission believes that while these bodies have the responsibility to design their own procedures, they should prepare these texts to be broadly consistent with the guidance in this report.

(151) Standards and operational instructions have to be enforceable either legally or managerially. They must both be unequivocal in their field of responsibility. Standards exist in a wide range of character from advisory codes of practice to statutory requirements enforceable by criminal penalties. Their scope and requirements must be clearly defined for the situations to which they are intended to apply.

(152) Many other organizations, including the press and public concern groups, take a legitimate interest in radiological protection. All these bodies should be aware of the Commission's publications, but the Commission's advice is aimed principally at the regulators and managements that have direct responsibility for radiological protection.

(153) Regulatory authorities should encourage the operational managements to develop a 'safety culture' within their organisations. Safety culture has been defined internationally by the inter-agency Basic Safety Standards (FAO et al., 1996) as

> 'The assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance'.

(154) Although it is not the task of the Commission to provide suitable texts for either standards or operational instructions, some quantitative features can be usefully recommended for international use. The components of the definitions of some dosimetric quantities are best adopted internationally. The Commission recommends values for such quantities. In the past, the Commission has recommended values for regulatory quantities such as the dose limit for individuals. Recommendations for dose limits have been useful in

avoiding inconsistency between national systems. They are not without problems because it is also necessary to define the conditions in which the limit applies.

(155) In the present Recommendations, the Commission recommends values for the components of the dosimetric quantities (Chapter 3). The Commission now recommends a scheme for setting the dose constraints needed to set the primary level of protection for single sources which is given in Chapter 6. These values are intended for international use. There is then more flexibility in the choice of other national constraints by the relevant competent authorities according to the characteristics of the source. The values of the dose limits recommended in *Publication 60* are retained as restrictions that apply only in normal situations.

6. THE COMMISSION'S REQUIRED LEVELS OF PROTECTION FOR INDIVIDUALS

(156) The Commission has concluded that its recommendations should be based on a simple, but widely applicable, general system of protection that will clarify its objectives and will provide a basis for the more formal systems needed by operating managements and regulators. It also recognises the need for stability in regulatory systems at a time when there is no major problem identified with the practical use of the present system of protection in normal situations. The use of the optimisation principle, together with the use of constraints and the current dose limits, has led to a general overall reduction in both worker and public doses over the past decade. The Commission now strengthens its recommendations by quantifying constraints for all controllable sources in all situations.

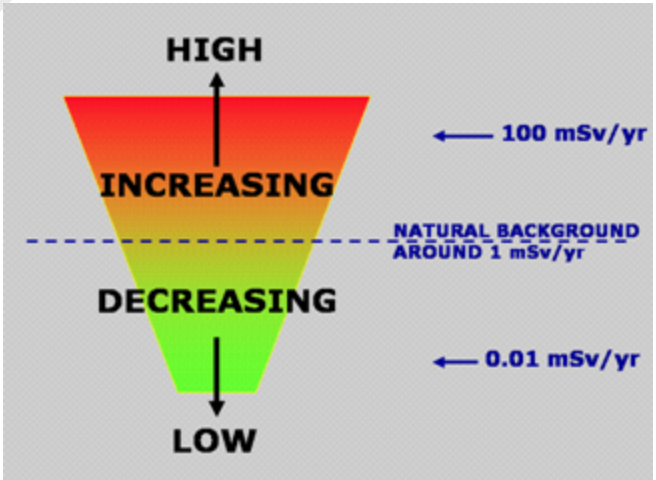
6.1. Factors influencing the choice of source -related individual dose constraints

(157) The Commission considers that the annual effective dose from natural radiation sources, and its variation from place to place, is of relevance in deciding the levels of maximum constraints that it now recommends. The existence of the natural background of radiation does not provide any justification for additional exposures, but it can be a benchmark for judgement about their relative importance and the need for action. The Commission uses the background dose without the radon contribution because that component is significantly enhanced by human activities and is thus subject to recommendations from the Commission for its control at home and at work.

(158) The worldwide average annual effective dose from all natural sources, excluding radon, quoted in the UNSCEAR (2000) report is 1.2 mSv with a range of 0.8 to 2.4 mSv. This has been rounded by the Commission to 1 mSv/yr. A general scheme for the need for action and the level of dose, as a fraction or multiple of the average annual natural background, has been proposed by ICRP and is shown in Figure 3.

(159) The need for action is likely to be high if an effective dose from a single source is more than about a hundred times the global average background dose. Individual effective doses of about 100 mSv are therefore about the most that should be allowed for workers in any other than saving life or preventing serious injury, or preventing catastrophic circumstances. Higher doses, if acute, either to whole body or to individual organs, can cause early tissue reactions or, if either acute or delivered over decades, can cause significant probability of increased cancer risk. At even higher individual doses, the risk from a source cannot be justified, except in extraordinary circumstances such as life saving measures in accidents, or possibly in manned space flights.

Figure 3. The need for action and individual effective dose proposed by ICRP.



(160) Doses above the natural background will entail an increasing need for action. Individual doses of several tens of millisieverts, whether they are received either singly or repeatedly, require that action be considered. Exposures that are within the natural background range are legitimate matters for concern, sometimes calling for significant action.

(161) The need for action should decrease for doses additional to those due to the background of natural sources, if they are well below the annual background dose. Provided that the additional sources come from practices that have not been judged to be frivolous, the need for action should be low for doses less than about one hundredth of background dose.

6.2. Selection of source-related individual dose constraints

(162) The Commission's recommended constraints are consistent both with the scale, in Figure 3 above, of need for action and, as far as possible, the quantified values of the current system which includes limits, specified constraints and action levels. The choice of the Commission's recommended constraints is thus influenced by the benefit of consistency with previous decisions. Finally, the rationale behind the establishment of the corresponding quantified values should be clear enough that the relevant constraint can be easily chosen so as to apply to the situation of exposure considered.

(163) Table 7 presents the Commission's recommended **maximum** values of dose constraints. In essence, four values are recommended according to the type of situation to be controlled. They should be considered as giving the upper restriction that is to be applied by the appropriate authorities to determine the most applicable constraints for the situation under consideration. The Commission expects that the resulting values normally will be lower than the maximum value recommended by the Commission, but probably not by as much as a factor of ten.

(164) The rationale for applying one value or another for the constraints would be the following:

- For workers, in emergencies but other than for saving life or preventing serious injury or preventing catastrophic circumstances, the constraint of 100 mSv effective dose, either acute or in a year, is taken as the maximum value to be received. This sets the maximum of the Commission's constraint to restrict exposure of individual members of the public following an accident, i.e., for evacuation, for permanent relocation, for high levels of controllable existing exposures, or from highly contaminated ground. This value corresponds to a high need in the scale of action (Figure 3). There is neither individual nor societal benefit from levels of individual exposure above this constraint. Any action taken may lead to both direct benefits and disadvantages.

- The maximum value of 20 mSv/year effective dose is recommended for selecting constraints in situations where there is a direct or indirect benefit for the exposed individuals. It applies in situations where there is individual surveillance or monitoring or assessment, and where individuals benefit from training and information, or situations where exposures are difficult to control. This range is coherent with the increasing need for action (Figure 3). It would be used in normal situations for occupational exposure. In emergencies it would apply for lower risk countermeasures for the public, such as sheltering or stable iodine administration. It would also be used generally for existing controllable exposures.

- The maximum effective dose of 1 mSv/year is recommended to select constraints in situations where there is no direct benefit for the exposed individuals. However, there may be a societal benefit. It also applies in situations where there is general information and environmental surveillance or monitoring or assessment and where individuals may receive information but no training. This value is also coherent with the scale of action: it represents a marginal increase of the natural background (a fraction of natural

background). It would be the maximum public constraint in normal situations while in case of multiple dominant sources a figure of 0.3 mSv/year would be appropriate (*Publication 77*).

- The value of an effective dose of 0.01 mSv/year is the minimum constraint that should be considered for application in any situation. This value corresponds to a low need for action (Figure 3), giving rise to trivial risk to the exposed individuals.

(165) It should be emphasized that the set of recommended 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 significant sources. The Commission still considers that the source-related system of constraints is the most effective tool for protection, whatever the situation, provided that the complementary requirement for optimisation is carried out below this level.

TABLE 7. Maximum dose constraints recommended for workers and members of the public from single dominant sources for all types of exposure situations that can be controlled.

Maximum constraint (effective dose, mSv in a year)	Situation to which it applies
100	In emergency situations, for workers, other than for saving life or preventing serious injury or preventing catastrophic circumstances, and for public evacuation and relocation; and for high levels of controllable existing exposures. There is neither individual nor societal benefit from levels of individual exposure above this constraint.
20	For situations where there is direct or indirect benefit for exposed individuals, who receive information and training, and monitoring or assessment. It applies into occupational exposure, for countermeasures such as sheltering, iodine prophylaxis in accidents, and for controllable existing exposures such as radon, and for comforters and carers to patients undergoing therapy with radionuclides.
1	For situations having societal benefit, but without individual direct benefit, and there is no information, no training, and no individual assessment for the exposed individuals in normal situations.
0.01	Minimum value of any constraint

(166) In practical protection, it is useful to introduce further constraints to deal with all situations in more detail. These include the normal situation, preparation for emergencies, dealing with contaminated land or existing controllable sources. These constraints may be recommended by the Commission's publications dealing with these situations, or may be chosen by operating managements or regulatory agencies. Authorities setting national dose constraints should consider, when selecting a particular constraint for a given source, the factors which characterise the source and its environment. Due attention should be given, *inter alia*, to the number of sources that could affect individuals and the distribution of individual doses so as to avoid unnecessary imbalance between the exposed individuals and

the controllability of the source. It must be remembered that the chosen constraints are a necessary but not sufficient criterion for protection in any given situation and must be complemented by the process of optimisation to arrive at the almost certainly lower level that will be authorized for, and achieved in, operation. This is dealt with further in Chapter 7.

6.3. Application of the dose constraints

(167) Constraints contribute to the level of protection for an individual by applying criteria for protection from a single source. They are specified for both normal 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 optimize the level of protection achieved as discussed in Chapter 7. There are three further issues needing clarification in the development of constraints as levels of protection for a source. They are the identification of the exposed individuals, the definition of a single source and the treatment of women who are exposed.

6.3.1. The identification of the exposed individuals

(168) It is necessary to deal separately with at least three types of exposed individual. These types can be called informed individuals, patients, and general individuals. They can, essentially, correspond to individuals whose exposures fall into the three classes of exposure defined in Chapter 5.3, i.e. occupational, medical and public.

Occupational exposure

(169) Workers in 'controlled areas' of workplaces are not strictly volunteers, but they are well informed and are specially trained, thereby forming a separate group of informed individuals. Other workers, such as administrative and support staff, might be included in the group of general individuals, and treated as members of the public.

Medical exposure of patients

(170) The exposure of patients is usually voluntary and both benefit and risk are mainly to the patient. Medical exposure of patients is therefore dealt with separately. 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 (See Section 9.3).

Public exposure

(171) The application of a constraint relates to protection of an individual from a source. In general, especially for public exposure, each source will cause a distribution of doses over many individuals, so it will be necessary to use the concept of a *critical group* to represent the most exposed individuals.

