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## PUBLICATION 147

### Use of Dose Quantities in Radiological Protection

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# Annals of the ICRP

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## Aims and Scope

The International Commission on Radiological Protection (ICRP) is the primary body in protection against ionising radiation. ICRP is a registered charity and is thus an independent non-governmental organisation created at the 1928 International Congress of Radiology to advance for the public benefit the science of radiological protection. ICRP provides recommendations and guidance on protection against the risks associated with ionising radiation from artificial sources such as those widely used in medicine, general industry, and nuclear enterprises, and from naturally occurring sources. These are published approximately four times each year on behalf of ICRP as the journal *Annals of the ICRP*. Each issue provides in-depth coverage of a specific subject area.

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The Main Commission consists of a Chair and twelve other members. Committees typically comprise just over 15 members each. Task Groups are usually chaired by an ICRP Committee member and usually contain a number of specialists from beyond the Main Commission and Committees. They are assigned the responsibility for drafting reports on various subjects, which are reviewed and finally approved by the Main Commission. These reports are then published as *Annals of the ICRP*.

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# Annals of the ICRP

ICRP PUBLICATION 147

## Use of Dose Quantities in Radiological Protection

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# CONTENTS

|                                                                |    |
|----------------------------------------------------------------|----|
| EDITORIAL .....                                                | 5  |
| ABSTRACT .....                                                 | 9  |
| MAIN POINTS .....                                              | 11 |
| EXECUTIVE SUMMARY .....                                        | 13 |
| 1. INTRODUCTION .....                                          | 17 |
| 2. HEALTH EFFECTS AND DETRIMENT .....                          | 21 |
| 2.1. Categories of radiation effects .....                     | 21 |
| 2.2. Tissue reactions (deterministic effects) .....            | 21 |
| 2.3. Stochastic effects (cancers and heritable diseases) ..... | 22 |
| 2.4. Nominal risk coefficients and detriment .....             | 24 |
| 2.5. Tissue weighting factors .....                            | 26 |
| 2.6. Age- and sex-specific cancer risks .....                  | 27 |
| 2.7. Risks from alpha-particle-emitting radionuclides .....    | 31 |
| 3. DOSE QUANTITIES .....                                       | 33 |
| 3.1. Requirements for protection quantities .....              | 33 |
| 3.2. Absorbed dose .....                                       | 33 |
| 3.3. Equivalent dose .....                                     | 33 |
| 3.4. Effective dose .....                                      | 36 |
| 3.5. Committed dose .....                                      | 37 |
| 3.6. Dose coefficients .....                                   | 38 |
| 3.7. Collective dose .....                                     | 40 |
| 3.8. Operational quantities .....                              | 41 |
| 4. OCCUPATIONAL AND PUBLIC EXPOSURES .....                     | 45 |
| 4.1. Occupational exposures .....                              | 45 |
| 4.2. Public exposures .....                                    | 49 |
| 4.3. Potential exposures .....                                 | 52 |

|                                                                     |    |
|---------------------------------------------------------------------|----|
| 5. MEDICAL EXPOSURES .....                                          | 55 |
| 5.1. Effective doses from medical procedures .....                  | 55 |
| 5.2. Applications using effective dose .....                        | 57 |
| 5.3. Applications for which effective dose is not recommended ..... | 60 |
| 5.4. Effective dose and risk communication .....                    | 62 |
| 6. CONCLUSIONS .....                                                | 71 |
| REFERENCES.....                                                     | 73 |
| ACKNOWLEDGEMENTS.....                                               | 81 |

## Editorial

### DOSE AND RISK: SCIENCE AND PROTECTION

The International Commission on Radiological Protection (ICRP) system of radiological protection aims to protect people and the environment from detrimental effects of exposure to ionising radiation. This relies on practical and effective management of radiation doses, which, in turn, relies on clear understanding and proper use of dose quantities.

The system of radiological protection has evolved over more than 90 years, adapting to progress in scientific knowledge about the effects of radiation exposure. Protection of people is based on two protection goals, implemented through application of the fundamental principles of justification, optimisation of protection, and individual dose limitation:

- keeping doses to organs and tissues below thresholds to avoid harmful tissue reactions (deterministic effects); and
- management of effective dose to limit the probability of occurrence of stochastic effects.

The close relationship between dose and health risk is inherent to construction of the system of radiological protection, specifically:

- the relationship between severity of an effect and dose above a threshold for tissue reactions; and
- the relationship between probability of occurrence of an effect and dose without a threshold for stochastic effects.

