NCRP DRAFT CC 1 Report

Council Review Draft (6-20-17)

RADIATION PROTECTION GUIDANCE FOR THE UNITED STATES (2018)

June 2017

Note: Copyright permission is being sought for the figures and tables requiring such permission prior to their use in the final NCRP publication.

National Council on Radiation Protection and Measurements

7910 Woodmont Avenue, Suite 400, Bethesda, Maryland 20814

Preface

In the first quarter of 2014, a proposal to write a National Council on Radiation Protection and Measurements (NCRP) report on *Radiation Protection Guidance for the United States* was approved by the Board of Directors. Council Committee 1 (CC 1) was formed in the second quarter of 2014. The current Report updates and expands on Report No. 116, *Radiation Protection Guidance for the United States* (NCRP, 1993a). The first meeting of CC 1 was held on September 3-4, 2014.

Since NCRP (1993a) was published, substantial advances in ionizing radiation effects knowledge, particularly for cancer, as well as radiation protection understanding and culture, have occurred. In addition, noncancer effects such as cardiovascular disease and cataracts are emerging as potentially important concerns. A discussion of basic ethical principles and their application to radiation protection had not been introduced in NCRP (1993a), and the severity of health outcomes had not been addressed in a context of radiation protection. The Fukushima nuclear reactor accident and the potential for a nuclear or radiological incident in the United States, as well as the increase in population exposure to medical use of radiation (particularly computed tomography examinations, positron emission tomography scans, and nuclear medicine procedures) have increased the awareness of the importance of radiation protection guidance in the United States.

In 2007, the International Commission on Radiological Protection (ICRP) published an update of their recommendations (Publication 103) (ICRP, 2007a). Subsequently an important ICRP report on tissue reactions (previously called deterministic effects) and noncancer effects was published (Publication 118) (ICRP, 2012). While the goals for radiation protection in the United States are the same as those for the international community, there are some differences in the specific approaches taken to achieve these goals [*i.e.*, in implementing the three principles of radiation protection: justification; the as low as reasonably achievable (ALARA) principle (optimization of protection), and control of dose to an individual] (Kase, 2016). These differences are discussed in this Report.

Council Committee 1 considered numerous radiation protection issues that are discussed in the Report at the relevant locations. There is overall consistency between the current NCRP guidance for the United States in this Report and international radiation protection guidance. Where the NCRP guidance is unique or has adapted the international guidance for the United States, the rationale is given for the differences.

Notably, two Scientific Committees were formed to assist in the development of this Report, one on *Guidance on Radiation Dose Limits for the Lens of the Eye* (NCRP, 2016a) and the other on *Implications of Recent Epidemiologic Studies for LNT and Radiation Protection* (NCRP, 2017a)

Unique aspects of the manner in which CC 1 operated include:

- It was the first Committee formed under the direct oversight of the NCRP Council as opposed to oversight by one of the NCRP Program Advisory Committees (PACs).
- All the PACs participated in the development and review of the recommendations.
- The 2015 NCRP Annual Meeting was on "Changing Regulations and Radiation Guidance: What Does the Future Hold?" and addressed the rulemaking activities ongoing within the U.S. Nuclear Regulatory Commission (NRC), U.S. Environmental Protection Agency (EPA) and U.S. Department of Energy (DOE) for which the CC 1 guidance should prove useful (Cool, 2016).
- An extensive effort was made to consult with and present to numerous national and international stakeholder groups during both the development and review phases of this work, including to name just a few: ICRP, the International Radiation Protection Association (IRPA), the Health Physics Society (HPS), the Radiation Research Society (RRS), the American Association of Physicists in Medicine (AAPM), and the American College of Radiology (ACR).

This Report was prepared by Council Committee 1 (CC 1) on Radiation Protection Guidance for the United States. Serving on Council Committee 1 and the PAC Advisors were:

Kenneth R. Kase, Co-Chair

Medford, Oregon

Donald A. Cool, Co-Chair
Electric Power Research Institute
Charlotte, North Carolina

Members

Armin Ansari
Centers for Disease Control and Prevention
Atlanta, Georgia

John D. Boice, Jr.
National Council on Radiation Protection and Measurements
Bethesda, Maryland

Jerrold T. Bushberg
U.C. Davis School of Medicine
Sacramento, California

Lawrence T. Dauer
Memorial Sloan Kettering Cancer Center
New York, New York

Darrell R. Fisher
Versant Medical Physics and Radiation Safety
Richland, Washington

Patricia A. Fleming
Saint Mary's College
Notre Dame, Indiana

Kathryn Higley
Oregon State University
Corvallis, Oregon

Randell N. Hyer
Center for Risk Communication
Stevensville, Maryland

William E. Irwin
Vermont Department of Health
Burlington, Vermont

Fred A. Mettler, Jr.
Albuquerque, New Mexico

Donald L. Miller
Food and Drug Administration
Rockville, Maryland

R. Julian Preston
Chapel Hill, North Carolina

Gayle E. Woloschak
Northwestern University
Chicago, Illinois

Consultants

S. James Adelstein
Harvard Medical School
Boston, Massacusetts

Ralph L. Andersen
Burke, Virginia

Michael A. Boyd
U.S. Envirnonmental Protection Agency
Washington, D.C.

PAC 7 Liaison

John E. Till
Risk Assesssment Corporation
Neeses, South Carolina

PAC Advisors

Gayle Woloschak (PAC 1)
Kathryn H. Pryor (PAC 2)
Tammy P. Taylor (PAC 3)
James A Brink (PAC 4)
S.Y. Chen (PAC 5)
Steven l. Simon (PAC 6)
Randell N. Hyer (PAC 7)

NCRP Secretariat

Marvin Rosenstein, Staff Consultant
Cindy L. O'Brien, Managing Editor
Laura J. Atwell, Office Manager
David A. Smith, Executive Director (2014 - 2016)
Kathryn D. Held, Executive Director and Chief Science Officer (2016 -)

NCRP expresses appreciation to the Committee members for the time and effort devoted to the preparation of this Report. NCRP would also like to thank the many colleagues not on the Committee, and some not on the Council, who provided critical reviews and guidance in a very timely manner when asked about specific areas of the Report. NCRP also gratefully acknowledges the financial support provided by the U.S. Nuclear Regulatory Commission (NRC) under Grant No. NRC-HQ-60-14-G-0012 and the Centers for Disease Control and Prevention (CDC) under Grant No. 5UE1EH000989. The contents of this Report are the sole responsibility of NCRP, and do not necessarily represent the views of NRC or CDC.

John D. Boice, Jr.
President

Contents

Executive Summary

The purpose of this Report is to provide recommendations of the National Council on Radiation Protection and Measurements (NCRP) to guide the control of exposures to ionizing radiation for the United States. The goal of the recommendations is to adequately protect potentially exposed humans and nonhuman biota (*i.e.*, animal and plant life) against adverse health effects known to be associated with such radiation exposure, without unnecessarily limiting the benefits to humans that may result from such exposure. The recommendations are designed to prevent the occurrence of serious acute and chronic radiation-induced tissue reactions in humans or nonhuman biota, and to reduce the probability of stochastic effects (primarily cancer) in radiation-exposed persons in relation to the benefit to the individual and to society from the activities that generate such exposures.

This Report is primarily to advise Federal and State agencies responsible for the health and well-being of workers and the public related to exposures from ionizing radiation as well as those with responsibility for protecting nonhuman biota from such sources.

In addition to the knowledge of human biological effects of ionizing radiation, the system of radiation protection and its radiation protection principles are informed by accepted ethical principles, experience gained in the use and management of radioactive materials and radiation-producing devices, and experience with approaches to the protection of individuals from adverse health effects resulting from radiation exposures.

The two primary dose quantities used in the specific recommendations for control of dose[1] to an individual in this Report are:

- Absorbed dose in a specified organ or tissue when the recommendation to control dose to an individual is for the purpose of avoiding acute or chronic tissue reactions (deterministic effects); and

[1] Dose is a general term used when the context is not specific to a particular dose quantity. When the context is specific, the name for the quantity is used (*e.g.*, absorbed dose, organ dose, effective dose, equivalent dose).

- Effective dose when the recommendation to control dose to an individual is for the purpose of controlling the overall potential for stochastic health effects for all organs and tissues in humans.

The previous recommendations for radiation protection in the United States were published in Report No. 116 (NCRP, 1993a). The recommendations in this Report supersede the NCRP (1993a) recommendations and cover sources and types of exposures that were not addressed in NCRP (1993a). These sources and types of exposure include:

- patients exposed in medical-imaging procedures and radiation therapy;
- comforters and caregivers for patients during medical-imaging procedures or being treated with radioactive materials;
- voluntary participants in biomedical research exposed to ionizing radiation;
- workers and the general public exposed to elevated levels of naturally-occurring radioactive materials including those enhanced by technology;
- emergency workers recruited by a responsible authority during a declared emergency involving radiation or radioactive material; and
- nonhuman biota (*e.g.*, plants and animals) exposed to elevated levels of ionizing radiation in the environment due to human activity (anthropogenic elevated levels).

This Report emphasizes the importance of the ethical bases supporting the three basic NCRP principles of radiation protection [*i.e.*, justification, the ALARA principle (optimization of protection), and control of dose to an individual[2]].

NCRP recommendations focus on the *prevailing exposure situation* (*i.e.*, the particular exposure situation occurring at the time) to provide protection through use of recommendations for control of dose to an individual and application of the ALARA principle.

[2] The term "control of dose to an individual" refers to specific numeric values of a dose quantity recommended by NCRP.

The ALARA principle [referred to as optimization of protection in ICRP (2007a)] is always to be applied. In this Report, the ALARA principle is applied to the various recommendations on control of dose to an individual in the following manner:

- In all prevailing exposure situations, the recommendation to control dose to an individual provides initial guidance for the application of the ALARA principle by the responsible or designated party.
- For certain prevailing exposure situations, in which the source is stable, characterized, and subject to an advance control program[3] by the responsible organization, the NCRP recommendation for control of dose to an individual may be designated as a dose limit (in the regulatory sense). Appropriate cases are noted in Section 6.

The responsibility of NCRP is to provide recommendations for radiation protection that best serve the United States, recognizing the legislative mandates that govern use of radiation and radioactive materials in the United States. Differences from international recommendations are made in support of fulfilling this responsibility. It is the NCRP's judgment that such differences in this Report primarily reflect U.S. experience with implementing radiation protection, NCRP evaluation of the latest available information, recognition of the primacy of the ALARA principle in the United States, and the need to facilitate understanding and acceptance in the United States of the recommendations in this Report.

Each recommendation for control of dose to an individual in this Report is based on the prevailing exposure situation, which is characterized by the:

- Nature of the source;
- Individuals exposed;
- Circumstances of exposure; and
- Ability of those with authority to control the:

[3] For a prevailing exposure situation in which the source is deliberately and intentionally introduced, an advance control program is the set of radiation protection programs intended to control exposure of an individual that is put in place by the responsible organization before the introduction of the source.

- source of radiation; and
- actions of the persons at risk of exposure.

Within the United States there is a well-established legislative and regulatory framework that requires consideration of potential impacts on the environment as a part of decision-making for significant actions. Therefore, with regard to protection of the environment, expressed in this Report as radiation protection for nonhuman biota, NCRP presents guidance in support of the existing National Environmental Policy Act (NEPA, 1969)

The judgments on the potential for radiation-induced health effects and other conclusions that underlie the decisions and specific recommendations for application of the fundamental NCRP radiation protection principles of justification, the ALARA principle (optimization of protection), and control of dose to an individual are listed here. Each judgment and conclusion is **highlighted and bolded** where it appears in this Report. The judgments and conclusions are followed by a listing of the recommendations for control of dose to an individual. Each of these recommendations is **shown in a box in bolded text** in Section 6. These two listings are all for human exposure. These two listings are then followed by corresponding statements for nonhuman biota. The statements for nonhuman biota are also identified in this Report as above. For each item in the three listings, the subsection in this Report where the statement appears and is discussed is noted. The statement should not be read in isolation. *The reader should consult the **indicated subsection** for a more complete explanation and further information.*

Underlying Judgments and Conclusions (Human Exposure):

- The ethical approach of NCRP is rooted in an extended anthropocentrism, placing protection of humans as a priority in which the protection of nonhuman biota is subject to human valuing for the prevailing exposure situation. **(2.1)**
- NCRP adopts the use of the ethical principles of doing good, avoiding harm, being just and respecting the autonomy of individuals in making decisions on radiation protection, particularly in circumstances and situations that present inherent conflicts in interests. NCRP also recognizes the need to use the virtue of practical wisdom in radiation protection. **(2.2.3)**

- The system of radiation protection presented in this Report is used to control exposure to radiation and radioactive materials in the United States to ensure adequate protection of humans and nonhuman biota while allowing for activities that are beneficial for human development. **(3)**
- The NCRP system of radiation protection is applied as appropriate to each prevailing exposure situation. **(3.1)**
- The following categories of exposure: occupational, public, medical, emergency worker, and nonhuman biota, are used to identify the individuals or other entities receiving radiation exposure. **(3.2)**
- The NCRP radiation protection principles of justification, the ALARA principle (optimization of protection), and control of dose to an individual provide a coherent and systematic approach to addressing exposure of humans. **(3.3)**
- Actions to add, increase, reduce, or remove a source of exposure to humans requires justification (*i.e.*, the action does more good than harm). All factors, both radiological and non-radiological, and particularly the economic, societal, psychological, and environmental implications (including to nonhuman biota), need to be considered in that justification. **(3.3.1)**
- In medical exposure of patients, justification includes a determination of the appropriate medical-imaging or treatment procedures. **(3.3.1.2)**
- The likelihood of incurring exposures, the number of individuals exposed, and the magnitude of the dose to an individual should be kept as low as reasonably achievable (ALARA), taking into account societal, economic, and environmental factors (the ALARA principle). The ALARA principle applies in all exposure situations. The ALARA principle is satisfied when the expenditure of further resources would be unwarranted by the reduction in exposure that would be achieved. **(3.3.2)**
- The ALARA principle (optimization of protection) applied to medical exposure of the patient is best described as management of the radiation dose to the patient to be commensurate with the medical purpose. **(3.3.2.3)**
- The ALARA principle for medical exposure to patients from imaging procedures using ionizing radiation takes into account both patient dose and image quality. Diagnostic

Reference Levels (and achievable doses) are tools for this purpose, but are neither limits nor absolute determinants of appropriate use of medical radiation. Diagnostic Reference Levels (and achievable doses) are not to be used for regulatory or commercial purposes or to establish legal standards of care. **(3.3.2.3)**

- Recommendations for control of dose to an individual given in Section 6 are specific for a prevailing exposure situation. **(3.3.3)**
- The responsible organization selects and uses values of dose to an individual, less than or equal to the relevant NCRP recommendation for control of dose to an individual for a prevailing exposure situation, to establish the range of acceptable options for applying the ALARA principle to that particular exposure situation. **(3.3.3)**
- For a prevailing exposure situation in which the source is stable, characterized, and subject to an advance control program by the responsible organization, NCRP recognizes that its recommendation for control of dose to an individual may be appropriate as a dose limit (in the regulatory sense). **(3.3.3)**
- Use of the NCRP recommended control on dose to a member of the public from continuous or reasonably anticipated operation of a source as a dose limit is appropriate only for sources under the control of a specified entity, and only in a prevailing exposure situation in which the source is stable, characterized, and subject to an advance control program by the responsible organization. Appropriate cases are noted in Section 6. **(3.3.3.2)**
- A radiation protection culture is fostered to effectively implement a radiation protection program commensurate with the radiation protection significance of an organization's nature, activities and functions. **(3.3.4)**
- For the system of radiation protection, NCRP uses the same nominal radiation detriment-adjusted risk coefficients for cancer and heritable effects as ICRP (2007a). **(5.2)**
- Quantitative assessment of risk from radiation exposure of an individual or population cannot be inferred from the effective dose. In addition, recommendations for control of effective dose to an individual established for radiation protection purposes are not interpreted as threshold levels at which stochastic health effects may or may not occur, nor as distinguishing between "safe" versus "unsafe" exposures. **(5.3.1)**

- In this Report, NCRP adopts a DDREF of 2 for radiation protection purposes. This value is consistent with the recommendation of ICRP (2007a). **(5.3.2)**
- Recommendations for control of dose to an individual are used in conjunction with the ALARA principle to establish adequate protection for an individual. When it is appropriate to apply one of these recommendations as a dose limit (in the regulatory sense), that is stated. **(6.1)**
- Control of radiation exposure for stochastic effects is based on application of the ALARA principle, in conjunction with the appropriate recommendation for control of dose to an individual. **(6.3)**
- NCRP recommendations for public exposure are intended to foster a coherent, *graded approach* to protection based on the prevailing exposure situation, and, in particular, whether the exposure is caused by a source whose introduction was intended and for which radiation protection programs and controls can be put in place in advance (referred to as an *advance control program*). If the prevailing exposure situation has not been previously subject to an advance control program, a higher effective dose for a member of the public may be necessary until an appropriate implementation of the ALARA principle can become effective. **(6.5.1)**
- There is a systematic, graded approach to control of radioactive material in the environment not previously subject to control, based on characterization of the exposure conditions, the level of dose received by individuals, and the possibilities for taking action to reduce exposures. **(6.5.2)**
- The radiation exposure an individual volunteer receives in the course of participating in a biomedical research study that would not have been received otherwise is considered separately from that received as a patient in the normal course of medical diagnosis or treatment. A suggested classification scheme for use of effective dose as a qualitative indicator of stochastic risk for biomedical research studies is provided in Table 6.6. **(6.6.3)**
- Emergency workers engaged in life-saving activities or actions to prevent a catastrophic situation are not subject to radiation dose limitation. Decisions on emergency worker actions are based on the totality of the prevailing exposure situation, where other risks may present a

474 greater risk than does the radiation exposure, and where one person may save many other
475 lives. **(6.7)**

476 • Incident commanders, incident managers and other decision makers need to be provided pre-
477 incident guidance and training sufficient to effectively inform their determination that
478 emergency workers be allowed to conduct specific life-saving actions. **(6.7)**

479 • Emergency workers who receive a dose in excess of the occupational recommendation for
480 control of dose to an individual are not precluded from returning to work provided that the
481 emergency work is done voluntarily and the individual receives counseling from radiation
482 protection and medical personnel regarding the consequence of such exposure. **(6.7)**

483 • Based on a comprehensive review of recent epidemiologic studies of irradiated populations,
484 NCRP (2017a) reaffirms that, for identified stochastic effects, the linear non-threshold model
485 for dose-response be used for radiation protection purposes as a prudent and practical tool for
486 managing potential radiation risks below an effective dose of 100 mSv. **(B.4.2)**

487 • The sensitivity of the embryo and fetus to radiation is considered when making protective
488 guidance specifically for occupationally-exposed pregnant females. **(B.4.5.2)**

489 • Specific radiation-related genetic susceptibilities are not incorporated into radiation risk
490 estimates for populations. Where such deleterious genetic susceptibilities can be identified at
491 the individual level, consideration would be given to appropriate dose levels for treatment or
492 imaging regimes for that individual. **(B.6)**

493 • There is not yet sufficient evidence in human studies or animal experiments that low to
494 moderate doses of radiation cause cardiovascular disease (CVD). At this time, no
495 recommendation is appropriate. Nevertheless, continued attention to the results of research
496 related to CVD at low and moderate doses is warranted. **(B.7)**

497 • Radiation effects on the central nervous system (CNS) are not considered a major factor in
498 evaluation of radiation protection. The possible exception is the exposure of crew members
499 in NASA space activities to high atomic number, high-energy particles during interplanetary
500 missions. **(B.8)**

501 • A threshold model for formation of lens opacities continues to be used for radiation
502 protection purposes. **(B.10)**

- Evaluation and additional research is needed to better evaluate radiation-induced cataracts: comprehensive evaluation of the overall effects of ionizing radiation on the eye, dosimetry methodology and dose-sparing optimization techniques, additional high-quality epidemiologic studies, and a basic understanding of the mechanisms of cataract development (NCRP, 2016a). **(B.10)**
- The recommendation to control dose to an individual from exposure of the skin (including the extremities) is designed to avoid clinically important adverse tissue reactions. **(B.11)**
- Psychosocial effects can be lessened by early communication of accurate and understandable information. **(B.12)**

Recommendations for Control of Dose to an Individual (Human Exposure):

- NCRP recommends, for occupational and public exposure, that the absorbed dose in the skin or extremities at a depth of 70 μm from any external source of irradiation not exceed 0.5 Gy annually, averaged over the most highly exposed 10 cm^2 of skin. This recommendation may be applied as a dose limit. **(6.2.1)**
- NCRP recommends the annual absorbed dose in the lens of the eye for occupational exposure not exceed 50 mGy. This recommendation may be applied as a dose limit. **(6.2.2)**
- NCRP recommends the annual absorbed dose in the lens of the eye for exposure to members of the public not exceed 15 mGy. **(6.2.2)**
- To avoid acute organ effects during emergency operations, NCRP recommends the absorbed dose in a significant portion of an organ or tissue not exceed 1 Gy. **(6.2.3)**
- NCRP recommends the annual effective dose to an individual from occupational exposure not exceed 50 mSv. This recommendation may be applied as a dose limit when the source is stable, characterized, and subject to an advance control program. **(6.4.1)**
- NCRP recommends the cumulative lifetime effective dose for an individual from occupational exposure not exceed 10 mSv multiplied by the individual's age in years. **(6.4.1)**
- NCRP recommends that for exposure of an individual under the age of 18 y in educational and occupational settings, the annual effective dose from all such activities in a year not exceed 1 mSv. **(6.4.1)**

- NCRP recommends the equivalent dose to the embryo and fetus not exceed 0.5 mSv per month due to occupational exposure of a pregnant worker once the pregnancy is declared by the pregnant worker. **(6.4.3)**
- The contribution of radon should be included if it comprises more than 20 % of the total occupational effective dose. **(6.4.4)**
- NCRP recommends the annual effective dose to a member of the public from the continuous or reasonably anticipated presence of a source not exceed 1 mSv. This recommendation may be applied as a dose limit, applicable to the source, when the source is stable, characterized, and subject to an advance control program. **(6.5.1)**
- NCRP recommends, for planning purposes, that the effective dose for a member of the public not exceed 20 mSv in the first year following identification of a prevailing exposure situation that was not previously subject to control. The annual effective dose for a member of the public for later years would be established based on application of the ALARA principle. **(6.5.1)**
- NCRP recommends that radon levels be assessed, and mitigation measures be taken when the air concentration of radon in homes and workplaces exceeds 300 Bq m^{-3}. **(6.5.3)**
- NCRP recommends the effective dose for comforters and caregivers of a patient (typically parents, other family members, or close friends) not exceed 5 mSv per episode. **(6.6.2)**
- NCRP recommends the effective dose for other patients, visitors to the medical facility, and staff who are not occupationally involved in providing medical care and who are not specifically trained in radiation protection not exceed 1 mSv per episode. **(6.6.2)**
- In exceptional situations, informed volunteer emergency workers may receive absorbed doses to an organ or tissue above the recommendation of 1 Gy noted in Section 6.2.3 to save lives or prevent the development of catastrophic conditions. **(6.7.2)**
- NCRP recommends that for urgent rescue activities during emergencies that do not involve lifesaving, the goal is to not exceed an effective dose of 500 mSv. **(6.7.2)**
- NCRP recommends that for extended activities during an emergency, following the initial lifesaving, rescue and damage control response, the goal is to not exceed an effective dose of 50 mSv. **(6.7.2)**

Underlying Judgments and Recommendation for Control of Dose (Exposure of Nonhuman Biota):

- For nonhuman biota, the consensus is to establish protective guidelines that focus on population maintenance. This goal is met through evaluation of the radiological impact on survival of species rather than protection of individual members of the species. **(B.14)**
- Within the system of radiation protection, the principle of justification and the ALARA principle (optimization of protection) are the features applicable to nonhuman biota. **(6.8)**
- An absorbed dose rate of 0.1 mGy d^{-1} is considered unlikely to have significant effects on nonhuman biota where existing conditions or proposed actions result in increased radiation levels. No additional evaluation would be considered necessary for organisms exposed below this absorbed dose rate. The 0.1 mGy d^{-1} absorbed dose rate is not to be viewed as a target for remediation, or that absorbed dose rates above this value automatically require remediation. **(6.8)**

1. Introduction

1.1 Purpose

The beneficial reasons for using sources of ionizing radiation (referred to as radiation throughout this Report) and radioactive materials have been recognized since the early days of the 20th century. The science and application of radiation protection has been based on the use of these sources for the benefit of humans and society.

The purpose of this Report is to provide recommendations of the National Council on Radiation Protection and Measurements (NCRP) to guide the control of exposures to ionizing radiation. The goal of these recommendations is to adequately protect potentially exposed humans and nonhuman biota (*i.e.*, animal and plant life) against adverse health effects known to be associated with such radiation exposure, without unnecessarily limiting the benefits to humans that may result from such exposure. The recommendations are designed to prevent occurrence of serious acute and chronic radiation-induced tissue reactions in humans and to reduce the probability of stochastic effects in radiation-exposed persons in relation to the benefit to the individual and to society from the activities that generate such exposures. For nonhuman biota, the goal is to establish a protective guideline that focuses on population maintenance.

Finally, this Report aims to:

- Provide the basis for its recommendations and the reasons for any changes from the previous recommendations in NCRP (1993a).
- Identify and explain differences from the recommendations in ICRP (2007a).
- State what is known and what is unknown about biological response to radiation, including new epidemiologic information and the significance relative to the recommendations.
- Explain the limitations of epidemiologic studies of radiation effects.
- Identify the uncertainties involved in assessing the risks of radiation health effects.
- Consider the ease of implementation of the recommendations.

- Specify the rationales for the recommendations that control dose to an individual.
- Explain the underlying ethical basis of the radiation protection guidance in this Report
- Introduce a framework for radiation protection of nonhuman biota.

1.2 Audience

This Report is written primarily to advise Federal and State agencies responsible for the health and well-being of workers and the public related to exposures from ionizing radiation as well as those with responsibility for protecting nonhuman biota from such sources. It provides recommendations that, in the judgment of NCRP, provide adequate protection for exposure to ionizing radiation for the purpose stated above, and the principles and scientific data supporting those recommendations. This Report will be of value to the practitioners of radiation protection to inform them of NCRP recommendations, their bases and application. It provides information for the public and the news media to assist their understanding of the bases and uses of these recommendations.

1.3 Bases for Recommendations

Based on extensive biological research and epidemiologic studies of exposed populations we know that, in addition to severe tissue and organ effects resulting from short-term high doses, the primary and controlling adverse health effect for people is induction of certain cancers. The relationship of radiation dose received and probability of this effect is based on the study of populations that have been exposed to relatively high doses of ionizing radiation, primarily the Japanese population exposed to the atomic-bomb detonations in 1945. Epidemiologic studies of other populations also have contributed to the understanding of radiation effects.

In addition to the knowledge of human biological effects of ionizing radiation, the system of radiation protection and its radiation protection principles are informed by accepted ethical principles, experience gained in the use and management of radioactive materials and radiation-

producing devices, and experience with approaches to the protection of individuals from adverse health effects resulting from radiation exposures.

Ionizing radiation is a relatively weak carcinogen; and there is at this time no approach to distinguish a cancer that may have been caused by radiation exposure from a cancer resulting from any number of other possible causes. Epidemiologic studies, by themselves, cannot provide definitive information about the relationship between radiation exposure and cancer incidence for exposure to low doses of radiation [*e.g.*, in the range of doses from ubiquitous background radiation (Glossary)]. Radiation biology has shown competing processes at the molecular, cellular, and tissue levels, with an exposure stimulating certain metabolic activities, and reducing others. While the presence of thresholds or even positive effects can be detected in some cellular systems, these observations cannot be generalized into a relationship that predicts the response of any particular individual. Consequently, recommendations for prospective radiation protection controls are based on a simplifying and prudent assumption of approximate linearity of the dose and effect relationship, even though the actual relationship is not known in detail, or for any specific individual or tissue. Further discussion is provided in Sections 4 and 5, and Appendix B.

For radiation protection purposes, the concept of *radiation detriment* at low doses has been defined by ICRP (2007a) as the combined effects due to excess cancer and heritable effects (Section 5). Radiation detriment includes the incidence of radiation-related cancer or heritable effects, adjustment for the lethality of these conditions, the reduced quality of life associated with living with a serious illness, and years of life lost due to death from these conditions. The concept of radiation detriment presupposes a linear dose-response relationship, modulated by an additional dose and dose-rate effectiveness factor (suggesting a lower biological effectiveness per unit of radiation dose at low absorbed dose and low absorbed dose rate[4] (low dose and low dose rate) compared with exposures at high doses and high dose rates). The risk coefficients representing the slopes of the dose-response function for stochastic effects have been used to

[4] For the purpose of this Report, for low linear-energy transfer (low-LET) radiation, a low absorbed dose is <100 mGy delivered acutely, and a low absorbed dose rate is <5 mGy h^{-1} for any accumulated absorbed dose [as adopted at the present time by NCRP (2015a)].

establish recommendations for controlling radiation dose to human populations under various exposure circumstances (Sections 4 and 6).

1.4 Principal Radiation Dose Quantities Used in this Report

The full array of radiation dose quantities and units used in radiation protection were identified and defined by ICRP (1991a) and NCRP (1993a), and continued and updated in ICRP (2007a). The two dose quantities used in the recommendations to control dose to an individual in this Report are:

- Absorbed dose in a specified organ or tissue (organ dose) (*e.g.*, active bone marrow, lens of the eye, localized area of skin) when the recommendation to control dose to an individual is for the purpose of avoiding acute or chronic tissue reactions (deterministic effects) in humans (absorbed dose in the relevant biological component is also used for nonhuman biota); and
- Effective dose when the recommendation to control dose to an individual is for the purpose of controlling the overall potential for stochastic health effects for all organs and tissues in humans.