(172) The concept of critical group, as defined in previous Commission *Publications 43* and *60* (ICRP, 1985a, 1991a), is retained. Such a group is chosen to be representative of the most highly exposed individuals as a result of the source. Its characteristics should be derived from the mean of a homogeneous and sustainable group. Additionally, it is important that the habits used in calculating the dose to the individuals are the average habits in the critical group and not the habits of a single extreme individual. The critical group may, however include some individuals with extreme or unusual habits and should be selected such that all relevant habits are taken into account. The question of reasonableness in selection of characteristics of the critical group is related to that of homogeneity because the constraints are intended to apply to doses derived from the mean characteristics in a reasonably homogeneous group.

(173) For the purpose of assessing compliance with the specified constraints, the Commission is considering the use of *age-averaged effective dose coefficients* and age-

averaged habit data for the individual in the case of continuing exposures of the public. The dose per unit intake to individuals can vary in age-specific manner due to different parameters. The Commission is investigating whether this method has advantages over the age-specific dose coefficients combined with age-specific intakes. Methods to assess such doses will be addressed by a Task Group of ICRP Committee 4.

6.3.2. The definition of a single source

(174) It has never been possible to reach simple formal definitions of a single source or of the total group of relevant sources. 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. Most situations will give rise to a predominant source of exposure for any single individual, or critical group, making it possible to treat sources singly when considering actions. Provided that the operating management and the regulators 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.

6.3.3. The exposure of women

(175) In *Publication 60* (ICRP, 1991a), the Commission concluded that there was no reason to distinguish between the two sexes in the control of occupational exposure. However, if a woman has declared that she is pregnant, additional controls have to be considered to protect the unborn child. It is the Commission's policy that the methods of protection at work for women who may be pregnant should provide a level of protection for any conceptus broadly comparable to that provided for members of the general public. This is reasonable since while the mother may have chosen to be a radiation worker, the unborn child has not made such a decision. 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 radiation weighted dose to the fetus will exceed about 1 mSv during the remainder of the pregnancy.

(176) The restriction of the dose to the conceptus 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 radionuclide intakes is insignificant. Specific recommendations on the control of exposures to pregnant workers are given in *Publication 84* (ICRP, 2000). The Commission is developing guidance for the restriction of intakes to breast-feeding mothers in a report from ICRP Committee 2.

(177) The exposure of patients who may be pregnant is dealt with in Chapter 9. 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 the report of a Task Group of ICRP Committee 1 (*Publication 90*; ICRP, 2003a).

6.4. Radon in dwellings and workplaces

(178) The Commission regards radon-222 at home and at work as a controllable source since exposures are principally due to human activities (paragraph 146). The current recommendations for protection against radon-222 at home and at work were issued by the

Commission in *Publication 65* (ICRP, 1993b). The policy has found wide acceptance and the present recommendations broadly continue the same policy.

(179) In *Publication 65*, the policy was based upon first setting a level of effective dose from radon-222 where action would certainly the warranted to reduce the exposure. This was an effective dose of 10 mSv per year which is coherent with the maximum constraints set above. 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 in *Publication 65*, within which so-called *Action Levels* were expected to be set. The result of the optimisation was to set action levels below which no account was taken in controlling the dose further. For practical application the Commission used environmental, rather than dosimetric, quantities for these levels. For dwellings this range was a radon concentration of between a maximum of 600 to no less than 200 Bq m^{-3}, while the corresponding range for workplaces was a maximum of 1500 to no less than 500 Bq m^{-3}.

(180) The upper levels of 600 Bq m^{-3} for homes and 1500 Bq m^{-3} for workplaces can now be seen as Maximum Constraints, since the Commission regards these levels as providing the basic level of protection. The Commission now reconfirms its recommended maximum constraints for radon-222, which are set out in Table 8. 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 to arrive at the most applicable level at which to act in their country. All efforts should be made to reduce radon-222 exposures at home and at work to below the levels that are set. For occupational exposure, below these levels the system of protection is not applied and the resulting doses should not be recorded in the worker's dose record. For the public, there should be no attempt to reduce exposures further, as they should not be regarded as controllable exposures subject to regulatory actions.

Table 8. Recommended Maximum Constraints for Radon-222[†]

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

[†]Head of chain activity level.

6.5. Individual Dose Limits

(181) The basis of choosing restrictions on the risks to which an individual may be subjected has always been difficult to specify. In its 1977 Recommendations for occupational exposure (*Publication 26*), the Commission used a comparison of the then estimated fatal risk associated with average worker exposures with average accident fatality rates in industries widely regarded as 'safe', from which it concluded that the limits provided an adequate degree of protection. However, comparisons with average accidental death rates in industries not associated with radiation are not very satisfactory, particularly as the mortality rates apply to averages over single sectors of industries, whereas dose limits apply to individuals.

(182) In the case of public exposures, the acceptable risk was inferred from the consideration of risks that an individual can modify only to a small degree and which are nationally regulated, such as public transport. From this the Commission concluded that the level of acceptability for fatal risks to the public is an order of magnitude less than for occupational risks. The dose limit for the public was, as in the case for workers, argued on the

comparison between average doses and the average accident fatality figure, which is again not very satisfactory.

(183) Because of these deficiencies the Commission developed, in *Publication 60*, the 1990 recommendations, a multi-attribute approach to express the detriment associated with radiation exposure. This included the probability of attributable death, the length of life lost due to an attributable death, and incidence of non-fatal conditions. Having established the detriment associated with unit radiation exposure, it was necessary to determine the values of risk that were likely not to be acceptable to regulators on any reasonable basis in authorizing , both for workers and the public, the normal operation of a practice of which the use was a matter of choice.

(184) This was achieved by a review of world-wide decisions by governments, courts, public inquiries, etc., of the quantitative levels of voluntary or imposed risks, not associated with radiation exposure, which had resulted in decisions to ban or modify human activities. The detriments associated with ranges of doses, for both workers and the public, were compared with the relevant risk limit and a judgement made on the levels of dose that would correspond to occupational and public dose limits. The Commission recognised that levels of exposure which would be regarded as unacceptable by regulatory authorities in this context may still have to be accepted in emergency situations such as accidents, or if they can only be reduced by abandoning a desirable practice such as space missions.

6.5.1. Limits on Effective Dose

(185) The Commission has concluded that the existing limits on effective dose that it recommended in *Publication 60* continue to provide an appropriate restriction on total regulated doses in normal situations. The reasons for this are twofold: firstly, the Commission now emphasizes the use of constraints on single sources which are more restrictive than limits in normal situations; and secondly, the nominal detriment coefficients for both a workforce and the general public (Table 6) are more than 10% lower than those specified in the 1990 Recommendations. Within a class of exposure, occupational or public, dose limits apply to the sum of exposures from sources related to practices that are already justified in normal conditions. For occupational exposure:

> 'A limit on effective dose of 20 mSv per year, averaged over 5 years (100 mSv in 5 years), with the further provision that the effective dose should not exceed 50 mSv in any single year' (paragraph 166, *Publication 60*).

And for public exposure:

> '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' (paragraph 192, *Publication 60*).

6.5.2. Limits for individual organs or tissues

(186) In addition, limits were set in *Publication 60* (ICRP, 1991a) for the lens of the eye and localised areas of skin since these tissues will not necessarily be protected against tissue reactions by the limit on effective dose. The relevant values were set out in Table 6 of *Publication 60* in terms of the radiation weighted absorbed dose. The Commission continues to recommend these limits. The values are reproduced in the present Table 9.

Table 9. Recommended annual dose limits for individual organs or tissues

Radiation weighted dose in	Workers	Public
Lens of the eye	**150 mSv**	**15 mSv**
Skin [1,2]	**500 mSv**	**50 mSv**
Hands and feet	**500 mSv**	**-**

[1] 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.
[2] Averaged over 1 cm^2 area of skin regardless of the area exposed.

6.6. Complementary levels of protection of individuals

(187) The Commission's dose or risk constraints are a necessary but not sufficient condition to ensure the proper protection of those actually, or liable to be, exposed Therefore the Commission's recommendations include a requirement to provide complementary protective action beyond that required by the use of the recommended constraints. This is because of the presumption that there is some risk of adverse health effect from exposures to ionising radiation, even at small doses above the natural background.

(188) This complementary requirement for protecting individuals has for many years been called the Optimisation of Protection. This procedure continues to include the requirement that all doses from a source are as low as reasonably achievable, social and economic factors being taken into account, but is broader than just considering the doses so as to assure safety culture, and is described in Chapter 7.

7. THE OPTIMISATION OF PROTECTION

7.1. The characteristics of the optimisation process

(189) Optimisation of protection is a process that is an important component of a successful radiological protection programme. In application, it involves evaluating and, where practical to do so, incorporating measures that tend to lower radiation doses to members of the public and to workers. An ICRP description of this procedure appeared in the 1990 Recommendations in *Publication 60*, where it is defined as follows:

> 'In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account'.

The Commission now wishes to emphasise that conceptually, the optimisation of protection is broader, in that it entails consideration of the avoidance of accidents and other potential exposures; it incorporates a range of qualitative and quantitative approaches and involves adopting a safety culture (paragraph 153).

(190) 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. This process must 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. It also requires the commitment from all levels of all concerned organisations as well as adequate procedures and resources. Both the operators and the appropriate national authority have responsibilities for optimisation. Operators design, propose and implement optimisation, and then use experience to further improve it. Authorities require and promote optimisation and may verify that it has been effectively implemented.

(191) The exposures that result from the continuous optimisation process are the levels with which, at a point in time, all parties involved are in agreement as a way to move forward. The numerical results of optimisation of protection will demonstrate that the process has been complementary to the use of the constraints and its application has led to a higher level of protection.

(192) For normal situations, much of the protection is built-in during the design phase of a project for controllable sources, when options are evaluated, often for the selection of engineered controls. The process of optimisation of protection must continue during the operational and termination phases. In emergency situations, optimisation should be used at the planning phase to determine levels for intervention actions, and during any actual emergency, is applied in a flexible manner to allow for the prevailing circumstances. In existing controllable situations, optimisation is used as part of the process to select and implement protective actions.

(193) Sometimes quantitative methods may provide an input; but given the many qualitative factors, they should never be the sole input. When quantitative methods are used, cost-benefit and cost-effectiveness analyses are among a number of alternative decision-aiding tools. These are sometimes advantageous, but have significant drawbacks; for example, they may over-emphasise the societal aspects at the cost of individual factors, and are particularly inappropriate where long time-scales or wide ranges of dose to different groups of exposed individuals are concerned.

(194) The procedure for judging that no further dose reduction is reasonable should involve the comparison of a number of feasible protection options aimed at reducing the planned or

potential doses to individuals. These options should first consider direct actions at the source, but should also include environmental actions. For exposures, the principle to be considered is whether these are as low as reasonably achievable. For the control of emissions to the environment, the 'best available technology not entailing excessive costs' principle may be used with due consideration to social and economic factors. The resulting 'optimal' protection option would then be said to result in exposures to individuals that represent the best choice under the prevailing circumstances.