The system of radiological protection for humans currently uses three dose quantities: absorbed dose, equivalent dose, and effective dose. Absorbed dose to organs and tissues is the fundamental scientific quantity and starting point for calculation of the other risk-adjusted quantities. Equivalent dose to organs and tissues enables the summation of doses from different radiation types, and is currently used to set limits to prevent harmful tissue reactions. Effective dose combines equivalent doses for protection from stochastic effects.

One key point in the present publication is that the Commission now considers absorbed dose to be the most appropriate quantity to use when limiting doses to

organs and tissues to avoid harmful tissue reactions. This draws a clear distinction between limits applying to tissue reactions, set in absorbed dose (Gy), and those applying to stochastic effects, set in effective dose (Sv).

This position is consistent with the approach taken by the US National Council on Radiation Protection and Measurements (NCRP, 2018) and proposals from the International Commission on Radiation Units and Measurements (ICRU, 2020) on changes to operational quantities.

However, ICRP does not recommend an immediate change to the system of radiological protection. Rather, this should be considered an important input into the next fundamental recommendations of the Commission. A review of the system of radiological protection is already underway, aiming to develop the next fundamental recommendations which will supersede *Publication 103* (ICRP, 2007) in about a decade.

For stochastic effects, it is now possible to provide an individual risk assessment taking into account the characteristics of the individual (sex, age at exposure, country of residence) and the dose received (acute or chronic, organs exposed), and thus to make an ad-hoc estimate of the risk for a specific type of cancer. The present publication indicates that this is the approach that should be favoured for risk assessment, using ad-hoc risk models from the epidemiological literature. Variations in health risk with age and sex are illustrated in Tables 2.4 and 2.5 of this publication. It is clear, for example, that the lifetime risk of cancer incurred by a young girl with breast exposure is not of the same nature and magnitude as that of a 60-year-old man with abdominal exposure.

Keeping this in mind, another key point in the present publication is that, under a variety of exposure conditions, effective dose can be an indicator of the magnitude of the associated health risk. Taking into account the age at exposure, which introduces an approximate variation of a factor of three, effective dose can be considered an approximate indicator of the stochastic risk. For most situations of practical radiological protection, this approximation is sufficient to inform judgements and the assessment of possible risks, for example in the medical uses of radiation and communication with patients.

Effective dose continues to be key to practical and effective management of the risk of stochastic effects for the purposes of radiological protection. It provides single values that relate to stochastic risk averaged over all organs and tissues as sites of radiation-induced cancer for both sexes, all ages, and even different populations around the world.

Likewise, detriment is also central to the well-established system of radiological protection. As organ and tissue doses are calculated using dosimetric phantoms of

the human body for males and females of various ages (newborn, 1 year, 5 years, 10 years, 15 years, and 20 years), it is possible to present cancer risks and detriment separately for each sex and for different age groups. It would then be clearer that the inferred risk associated with a given effective dose depends on the age and sex of the exposed individuals. The corollary is that optimisation is applied with a better understanding of possible risks. This evolution towards increased scientific precision and clarity could help facilitate the practical application of appropriate protective measures.

As noted previously, a review of the system of radiological protection is underway, aiming towards development of the next fundamental recommendations of ICRP. Considerations include improvement of the discrimination between tissue reactions and stochastic effects, updating of radiological risk models, and revision of the parameters involved in the construction of radiological damage, based on progress in scientific and health knowledge since *Publication 103* (ICRP, 2007). Several task groups have been established or are being considered on related topics, such as the calculation of detriment, the determination of dose and dose-rate effectiveness factors, and the integration of heritable effects and cardiovascular disease risks. The conclusions of these task groups will form cornerstones of the new recommendations. The present publication is part of this dynamic, considering the ways in which the dose quantities used in the system of radiological protection relate to risks, and are used to prevent or optimise protection against these risks, paving the way for future changes.