1.4.1 Absorbed Dose in an Organ or Tissue

Absorbed dose is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the point of interest. It is the fundamental radiation dose quantity related to ionizing radiation health effects. For humans, *mean absorbed dose in an organ or tissue* (often referred to as *organ dose*, or dose in the specific organ or tissue) is obtained by integrating or averaging the absorbed dose over the entire volume of an organ or tissue (*i.e.*, the total energy deposited in the organ or tissue divided by the total mass of the organ or tissue). In the case of skin (and the extremities) for tissue reactions, absorbed dose in a localized area is the quantity of interest. The Systeme Internationale (SI) unit for all cases of absorbed dose is joule per kilogram

693 (J kg^{-1}) with the special name gray (Gy). The quantity absorbed dose averaged over the
694 biological or anatomical component of interest is also relevant for nonhuman biota.
695
696 **1.4.2** Effective Dose
697
698 *Effective dose* is a practical quantity used for radiation protection purposes that takes into
699 account: first, the differences in biological effectiveness of the same organ dose delivered by
700 various types of ionizing radiation [using a set of nominal radiation weighting factors (Section
701 A.3.2)], and second, the different probabilities of stochastic effects for that radiation-weighted
702 organ dose [using a set of nominal tissue weighting factors (Section A.3.4)]. Effective dose is
703 determined from the organ doses of a specified set of organs and tissues and includes exposures
704 to the organs and tissues from both external sources and intakes of radionuclides. The unit for
705 effective dose is joule per kilogram (J kg^{-1}) with the special name sievert (Sv). Effective dose
706 applies only to stochastic effects (*i.e.*, cancer and heritable effects) in humans.
707
708 **1.4.3** Other Quantities and Units for Radiation Protection Dosimetry
709
710 More complete technical definitions and related commentary for absorbed dose and
711 effective dose are provided in Appendix A, along with definitions and commentary for other
712 quantities or concepts used in the system of radiation protection, including: energy imparted;
713 absorbed dose rate, exposure, exposure rate, relative biological effectiveness, radiation weighting
714 factor, equivalent dose, tissue weighting factor, and committed dose.
715
716 **1.5 Comparison with Current NCRP Recommendations**
717
718 The previous recommendations for radiation protection in the United States were
719 published in Report No. 116 (NCRP, 1993a). The recommendations in this Report supersede the
720 NCRP (1993a) recommendations and cover sources and types of exposures that were not
721 addressed by NCRP (1993a). These sources and types of exposure include:
722

- patients exposed in medical-imaging procedures and radiation therapy;
- comforters and caregivers for patients undergoing medical-imaging procedures or treatment with radioactive materials;
- voluntary participants in biomedical research exposed to ionizing radiation;
- workers and the general public exposed to elevated levels of naturally-occurring radioactive materials including those enhanced by technology;
- emergency workers recruited by a responsible authority during a declared emergency involving radiation or radioactive material; and
- nonhuman biota (*e.g.*, plants and animals) exposed to elevated levels of ionizing radiation in the environment due to human activity (anthropogenic elevated levels).

This Report emphasizes the importance of the ethical bases supporting the three basic principles of radiation protection [*i.e.*, justification, the ALARA principle (optimization of protection), and control of dose to an individual[5]] and in decisions related to the application of these three principles.

The role of stakeholders in making decisions concerning control of their radiation exposures is emphasized. In addition, the role of a radiation protection culture that engages workers who may be exposed to radiation, as well as members of the public, in the control of their exposure is introduced (Section 3.3.4).

1.6 Relation to Current ICRP Recommendations

Publication 103 (ICRP, 2007a) promulgated recommendations for international guidance, including recognition of the need for radiation protection of the environment (*i.e.*, nonhuman biota). In the interest of a uniform international approach to radiation protection the recommendations of ICRP (2007a) have, in general, been incorporated in this Report. NCRP acknowledges the specification of categories of exposure situations in ICRP (2007a) as planned,

[5] The term "control of dose to an individual" refers to specific numeric values of a dose quantity recommended by NCRP.

existing, and emergency, but does not use that terminology to organize the recommendations in this Report. NCRP recommendations focus on the *prevailing exposure situation* (*i.e.*, the particular exposure situation occurring at the time) to provide protection through use of recommendations for control of dose to an individual and application of the ALARA principle (Sections 3 and 6).

Similar to the ICRP (2007a) recommendations for protection of humans, NCRP specifies that the ALARA principle [referred to as optimization of protection in ICRP (2007a)][6] is always to be applied. In this Report, the ALARA principle is applied to the various recommendations on control of dose to an individual in the following manner.

- In all prevailing exposure situations, the recommendation to control dose to an individual provides initial guidance for the application of the ALARA principle by the responsible or designated party.
- For certain prevailing exposure situations, in which the source is stable, characterized, and subject to an advance control program[7] by the responsible organization, the NCRP recommendation for control of dose to an individual may be designated as a dose limit (in the regulatory sense). Appropriate cases are noted in Section 6.

For all recommendations for control of dose to an individual, the objective is to achieve a unique and appropriate protection strategy for the prevailing exposure situation. The responsibility of NCRP is to provide recommendations for radiation protection that best serve the United States, recognizing the legislative mandates that govern use of radiation and radioactive materials in the United States. Differences with international recommendations are made in support of fulfilling this responsibility. It is the NCRP's judgment that such differences in this Report primarily reflect U.S. experience and approach in implementing radiation protection,

[6] Throughout this Report, the term "the ALARA principle" is used, but is intended to always be coincident with the ICRP term "optimization of protection."
[7] For a prevailing exposure situation in which the source is deliberately and intentionally introduced, an advance control program is the set of radiation protection programs intended to control exposure of an individual that is put in place by the responsible organization before the introduction of the source.

NCRP evaluation of the latest available information, recognition of the primacy of the ALARA principle in the United States, and the need to facilitate understanding and acceptance in the United States of the recommendations in this Report.

Specific differences from ICRP (2007a) in the numerical values for control of dose to an individual in this Report occur for occupational exposure, absorbed dose to the lens of the eye, and absorbed dose to the skin and extremities. These are explained in Section 6.

1.7 Use of the Recommendations

As stated above, these recommendations are to guide the control of exposures to ionizing radiation in a reasonable manner. It is clearly necessary to use informed judgment to determine adequate protection and reasonableness. For NCRP the judgment used to determine the recommendations in this Report is based on accepted ethical principles (Section 2) in accordance with the three basic principles of radiation protection (Section 3). The assumed radiation detriment in an exposed population that is related to a specific radiation dose is averaged over all health effects, age and sex. Consequently, the risk of radiation detriment cannot be applied to any specific individual.

Each recommendation for control of dose to an individual in this Report is based on the: prevailing exposure situation, which is characterized by the:

- Nature of the source;
- Individuals exposed;
- Circumstances of exposure; and
- Ability of those with authority to control the:
    - source of radiation; and
    - actions of the persons at risk of exposure.

The recommendations for control of dose to an individual in this Report, together with application of the principle of justification and the ALARA principle, is regarded as providing adequate protection. The recommendations to control dose to an individual do not, *per se,* represent a sharp line designating a "safe" from an "unsafe" radiation exposure. If, in a specific exposure circumstance, the expected radiation dose exceeds the recommended value, efforts should be undertaken to reduce the expected dose to the recommended value. The urgency of such actions depends on the circumstance. Subsequent efforts should be made to further reduce the expected dose consistent with the ALARA principle (Section 3).

1.8 Protection of Nonhuman Biota

NCRP proposes an approach in the United States for radiation protection of nonhuman biota for several specific reasons. Within the United States there is a well-established legislative and regulatory framework that requires consideration of potential impacts on the environment as a part of decision-making for significant actions. Radiation is only one factor to be considered within the context of the National Environmental Policy Act (NEPA, 1969) and decision-making documents such as Environmental Impact Statements under NEPA (1969). The guidance in this Report (Section 6.8) is intended to support NEPA (1969), consistent with the NCRP radiation protection objective to prevent the occurrence of adverse radiation-induced effects in nonhuman biota while still enabling those activities which provide benefit to society from such exposures. The guidance, in the form of a dose rate level, above which further analysis is initiated, should help facilitate discussions on the prevailing exposure situation with stakeholders, and provide a mechanism to understand the assumptions and decisions that may need to be made to avoid or control adverse radiation-induced effects in nonhuman biota for the prevailing exposure situation.

With regard to protection of the environment, expressed in this Report as radiation protection for nonhuman biota, NCRP presents guidance in support of the existing National Environmental Policy Act (NEPA, 1969) and decision-making documents such as Environmental Impact Statements under NEPA (1969).

2. Ethical Foundations for the System of Radiation Protection

In the late 1950s Lauriston S. Taylor mentioned the need for an ethical approach to radiation protection (Taylor, 1957) as also did the ICRP (1959). More recently, NCRP has been addressing ethical considerations in such matters as radiation risk for crew members in NASA space activities (Report No. 167) (NCRP, 2010a), for occupational exposure during fluoroscopically-guided interventional procedures (Report No. 168) (NCRP, 2010b; spaceflights to Mars (NCRP Commentary No. 23) (NCRP, 2014a), treatment of human subjects of research using radiation (NCRP, 201Y), and protection of the environment (NCRP, 1991). Explicitly identifying the ethical foundation for the system of radiation protection in this Report provides transparency about the values that underlie the system. Such identification normally includes three elements:

1. *moral significance* [*i.e.*, an assumption (sometimes an explicit statement) regarding to whom ethical duties are owed];
2. *ethical theory* (*i.e.*, reasoning about the bases for ethical duties); and
3. *ethical principles* (*i.e.,* a statement of key duties relevant to the field of application, in this case, radiation protection).

2.1 Moral Significance and What to Protect

Radiation protection is primarily applied to humans, but needs to be extended to the environment in which humans reside. How should protection of the environment be addressed in the NCRP system of radiation protection, particularly as more attention is being paid to repercussions of human activity on the environment? The goal for NCRP was to provide a factual basis and a coherent philosophy for a framework that included an appropriate level of protection of the environment (expressed in this Report as protection of nonhuman biota) against the detrimental effects of ionizing radiation exposure. The guidance for protection of nonhuman biota in this Report (Section 6.8) is consistent with the other radiation protection

recommendations of NCRP in this Report for humans. However, for nonhuman biota, the guidance focuses on population maintenance.

The ethical approach of NCRP is rooted in an extended anthropocentrism (Desjardins, 2012), placing protection of humans as a priority in which the protection of nonhuman biota is subject to human valuing for the prevailing exposure situation.

While according moral significance to nonhuman entities (captured in other approaches such as biocentrism and ecocentrism) is *not* NCRP's approach, nevertheless significant protection of the environment can result from the extension of human interest to the environment. For radiation protection of humans, the intent has been to prevent tissue reactions and minimize stochastic effects in individuals. The objective of radiation protection of nonhuman biota is, insofar as humans value the ecosystem, to ensure its structure and function are not altered in a way that humans consider detrimental as a consequence of radiation exposure arising from human actions.

2.2 Ethical Theories, Ethical Principles, and the Principles of Radiation Protection

2.2.1 Ethical Theories

Ethical theories about right and wrong generally can be categorized as: teleological (*e.g.*, utilitarian), deontological (egalitarian), and virtue-based. Teleological foundations refer to ends or purposes. For those that adopt this approach, consequences establish duties, hence the name "consequentialism" (Mill, 1879). Deontology (root "deon", meaning duty) emphasizes the determination of one's duties *without* referring to consequences. "Respect persons as an end only, never as a means." is one accessible formulation of this view (Kant, 1785). This is often referred to as "egalitarianism." A virtue-based approach to ethics is less inclined to create rules and instead emphasizes a way of living. Virtuous behavior involves living in the mean and not at the extremes (Aristotle, 1999). These three main theoretical foundations have been adapted by persons interested in including the environment in ethical considerations.

Much of the foundation of NCRP recommendations is utilitarian, although there is some consideration of the egalitarian viewpoint around specific issues. The virtue-based approach is not used as an ethical foundation in radiation protection but it is captured in the value NCRP places on wise judgment among competing courses of action in specific situations. In this approach persons who work in the field of radiation protection strive to be virtuous.

2.2.2 Ethical Principles

Ethical principles allow us to note important differences among values and they also aid in identifying ethical duties, but this type of principle is not merely descriptive of value differences. Ethical principles are prescriptive statements about which values we ought to hold. When these principles are applied, however, they will sometimes support different duties regarding the same situation. Examples of duties that have their basis in ethical principles are the obligation to seek informed consent, the duty to be transparent in the information shared, and the duty to distribute risk and harm equitably.

The NCRP system of radiation protection focuses on four ethical principles (Beauchamp and Childress, 2013):

1. Provide good (beneficence).
2. Prevent harm (non-maleficence).
3. Respect an individual's autonomy (autonomy).
4. Act fairly (justice).

Three of these principles were used in the Belmont Report (DHEW, 1979) in addressing ethical issues in research on human subjects. Non-maleficence, a fourth principle, was subsumed under beneficence in that document. These ethical principles are not reducible to each other (*e.g.*, in preventing harm one may not always be able to protect autonomy or provide a good).

The view of NCRP is to rank these principles such that prevention of harm (non-maleficence) holds priority. However, provision of good is fundamentally important to NCRP since there is benefit in the use of radiation. Ethicists keep these two principles distinct from each other. In addition, NCRP increasingly recognizes the value of autonomy, particularly in those instances where informed consent mitigates intentional radiation exposure at a level higher than normal exposure. Involvement of the relevant stakeholders (inclusiveness as an example of respecting the autonomy of individuals) is essential to clearly understand the interests that should be considered, and to develop a radiation protection approach that best meets those interests. Finally, justice has been introduced into NCRP recommendations, as equity, not merely equality, with respect to radiation exposure.

2.2.3 Ethics and the Principles of Radiation Protection

The international and U.S. radiation protection communities have established three principles of radiation protection. Kase (2004) notes that historically "…the fundamental principles of justification, optimization, and dose limitation as initially stated in Publication 26 (ICRP, 1977) have been adopted and applied by the NCRP in its recommendations (NCRP, 1993a)." These radiation protection principles function *as norms of practice.* They do express commitments to certain values and to the relationship among the values. While not identical to norms of practice, the ethical principles mentioned in Section 2.2.2 underlie the NCRP implementation of the radiation protection principles. Ethicists have explored the relationship between the major ethical theories mentioned in Section 2.2.2 and justification, optimization of protection, and application of dose limits (the radiation protection principles as stated in ICRP publications) (Gonzalez, 2011; Hansson, 2007). In this NCRP Report (Section 3) a different analysis is offered, one that closely examines these norms of practice, demonstrating their ties to the ethical principles mentioned in Section 2.2.2.

Additionally, this Report makes note of the important role ethics plays in other considerations taken up in subsequent sections. While it is not necessary to consider the underlying interests and the values they reflect in many routine decisions, it is useful to

remember the reasons for taking specific actions, and to explicitly consider those interests and values when there may be conflicts among them in making a particular decision. Involvement of the relevant stakeholders (inclusiveness, as expressed in respect for autonomy) is essential to clearly understand the values that should be considered, and to develop a radiation protection approach that best meets these values.

NCRP adopts the use of the ethical principles of doing good, avoiding harm, being just and respecting the autonomy of individuals in making decisions on radiation protection, particularly in circumstances and situations that present inherent conflicts in interests. NCRP also recognizes the need to use the virtue of practical wisdom in radiation protection.

3. The System of Radiation Protection

The system of radiation protection presented in this Report be used to control exposure to radiation and radioactive materials in the United States to ensure adequate protection of humans and nonhuman biota while allowing for activities that are beneficial for human development.

The system of radiation protection[8] described in this Report has been developed based upon scientific information on the health effects of radiation, the application of fundamental ethical principles, and expert opinion derived from experience with radiation sources and events.

3.1 Exposure Situations

The NCRP system of radiation protection is applied as appropriate to each prevailing exposure situation.

For purposes of radiation protection, it is useful to organize exposures into various situations based on the individuals or entities receiving the exposures. An exposure situation is a way of generally classifying a circumstance by which a source of radiation, through various pathways, causes the exposure of an individual or other entity. Sources may be either radioactive materials, or machines which emit radiation, and may be of natural origin, or be man-made. Protection can be achieved by taking action at the source, or at points in the exposure pathways, and by modifying the location or characteristics of the exposed individuals or other entities. The specific opportunities for protection, and the optimum level of protection, depend upon the prevailing exposure situation. For protection of nonhuman biota, the objectives and concerns are different than they are for humans. Nevertheless, assessment of sources, pathways, and the receptor organism is a valid approach which allows for use of modeling in a consistent and coherent manner.

[8] Refers to the system of radiation protection as embodied in the NCRP recommendations for the United States in this Report. Shortened to read system of protection in the text of this Report.

ICRP (2007a) recommended three exposure situations (planned, emergency, and existing), as a way of organizing radiation protection. With the experience gained since that time, NCRP believes that distinctions of this type are not necessary to effectively implement the system of protection, and that rigidly organizing a radiation protection regulation or program in that way may be confusing in some cases. Irrespective of the exposure situation, the system of protection is implemented through reducing exposures to levels that meet the ALARA principle[9] [equivalent to the principle stated as optimization of protection in ICRP (2007a)][10] within appropriate control of dose to an individual. Further, there may be occasions when the situation is not well defined and the application of the system of protection should allow some flexibility for informed judgment.

Throughout this Report, reference may be made to circumstances where the source of exposure is already existing, where protection has been planned before the introduction of the source, or the source is not under control and is causing an emergency. These circumstances correspond to the three exposure situations of ICRP (2007a), but are intended only as a way to assist in understanding the context of the specific circumstances, not as a specification of a particular set of radiation protection requirements. NCRP recognizes that in transitions from an emergency to a more controlled set of circumstances there may be changes in regulatory authorities and responsibilities. While such changes are important, and communication of the basis for change is critical, they do not, in the view of NCRP, alter the way the system of protection is applied.

[9] The ALARA principle: a principle of radiation protection philosophy that requires that exposures to ionizing radiation be kept as low as reasonably achievable (ALARA), economic and societal factors being taken into account. The ALARA principle is satisfied when the expenditure of further resources would be unwarranted by the reduction in exposure that would be achieved.
[10] The ALARA principle is the term used throughout this Report.

3.2 Categories of Exposure

The following categories of exposure: occupational, public, medical, emergency worker, and nonhuman biota, are used to identify the individuals or other entities receiving radiation exposure.

The prevailing exposure situation for an individual, or for nonhuman biota, is a defining component in applying the system of protection. In particular, a distinction is made between occupational, public and medical exposure (the previous traditional categories of exposure), along with the recognition by NCRP of additional categories, namely exposure of emergency workers and exposure of nonhuman biota, as described below.

3.2.1 Occupational Exposure

Occupational exposure, in its broadest context, involves the exposure to ionizing radiation of individuals in the course of their work. Occupational exposure does not include exposure as a part of employment fitness screening, exposure as a patient, biomedical research subject, or comforter or caregiver, nor exposure outside of the work environment when the individual is to be regarded as a member of the public. Because radiation is ubiquitous in the environment, from a practical standpoint occupational exposure is limited to exposures for which it is reasonable and feasible for the employer of the workers to have responsibility for exercising control of the dose to the workers. A designation as occupational exposure is not necessarily dependent upon the magnitude of the dose[11] individuals might receive. Occupational exposure can occur in any exposure situation, and should be treated appropriately in each circumstance. Health care workers who receive exposure during the care of patients are considered

[11] In this Report, dose is the general term used when the context is not specific to a particular dose or dose-related quantity. When the context is specific, the name or symbol for the quantity is used [*e.g.*, mean absorbed dose in a tissue or organ (organ dose) (D_T), effective dose (E)], and when a specific value for the quantity is given it is accompanied by the special name of the appropriate unit [*e.g.*, gray (Gy); sievert (Sv)].

occupationally exposed. The recommendations for control of dose to an individual for occupational exposure are described in Section 6.4.

3.2.2 Public Exposure

Public exposure comprises any exposure of individuals outside of the described occupational, medical or emergency worker categories. Public exposure can occur in numerous exposure situations. For example, when the radon level in a home is in excess of that expected in the outdoor environment, the residents of the dwelling would be receiving public exposure. Similarly, an individual living in an area that continued to have some level of residual radioactive material from a past event would be receiving public exposure, while workers doing decontamination of homes or buildings would be receiving occupational exposure. In a declared emergency, members of the public may be recruited by the responsible authority to assist in various ways in the response. These individuals are considered emergency workers and are dealt with separately. Further, individuals who would be considered as occupationally exposed at their workplace, would be considered to be members of the public at other times. The recommendations for control of dose to an individual for various situations of public exposure are described in Section 6.5.

3.2.3 Medical Exposure

Medical exposures of patients are unique and are dealt with separately in the system of protection because they are for purposes of diagnosis or therapy of injury or disease and provide a direct benefit to the individual exposed. The category of medical exposure also includes individuals who may be participating voluntarily in biomedical research that results in their exposure to radiation, and individuals who may be engaged in the comfort and care of a patient who has been administered a radionuclide for the purpose of medical diagnosis or therapy. The latter group is limited to those individuals who are not occupationally involved in medical treatment, and are usually close friends, family members, or parents of the patient. Individuals who may be inadvertently exposed as a result of proximity to a treated individual are to be

protected as members of the public. The radiation protection recommendations for medical exposure are described in Section 6.6.

3.2.4 Exposure of Emergency Workers

In a declared radiological or nuclear emergency, a unique category of exposure will exist, that of the emergency worker. This is a transitory exposure category that will start soon after a radiological or nuclear emergency begins. These emergency workers may include typical responders like firefighters, law enforcement officers and emergency medical service providers. Utility workers and others essential in restoring critical infrastructure may also become emergency workers. There will also be support personnel recruited by the responsible authority in large numbers to serve as vehicle operators or administrative service providers. Some may serve for only the first few hours or days following the initial response; others may transition from emergency workers to occupationally exposed people when they take on more permanently some response or recovery role days or weeks into response and recovery. For the worst scenarios, like extensive contamination from a radiological dispersal device, an uncontrolled release from a severely damaged nuclear reactor or spent fuel storage pool, or a nuclear detonation, numerous emergency workers may be involved, and the responsible authority assumes a radiation protection role for all of them. The recommendations for emergency workers are described in Section 6.7.

3.2.5 Exposure of Nonhuman Biota

Exposure of nonhuman biota includes exposures that occur from radiation sources dispersed within the environment, and may or may not concurrently result in exposure of humans. The objective of radiation protection for nonhuman biota is associated with population endpoints (*i.e.*, survival of a species) rather than protection of individual members of the species. Guidance for exposure of nonhuman biota is described in Section 6.8.

3.3 Principles of Radiation Protection

The NCRP radiation protection principles of justification, the ALARA principle (optimization of protection), and control of dose to an individual[12] provide a coherent and systematic approach to addressing exposure of humans.

The principles of radiation protection are applicable in all prevailing exposure situations for humans, and can be applied in essentially the same manner, except for exposure to patients for purposes of diagnosis or therapy of injury or disease. Specifically, it first should be determined that taking action(s) is justified (does more good than harm), and then the ALARA principle should be applied relative to appropriate control of dose to an individual.

This Report makes use of the ethical values of doing good, avoiding harm, being just and respecting the autonomy of individuals. These values were captured in a broader discussion in Section 2.2. Decisions in a particular circumstance may involve considerations to balance these ethical principles that serve as the foundation of radiation protection. These decisions may require resolving conflicts between the ethical principles by giving priority to one or more of them, and are best made with the involvement of stakeholders, a process which is referred to here as inclusiveness.

Implementation of radiation protection relies upon the consistent use of the following requisites: assessment of the exposure, accountability for protection, transparency in communications regarding the exposure, and inclusiveness of all relevant stakeholders. The radiation protection principles are described in Sections 3.3.1, 3.3.2 and 3.3.3.

[12] The term "control of dose to an individual" refers to specific numeric values of a dose quantity recommended by NCRP.

3.3.1 Justification

Actions to add, increase, reduce, or remove a source of exposure to humans requires justification (*i.e.*, the action does more good than harm). All factors, both radiological and non-radiological, and particularly the economic, societal, psychological, and environmental implications (including to nonhuman biota), need to be considered in that justification.

Two ethical principles are key in decisions on justification: avoiding harm and doing good, with the latter outweighing the former, insofar as the benefit created should exceed any harm that may result. The principle of justice also comes into play, in that there should be a commitment to ensuring that benefit be fairly distributed or, minimally, that harm be equitably shared. However, the principle of justification does not guarantee that justice plays the primary role. When considering benefit and harm, consideration should be given to the wide range of possibilities, not just the radiation benefit or harm. Thus, radiation protection may be, and usually is, only one input in a much broader consideration of benefit and harm, which include societal and economic considerations.

Experience has shown that many of the most important factors in dealing with radiation are not directly related to hazards caused by radiation exposure, but are rather related to non-radiological impacts. Benefit and harm may accrue in various ways. Thus, it is particularly important to be inclusive, and involve relevant stakeholders and interested parties in the process of justification. Doing so respects the autonomy of individuals, and provides the most complete insights into the implications of taking an action.

Application of the principle of justification should consider not only exposure that is expected or anticipated to occur but should also include consideration of less likely, but plausible, exposure that might occur due to unintended or unanticipated circumstances or accidents.

3.3.1.1 Addition or Removal of a Source. The introduction of a new source of exposure needs to be carefully considered before any exposures occur, and a determination made as to whether such an introduction is justified. In other circumstances, the decision is not whether to introduce the source, but rather to decide what should be done with a source that is already causing exposure. Both occupational and public exposure to humans should be considered, as well as exposures in the environment that are in keeping with human interests. In each case, the decision is whether action to reduce or eliminate the exposure has an overall beneficial effect, particularly in prevailing exposure situations in which the actions may be hazardous to those performing them or significantly intrusive to individuals, society, or the environment.

3.3.1.2 Medical Exposure of Patients.

In medical exposure of patients, justification includes a determination of the appropriate medical-imaging or treatment procedures.

The application of radiation or radioactive materials in medicine is unique because individuals are being deliberately exposed for the purpose of diagnosis and treatment of disease. The process of justification in the context of medical exposure thus requires additional considerations.

For medical exposure of patients, beneficence takes precedence over the avoidance of harm. The benefit-to-harm considerations in medical exposures are different from those used for occupational and public exposures. For patients, the benefit is direct and personal, and the result of the medical exposure should be preservation or improvement in the patient's health, not merely protection from harm.

There are three levels of justification of a radiological practice in medicine (ICRP, 2007a):

- At the first and most general level, the proper use of radiation in medicine is accepted as doing more good than harm to society. This general level of justification is now taken for granted, and is not discussed here further.
- At the second level, a specified procedure with a specified objective is defined and justified (*e.g.*, chest x rays for patients showing relevant symptoms, or a group of individuals at risk for a condition that can be detected and treated). The aim of the second level of justification is to judge whether the radiological procedure will improve the diagnosis or treatment, or will provide necessary information about the exposed individuals.
- At the third level, the application of the procedure to an individual patient should be justified (*i.e.*, the particular application should be judged to do more good than harm to the individual patient). Hence all individual medical exposures should be justified in advance, taking into account the specific objectives of the exposure and the clinical status of the individual involved.

While a medical exposure may be properly justified on each level for a particular patient, individual patients may refuse treatment, thereby exercising their autonomy. Refusal may represent a conscious choice based on individual values and preferences, but it could also be based on an incomplete or incorrect appreciation of the relative benefit and harm. This emphasizes the necessity for medical personnel to effectively interact with the patient to provide information and facilitate understanding of the implications of consenting to or refusing the examination or treatment.

NCRP recommends that third-level justification, as practiced by the referring practitioner and the practitioner responsible for the performance of the diagnostic or therapeutic procedure, include a determination of the most appropriate medical-imaging or treatment procedure. This determination will depend on the clinical status of the patient, the indication for the examination (the clinical question), and other factors (*e.g.*, availability, local expertise, cost). Radiation dose is only one factor in this determination. While the medical determination should be based on the strength of available clinical evidence, socio-economic factors will vary by location and

circumstance, and may be more important to the patient than radiation considerations. Clinical decision support, in the form of professional society recommendations is available to guide the selection of the most appropriate medical-imaging procedures and should be used when applicable.

Justification of screening examinations (second-level justification) is a separate issue. There are situations where it is appropriate to avoid patient-initiated screening examinations (also called individual health assessments), but that avoidance is principally due to medical consequences (false-positive and false-negative examinations can cause a deterioration in health) and economic considerations (screening examinations cost money). Certain screening programs have been demonstrated to have significant clinical value and have been justified at the second-level (*e.g.*, mammography). Criteria for selection of screening programs have been suggested in Europe by the Heads of the European Radiological Protection Competent Authorities (Griebel and Ebdon-Jackson, 2012). Protecting individuals from excessive screening is supported by the exercise of the principle of non-maleficence and, depending on a patient's knowledge, may not really involve interference in the patient's autonomy.

3.3.2 The ALARA Principle (Optimization of Protection)

The likelihood of incurring exposures, the number of individuals exposed, and the magnitude of the dose to an individual should be kept as low as reasonably achievable (ALARA), taking into account societal, economic, and environmental factors (the ALARA principle). The ALARA principle applies in all exposure situations. The ALARA principle is satisfied when the expenditure of further resources would be unwarranted by the reduction in exposure that would be achieved.

Application of the ALARA principle in radiation protection is the process of determining how best to use resources in reducing radiation risks to individuals and the population by ensuring that exposures are as low as reasonably achievable, societal, economic, and environmental factors being taken into account. This means that the level of protection should

be the best under the prevailing exposure situation, maximizing the margin of benefit over harm. In order to avoid severely inequitable outcomes from implementing the ALARA principle, there should be boundaries established on the dose to an individual from a particular source that will be considered as appropriate. In all cases, application of the ALARA principle is coincident with the term optimization of protection as it is used internationally in radiation protection.

Application of the ALARA principle should consider not only exposure that is expected or anticipated to occur but should also include consideration of less likely, but plausible, exposure that might occur due to unintended or unanticipated circumstances or accidents.

Application of the ALARA principle to medical exposure of patients is different from application to other planned exposures. In medical exposure of the patient, the intention is to achieve the necessary diagnostic or therapeutic outcome, and thus the ALARA principle means as low as reasonably achievable to realize the intended clinical outcome. In this context, the ALARA principle is best described as management of the radiation dose to the patient to be commensurate with the medical purpose (Section 3.3.2.3).

The expectation that radiation exposure should meet the ALARA principle is a direct appeal to prevent harm or to reduce the risk of harm. The ALARA principle is contextualized, however, by economic, societal, and environmental concerns. Hence, what constitutes "reasonably achievable" is related to costs associated with radiation protection (including those resulting from negative health or environmental outcomes) as well as societal goods that are achievable.

In Report No. 116 (NCRP, 1993a), NCRP recommended that an annual effective dose of 0.01 mSv be considered a Negligible Individual Dose per source or practice. NCRP recognizes that the perception of risk is closely related to the circumstances of the individual, and the activity being considered at that moment. Thus, at any given time a person may, or may not, believe that a given dose, and its assumed corresponding risk, is acceptable. The scientific understanding of the risk of radiation exposure at very low doses and low dose rates is uncertain,

including the competing damage and repair mechanisms, and continues to be refined. NCRP therefore no longer recommends a specific Negligible Individual Dose. However, a numerical value may be one useful guide for evaluating when efforts to reduce further the dose to an individual may not be warranted. NCRP recognizes that the authority responsible for implementing the ALARA principle for a prevailing exposure situation may decide to apply different criteria. The selection of any criterion used is also a matter for stakeholder interaction. Regardless of the rationale for a particular decision, the ALARA principle is satisfied when the expenditure of further resources would be unwarranted by the reduction in exposure that would be achieved.