(195) The basic role of the optimisation of protection is to foster a 'safety culture' as discussed in paragraph 153 and thereby to engender a state of thinking in everyone involved in the control of radiation exposures, such that they are continuously asking themselves the question, 'Have I done all that I reasonably can to reduce these doses?'. Clearly, the answer to this question is a matter of judgement and necessitates co-operation between all concerned parties and, as a minimum, the operating management and the regulatory agencies.

(196) The involvement of *stakeholders*, a term which has been used by the Commission in *Publication 82* to mean those parties who have interests in and concern about a situation, is an important input to optimisation. While the extent of stakeholder involvement will vary from one situation to another in the decision-making process, it is a proven means to achieve the incorporation of values into decisions, 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 parties affected by the decision reinforces the protection culture and introduces the necessary flexibility in the management of the radiological risk that is needed to achieve more effective and sustainable decisions.

7.2. Distribution of exposures in time and space

(197) 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 involves consideration of the distribution of the doses within all the groups of exposed individuals. No single characteristic of this distribution is adequate for making these comparisons. A particular issue is the one related to the comparison of the distribution of the exposures over long time periods and distant populations.

(198) One way to take into account this type of distribution has been the collective effective dose concept defined in *Publication 60* as the product of the arithmetic mean dose and the number of exposed individuals:

$$S = \int_0^\infty E \cdot \frac{dN}{dE}\, dE \quad \text{or} \quad \sum_i E_i \cdot N_i$$

where E_i is the mean effective dose in the population subgroup i and N_i is the number of people in subgroup. The collective effective dose S_k committed by an event k is the infinite time integral of the effective dose rate

$$S_k = \int_0^\infty \frac{dS_k}{dt}\, dt$$

However, the integral of low individual exposures over large populations, large geographic areas, and over large periods of time is generally not a useful tool for decision aiding because this may aggregate information excessively.

(199) The concept of the collective dose was originally introduced in the 1970s for two reasons, one of which was for using collective dose in order to restrict the uncontrolled build-up of exposure to long-lived radionuclides in the environment. This was because, at the time,

a global expansion of nuclear power reactors and reprocessing facilities was foreseen. Restricting collective dose per unit of practice can effectively set a maximum future annual effective per caput dose from all sources from that practice. The second reason was to facilitate optimisation by cost-benefit analysis in answering the question 'How much does it cost and how many lives are saved?' when moving from one protection option to another one.

(200) The Commission considers that collective dose, as defined above, is not to be used on its own in making decisions, because it may aggregate information excessively. For making decisions, a large dose to a small number of people is not equivalent to a small dose to many people, even if the two cases correspond to numerically equal collective doses. The highest individual dose is useful for checking that the constraints have been successfully applied, but it contributes little to the reasonable reduction of the distribution of individual doses. To avoid excessive aggregation, it will often be helpful to present the necessary information describing when, where, and by whom exposures are received.

(201) The Commission now recommends the maintenance of the distribution of individual doses related to a given source in components reflecting the characteristics of the exposed individuals and the time and space distributions of exposures, relevant for the decision making process considered. This disaggregating process results in a '**dose matrix**' which may be defined on a case by case basis. Furthermore, the components of this dose matrix can be individually weighted to perform appropriately the optimisation process. The weighting of these various elements will depend on the preferences and values of those involved in the decision making process, as well as on the feasibility of actions considered. Therefore, in the presentation of results, such case-specific weighting factors should be distinguishable from the elements of the actual dose matrix.

(202) Key matrix elements of such a matrix include the characteristics of exposed individuals, and the dose distribution in time and space. Aspects to be considered when establishing the importance of each matrix element in the decision-making process may include: -

- Number of exposed individuals
- Magnitude of individual doses
- Dose distribution in time
- Age and gender dependent risks as modifiers to dose distributions
- Equity considerations (achieving a balanced dose distribution)
- Real or potential exposure

(203) The Commission intends to publish a specific 'foundation document', drafted by ICRP Committee 4, on the principles and methods to implement optimisation of protection.

8. EXCLUSION OF SOURCES FROM THE SCOPE OF THE RECOMMENDATIONS

(204) Controllable sources and the associated radiation exposures fall within the scope of these recommendations. However, as stated in Section 2.3, the development of exclusion criteria would be beneficial in the practical application of protection and avoid the excessive regulation of radiation sources, both natural and artificial. The situation differs somewhat from the use of constraints and reasonable dose reduction by optimisation (See Chapters 6 and 7) but may be aided by their use.

8.1. Exclusion of quantities of artificial radionuclides

(205) The starting point for consideration of values at which artificial radionuclides may be excluded from the scope of the Commission's recommendations is the minimum constraint recommended in Section 6.2. This constraint of 0.01 mSv in a year has been used extensively to establish the Exemption criteria used internationally and regionally. The inter-Agency Basic Safety Standards (FAO et al., 1996) and the Euratom Basic Safety Standards (Council of the European Union, 1996) have derived radionuclide-specific activities and activity concentrations, principally for users of small quantities of radionuclides. Recently, the IAEA has extended the use of the minimum constraint criterion to derive radionuclide-specific exemption activity concentrations for bulk materials (IAEA, 2005). Finally, the UN Food and Agriculture Organization (FAO) has revised its recommended activity concentrations in foodstuffs that can be traded internationally (CODEX, 2004).

(206) Inspection of the whole spectrum of activity concentrations that have been generated in these large international exercises, and consideration of the practicality of control, leads the Commission to observe that whatever the scenario - workplaces, homes or foodstuffs - no activity concentrations have been proposed internationally that are below 0.1 Bq g^{-1} for any artificial ß/? emitters or below 0.01 Bq g^{-1} for artificial a-emitters. The Commission has concluded that these values provide a practical definition of what is to be considered radioactive and therefore the levels at which materials are to be within the scope of its recommendations. It now recommends the figures in Table 10 as the basis of exclusion from the scope of its recommendations.

8.2. Natural radioactive substances in environmental materials

(207) Most natural materials are radioactive to a greater or lesser degree. Thus, there are many situations where control is impracticable because of the ubiquity of the materials or exposures. Such situations may be excluded from the scope of regulations on the grounds that they are not amenable to control. Examples are cosmic radiation at ground level and potassium-40 in the body.

(208) The principal exposures from both internal and external sources in environmental materials are from potassium-40 and the decay series of uranium-238 and thorium-232. The only conceivable protective actions are; prevention of consumption of foodstuffs produced, relocation of populations, and, if the source is mainly potassium-40 in building materials, extensive rebuilding. These actions are disruptive and require considerable resources.

(209) The Commission proposes a set of exclusion values shown in Table 10 for the activity concentrations of natural radionuclides in materials. These levels were established from consideration of the distribution of concentrations of natural radionuclides in natural materials, representing a value towards the higher end of the generally observed range. In the UNSCEAR (2000) report, activity concentrations of the naturally occurring radionuclides in food range from less than 0.001 up to about 0.1 Bq g^{-1}. The exception is shellfish where ^{210}Po, in the decay series of ^{238}U can have activity concentrations of the order of 1 Bq g^{-1}. Exposures from environmental materials and intakes of food and water, at these activity concentrations,

would lead to individual annual effective doses of no more than about 0.2 millisieverts, which does not in the Commission's opinion imply an unacceptable level of exposure.

(210) The Commission notes the recent work undertaken by the IAEA in the production of its report DS161 in which the exclusion levels for the uranium and thorium series and for ^{40}K have been agreed internationally. These activity concentrations are shown in Table 10 and are recommended by the Commission as the levels below which materials do not enter the scope of its recommendations.

Table 10. Recommended Exclusion Levels

Nuclides	Exclusion activity concentration
Artificial a -emitters	**0.01 Bq g^{-1}**
Artificial ß/? emitters	**0.1 Bq g^{-1}**
Head of chain activity level†, ^{238}U, ^{232}Th	**1.0 Bq g^{-1}**
^{40}K	**10 Bq g^{-1}**

† For ^{238}U and ^{232}Th chains, this value also applies to any nuclide in a chain that is not in secular equilibrium excluding ^{222}Rn and daughters in air which in all situations are controlled separately.

8.3. Cosmic rays

(211) Cosmic rays at ground level and the resultant exposures are not controllable. They are thus excluded from the scope of the Commission's recommendations. Limiting the time spent by passengers and crew at high altitudes would be the only practical way in which to control exposure to cosmic rays in aircraft. The average annual effective doses to most aircrew are in a narrow range, previously estimated at around 3 mSv, although this will reduce significantly with the Commission's revised radiation weighting factors for neutrons and protons (Chapter 3). The exposure of some specialist aircrew, such as security staff, and a small number of professional couriers may be twice the average value for aircrew. These exposures of aircrew and couriers in the operation of commercial jet aircraft should be dealt with as occupational exposure in the general system of protection and thus of informed individuals.

(212) The Commission is convinced that the exposure of passengers is not controllable by any reasonable action. It is therefore excluded by the Commission from the scope of its recommendations.

9. MEDICAL EXPOSURE

(213) 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 do 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 constraints in Chapter 6.4, 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.

(214) Secondly, the patient needs 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 minimized 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.

(215) The physicians involved in the processes that irradiate patients should always be trained in the principles of radiological protection. This is because the exposures of patients are deliberate. Except in radiotherapy, it is not the aim to deliver a dose of radiation, but rather to use the radiation to provide diagnostic information or to conduct interventional radiology. That exposure is not limited by any regulatory process, but is controlled by the physician, who therefore should be aware of the risks and benefits of the procedures involved. The need for training is accentuated by several recent cases of radiation injury to patients, the root cause of which appears to be insufficient training.

9.1. Justification of radiological procedures

(216) At the most general level, the use of radiation in medicine is accepted as doing more good than harm to the patient. There are then 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.

(217) This procedure should be reviewed regularly to keep the doses to patients as low as is consistent with the medical objectives. In diagnosis, this means reducing unnecessary exposures, while in therapy it requires delivery of the required dose to the volume to be treated, avoiding unnecessary exposure of healthy tissues.

9.1.1. The generic justification of a defined radiological procedure

(218) 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 (potential exposure) 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.

9.1.2. The justification of a procedure for an individual patient

(219) 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 usually be possible to speed up the procedure significantly by defining criteria and patient categories in advance.

9.2. Exposure of pregnant patients

(220) Prenatal doses from most properly done 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 can result in developmental harm.

(221) 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 fetus. The Commission has given detailed guidance in *Publication 84*.

9.3. The optimisation of protection for patient doses

(222) The medical procedures causing patient exposures are clearly 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 exposures 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. The use of diagnostic reference levels is seen by the Commission as an important and useful reminder to check that doses are not excessive.

(223) Diagnostic Reference Levels are used in medical diagnosis to indicate whether, in routine conditions, the levels of patient dose or administered activity from a specified imaging procedure are unusually high for that procedure. If so, a local review should be initiated to determine whether protection has been adequately optimized or whether corrective action is required (*Publication 73*; ICRP, 1996a). The derived reference level should be expressed as a readily measurable patient-related quantity for the specified procedure.

(224) 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, 1985b).

9.4. Helpers and carers, and the public

(225) 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, since 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

millisieverts per episode is likely to be reasonable. This constraint is not to be used rigidly. For example, higher doses may well be appropriate for the parents of very sick children, if they are properly informed of the risks.