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## USE OF DOSE QUANTITIES IN RADIOLOGICAL PROTECTION

ICRP PUBLICATION 147

Approved by the Commission in May 2019

**Abstract**—The central dose quantities used in radiological protection are absorbed dose, equivalent dose, and effective dose. The concept of effective dose was developed by the International Commission on Radiological Protection (ICRP) as a risk-adjusted dosimetric quantity for the management of protection against stochastic effects, principally cancer, enabling comparison of estimated doses with dose limits, dose constraints, and reference levels expressed in the same quantity. Its use allows all radiation exposures from external and internal sources to be considered together and summed, relying on the assumptions of a linear non-threshold dose–response relationship, equivalence of acute and chronic exposures at low doses or low dose rates, and equivalence of external and internal exposures. *ICRP Publication 103* provides detailed explanation of the purpose and use of effective dose and equivalent dose to individual organs and tissues. This publication provides further guidance on the scientific basis for the control of radiation risks using dose quantities, and discusses occupational, public, and medical applications. It is recognised that best estimates of risk to individuals will use organ/tissue doses and specific dose risk models. Although doses incurred at low levels of exposure may be measured or assessed with reasonable accuracy, the associated risks are increasingly uncertain at lower doses. Bearing in mind the uncertainties associated with risk projection to low doses or low dose rates, it is concluded that effective dose may be considered as an approximate indicator of possible risk, recognising also that lifetime cancer risks vary with age at exposure, sex, and population group. A further conclusion is that equivalent dose is not required as a protection quantity. It will be more appropriate for limits for the avoidance of tissue reactions for the skin, hands and feet, and lens of the eye to be set in terms of absorbed dose rather than equivalent dose.

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**Keywords:** Absorbed dose; Equivalent dose; Effective dose; Stochastic risks; Tissue reactions; Occupational, public, and medical exposures



## MAIN POINTS

- The purpose of this publication is to consolidate and expand the explanations provided in *Publication 103* (ICRP, 2007a), but also to clarify the use of dose quantities in relation to risks to health, reaching conclusions that go beyond the advice given in *Publication 103*.
- Effective dose and collective effective dose are valuable tools for use in the optimisation of protection against stochastic effects, principally cancer, for occupational and public exposures.
- Effective dose is used in medicine for comparing doses from different medical procedures, informing judgements on justification, and establishing constraints for carers and volunteers in medical research. Where doses from the same technique are being compared, measurable quantities are preferred.
- Effective dose will generally be used at doses below 100 mSv, but its use at acute doses in the range up to approximately 1 Sv is reasonable, noting the possibility of occurrence of tissue reactions, particularly from non-uniform distribution of dose.
- Bearing in mind the uncertainties associated with risk projection to low doses or low dose rates, effective dose may be considered as an approximate indicator of possible risk, recognising that lifetime cancer risks vary with age at exposure, sex, and population group. It is emphasised that use of effective dose in this way is not a substitute for specific risk analysis for individual cancer types using organ/tissue doses.
- The use of collective effective dose to predict potential/possible health effects should be treated with caution, put into context, and judged in relation to background morbidity rates.
- Absorbed dose is the most appropriate quantity for use in setting limits on organ/tissue doses to prevent tissue reactions (deterministic effects). The Commission expects to change from the use of equivalent dose to set limits on organ/tissue doses at the time that new general recommendations are issued.



## EXECUTIVE SUMMARY

(a) The dosimetric quantities used in radiological protection are absorbed dose [with the unit of gray (Gy)], equivalent dose, and effective dose [both with the unit of sievert (Sv)]; the base unit is  $\text{J kg}^{-1}$  in each case. Absorbed dose is calculated for protection purposes as an average over organs and tissues, and is the primary scientific quantity from which effective dose is calculated. Absorbed dose is the most appropriate quantity for use in setting limits on organ/tissue doses to prevent tissue reactions (deterministic effects). Equivalent dose is an intermediate quantity in the calculation of effective dose, and the radiation weighting factors ( $w_R$ ) applied to absorbed doses and used in the calculation of equivalent dose relate to stochastic effects at low levels of exposure rather than tissue reactions. The Commission considers that the use of equivalent dose to set limits on organ/tissue doses to prevent tissue reactions should be discontinued, but that current limits can continue to be applied until new general recommendations are issued. Radiation weighting for tissue reactions will require further consideration.