Application of the ALARA principle is a key component of radiation protection, and should be applied to any prevailing exposure situation in conjunction with the recommendations for control of dose to an individual (Section 6). In circumstances where dose to an individual may be initially greater than the appropriate recommendation, actions would first seek to reduce the initial dose to a level below the relevant recommendation, but then continue to reduce dose as appropriate using the ALARA principle. This is in contrast to simply reducing the initial dose below the relevant recommendation.

3.3.2.1 Public. NCRP recognizes that application of the ALARA principle can only effectively be undertaken for a particular source that has an accountable party responsible for radiation protection. Consequently, for public exposure, the ALARA principle should be applied to each particular source by the accountable party responsible for that source.

Exposures may take place *via* any pathway, including direct irradiation, inhalation and ingestion. When introduction of a source can be planned in advance, the ALARA principle should be applied to control at the source, reducing direct irradiation and the release of effluents, and not be directly dependent upon actions of the individuals who may be exposed. For situations when the introduction of the source was not preplanned, such as the wide distribution of deposited radionuclides on the ground, it may not be possible to take actions directly on the

source. Actions may, however, be possible on some of the pathways, such as food and water, and upon the location and habits of potentially-exposed individuals.

Emergencies are a special case where a source of exposure was not preplanned, controls on the source are not in place or are insufficient, and urgent actions are necessary to protect public health and safety. While the circumstances were not planned, preplanning for possible scenarios should have taken place for large facilities, and in urban areas, and those emergency plans should be rapidly implemented to reduce exposures. The preplanning for possible emergencies should include all possible exposure pathways, rather than separate considerations for each pathway. Furthermore, emergency actions such as evacuation can have significant non-radiological impacts, and these should be carefully factored into the emergency planning process to avoid doing more harm than the radiological impacts they are designed to avoid.

For some circumstances, the exposed individuals themselves may be responsible for applying the ALARA principle, such as in the case of radon exposure in the home. In this case, those individuals would be responsible for obtaining an assessment of radon in their home, and if necessary, for enlisting a qualified remediation contractor to develop and implement the best options for effectively reducing the radon concentration.

3.3.2.2 Occupational. Application of the ALARA principle for occupational exposure focuses upon workers in the particular circumstance. In theory, any individual at work could also be receiving some exposure from ubiquitous background radiation, and possibly from medical procedures. To avoid confusion, NCRP focuses its attention upon occupational exposures from sources that are reasonably under the control of the individual's employer or the specific user of the source.

Application of the ALARA principle needs to consider all the contributions to the occupational exposure of the individual that are reasonably under the control of the employer. Individuals may need to be specifically identified, monitored as appropriate, and records of exposure should be maintained and made available if the individual works for other entities. In

some cases, a balancing of the exposure pathways, such as external exposure and inhalation, may be needed to reduce the effective dose consistent with the ALARA principle. Preference should always be given to controlling the source, rather than relying on controls on the pathways or the actions of the individual.

In many ongoing applications, the ALARA principle is simply the continuation of good radiation protection programs and practices that traditionally have been effective in keeping the average and individual doses for monitored workers well below the recommendations to control dose to an individual (NCRP, 2009). Approaches employing quantitative estimates of total radiation detriment and costs of protection have been developed by ICRP (1983; 1990a) including a more holistic multi-attribute consideration (ICRP, 2006). NCRP agrees that this is a more robust and realistic approach to protection. However, the ALARA principle is also qualitative, with a fundamental mindset to always ask the question about whether there are ways to improve protection. NCRP recognizes a strong connection between a robust radiation protection program, the effective use of the ALARA principle, and the concept of a radiation protection culture that has emerged in recent years (Section 3.3.4).

In a prevailing exposure situation such as an isolated workplace emergency, the ability to assess, monitor and control exposure may be reduced. Nevertheless, every attempt should be made to characterize the workplace circumstances, and provide protection that meets the ALARA principle.

3.3.2.3 Medical Exposure of the Patient.

The purpose of medical exposure of patients is to provide benefit to the patient, while limiting harm to the patient. The ethical principle of beneficence may outweigh non-maleficence, even though the magnitude of the patient dose necessary to achieve the benefit may be high. Commensurability is sought, not with harm but with the medical purpose.

The ALARA principle (optimization of protection) applied to medical exposure of the patient is best described as management of the radiation dose to the patient to be commensurate with the medical purpose.

Application of the ALARA principle in medical exposure is a multidisciplinary task involving the technologist, medical and health physicist, medical or dental practitioner, quality assurance and quality control personnel (or committees) and, to some extent, the equipment manufacturer and professional societies. The objective is to design and use the equipment in such a way that an appropriate dose to obtain the desired image or desired therapy is consistently achieved.

Report No. 172 (NCRP, 2012a) provides specific recommendations for applying the ALARA principle (optimization of protection) to medical exposure of patients, and describes use of Diagnostic Reference Levels (DRLs)[13] and achievable doses[14] as the specific and appropriate mechanisms to manage image quality and the radiation delivered to patients for imaging procedures to help reduce the risk of stochastic effects from such procedures. DRLs and achievable doses do not apply to radiation therapy. This Report reaffirms the recommendations in NCRP (2012a).

The ALARA principle for medical exposure to patients from imaging procedures using ionizing radiation takes into account both patient dose and image quality. Diagnostic Reference Levels (and achievable doses) are tools for this purpose, but are neither limits

[13] The term "Diagnostic Reference Level" was first introduced by ICRP (1996) as the term for a form of investigation level used to identify situations where application of the ALARA principle may be required in the medical exposure of patients. A diagnostic reference level (DRL) is a selected level (usually at the 75th percentile of the distribution at initially surveyed facilities of the relevant DRL quantity) for a defined type of imaging procedure. A DRL serves as a tool to help determine when an investigation of practices at a facility is warranted. When assessed values of the DRL quantity exceed the DRL at an evaluated facility, the reasons for the higher values should be investigated. The purpose of the investigation is to assure that the assessed values for the DRL quantity are appropriate and to assure that the image quality is adequate for the clinical task (NCRP, 2012a).

[14] Achievable dose is a selected level of a DRL quantity which serves as a goal for optimization efforts. This level is achievable by standard techniques and technologies in widespread use, while maintaining clinical image quality adequate for the medical-imaging purpose. The achievable dose is typically set at the median value of the distribution of the relevant DRL quantity (NCRP, 2012a).

nor absolute determinants of appropriate use of medical radiation. Diagnostic Reference Levels (and achievable doses) are not to be used for regulatory or commercial purposes or to establish legal standards of care.

Application of the ALARA principle with respect to the risk of adverse tissue reactions, in particular from fluoroscopically-guided interventional (FGI) procedures, was addressed in Report No. 168 (NCRP, 2010b) and NCRP Statement No. 11 (NCRP, 2014b). NCRP (2010b) emphasizes that the safe performance of FGI procedures requires controlling patient dose in order to prevent unexpected or avoidable adverse tissue reactions and to minimize the severity of medically unavoidable injuries. NCRP (2010b) also provides guidance for controlling dose and for patient post-procedure follow-up for these procedures. NCRP (2014b) provides an administrative approach to managing radiation use for FGI procedures. It provides a process for evaluating procedures that result in a clinically important tissue reaction, and states that the quality assurance and peer review process "*shall* include a careful assessment of procedure justification, patient-specific factors, radiation dose optimization, the time course over which radiation doses were administered, disease severity, and procedure complexity."

3.3.2.4 Nonhuman Biota

Application of the ALARA principle is relevant to nonhuman biota, and is applied to any prevailing exposure situation and consistent with the recommendations for consideration of environmental impacts.

3.3.3 Control of Dose to an Individual

Recommendations for control of dose to an individual given in Section 6 are specific for a prevailing exposure situation.

The radiation protection principle of controlling or limiting dose to an individual is fundamental and is intended to ensure adequate protection. It also is intended to ensure that

application of the ALARA principle does not result in individuals or groups of individuals receiving a dose that is inappropriate under the prevailing exposure situation. Although historically the principle of limitation has been focused upon the definition of dose limits in what is now identified by ICRP (2007a) as planned exposure situations, the principle is, in fact, broader, and encompasses all uses of control of dose to an individual to ensure equity and prevent harm.

The principle of control of dose to an individual receives its support from the ethical principle of non-maleficence (avoiding harm). A recommendation for control of dose to an individual places a boundary on harm for a particular individual irrespective of the balancing of benefit. It also receives support from the ethical principle of justice, to ensure that the distribution of doses to individuals is equitable.

The responsible organization selects and uses values of dose to an individual, less than or equal to the relevant NCRP recommendation for control of dose to an individual for a prevailing exposure situation, to establish the range of acceptable options for applying the ALARA principle to that particular exposure situation.

Although many factors may help to define the acceptable range of options in applying the ALARA principle, from a radiation protection standpoint the most significant is the selection of a dose to an individual that, from a protection standpoint, ought not to be exceeded when planning the protection strategy. These are the recommendations for control of dose to an individual provided in this Report, and have been called constraints or reference levels by ICRP (2007a). For an effective application of the ALARA principle, it is important for the responsible party to select values of dose, based on the prevailing exposure situation, so that effective decisions can be made. Such values are almost always less than the relevant recommendation to control dose to an individual contained in this Report, and should be selected based on assessment of the known or expected dose distribution across the exposed population for the prevailing exposure situation.

In the United States and internationally, many different terms have been used to describe values that are selected to control dose to an individual that are then used in applying the ALARA principle. NCRP believes it is better to focus on the specific use for each prevailing exposure situation, rather than on the different terms that have been or are in use. What is most important is that recommendations to control dose to an individual are used to establish the boundary of adequate protection, and then values below that are used to further define the range of acceptable options in applying the ALARA principle.

NCRP emphasizes that, in general, the use by a responsible organization of an NCRP recommended value to control dose to an individual, in the context of application of the ALARA principle, is not to be seen as a limit, but rather as a mechanism to define the acceptable range of outcomes in planning and implementing the ALARA principle. If, during operations, the dose to an individual is found to exceed the value selected by the responsible organization during the planning stage, the appropriate response is to investigate and determine if further steps to reduce dose are reasonable.

For a prevailing exposure situation in which the source is stable, characterized, and subject to an advance control program by the responsible organization, NCRP recognizes that its recommendation for control of dose to an individual may be appropriate as a dose limit (in the regulatory sense). The cases where these conditions are met are identified by NCRP in Section 6.

NCRP recognizes and retains the concept of a dose limit, but, for purposes of this Report, only uses of the term to mean a legal boundary established in a very specific circumstance by a regulatory authority or other responsible party, as described below. In other circumstances, it is not appropriate to establish a dose limit.

The term “dose limit” denotes a specific and absolute value of dose to an individual, from all sources of exposure under the control of the responsible organization. Regulatory authorities establish dose limits as the basis for judging the adequacy of radiation protection for an

individual in specific defined circumstances as a part of the radiation protection program. Although NCRP emphasizes that a dose limit is not a boundary between a safe and an unsafe exposure, from the standpoint of accountability and responsibility, exceeding the numerical value of a dose limit is automatically regarded a violation by regulatory authorities.

NCRP believes that dose limits can only be applied in specific, well-defined circumstances. These circumstances include first that the source of exposure is well known and characterized, and that the source is stable, in the sense that significant variations of exposure are not expected to occur in routine activities. Second, a dose limit is only appropriate when protection strategies for controlling exposure can be preplanned (an advance control program), and operate on the source itself. A dose limit is not an appropriate tool when a source of exposure is not well known or characterized, may be rapidly changing or unpredictable, or when the circumstances only allow for doses to be controlled by controlling the behavior of the individuals themselves.

NCRP believes that the term dose limit has, in too many cases, been used in contexts when it was not appropriate. Furthermore, it should be recognized that other terms have been used on occasion when, in actuality, a dose limit is being imposed because exceeding the absolute value imposed by the term constituted a violation. This has caused confusion on the part of regulatory agencies, entities that use radiation, and in communicating to the public, sometimes to the detriment of establishing a robust radiation protection program. In some circumstances, such as the carefully preplanned introduction and use of a source, it is appropriate for an authority to impose a dose limit based on the NCRP recommendation for control of dose to an individual. In these cases, the use of that NCRP recommendation as part of the application of the ALARA principle is in addition to the dose limit, and values considered in using the ALARA principle in planning should be no greater than the established dose limit, in order to maintain a coherent protection paradigm and avoid a violation.

When the prerequisites noted above for a dose limit are not met, use of the NCRP recommended dose to an individual as a dose limit is not appropriate. In these cases, the

fundamental approach of the ALARA principle is still operative, and the principle of control of dose to an individual simply refers to using the recommendation to control dose to an individual to establish the acceptable range of options in using the ALARA principle. The level of dose to an individual should be selected based on the prevailing exposure situation and the relevant recommendation to control dose to an individual, and may or may not, need to be greater than a dose limit that was set for an entirely different circumstance. The NCRP again emphasizes that the values of dose limits in specific circumstances are not the boundary between safe and unsafe, and have been established only to facilitate a sound legal and regulatory structure when sources are preplanned and clearly under control.

3.3.3.1 Occupational. Control of dose to an individual for occupationally-exposed individuals is applied to specifically identified individuals, and may be in the form of an annual value, or values for shorter time frames (including specific tasks or events) as may be appropriate for effective planning of radiation protection. It is often useful to apply the ALARA principle to certain tasks (*e.g.*, entry into containment to fix a valve), in addition to its application on an annual basis.

Application of the ALARA principle for occupationally-exposed individuals makes use of the NCRP recommended dose to an individual to define the protection options with respect to the doses received by specifically identified individuals in their work environment. Comparison of actual doses received during work with the values used in planning before the work started, can provide an assessment of the effectiveness of the radiation protection program as well as help to ensure that individuals are properly protected. It is incumbent upon licensees, employers, and other responsible entities to provide appropriate monitoring, to maintain dose records, and to exchange information so that an accurate record for a year is produced, irrespective of the number of different entities for whom an individual may work during the year.

Occupational exposure may occur in many circumstances, and in situations where there was preplanning for the source, the source was existing before any protection planning could take place, or there is an emergency. As such, the use of the NCRP recommended dose to an

individual dose as a dose limit will be dependent upon whether it is possible to have sound, ongoing controls, assessment, and recording of exposures. This will always be the case for circumstances in which the source and controls are preplanned, and may be the case in circumstances in which the introduction of the source was not preplanned, but there is a good characterization of the source and exposures.

An example is work to remediate contaminated areas after the radiation exposures in the areas have been characterized, or to conduct radon mitigation measures in a house after radon measurements. However, this usually is not the case in circumstances that are unanticipated, or unknown, or rapidly changing, as in an emergency. Clearly the criteria for use of an NCRP recommended dose to an individual as a dose limit does not apply in these circumstances, and protection should be based on the best available information, and ongoing assessment as the activities progress. In these cases, reliance should be placed on the ALARA principle guided by the recommended dose to an individual that is appropriate for the prevailing exposure situation. Furthermore, there may be different levels of protection expectation that need to be used on the basis of the tasks to be performed, the information on doses that is available, the training and experience of the individuals, and the availability of monitoring and protective equipment.

For occupational exposure, Report No. 168 (NCRP, 2010b) provides recommendations for medical personnel involved in certain fluoroscopically-guided interventional procedures, where on rare occasions, in order to save a patient's life or to prevent severe and irreparable injury to a patient, it may be necessary for the medical personnel to be exposed to a radiation dose (from that specific procedure) that when added to the cumulative dose received thus far in the year would exceed the recommended occupational dose. This is discussed in Section 6.4.2.

3.3.3.2 Public.

Use of the NCRP recommended control on dose to a member of the public from continuous or reasonably anticipated operation of a source as a dose limit is appropriate only for sources under the control of a specified entity, and only in a prevailing exposure

situation in which the source is stable, characterized, and subject to an advance control program by the responsible organization. Appropriate cases are noted in Section 6.

The concept of a dose limit for a member of the public can only be applied to sources of exposure that are under the control of a licensee or other specified entity. This is because it is not generally realistic to provide monitoring and assessment of all the exposures members of the public might receive in the course of their daily lives. Reliance is to be placed upon the ALARA principle guided by recommendations on control of dose to an individual, taking into account the possibility of other sources of exposure beyond that for which the licensee or other specified entity has control. The change to a source-specific recommendation is not viewed by the NCRP as a reduction in the level of protection afforded, because application of the ALARA principle is the primary mechanism for reducing exposure in all prevailing exposure situations.

When the introduction and operation of a source has been preplanned, control of dose to an individual should be applied to the total contributions from that source and all other sources under the control of the responsible organization. In public exposure, the recommendation for control of dose to an individual is generally not specific to any particular individual, and instead is applied to a *representative individual*, defined to be representative of the more highly-exposed individuals in the population (ICRP, 2006). This term is the equivalent of, and replaces the term average member of the critical group. Thus it may be appropriate to use calculations of dose to a representative individual as the basis for establishing the conditions for assessment using the ALARA principle. Monitoring during operations should be conducted to assure that the sets of controls placed on the source are accomplishing the desired results of applying the ALARA principle.

When a source of exposure already exists, causing exposure of individuals, an assessment is needed of the doses that may be received, or are being received by individuals. The assessment is then used in consultation with the appropriate stakeholders to begin defining the needed protection and strategies. The recommendation on control of dose to an individual is to be used to guide application of the ALARA principle in planning and designing any remedial

action. Values at or below the relevant recommendation for control of dose to an individual should also be selected based on the particular circumstances and assessment of doses. When an emergency situation is discovered requiring urgent protective actions, it will be necessary to rapidly take those actions on the basis of whatever information is available, and refine the protection strategies as a more accurate assessment of doses becomes available.

In some cases, this is a rather simple process, such as the assessment of radon in a home, discussion of options for remediation with the homeowner, and completion of the remediation. In other cases, communities will need to be involved because the process may involve many members of the community, and the ethical principles of autonomy and justice become particularly important for a sustainable, acceptable outcome. Adjustment of these expectations during a remediation activity may be a long and continuous process, depending on the circumstances, as described in Report No. 175 (NCRP, 2014c).

In an emergency, actions will need to be taken urgently to protect public health and safety, usually based on facility conditions or limited information. As such, the planning for response, including the recommendation to be used for control of dose to an individual, should be established in advance. As assessments of dose can be made, there can be subsequent refinements and changes in the planned response to better fit the circumstances. In planning for emergency response measures, the application of the ALARA principle applies to all pathways of exposure to effect a reduction in the overall residual dose.

In emergencies, as well as for existing situations at contaminated sites that do not require urgent actions, the numeric values for control of dose to an individual may be selected from within a relatively broad band of values, as described in Section 6. Application of the ALARA principle is to be pursued irrespective of whether the assessed dose to an individual is initially greater than or less than the recommendation for control of dose to an individual when protection activities begin. At that point, the priority should be given to reducing exposures of any individuals that may be receiving doses greater than the value recommended for control of dose to an individual.

3.3.3.3 Medical. Medical exposures include exposures of patients in the course of their medical examination and treatment, exposure of individuals who may voluntarily take part in biomedical research, and exposure of individuals (other than those who are occupationally exposed) who are specifically engaged in the comfort or care of a patient (Section 3.2.3). For the latter two situations, volunteers in biomedical research and comforters and caregivers (namely, parents and other family members, or close friends), recommendations for control of dose to such individuals are appropriate, and are provided in Sections 6.6.3 and 6.6.2, respectively.

For medical exposure of a patient undergoing diagnostic or therapeutic procedures, restriction of patient dose in the form of a dose limit per procedure or per period of time (and therefore a recommendation for restricting dose to an individual for a given medical procedure) does not apply because from an ethical perspective beneficence outweighs non-maleficence.

Public and occupational exposure that may be concurrent with medical diagnosis or treatment is handled in accordance with the provisions described in Sections 3.3.3.1 and 3.3.3.2, respectively.

3.3.3.4 Nonhuman Biota. Control of dose to individual members of a species of nonhuman biota is warranted only under very specific circumstances where the species of concern has protected status in law, and loss of any single individual member of the species can threaten the survival of the species.

3.3.4 Radiation Protection Culture

A radiation protection culture is fostered to effectively implement a radiation protection program commensurate with the radiation protection significance of an organization's nature, activities and functions.

Radiation protection culture includes the core values and behaviors resulting from a collective commitment by leaders and individuals within an organization[15] to emphasize radiation protection over competing goals to ensure protection of people and the environment. The overriding principle is to "put safety first."

Radiation protection culture is consistent with and may be included within an overall *safety culture.* The specific focus in this Report on fostering a radiation protection culture is to recognize its intrinsic value as a force multiplier in supporting and sustaining effective implementation of other recommendations contained in this Report.

Guiding principles for establishing a radiation protection culture have been developed by the International Radiation Protection Association (IRPA, 2014) and have been endorsed by radiation protection professional organizations throughout the world.

Some key attributes of a radiation protection culture include the following (adapted from IRPA, 2014):

- Leaders demonstrate commitment to radiation protection in their decisions and actions.
- Individuals throughout the organization take responsibility for radiation protection of themselves and others.
- Radiation protection issues are promptly identified, evaluated, and addressed commensurate with their significance.
- Radiation protection is integral to the planning and control of work activities.
- Opportunities to learn from radiation protection experience are sought out and identified improvements are implemented.
- Processes for raising radiation protection concerns are open, non-judgmental and responsive.

[15] As used here, the term "organization" refers broadly to any enterprise in which there is work with radiation or decisions impacting radiation exposures are made.

- Communication on radiation protection matters is timely and effective.
- Shared trust and respect permeate the radiation work environment.
- Individuals continually demonstrate a questioning attitude about radiation protection conditions and activities.

Individuals also need to take responsibility for their own exposure. An effective radiation protection culture fosters engagement by these individuals, and is necessary to have effective radiation protection, and to control doses consistent with the ALARA principle. Radiation protection professionals and organizations can help individuals participate in, and take responsibility for, their own exposure mainly by sharing radiation protection information, especially through a genuine dialog with those exposed.

4. Main Judgments on Human Health Effects and Effects on Nonhuman Biota

The judgments on radiation-induced human health effects and effects on nonhuman biota that underlie the NCRP conclusions, decisions and specific recommendations for application of the fundamental radiation protection principles of justification, the ALARA principle (optimization of protection), and control of dose to an individual are highlighted here in Section 4. A more detailed discussion of radiation effects in humans and nonhuman biota is found in Appendix B. For each of the judgments described in Section 4, the sections in Appendix B that give additional information are noted.

4.1 Epidemiology

Epidemiology remains the basis for the system of radiation protection. The estimates of cancer risk attributable to radiation have changed somewhat but not greatly in the past 25 y, whereas the estimated risk of heritable effects is now much lower than before. New human studies provide a firmer basis on which to model risks at low doses and to assess radiation detriment. The major unanswered question that would improve the system of radiation protection is understanding the level of risk when exposure is gradual over time (years) (as relevant to public and occupational circumstances) rather than in a relatively brief time frame (seconds to days). [Throughout Appendix B]

4.2 Integration of Epidemiology and Biology

NCRP recognizes that it is not possible to detect radiation effects in humans, consistently and convincingly, below ~100 mGy organ dose. Thus judgment is used to interpolate risks from higher dose using various empirical mathematical models (*e.g.*, the linear non-threshold model). Biologically-based models are rarely used for the purposes of radiation protection. NCRP (2015a) recommends that a stronger emphasis be placed on integration of the substantial literature on radiation biology with the best epidemiology to improve assessment of low dose risks needed for radiation protection. [Throughout Appendix B]

4.3 Cancer

4.3.1 Age-at-Exposure Effects

Although there are exceptions, the younger the age-at-exposure, the greater is the lifetime risk of cancer (UNSCEAR, 2013). The risk of developing some cancers, such as thyroid cancer is only elevated following exposures as children and young adults. Other cancers have a remarkable dependence on age-at-exposure, especially cancers of the brain and female breast. Accordingly, the computation of effective dose, used for radiation protection guidance and compliance, takes age sensitivity into account. [Section B.4.3]

4.3.2 Sex Effects

The lifetime risk of cancer following irradiation appears greater for females than for males. This might be expected since the sex organs differ greatly in radiosensitivity; the female breast and ovaries are highly sensitive to cancer induction whereas cancers of the male testes and prostate have not been shown to be as sensitive. Atomic-bomb survivor studies, however, indicate that on a relative scale, the rates of cancers excluding the sex organs are still 2 to 3 times higher among females than males. Strong conclusions are tempered because the female-to-male ratio of cancer rates depend on whether a relative or absolute risk model is chosen and the female-to-male ratio appears to depend on dose (Grant *et al,* 2017). Sex differences are accounted for in the computation of effective dose used for radiation protection guidance and compliance. [Section B.4.4]

4.3.3 Linear Non-threshold Model

Based on a comprehensive review of recent epidemiologic studies of irradiated populations, NCRP (2017a) reaffirms that, for identified stochastic effects, the linear non-threshold model for dose-response should be used for radiation protection as a prudent and

practical tool for managing potential radiation risks below an effective dose of 100 mSv. [Section B.4.2]

4.3.4 Lifetime Recommendation for Occupational Exposure

NCRP continues to support a lifetime recommendation for control of dose to an individual for occupational exposure of 10 mSv (effective dose) times age (NCRP, 1993a). This has been shown to be the appropriate approach in many epidemiologic studies described in Appendix B (*i.e.*, cumulative dose over time is related to risk and annual dose is not). Annual effective dose values of 20 mSv or 50 mSv over a working life allow for higher cumulative effective doses than does the NCRP recommendation of 10 mSv times age (*i.e.*, this NCRP recommendation is the most protective of the worker). The lifetime recommendation is utilized in combination with the annual effective dose recommendation of 50 mSv (NCRP, 1993a). With the availability of large-scale dosimetry systems within the government and private enterprises (*e.g.*, NRC REIRS, DOE REMS, military dosimetry systems, and commercial dosimetry firms), used to capture career doses in many epidemiologic studies (Boice *et al.*, 2006), as well as individual requests for prior occupational doses from previous employers, the ability to obtain lifetime cumulative doses for individuals is improved. [Throughout Appendix B]

4.3.5 Embryo and Fetus

By virtue of the increased risk of malformation during critical periods of brain development and the increased risk of cancer compared with adults, special attention is given to protection of the embryo and fetus (NCRP, 2013). Once a pregnancy is declared, special guidance comes into play for the pregnant worker to minimize dose to the embryo and fetus. [Section B.4.5.2]

4.4 Heritable (Genetic) Effects

Continued studies of the children of atomic-bomb survivors and new studies of the children of cancer survivors treated with radiation have reinforced the conclusion that heritable effects in human populations have not been detected and are even less likely than previously thought. The absence of direct evidence of genetic effects in humans is a comforting conclusion from epidemiologic studies. NCRP agrees with ICRP in reducing the contribution of genetic effects in the revised radiation detriment equation (ICRP, 2007a). [Section B.5]

4.5 Genetic Susceptibility

Genetic susceptibility to radiation-induced cancer involving strongly expressed genes is judged to be too rare to appreciably distort estimates of population risk, and the potential impact of common but weakly expressing genes remains uncertain. For the purposes of radiation protection, genetic susceptibility will not significantly influence the NCRP recommendations since substantially <1 % of a general population is very susceptible. Further, it is not yet possible to determine accurately the genetic susceptibility of individuals by using cellular or molecular tests (ICRP, 2007a). In situations where individual risk could be more of an issue, such as patients treated with radiation therapy, accounting for possible radiation-susceptible genotypes, if known, would be encouraged. [Sections B.4.4.5 and B.6]

4.6 Cardiovascular Disease

On the basis of a critical review (Boice, 2017b; NCRP, 2017a) of recent epidemiologic studies of atomic-bomb survivors, occupationally-exposed workers (including the INWORKS study and the One Million U.S. Workers and Veterans Study), and tuberculosis patients receiving repeated fluoroscopic x-ray exposures, and other patient populations, NCRP (2017a) concluded that there is not yet sufficient evidence that cardiovascular disease (CVD) is increased at absorbed doses to the heart below ~0.5 Gy. The absence of more information and a clear mechanism for low-dose effects contributes to the conclusion that it is not appropriate for CVD,

at this time, to be included as a component of radiation detriment for radiation protection purposes. Additional research is needed on the relationship between CVD and absorbed doses < 0.5 Gy. [Section B.7]

4.7 Central Nervous System

Dementia, Alzheimer's disease, Parkinson's disease and motor neuron disease have not been found to be associated with exposure to low-LET radiations in epidemiologic studies. Experimental studies of rodents concluded that Alzheimer's disease and dementia occur after exposure to high energy and high atomic weight (HZE) particles at a high dose rate. These experiments have raised concern that, if relevant to humans, crew members on interplanetary space missions might suffer cognitive deficits that would prevent or impede completion of their mission to Mars and/or might cause dementia later in life after they return (NCRP, 2016b). Guidance for crew members on long-term space missions is being developed but is particularly challenging when the outcome (behavior cognitive dysfunction) is not well defined, the cells or groups of cells at risk are not well defined, the pattern of dose distribution in brain from HZE particles is not well defined, and the mechanism for such effects is not well defined. It is clear that the mechanism is not related to DNA damage as is the case for carcinogenesis. [Section B.8]

4.8 Cataracts

NCRP (2016a) reviewed the most recent literature on radiation-related cataract and serious lens opacities, and systematically judged the quality of published epidemiologic studies. NCRP (2016a) concluded that the existing annual limit of 150 mSv equivalent dose to the lens of the eye for occupational exposure should be lowered and the quantity changed to 50 mGy absorbed dose to the lens of the eye. This judgment also considered the seriousness of the condition, the cost of implementation, and the level of protection provided by lowering the limit. It remains unclear whether radiation-related cataracts should remain categorized as a tissue reaction (deterministic effect) or categorized as a stochastic effect. At present a threshold model is assumed, but the level of the threshold is uncertain. These conclusions differ from those of

ICRP (2012) which recommends a 20 mSv equivalent dose limit for lens of the eye. [Section B.10]

4.9 Psychosocial Effects

Serious mental and behavioral disorders after a major radiological or nuclear incident have repeatedly been found to occur (*e.g.*, after Chernobyl and Fukushima). The effects are not related to dose (*i.e.*, "fear has no threshold"), and occur even in the absence of any measurable or demonstrable dose. The disorders occur relatively shortly after the disaster compared with the late and theoretical increase in cancer that might occur decades into the future. Such realities necessitate awareness and communication skills to respond when a major radiological or nuclear incident occurs. Monitoring by health officials should be considered to respond to psychosocial problems leading to ill health. [Section B.12]

4.10 Nonhuman Biota

NCRP has not addressed or integrated the protection of the environment (expressed in this Report as nonhuman biota) with the protection of humans until this Report. The ethical rationale might be considered "extended anthropocentrism," that is, nonhuman biota are valuable and should be protected because of their benefit to humans. Equally important, government agencies develop environmental impact statements and have legislative requirements, but little guidance on radiation effects and protection approaches for nonhuman biota. [Section B.14]

5. Radiation Detriment, Nominal Risk Coefficients for Stochastic Effects, and Uncertainties

5.1 Radiation Detriment

The concept of radiation detriment for radiation protection purposes was originally introduced in Publication 26 (ICRP, 1977) where it was defined as the mathematical "expectation" of the harm incurred from an exposure to radiation. For radiation protection purposes, Publication 60 (ICRP, 1991a) utilized the concept of health detriment to describe the overall health impact of radiation beyond cancer and noncancer risks. Radiation detriment is defined as a measure of stochastic effects from exposure to ionizing radiation that takes into account the probability of fatal cancers, probability of severe heritable effects in future generations, probability of nonfatal cancers weighted by the lethality fraction, and relative years of life lost per fatal health effect.