(226) Also, medical exposures are incurred by those volunteering for research involving exposures to radiation and insurance companies may require individuals to receive medical exposures. In these cases again, the public constraints are not appropriate and national authorities should use higher values similar to those quoted in the paragraph above.

(227) 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 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*; ICRP, 1996a, 2004).

10. POTENTIAL EXPOSURES

(228) Potential exposures are those that may or may not occur. Such events can be foreseen and their probability of occurrence estimated, but they cannot be predicted in detail. It is necessary to control both the probability and the severity of exposures. There is usually an interaction between potential and normal exposures (see *Publication 64*; ICRP, 1993a). For example, actions taken to reduce the probability of a potential exposure may increase the normal exposures. On the other side, storage of waste rather than its dispersal will reduce normal exposures, but will increase the potential exposures.

(229) Dose constraints do not apply directly to potential exposures. Ideally, they should be supplemented by risk constraints, which take account of both the probability of incurring a dose and the detriment associated with that dose if it were to be received. Although dose constraints are not generally selected on the basis of risk, it may sometimes be useful to set risk constraints based on the risk implied by the existing dose constraints. This procedure would require the use of probability assessment.

(230) Conceptually, the simplest way of dealing with the potential exposure of individuals is to consider the individual probability of attributable death, rather than the effective dose, as the quantity to be used in the system of protection (see *Publications 64* and *76*; ICRP, 1993a, 1997b). For this purpose, the probability is defined as the product of the probability of incurring the dose and the lifetime conditional probability of attributable death from the dose if it were to have been incurred. A restriction corresponding to a dose constraint can then be expressed in the form of a risk constraint. This was done in *Publication 81* (ICRP, 1998) for geologic disposal of solid radioactive wastes.

(231) The conditional probability of attributable death is given by the nominal probability coefficients for stochastic effects f the dose, if it occurs, is small enough to be in the proportional region of the dose-response relationship. However, in some cases, there is a potential for higher doses. If the forecast effective dose is more than a few hundred millisieverts, individual organ doses may exceed the thresholds for tissue reactions and none of the dosimetric protection quantities (effective dose, radiation weighted dose) would be valid. It can then be presumed that the detriment from the forecast dose is certain, i.e. the conditional probability of detriment from the dose is unity. (*Publication 76* discusses the special case of certain types of equipment and exposure scenarios that can generate only localised, serious but non-fatal, tissue reactions).

(232) Radiological protection measures in this context are, thus, aimed at keeping the risk due to potential exposure below a risk constraint. The focus of the effort is usually upon prevention of the undesirable scenarios or sequences which could lead to an exposure. When applicable, mitigative measures will be undertaken to reduce doses if an undesirable event does occur. If this is not possible, the only available action is to make all reasonable reduction in the probability of the event occurring.

(233) Risk constraints, like dose constraints, are source-related and in principle should be similar in magnitude to 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.

(234) In *Publication 76*, the Commission recommended such a generic risk constraint for occupational potential exposures of $2\ 10^{-4}$, based on the observation that where the Commission's system of radiological protection (including optimisation) had been applied, annual occupational doses to an average individual were rarely greater than about 5 mSv, and the ICRP cancer death risk for occupational exposure in *Publication 60*, $4\ 10^{-2}$ Sv^{-1}. The

reasoning also assumed a scenario unlikely to affect more than a limited number of individuals at the same time (see also paragraph 237). For potential exposures of the public, *Publication 76* recommended a corresponding risk constraint of $5\ 10^{-6}$, based on an assumed average dose to individual members of the public from normal authorised discharges of 0.1 mSv or less, and again limited to potential exposure scenarios that could only be expected to affect a limited number of individuals.

(235) Thus, conceptually *Publication 76* equated risks from normal and from potential exposures, but it stated that simultaneous, formal optimisation of protection against both types of exposure would be difficult. It observed that the use of safety devices for protection against potential exposures includes an element of optimisation. Also, the generic occupational risk constraint recommended corresponded to the risk associated with occupational doses in an optimised operation. As emphasised in *Publication 76*, optimisation of protection against potential exposures is primarily a matter of 'safety culture' (see paragraph 153) and the use of sound engineering principles and common sense. Optimal protection against potential exposures is not necessarily achieved at the same level of risk as optimal protection against normal exposures, since the costs of reducing risks due to normal exposures and risks due to potential exposures may be quite different.

(236) 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.

(237) Furthermore, the approach described here would be sufficient only in situations where the potential exposure would affect a small number of persons and the health detriment to those persons would be the major result of the exposure. This would include such occupational hazards as, for instance, potential unsafe entry into an irradiation room at a sterilising installation. In contrast, some potential exposures could affect a large number of people and involve not only the risk to health but also other possible detriments (land being made unusable, need to control food consumption, etc.). The mechanisms involved in the occurrence of such potential exposures are complicated and their evolution can lead to many different end results. The potential for a major accident in a nuclear reactor is an example. Obviously, an assessment based on health effects as an immediate consequence of direct exposure to radiation would be insufficient under these circumstances. INSAG (1995) discusses some additional aspects that need to be taken into account in such cases.

(238) At nuclear installations, safety planning is usually well developed and potential exposures are usually taken into account in such planning. *Publication 76* underscores the importance of, and feasibility of, similar planning at workplaces outside the nuclear fuel cycle. It emphasises that 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, and provides some practical advice on the avoidance of and mitigation after potential exposures.

(239) Sometimes, after the termination of practices and in the aftermath of events involving radioactive contamination, radioactive residues may remain in the environment and fragments may become very sparsely distributed in the environment, usually as *'hot particles'*. For these situations, the Commission continues to recommend the derivation of protection criteria based on the principles described in this section, namely of the unconditional probability that members of the public would develop fatal stochastic health effects attributable to the exposure situation.

(240) In these situations, such a probability should be assessed by combining the following probabilities: the probability of being exposed to the hot-particle residues; the probability of incorporating a hot particle into the body as a result of such exposure; the incurred average

radiation weighted dose as a result of such incorporation; and, the probability of developing a fatal stochastic effect from that dose. These probabilities should be integrated over all the range of situations and possible doses. In establishing such criteria, consideration should be given to the possibility that localised tissue reactions may also occur as a result of the incorporation of hot particles.

11. THE PROTECTION OF THE ENVIRONMENT

(241) The Commission has not made any specific recommendations with regard to protection of species other than the human, but in its 1990 Recommendations in *Publication 60* it did express the view that

> 'The Commission believes that the standards of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk. Occasionally, individual members of non-human species might be harmed, but not to the extent of endangering whole species or creating imbalance between species. At the present time, the Commission concerns itself with mankind's environment only with regard to the transfer of radionuclides through the environment, since this directly affects the radiological protection of man.'

(242) The Commission still believes that this judgement is correct in general terms. Thus it is probably true that the human habitat has been afforded a fairly high level of protection through the application of the current system of protection. However, there are now also other demands upon regulators, in particular the need to comply with the requirements of legislation directly aimed at the protection of wildlife and natural habitats; the need to make environmental impact assessments with respect to the environment generally; and the need to harmonise approaches to industrial regulation, bearing in mind that releases of chemicals from other industries are often based upon their potential impact upon both humans and wildlife. All of these demands are currently being met in a multitude of differing ways, partly because of the lack of advice on the subject at international level, and partly because there are therefore no agreed assessment procedures, criteria, guidelines or data sets with which to approach these issues in a coherent way. This, in turn, leads to different national approaches being developed and makes international harmonisation difficult.

(243) The Commission recognises that there is a need to explore further the nature of the 'risks' that may apply to other species, how such risks may be quantified, and thus how it can be positively demonstrated that they are, indeed, '…not put at risk'. The Commission has therefore decided to develop a combined approach to the protection of humans and other species, and to do so within an overall framework that recognises the different but complementary aims and objectives that this involves. The approach recognises that humans, as well as fauna and flora, are part of the same ecosystem, but whereas the protection of human beings has aims and objectives that may be universally applied, the aims and objectives with respect to other species will vary considerably, depending on the species involved, and the nature and the circumstances relating to the risks to which they are exposed.

(244) The second need is for the Commission to develop a common scientific basis and approach for relating exposure to dose, and dose to effect, for all living things. In the case of human radiation protection, this approach has been based on an entity called Reference Man. The Commission has therefore concluded that a parallel approach would be of value in order to serve as a basis for developing recommendations for the protection of other species. To achieve this, the Commission is developing a small set of Reference Animal and Plants, plus their relevant databases, for a few types of organisms that are typical of the major environments. This approach cannot provide a general assessment of the effects of radiation on the environment as a whole, but it could provide the basis for judgments about the probability and severity of the likely radiation effects on such individuals, or on other types of organisms that differ in specific characteristics from the reference types.

(245) It is intended that each reference organism would serve as a primary point of reference for assessing risks to organisms with similar life cycles and exposure characteristics. More locally relevant information could be compiled for any other fauna and flora; but each such data set would then have to be related in some way to the reference organisms. Such a set of

information could then serve as a basis from which national bodies could develop, as necessary, more applied and specific approaches to the assessment and management of risks to non-human species as national needs and situations arise.

(246) This decision to develop a framework for the assessment of radiation effects in non-human species has not been driven by any particular concern over environmental radiation hazards. It has rather been developed to fill a conceptual gap in radiological protection and to clarify how the proposed framework can contribute to the attainment of society's goals of environmental protection. The Commission's decision to develop an explicit assessment framework will support and provide transparency to the decision making process.

(247) The objectives of a common or combined approach to the radiological protection of humans and other living organisms could be to:

- safeguard human health by preventing the occurrence of deterministic effects; limiting stochastic effects in individuals and optimising the protection of populations; and to
- safeguard the environment by reducing the frequency of effects likely to cause early mortality, or reduced reproductive success, in animals and plants to a level where they would have a negligible impact on conservation of species, maintenance of biodiversity, or the health and status of natural habitats or communities.

(248) The Commission recognises that the reduction of the frequency of radiation effects in individual animals or plants does not imply that the individual is necessarily the object of protection. Effects upon ecosystems are usually observed at the population or higher levels of organization, whereas information on dose responses is usually obtained at the individual level. Radiation effects at the population level - or higher - are mediated via effects on individuals of that population, and it therefore seems appropriate to focus on the individual for the purpose of developing an assessment framework. The Commission also notes that a large number of animals and plants are already afforded protection at the level of the individual in international or national law, and it would be inappropriate to provide advice that could not be used in such legal contexts. The question of whether one should protect individuals or populations from harmful effects of radiation in any particular circumstance is not an issue of direct concern to the Commission.