(b) Effective dose is calculated as the weighted average of organ/tissue equivalent doses, summing equivalent doses multiplied by tissue weighting factors ( $w_T$ ) which provide a simplified representation of fractional contributions to total stochastic detriment from cancer and heritable effects. Detriment-adjusted nominal risk coefficients ( $\text{Sv}^{-1}$ ) are calculated as averages from sex-, age-, and population-specific values to provide internationally applicable coefficients for all workers (18–64 years of age at exposure) and the whole population (0–84 years of age at exposure). Effective dose is accepted internationally as the central radiological protection quantity, providing a risk-adjusted measure of total body dose from external and internal sources in relation to risks of cancer and heritable effects. It has proved to be a valuable and robust quantity for use in the optimisation of protection for workers and members of the public, the setting of control criteria (constraints, reference levels, and limits), and the demonstration of compliance. Its use requires the assumption of a linear non-threshold dose–response relationship between dose and risk at low doses or low dose rates, the equivalence of effect of acute and chronic low-level exposures, and the equivalence of effect of internal and external exposures. Although effective dose is most commonly used at doses below 100 mSv, its use in emergency exposure situations at acute doses in the range up to approximately 1 Sv is reasonable. However, it should be noted that in addition to the increased risk of stochastic effects at higher doses, the possibility of occurrence of tissue reactions should also be considered at such doses, particularly if a significant contribution is made by non-uniform distribution of absorbed dose from external sources or from radionuclides concentrated in specific tissues/organs.

(c) Effective dose is calculated for sex-averaged Reference Persons of specified ages. The *Publication 103* (ICRP, 2007a) definition of effective dose includes the specification of Reference Male and Female anatomical models for radiation transport calculations. While exposures may relate to individuals or population groups, effective dose is calculated for Reference Persons exposed in a defined way.

The Commission provides effective dose coefficients for situations of external and internal exposures of workers and members of the public, and for radiopharmaceutical administrations to patients, as reference coefficients for use in prospective and retrospective dose assessments. Reference dose coefficients are provided for particular circumstances of exposure, including specific chemical and physical forms of ingested and inhaled radionuclides. Site-specific information on the exposure should be used if available and if the level of exposure warrants more precise estimation of dose.

(d) In evaluating annual exposures, effective dose is calculated as the sum of external dose received in the year and committed dose from internal exposures during the year, where committed dose is integrated over a 50-year period for adults and up to 70 years of age for children. This procedure introduces an element of conservatism for long-lived radionuclides with long biological half-times, but for many radionuclides, all or most of the dose is delivered in the first year after intake. Although effective dose coefficients are provided for a number of paediatric age groups, it is normally sufficient in public dose assessments to consider the age groups of 1 year and 10 years, together with adults. Effective dose coefficients for the fetus following intakes of radionuclides are provided for comparison with dose for other age groups, showing that it is only in the case of a few radionuclides that fetal doses may need to be considered.

(e) While age-, sex-, and population-related differences in risks per Gy are recognised, the use of constraints, reference levels, and limits expressed in effective dose and applied to all workers and all members of the public, together with optimisation, provides a pragmatic, equitable, and workable system of protection that does not distinguish on an individual basis. A distinction should be drawn between the use of scientific information to construct a workable and acceptable protection system and the provision of best scientific estimates of dose and risk to individuals and specific population groups.

(f) In medical applications, estimates of effective dose can be used for comparing doses from different diagnostic and interventional imaging modalities (e.g. computed tomography and nuclear medicine) and exposure techniques that give different spatial distributions of radiation within the body tissues. In this context, effective dose is used to provide a generic indicator for classifying different types of medical procedure into broad risk categories for the purpose of communicating risks to clinicians and patients. Effective dose is also used to inform decisions on justification of patient diagnostic and interventional procedures, planning requirements in research studies, and evaluation of unintended exposures. In each of these cases, effective dose provides an approximate measure of possible detriment. Thus, effective dose can be used prospectively as an indicator of radiation detriment in justification decisions and when planning medical research studies involving radiation exposure, or retrospectively in assessments of accidental exposures. However, measurable quantities are used directly in applications comparing doses from particular procedures in different health centres, including the setting of diagnostic reference levels and in maintenance of patient records.

(g) Bearing in mind the uncertainties associated with risk projection to low doses or low dose rates, effective dose may be considered as an approximate indicator of possible risk, recognising also that lifetime cancer risk varies with age at exposure, sex, and population group. For medical procedures or other situations in which a single organ receives the majority of the dose, such as the breast in mammography or the thyroid from therapeutic administration of radioiodine, mean absorbed doses to the tissues of interest should be used rather than effective dose. In considering doses to patients with diseases with poor prognoses, life expectancy will be a consideration in evaluating radiation risks. The use of effective dose as an approximate indicator of possible risk is not a substitute for a risk analysis using best estimates of organ/tissue doses; appropriate information on the relative effectiveness of different radiation types; and age-, sex-, and population-specific risk factors, with consideration of uncertainties.