The calculation of radiation detriment is complex and has a number of associated uncertainties and assumptions. ICRP (1991a) used sex and age averaged cancer mortality and incidence risk coefficients and included adjustments for nonlethal cancer and remaining lifespan as well as potential heritable effects. Stochastic risks were converted to nominal risk coefficients (Section 5.2). This general concept of radiation detriment was continued in Publication 103 (ICRP, 2007a). The use of more recent epidemiologic cancer incidence and mortality values resulted in revised values for radiation detriment and tissue weighting factors. The resulting radiation detriment-adjusted nominal risk coefficients for fatal cancer per sievert (effective dose) for adult workers and the whole population are $4.1\ 10^{-2}\ Sv^{-1}$ and $5.5\ 10^{-2}\ Sv^{-1}$, respectively (ICRP 2007a).

Epidemiologic studies provide the cancer incidence data, the fatality factors and the measures of years of life lost. Radiation detriment is seen to change over the years as cancer incidence coefficients are updated, survival after cancer diagnosis improves and the lifespan of the population increases.

5.2 Nominal Risk Coefficients for Stochastic Effects, and Age and Sex Averaging

Nominal risk coefficients for stochastic effects are derived by averaging sex and age-at-exposure lifetime risk estimates in representative populations. Nominal risk coefficients are for use in radiation protection and are not actual or real specifications of risk for an individual. For radiation protection purposes, the nominal risk coefficients are age- and sex-averaged to produce the tissue weighting factors needed to compute effective dose and radiation detriment. Related in part to the uncertainties associated with defining tissue weighting factors (they are based on judgment informed by science) and the even greater uncertainties in defining and computing radiation detriment, NCRP concludes that the practice of averaging sex and age coefficients should continue as a practical and prudent approach that provides adequate protection for both sexes and all ages. It also obviates the complexity of incorporating sex- and age-specific criteria for individuals into an already robust system of protection (*e.g.*, the criteria would continually change as a person ages). Further, sex and age specific criteria might prove discriminatory as suggested for female crew members in NASA space activities (NCRP, 2014a).

The radiation detriment-adjusted nominal risk coefficients for stochastic effects used by ICRP (1991a) and ICRP (2007a) are shown in Table 5.1.

The nominal values for lifetime fatal cancer risk per sievert (effective dose) used in Report No. 116 (NCRP, 1993a) for low dose or low dose-rate exposure are very similar (*i.e.*, 4×10^{-2} Sv^{-1} for adult workers and 5×10^{-2} Sv^{-1} for the whole population). The values for severe heritable effects used were the same as in ICRP (1991a).

The ICRP (2007a) nominal radiation detriment-adjusted risk coefficients for each cancer site were calculated by a complex process based on lethality, reduction in quality of life, and life shortening. These lifetime risk estimates rely on atomic-bomb survivor data for a Japanese population, but background cancer rates differ across different populations. Publication 103 (ICRP, 2007a) states that for risk transfer across populations for each cancer site a weighting

Table 5.1 --- Detriment-adjusted nominal risk coefficients (10^{-2} Sv^{-1}) for stochastic effects after exposure to radiation at low dose rate (ICRP, 2007a).

Exposed Population	Cancer		Heritable Effects		Total	
	ICRP (2007a)	ICRP(1991a)	ICRP (2007a)	ICRP(1991a)	ICRP (2007a)	ICRP(1991a)
Whole	5.5	6.0	0.2	1.3	5.7	7.3
Adult	4.1	4.8	0.1	0.8	4.2	5.6

factor of the excess relative risk (ERR) and excess absolute risk (EAR) lifetime risk estimates was established that provided a reasonable basis for generalizing across populations with different baseline risks. When these weighted risk estimates were averaged across seven western and Asian populations, the resulting nominal risk coefficients were those used by ICRP (2007a) in their calculation of radiation detriment. For the purposes of radiation protection recommendations, NCRP judged it not necessary to adjust the ICRP (2007a) values to be specific for the U.S. population.

For the system of radiation protection, NCRP uses the same nominal radiation detriment-adjusted risk coefficients for cancer and heritable effects as ICRP (2007a).

For a defined group of individuals, sex and age specific risk estimates derived from epidemiologic studies as described in Appendix B are used. The nominal risk coefficients that are sex- and age-averaged for a reference population and developed for radiation protection purposes are not appropriate for this purpose (ICRP, 2007a). For risk assessments in the United States, risk coefficients derived for the characteristics of the U.S. population would be more appropriate.

5.3 Uncertainties

For setting radiation protection recommendations for control of dose to an individual, there are several essential, and linked, factors that have associated uncertainties. These factors include issues related to attributability, dose and dose-rate factors, weighting factors and the models used. For the purposes of this Report and for organ doses <1 Gy, the discussion of attribution, inferring risks and uncertainties is limited to radiation-induced cancer. When a detailed analysis for a specific situation is performed, the uncertainty interval is generally a factor of about 2 to 3 about a central estimate of risk based on a uniform whole-body exposure.

5.3.1 Attributability

For purposes of radiation protection and establishing recommendations for control of dose to an individual for occupational and public exposure, it is important to understand the

scientific process of determining whether a specific health effect can be attributed to radiation exposure and if so, with what certainty. In addition, it is necessary to determine what risks might occur in the future after radiation exposure of a person or a population. These issues have been dealt with in the past in NCRP Statement No. 7 (NCRP, 1992) and more recently in Annexes A and B by UNSCEAR (2015).

Regardless of the level of exposure, a specific cancer or cancers in an individual or population cannot be unequivocally attributed to radiation exposure since at present there are no biomarkers specific to radiation-induced cancer and there are always competing causes and confounding factors. If there is a statistically significant increase in cancer incidence in those tissues known to be radiosensitive following radiation exposure then attribution is plausible. The probability of causation depends upon the type of cancer, organ dose, radiation type and quality, age-at-exposure, latent period and other risk factors. An increase in health effects in an individual or population cannot reliably be attributed to chronic low-LET doses in the range of average ubiquitous background radiation.

NCRP also understands that there are substantial uncertainties in multiplying very low doses by large numbers of individuals to estimate numbers of future radiation-induced stochastic health effects in an exposed population.

Risks from radiation exposure of an individual or population cannot and should not be inferred from the effective dose values provided in the recommendations for radiation protection provided in this Report. These effective dose values are not threshold levels at which stochastic health effects may or may not occur, nor do they distinguish between safe versus unsafe levels.

Quantitative assessment of risk from radiation exposure of an individual or population cannot be inferred from the effective dose. In addition, recommendations for control of effective dose to an individual established for radiation protection purposes are not interpreted as threshold levels at which stochastic health effects may or may not occur, nor as distinguishing between "safe" versus "unsafe" exposures.

5.3.2 Adjustment for Dose and Dose Rate

Based on a range of biological studies and selected epidemiologic studies, a dose and dose-rate effectiveness factor (DDREF) is used for converting cancer risks obtained at relatively high absorbed doses and absorbed dose rates [*e.g.*, from the atomic-bomb survivor study (acute exposure)] for predicting risks at low absorbed doses (<100 mGy) and low absorbed dose rates (<5 mGy h^{-1}) (*e.g.*, experienced by workers and members of the public). The choice of a DDREF is somewhat arbitrary and based on judgment that considers a wide range of molecular, cellular, animal and epidemiologic studies.

NCRP (1980) was the first to introduce the term "dose rate effectiveness factor" (DREF) to compare effects from acute exposures to low-LET radiation with those from fractionated or protracted exposures and proposed values between 2 and 10, for purposes of establishing the system of protection. After considering various human and experimental data, a value of 2 was selected in Publication 60 (ICRP, 1991a). Report No. 116 (NCRP, 1993a) also selected a value of 2. Analyzing the same data, ICRP in its most recent set of recommendations (ICRP, 2007a) retained a value of 2; BEIR VII (NA/NRC, 2006) selected a value of 1.5; and UNSCEAR (2008) most recently elected not to use a DDREF. A number of epidemiologic studies for populations exposed at low dose rates have proposed values consistent with a value of 2 and as low as 1 for DDREF conversion [reviewed, for example, in Report No.171 (NCRP, 2012b)].

It has been proposed by a number of sources, based on animal experiments, that it might be more appropriate and more correct to consider separately a low-dose effectiveness factor (LDEF) and a dose-rate effectiveness factor (DREF) for risk estimate calculations (reviewed in Ruhm *et al.*, 2015). Ongoing epidemiologic research directed by NCRP will provide estimates of the DREF (Boice, 2017b; Bouville *et al.*, 2015). Further, studies (*e.g.*, Boice *et al.*, 2017a; Richardson *et al.*, 2015) and ongoing comprehensive evaluations by ICRP and others may change this assessment (Ruhm *et al.*, 2015, 2016).

NCRP recognizes that dose-response relationships depend on a large number of factors, including differences in responses of various organs and cancer types, and cannot be simplified

for risk assessments to a single value. NCRP continues to monitor developments in epidemiologic, biological and statistical analyses that may contribute to improved understanding of the implications. However, for purposes of prospective radiation protection, NCRP continues to recommend a DDREF value of 2 for estimating cancer stochastic responses at low doses and low dose rates.

In this Report, NCRP adopts a DDREF of 2 for radiation protection purposes. This value is consistent with the recommendation of ICRP (2007a).

6. Recommendations for Control of Dose to an Individual

6.1 Introduction

The recommendations for control of dose to an individual made in this Report are expressed in terms of absorbed dose in a specific organ or tissue (organ dose) or effective dose. These recommendations are similar to those made previously by NCRP (1993a) and ICRP (2007a). However, some changes have been made for clarity in language and terminology, and in some cases the dose values recommended have been changed. In Section 6, key statements about recommendations for control of dose to an individual are **highlighted and bolded** for emphasis and the recommendations themselves that contain the specific dose values are **shown in a box in bolded text**.

Recommendations for control of dose to an individual are used in conjunction with the ALARA principle to establish adequate protection for an individual. When it is appropriate to apply one of these recommendations as a dose limit (in the regulatory sense), that is stated.

The system of protection in this Report uses the three radiation protection principles of justification, the ALARA principle (optimization of protection), and control of dose to an individual. Recommendations for control of dose to an individual are used in implementing the ALARA principle, as well as for providing the establishment of adequate protection for an individual for a prevailing exposure situation. Recommendations for control of dose to an individual do not apply to the medical exposure of patients, or to exposure of members of the public to the ubiquitous background radiation (other than elevated radon levels in homes and workplaces).

Recommendations for control of dose to an individual are based on two adverse health outcomes: tissue reactions (formerly named deterministic effects) and stochastic effects (primarily cancer mortality). The recommendations related to adverse tissue reactions are

discussed in Section 6.2 (for general considerations) and Section 6.7 (in the context of decision points for emergency workers). The recommendations related to stochastic effects are discussed in Sections 6.3 through 6.6. In addition to the recommendations, it is expected that the ALARA principle will be applied to reduce the actual dose received to as low a value as is reasonably achievable, taking into account societal, economic and environmental factors.

For nonhuman biota, a recommendation, in absorbed dose rate, is made with the specific intent to ensure the protection of the population, although it is evaluated for individuals in the species.

6.2 Tissue Reactions

Recommendation to control dose to an individual are given in Section 6.2 to protect against adverse tissue reactions and acute organ effects related to exposure of the skin (including the extremities) and the lens of the eye. Special considerations are necessary for exposures during a declared emergency, which are covered in Section 6.7. The recommendations related to tissue reactions are stated using the quantity absorbed dose in the relevant organ or tissue (organ dose).

6.2.1 Skin, Including Extremities

NCRP recommends, for occupational and public exposure, that the absorbed dose in the skin or extremities at a depth of 70 μm from any external source of irradiation not exceed 0.5 Gy annually, averaged over the most highly exposed 10 cm^2 of skin. This recommendation may be applied as a dose limit.

Both NCRP (1993a) and ICRP (2007a) have stated that specific recommendations are necessary to protect localized areas of skin (including the extremities) against tissue reactions because these tissues will not necessarily be protected by control of effective dose.

NCRP (2001b) recommended an approach somewhat different from ICRP (2007a) to assess skin dose relevant to radiation protection. Following a detailed report on biological effects

for "hot particles" on the skin (NCRP, 1999), NCRP (2001b) reassessed its recommendation for skin exposures (including the extremities) and made the following recommendation:

> "For skin, limitation of occupational radiation exposure from external sources be based on ensuring that irradiation from any source would not be expected to result in breakdown of skin barrier function with the consequent possibility of infection. The absorbed dose in skin at a depth of 70 μm from any external source of irradiation be limited to 0.5 Gy averaged over the most highly exposed 10 cm^2 of skin. This can be viewed as a per-irradiation event limit so long as the exposed areas of skin do not overlap in such a way that the total absorbed dose to the most highly exposed 10 cm^2 of skin exceeds the limit during a given year. In the event that the areas of exposed skin overlap, then the limit applies to the calendar year, consistent with the annual general skin limit of 0.5 Gy y^{-1}, rather than to the individual events."

If it is necessary to apply this recommendation for skin to a high-LET radiation exposure, NCRP prefers the approach taken in Report No. 132 (NCRP, 2000) in which the absorbed dose in the skin is multiplied by the biological effectiveness of the high-LET radiation to obtain a radiation-weighted absorbed dose (expressed in gray). This may then be compared to the recommendation for low-LET radiation expressed in gray. Values of biological effectiveness for various high-LET radiations are given in Table 6.1.

The extremities are defined as: the arms and hands from the elbow to the tips of the fingers; and the legs and feet from the knee to the tips of the toes. When the radiation exposure is restricted to the extremities, the recommendation is the same as for the skin.

It is not likely that radiation exposure outside of the occupational setting or certain medical procedures will approach any of the threshold doses cited in Table 6.2. However, if such an exposure were to occur, the same recommendation related to exposure of the skin and extremities would apply to members of the public.

Table 6.1 --- Biological effectiveness values for converting absorbed dose in tissue (gray) to radiation-weighted absorbed dose in tissue (gray) for tissue reactions (adapted from ICRP, 1990b).[a]

Radiation Type	Recommended Biological Effectiveness Values[b]	Range[b]
1 to 5 MeV neutrons	6.0[b]	(4-8)
5 to 50 MeV neutrons	3.5[b]	(2-5)
Heavy ions (helium, carbon, neon, argon)	2.5[c]	(1-4)
Protons >2 MeV	1.5	----

[a]Biological effectiveness values for late tissue reactions are higher than for early effects in some tissues and are influenced by the doses used to determine the biological effectiveness.

[b]There are not sufficient data on which to base biological effectiveness values for early or late effects induced by neutrons of energies <1 MeV or greater than about 25 MeV. However, based on the induction of chromosome aberrations, using 250 kV (peak tube potential) x rays as the reference radiation, the biological effectiveness for neutron energies <1 MeV is comparable to those for fission spectrum neutrons. It is reasonable to assume that the biological effectiveness values for energies >50 MeV will be equal to or less than those for neutron energies in the 5 to 50 MeV range.

[c]There are few data for the tissue reactions of ions with a $Z > 18$ but the biological effectiveness values for iron ions ($Z = 26$) are comparable to those for argon ions. Based on the available data a value of 2.5 for the biological effectiveness of heavy ions is reasonable. One possible exception is cataract of the lens of the eye because high biological effectiveness values for cataracts in mice have been reported.

Table 6.2 --- Approximate threshold single doses and time of onset for the reaction of human skin to ionizing radiation delivered in fluoroscopy exposures. These threshold doses are considered to be near to ED_1 (the estimated dose for 1% incidence). Note that the threshold doses are given as absorbed dose in gray (ICRP, 2012).

Effect	Approximate Threshold Dose (Gy)	Time of Onset
Early transient erythema (skin reddening)	2	2–24 h
Main erythema reaction	6	~1.5 weeks
Temporary epilation (loss of hair)	3	~3 weeks
Permanent epilation	7	~3 weeks
Dry desquamation (dry scaling skin)	14	~4–6 weeks
Moist desquamation (weeping loss of skin)	18	~4 weeks
Secondary ulceration (open skin sore)	24	>6 weeks
Late erythema	15	8–10 weeks
Ischemic dermal necrosis (tissue death caused by loss of blood supply)	18	>10 weeks
Dermal atrophy (first phase) (wasting away of skin)	10	>52 weeks
Telangiectasia (red blotches on skin)	10	>52 weeks
Dermal necrosis (late phase)	>15?	>52 weeks

6.2.2 Lens of the Eye

NCRP recommends the annual absorbed dose in the lens of the eye for occupational exposure not exceed 50 mGy. This recommendation may be applied as a dose limit.

NCRP recommends the annual absorbed dose in the lens of the eye for exposure to members of the public not exceed 15 mGy.

NCRP (2016a) determined that it is prudent to reduce the previous annual lens of the eye recommendation for occupational exposure from an equivalent dose of 150 mSv (NCRP, 1993a) to an absorbed dose of 50 mGy. More detail on this recommendation to control dose to an individual is provided in Section B.10. If it is necessary to apply this recommendation to high-LET radiation, NCRP recommends the approach described in Section 6.2.1 for exposures to the skin or extremities.

No change in the previous numerical value is recommended for members of the public for the lens of the eye. NCRP judges that the existing annual value is adequately protective (NCRP, 1993a), but that value also now be expressed as absorbed dose. Therefore, the annual absorbed dose for members of the public for lens of the eye is 15 mGy absorbed dose [previously expressed as 15 mSv equivalent dose to lens of the eye (NCRP, 1993a)].

6.2.3 Acute Organ Effects

To avoid acute organ effects during emergency operations, NCRP recommends the absorbed dose in a significant portion of an organ or tissue not exceed 1 Gy.

The principal organ effects that could lead to serious injury or death from radiation exposure are given in Table 6.3 and can be used to guide decision-making in emergency operations. ICRP (2007a) has established a maximum effective dose for its reference level of 100 mSv. Further ICRP (2007a) stated, “Exposures above 100 mSv incurred either acutely or in a year would be justified only under extreme circumstances, either because the exposure is

Table 6.3. --- Estimates of the threshold doses for mortality[a] in adults exposed to acute irradiation (adapted from Table 4.5 in ICRP, 2012).

Effect (Mortality)	Organ/Tissue	Time to Develop Effect	Absorbed Dose[b] Resulting in Approximately 1 % Incidence for an Acute Exposure (Gy)
Bone marrow syndrome			
Without good medical care	Bone marrow	30–60 d	~1
With medical care	Bone marrow	30–60 d	2–3
Gastrointestinal syndrome			
Without medical care	Small intestine	6–9 d	~6
With conventional medical care	Small intestine	6–9 d	>6
Pneumonitis – mean lung dose	Lung	1–7 months	7–8
Cardiovascular disease – whole-body exposure	Heart	>10–15 y	~0.5
Cerebrovascular disease	Carotid artery	>10 y	~0.5

[a] Some of these diseases may not be fatal, if good medical care or biological response modifiers are used. In the cases of cardiovascular disease and cerebrovascular disease, from the evidence currently available, the values given here are also assumed to apply to morbidity from these diseases.

[b] Most values rounded to nearest 1 Gy; range indicate differing medical support for bone marrow.

unavoidable or in exceptional situations such as the saving of life or the prevention of a serious disaster." Nevertheless, in footnotes b and c associated with its Table 5, ICRP (2007a) stated, "In exceptional situations, informed volunteer workers may receive doses above this band (above 100 mSv) to save lives, prevent severe radiation-induced health effects, or prevent the development of catastrophic conditions." ICRP (2007a) further stated "Situations in which the dose threshold for tissue reactions in relevant organs or tissues could be exceeded should always require action." Within that framework, guidance can be given for specific emergency situations.

NCRP made specific recommendations related to emergency situations in Report No. 165 (NCRP, 2010c). NCRP did not recommend a dose limit for emergency responders performing time-sensitive, mission critical activities such as lifesaving. Instead, NCRP (2010c) recommended that decision dose points be established based upon operational awareness and mission priorities. A 0.5 Gy decision absorbed dose was recommended to keep the dose to an emergency responder from unintentionally surpassing 1 Gy, below which clinically-significant early health effects are not likely to occur.

6.3 Stochastic Effects

Control of radiation exposure for stochastic effects is based on application of the ALARA principle, in conjunction with the appropriate recommendation for control of dose to an individual.

NCRP reviewed the estimated risks for radiation exposure and the uncertainties in these risk estimates (NCRP, 2017a). As a result, NCRP has determined that appropriate values of dose to an individual should be selected that are less than or equal to the recommendation for control of dose to an individual, for the prevailing exposure situation. NCRP does not use the ICRP terminology of dose constraints and reference levels, but has established a single general term, *recommendation for control of individual dose*, to provide adequate protection for a prevailing exposure situation. This approach retains the NCRP basic recommendation for control of annual

effective dose (NCRP, 1993a), goes beyond those recommendations by basing the control of dose to an individual, and the selection of appropriate values to guide the ALARA principle, on the following characteristics of each prevailing exposure situation, namely the:

- nature of the source;
- individuals exposed;
- circumstances of exposure; and
- ability of those with authority to control the:
    - source of radiation; and
    - actions of the persons at risk of exposure.

When the exposure can be reasonably expected to be under the control of the party responsible for the radiation source causing the exposure, the recommendations to control dose to an individual are more restrictive than in exposure situations where there may not (at least initially) be control of the source. In the latter situations, control is most often exerted on the exposure pathways, or actions on the individuals themselves, rather than on the source itself. However, in all situations the recommendations represent adequate protection. The ALARA principle should also be employed to each prevailing exposure situation.

In prevailing exposure situations in which the source is stable, characterized, and subject to an advance control program by the responsible organization, the NCRP recognizes that its recommendation for control of dose to an individual may be appropriate as a dose limit (in the regulatory sense).

Recommendations on control of dose to an individual, based on the radiation detriment related to stochastic effects, are given for occupational exposure in Section 6.4, and for public exposure in Section 6.5.

6.4 Occupational Exposure

6.4.1 General

NCRP recommends the annual effective dose to an individual from occupational exposure not exceed 50 mSv. This recommendation may be applied as a dose limit when the source is stable, characterized, and subject to an advance control program.

NCRP recommends the cumulative lifetime effective dose for an individual from occupational exposure not exceed 10 mSv multiplied by the individual's age in years.

The definition of occupational exposure is discussed in Section 3.2.1. NCRP continues to endorse the annual effective dose value of 50 mSv for occupationally exposed individuals stated in NCRP Publication No.116 (NCRP, 1993a).

Previously, NCRP (1993a) recommended that the cumulative lifetime dose for an individual not exceed 10 mSv multiplied by the individual's age. NCRP continues to recommend this restriction on the cumulative lifetime dose for an individual. NCRP recognizes that practical application costs may make cumulative lifetime recording difficult, and notes that, while less restrictive, the approach recommended by ICRP (2007a) for controlling the exposure to 100 mSv over a defined 5 y period is an alternative approach to *de facto* control of cumulative dose.

NCRP recommends that for exposure of an individual under the age of 18 y in educational and occupational settings, the annual effective dose from all such activities in a year not exceed 1 mSv.

As in the past, NCRP continues to recommend that minors who are involved in educational and occupational settings in which exposure to radiation is possible be protected during those activities at a level consistent with that afforded to a member of the public.

For educational and training purposes, it may be necessary and desirable to accept occasional exposure of persons under the age of 18 y. As in NCRP (1993a), it is recommended that exposures for these purposes be permitted only under conditions presenting high assurance that the resulting annual effective dose from all such activities in a year not exceed 1 mSv. This is consistent with the recommendation for control of dose to a member of the public (Section 6.5.1). Intentional exposure of trainees should be avoided. It is recognized that a productive part of the training experience may be better conducted in an industrial or hospital situation, which might constitute part-time work experience, supervised in some manner by an educational institution.

6.4.2 Unique Circumstances for Medical Staff.

In some unique circumstances, it may be necessary for a healthcare worker to exceed the recommended annual effective dose for occupational exposure of 50 mSv in order to save a patient's life or to prevent severe and irreparable injury to a patient. As an example, Table 5.3 in NCRP (2010b) describes situations where this may be necessary in fluoroscopically-guided interventional procedures. In such situations policies and procedures should be in place in advance so that in the event of a reasonably foreseeable time-critical urgent or emergent situation, provision exists for exceeding the recommendation for annual occupational effective dose (*i.e.*, 50 mSv). However, the recommendation for cumulative lifetime effective dose for the individual (*i.e.*, 10 mSv times the age of the individual in years) still applies NCRP (2010b).

6.4.3 Embryo and Fetus.

NCRP recommends the equivalent dose to the embryo and fetus not exceed 0.5 mSv per month due to occupational exposure of a pregnant worker once the pregnancy is declared by the pregnant worker.

The sensitivity of the embryo and fetus for both mental retardation and cancer should be considered in all situations involving irradiation of an embryo and fetus (NCRP, 1993a). This is

a special consideration for occupational exposure of pregnant workers. This situation could be thought of as occupational exposure to the mother while the unborn child is treated separately as a member of the public. In the context of occupational exposure, consideration should be given to the right of the mother to retain her job. The ethical principles of autonomy and justice permit the mother to accept risks for her unborn child.

Therefore, for occupational situations, NCRP recommends the monthly equivalent dose to the embryo and fetus not exceed 0.5 mSv (excluding medical and ubiquitous background radiation) once the pregnancy is declared by the pregnant worker. This is based on the philosophy that a monthly value will allow for reasonable opportunities to continue to work while providing practical controls during potentially sensitive periods of gestation. The recommendation reflects the need to control the total lifetime risk of leukemia and other cancers in individuals exposed *in utero*. At doses below the recommended value, all adverse tissue reactions (deterministic effects) as well as small head size and mental retardation are expected to be negligible. This recommendation is consistent with the previous NCRP recommendation (NCRP, 1993a), and a full discussion of health effects and protective guidance for the embryo and fetus is provided in Report No. 174 (NCRP, 2013).

There is no new epidemiologic information or evidence of operational problems to suggest a need to change this approach. However, situations expected to expose a worker who has declared her pregnancy to radioiodine need to be avoided because of the risk of congenital hypothyroidism.

6.4.4 Radon and Naturally-Occurring Radioactive Material.

The contribution of radon should be included if it comprises more than 20 % of the total occupational effective dose.

The first step in any consideration of radon is an assessment of concentrations in air (Section 6.5.4). Radon mitigation measures should be taken for structures in the workplace, just

as for homes in the case of exposure to members of the public. While mitigation measures are normally effective in controlling exposure to the recommended air concentration (Section 6.5.4), certain circumstances may make this impossible.

In situations in which occupational exposure is being controlled, the contribution of radon should be included if it comprises more than 20 % of the total occupational effective dose. Organizations and regulatory authorities may choose to use the relevant requirements for occupational exposure, including monitoring and record keeping, when it is not possible to maintain radon levels below the recommended concentration control target.

Many industrial applications may use materials that contain natural radioactivity, or processes that concentrate the natural radioactivity. In most of these cases, the radioactive materials are not the subject of the industrial process. The possibilities for concentration and significant levels of dose have been seen (*e.g.*, in the use of filters for gas extraction activities). These industrial processes should be examined for the possible presence of radioactive materials, and an assessment made of concentrations and exposures. If necessary, actions should be taken to control, and properly dispose of waste streams that contain radioactive materials, to prevent exposure and possible environmental damage. The recommendation to control dose to an individual for occupational exposure applies.

For the purposes of radiation protection, NCRP does not recommend distinguishing between smokers and nonsmokers in the management of exposure. This recommendation, similar to ICRP (2014a), holds for the management of radon exposures despite the epidemiologic evidence that the absolute risk of radiation-associated lung cancer is significantly greater in smokers than in non-smokers (Section B.4.1.5). The excess relative risk is similar. In practice, it would be difficult and perhaps impossible to address the radon issue separately and differently for current smokers, nonsmokers, passive smokers, or past smokers. Discrimination between smokers and nonsmokers in the workplace would cause ethical and social problems. NCRP considers this approach appropriate for radiation protection purposes.

6.4.5 Crew Members in NASA Space Activities

NCRP has provided guidance for exposures from missions in space for over 30 y (NCRP, 2014a) and continues to do so (NCRP, 2016b). The National Aeronautics and Space Administration (NASA) has established standards to protect the health and safety of flight crew members who take part in NASA human space flight programs (crew members) that include ionizing radiation in space (NASA, 2014). The standards for exposure to radiation space activities in NASA (2014) draw from basic NCRP guidance and are unique in that limits for crew members from space radiation are directly related to an individual and take into account sex, age and smoking history. In practice, NASA (2014) applies a career limit for the risk of exposure-induced death (REID) for cancer from space radiation exposures for each crew member; the career limit cannot exceed the upper 95 % confidence boundary for a 3 % REID for cancer. At the 95 % confidence boundary, this career limit translates into approximately a 1 % REID for cancer.

Important health effect issues related to NASA space missions still being addressed include: differences in sex sensitivity, differences in the effects of long-term exposures (up to 3 y on a trip to Mars) versus acute exposures, the appropriateness of translating experimentally-derived observations on effects in cells and animals from high energy and high atomic weight (HZE) particles (such as iron ions) to humans, and the possible incorporation of other health outcomes such as cardiovascular disease and central nervous system effects (*e.g.*, dementia) in the NASA risk standards (see the corresponding studies mentioned in Appendix B).

6.4.6 Summary of Recommendations for Occupational Exposure

A summary of the recommendations to control dose to an individual from occupational exposure is given in Table 6.4.

Table 6.4 --- Recommendations to control dose to an individual from occupational exposure.

Prevailing Exposure Situation	Recommendation (Effective Dose) (mSv)
General	
Annual	Not to exceed 50
Cumulative	Not to exceed [10 (times age in years)]
Pregnancy	
Following declaration of pregnancy	Not to exceed 0.5 mSv per month (equivalent dose to the embryo and fetus)[a]
Minors under 18 y	
Annual	Not to exceed 1
Radon	Include if >20 % of the general annual value of 50, after application of radon mitigation measures
NORM[b]	If action is necessary, include with the general annual value of 50

[a] Situations expected to expose a worker who has declared her pregnancy to radioiodine need to be avoided because of the risk of congenital hypothyroidism.
[b] Naturally-occurring radioactive material.

6.5 Public Exposure

6.5.1 General

NCRP recommends the annual effective dose to a member of the public from the continuous or reasonably anticipated presence of a source not exceed 1 mSv. This recommendation may be applied as a dose limit, applicable to the source, when the source is stable, characterized, and subject to an advance control program.