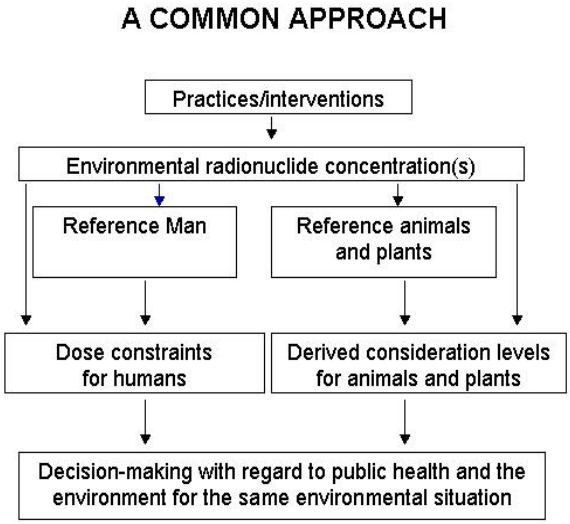
(249) In order to be of practical value, and to assist in their interpretation, the Commission believes that bands of *derived consideration levels* for Reference Animals and Plants could be set out in logarithmic bands of dose rates relative to normal natural background dose rates of the reference organisms. Additions of dose rate that are below their background might then be considered to be of low concern, and those that are orders of magnitude greater than background would be of increasingly serious concern because of their known adverse effects on individual organisms. But the need for any managerial action, however, would be dependent upon, for example, factors including the numbers and types of individuals affected, the nature of the effects, the spatial and temporal aspects of contamination, and legal requirements.

(250) The Commission wishes to point out that the recommended system is not intended to set regulatory standards. The Commission rather recommends a framework that can be a practical tool to provide high-level advice and guidance, and help regulators and operators demonstrate compliance with existing or forthcoming legislation. The system does not, however, preclude the derivation of standards; on the contrary, it provides a basis for such derivation.

(251) The new framework will also ensure that decision-making with regard to public health and the environment, for the same environmental situation, are explicitly carried out on the same scientific basis with respect to what is known about the effects of ionising radiation

(Figure 4). More detailed information concerning the Commission's framework and the reference animals and plants is presented in Annex B.

Figure 4. Developing a common approach for the radiological protection of humans and non-humans organisms for the same environmental situation.



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ANNEX A. NOMINAL RISK COEFFICIENTS, TRANSPORT OF RISK, RADIATION DETRIMENT AND TISSUE WEIGHTING FACTORS

A.1 Introduction

(A1) The concept of 'effective dose' associated with a given exposure involves weighting individual tissues of interest, in some useful partition of the human body, to reflect the relative 'detriments'. These detriments are expressed in common metrics such as estimated mortality, loss of expected lifetime or some combination of these, associated with unit radiation weighted doses to each of the various tissues. With such a system of standard, tissue-specific weights, the (tissue) weighted sum of the tissue-specific radiation weighted doses, called the 'effective dose', should be proportional to the total estimated detriment from the exposure, whatever the distribution of radiation weighted dose within the body.

(A2) The components of detriment are essentially the same for cancer and hereditary disease and, if desired, these detriments may be combined. These quantities are averaged over both genders and all ages at exposure, but with age-specific factors taken into account. Because the data for a number of human tissues and organs are insufficient to judge the magnitude of their radiation risk, they were consigned to a 'remainder' category and treated in a systematic manner as showing a low level of risk. Parallel calculations were also performed for a working population (exposure from age 20 to age 64 was assumed).

(A3) For generality, the estimates summarised here are derived as averages across Asian and Euro-American populations. An attempt was made to choose an appropriate model to use for transferring risks across various populations whenever there is sufficient evidence to favour one model over another. The risk modelling was conducted principally with the data from the Japanese Life Span Study (LSS), but the broader radiation epidemiology literature was examined for compatibility with the LSS-derived estimates. For several tissues it was possible to use a group of data sets to estimate cancer risk.

(A4) The following text outlines briefly the general models of risk and the sources of data used; methodological aspects of the risk estimates; and the detriments associated with a range of tissues. The recommendations that derive from this work are summarised in Tables A1 and A2..

A.2 The modelling of tissue weights and detriment

(A5) The tissue-weighting factors recommended here are based on detriment-adjusted nominal risk coefficients. The unadjusted nominal risk coefficients were computed by averaging estimates of the radiation-associated lifetime risk for cancer incidence for two composite populations. For each of these tissues, detriment is modelled as a function of life lost, lethality and loss of quality of life.

(A6) Gender-specific lifetime risk estimates were computed for selected ages at exposure by application of simple radiation effect models to the rates in the population of interest. Lifetime risks corresponding to different exposure ages were then averaged using weights reflecting the age distribution of the full population or for a working age (20-64 year old) population. With the exceptions noted below, the parameters in these risk models were estimated using incidence data from the studies of the Japanese atomic bomb survivors with follow-up from 1958 through 1998 for solid cancers. Both excess relative risk (ERR) and excess absolute risk (EAR) models were developed for most sites. For solid cancers these models involved a linear dose response allowing for modifying effects of gender, exposure age, and attained age. These effects were constrained to equal the value seen for all solid

cancers as a group unless there were indications that these constraints resulted in a marked reduction in the goodness of fit.

(A7) Because the recent pooled analysis of radiation effects on breast cancer risk [Preston et al 2002] provides strong evidence against the use of common ERR models, breast cancer risks were based solely on an EAR model suggested in the pooled analysis. The use of EAR models for predicting thyroid cancer risks is problematic because variation in screening intensity will have a marked effect on the rate of radiation-associated thyroid cancers. Therefore, thyroid cancer risks were based solely on the ERR model developed from the pooled analysis of radiation-associated thyroid cancer risks [Ron et al, 1995]. Leukaemia risk estimates were based on an EAR model with a linear-quadratic dose-response [Preston et al, 1994]. The leukaemia model allows for effect modification of EAR by gender, age at exposure, and time following exposure.

(A8) Within a given exposed population, comparable descriptions of the radiation-associated risk can be made using either excess relative risk (ERR) or excess absolute risk (EAR) models as long as the models allow for variation in the excess risk with factors such as gender, attained age, and age-at-exposure. While suitably rich multiplicative (ERR) or additive (EAR) models lead to virtually identical descriptions of the excess risk in the population used to develop the risk estimates, they can lead to markedly different excess risk estimates when applied to populations with different baseline rates.

(A9) Therefore, the population risks were defined as weighted averages of the additive (absolute) and multiplicative excess risk estimates with weights based on judgments concerning the relative applicability of the two risk estimates. Weights of 0.5 were used for all tissues except breast and bone marrow in which only an EAR model was used, thyroid and skin for which only an ERR model was used, and lung for which the ERR model was given a weight of 0.3 because of suggestions in the atomic bomb survivor data that the radiation-associated excess rate is more comparable across sexes than the ERR and also that radiation dose and smoking history interact additively as lung cancer risk factors.

(A10) Relative life lost is an important component of the detriment computation. Average life lost for a given cause was computed for each gender in each composite population as the average over ages at exposure and subsequent attained ages of the residual lifetime. The weights were equal to the number of deaths from the cause of interest in each age group. These were converted to relative values by division by the average life lost for all cancers.

A.2.1 Sources of data

(A11) Three main sources of data were used in computing the new nominal risk estimates: (1) baseline cancer incidence rates for specific tumour sites, (2) site-specific cancer incidence risk estimates, and (3) 5- and 20-year population-based relative cancer survival statistics. Composite baseline rates were computed using incidence rates averaged across six populations for cancers of the oesophagus, stomach, colon, liver, lung, female breast, ovary, bladder, thyroid, leukaemia, excluding chronic lymphocytic leukaemia, and solid cancers combined. Population-based cancer incidence rates were obtained from the 8th edition of Cancer Incidence In Five Continents (Parkin et al, 2003) and population size data were obtained from the WHO international mortality statistics database. The cancer rates used are for selected Asian (Shanghai, Osaka, Hiroshima, Nagasaki) and Euro-American (Sweden, UK, US SEER) populations and then an unweighted average was calculated to form a composite population.

(A12) In ICRP 60, nominal cancer risks were computed based on mortality data; however, in the current report, risk estimates are based on incidence data. The reason for the change is that incidence data provide a more complete description of the cancer burden than do mortality data, particularly for cancers that have a high survival rate. In addition, cancer registry (incidence) diagnoses are more accurate and the time of diagnosis is more precise. At the time of ICRP 60, comprehensive incidence data were not available. Since then, a thorough evaluation of cancer incidence in the Life Span Study (LSS) of Japanese atomic bomb survivors has been published (Thompson et al., 1994; Preston et al., 1994), and recently. Site-specific risk estimates were taken from the most recent solid cancer incidence analyses of the atomic bomb survivor LSS, with follow-up from 1958 through 1998, and using DS86 doses corrected for measurement errors.

(A13) Although the primary estimates are based on models derived from the LSS data, information from other radiation-exposed populations was also considered. Because the baseline rates of breast cancer are very low in Japan, data from seven cohorts were used in addition to the LSS for determining the site-specific risk estimate (Preston et al., 2002). For thyroid cancer, data from four radiation-exposed populations were considered in addition to the LSS (Ron et al., 1995). 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 sites, e.g., lung, there are significant differences (UNSCEAR 2000).

(A14) In ICRP 60, the liver cancer risk estimate was based on estimates derived from studies of patients injected with the radioactive contrast medium Thorotrast, for which generalizations to low-LET radiation exposures are problematic. In the current report, the LSS liver cancer risk estimate was preferred. However, this estimate was substantially higher than that of other groups exposed to x- or gamma-radiation (UNSCEAR, 2000), probably because of a strong interaction between hepatitis C and radiation reported in the LSS (Sharp et al., 2003), which would not be expected to occur in populations with lower rates of hepatitis C infection. Accordingly a nominal 50% reduction was applied in the transfer of liver cancer risk from the LSS.

(A15) Gender-specific, all-stage relative survival statistics from the U.S. SEER program for 1994-1999 (5-year survival) and 1979-1999 (20-year survival) were averaged to compute overall relative survival rates for different cancer sites. Although the SEER relative survival rates are higher than those found for many European and Asian countries, reducing the survival rates did not change estimates of relative detriment appreciably.

A.2.2 Cancer Risk in Different Tissues

(A16) Nominal cancer risks and tissue weights were developed for 12 individual tissues and organs (oesophagus, stomach, colon, liver, lung, bone surface, skin, breast, ovary, bladder, thyroid, bone marrow) with the remaining tissues and organs grouped into one "remainder" category. These individual tissues and organs were selected because it was deemed that there was sufficient epidemiological information on the tumorigenic effects of radiation to make the judgements necessary for estimating cancer risks. Leukaemia, excluding chronic lymphocytic leukaemia (CLL) and multiple myeloma were included in the bone marrow category. The remainder category also includes all other tissues not explicitly evaluated as individual cancer sites.

A.2.3 Hereditary risks

(A17) The estimate of genetic (hereditary) risk from radiation has been substantially revised since the ICRP 60 report as a result of new information that has become available and the work of ICRP during the interim. Several factors have led to this change, in brief:

- Most radiation-induced mutations are large multi-gene deletions, which are more likely to cause multi-system developmental abnormalities rather than single gene (i.e., Mendelian) diseases. Importantly, only a fraction of these are likely to be compatible with live births.
- Nearly all chronic diseases have a genetic component, but because most of these are multi-genic and multi-factorial, the mutation component (i.e., the responsiveness of these diseases to an alteration in mutation rate) is small, so that chronic diseases respond only minimally to a radiation-induced increase in mutation rate.
- The ICRP 60 report made the implicit assumption that all genetic diseases should be treated as lethal. In view of the range of severity and lethality for the various types of genetic disease, the lethality fraction for genetic diseases now has been explicitly designated as 80%.
- New genetic risk coefficients recommended by ICRP consider exposure and genetic risk for two generations only – the equilibrium value used in ICRP60 is judged to be of questionable scientific validity because of the unsupported assumptions necessary on selection coefficients, mutation component and population changes over hundreds of years.