(h) Collective effective dose is a valuable tool in the optimisation of protection of workers and the public. It can be used, together with the distribution of individual doses, to inform decisions on the optimum balance between relatively large exposures of a few workers and smaller exposures of a larger number of workers. For public exposures, it can be used as part of the optimisation process for planned, existing, and emergency exposure situations. For occupational, public, and medical exposures, it has been used in comparisons of exposure levels in different countries and changes in dose levels with time (e.g. UNSCEAR, 2008; NCRP, 2019). Its use to predict potential/possible health effects may be useful in particular circumstances – for example, to inform judgements on the need for medical or epidemiological follow-up – but should be treated with caution and judged in relation to background morbidity rates, with consideration of the distribution of doses in time and space, and uncertainties in dose and risk estimation. The computation of numbers of cases of cancer based on collective effective doses involving extremely low exposures to very large populations should be avoided. Due to the large uncertainties associated with such estimates, the results will be more misleading than informative. The Commission has given advice on the use of collective dose as a tool for optimisation of protection in *Publication 101* (ICRP, 2006), taking account of the need to disaggregate doses when necessary to allow separate consideration of homogenous parts of the dose distribution in time and space.



# 1. INTRODUCTION

(1) The system of radiological protection requires dose quantities to set limits to prevent tissue reactions and dose criteria (limits, constraints, reference levels) to optimise protection from stochastic effects. The Commission uses absorbed dose, equivalent dose, and effective dose for these purposes as described in the 2007 Recommendations (ICRP, 2007a). In addition to these quantities, committed dose and collective dose are also used. The Commission provides dose coefficients for circumstances of exposure of workers, members of the public, and patients. The International Commission on Radiation Units and Measurements (ICRU) has defined operational quantities for occupational exposures to external sources that are measurable quantities providing reasonable estimates of the ICRP protection quantities. Detailed guidance on the use of dose quantities in radiological protection is provided in *Publication 103* (ICRP, 2007a). The purpose of this publication is to consolidate and expand the explanations provided previously, but also to clarify the use of dose quantities in relation to risks to health, reaching conclusions that go beyond the advice given in *Publication 103*.

(2) Effective dose was introduced in the 1990 Recommendations (ICRP, 1991a), although the original concept of the use of a single quantity for the control of occupational and public exposures to external and internal sources of radiation dates back to the 1977 Recommendations (ICRP, 1977). Its use has been extended to members of the public of all ages, and in-utero exposures of the fetus (ICRP, 2001, 2003a, 2012b). In addition, it is widely used in medical applications for which the primary requirement is for estimates of detriment, mainly from cancer, for the purpose of understanding the implications of different diagnostic modalities.

(3) The ICRP protection quantities – equivalent dose and effective dose – enable the summation of doses from external sources and from internal emitters to provide a single number for comparison with dose limits, dose constraints, and reference levels that relate to potential stochastic effects of uniform whole-body radiation exposure; that is, risks of developing cancer and of heritable effects. The primary application of effective dose is in the planning of protection, and demonstration of compliance in various situations of exposure of workers and members of the public. The calculation of effective dose can be seen as a three-step process, starting with the mean absorbed dose to organs and tissues [in grays (Gy),  $\text{J kg}^{-1}$ ]. As radiation types differ in their ability to cause biological effects including cancer, the second step is to multiply the calculated values of absorbed dose by radiation weighting factors that take account of the greater effectiveness of densely ionising radiations, including alpha particles and neutrons, compared with sparsely ionising beta particles and gamma rays. The result is termed ‘equivalent dose’ [in sieverts (Sv)]. The final step is to sum the equivalent doses to individual organs and tissues, multiplying each by a tissue weighting factor that represents its contribution to total detriment from uniform whole-body irradiation. Thus, effective dose is a doubly weighted average of organ/tissue absorbed doses. The intention is that the overall risk per Sv should be comparable irrespective of the type and distribution of radiation exposure; effective

dose, expressed in Sv, is the well-known quantity in radiological protection that is often referred to simply as ‘dose’.