NCRP recommends, for planning purposes, that the effective dose for a member of the public not exceed 20 mSv in the first year following identification of a prevailing exposure situation that was not previously subject to control. The annual effective dose for a member of the public for later years would be established based on application of the ALARA principle.

NCRP recommendations for public exposure are intended to foster a coherent, *graded approach* to protection based on the prevailing exposure situation, and, in particular, whether the exposure is caused by a source whose introduction was intended and for which radiation protection programs and controls can be put in place in advance (referred to as an *advance control program*). This latter prevailing exposure situation is referred to as a Planned Exposure Situation by ICRP (2007a). If the prevailing exposure situation has not been previously subject to an advance control program, a higher effective dose for a member of the public may be necessary until an appropriate implementation of the ALARA principle can become effective.

NCRP (1993a) recommended an annual effective dose of 1 mSv as the dose limit to members of the public for continuous or frequent exposures. NCRP now recommends the 1 mSv value be applied to a single source of radiation (*i.e.*, not to exceed 1 mSv per year to a member of the public who may be exposed to that source). This recommendation may be applied as a dose limit for the source when that source is stable, characterized, and subject to an advance control program.

NCRP (1993a) also previously recommended a maximum annual effective dose of 5 mSv for infrequent exposures. The 5 mSv recommendation was made because an annual effective dose in excess of 1 mSv, usually to a small group of people, need not be regarded as especially hazardous, provided it did not occur often to the same groups, and that the average annual effective dose over multiple years for individuals in these groups did not exceed 1 mSv. The 5 mSv recommendation is no longer included, as the specific cases where such a value has been used (*i.e.*, contact of members of the public with patients administered a radionuclide for the purpose of medical diagnosis or therapy) are covered separately (Section 6.6.2), and any prevailing exposure situation in which values greater than 1 mSv could be necessary are covered by applying a 20 mSv recommendation and the application of the ALARA principle..

NCRP is now incorporating the ICRP (2007a) recommendation that established a band for dose constraints or reference levels of up to 20 mSv for members of the public under certain prevailing exposure situations, recognizing the need to account for elevated levels of naturally-occurring radioactive material and other circumstances in which the source is not under control. NCRP does not envision any prevailing exposure situation in which the 20 mSv recommendation for control of exposure to an individual would be considered as a dose limit.

The NCRP recommendations of 1 mSv and 20 mSv are a graded approach to controlling dose to an individual, and when coupled with the continuous application of the ALARA principle, will provide adequate protection while recognizing that not all prevailing exposure situations can be controlled to the same degree. This graded approach recognizes that the recommendations for control of dose to an individual are not a demarcation of safe versus unsafe, and that the acceptability of a prevailing exposure situation will be dependent upon a number of factors, including the expected duration of the exposures. The value of 20 mSv, establishes a reasonable maximum for planning purposes to begin implementation of protection strategies. Application of those protection strategies, and the ALARA principle, then provides the basis for adequate protection. These recommendations do not apply to exposures to members of the public from ubiquitous background radiation, or exposures received by a patient

from medical diagnosis or treatment. However, see Section 6.5.3 for the special situation of elevated radon levels in homes and workplaces.

Previous ICRP (2007a) and NCRP (1993a) recommendations were expressed as a value applied to the sum of the dose contributions from all sources to which a member of the public were exposed. However, it is not pragmatically possible to demonstrate compliance with such an all-source criterion, and in the United States regulations are applied to a source, or set of sources that are under the control of a responsible party. Application of the ALARA principle in all prevailing exposure situations is expected to reduce the actual doses received by an individual to a fraction of the recommendation for control of dose to an individual. The possibility that an individual would be the most highly-exposed individual to multiple independent sources that are stable, characterized, and subject to an advance control program is small. Consequently, this Report recommends that control of dose to members of the public be an annual effective dose of 1 mSv to the most-highly exposed individuals for the planning and operation of such a source, or set of sources under the control of a responsible party, and that this approach will result in adequate protection.

6.5.2 Radioactive Material Not Previously Subject to Control

There is a systematic, graded approach to control of radioactive material in the environment not previously subject to control, based on characterization of the exposure conditions, the level of dose received by individuals, and the possibilities for taking action to reduce exposures.

Circumstances may result in radioactive material that was not previously subject to control causing exposure to members of the public. Naturally-occurring radioactive material (NORM) or other unplanned environmental contamination poses unique challenges because of the difficulties in providing protection by actions taken on the source. In general, action can only be taken on the pathways of exposure, or upon the presence and actions of individuals. Nevertheless, the fundamental approach of protection using the ALARA principle within the

recommendations for control of dose to an individual should be applied. The approach should be commensurate with the risks posed by the circumstances.

Human activities often change the prevailing exposure situation, in some cases enhancing the concentration of NORM. It is these circumstances that warrant particular attention from a radiation protection standpoint. NCRP (1993a) provided recommendations for remedial actions for NORM. In this situation NCRP (1993a) recommended "that remedial action be undertaken when continuous exposures from natural sources, excluding radon, are expected to exceed five times the average, or 5 mSv annually." NCRP is no longer making this recommendation, and instead emphasizes the application of the ALARA principle in all prevailing exposure situations. Irrespective of whether the annual doses from natural sources is greater or less than 5 mSv there should be an examination to determine if protection can be improved by applying the ALARA principle.

There also may be some instances of potential radiation exposure in areas that have been contaminated by activities that result in accidental or intentional release of radioactive materials. This potential exposure to members of the public may be elevated over the normal level expected from ubiquitous background radiation. In these situations, remedial actions, which are developed with active public participation, can be taken to reduce this exposure. Such a process may have a very long duration, and the need for further actions is best decided by the informed stakeholders. Application of the ALARA principle, including the options for consideration, should be guided by the selection of dose values to an individual within the relevant recommendation.

NCRP recognizes that the long-term outcome of each application of the ALARA principle, as informed by the involvement of the relevant stakeholders, will be unique. Thus, the result may be well within the recommendation for a continuous or reasonably anticipated operation of a source that is stable, characterized, and subject to an advance control program (Section 6.5.1), while there may be instances where it is not reasonable to achieve such levels.

6.5.3 Radon

NCRP recommends that radon levels be assessed, and mitigation measures be taken when the air concentration of radon in homes and workplaces exceeds 300 Bq m^{-3}.

High levels of radon may be found in homes, public buildings, and in workplaces. For exposure to radon, the equivalent dose to the lung is the most relevant radiation protection quantity. However, equivalent dose to the lungs for radon is difficult to determine on an individual basis and is not practicable to use for this case of radiation protection. Consequently, ICRP (2014a) recommends a radon concentration in air of 300 Bq $m^{-3.}$ This concentration roughly corresponds to a range of annual effective dose between 10 and 20 mSv depending on the hours of exposure (ICRP, 2014a; NCRP, 2009). NCRP adopts this radon air concentration and recommends that radon levels be assessed, and mitigation measures be taken when the air concentration of radon in homes and workplaces exceeds 300 Bq m^{-3}. This recommendation applies to both occupational and public exposure as a recommendation for taking mitigation measures.

In most cases, radon mitigation actions based on air concentration will be sufficient, and further actions are generally not warranted under the ALARA principle.

As noted in Section 6.4.4, NCRP does not recommend distinguishing between smokers and nonsmokers in the management of exposure. Discrimination between smokers and non-smokers in the in the public would cause ethical and social problems. NCRP considers this approach appropriate for radiation protection purposes.

6.5.4 Summary of Recommendations for Public Exposure

A summary of recommendations to control dose to an individual from public exposure is given in Table 6.5.

Table 6.5 --- Recommendations to control dose to an individual from public exposure.

Prevailing Exposure Situation	Recommendation (Annual Effective Dose) (mSv)
General	
Source is stable, characterized, and subject to an advance control program	Not to exceed 1
Radioactive material not previously subject to control [a]	
First year (after identification of situation)	Not to exceed 20
Later years	Based on the ALARA principle
Radon	Air concentration >300 Bq m^{-3}, take mitigation measures

[a] For example: elevated levels of naturally-occurring radioactive material; environmental contamination.

6.6 Medical Exposure

6.6.1 General

The category of medical exposure includes individuals who may be engaged in the comfort and care of a patient who has received a radionuclide for the purpose of medical diagnosis or therapy (comforters and caregivers) and individuals who may be participating voluntarily in biomedical research that results in their exposure to radiation. The group of comforters and caregivers is limited to those individuals who are not occupationally involved in providing medical care, and are typically parents, other family members, or close friends of the patient. Other individuals who may be inadvertently exposed as a result of proximity to a treated individual are to be protected as members of the public.

6.6.2 Comforters and Caregivers

NCRP recommends the effective dose for comforters and caregivers of a patient (typically parents, other family members, or close friends) not exceed 5 mSv per episode[16].

NCRP recommends the effective dose for other patients, visitors to the medical facility, and staff who are not occupationally involved in providing medical care and who are not specifically trained in radiation protection not exceed 1 mSv per episode.

ICRP (2007a) and NCRP (2006a) addressed radiation exposure to comforters and caregivers. These exposures are infrequent and normally of low dose and short-term. For example, a parent may elect to stay by a child's side during an imaging procedure, such as a CT scan or a fluoroscopically-guided interventional (FGI) procedure. This is generally permissible

[16] In the context of the Section 6.6.2 recommendations, "per episode" means for the duration of care associated with a given diagnostic or therapeutic medical procedure that employed radiation or a radionuclide.

for a family member. Appropriate radiation protection measures should be employed, such as shielding with lead aprons or screens.

Procedures involving administration of radionuclides may result in exposure of the patient's family members and friends during hospital or home care after the procedure. These exposures occur infrequently and merit special consideration. ICRP (2007a) recommends an effective dose of 5 mSv per episode. NCRP (2006a) recommends that an effective dose of 5 mSv per episode be applied for immediate members of the family, or close friends and relatives of a patient.

Other patients, visitors to the medical facility, and staff who are not occupationally involved in providing medical care and who are not specifically trained in radiation protection are considered members of the public, and should not exceed an effective dose of 1 mSv per episode for such a prevailing exposure situation. This recommendation only applies when the criteria of an episode being infrequent can be reasonably assured for the individuals. For example, staff in a licensed facility providing medical treatment, even if not considered as occupationally exposed, still have the potential for more frequent interaction with a medical procedure that employs radiation or a radionuclide. Licensees should treat these individuals as members of the public, and the recommendation for control of dose to these individuals would be based on the reasonable expectation of the exposure during an entire year.

6.6.3 Biomedical Research Subjects

The radiation exposure an individual volunteer receives in the course of participating in a biomedical research study that would not have been received otherwise is considered separately from that received as a patient in the normal course of medical diagnosis or treatment. A suggested classification scheme for use of effective dose as a qualitative indicator of stochastic risk for biomedical research studies is provided in Table 6.6.

Table 6.6 --- Suggested classification scheme for use of effective dose as a qualitative indicator of stochastic risk for biomedical research studies [adapted from Report No. 168 (NCRP, 2010b)].

Effective Dose (mSv)	Qualitative Risk Descriptor	Expected Minimum Individual or Societal Benefit
< 0.1	Negligible	Acquisition of knowledge
0.1 – 1	Minimal	Acquisition of knowledge, resulting in health benefit
1 – 10	Minor	Acquisition of knowledge, directly aimed at prevention or cure of disease
10 – 100	Low	Acquisition of knowledge, directly aimed at prevention or cure of serious disease
> 100	Acceptable (in context of the expected benefit)	Acquisition of knowledge, directly aimed at saving lives or mitigation of serious disease

Additional guidance is provided by NCRP (201Y) with an extended list of considerations for those developing research protocols and conducting biomedical research on human subjects, and for members of Institutional Review Boards. Some general examples of such considerations are listed here:

- When reviewing a clinical trial, Institutional Review Boards either have knowledge of the current definition of Standard of Care as it relates to radiological procedures for the population being studied or solicit the assistance of appropriate clinicians, their local Radiation Safety Committees, or Radiation Safety Officers for guidance.
- When clinically appropriate and feasible, an imaging modality that does not employ ionizing radiation is substituted for one that does, as long as the necessary information can be obtained. The determination of appropriateness and feasibility may include economic considerations.
- When the dose to a subject indicates that the radiation exposure may cause tissue reactions, there is counseling and arrangements for follow-up of the subject.
- Radiation doses to human subjects from proposed research studies are estimated in order to: (a) enable estimation of the risk to the subjects and development of appropriate risk language for informed consent; and (b) assist in optimizing the study design to keep radiation doses to human subjects consistent with the ALARA principle.

6.7 Exposure of Emergency Workers

6.7.1 General

In a radiological or nuclear emergency, a unique exposure category will exist, that of emergency worker. This is a transitory exposure category that will likely start soon as a radiological or nuclear emergency begins. These emergency workers may include typical responders like firefighters, law enforcement officers and emergency medical service providers. Utility workers and others essential in restoring critical infrastructure may also become emergency workers. There will also be support personnel recruited in large numbers to serve as

vehicle operators or administrative service providers. Some may serve for only the first few hours or days following the initial response; others may transition from emergency workers to occupationally-exposed individuals when they take on more permanently some response or recovery role many days or weeks into response and recovery. For the worst scenarios, like a high-yield improvised nuclear device, an uncontrolled release from a severely damaged nuclear reactor or spent fuel storage pool, many emergency workers may exist and the responsible authority will assume a radiation protection role for all of them.

To help the nation prepare for these conditions and to help manage the radiation protection needs of emergency workers, Report No. 17y (NCRP, 2017b) provided guidance on how to collect or reconstruct radiation dose information for emergency workers. Relative to this Report on radiation protection guidance for the United States, NCRP (2017b) explicitly deviates from past guidance as expressed in Report No. 165 (NCRP, 2010c), and places emergency workers in a separate category. Emergency workers are not to be considered occupationally exposed (NCRP, 2017b). The most recent guidance for emergency-response dosimetry sustains a critical tenet from NCRP (2010c), namely that there is no limitation on radiation dose for emergency responders performing time-sensitive, mission-critical activities such as lifesaving. This is consistent with recommendations of ICRP (2007a) that "dose limits do not apply in emergency exposure situations where an informed, exposed individual is engaged in volunteered life-saving actions or is attempting to prevent a catastrophic situation."

Emergency workers engaged in life-saving activities or actions to prevent a catastrophic situation are not subject to radiation dose limitation. Decisions on emergency worker actions are based on the totality of the prevailing exposure situation, where other risks may present a greater risk than does the radiation exposure, and where one person may save many other lives.

An *emergency worker* is an individual "who would be called upon to assist with the response to a radiological or nuclear incident" (NCRP, 2017b). Most of these individuals, like the fire service, law enforcement officers and emergency medical service providers, are not

routinely exposed to radiation, though they are trained emergency responders. Others, like transportation, utility and public works personnel, may not have any kind of emergency experience or training. Some members of the public are spontaneously incorporated into the ranks of emergency workers by events unforeseen. This includes, for example, individuals who rush to aid injured people following an explosion, or medical workers who may become emergency workers as "first receivers," handling contaminated or irradiated patients entering the healthcare system. The agency having jurisdiction for the emergency response will have to take on an unexpected and complex responsibility, that is, the radiation protection of these emergency workers. This may start in the earliest moments of response and last several hours, days or weeks until outside resources arrive and become fully operational and operating under the radiation protection criteria for the occupational exposure category.

Radiation protection for emergency workers presents numerous unique challenges. First, decision makers, typically incident commanders at the front lines of an emergency response or emergency managers at local, state and federal emergency operations centers, need to be provided radiation dose and related health effects guidance from subject-matter experts so they can calculate whether emergency workers should engage in specific life-saving activities. Table 6.3 in Section 6.2.3 provides this guidance, and the authority having jurisdiction should share this guidance with decision makers so they can quickly calculate whether a radiation dose, along with other risks, justifies the life-saving action. Note that the risk from the radiation dose may be the least among many risks for the emergency worker. In many circumstances, the radiation risks are compounded by other incident consequences, and in some scenarios, the potential radiation dose may have such serious health consequences for emergency workers that the decision made is to not conduct a life-saving activity.

Another challenge is that few authorities having jurisdiction recognize that they have responsibility for the radiation safety of emergency workers, some of whom spontaneously volunteer or are hastily deputized when an incident occurs. The responsibilities for radiation protection are far-reaching. Even those jurisdictions with significant resources will find the technical challenges daunting. In a catastrophic incident, like a nuclear detonation or an

industrial accident on the scale of what occurred at Chernobyl in 1986 or Fukushima in 2011, there could be thousands or more emergency workers, radiation protection will be more difficult, and the conditions of most work will be austere at best. Authorities should identify which agencies will be responsible for, and create procedures for, collecting emergency worker dose information and managing emergency worker dose within appropriate guidelines.

. When a radiation worker is engaged in life-saving actions as an emergency worker, his or her radiation dose is not occupational. It is important for emergency workers to know that any radiation dose received for life-saving actions will not limit their ability to work as they had prior to the emergency (NCRP, 2017b).

Emergency workers who receive a dose in excess of the occupational recommendation for control of dose to an individual are not precluded from returning to work provided that the emergency work is done voluntarily and the individual receives counseling from radiation protection and medical personnel regarding the consequence of such exposure.

Table 6.3 in Section 6.2.3 provides radiation dose levels and their potential consequences (ICRP, 2012). Recognizing this information may be new and complex for many people, NCRP recommends that pre-incident planning and pre-incident training be provided to incident commanders, incident managers and other decision makers so they can make effective decisions about emergency workers in a life-threatening radiation environment.

Incident commanders, incident managers and other decision makers need to be provided pre-incident guidance and training sufficient to effectively inform their determination that emergency workers be allowed to conduct specific life-saving actions.

The determination by incident commanders and other decision makers that certain life-saving activities be allowed is more than a simple comparison of individual or group good versus individual or group harm. People who engage in tasks with increased risk of harmful radiation

dose must volunteer to do so. The agency having jurisdiction needs to provide these volunteers with information about the risks they are taking, as well as guidance and tools available to them for their protection. When selecting individuals to engage in these activities, it is also important that decision makers act fairly, to prevent overburdening individuals or groups of individuals. The intention should be that after some finite time, radiation dose management transitions from that for emergency workers to that appropriate for the occupational, public and medical recommendations provided in Sections 6.4, 6.5 and 6.6, respectively.

6.7.2 Goals for Control of Dose to an Emergency Worker

In exceptional situations, informed volunteer emergency workers may receive absorbed doses to an organ or tissue above the recommendation of 1 Gy noted in Section 6.2.3 to save lives or prevent the development of catastrophic conditions.

NCRP recommends that for urgent rescue activities during emergencies that do not involve lifesaving, the goal is to not exceed an effective dose of 500 mSv.

NCRP recommends that for extended activities during an emergency, following the initial lifesaving, rescue and damage control response, the goal is to not exceed an effective dose of 50 mSv for the duration of the emergency operation.

When an individual's prevailing exposure situation is that of an emergency worker, the dose is no longer controlled as for public or occupational exposure. The individual's dose is still controlled consistent with the ALARA principle, but the worker is allowed to fully and effectively engage in activities governed by the prevailing exposure situation. For some circumstances, the individual's dose may be manageable under the recommendations of control of dose for occupational exposure (Section 6.4.1), or as recommended in Section 6.2.3 to avoid acute organ effects. For other circumstances, special guidance like that of the Environmental Protection Agency's Protective Action Guidelines (EPA, 2017) may be appropriate. In EPA (2017), doses are related to specific emergency worker activities. For those engaged in lifesaving

activities, there is no limitation on dose. The totality of the prevailing exposure situation defines the actions taken. It is critical that there be a clear separation of the emergency worker dose activities and records from dose received from public and occupational exposures. Dose received as an emergency worker should not impact future occupational exposure, either in the same year, or future year after the emergency.

During the early response phase, there may be individuals who need immediate rescue and evacuation to treat injuries and reduce the probability of fatalities. There also may be actions required to control the spread of the radiation source, prevent access to the area, and limit the possibility of continuing exposure to high dose rates. Recommendations for control of dose to an emergency worker that are higher than those for other prevailing exposure situations should apply only to volunteers and should provide the flexibility needed for responders to accomplish these tasks.

NCRP (1993a) previously recommended, "Exposures during emergency actions that do not involve lifesaving should, to the extent possible, be controlled to the occupational dose limits. Where this cannot be accomplished, it is recommended that a limit of 0.5 Sv effective dose and an equivalent dose of 5 Sv to the skin be applied." ICRP (2007a) recommends for life saving, "no dose restrictions if benefit to others outweighs rescuer's risk". For other urgent rescue operations, the recommendation is 1,000 or 500 mSv and for other rescue operations, 100 mSv. NCRP (2010c) does not recommend a dose limit for emergency responders performing time-sensitive, mission-critical activities such as lifesaving. Rather the recommendation is made to adopt an absorbed dose (to a significant portion of the body) of 0.5 Gy as a decision point at which the benefit of further exposure is evaluated.

Dose control for lifesaving and other urgent rescue activities should be based on the potential acute effects of radiation and specifically on preventing death of the responders by limiting the absorbed dose to the active bone marrow.

Following the immediate response, emergency operations may continue for some time. During this period, additional information on the dose levels will be available, and opportunities for control of dose will increase. Thus, the recommended goal for effective dose is 50 mSv for the duration of these operations. While there will be a gradual transition, application of sound radiation protection planning and the ALARA principle implies that a return to the 50 mSv annual effective dose value will be accomplished as soon as it is reasonable to do so. But in the context of the emergency, the prerequisites for this value being a dose limit are not met. Until an individual's prevailing exposure situation is again public or occupational exposure, and not for the unique circumstances of an emergency, doses received as an emergency worker remain segregated from those received under normal public or occupational exposure situations.

6.8 Exposure of Nonhuman Biota

For controls on radiation exposure of nonhuman biota in support of environmental protection and implementation of the National Environmental Policy Act (NEPA, 1969), there are separate considerations regarding the radiation protection objectives, the endpoints of interest, and the approach to radiation protection.

Within the system of radiation protection, the principle of justification and the ALARA principle (optimization of protection) are the features applicable to nonhuman biota.

Control of dose to an individual of a given species is not appropriate, given the population endpoints of interest (*i.e.*, endpoints which substantively affect reproductive success; the focus is on population maintenance), as discussed in Section B.14. For justification and application of the ALARA principle, representative populations of flora and fauna are used to judge the acceptability of a proposed action or existing condition, and the impacts of various options for control of radiation exposure from the source are assessed based on the absorbed dose rate.

An absorbed dose rate of 0.1 mGy d^{-1} is considered unlikely to have significant effects on nonhuman biota where existing conditions or proposed actions result in increased radiation levels. No additional evaluation would be considered necessary for organisms exposed below this absorbed dose rate. The 0.1 mGy d^{-1} absorbed dose rate is not to be viewed as a target for remediation, or that absorbed dose rates above this value automatically require remediation.

NCRP suggests that a guideline of absorbed dose rate may be an appropriate approach to determining when additional efforts may be needed within the context of NEPA (1969) to inform decision-making processes. NCRP acknowledges that the current science on radiation impacts on nonhuman biota is evolving. However, to ensure radiation protection of nonhuman biota, the following approach to assess potential dose and risk to nonhuman biota is suggested. If estimates of absorbed dose to the more sensitive plants or animals are below 0.1 mGy d^{-1}, no additional assessment for radiological impacts on nonhuman biota is likely necessary to ensure adequate protection. Where this absorbed dose rate is exceeded, additional assessments may be needed to determine if control alternatives under the ALARA principle need to be considered. Specifics of the assessment are outside the purview of NCRP and are implemented by the agency or other party responsible for determining the environmental impact of specific actions involving the radiation source.

NCRP recognizes that the ultimate determination of what constitutes an appropriate or allowable environmental impact requires much more than a comparison to a single numerical value of absorbed dose rate. Particularly in environmental assessments, many factors need to be considered, such as the:

- presence of threatened or endangered species;
- spatial extent of the impact;
- abundance and diversity of species present;
- necessity of the action to be taken; and
- the inherent value of the environment being evaluated.

Appendix A. Quantities and Units for Radiation Protection Dosimetry

A.1 Introduction

Discrete amounts of energy are imparted to organs and tissues of the body when a living organism is irradiated by external or internal radiation sources. These quanta may be measured or calculated. Radiation dose and dose rate are expressed using well-defined quantities and units. The science of radiation dosimetry accounts for all relevant contributions to energy imparted to matter by radiation of different types and qualities, including x rays, gamma rays, alpha particles, beta particles, neutrons, fragments from spontaneous fission, cosmic rays, solar particles, and charged-particle recoil ions. Each radiation type differs spatially in localized energy deposition patterns produced in living tissue and density of localized chemistry changes at the microscopic level, such as relative yields of highly reactive free radicals. The resulting ionization patterns influence the type and frequency of cellular-level biological effects that may result, such as single-strand and double-strand deoxyribonucleic acid breaks. Consequently, radiations differ in their relative biological effectiveness per unit absorbed dose.

Protection against the harmful effects of radiation requires a well-defined, coherent system of fundamental quantities and units. The biological environment is complex; biological systems vary widely in their response to a constant radiation absorbed dose. Tissue radiosensitivity differs among the various cell types, tissues, and organs in the body. The biological response to irradiation may be expressed locally as a whole-organ effect, partial-organ or tissue effect, or as a cellular-level effect. Correct interpretation of dose and dose rate in terms of biological effects accounts for localized energy deposition and modifying factors (such as repair of sub-lethal damage). Biological response may be classified as a near-term adverse tissue reaction or as long-term or "late" stochastic effect. The radiation protection system needs to accommodate many different radiation types and qualities within a complex biological environment and to employ relevant quantities and units for expressing dose and dose-response relationships, dose-rate effects, and radiobiological responses. Consequently, the foundations of radiation protection require highly rational systems for relating absorbed dose and absorbed dose

rate to observed changes after radiation exposure. Radiation protection quantities and units are generally applicable to occupational, environmental, and medical exposures to ionizing radiation.

A.2 Base Quantities

The ability to determine, quantify, and express dose and dose rate for radiation exposure is fundamental to the science of radiation protection. The concept of radiation dose incorporates the sum of all energy-deposition events within a defined target volume over a specified time for each well-defined source-target geometry. Conditional parameters defining the radiation source include the source activity, emissions, spatial distribution, and material density. Biological target conditional parameters include target mass and geometry, material composition and density, tissue type, and radiation sensitivity for a defined endpoint.

A.2.1 Energy Imparted by Ionizing Radiation

The energy imparted (ε) is the quantum of energy, expressed in joules, deposited in matter when charged and uncharged ionizing particles interact with atoms and molecules in the absorbing medium. The energy imparted is the sum of the energy deposited, by ionization and excitation, by one or more discrete energy deposition events

A.2.2 Absorbed Dose

The basic unit of energy deposition by ionizing radiation is *absorbed dose* [$D(r_T)$], the energy imparted to a target region r_T per unit mass. $D(r_T) = d\varepsilon/dm$, where ε is the energy imparted to a target region and m is the mass of the absorbing medium (ICRU, 2011). The SI unit of absorbed dose is joule per kilogram (J kg^{-1}), with the special name gray (Gy); 1 Gy equals exactly 1.0 J kg^{-1}.

Absorbed dose is the fundamental physical quantity applicable to all radiation exposures, for all types of ionizing radiation, for any absorbing medium, and for all biological targets and

geometries. Absorbed dose is a measurable quantity. The concept of absorbed dose applies to individual subjects (humans or animals), workers, medical patients, and members of the public of any age.

Absorbed dose is defined as a point function, or the expectation value as the limit of $d\varepsilon/dm$ as the mass approaches zero. Since the actual amount of radiation energy imparted to a volume of mass at the microscopic scale may be highly variable for all radiation types (such as the non-uniform distribution of radionuclides in tissues, or densely ionizing particle tracks), the definition of the absorbed dose allows one to specify dose in terms of spatial distributions and linear energy transfer.

A.2.3 Absorbed Dose Rate

The absorbed dose rate [$\dot{D}(r_T, t)$] expresses the amount of energy imparted to an absorbing tissue or region r_T per unit time t. The time-integral of the absorbed dose rate is the total absorbed dose. For a defined dose-integration period τ, the absorbed dose is therefore:

$$D(r_T, \tau) = \int_0^{\tau} \dot{D}(r_T, t)\,dt \qquad (A.1)$$

A.2.4 Exposure to External Radiation Fields

Exposure (X), is a precise quantity given to irradiation of matter *in air* by x rays or gamma rays, where the quantity exposure is defined as the quotient of the absolute value of the total charge [Q, coulomb (C)] of the ions of one sign (+ or -) produced in air (when all of the electrons liberated by photons in a defined volume of dry air are completely stopped in air), and the mass of the volume of air [m_{air}, kilogram (kg)]; $X = Q/m_{air}$. The concept of exposure represents the ability of photons (x rays and gamma rays) to ionize air molecules. The SI unit of exposure is coulomb per kilogram (C kg^{-1}). The special quantity for exposure is roentgen (R), where 1 R = 2.58 × 10^{-4} C kg^{-1}.

The quantity exposure received by persons or objects in a radiation field may be evaluated using radiation detectors placed in the same field (Section A.4); these detectors

measure the ionizations produced when energy is transferred to an absorbing medium. The energy transferred to an absorbing detector medium in free space may be directly compared to the energy that would be imparted to another material, person, or object in the same field, but that cannot be measured directly. Thus, one may use radiation detectors to estimate the quantity exposure (or exposure rate) and hence infer dose to persons or objects in the same radiation field.

A.2.5 Exposure Rate

Exposure rate is exposure per unit time t, or $\dot{X} = \dot{Q}/m_{\text{air}}\,t$ (C kg^{-1} s^{-1}), where t is given in seconds or hours. Exposure-rate meters used in radiation protection measure and display the exposure rate per unit time [commonly microroentgen per hour (μR h^{-1}) or milliroentgen per hour (mR h^{-1})], or in units of a derived operational quantity (Section A.4). The terms exposure and exposure rate do not apply to irradiation by charged particles or to radiation from internally-deposited radionuclides. In an occupational setting, measurements of exposure rate support calculation of radiation doses to workers (Section A.4).

A.3 Derived Quantities

Derived quantities are multiples of the absorbed dose that account for observed differences in biological effect for a single target tissue when radiations of different ionization qualities are compared, or when the radiosensitivities of different tissues are compared for a single radiation type. For a constant value of absorbed dose, the biological effects observed may be different for each radiation type and quality, pattern of energy deposition, and dose rate. Organs and tissues also differ in radiosensitivity per unit absorbed dose. The biological effectiveness of an absorbed dose depends also on biological endpoint, cellular-level defense mechanisms, and other modifying factors. Therefore, a rational system for radiation protection accounts for both physical interactions and biological-response factors.