As a result, the risk associated with gonadal dose is now estimated to be around 20 cases per 10,000 people/Sv, rather than around 100 cases per 10,000/Sv in ICRP 60, and the corresponding relative contribution of the gonadal dose to the total detriment is now estimated as 4%, versus the former 18. 3%.

A.3 Methodological Aspects

A.3.1 Uncertainty and sensitivity analyses

(A18) The estimated risk of radiation-related cancer is uncertain, and the sources of this uncertainty are many. The most familiar is statistical uncertainty, represented by confidence limits or statistical likelihood distributions. For a chronic or low-dose exposure, the estimate and its statistical uncertainty are divided by an uncertain dose and dose-rate effectiveness factor (DDREF), a process that both reduces the estimate and further increases its uncertainty (see below).

(A19) When an estimate based on a particular exposed population is applied to other populations or to other radiation sources, further uncertainty is introduced. Differences between radiation sources can produce uncertainty due to random or systematic error in dose estimates in either the original or secondary population.

(A20) Risk-based radiation protection depends heavily on the assumption that estimates based on studies of informative exposed populations, such as the Life Span Study cohort of atomic bomb survivors, can be applied to other exposed populations. Combined analyses of dose-response data from different populations (e.g., Preston et al 2002) provide valuable information relevant to that assumption. Unfortunately, such information is available for very few site-specific cancers. Transfers of risk estimates between populations pose a particularly difficult problem for cancer sites for which baseline rates differ widely between the two populations. This problem is discussed in more detail below.

(A21) Other major sources of uncertainty include possible interaction of radiation exposure with other cancer risk factors, notably including smoking history in the case of lung cancer, and reproductive history in the case of female breast cancer. This problem is similar to that of transfer of risk estimates between populations, in that the interaction can be represented as an uncertain linear combination of an additive and a multiplicative model. Although not entirely consistent across studies, there is epidemiological evidence favouring an additive interaction in the case of lung cancer and smoking, and a multiplicative interaction in the case of breast cancer and reproductive history.

(A22) Another uncertain factor is the relative biological effectiveness, relative to high-energy photons, of radiations of different qualities including medical x-rays in the 30-200 kev range, electrons, neutrons, protons, and alpha particles. Quantification has been discussed in some detail elsewhere, e.g. in NCI/CDC (2003). The use of central values is preferred by ICRP for radiation protection purposes, but it should be kept in mind that RBE values for specific radiations are intrinsically uncertain.

A.3.2 Dose and dose-rate effectiveness factor

(A23) For reasons related to statistical power, the dose-specific statistical estimates of radiation-related risk upon which this report is based reflect observed cancer excesses at radiation weighted doses greater than about 200 mSv, mainly delivered acutely. However, many of the more contentious issues in radiation protection involve risks from continuous exposures, or fractionated exposures with acute fractions of a few mSv or less. Experimental investigations tend to show that fractionation or protraction of dose is associated with reduced dose-specific risk, suggesting that dose-specific estimates based on high-dose, acute exposure data should be divided by a dose and dose-rate effectiveness factor (DDREF) for applications to low-dose, continuous, or fractionated exposures.

(A24) The magnitude of DDREF is uncertain, and has been treated as such in a number of recent reports based on quantitative uncertainty analysis (e.g., NCRP, 1997; EPA 1999; NCI/CDC 2003). However, the mean of the probabilistic uncertainty distribution for DDREF employed in those analyses differs little from the value of 2 recommended by ICRP (1991) and UNSCEAR (1993).

A.3.3 Transfer of risk between populations

(A25) If two populations differ with respect to prevalence of known modifiers of radiation-related risk, their responses to radiation exposure might be expected to differ. However, even in the absence of such information, it is problematic to transfer site-specific estimates of radiation-related risk from one population to the other if the corresponding baseline rates differ.

(A26) For (an extreme) example, the LSS population provides by far the most usable estimates available of radiation-related gastric cancer risk, but age-specific baseline rates differ by a factor of 12 between Japan and the United States. There is rough equivalence between dose-specific excess absolute risk (EAR_{LSS}) and the product of excess relative risk (ERR_{LSS}) and baseline rates for the population of Japan, but the relationship

$$EAR_{LSS} = ERR_{LSS} \times baseline_{Japan}$$

corresponds approximately to

$$EAR_{LSS} = 12 \times ERR_{LSS} \times baseline_{US}.$$

Thus, a multiplicative model estimate of excess risk for stomach cancer in the US population based on an ERR model i.e.

$$ERR_{US} = ERR_{LSS,}$$

is about one twelfth as high as the estimate based on directly transferring the EAR_{LSS}:

$$ERR_{add}=EAR_{LSS} / baseline_{US} =ERR_{LSS} H (baseline_{Japan} /baseline_{US})$$

(A27) Assuming that ionising radiation exposure acts primarily as a cancer initiator, multiplicative transfer would be plausible if the difference in population rates were associated with differential exposure to cancer promoters, and additive transfer would be plausible if the rate difference could be ascribed to differential exposure to competing cancer initiators. Given little or no information about radiation-related stomach cancer risk in the US population, or about modification of radiation-related risk by whatever factors are responsible for the 12-fold difference between gastric cancer rates in the two countries, it would not be unreasonable to consider all estimates of the form

$$ERR_{US}(p) = p H ERR_{add} + (1-p) H ERR_{mult},$$

for 0 = p = 1, as equally likely. With this approach, the overall uncertainty is high, and the mean value, $ERR_{US}(1/2)$, does not really represent the range of (presumably) equally likely transfer estimates.

(A28) For most sites, the difference between Japanese and US rates is considerably less than 12-fold, which means that inability to discriminate between the additive and multiplicative transfer models is less consequential. However, among the sites considered for the present report, only for lung, skin, breast, thyroid, and leukaemia was it considered that there was sufficient information to justify a representative value other than $ERR_{US}(1/2)$.

A.3.4 Gender averaging

(A29) Some radiation-related cancers are sex-specific, and for many others gender is a major modifier of radiation-related risk. In accord with current ICRP procedures, intermediate and final numerical risk estimates presented here are gender-averaged. Radiation risks were also calculated by retaining gender specificity of intermediate results and gender-averaging only at the final stage. The final results were similar, within acceptable limits, for the two methods of calculation and gender specific data are not recommended for the general purposes of radiological protection.

A.3.5 Quality of life detriment

(A30) Since there are quality-of-life detriments resulting from cancer in addition to lethality detriments, the Commission judges that cancers should be weighted by both lethality and a smaller added component to account for pain, suffering and any adverse effects of cancer treatment. To achieve this, a factor termed q_{min} is applied to the non-lethal fractions of cancers to produce an adjusted lethality fraction termed q_T. The formula used to calculate q_T with an adjustment for non-lethal detriment is:

$$q_T = q_{min} + k_T (1 - q_{min})$$

where k_T is the lethality fraction and q_{min} is the minimum weight for non-lethal cancers.

(A31) The value of q_{min} was set equal to 0.1 (the result is not highly sensitive to the value chosen.) In effect, the q_{min} adjustment has an impact upon detriment calculations in

proportion to the fraction of cancers that are non-lethal. Accordingly, highly lethal cancers such as lung and stomach cancer are little affected by q_{min} whereas relatively non-lethal cancers such as breast or thyroid are. For example, if the lethality of a cancer type was 0.30, the adjusted q_r would be 0.37. However, the q_{min} adjustment was not used for skin cancer because radiogenic skin cancer is almost exclusively of the basal cell type which is usually associated with very little pain, suffering or treatment sequelae.

A.4 Principal features of new estimates of cancer risk

(A32) In ICRP 60 the ERR and EAR models were given equal weights for various tissues, except for bone marrow. In the present assessment, the relative weights assigned to the ERR and EAR models were allowed to depart from 50:50 when warranted by the available data. This made a more realistic model for the inter-country transfer of radiogenic breast cancer risks and largely prevented the potential problem of thyroid cancer or skin cancer risk estimates being affected by differing degrees of cancer screening.

(A33) The present relative detriments (Table A1) are similar to the values calculated in ICRP 60 except for four tissue groups: breast, bone marrow, remainder tissues and gonads. The primary reason that the breast cancer risk estimate has increased by a factor of about three is that those exposed as juveniles in the LSS cohort now make a larger contribution to the overall risk, whereas the mortality data used for the ICRP 60 analysis only partially reflected this contribution. In the 1958-1987 LSS Tumour Registry report on radiation and solid cancer incidence (Thompson et al, 1994), breast cancers contributed about 11% of the total excess cancers as averaged over males and females.

(A34) Studies of other exposed populations also have confirmed the substantial breast cancer risk from radiation (Preston et al, 2002). Furthermore, the detriment is increased by the combination of a younger age distribution of spontaneous breast cancer compared to most other sites, and an especially strong age-at-exposure effect in which exposure at young ages confers much greater breast cancer risk than exposure at older ages.

(A35) On the other hand, the lethality fraction for breast cancer has decreased in the past 15 years, probably reflecting increased early detection and improved treatments. Appropriate modelling of the temporal diminution of leukaemia risk, while solid tumour risks have changed less, has contributed to a reduction of relative tissue weight for bone marrow from 14.3% to 9.3%. The reduction of gonadal risk has already been explained above and pertains to new information and a revised approach for assessing risks of hereditary disease.

(A36) The further accumulation of LSS data in the period following ICRP 60 has significantly influenced the "remainder tissues" category. There is now evidence for excess radiation risk, in the aggregate, among a variety of other tissues, although the degree of risk for any single tissue is unclear. This has led to a composite increase in risk for the remainder-tissues category from an ICRP 60 judged value of 5% to 26%.

(A37) However, because this risk in the remainder category is spread over a large number of tissues and organs, the judgement of the Commission is that any given tissue should receive a small weight. This judgement is consistent with LSS and/or other evidence suggesting the risk is probably very small or that evidence is lacking - especially for rare cancer sites.