(4) *Publication 103* (ICRP, 2007a) provided detailed explanation of the purpose and use of the ICRP protection quantities. However, experience has shown the need for further clarification and guidance, with identified issues including the following:

- Confusion between equivalent dose and effective dose expressed in the same units (Sv) when they are not distinguished carefully, particularly when considering doses from internal emitters that concentrate in specific organs, such as  $^{131}\text{I}$  (Gonzalez et al., 2013) (see Section 3.3, Para. 42).
- The use of equivalent dose in setting limits for the avoidance of tissue reactions in the cases of irradiation of the hands and feet, lens of the eye, and skin; that is, limits set below thresholds for the occurrence of acute damage to organs and tissues, with different limits for workers and members of the public (see Section 2.2).
- Confusion between operational quantities used to measure exposures to external sources and the protection quantities: specifically between dose equivalent (the measured quantity for external radiation used as an estimate of effective dose) and equivalent dose (an intermediate quantity in the calculation of effective dose) (see Sections 2.2, 3.3, and 3.8).
- Apparent inconsistencies in the setting of radiation weighting factors, with a simple approach for all low-linear energy transfer (LET) radiations and alpha particles but greater complexity for neutrons, and the use of a different weighting approach using quality factor for the operational quantities (see Section 3.3).
- The use of a single set of tissue weighting factors in the calculation of effective dose for all age groups and both sexes, despite recognised age-, sex-, and population-related differences in cancer risks (see Sections 2.5, 3.4, and 4.2, Para. 81).
- The calculation of effective dose for a sex-averaged Reference Person rather than separately for males and females, and for children as well as adults, and confusion between Reference Person and Representative Person (see Sections 3.6 and 4.2, Paras 79, 80).
- The dose range over which effective dose is applicable, particularly in considering higher exposures that may occur in accidents that may involve high absorbed doses to individual organs/tissues (see Section 3.4).
- The apparent conservatism of calculating committed dose from internal emitters; that is, dose integrated over a 50-year period for adults and to 70 years of age for children (ICRP, 2007a) (see Section 3.5).
- The calculation of effective dose to the fetus following maternal exposures to internal emitters (see Sections 3.6 and 4.2).
- The use of effective dose to estimate risks, particularly in evaluating exposures of patients from medical procedures (see Section 5).
- The use of collective effective dose to evaluate risks to population groups (see Section 3.7).

(5) Section 2 of this publication summarises information on tissue reactions and stochastic effects resulting from radiation exposures, updating *Publication 103* (ICRP, 2007a); explains the methodology adopted to derive detriment-adjusted nominal risk coefficients and the tissue weighting factors used in the calculation of effective dose; and provides more information than presented in *Publication 103* on variations in estimates of lifetime excess cancer risk with age at exposure and between sexes. Section 3 presents and discusses absorbed dose, equivalent dose, and effective dose, and also discusses committed and collective dose, and the ICRU operational quantities. Section 4 considers the application of dose quantities in the evaluation and control of exposures of workers and members of the public in planned, existing, and emergency exposure situations. Section 5 examines the use of dose quantities in medicine, and the use of effective dose as an approximate indicator of possible risk.



## 2. HEALTH EFFECTS AND DETRIMENT

### 2.1. Categories of radiation effects

(6) *Publication 103* (ICRP, 2007a) provides detailed explanations of the judgements made, and approaches taken, regarding the quantification of radiation risks for radiological protection purposes. A distinction has been made between two major classes of health effects:

- Tissue reactions (deterministic effects – impairment of organ/tissue function occurring above dose thresholds, with severity increasing with increasing dose.
- Stochastic effects (cancers and heritable diseases – predominantly the risk of cancer occurring in exposed populations, with increasing frequency (but not severity) with increasing dose, and assuming that there is no threshold below which there is no risk.

### 2.2. Tissue reactions (deterministic effects)

(7) *Publication 103* (ICRP, 2007a) made no changes to previously recommended annual dose limits for tissue reactions in relation to planned exposure situations, set in terms of equivalent dose, of 150 mSv for the lens of the eye and 500 mSv for skin and the hands and feet for occupational exposures, and 15 mSv for the lens of the eye and 50 mSv for skin for public exposures. However, there was accumulating evidence that the lens of the eye may be more sensitive to induction of opacities than indicated by earlier data (Neriishi et al., 2007; Worgul et al., 2007). *Publication 118* (ICRP, 2012a) provided a comprehensive review and analysis of tissue reactions caused by radiation that confirmed the judgements made in *Publication 103* (Annex A) regarding threshold doses in most cases. However, more recent epidemiological data reviewed in *Publication 118* suggested a lower threshold for induction of lens opacities of approximately 0.5 Gy compared with the values given in *Publication 103* of 2 Gy for acute exposures and 4–5 Gy for fractionated and protracted exposures. The available data suggested that acute and protracted exposures were similarly effective and were consistent with the assumption of a non-threshold relationship as well as a threshold of approximately 0.5 Gy (ICRP, 2012a; Bouffler et al., 2015). In response to this evidence, the Commission (ICRP, 2012a) issued a statement on tissue reactions recommending that the annual limit on equivalent dose to the lens of the eye for occupational exposures should be reduced to 20 mSv, averaged over 5 years with dose in any year not exceeding 50 mSv.