Derived quantities account for the relative biological effectiveness of radiation per unit absorbed dose for radiations of different qualities or ionization density, and for biological targets having different responses per unit absorbed dose. Derived quantities may also account for age and gender determinants of radiation effectiveness for a given absorbed dose.

A.3.1 Relative Biological Effectiveness

Relative biological effectiveness (RBE) of any given radiation is a modifying factor by which the absorbed dose for that radiation may be multiplied such that its biological effect, for a specified tissue and endpoint, is the same as that for a reference radiation of the same absorbed dose. By definition, RBE is the ratio of the absorbed dose of a reference radiation to the absorbed dose of a test radiation that produces the same level of biological effect, all other conditions being equal; RBE = $D_{\text{reference}}/D_{\text{test}}$. Typical reference radiations include ^{60}Co and ^{137}Cs gamma rays, or filtered 250 kV (peak tube potential) x rays. If the reference and the test radiations produce different types of biological effects, the radiations cannot be compared and an RBE cannot be specified for the test radiation. RBE is commonly used in radiobiology research for comparing short-term adverse tissue reactions for radiation types of different qualities or energies.

A.3.2 Radiation Weighting Factors

For radiation protection purposes, dimensionless weighting factors (w_R) are assigned to radiations of different qualities and energies (*e.g.*, x rays and gamma rays, beta particles, alpha particles, neutrons, and heavy charged particles) to represent an approximate value of relative biological damage or risk of radiation detriment produced by each for a constant absorbed dose. Radiation weighting factors are used to derive the radiation protection quantity equivalent dose (Section A.3.3) from the absorbed dose (averaged over an organ or tissue). The current w_R values are set by ICRP relative to a baseline for x rays or gamma rays ($w_R = 1.0$). The w_R values apply only to stochastic effects, and are nominal values based on experimentally observed data. The ICRP w_R values are not applicable to short-term adverse tissue reactions or for individuals. Current values of w_R from Publication 103 (ICRP, 2007a) are listed in Table A.1.

Table A.1. --- Recommended radiation weighting factors (ICRP 2007a).

Radiation Type	Radiation Weighting Factor (w_R)
Photons	1
Electrons and muons	1
Protons and charged pions	2
Alpha particles, fission fragments, heavy ions	20
Neutrons	A continuous function of neutron energy (E_n) (Equation A.2)[a]

[a] Equation A.2 is shown below.

$$w_R = \begin{cases} 2.5 + 18.2\ exp\text{-}\{[\ln (E_n)]^2/6\}; & E_n < 1 \text{ MeV} \\ 5.0 + 17.0\ exp\text{-}\{[\ln (2\ E_n)]^2/6\}; & 1 \text{ MeV} \leq E_n \leq 50 \text{ MeV} \\ 2.5 + 3.25\ exp\text{-}\{[\ln (0.04\ E_n)]^2/6\}; & E_n > 50 \text{ MeV} \end{cases} \quad \text{(A.2)}$$

A.3.3 Equivalent Dose

Equivalent dose [$H(r_T, \tau)$] for an organ or tissue r_T over a time period τ is a derived, intermediate quantity used in radiation protection for calculating effective dose (Section A.3.4) (ICRP, 1991a; 2007a; 2015). Equivalent dose is the sum of the products of the absorbed dose in an organ or tissue $D_R(r_T, \tau)$ multiplied by their respective radiation weighting factor (w_R) from all contributions by radiations of different types (ICRP, 2015).

$$H(r_T, \tau) = \sum_R w_R \, D_R(r_T, \tau) \qquad \text{(A.3)}$$

The unit of equivalent dose is joule per kilogram (J kg^{-1}), with the special name sievert (Sv). The concept of equivalent dose applies only to population group averages (reference models) for radiation protection planning, and not to individuals for risk assessment. In practice, equivalent dose for an organ or tissue should not be used as a quantity to predict individual risk of cancer or heritable effects; instead, the absorbed dose to the organ or tissue [$D(r_T)$] is the primary quantity relevant to biological effects.

A.3.4 Tissue Weighting Factors

Tissue weighting factors are used for calculating effective dose (Section A.3.5) for radiation protection purposes and for comparing an individual worker's dose against the applicable recommendation to control dose to an individual. Tissue weighting factors (w_T) have been selected (ICRP, 2007a) for organs and tissues (r_T) of the body to represent the approximate relative contribution of tissue radiosensitivity to total risk of radiation detriment from *stochastic effects* after exposure to radiation, subject to the limiting condition that the sum of all the tissue weighting factors is equal to 1.0 in a reference model (Table A.2). Tissue weighting factors apply to both penetrating external radiation sources and to internally-deposited radionuclides. The current practice applies age- and gender-averaged tissue weighting factors specified by ICRP (2007a) that represent mean values for humans averaged over both sexes and all ages.

Table A.2 --- Recommended tissue weighting factors (w_T) (ICRP 2007a).

Tissue	w_T	$\sum w_T$
Active (red) bone marrow, colon, lung, stomach, breast, remainder tissues[a]	0.12	0.72
Gonads	0.08	0.08
Urinary bladder, esophagus, liver, thyroid	0.04	0.16
Bone surface, brain, salivary glands, skin	0.01	0.04
Total		1.00

[a] Remainder tissues: adrenals, extrathoracic region, gallbladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate (male), small intestine, spleen, thymus, uterus/cervix (female).

The scientific basis for selecting tissue weighting factors is observed cancer incidence among Japanese atomic-bomb survivors; thus, the organ and tissue weighting factors are stipulated only for late effects, and do not apply to short-term adverse tissue reactions or other degenerative outcomes. Organs and tissues vary in radiation sensitivity and propensity to undergo radiation-induced changes that could lead to cancer induction and heritable effects. Tissue weighting factors ($\underline{w_T}$) consider the comparative mortality and morbidity risks of cancer, the risk of severe heritable effects for all generations, and the length of life lost due to these effects, apportioned by organ or tissue. However, tissue weighting factors apply only to population groups and not to individuals. The choice of tissue weighting factors as measures of relative radiation detriment representing all population groups implies a high degree of uncertainty in the values for each organ or tissue (ICRP, 2007a).

A.3.5 Effective Dose

Effective dose (E) is a mathematical construct, concept, or surrogate for risk used in radiation protection for establishing recommendations to control dose to an individual. It includes exposures to external radiation sources and to radionuclide intakes. Effective dose is a population-averaged, doubly-weighted construct, in which equivalent doses (Section A.3.3) for organs or tissues are further weighted according to estimates of radiation detriment for stochastic effects. Thus, effective dose is not a physical radiation dose to a person *per se*, but rather is a computed number representing a population-averaged derivative of stochastic risk based on the calculated absorbed dose to all organs and tissues of the body, applied to a representative model (Paquet *et al.*, 2016).

The unit of effective dose (E) is also joule per kilogram (J kg^{-1}), with the special name sievert (Sv). Numerically, the effective dose is the sum of all the weighted equivalent doses for all irradiated organs and tissues of the body of a reference model, whether the body is irradiated uniformly or non-uniformly. This reference model was averaged to represent a hybrid reference (50th percentile) male and female representing all ages and sizes in a standard population (Equation A.4) (ICRP, 2015):

$$E = \sum_{\mathrm{T}} w_{\mathrm{T}} \left[\frac{H(r_{\mathrm{T}},\tau)^{male} + H(r_{\mathrm{T}},\tau)^{female}}{2} \right] \quad \text{(A.4)}$$

Effective dose includes all contributions from external exposures and internally-deposited radionuclides. Doses to organs and tissues for external sources and intakes of radionuclides are calculated to reference phantoms using standard exposure conditions, assumed biokinetic parameters, and estimates of intake (as appropriate for the specific source) (ICRP, 2007a). Radionuclide intakes are estimated from direct measurements, air sampling, and bioassay data, as may be available. Computational methods have been developed for modeling radionuclide metabolism, including uptake, retention, clearance, and excretion. When biokinetic models are used together with nuclear radiation transport codes, radiation doses to organs and tissues may be calculated (ICRP, 2015).

In occupational radiation safety, effective dose for a worker is estimated to establish the dose of record for comparison to or compliance with dose limits established by regulatory bodies. Effective dose is an appropriate quantity for prospective dose assessment, planning, and optimization, to compare exposures that might result from different work activities. Equation A.4 shows that calculation of effective dose applies to reference models only, and not specifically to any individual. In a medical setting, effective dose is not applicable to individual patients (Poston *et al.*, 1993). Effective dose may guide planning by Institutional Review Boards and radiation safety committees. However, use of effective dose is problematic for procedures where organs and tissues receive only partial or heterogeneous irradiation (ICRP, 2007a).

Although effective dose may be viewed as a measure or surrogate of risk, no single quantity that takes into account the absorbed doses to the various organs and tissues of the whole body adequately expresses risk or the probability of cancer induction for all possible cancer types, ages, gender, and radiation qualities. Since effective dose is not predictive of cancer incidence, values of effective dose should not be used to estimate future cancer risk from specific

sources of radiation exposure. Effective dose should not be used for epidemiologic evaluations and retrospective investigations of individual risk (ICRP, 2015). Instead, assessments of potential harm from ionizing radiation should only be based on the absorbed doses to each organ or tissue.

A.3.6 Committed Dose

Committed equivalent dose and committed effective dose are derived quantities that apply only to intakes of long-lived, long-retained radionuclides. Committed doses are calculated using reference phantoms and biokinetic models. The time integral τ for calculating a committed dose is 50 y for reference adult phantoms, and 70 y for reference child phantoms (ICRP, 2015).

The concept of future dose from intakes of such radionuclides that is assigned to the year of intake includes substantial uncertainties in addition to uncertainties already associated with the derivative quantities equivalent dose and effective dose. Calculated values of committed effective dose may be used to assign an occupational dose of record and to compare exposures that could result from different work activities involving long-lived, long-retained internally-deposited radionuclides. In practice, committed effective dose should not be used for predicting adverse tissue reactions, for epidemiologic studies, or for predicting individual risk of cancer or heritable effects.

A.3.7 Collective Effective Dose

Collective effective dose (the sum of individual effective doses in a population) has been used to evaluate various options in applying the ALARA principle and for comparing the relative qualitative impact of radiological technologies. It is not intended for epidemiologic risk assessment, and it is inappropriate to use in risk projections. Predicting theoretical numbers of cancer deaths in a population based on the aggregation of tiny individual effective doses is inappropriate. Effective dose is a radiation protection quantity based on nominal risk coefficients. NCRP reaffirms that collective effective dose not be used to predict excess health effects.

A.4 Direct Measurements of Radiation Dose

Modern radiation detectors, personal dosimeters, and associated electronic instrumentation provide direct measurements of external penetrating (gamma-ray, x-ray, or neutron) radiation fields to which people may be exposed. Passive dosimeters (condenser-type pocket dosimeters, film badges, thermoluminescent dosimeters, optically stimulated luminescent dosimeters, chemical dosimeters, track-etch films) record an integrated exposure over time by manual or systematic electronic read-out. Active electronic dosimeters (ion-current chambers, personnel dose-rate meters, and survey instruments) record absorbed dose and absorbed dose-rate.

Radiation doses to workers from external sources are estimated using area-monitoring instruments and personal dosimeters. Properly calibrated ionization chambers, Geiger-Mueller counters, and other survey instruments measure exposure rates at points in air. Conversion of exposure measurements in air to absorbed dose in the body requires additional calculation steps. Absorbed dose is approximately equal to measured exposures from photons with energies less than about 1 MeV. For beta particles with energies greater than about 3 MeV, the absorbed dose rates to skin are similar to measured exposure rates at the corresponding points in air (NCRP, 2006a). For calculating absorbed dose to internal organs of the body from external gamma-ray, beta-particle, or neutron radiation sources, the information obtained from personal dosimeters and area-monitoring instruments are converted to operational quantities that may be used to compare an individual's radiation dose with established recommendations to control dose to an individual.

Radiation survey instruments are calibrated by exposing the detector to a well-characterized radiation field (traceable to a national standards laboratory). Instruments used under different field conditions may exhibit energy dependence, temperature and pressure dependence, directional dependence, source distance and geometry effects, and contributions from scattered radiation. Therefore, appropriate correction factors are needed to relate field instrument readings to laboratory-controlled calibration conditions.

Conversion of a radiation measurement in air to absorbed dose in the body requires an anatomical model. The absorbed dose to a given organ can vary substantially depending on the incident photon energy, angle of entry, organ size, shape and position, and body size. In practice, without detailed knowledge of the photon energies, irradiation geometries, and attenuation factors, the absorbed dose in an organ or tissue may only be estimated, and the overall uncertainties in translating the air-measurement to organ or tissue dose may be great (NCRP, 2015b).

Appendix B. Health Effects of Concern in Radiation Protection

B.1 Introduction

Sections B.1 through B.13 focus entirely on the health effects of ionizing radiation directly on humans. Section B.14 considers the radiological impacts on nonhuman biota.

Ionizing radiation can damage or kill cells and thus harm tissues and organs. The number of cells affected depends on the absorbed dose in the organs or tissues of the body (organ dose) and the sensitivity of the specific cells affected.

The NCRP recommendations for radiation protection have been developed from an extensive body of scientific research on the effects of radiation in humans and nonhuman species, acquired over more than a century. The recommendations encompass the knowledge of advanced biology and mechanistic studies of radiation effects at the molecular and cellular levels. For cancer and heritable effects, the critical information arises from epidemiologic studies, research on animal and human genetics, and current scientific data on fundamental mechanisms of carcinogenesis and heritable effects.

Risk coefficients have been derived from analysis of dose-response functions. The epidemiologic studies of radiation effects on Hiroshima and Nagasaki atomic-bomb survivors provide the principal risk coefficient data on which current standards for radiation protection are based.

Radiation protection programs are designed to minimize adverse health effects and keep doses as low as reasonably achievable (the ALARA principle). Therefore, the most relevant health effects to be considered are those that occur at low absorbed doses and low absorbed dose rates (low doses and low dose rates). The health risk of most interest under these circumstances is cancer and, to a much lesser extent, potential heritable effects. There are circumstances when there are moderate or even high absorbed doses to specific organs or tissues and there are

specific effects which need to be considered (*e.g.* effects on the lens of the eye, embryo and fetus, thyroid, brain, skin, cardiovascular system).

Appendix B reviews the basic types of radiation effects, description and limitations of epidemiologic studies, information related to grouped and specific cancers as well as effects on specific tissues. Much of this material has been previously collated and reviewed in reports published by NCRP (1993a; 1997; 2001a; 2005; 2012b; 2015a), NA/NRC (2006), UNSCEAR (2008) and ICRP (2007a), and these reports will be used as comprehensive base references. NCRP has reviewed a large number of the well-designed statistically powerful newer studies that could potentially affect the prior judgments and conclusions of NCRP.

B.2 Categories of Adverse Health Outcomes

It has been the common practice in the development of radiation protection standards to categorize radiation-induced health effects into stochastic effects and adverse tissue reactions.

The term "stochastic effects" has been applied to cancer and heritable (genetic) effects that occur by chance and have no observable threshold. Cancer and heritable mutation frequencies increase with absorbed dose but the severity of the effect is not dose-dependent (*i.e.*, the cancer is not more advanced if the dose is higher). At absorbed doses above ~0.1 Gy (100 mGy) an increase in cancer can be detected in epidemiologic studies. At very low absorbed doses, if there are carcinogenic or heritable effects in humans, they so far, have eluded detection. Stochastic effects following radiation exposure generally have a very long latency period. Heritable effects observed in mice occur in the next generation. At moderate and high absorbed doses, most solid cancers in humans do not appear for more than a decade post exposure and some level of risk persists for most of life.

The other major class of adverse health outcomes are "deterministic" effects. This term stems from the assumption that these were determined directly by the radiation exposure. In addition, the severity of the disease increases with increasing absorbed dose. These outcomes

were renamed as adverse tissue reactions in the most current recommendations of ICRP (2007a) because of the growing evidence that such responses could be modified after irradiation rather than being determined at the time of irradiation. Tissue reactions can occur at early or late times after irradiation, and they typically exhibit a threshold response. The underlying mechanism for the early effects involves cell killing whereas the later effects involve modifications of the tissue involved.

There are some effects that do not clearly fit into either the stochastic or tissue reaction category (*e.g.*, cardiovascular disease and lens of eye opacities).

B.3 Epidemiologic Studies of Radiation Effect

The bulk of the scientific evidence used by NCRP in forming its judgments comes from epidemiologic studies supplemented by animal and cellular observational and mechanistic studies. Well-designed epidemiologic studies provide valuable information for estimating the probability of radiation effects because they provide direct information about effects on humans, but at the same time, they have some well-recognized limitations and uncertainties.

The three main types of epidemiologic studies for radiation exposures vary in their respective strengths and weaknesses. The strongest of the three types for ascertaining the relationship between radiation exposure and long-term response is a cohort study, in which a defined group of individuals (preferably with a wide range of exposures) is followed over time and their health outcomes analyzed. Cohort studies may be conducted prospectively or retrospectively. Another common type is the case-control study. For a case-control study, persons with some specified disease (such as cancer) are matched for characteristics such as age and sex with a set of persons who do not have the disease. The groups are then compared to assess differences due to radiation exposure. Compared with cohort studies it is easier in case-control studies to collect detailed radiation exposure history and information on other risk factors which may influence the probability of developing the disease. However, case-control studies are prone to more types of bias than are cohort studies. The third type is the ecological study. In

ecological studies, disease rates are assessed at the group or population level. Prevalence rates are compared among different geographic areas or time periods. Since this type of study does not measure disease and exposure at the individual level it may contain hidden biases and is the weakest type of study for determining cause and effect. However, ecological studies can on occasion be useful for formulating hypotheses.

All epidemiologic studies have limitations. Biases can lead to an artificial increase or decrease compared to the actual disease outcome. Some examples are follow-up bias, ascertainment bias, and recall bias. Confounding factors also limit the interpretation and application of epidemiologic studies. Tobacco use is perhaps the most serious confounding factor as it is, by itself, associated with significantly increased risk of cardiovascular disease and many cancers. Other confounding factors include but are not limited to genetic background, population heterogeneity, medications, hormone levels, diet, alcohol use, and chemical and other occupational or environmental exposures.

Limitations on the statistical power of epidemiologic studies result from both the absorbed dose level and the sample size. Assuming a linear association between absorbed dose and the probability of cancer induction, the sample size required to detect an effect with adequate statistical power is approximately proportional to the inverse of the dose squared (Land, 1980; 1981). Thus, assuming that a sample size of 1,000 is needed to detect a given desired magnitude of effect at an absorbed dose of 1 Gy, a sample size of 100,000 would be needed if the absorbed dose were 0.1 Gy (100 mGy), and a sample size of 10,000,000 would be needed if the absorbed dose were 0.01 Gy (10 mGy). To demonstrate a radiation effect for absorbed doses <0.01 Gy would require epidemiologic studies involving millions of exposed persons with suitable controls and subject to similar risk factors who are followed for decades. A study group of that size is usually impracticable, so in the very low dose range estimates of effects can only be made using a number of assumptions rather than by direct observation.

B.4 Cancer Incidence and Mortality

Human epidemiologic studies of radiation-induced cancers form the basis for radiation protection guidance (ICRP, 2007a; NCRP, 1993a). Nominal risk coefficients are derived by averaging sex and age-at-exposure lifetime risk estimates obtained from studies with adequate dose-response data. For estimation of the risk of radiation-induced cancers, uncertainties arise from dosimetry, transfer across populations, the effects of low dose and low dose rate, radiation quality, methodology, presence of bias, and other physical and biological confounding factors that cannot be controlled for. When a detailed analysis is performed, the 95 % confidence interval (CI) is generally a factor of about 2 to 3 around a central estimate of risk based on a uniform whole-body exposure. By definition, however, the derived detriment-adjusted nominal risk coefficients for stochastic effects (Table 5.1) that are used as a basis for radiation protection purposes are expressed without uncertainty.

The Japanese Life Span Study (LSS) is currently relied upon for the nominal risk computations used for radiation protection, supplemented with supportive or complementary data from studies of patients given radiation for medical purposes, workers exposed to radiation, survivors of radiation accidents, and populations exposed to elevated levels of ubiquitous background radiation. Pooled analyses of selective studies for specific cancers, such as breast cancer, have also been important. Incidence data tend to have less diagnostic misclassification than mortality data and provide better estimates for cancers that have relatively low lethality.

However, incidence data are often not available and are difficult to obtain for populations with a long follow-up. Even the LSS incidence data are limited since the data only include residents in two areas in Japan (Hiroshima and Nagasaki) with challenges to adjust for migration. The Japanese registries started 13 y after the bomb detonations. For the LSS and other populations, mortality data are often stronger in the sense of size, overall coverage and being less susceptible to biases in obtaining incidence data.

The One Million U.S. Workers and Veterans Study of Low Dose Health Effects (MWS) was designed to provide definitive results on the effect of low dose-rate exposure cumulating to a

moderate to large dose, and on the shape of the dose-response relationships and the appropriateness of the LNT model for radiation protection (Boice 2017a; 2017b; Bouville *et al.*, 2015).[17] The MWS investigates the effects of radiation when doses are delivered gradually over time. The study was started over 25 y ago and the component study groups include nuclear power plant workers (150,000), industrial radiographers (135,000), DOE workers (360,000), atomic veterans (115,000), and early medical workers (240,000) such as radiologists, technologists, nuclear medicine personnel and radiation oncologists. There have been a number of publications over the years on the component study groups (Beck *et al.*, 2017; Boice *et al.*, 2011; 2014; 2017a; 2017b; Bouville *et al.*, 2015; Stram *et al.,* 2015; Till *et al.*, 2014), but combined analyses have yet to be conducted. Nonetheless, the studies of nuclear power plant workers, industrial radiographers and nuclear weapons test participants represent over 400,000 workers and veterans, are nearing completion and each is large enough to provide information on dose-response relationships.

Estimates of radiation risk can be influenced by the following:

- quality of the exposure data available (measured or reconstructed);
- dose rate (acute or chronic), the type of exposure (external or internal);
- quality of the radiation (low or high linear energy transfer);
- organs and tissues exposed;
- population characteristics (such as age-at-exposure, attained age, time-since-exposure sex, genetic predisposition, and period of observation);
- presence of co-factors or lifestyle factors (such as tobacco use and viral infections); and
- study biases.

[17] The statistical power in the MWS is related to the very large numbers, ten times that of the LSS, and a broad dose distribution. The numbers of workers with cumulative doses over 10 mGy and 50 mGy are larger than those in the LSS. Cumulative dose over 1 Gy are observed for several thousand workers. The MWS individual cohorts are all healthy Americans, and studied in the same way. The approach to dosimetry is comprehensive and conducted by the same specialists in dose reconstruction. The approach to vital status determination and outcome ascertainment is the same across cohorts. More than 200,000 women are being studied. The MWS is more representative of healthy Americans today than was the Japanese population exposed acutely in 1945 to atomic weapons and living in a war-torn country with deprivation, malnourishment, and infectious diseases.

NCRP considered the comprehensive reviews of radiation studies published by UNSCEAR (2008), the BEIR VII Committee (NA/NRC, 2006) and EPA (2011), the most recent available data from the LSS (Grant *et al.*, 2017; Ozasa *et al.*, 2012) and other worker, patient and environmental data (Dauer *et al.*, 2010; Gilbert, 2009; Shore, 2014). In addition, NCRP published a recent review of epidemiologic investigations and their associated uncertainties in Report No. 171 (NCRP, 2012b), and the 2013 NCRP Annual Meeting reviewed exposed populations that have contributed to our understanding of radiation effects (Boice, 2014).

NCRP has recently completed a comprehensive review of recent epidemiologic studies, assessing their quality and whether they support the LNT model that is currently used for radiation protection (Boice, 2017b; NCRP, 2017a). The ongoing large-scale worker studies in Europe and the United States are designed to provide quantitative estimates of risk following exposures received gradually over time that cumulate to a level where excesses, if present, should be observed. For radiation epidemiologic studies conducted to date at low doses, the dose ranges were too narrow and the number of excess cancers too small to be informative.

It is clear that the risk of cancer is a function of cumulative dose (and not a dose received in a single year). Thus radiation protection programs should take this into account in protecting the individual and populations. Previous NCRP guidance took this directly into account when recommending that occupational limits be related to age times 10 mSv.

Section B.4.1 provides a brief review of selected site-specific radiation effects, Section B.4.3 discusses age-specific differences in cancer risk and Section B.4.4 discusses sex-specific differences in cancer risks.

B.4.1 Site-Specific Risk Estimates

B.4.1.1 Cancers Not Strongly Linked to Radiation Exposure. Not every cancer has been consistently seen to be increased following radiation exposure. For example, there is less

evidence for an association with radiation for induction of chronic lymphocytic leukemia, pancreatic cancer, prostate cancer, cervical cancer, testicular cancer, non-Hodgkin lymphoma, Hodgkin lymphoma or multiple myeloma (UNSCEAR, 2008). For solid cancers among the LSS, rectum, pancreas, uterus, prostate and kidney parenchyma were not significantly elevated (Ozasa *et al.*, 2012). For some cancers, an excess risk has only been seen following very high (radiotherapeutic) absorbed doses (*e.g.*, cancers of the small intestine, rectum, uterus and kidney) (NCRP, 2011a). Thus, for a number of cancers the risk following low doses of radiation either does not exist, or is very small and not detectable, and is highly uncertain.

B.4.1.2 Leukemia. Leukemia is one of the most prominent stochastic radiation effects. It is observed in many radiation-exposed populations, has one of the highest risk coefficients, has a short minimum latency of about 2 y, and shows a wave-like pattern of risk over time (peaking about 10 y after exposure and decreasing in risk thereafter). The dose-response relationship is most consistent with a linear-quadratic model. Children are at highest risk; the embryo and fetus are not considered more vulnerable than young infants. Risk varies by cell type with acute myelogenous leukemia (AML) predominating in most studies. Chronic lymphocytic leukemia historically has not been considered a radiation effect. Myelodysplastic syndrome (MDS) has recently been reported to be increased among Nagasaki survivors of the atomic bomb and an association has been reported following multiple CT exposures in childhood. However, MDS is biologically and clinically different from AML and it is questioned whether MDS should be considered an early phase of AML (Albitar *et al.*, 2002). MDS is not classified as a malignancy, and should be considered a discrete entity and not combined with leukemia for risk estimation.

The MWS has begun to produce results relevant to dose-response relationships, particularly for leukemia. Among nuclear power plant workers and industrial radiographers, the dose-response relationships for leukemia are consistent with a linear-quadratic shape among the worker studies. For atomic veterans there was no dose response, most likely because of the very narrow dose range with few veterans receiving more than 20 mSv. For the nuclear power plant workers, 333 leukemia (excluding CLL) cases where evaluated in comparison with the atomic-

bomb survivors of 94 cases among adult males. The industrial radiographers include nearly 300 leukemia. CLL was not associated with radiation.

B.4.1.3 Breast Cancer. Radiation-induced breast cancer has been observed in many cohorts of exposed young women. Excess risk is seen to decrease with increasing age-at-exposure and there is little evidence for a risk following exposures around menopause, over about age 45 y. Exposures to young girls around the age of menarche and breast budding carry a high risk. The dose-response relationship is consistent with linearity and fractionation does not diminish risk appreciably. The latency for radiation-related breast cancer is long and inversely related to age-at-exposure (*i.e.*, it takes young girls many years for a radiogenic cancer to develop and a shorter time for older women). Excess absolute risks (EAR) are more similar than excess relative risks (ERR) across different populations. The ERR is highly dependent on the naturally occurring background rate of disease (*e.g.*, for the same radiation dose, the Japanese bomb survivors have a much higher ERR than western women, reflecting the very low breast cancer rates among Japanese women). Such major differences are extremely important when transferring risks from one country to another and when projecting risks forward in time. Despite comprehensive genetic studies, there is little evidence to date that inherited genetic mutations in breast cancer genes (*e.g.*, *BRCA1*) enhance the risk of radiogenic breast cancer developing.

B.4.1.4 Thyroid Cancer. Radiation-induced thyroid cancer was the first solid tumor reported to be increased among Japanese atomic-bomb survivors. Numerous studies of children irradiated for benign and malignant conditions report very high relative risks. The age-at-exposure effect is remarkable with the highest risk among those exposed under age 5 y, including newborns, and very little risk observed among those exposed after age 15 y. Incidence studies of adults administered diagnostic levels of radioactive ^{131}I find no evidence of an effect. Radioactive iodine exposures following the Chernobyl accident are linked to excess thyroid cancer among children who drank contaminated milk. Several comprehensive studies (*e.g.*, Davis *et al.*, 2002), however, find little evidence for an increase in thyroid cancer or disease following intakes of radioactive ^{131}I. This reflects the possibility that the shorter-lived radioiodines contributed to the thyroid excess among Chernobyl residents exposed as children, possibly because of a higher

dose rate and more energetic and penetrating beta particles giving a uniform dose distribution across the thyroid than ^{131}I. It also may reflect the strong influence of goiter and iodine deficiency in the Chernobyl areas that apparently greatly enhanced the risk (Cardis *et al.*, 2005a)

B.4.1.5 Lung Cancer. Radiation-induced lung cancer is a major consequence of exposure to the atomic bombs among Japanese survivors, although the confounding influence of smoking is not easily interpretable. For example, survivors who smoked the most had no or little radiation risk for lung cancer. Also the peculiar sex difference in risk with females having twice the risk as males is yet to be explained. New incidence studies reinforce and expand these observations but shines little light on the reasons for these peculiarities (Cahoon *et al.*, 2017; Grant *et al.*, 2017). Notable is that the female-to-male ratio appears to decrease with increase with dose at least for the combined data analyses. Excess lung cases are strongly linked to radon progeny exposure among underground miners and following prolonged exposure to high residential levels.

Patients given radiation therapy for malignant conditions are at high risk of subsequent lung cancer and smoking appears to interact in a more than additive fashion. However, there is little evidence for lung cancer risk following low dose exposures to low-LET radiation. Most notable is the absence of increased lung cancer risks among tuberculosis patients who received up to several hundred chest fluoroscopic examinations (several gray) and among patients with severe scoliosis who received up to 160 spinal x-ray examinations (over a gray). These patient populations are notable because significant increases in breast cancer were clearly evident but not lung cancer. Occupational studies are difficult to interpret because of the inability to adequately control for the effect of cigarette smoking on lung cancer risk coupled with the low cumulative doses normally seen in occupational studies.

B.4.1.6 Stomach Cancer. Similar to lung cancer, radiation-induced stomach cancer is a major effect among Japanese atomic-bomb survivors. There is clear evidence for excess risks among patients treated with radiation for malignant and benign conditions. There is little evidence for a demonstrable effect in other populations exposed to low doses of low-LET radiation. The appropriate way to ‘transfer’ risk estimates from one population is especially important when

there are major differences between the underlying background cancer rates in the two populations. For example, lifetime risk estimates for stomach cancer based on transfer of absolute risks are several times higher than those based on transfer of relative risks. The attributable risk estimates in studies conducted in Western populations are appreciably lower on average than those in the LSS, suggesting that using the ERR model may be a better way to 'transfer' stomach cancer risk than using the EAR model. Data from the peptic ulcer study (reference to be added) confirm that ERR estimates are very similar to those based on survivors of the atomic bombings.