Table A1. Summary of Nominal risks and Detriment

a) Whole population

Tissue	Nominal Risk Coefficient (cases per 10,000 PYSv)	Lethality	Lethality-adjusted nominal risk*	Relative cancer free life lost	Detriment	Relative detriment+
Oesophagus	17	0.93	**17**	0.87	15.0	***0.023***
Stomach	91	0.83	**89**	0.88	78.1	***0.120***
Colon	101	0.48	**76**	0.97	73.9	***0.113***
Liver	19	0.95	**19**	0.88	16.6	***0.025***
Lung	100	0.89	**99**	0.8	79.5	***0.122***
Bone surface	7	0.45	**5**	1	5.1	***0.008***
Skin	1000	0.002	**4**	1	4.0	***0.006***
Breast	121	0.29	**67**	1.29	86.5	***0.133***
Ovary	13	0.57	**10**	1.12	11.7	***0.018***
Bladder	43	0.29	**23**	0.71	16.3	***0.025***
Thyroid	24	0.07	**7**	1.29	9.5	***0.015***
Bone Marrow	41	0.67	**37**	1.63	60.8	***0.093***
Other Solid	214	0.49	**164**	1.03	169.1	***0.259***
Gonads / Hereditary	20	0.80	**19**	1.32	25.4	***0.039***
Total	**1812**		**638**		**651.5**	***1.000***

b) Working age population (20-64 y)

Tissue	Nominal Risk Coefficient (cases per 10,000 PYSv)	Lethality	Lethality-adjusted nominal risk*	Relative cancer free life lost	Detriment	Relative detriment+
Oesophagus	13	0.93	**13**	0.91	12.0	***0.024***
Stomach	89	0.83	**86**	0.89	76.9	***0.156***
Colon	64	0.48	**48**	1.13	54.8	***0.111***
Liver	15	0.95	**15**	0.93	14.0	***0.028***
Lung	108	0.89	**107**	0.96	103.1	***0.209***
Bone surface	6	0.45	**4**	1	4.1	***0.008***
Skin	1000	0.002	**4**	1	4.0	***0.008***
Breast	79	0.29	**43**	1.20	52.0	***0.105***
Ovary	9	0.57	**7**	1.16	8.4	***0.017***
Bladder	40	0.29	**21**	0.85	18.2	***0.037***
Thyroid	5	0.07	**1**	1.19	1.7	***0.003***
Bone Marrow	46	0.67	**41**	1.17	48.1	***0.097***
Other Solid	110	0.49	**84**	0.97	81.5	***0.165***
Gonads/ Hereditary	12	0.80	**12**	1.32	15.3	***0.031***
Total	**1594**		**488**		**494.0**	***1.000***

* Defined as $R*q + R*(1-q)*((1 - q_{min}) q + q_{min})$, where R is the nominal risk coefficient, q is the lethality, and $(1 - q_{min}) q + q_{min}$ is the weight given to non-fatal cancers. And q_{min} is the minimum weight for nonfatal cancers. The q_{min} correction was not applied to skin cancer (see text).

+ The values given should not be taken to imply undue precision but are presented to 3 significant figures to facilitate the traceability of the calculations made.

A.5 The use of relative detriment for a tissue weighting system

(A38) The Commission has made a policy decision that there should only be a single set of w_T values that are averaged over both genders and all ages.

(A39) A set of w_T values could be proposed that closely follows the respective values of relative detriment given in Table A1. However, the Commission feels that additional judgements need to be exercised to include subjective factors, not reflected in the mathematical formulation of detriment. In particular, the following judgements were applied.

- The detriments for heritable effects and cancer following gonadal irradiation were aggregated to give a w_T of 0.05.
- The detriment of thyroid cancer was increased to 0.05 to take account of the concentration of cancer risk in childhood, i.e. young children are considered to be a particularly sensitive sub-group.

(252) Cancer risk in salivary glands, brain and kidney whilst not specifically quantifiable, is judged to be greater than that of other tissues in the remainder fraction and for this reason each is ascribed a w_T of 0.01

(A40) Re-ordering of w_T values using the above judgements was made ensuring that these values did not diverge from the relative detriments of Table A1 by more than around two-fold. This reassignment gives a w_T value for the remainder tissues of 0.1 and it is proposed that this is distributed equally amongst fourteen named tissues

(A41) The w_T for remainder (0.1) is divided equally between the 14 tissues given in the footnote to Table A2, approximately 0.007 each, which is lower than the w_T for the lowest of the named tissues (0.01). The number of tissues included in remainder could be increased if necessary. The system preserves additivity in effective doses. Mass weighting of tissues in the remainder fraction was explored but rejected. The principal reason for this rejection was that the very large disparities in tissue masses caused unacceptable distortions of effective dose for certain radionuclides. A notable feature of detriment in Table A1 is that the heritable detriment from gonadal irradiation is distinguished from that of cancer risk (i.e. in ovary and testes). For the purposes of the 2005 Recommendations, these w_T values have been aggregated (see Table A2).

Table A2. Tissue weighting factors

Tissue	w_T	? w_T
Bone-marrow, Breast, Colon, Lung, Stomach	**0.12**	0.60
Bladder, Oesophagus, Gonads, Liver, Thyroid	**0.05**	0.25
Bone surface, Brain, Kidneys, Salivary glands, Skin	**0.01**	0.05
Remainder Tissues* (Nominal w_T applied to the average dose to 14 tissues)	**0.10**	0.10

***Remainder Tissues (14 in total)**

Adipose tissue, Adrenals, Connective tissue, Extrathoracic airways, Gall bladder, Heart wall, Lymphatic nodes, Muscle, Pancreas, Prostate, SI Wall, Spleen, Thymus, Uterus/cervix.

(A42) It should be noted that the w_T for gonads is applied to the mass-weighted mean of the doses to testes and ovaries (i.e. the average dose in gonadal tissue), and that the dose to the

colon is taken to be the mass-weighted mean of ULI and LLI doses, as in the Publication 60 formulation.

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ANNEX B. THE PROTECTION OF NON-HUMAN ENVIRONMENTAL SPECIES

B.1 Introduction

(B1) ICRP's advice is aimed primarily at those who have the responsibility for establishing and implementing human radiological protection standards that apply to a wide variety of situations and circumstances. The Commission has not made any recommendations with regard to protection of other species, but in its 1990 Recommendations [1] it did express the view that

> "The Commission believes that the standards of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk. Occasionally, individual members of non-human species might be harmed, but not to the extent of endangering whole species or creating imbalance between species. At the present time, the Commission concerns itself with mankind's environment only with regard to the transfer of radionuclides through the environment, since this directly affects the radiological protection of man."

(B2) Because these standards of environmental control result in constraints being placed on the quantities of radionuclides deliberately introduced into the environment, the Commission still believes that this general judgement is correct in general terms. But it also recognises that much depends on the interpretation of what is meant by 'at risk' in the context of other species, and that there is a need to explore further the nature of the 'risks' that may apply to other species, how such risks may be quantified, and thus how it can be positively demonstrated that they are, indeed, "……not put at risk".

(B3) Of even greater importance, however, is the manner by which such an interpretation may need to be interfaced with other environmental regulatory requirements that increasingly apply to practices involving ionising radiation. Furthermore, and as has been the case with human radiation protection, there is also clearly a need to address those situations where the standards of environmental control needed to protect man may, from time to time, be exceeded, and to those situations where the human standards may be deemed not to apply because of the absence of pathways leading to human exposure.

(B4) Thus although it is probably true that the human habitat has been afforded a high level of protection through the application of the Commission's system for the protection of humans, there are now other demands upon regulators, in particular the need to comply with the requirements of legislation directly aimed at the protection of wildlife and natural habitats; the need to make environmental impact assessments with respect to the environment generally; and the need to harmonise approaches to industrial regulation, bearing in mind that releases of chemicals from other industries are often based upon their potential impact upon both humans and wildlife. All of these demands are currently being met in different ways, partly because of the lack of advice on the subject at international level, and partly because there are therefore no agreed assessment procedures, criteria, guidelines or data sets with which to approach these issues in a coherent way. This, in turn, leads to different national approaches being developed and makes international harmonisation difficult.

(B5) The Commission has therefore decided that two things need to be done. The first is to develop a combined approach to the protection of both humans and other species, and to do so within an overall framework that recognises the different but complementary aims and objectives that this involves. The approach recognises that both humans, and fauna and flora, are part of the same ecosystem, but whereas the protection of human beings has aims and objectives that may be universally applied, the aims and objectives with respect to other species will vary considerably, depending on the species involved, and the nature and the circumstances relating to the risks to which they are exposed.

(B6) The second need is for the Commission to develop a common scientific basis and approach for relating exposure to dose, and dose to effect, for all living things. In the case of human radiation protection, this approach has been based on an entity called Reference Man. The Commission has therefore concluded that a parallel approach would be of value in order to serve as a basis for developing recommendations for the protection of other species.

B.2 Aims of Radiological Protection of Non-Human Species

(B7) Philosophical approaches and general principles relating to environmental protection have developed considerably at international level since the Commission's recommendations were published in 1990 (Publication 60). An increasing public concern over environmental damage generally, has resulted in many international conventions, treaties and agreements on the subject, and the need to protect the environment in order to safeguard the future well being of man is one of the cornerstones of the Rio Declaration [2].

(B8) The Commission has therefore given consideration to this wider issue and recently adopted a report (Publication 91) dealing specifically with environmental protection, in so far as it affects animals and plants [3]. This report addresses the role that the Commission could play in this important and evolving area, building on the approach that has been developed for human protection, and on the specific area of expertise available to the Commission, namely that of radiological protection. The report recognises that although there are many moral, ethical, and social approaches to the protection of the environment and, in particular, to the protection of living things, there are nevertheless a number of areas upon which there is widespread international agreement. These essentially relate to the need to protect or conserve those species that are in decline in particular areas; the need to maintain the biological diversity found globally within species, amongst species, and within mixtures of species; plus the need to protect natural habitats within which wildlife can flourish.

(B9) It has therefore been suggested [4] that the objectives of a common or combined approach to the radiological protection of humans and other living organisms could be to:

safeguard human health by preventing the occurrence of deterministic effects; limiting stochastic effects in individuals and optimising the protection of populations; and to

safeguard the environment by reducing the frequency of effects likely to cause early mortality, or reduced reproductive success, in animals and plants to a level where they would have a negligible impact on conservation of species, maintenance of biodiversity, or the health and status of natural habitats or communities.

(B10) The Commission accepts that if the latter of these two objectives is to be met, then it needs to expand its existing system of protection in order to provide a sufficient data base for those whose task it is to protect the natural environment directly, through such practices as natural resource management, or nature conservation, or pollution control. The Commission also accepts that such a data base should be derived from a scientific approach that complements that used for human radiation protection. It therefore needs to draw upon the widest possible range of information, and be presented in a format that would be of practical value across a wide range of applications. The Commission believes that these aims could best be met by deriving a set of Reference Animals and Plants that could be used to examine such issues as the relationships between exposures to radiation and the resulting dose, and the relationships between dose and different types of biological effects that would then be useful in the context of a range of environmental management practices. The concept is therefore similar to that of the reference individual, Reference Man, [5] used for human radiological protection, and each reference organism will serve as a primary point of reference for assessing risks to organisms with similar life cycles and exposure characteristics.

B.3 Reference Animals and plants

(B11) The Commission is therefore developing a small set of Reference Animal and Plants, plus their relevant databases, for a few types of organisms that are typical of the major environments. This approach cannot provide a general assessment of the effects of radiation on the environment as a whole, but it could provide the basis for judgements about the probability and severity of the likely radiation effects on such individuals, or on other types of organisms that differ in specific characteristics from the reference types. Using these and other environmental data, one should then be able to assess the likely consequences for either individuals or the relevant population in order to make managerial decisions.

(B12) With such an enormous variety of living animals and plants, it is clearly not easy to select a few species for the purposes of radiation protection. A number of basic scientific criteria for their selection can and have been considered, together with an evaluation of what the information is likely to be used for, and under what circumstances. These were anticipated to include the need to meet new environmental legislation, particularly in relation to wildlife conservation and habitat protection, which may need to be applied retrospectively to existing nuclear facilities. It was also considered necessary to provide advice to meet requirements for 'environmental impact assessments' in relation to new or proposed nuclear facilities that, as well as including the above requirements, may necessitate evaluations to be made with respect to potential impacts on other forms of environmental management, such as those relating to fisheries and agriculture, and of the consequences of major accidents and emergencies. Finally, it was also noted that there is now pressure to meet requirements to achieve consistency in regulatory approaches to large industries, particularly with regard to the need to consider, explicitly, not only their potential impact on the general public but also their potential impact on the environment generally, either on the basis of 'toxicity testing' or by way of 'ecotoxicology' evaluations that assess how a chemical is likely to be dispersed throughout any particular ecosystem, and what effects it might have on different biota.