(8) Judgements on the risks of cataract are based largely on epidemiological studies of the effects of external exposures to gamma rays (Ainsbury et al., 2009; ICRP, 2012a). In general, there is limited information available that can be used to compare the effectiveness of radiations of different qualities in causing tissue reactions (Hamada and Sato, 2016). However, the available data indicate that differences

between radiation types (e.g. alpha particles and neutrons relative to gamma rays) in their effectiveness per Gy in causing tissue reactions are smaller than differences in their effectiveness in relation to cancer induction (ICRP, 1990, 2003b).

(9) The Commission considers that instead of using equivalent dose to set limits to prevent tissue reactions, the more appropriate quantity is absorbed dose. This change will draw a clear distinction between limits applying to tissue reactions, set in absorbed dose (Gy), and those applying to stochastic effects, set in effective dose (Sv). The Commission expects to introduce this change at the time of its next general recommendations. The limits for the lens of the eye (cataract), skin, and hands and feet are relevant mainly to circumstances of exposure to penetrating low-LET radiations. However, exposures to neutrons and other high-LET radiations may require consideration in some situations, and it may then be necessary to take account of increased effectiveness per Gy compared with low-LET radiation. Consideration will therefore be given to radiation weighting for tissue reactions (see also Section 3.3). The anticipated change is consistent with the approach taken by the US National Council on Radiation Protection and Measurements (NCRP, 2018) and proposals from ICRU for changes to operational quantities (Sections 3.3 and 3.8).

(10) *Publication 118* (ICRP, 2012a) concluded that a threshold dose as low as 0.5 Gy may apply to circulatory diseases; that is, cardiovascular and cerebrovascular diseases caused by doses delivered to the heart and brain, and associated tissues. The statement on tissue reactions (ICRP, 2012a) drew attention to the need for medical practitioners to be aware, as patient doses of this magnitude could be reached during some complex interventional procedures. The meta-analysis of epidemiological data by Little et al. (2012) suggested that a linear non-threshold (LNT) dose–response relationship could be applied, resulting in risks at low doses or low dose rates of a similar magnitude to those inferred for cancer detriment at low doses or low dose rates (Little, 2016). However, the National Council on Radiation Protection and Measurement (NCRP) (2018) concluded from a review of human studies that there is insufficient evidence that absorbed doses  $\leq 0.5$  Gy to the heart cause cardiovascular diseases (NCRP, 2018). The Commission will continue to review scientific developments that inform judgements on whether circulatory disease should be included as a component of low dose or low dose rate detriment, but further mechanistic understanding is required to determine whether stochastic processes are involved in the development of radiation-induced circulatory disease (Hendry, 2015).

### 2.3. Stochastic effects (cancers and heritable diseases)

(11) The main stochastic effect of radiation is cancer, with the principal source of information on risk being the epidemiological studies of the Japanese survivors of the atomic bombings at Hiroshima and Nagasaki, although with important information also coming from other studies (ICRP, 2007a; UNSCEAR, 2008; NCRP, 2018). In general, the epidemiological data show a linear dose–response relationship between cancer rates and absorbed dose from gamma rays from approximately

100 mGy to a few Gy. Attempts are being made to extend observations to lower doses or lower dose rates, notably studies on large worker cohorts (Muirhead et al., 2009; Leuraud et al., 2015; Richardson et al., 2015, 2018; Sokolnikov et al., 2015; Kuznetsova et al., 2016; Haylock et al., 2018) and studies of children receiving computed tomography (CT) scans (Pearce et al., 2012; Mathews et al., 2013; Huang et al., 2014; Journy et al., 2015; Berrington de Gonzalez et al., 2016; Meulepas et al., 2019). The CT studies reported some statistically significant elevation of cancer rates at doses of a few tens of mSv. However, caution has been advised in the interpretation of these studies (Walsh et al., 2013, 2014; Boice, 2015). A number of problems were identified, including lack of information on the reasons for the scans, and lack of individual dose reconstruction. It is considered that the patients may well have had undetected cancers that prompted their CT examinations (an example of reverse causation), or factors that predispose to cancer may have led to medical conditions that require CT scans (an example of confounding by indication) (UNSCEAR, 2013; Walsh et al., 2013, 2014; Boice, 2015).