B.4.1.7 Other Cancers. The other cancers that are reported in the mortality data to be significantly elevated among Japanese atomic-bomb survivors include cancers of the esophagus, colon, liver, gallbladder, ovary, urinary bladder, non-melanoma skin cancer, renal pelvis (but not renal parenchyma) and ureters. The site-specific cancer incidence data confirm these increases as well as the previously mentioned cancers that were not significantly elevated (Section B.4.1.1), that is, the dose responses were not statistically significant for cancers of the pancreas, prostate, kidney, rectum, gallbladder and uterus (Preston *et al.*, 2008).

Ionizing radiation can induce several types of nervous system tumors. There are marked differences with age-at-exposure. Malignant tumors of the CNS are seen mostly after high doses of radiation therapy and after exposure in childhood. The risk of glioma is highest among children exposed under the age of five, and largely disappears at the age of 20 y or more at irradiation, suggesting that susceptibility decreases as brain development nears completion. The risk from exposure in adulthood is more commonly seen for benign (and not malignant) tumors such as meningioma, neurilemmoma and schwannoma (UNSCEAR, 2013).

B.4.1.8 Combined Solid Cancers. Review of the observations for site-specific cancers indicates that a single dose-response model does not fit all individual cancers; incidence rates of some cancers are not significantly or consistently elevated (*e.g.*, pancreas), some are elevated only after high organ doses (*e.g.*, rectum), some depend entirely on a young age-at-exposure (*e.g.*, thyroid), and some are sex-specific (*e.g.*, breast). Thus, the combined cancer evaluations should

be interpreted cautiously, especial for biological implications and mechanisms of damage at low doses. The combination, however has been consistently used to help assess the relevance of the LNT model for use in radiation protection.

B.4.2 Shape of the Dose Response

Combining all cancers mingles heterogeneous data with different dose-response shapes, latencies, and age modifications of risk. Thus, although a common practice for radiation protection purposes, combining all cancers to make inferences of risks at low doses is a tenuous approach. The results are specific to the population studied and reflect age and sex characteristics as well as the exposure patterns (acute or chronic). The most recent discussion to reinforce this concern of inferences from combined cancers comes from the incidence study of atomic-bomb survivors (Grant *et al.*, 2017): the combined cancer data showed a linear relationship for females but a significant curvilinear relationship for males; but when the analysis was restricted to non-sex specific cancers (*e.g.*, removing breast and prostate), the female dose response showed significant curvilinearity. The mix of cancers that were markedly elevated in a recent U.K. male worker study (*i.e.*, pleural cancer, and cancers of the rectum and testes) were not the types expected following low-dose radiation exposure (Muirhead *et al.*, 2009). The findings in the Techa River populations were peculiar in that the significant excess in the combined cancer analyses were driven by cancers not sensitive to radiation (cervix) or infrequently associated with radiation (esophagus) (Davis *et al.*, 2015). Combining all cancers together increases statistical precision but lacks biological plausibility, so interpretation and application to radiation protection and other circumstances should be done with caution and awareness.

Nonetheless, combined cancer analyses are used to assess the appropriateness of the LNT model for radiation protection purposes. Recent studies evaluated by Boice (2017b) and NCRP (2017a) that have combined all cancers together to investigate the shape of the dose-response relationship include the studies of Japanese atomic-bomb survivor (Grant *et al.*, 2017; Hsu *et al.*, 2013; Ozasa *et al.*, 2012; Preston *et al.*, 2007), U.K. workers (Muirhead *et al.*, 2009), the 15-country study (Cardis *et al.*, 2007), U.S. workers (Daniels *et al.*, 2013; Schubauer-Berigan *et al.*,

2015), the INWORKS study (Hamra *et al.*, 2016; Richardson *et al.*, 2015), Chernobyl residents who drank radioiodine-contaminated milk as children (Brenner *et al.*, 2011), Mayak workers (Hunter *et al.*, 2013), Chernobyl cleanup workers (Kashcheev *et al.*, 2015), Techa River populations (Davis *et al.*, 2015; Krestinina *et al.*, 2013; Schonfeld *et al.*, 2013), residents of an area in Kerala of high ubiquitous natural background radiation (Nair *et al.*, 2009), females with scoliosis monitored repeatedly with spinal x-ray examinations (Ronckers *et al.*, 2010), and children exposed to medical radiation (Ron *et al.*, 1989; Veiga *et al.*, 2016), children exposed to CT examinations (Boice, 2015a; UNSCEAR, 2013; Walsh *et al.*, 2014), and several others including nuclear weapons test participants, U.S. radiologic technologists, radiation fallout studies, prenatal x-ray studies, and Taiwan residents of building constructed with radioactive ^{60}Co rebar rods (Boice, 2017b). NCRP (2017a) also evaluated pooled studies of breast cancer (Preston *et al.*, 2002) and previous reports from the NCRP (2001a; 2011a; 2012b) and the ICRP (2005; 2007a) in providing judgment on the appropriateness of the LNT model for radiation protection (Boice, 2015b; 2015c).

For over 40 y, the LNT dose-response model has been commonly used to provide practical and prudent guidance on ways to protect workers and the public from the potential for harmful effects from radiation while balancing the beneficial, justified, and optimized uses of radiation in our society. In developing its basic radiation protection recommendations, as currently given in Report No. 116 (NCRP, 1993a) and supported by Report No. 136 (NCRP, 2001a), NCRP reiterated its acceptance of the LNT model for radiation protection purposes. While it is well known that "all models are wrong but some are useful" (Box, 1979), the LNT model is an assumption that has not been and likely cannot be scientifically validated in the low-dose range. Other dose-response models for the mutagenic and carcinogenic or detrimental effects of low-level radiation cannot be excluded, and there are notable exceptions to the LNT relationship seen in experimental and epidemiologic studies (Boice, 2015b; Dauer *et al.*, 2010).

Nonetheless, on the basis of the scientific knowledge to date and the current review of recent epidemiologic studies by NCRP (2017a), no alternative dose-response relationship appears more pragmatic or prudent for radiation protection purposes than the LNT model. This

conclusion is also consistent with the current judgment by national and international scientific committees. The ongoing development of science, however, requires a constant re-assessment of prior and emerging evidence to provide an optimum, though not necessarily perfect, approach to radiation protection. NCRP also recognizes that a pragmatic, predictable approach to radiation protection depends on being able to add doses together, across different dose rates and times. This is the advantage of the LNT paradigm for radiation protection policy. NCRP continues to suggest the LNT model for radiation protection purposes, while recognizing the varied and complex dose-response relationships seen at different subcellular, cellular, tissue, and organism levels.

Based on a comprehensive review of recent epidemiologic studies of irradiated populations, NCRP (2017a) reaffirms that, for identified stochastic effects, the LNT model for dose-response be used for radiation protection purposes as a prudent and practical tool for managing potential radiation risks below an effective dose of 100 mSv.

B.4.3 Effect of Age-at-Exposure

Radiation protection of a population typically uses recommendations that apply to all persons: men and women, children and adults. It is clear however that there are differences in the risk of radiation-induced cancers that depend upon the sex and age of an individual. In general, persons exposed at younger ages are at increased risk compared with older persons. One reason is that those exposed at young ages are likely to live longer and have more time to express radiation risk and radiation detriment. At the other end of the age spectrum, exposed elderly persons are at lower risk since they generally die from other causes before radiogenic cancer can develop. Furthermore, sensitivity for a given absorbed dose varies with age for specific tissues (*e.g.*, the thyroid gland is more sensitive among children than adults). An additional complication is that depending upon the model used (relative risk versus absolute risk; age-at-exposure versus attained age) differing conclusions are reached regarding the effect of age. For solid cancers there is a large body of evidence that excess relative risks (ERRs) diminish with increasing age-at-exposure (UNSCEAR, 2008). This pattern of risk is observed in the Japanese atomic-bomb

survivor data for both solid cancer incidence and mortality, related to absorbed dose (Grant *et al.*, 2017; Ozasa *et al.*, 2012). On the other hand, for a constant attained age the excess absolute risks (EAR) for solid cancers increases with age-at-exposure. Using the different risk models can lead to substantially different risk projections. Concern about the influence of models on age-at-exposure effects and risk projections are reinforced when looking at site-specific cancer where the differences in age patterns and risk projections are even more glaring.

B.4.4 Effect of Sex

In general, females have higher risks for radiation-induced cancer than do males for a given absorbed dose (EPA, 2011; Grant *et al.*, 2017; NCRP, 1989; 2000; Ozasa *et al.*, 2012). The magnitude of the difference depends upon the model used (ERR versus EAR). The largest and most recent pool of data in this regard comes from the atomic-bomb survivors (Ozasa et. al., 2012). The difference in risk appears related to most tissues and not limited only to sex-specific cancers, as discussed in NCRP Commentary No. 23 (NCRP, 2014a). For example, breast and ovary are relatively high in radiation sensitivity whereas the testis and prostate are very low in terms of radiation-induced cancer. There are however additional differences in most other organs with females being more sensitive than males for cancer of the esophagus, stomach and lung. Using an ERR model for cancer incidence at age 70 y with exposure at age 30 y, the ERR is 0.66 Gy^{-1} for females and 0.31 Gy^{-1} for males (Ozasa *et al.*, 2012). The female-to-male ratio using the ERR model for all solid cancers is 2.1 (95 % CI: 1.4, 3.1). Using an EAR model, the female-to-male ratio is insignificantly elevated at 1.1 (95 % CI: 0.8, 1.7).

The current incidence data have been updated through 2009, representing 11 additional years of follow-up since the last follow up in 1998 (Preston *et al.*, 2007), and the data indicate significant differences in the shape of the dose-response curve between females and males (Grant *et al.*, 2017). For all solid cancer combined the best fit to the data for females is linear while for males the best fit is curvilinear. However, when sex-specific cancers are excluded, the best fit becomes curvilinear for females. The age specific female-to-male (F:M) cancer rate ratio decreased from approximately 3 at age 30 to 1 at around age 50, falling below 1 at older ages. When sex-specific cancers were excluded, the F:M cancer rate ratios were consistently below

one in adulthood. Similar to the mortality data, the F:M depended on choice of model and, more interesting on absorbed dose: the F:M ratio was 4.0 at 1 Gy and greater than 10 at 0.1 Gy. On the EAR scale, the F:M ratio was 1.3 at 1 Gy. Thus sex difference may depend not only on choice of model, age at exposure, attained age, and on the specific cancers chosen for comparison, but also on absorbed dose.

B.4.5 Infants, Children, and Pregnant Women Require Special Attention.

There are specific groups that require special attention: infants, children, and the embryos or fetuses of pregnant women. This not only because of increased radiation sensitivity compared with adults, but because of vulnerability and ethical considerations. In particular, the ethical principle of justice would urge special protection treatment because of the increased radiation sensitivity compared with adults.

B.4.5.1 Infants and Children. Radiation exposure of infants and children is of fundamental concern. This is true whether the exposure is accidental, from ubiquitous background radiation, or due to medical or industrial sources. Infants and children represent the largest of the groups considered most at risk for radiation-induced adverse health effects. They represent a substantial percentage of persons exposed as members of the public. In 2014, 23 % of the U.S. population was in the age group of 0 to 17 y.

There are significant anatomical and physiological differences between infants, children and adults that result in differing absorbed doses and potential effects based upon age-at-exposure. It is commonly assumed that children might be 2 to 3 times more sensitive to cancer than adults. This generality, however, does not pertain to specific cancer types. UNSCEAR (2013) has conducted a rigorous scientific review of the literature regarding 23 specific tumor types and concluded that for about 25 % of cancer types (including leukemia, thyroid, breast, skin and brain cancer), children were clearly more radiosensitive. For about 15 % of the cancer types (*e.g.*, colon cancer) children appear to have the same radiosensitivity as adults. For about 10 % of the cancer types (*e.g.*, lung cancer) children appear to be less sensitive to external

radiation cancer induction than are adults. For about 20 % of cancer types (*e.g.*, cancer of the esophagus) the data are too weak to draw a conclusion. Finally, for about 30 % of cancer types (*e.g.*, Hodgkin lymphoma, prostate, rectum, pancreas, cervix and uterine cancer) there is only a very weak or no relationship between radiation exposure and risk of cancer.

It should be noted that effective dose and associated risk estimates are based upon an age-averaged population and do not take into account the issues discussed above. Currently the recommendations for members of the public also apply to infants and children. At present, projections of lifetime risk for specific cancer types following exposure at young ages are highly uncertain for all but a handful of cancers such as thyroid and breast.

The data regarding potential radiation effects on children has become clearer over the last decade, especially with regard to specific tumor types. However, the overall risk coefficient has not changed significantly since the prior NCRP recommendation (NCRP, 1993a). The greater sensitivity of children was already factored into that recommendation which followed the ICRP (1991a) 1 mSv effective dose limit for members of the public. While cancer risk estimates for an age-averaged population are used for broad radiation protection purposes, when infants and children are involved, attention should be directed, if possible, to the specifics of exposure, age-at-exposure, absorbed doses to certain tissues and the particular effects of interest. This attention to the sensitivity of infants and children is supported by both the principle of non-maleficence (do no harm) as well as the principle of justice, which requires unequal treatment (*i.e.*, special protection for the young) to achieve an equitable situation.

B.4.5.2 Embryo and Fetus. Insofar as the embryo and fetus are considered more radiosensitive than adults, NCRP provides special protection guidelines for them. Recent extensive reviews of the effects of *in utero* exposure have been published by both NCRP (2013) and ICRP (2003).

Potential radiation-induced effects on the embryo or fetus include embryonic loss, malformations, and CNS effects. However these are not known to occur at acute absorbed doses to the embryo or fetus below about 0.15 to 0.2 Gy. Data on induction of neoplasms following *in utero* exposure is somewhat contradictory, unresolved and has been debated for years. The case-

control Oxford study (Bitthell and Stewart, 1975) following diagnostic radiology pelvimetry examination indicated an increased risk of childhood neoplasms but with the same risk for all types of neoplasms, including embryonic tumors that develop before pelvimetry examinations. On the other hand, data from all cohort studies following *in utero* medical or occupational exposures have failed to observe statistically significant increases in childhood leukemia or cancer (*e.g.*, Court Brown and Doll, 1960; Schonfeld *et al.*, 2012). The children of Japanese women who were pregnant at the time of the atomic bombings also did not show a significantly increased risk of childhood cancer or leukemia.

Analyses of the Japanese atomic-bomb survivor data indicate that for the irradiated embryo or fetus there is a significant risk of cancer, although not childhood cancer, and that the lifetime risk appears lower for the irradiated embryo or fetus than for the irradiated child (Preston *et al.*, 2008). Overall, it is prudent to assume there is a risk of cancer following prenatal exposure and that the risk of developing cancer later in life is similar to the risk following childhood irradiation which is, at most, about 3 times that of a general population of all ages (UNSCEAR, 2013).

The sensitivity of the embryo and fetus to radiation is considered when making protective guidance specifically for occupationally-exposed pregnant females.

B.5 Heritable (Genetic) Effects

For more than half a century, a range of studies have been conducted to establish whether there are risks of heritable disease to offspring of parents exposed to ionizing radiation as a result of the atomic bombings (Grant *et al.*, 2015; Tatsukawa *et al.*, 2013), accidents or medical exposures. The overall conclusion is that there is no direct evidence that parental exposure results in heritable disease in offspring. There have been a number of studies on genetic disease in the offspring of long-term survivors of childhood cancer (Signorello *et al.*, 2010; Winther *et al.*, 2012). In such studies and as with adults, there is no evidence that radiation exposure in childhood confers any measurable risk of heritable effects in offspring (UNSCEAR, 2013).

There has been no consistent evidence of heritable effects after these childhood exposures. This conclusion is supported by a number of national and international organizations (*e.g.*, ICRP, 2007a; NA/NRC, 2006; NCRP; 2005; UNSCEAR, 2001).

However, in contrast to the lack of an observable increase in radiation-induced heritable effects in comprehensive long-term human studies, there are clearly heritable effects observable in the offspring of mice and other mammalian and non-mammalian species and so, it has long been practice to develop a risk estimate for human exposures based on mouse data. For the purposes of incorporating heritable risk into the overall risk from ionizing radiation, heritable risk is calculated for continuous low dose-rate exposures over two generations. In this way, the present heritable risk estimates developed by UNSCEAR (2001) and ICRP (2007a) essentially using the same methods, is about 0.2 % per gray. This value is more than 20-fold less than the nominal risk estimate for cancer (5 % per sievert). In this Report, NCRP accepts the ICRP (2007a) heritable risk estimate. The current ICRP (2007a) value was substantially reduced from previous estimates due to the mounting evidence of the absence of a detectable heritable effect from the studies of the children of atomic-bomb survivors and of cancer survivors treated with radiation.

B.6 Effect of Genetic Susceptibility

Over the past decade or so, there has been an extensive increase in knowledge of the genetic basis of diseases, especially cancers of many different types (Weinberg, 2013). How such information might convert into inter-individual differences in susceptibility to radiation-induced cancer has been quite extensively discussed by ICRP (1998), NA/NRC (2006), and UNSCEAR (2001; 2008). However, it remains unclear as to the magnitude of the effect of any such sensitivities even at the individual level, let alone a population level.

It is thought that the increase in cancer risk to a heterogeneous population of susceptible and nonsusceptible genotypes will generally be quite small if the proportion of susceptible individuals is small and the radiation sensitivity relatively low. On the other hand, cancer risks

assessed on the basis of an individual (in radiation therapy situations, for example) might be greatly influenced by genotype. For the purposes of radiation protection, recommendations for members of the public will not be significantly influenced by genetic susceptibility. In situations where individual risk could be more of an issue (*e.g.*, occupational or medical exposures), how to account for susceptible genotypes in recommendations needs to be considered further.

Research to date has revealed little evidence for an interaction with radiation therapy and genetic susceptibility in breast cancer patients. For the most common breast cancer genes, deleterious mutations in the *BRAC1* or *BRACA2* genes, breast cancer patients treated with radiation were not at an enhanced risk of developing breast cancer in the contralateral breast (Bernstein *et al.*, 2013). In the same comprehensive international study, women with rare deleterious *ATM* missense variants who were treated with radiation may have an elevated risk of developing contralateral breast cancer. However, the rarity of these deleterious missense variants in human populations implies that *ATM* mutations could account for only a small portion of second primary breast cancers (Bernstein *et al.*, 2010). More research is needed on the genetic basis for such susceptibilities and the magnitude of effects.

Specific radiation-related genetic susceptibilities are not incorporated into radiation risk estimates for populations. Where such deleterious genetic susceptibilities can be identified at the individual level, consideration would be given to appropriate dose levels for treatment or imaging regimes for that individual.

B.7 Cardiovascular Disease

The term cardiovascular disease (CVD) encompasses both heart disease and vascular disease, and there are various subsets of these two categories. Types of heart disease include: coronary heart disease, cardiomyopathy and congestive heart failure, and valvular heart disease. Types of vascular disease include: cerebrovascular disease, peripheral vascular disease, and aortic disease. Even within each of these categories of CVD, there exist a range of subtypes which may have completely different etiologies. For example, cardiomyopathy may be caused

by coronary disease (ischemic cardiomyopathy), by genetic mutations (*e.g.*, hypertrophic or dilated cardiomyopathy), by toxins such as high-dose ionizing radiation or alcohol, by infectious agents such as *Trypanosoma cruzi* (in Chaga's disease), by arrhythmias such as atrial fibrillation, or by hypertension. Similarly, stroke can either be hemorrhagic or ischemic and both have multiple causes. Hypertension is not only a risk factor for many types of cardiovascular disease, but it may be implicated as a cause in some cases or conversely be caused by CVD in some cases (*e.g.*, renal artery stenosis). Even in the absence of other CVD, hypertension is often included within the general category of CVD. The literature regarding CVD after radiation exposure is difficult to interpret because most studies to date have not delineated a number of important factors and have often lumped together diverse subtypes and etiologies, thus confounding relationships between ionizing radiation and CVDs.

Moreover, this literature is beset with several additional challenges, including accuracy of disease diagnosis, changes in detection technology, classification (including ICD codes which have evolved), diagnostic criteria, and temporal trends in disease incidence. Unless all these issues are carefully spelled out and controlled for, results of published studies about low-dose radiation and CVD can be misleading (Ozasa *et al.*, 2016; 2017).

Studies of radiation-related CVD are judged, at this time, to not to be sufficient or consistent to definitely conclude that low to moderate doses of radiation are associated with CVD (NCRP, 2017a). Thus, no estimate of potential adverse effects to the cardiovascular or cerebrovascular systems is provided in this Report. It follows that CVD is not currently included as a component of radiation detriment for purposes of radiation protection at the low doses typically associated with occupational and public exposure.

While there are a number of hypotheses, at present there is no clear understanding of biological mechanism for CVDs at low doses of radiation. For some disorders (*e.g.,* hypertension) there is no clear understanding of the target cells or tissue (e.g., it is unknown for whole-body exposure whether exposure of the kidneys, the heart, or the vasculature is more important). Without a convincing mechanistic explanation for the existing (and less than persuasive) epidemiologic evidence, a cause-and-effect interpretation of the reported statistical

associations cannot be reliably inferred (Little *et al.*, 2008). Thus application of a linear dose-response model at low doses, that assumes a stochastic effect, is not justified at this time.

Atomic-bomb survivor data do not demonstrate convincing evidence for CVD risk at absorbed doses in cardiovascular tissues <0.5 Gy (Ozasa *et al.*, 2017). A recent publication is internally inconsistent and not easily interpretable (Takahashi *et al.*, 2017): heart diseases known to be caused by factors other than radiation, such as rheumatic heart disease are significantly increased, whereas those known to be caused at high radiation-therapy doses, such as coronary heart disease, are not increased. There are also inconsistencies between this mortality data from the Life Span Study (LSS) and the morbidity data from the smaller Adult Health Study (AHS) (*e.g.*, in ischemic heart disease) (Ozasa *et al.*, 2017).

Among the atomic-bomb survivors, radiation exposure was associated with some cardiovascular diseases that are often associated with hypertension, and dose response appeared to be primarily nonlinear among those who were exposed at younger ages. These effects are thought to possibly reflect the nature of whole-body irradiation. But some findings remain inconsistent, perhaps because of possible misclassification in death certificate diagnoses in the LSS as well as selected information from the AHS which was limited to participants, focused on specific outcomes, and gathered in selected periods of follow-up. Therefore, a comprehensive and balanced interpretation of the results from both the LSS (mortality) and the AHS (morbidity) groups is necessary (Ozasa *et al.*, 2016; 2017).

Studies of TB patients receiving repeated chest fluoroscopies to monitor lung collapse (pneumothorax therapy) in Massachusetts and Canada have provided consistent and convincing evidence for a linear dose response for radiation-related breast cancer (Boice *et al.*, 1991; Miller *et al.*, 1989). Studies of CVD have not. These studies, overall, provide no convincing evidence that low-dose fractionated exposures accumulating to a moderate to high dose are associated with heart or circulatory diseases either in Canadian (Zablotska, 2014) or Massachusetts (Davis, 1989; Little, 2016) cohorts.

A recent combined study of the tuberculosis cohorts reported a negative dose response for all circulatory disease and a significantly negative dose response for ischemic heart disease over the full range of estimated doses to the heart (up to 4 Gy). In contrast, a subgroup of patients with doses below 0.5 Gy showed a significant dose response for all circulatory diseases and ischemic heart disease (Tran *et al.*, 2017). The subgroup analyses are difficult to interpret, in that contrary to breast cancer in these same series which showed a significant positive dose response over the full dose range, for heart disease and ischemic heart disease low doses (< 0.5 Gy) showed a significant positive dose response whereas high doses (up to 4 Gy) showed a significantly negative dose response. These peculiarities might point to novel biases in the TB heart studies such as the uncertainties in using average lung dose as a surrogate for heart dose, the inability to account or identify patients given few fluoroscopy examinations because of a failed pneumothorax therapy that would entail few but lengthy fluoroscopic examinations (and much higher heart doses), or the possibility that *cor pulmonale* (enlargement of the right side of the heart due to pulmonary hypertension caused by tuberculosis) affected heart and circulatory disease. While the studies of heart and circulatory disease are important, at this time they provide little evidence for an association between radiation and heart disease and much less evidence for a dose response that might be relevant in the low-dose domain (NCRP, 2017a).

NCRP (2017a) reviewed the recent epidemiologic studies as to whether there was sufficient evidence to include CVDs as plausible outcomes following low dose exposures typically associated with occupational and public exposure. The study of atomic-bomb survivors had a complex pattern of types of cardiovascular disease associated with radiation exposure and did not have clear evidence of excess risk below about half a gray. The occupational data represent assessments at low doses and low dose rates. The majority of those studies were positive, but most had inconsistencies, apparent biases of screening, surveillance, or ascertainment, or other particular problems in interpretation. In addition, most of them did not have information on smoking or other CVD risk factors, so possible confounding could not be ruled out. The two studies with environmental exposures had low statistical power to detect a radiation effect had there been one. So at this time, the data on CVDs at low doses and low dose

rates do not present clear evidence regarding LNT or applicability to radiation protection, and additional evidence is needed, particularly from studies involving larger cohorts.

There is not yet sufficient evidence in human studies or animal experiments that low to moderate doses of radiation cause cardiovascular disease (CVD). At this time, no recommendation is appropriate. Nevertheless, continued attention to the results of research related to CVD at low and moderate doses is warranted.

B.8 Central Nervous System Effects

Most cell types in the central nervous system (CNS) are considered to be resistant to the effects of low and medium doses of radiation. Noncancer CNS damage can include necrosis, loss of myelin, white matter necrosis, cortical atrophy and significantly reduced cognitive function. All of these changes have been observed after extremely high doses of radiation (usually after aggressive radiation therapy or accidents). There are a few scattered reports of changes in cognitive function at lower doses from low-LET radiation, primarily in children treated for *tinea capitis* or hemangiomas as well as occasional reports related to multiple sclerosis and schizophrenia. These reports are often based upon vague criteria and poor dosimetry. The incidence of dementia was examined among atomic-bomb survivors >12 y old at exposure within the Adult Health Study cohort (Yamada *et al.*, 2009), no association with radiation exposure was found. Results are not available for those exposed as young children. A study of Mound workers (Boice, 2017b) with intakes of polonium and plutonium received direct exposure to brain tissue from high-LET alpha particles and a suggested radiation-related increase was observed for combined dementia, Alzheimer's disease, Parkinson's disease and motor neuron disease (*e.g.*, ALS).

Recent experiments have shown a number of early and delayed deleterious effects in animals exposed to high-atomic number, high-energy particles and at radiation levels lower than previously suspected as being damaging. Evidence for the deleterious effects of low-dose charged-particle radiation has been reviewed in Cucinotta *et al.*, (2014), Nelson (2009), Report

No. 153 (NCRP, 2006b), and NCRP Commentary No. 23 (NCRP, 2014a). Anatomical connectivity and neurophysiological dynamics involving networks of interacting neuronal systems throughout the brain yield the properties that we associate with cognition, perception, affect, and consciousness. Ultimately, it is impairment in these higher functions of the CNS that is of concern with respect to galactic cosmic radiation effects on human performance, health, and disease during and after extended deep space missions (NASA, 2009; NCRP (2014a). A NASA radiation-exposure standard based on lifetime fatal cancers is in place (NASA, 2014). Additional considerations for lifetime fatal risks from circulatory and CNS diseases are contained in dose limits for these tissues.

In utero exposure and CNS effects on the embryo and fetus are discussed in Section B.4.5.2.

Radiation effects on the central nervous system (CNS) are not considered a major factor in evaluation of radiation protection. The possible exception is the exposure of crew members in NASA space activities to high atomic number, high-energy particles during interplanetary missions.

B.9 Thyroid (Noncancer Effects)

Noncancer effects on the thyroid refers to tissue reactions on thyroid function and possible thyroiditis. There are many large sources of human data on thyroid function and autoimmune issues, including atomic-bomb survivors, fallout, external radiation therapy, and radionuclide treatment for thyroid conditions. At high absorbed doses the main concern is reduced production of thyroid hormone (hypothyroidism) and at lower thyroid doses the issue of thyroiditis is of greater concern.

Studies of atomic-bomb survivors at absorbed doses <1 Gy do not show a definite increase in hypothyroidism. The largest study of the Chernobyl population was performed by the Sasakawa Foundation and reported by Ito *et al.* (1995) and Yamashita and Shabita (1996) did not find any increase in thyroid antibodies, hypothyroidism or hyperthyroidism that could be related

to ionizing radiation. In an analysis of I^{131} releases from the Hanford, Washington fuel processing facilities, Davis et.al. (2002) found a negative dose-response curve for both hypothyroidism and autoimmune thyroiditis.

In summary, thyroid doses above a few gray can induce subclinical hypothyroidism and thyroid doses >20 Gy can cause clinical hypothyroidism. The incidence increases with time and is quite variable among individuals. Autoimmune thyroiditis and hypothyroidism, however, are unlikely at the low doses associated with occupational or public exposure.

B.10 Lens of the Eye (Cataract)

The major radiation damage response of the clear crystalline lens of the eye is the loss of lens clarity resulting in clouding or opacification known as a cataract that in an extreme case (usually after high absorbed doses in the lens >5 Gy in a single acute exposure) can cause significant visual impairment. However, exposure to low doses of radiation can lead to minor opacifications many years later. The impact of cataract outcomes on vision following either high or low doses are highly dependent on the type of radiation, the time over which the exposure was delivered, the genetic susceptibilities of the individual exposed, and also the actual location of the opacity within the lens that may form relative to the visual axis of the individual.

There is still uncertainty surrounding the relationship between low dose and radiation lens opacity development (ICRP, 2012). Several reviews of recent radiation cataractogenesis epidemiologic studies have been published [see NCRP (2016a) for detailed review of this literature]. Overall, the data were consistent with an association between exposure to ionizing radiation at >1 Gy absorbed dose to the lens of the eye and initiation or development of post-subcapsular cataracts, mixed, and cortical cataracts (NCRP, 2016a).

The apparent simplicity of the association between ionizing radiation exposures and the formation of lenticular opacities belies the complex underlying biological factors and mechanisms. The epidemiologic evidence to date indicates a threshold model, and NCRP (2016a) determined that this model continue to be used for radiation protection purposes. The

epidemiologic evidence has large associated uncertainties, but currently indicates a threshold absorbed dose in the lens of 1 to 2 Gy for vision-impairing cataracts. The specific value of the threshold for detectable opacities or non-vision-impairing cataracts is less clear, NCRP (2016a) concluded that it is not possible to make a specific quantitative estimate of lens effect thresholds at this time.