(B13) The Commission therefore considered that a mixture of animals and plants was needed that reflected both the variety of operational and regulatory requirements, and the need to be pragmatic in terms of developing a flexible framework to accommodate future needs and the acquirement of new knowledge. Thus it was concluded that:

for the purposes of wildlife and habitat conservation, any likely list of types would need to include a number of vertebrate animals, particularly a bird and a mammal, and possibly even a reptile or amphibian, and that wetland habitats appeared to be particularly subject to international and national concerns;

that for evaluations in relation to environmental exploitation, any list would necessarily require examples of animals and plants that were relevant to such practices as fisheries, agriculture, and forestry; and

with regard to the requirements of pollution control, it was noted that a number of 'toxicity-test' type organisms are already routinely used, and thus some overlap with such types would be desirable; and that

- with regard to ecotoxicological studies, it would be important to ensure that the total set had a reasonable coverage of the major ecological compartments of terrestrial and aquatic ecosystems.

(B14) It was also recognised that it was necessary to have a reasonable amount of information on the animals and plants selected and that, where data were lacking, particularly in relation to radiation effects, there was a reasonable prospect that such information gaps could be filled. Similarly, it was accepted that the reference animals and plants chosen should have some form of public or political resonance, so that both decision makers and the public

are likely to know what these organisms actually are, in common language – such as a duck, or a crab.

(B15) The Commission is therefore developing a set of Reference Animals and Plants based on a rodent, a duck, a frog, a freshwater fish, a marine flatfish, a bee, a crab, a marine snail, an earthworm, a pine tree, a grass, and a seaweed. For each reference animal and plant, the Commission is developing a reference set of *dosimetric models* and a reference set of *environmental geometries*. These, together with data on their basic life-cycle biology, and pathways of exposure to radiation, will be used to provide a means of estimating doses received from both external and internal sources.

(B16) This Reference set will also be used to examine the data available on radiation effects on these types of organisms, or the nearest data available. The Commission considers that the radiation-induced biological effects in non-human organisms that would be of greatest use to others could be summarized into three or four broad categories: early mortality, morbidity, reduced reproductive success, and scorable DNA damage. The Commission recognises that these categories comprise many different and overlapping effects, and that the limitations of current knowledge of such effects makes further differentiation impractical at this stage.

(B17) The variety of dose models needed for reference animals and plants, in addition to the considerations of **target size and shape**, will depend upon the biological effect of interest. Equally important, however, is consideration of how to interpret relationships between doses and biological effects. There are currently only two bases upon which to assess the potential consequences for fauna and flora: natural background dose rates, and dose rates known to have specific biological effects on individuals. For the protection of humans, the Commission is recommending an approach based on radiation levels where action is needed, and with explicit reference to background dose rates. For animals and plants, the Commission believes that data could be set out in similar scales of dose-effect levels to aid in the *consideration* of different management options [3]. Such levels would therefore be described as *dose consideration levels*.

B.4 The Use of Reference Animals and Plants

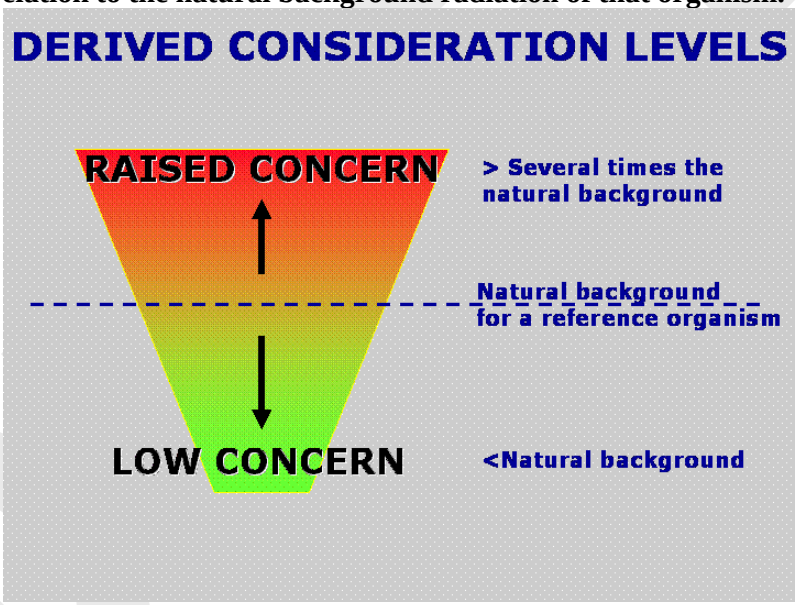
(B18) A framework for radiological protection of the environment must be practical and simple. The Commission recognises that it will not be possible to provide a general assessment of radiation effects on all the components of the environment. The concept of deriving reference data sets for Reference Animals and Plants is therefore considered to be similar to the approach used for human radiological protection, in that they are intended to act as a basis for calculations and for decision making. The approach is also considered to be similar to the concept and use of assessment and measurement endpoints used in environmental risk assessment frameworks for other environmental hazards [6]. Each reference animal or plant would thus serve as a *primary* point of reference for assessing risks to organisms with similar life cycles and exposure characteristics. More locally relevant information could be compiled for any other fauna and flora; but each such data set would then have to be shown to be related in some way to the primary reference set. The data sets compiled for a number of Reference Animals and Plants could also serve as 'default' values for use in various generic environmental risk assessment scenarios.

(B19) The Commission recognises that the reduction of the frequency of radiation effects in individual animals or plants does not imply that the individual is necessarily the object of protection. Effects upon ecosystems are usually observed at the population or higher levels of organization, whereas information on dose responses is usually obtained at the individual level. Radiation effects at the population level - or higher - are mediated via effects on individuals of that population, and it therefore seems appropriate to focus on the individual for the purpose of developing an assessment framework. The Commission also notes that a

large number of animals and plants are already afforded protection at the level of the individual in international or national law, and it would be inappropriate to provide advice that could not be used in such legal contexts. The question of whether one should protect individuals or populations from harmful effects of radiation in any particular circumstance is not an issue of direct concern to the Commission.

(B20) In order to be of practical value, and to assist in their interpretation, the Commission believes that bands of *derived consideration levels* for Reference Animals and Plants could be set out in logarithmic bands of dose rates relative to normal natural background dose rates (Figure B1). Additions of dose rate that are only fractions of their background might then be considered to be of low concern, and those that are orders of magnitude greater than background would be of increasingly serious concern because of their known adverse effects on individual organisms. But the need for any managerial action, however, would be dependent upon the numbers and types of individuals affected, the nature of the effects, the spatial and temporal aspects of contamination, legal requirements, and so on.

Figure B1. Example of derived consideration levels for a reference animal or plant in relation to the natural background radiation of that organism.



(B21) The Commission considers that presentation of these data in terms of dose rates that are known to have particular radiation effects on different types of animals and plants would appear to be an appropriate and transparent format in which to provide general advice. This could be used to support legal frameworks at a national level, or in terms of using dose rates as the basis of any form of guidance or stricter form of legislative control.

(B22) Nevertheless, the Commission is keen to point out that the recommended system is not intended to set regulatory standards. The Commission rather recommends a framework that can be a practical tool to provide high-level advice and guidance, and help regulators and operators demonstrate compliance with existing or forthcoming legislation. The system does not, however, preclude the derivation of standards; on the contrary, it provides a basis for such derivation.

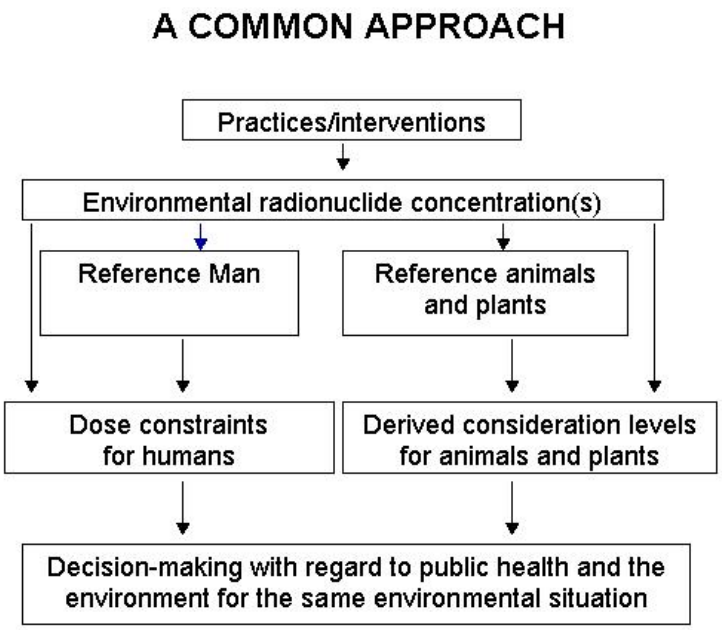
B.5 A Common Approach for Protecting Humans and Non-Human Species

(B23) The Commission's new framework will be designed so that it is harmonized with its proposed approach for the protection of human beings. To achieve this, an agreed set of

nomenclature, plus a set of reference dose models, data sets to relate exposure to dose, and interpretation of effects will be developed for a limited number of animal and plant types. This will also ensure that the protection of both humans and other organisms are protected on the same scientific basis, in terms of the relationships between exposures to ionising radiation and dose, and between dose and effects at the molecular, cellular, tissue and organ, and whole organism level.

(B24) The new framework will also ensure that decision-making with regard to public health and the environment, for the same environmental situation, are explicitly carried out on the same scientific basis with respect to what is known about the effects of ionising radiation (Figure B2).

Figure B2. Developing a common approach for the radiological protection of humans and non-humans organisms for the same environmental situation.



(B25) The Commission's system of protection has evolved over time as new evidence has become available and as our scientific understanding of the underlying mechanisms has increased. Consequently, the Commission's risk estimates for humans have been revised regularly, and substantial revisions made at intervals of about 10-15 years. It is therefore likely that any system designed for the radiological protection of the environment will also take time to develop, and similarly be subject to revision as new information is obtained and experience gained in putting it into practice.

(B26) The Commission recognises that a framework for radiological protection of the environment must be practical and, ideally, a set of ambient activity concentration levels would be the simplest tool. There is a need for international standards of discharges into the environment, and the Commission's common approach will provide a basis for the development of such standards. In order to demonstrate, transparently, the derivation of ambient activity concentration levels or standards, the reference-animal-and-plant approach will be helpful.

(B27) At present, there are no internationally agreed criteria or policies that explicitly address protection of the environment from ionising radiation, although many international agreements and statutes call for protection against pollution generally, including radiation. The Commission's decision to develop an explicit assessment framework will support and provide transparency to the decision- making procedure.

B.6 References To Annex B

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