(12) A number of assumptions and judgements are made in quantifying low dose or low dose rate cancer risks (ICRP, 2007a). Based on epidemiological analyses from the 1990s, a dose and dose rate effectiveness factor (DDREF) of 2 was applied to the solid cancer risks derived from the atomic bomb survivor studies. Currently, epidemiology provides limited evidence of a DDREF >1 for solid cancer in humans, although analyses continue (Rühm et al., 2016; Shore et al., 2017), but animal and in-vitro data indicate curvilinear dose–response relationships that provide some support for the use of a DDREF >1. As discussed in *Publication 131* (ICRP, 2015c), the component factors, dose effectiveness factor and dose-rate effectiveness factor, may be considered to be mechanistically distinct, with the former applying to low acute doses, and the latter applying to protracted doses for which long-term kinetics of target stem cells may modify responses. For leukaemia, the atomic bomb survivor data are consistent with the use of a linear-quadratic dose–response relationship, with the dose–response being linear at doses <0.1 Gy. Having obtained cancer risk estimates for exposures at low doses of a few tens of mGy, an LNT dose–response relationship is assumed. This LNT dose–response assumption is considered to represent a prudent interpretation of current evidence including mechanistic understanding of radiation-induced cancer at low doses or low dose rates (Preston et al., 2003, 2007; ICRP, 2007a; UNSCEAR, 2012b). In a review of all relevant epidemiological studies, NCRP (2018) concluded that current epidemiological data support the continued use of the LNT dose–response relationship for radiological protection purposes, with no other model representing a more pragmatic or prudent interpretation.

(13) The LNT dose–response assumption underpins the use of effective dose as a protection quantity, allowing the addition of external and internal doses of different magnitudes, with different temporal and spatial patterns of delivery. However, it should be recognised that while low doses may be measured or estimated with reasonable reliability, the associated cancer risk is uncertain, and becomes increasingly uncertain as dose decreases.

(14) *Publication 103* (ICRP, 2007a) notes that there is no reliable direct evidence from human epidemiological studies of deleterious heritable effects of radiation, but considers the inclusion of heritable risk in overall stochastic risks to be a prudent interpretation of evidence of heritable effects in experimental animals. Following a detailed analysis by UNSCEAR (2001) and ICRP (2007a), estimates of heritable risk over two generations have been applied in calculations of radiation detriment.

## 2.4. Nominal risk coefficients and detriment

(15) Annex A of *Publication 103* (ICRP, 2007a) explains the methodology applied to calculate nominal risk coefficients for radiation-induced stochastic health effects and associated values of detriment. Detriment is a concept used to quantify the harmful effects on health of radiation exposures at low doses or low dose rates, taking account of the severity of disease in terms of lethality, quality of life, and years of life lost. The steps in the calculation are outlined in Annex A of *Publication 103* and summarised here. The Commission is preparing a separate report that examines the calculation of detriment, and considers sensitivity to assumptions made in the calculations.

(16) Largely using analyses of follow-up data on the Japanese atomic bomb survivors, male and female lifetime excess cancer risks were estimated for 14 organs or tissues, using both excess relative risk (ERR) and excess absolute risk (EAR) models. Lifetime risk estimates were adjusted downward by a factor of 2 to account for a DDREF, except for leukaemia, for which a linear-quadratic model for risk was used. For each specified organ or tissue, a weighting of the ERR and EAR lifetime risk estimates was established based on judgments on the relative applicability of the two models; for example, ERR:EAR weights of 0:100% were assigned for breast, 100:0% for thyroid, 30:70% for lung, and 50:50% for other cancers. The resulting risk estimates were averaged across selected Asian and Euro-American populations, and between sexes to provide the nominal risk coefficients given in Table 2.1. The Asian population is a composite of the populations covered by the cancer registries for China (Shanghai) and Japan (Osaka, Hiroshima, and Nagasaki), and the Euro-American population is a composite of the populations of cancer registries from Sweden, the UK, and the USA (Surveillance, Epidemiology, and End Results Program).

(17) Lifetime excess risks of cancer incidence were adjusted for fatality by multiplying by lethality fractions derived from cancer survival data. A further adjustment was applied to account for the morbidity and suffering associated with non-fatal cancers. As cancer types differ in their age at onset and the consequent number of years of life lost, a weighting factor was applied to adjust for this difference. The cancer detriment values resulting from these calculations and estimated risks of heritable effects from irradiation of the gonads are shown in Table 2.1. The forthcoming report on detriment calculations will provide further details, clarifying the description given in *Publication 103* (ICRP, 2007a).