NCRP (2016a) determined that it is prudent to reduce the current annual lens of the eye recommendation for occupational exposure from an equivalent dose of 150 mSv (NCRP, 1993a) to an absorbed dose of 50 mGy. This recommendation would not result in an individual accumulating an annual absorbed dose to the lens of the eye in excess of the likely range of threshold values. Although no new numerical value is recommended for members of the public for the lens of the eye, as NCRP judges that the existing annual value is adequately protective (NCRP, 1993a), it is recommended that the recommendation also be expressed as absorbed dose. Therefore, the annual recommendation for members of the public for the lens of the eye is now 15 mGy absorbed dose [previously expressed as 15 mSv equivalent dose to the lens of the eye (NCRP, 1993a)].

A threshold model for formation of lens opacities continues to be used for radiation protection purposes. The recommendation for annual absorbed dose to the lens of the eye for occupational exposure is now to not exceed 50 mGy, and for public exposure is now to not exceed 15 mGy.

Evaluation and additional research is needed to better evaluate radiation-induced cataracts: comprehensive evaluation of the overall effects of ionizing radiation on the eye, dosimetry methodology and dose-sparing optimization techniques, additional high-quality epidemiologic studies, and a basic understanding of the mechanisms of cataract development (NCRP, 2016a).

B.11 Skin Effects

There are both stochastic effects and tissue reactions of ionizing radiation on the skin. The biologic basis for dose restriction for the skin was reviewed by ICRP (1991b; 2012).

The stochastic effects are induction of non-melanoma skin cancers (most commonly basal cell and less commonly squamous cell types). There are some differences with basal cell cancers occurring at lower dose levels and squamous cell cancers being more common after higher doses associated with radiation therapy. There is no significant evidence that melanoma is induced by ionizing radiation.

Regardless of the variable estimated risks among the epidemiologic studies, the low fatality and morbidity rate for non-melanoma skin cancers means that for radiation protection purposes, the restriction placed on effective dose provides sufficient protection against stochastic skin effects.

The tissue reactions from ionizing radiation on the skin occur at absorbed doses >2 Gy and include a number of different effects due to the various layers of skin which have different cell types, functions and radiosensitivities (ICRP, 2013; NCRP, 2010b).

The recommendation to control dose to an individual from exposure of the skin (including the extremities) is designed to avoid clinically important adverse tissue reactions.

Special radiation protection considerations arise from the issue of tiny radioactive "hot particles" which range from a few microns to a millimeter or two and which can produce very high localized doses to the skin and cause a small acute ulceration. The pathology of these small ulcers is different from larger field irradiation and does not cause loss of reproduction of the basal cells. Another special circumstance is irradiation with beta particles which may or may not affect the basal cells and typically do not cause long-term reduction in the underlying vasculature. Both of these special cases may cause significant variations in effects for different parts of the body depending upon the thickness of the epidermis (*e.g.*, ~40 um for the eyelid and ~450 um for the finger).

B.12 Psychosocial Effects

Psychosocial impacts are recognized as an important effect that may follow radiation exposure and these have been well documented as perhaps the major health effect after the Chernobyl and Fukushima accidents (Bromet, 2012; Bromet *et al.*, 2011; González *et al.*, 2013; Goto *et al.*, 2017). These effects are rarely or often poorly correlated with dose. They can occur with any unwanted, involuntary, poorly documented or even suspected exposure. The effects include, but are not limited to anxiety, fear, social stigma, insomnia, post-traumatic stress response and medically unexplained physical symptoms.

These effects are heightened by loss of faith in authorities and receiving contradictory information from authorities, media and scientists. These affects can be persistent and disabling in certain subgroups. Subgroups that are at increased risk of such effects include pregnant females, mothers of children, rescue and cleanup workers, evacuees and those with prior mental health issues.

Psychosocial effects can be lessened by early communication of accurate and understandable information (Covello, 1993; 2011; EPA, 2007; NCRP 2011b).

The subject of radiation consistently elicits some of the strongest levels of fear and anxiety. In this high-concern, low-trust setting, special tools and techniques can be very effective in getting helpful information across, which will help mitigate psychosocial effects (Hyer and Covello, 2007; 2017). Notably, trust is paramount and can be gained with sincere expressions of empathy, compassion, openness, and honesty. Decades of research on how people respond to concerning information can be organized into simple concepts to include: perception trumping reality, importance of three discreet pieces of information, influence of mental noise, reduced mental capacity, primacy and recency factors, dominance of negative messages, and an altered perception of risk.

Anticipation, preparation, and practice are critical success factors. There are seven cardinal rules for effectively communicating information in the high-concern, low-trust

environment (Covello and Allen, 1988). These cardinal rules are the foundation for effective risk communication.

1. *People have the right to have a voice and participate in decisions that affect their lives*.
2. *Plan and tailor risk communication strategies.* Different goals, audiences, and communication channels require different risk communication strategies.
3. *Listen to your audience.*
    a. People's perceptions of risk are influenced by factors other than numerical data.
    b. People are usually more concerned about psychological factors, such as trust, credibility, control, voluntariness, dread, familiarity, uncertainty, ethics, responsiveness, fairness, caring, and compassion, than about the technical details of a risk. To identify public concerns about risk, organizations must be willing to listen carefully to and understand the audience.
4. *Be honest and transparent.* Honesty and transparency are critical for establishing trust and credibility. Trust and credibility are among the most valuable assets of a risk communicator. Once lost, it is extremely difficult to regain.
5. *Coordinate and collaborate with credible sources of information and trusted voices.* Communications about risks are enhanced when accompanied by validation by sources of information perceived to be credible, neutral, and independent. Few things hurt credibility more than conflicts and disagreements among information sources.
6. *Plan for media influence.* The media plays a major role in transmitting risk information. It is critical to know what messages the media are delivering and how to deliver risk messages effectively through the media.
7. *Speak clearly and with compassion.* Technical language and jargon are major barriers to effective risk communication. Abstract and unfeeling language often offends and confuses people. Acknowledging emotions, such as fear, anger, and helplessness, is typically far more effective.

Communicators should consult current guidelines and best practices published by national and international health authorities (CDC, 2011; WHO, 2007).

B.13 Summary on Health Effects on Humans

- NCRP (2017a) review of the recent literature regarding stochastic effects of radiogenic cancer and heritable risks does not indicate a need to deviate from nominal values published by ICRP (2007a).
- Cancer risks remain the predominant issue following low-dose exposure and at very low doses it is prudent to continue using the LNT hypothesis for radiation protection purposes (NCRP, 2017a). NCRP realizes that other relationships are scientifically plausible but the LNT model is preferred for radiation protection purposes.
- The likelihood of a significant genetically-susceptible population in the public or occupational setting is low and need not be considered in radiation protection limits. However, this can be of importance in individual high-dose situations (*e.g.*, radiation therapy).
- There is a need for caution regarding CNS effects in crew members in NASA space activities exposed to high atomic number, high-energy particles during interplanetary missions (NCRP, 2016a).
- NCRP (2016a) review of the data on cataracts led to recommending a lower value and change in the dose quantity for the lens of the eye for occupational exposure, from 150 mSv equivalent dose to 50 mGy absorbed dose and a change in the dose quantity from 15 mSv equivalent dose to an absorbed dose of 15 mGy for members of the public.
- There is not yet sufficient evidence in human studies or animal experiments that low to moderate doses of radiation cause cardiovascular disease (NCRP, 2017a). Thus CVD should not be considered in radiation detriment calculations at this time.
- Review of the data on tissue reactions regarding the thyroid and skin do not indicate a need for change in the relevant recommendations to control dose to an individual.
- Psychosocial issues can often be the major health impact of low-dose radiation exposure, are not correlated with dose, and should be recognized and addressed in radiation protection programs.

B.14 Radiological Impacts on Nonhuman Biota

For radiation protection of humans, NCRP (1993a) states the specific objectives are to:

- prevent the occurrence of clinically significant radiation-induced tissue reactions (deterministic effects) by adhering to doses that are below the apparent threshold levels, and
- limit the risk of stochastic effects (primarily cancer) to a reasonable level in relation to societal needs, values, benefit gained and economic factors.

For nonhuman biota, there is still considerable debate as to what constitutes acceptable risk, and how to balance benefit and harm.

Where limitations of radiation exposure of nonhuman biota have been developed, it is argued that they be protective, but not overly conservative. The evolving consensus has been to target impacts that are likely to affect population maintenance (ICRP, 2007a; UNSCEAR, 2011). Endpoints generally viewed as significant include those which substantively affect reproductive success: mortality, fertility, fecundity, and genetic variation (Andersson *et al.*, 2008). It has also been asserted that minor radiation effects to the most exposed individual in a population are not likely to produce measureable population level disturbance (UNSCEAR, 2011). As a consequence, reference organism approaches are used to evaluate the radiation dose (or dose rate) to an individual of the species and infer impacts to the larger population of the species. Alternative approaches to assessment (such as the ecosystem approach) have yet to be developed such that they can be widely applied (Strand *et al.*, 2017).

There are various arguments against using stochastic, rather than population maintenance impacts, endpoints for nonhuman biota. For example, it has been proposed that animals in the wild do not develop cancer, or if they do, it does not affect their reproductive fitness (IAEA, 1992). Recent work directly challenges both these assertions. Animals in the wild definitely can develop cancer when exposed to carcinogenic substances (Browning *et al.*, 2015; Harrison *et al.*,

1997; Martineau *et al.*, 2002; McAloose and Newton, 2009). As to the impact on reproductive fitness, Vittecoq *et al.* (2013) argue that oncogenic phenomena can have significant ecological consequences and should be examined at greater depth.

For nonhuman biota, the consensus is to establish protective guidelines that focus on population maintenance. This goal is met through evaluation of the radiological impact on survival of species rather than protection of individual members of the species.

Past efforts on environmental radiation protection assumed that humans were the most radiosensitive species, and that by protecting them all other populations would be protected, although not necessarily at the level of the individual (ICRP, 1977). For more than 20 y it has been recognized that while humans are radiosensitive, other organisms are as sensitive, or very nearly so (*e.g.*, Rose, 1991).

The range for ionizing radiation-induced effects on nonhuman biota, as determined in field, controlled and laboratory studies and reported in the peer-reviewed literature, spans the range of 10^{-4} to hundreds of milligray per day (Figure B.1) (Mousseau and Møller, 2013; Sazykina and Kryshev, 2006). The methodologies for assessing, and the lower limits for observing impacts on nonhuman biota from ionizing radiation exposure are not settled and the multiple assessments have led to substantially different conclusions (Strand *et al.*, 2017). The most common approach for assessment is to evaluate radiation doses to individual organisms, and compare such doses to data provided in the literature. For example, UNSCEAR (2011) stated that 100 μGy h^{-1} (2.4 mGy d^{-1}) to the highest exposed individual in a terrestrial population was unlikely to produce significant effects. For aquatic populations, UNSCEAR (2011) specified 400 μGy h^{-1} (10 mGy d^{-1}). However, Garnier-LaPlace (2013) through statistical analysis determined that populations exposed in controlled or laboratory settings may be substantially more resistant (up to 8 fold) than those exposed in the wild.

Unlike plants and animals, humans are able, under most circumstances, to intentionally limit their radiation exposure by controlling pathways or duration of exposure. The accident at Fukushima-Daiichi has been evaluated by several international organizations, including the

4172 World Health Organization (WHO), the United Nations Scientific Committee on the Effects of
4173 Atomic Radiation (UNSCEAR) and International Atomic Energy Agency (IAEA). WHO (2012)
4174 concluded that the radiation doses received by the Japanese population following the accident,
4175 while substantial, are unlikely to result in measurable excesses of cancer in the human
4176 population. However, in contrast, a recent publication has matched field observations of impacts
4177 on birds near Fukushima using a rigorous assessment of dose (Garnier-Laplace *et al.*, 2015).
4178 This assessment has concluded that dose rates and doses experienced by numerous avian species
4179 at Fukushima were within the range where adverse population effects are expected to occur.
4180 Studies on red pine in areas impacted by Fukushima have also shown evidence of population
4181 effects (Yoschenko *et al.*, 2016). Because pathways of exposure and dose, even within the same
4182 environment, differ markedly amongst organisms, steps taken to limit human exposures may not
4183 restrict doses of nonhuman biota to levels that would prevent adverse population effects,
4184 particularly in the wild (Higley, 20XX).

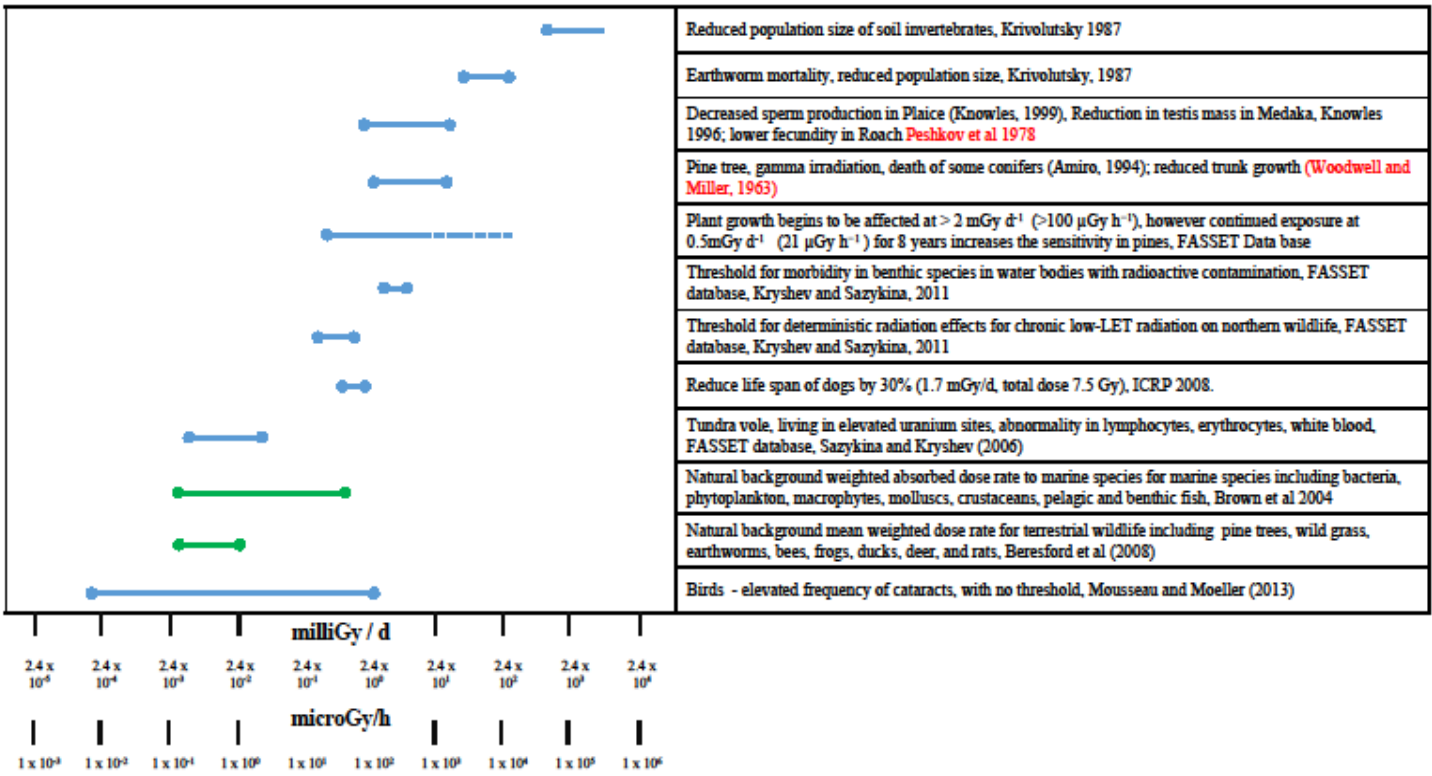


Fig. B.1. Observed ranges for ionizing radiation-induced effects on nonhuman biota, as determined in field, controlled and laboratory studies and reported in the peer-reviewed literature (Mousseau and Møller, 2013; Sazykina and Kryshev, 2006).

NOTES … In Fig. B.1:

- **milliGy / d: will be changed to mGy d^{-1}**
- **microGy / h: will be changed to µGy h^{-1}**
- **full citations for the following references given on the right-hand side are still needed**
  - **Knowles (1996)**
  - **Kryshev and Sazykina (2011) … see notes at reference list**
  - **Also, FASSET is (Framework for Assessment of Environmental Impact)**

Radiation protection of nonhuman biota, as a concept distinct from protection of humans has been vigorously debated for more than 20 y (Higley, 20XX). ICRP, UNSCEAR, IAEA and many governments have reviewed the radiobiological data, recommended screening criteria, and written legislation or guidance to address this concern. Consequently, systems for radiation protection of nonhuman biota have been widely developed and implemented both within and outside the United States. A comparison of recent recommendations is shown in Table B.1.

DOE, in the absence of guidance from advisory bodies, and after considerable stakeholder consultation, issued a technical standard (DOE, 2002) which explicitly addressed radiation protection of the environment. In addition to setting radiation protection criteria, the DOE technical guidance included a graded approach to screening sites for impact. DOE also commissioned the creation of computer software to streamline the assessments (RESRAD, 2016); this system has been used at DOE facilities for more than a decade.

ICRP (2008) recommended a framework for consideration of environmental radiation protection. ICRP published its derived consideration reference levels (DCRLs) (ICRP, 2007a), dose conversion factors (ICRP, 2008), and guidance for application of the ICRP methodology (ICRP, 2014b). Within the European Union, both guidance and computational tools have been broadly applied (Andersson *et al.*, 2009; Brown *et al.*, 2008). None of these systems of guidance have proven particularly burdensome, and they have provided regulators with concrete, defensible, and scientifically-based criteria from which to conduct assessments of radiological impact.

Scientific data provide an indication of the levels of absorbed dose rate likely to cause measurable impacts in nonhuman biota. Bradshaw *et al.* (2014) have provided a qualitative comparison of current radiation guidance and dose rates resulting from anthropogenic and natural sources in comparison with measured, predicted and observed effects (Figure B.2). Although not shown on Figure B.2, current DOE recommendations would align with the upper level of ICRP recommendations.

Table B.1 --- Published benchmarks for chronic exposure situations for nonhuman biota[a]

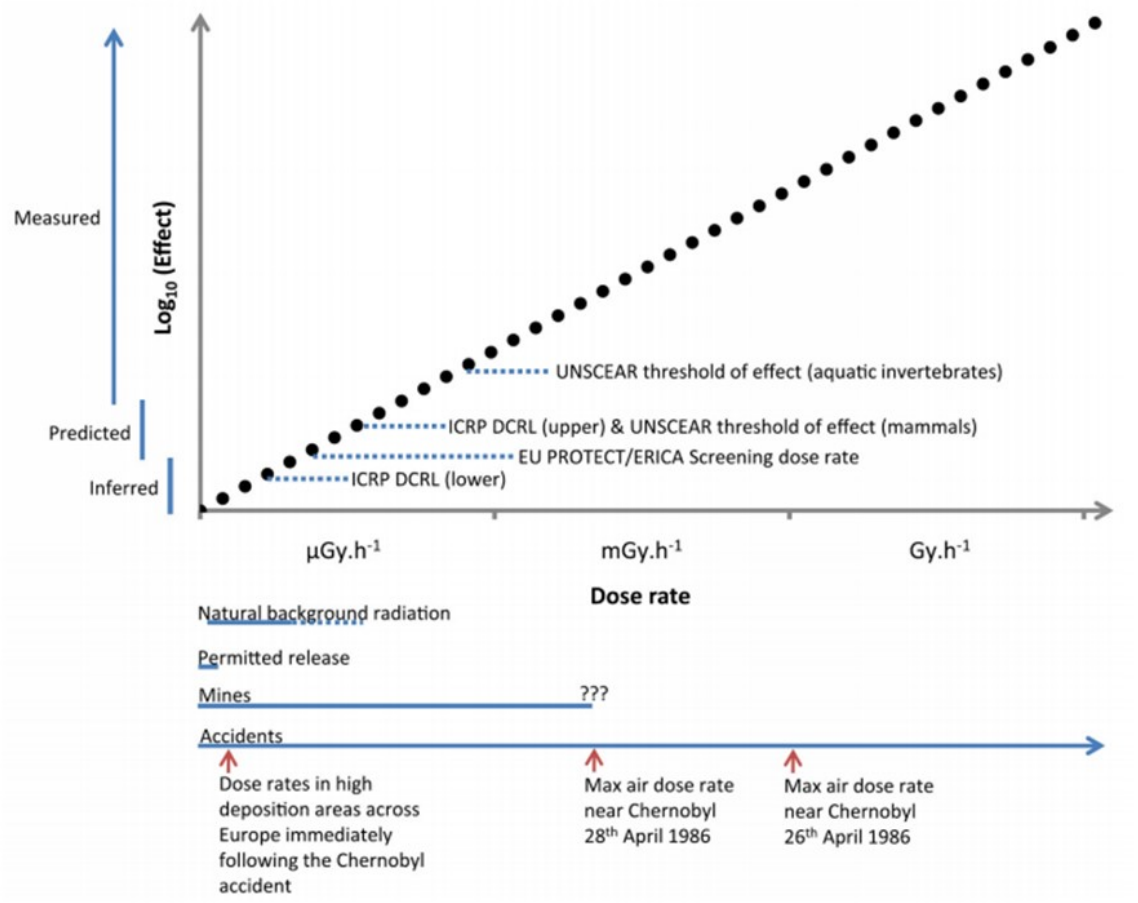
Organization	Dose Rate (mGy d^{-1})	Stated Basis of Benchmark	Reference
ICRP	10-100	A dose rate band within which there is likely to be some chance of the occurrence of deleterious effects on terrestrial annelids and seaweed, and due to the absence of information adopted for the reference bee and crab.	ICRP (2008)
U.K. Environment Agency	24	Dose-rate [threshold] below which it is unlikely that there will be any significant effects from chronic exposure of populations of organisms in the deep ocean.	R&D 128 (2001)
DOE	10	Guidance[Threshold] for terrestrial plants and aquatic animals; presumes no measurable adverse effects to populations exposed below this dose rate.	DOE (2002)
NCRP	10	Upper limit on chronic dose rate to maximally exposed individual to protect population of aquatic organisms.	NCRP (1991)
ICRP	1-10	A dose rate band within which there is likely to be some chance of the occurrence of deleterious effects on the reference trout, and flatfish, and due to the absence of information adopted for the reference wild grass and frog.	ICRP (2008)
U.K. Environment Agency	10	Dose rate [threshold] below which it is unlikely that there will be any significant effects from chronic exposure of terrestrial plant populations or populations of freshwater and coastal organisms.	R&D 128 (2001)
UNSCEAR	2	Lowest reported value for chronic ecosystem level effects.	UNSCEAR (2011)
DOE	1	[Threshold] Guidance for terrestrial animals; presumes no measurable adverse effects to populations exposed below this dose rate.	DOE (2002)
U.K. Environment Agency	1	Dose rate [threshold] below which it is unlikely that there will be any significant effects from chronic exposure of terrestrial animal populations.	R&D 128 (2001)
ERICA-PROTECT	0.2	Proposed screening [(threshold)] level for all species set at a predicted no effects dose rate presumed to protect 95 % of all species and 85 % of vertebrate species. Includes a safety factor of 5.	Andersson *et al.* (2009)
ICRP	0.1-1	A dose rate band within which there is considered a very low probability of deleterious effects on the reference deer and rat, and due to the absence of information adopted for the reference duck and pine tree.	ICRP (2008)
U.K. Environment Agency	0.1	Screening level.	R&D 128 (2001)
ERICA-PROTECT	0.05	Vertebrate screening level presumed to protect 95 % of all vertebrate species.	Andersson *et al.* (2009)

[a] Dose rates as published are in a variety of units. Units have been standardized and reported to one significant figure for clarity.

4230

4231

4232



4233

4234

4235 **Fig. B.2.** A qualitative comparison of radiation guidance and doses from anthropogenic
4236 and natural sources in comparison with measured, predicted and inferred effects (Bradshaw *et*
4237 *al.*, 2014).

Glossary

absorbed dose: (see Section A.2.2).

absorbed dose rate: (see Section A.2.3).

achievable dose: A selected level of a DRL quantity which serves as a goal for optimization efforts for diagnostic and interventional medical procedures. This level is achievable by standard techniques and technologies in widespread use, while maintaining clinical image quality adequate for the medical purpose. The achievable dose is typically set at the median value of the distribution of the relevant DRL quantity.

activity: The number of spontaneous nuclear transformations occurring in an amount of radionuclide in a particular energy state in a given time interval. The unit for activity in the SI system is reciprocal second (s^{-1}) (*i.e.*, one nuclear transformation per second), with the special name becquerel (Bq).

advance control program: For a prevailing exposure situation in which the source is deliberately and intentionally introduced, an advance control program is the set of radiation protection programs intended to control exposure of an individual that is put in place by the responsible organization before the introduction of the source.

ALARA principle: A principle of radiation protection philosophy that requires that exposures to ionizing radiation be kept as low as reasonably achievable (ALARA), economic and societal factors being taken into account. The ALARA principle is satisfied when the expenditure of further resources would be unwarranted by the reduction in exposure that would be achieved.

alpha particle: A positively charged particle ejected spontaneously from the nuclei of some radioactive elements. It is identical to a helium nucleus with a mass number of 4 and an electric charge of +2. Alpha particles from radioactive decay (<10 MeV) have low penetrating power and a short range (*e.g.*, a few centimeters in air).

anthropocentrism: Considering human beings as the most significant entity of the universe; interpreting or regarding the world in terms of human values and experiences.

anthropogenic: Caused or produced by humans.

as low as reasonably achievable (ALARA): (see *ALARA principle*).

atomic number: The number of positively charged protons in the nucleus of an atom.

background radiation: (see *ubiquitous background radiation*).

becquerel (Bq**):** The special name for the unit of activity in the SI system [*i.e.*, one nuclear transformation per second (s^{-1})].

beta particle: An energetic electron emitted spontaneously from nuclei in the decay of many radionuclides.

biocentric: Considering all forms of life as having intrinsic value.

biota: (see *nonhuman biota*).

cancer: A general term for over 100 diseases characterized by abnormal cells and altered control of proliferation of malignant cells.

carcinogenesis: Induction of cancer (*e.g.*, by radiation or other agent).

charged particle: An atomic or subatomic quantity of matter (*e.g.*, electron, proton, alpha particle, ionized atom) having a net positive or negative electrical charge of one or more elementary units of charge.

cleanup: Decontamination and removal of radioactive or other hazardous materials from a contaminated site. Sometimes used to refer to the more general concept of remediation (see *decommissioning*).

comforters and caregivers: Individuals who are not occupationally involved in providing medical care, and are typically parents, other family members, or close friends of the patient.

collective effective dose: (see Section A.3.7).

committed dose: (see Section A.3.6).

committed equivalent dose: (see Section A.3.6).

committed effective dose: (see Section A.3.6).

computed tomography (CT**):** An imaging procedure that uses multiple x-ray transmission measurements and a computer program to generate tomographic images of the patient.

confidence interval (CI**):** A measure of the extent to which an estimate of dose or other parameter is expected to lie within a specified interval (*e.g.*, a 90 % confidence interval of a dose estimate means that, based on available information, the probability is 0.9 that the true but unknown dose lies within the specified interval).

contamination (radioactive): Radioactive material that is present in undesired locations such as on the surface of or inside structures, areas, objects or individuals.

control of dose to an individual: One of the three basic NCRP principles of radiation protection [*i.e.*, justification, the ALARA principle (optimization of protection), and control of dose to an individual]. Control of dose to an individual refers to specific numeric values of a dose quantity recommended by NCRP.

critical group: Subgroup of an exposed or potentially exposed population that receives or is expected to receive the highest dose due to exposure.

decommissioning: The process of closing down a facility followed by reducing the residual quantities of radioactive material to a level that permits the release of the property for either limited (restricted) or unrestricted use.

deterministic effect: (see *tissue reaction*).

detriment: (see *radiation detriment*).

diagnostic reference level (DRL): A selected level (usually at the 75th percentile of the distribution of the relevant DRL quantity) serving as an investigational level for diagnostic and interventional medical procedures. When assessed values of the DRL quantity exceed the DRL, the reasons for the higher values should be investigated.

disposal: Placement of waste in a facility designed to isolate waste from the accessible environment without an intention to retrieve the waste, irrespective of whether such isolation permits recovery of waste.

dose of record: The estimated effective dose or other monitoring quantity for a worker for comparison to or compliance with dose limits established by regulatory bodies.

dose (radiation dose): A general term used when the context is not specific to a particular dose quantity. When the context is specific, the name or symbol for the quantity is used (*e.g.*, mean absorbed dose, effective dose).

dose limit: In this Report, a limit on dose that is applied by the responsible organization to control dose to an individual for a prevailing exposure situation in which the source is stable, characterized, and subject to an advance control program by the responsible organization.

dose rate (radiation dose rate): Dose delivered per unit time. Can refer to any dose quantity (*e.g.*, absorbed dose).

dosimeter: Dose measuring device (see *monitoring*).

dosimetry: The science or technique of determining radiation dose.

ecocentric: A philosophy or perspective that places intrinsic value on all living organisms and their natural environment, regardless of their perceived usefulness or importance to human beings.

effective dose (E): (see Section A.3.5).

electron: Subatomic charged particle. Negatively charged electrons are parts of stable atoms. Both negatively and positively charged electrons (positrons) may be expelled from the radioactive atom when it disintegrates (see *beta particle*).

emergency worker: An individual who would be called upon to assist with the response to a radiological or nuclear incident (NCRP, 2017b).

energy imparted: (see Section A.2.1).

equivalent dose (H_T): (see Section A.3.3).

exposure (general): A general term used to express the act of being exposed to ionizing radiation.

exposure (radiation quantity): (see Section A.2.4).

exposure rate: (see Section A.2.5).

external dose: Dose to organs or tissues of an organism due to radiation sources outside the body.

fission (nuclear): A nuclear transformation characterized by the splitting of a nucleus into at least two other nuclei and the release of a relatively large amount of energy.

fluoroscopy: A technique for generating x-ray images and presenting them simultaneously and continuously as visible images.

galactic cosmic radiation: The charged-particle radiation outside the magnetosphere comprised of 2 % electrons and positrons, and 98 % nuclei, the latter component consisting (by fluence) of 87 % protons, 12 % helium ions, and 1 % high atomic number, high-energy particles.

gamma rays: Electromagnetic radiation emitted by the atomic nucleus. Gamma rays have high penetrating ability compared with alpha and beta particles.

graded approach: Application and implementation of the system of radiation protection proportionate to the characteristics and complexity of the prevailing exposure situation and the magnitude and likelihood of the exposures.

gray (Gy**):** The special name for the SI unit J kg^{-1} (*i.e.*, energy imparted per unit mass of a material). 1 Gy = 1 J kg^{-1}.

heritable (genetic) effects: Effects expressed in offspring due to alteration of reproductive cells in the parent(s).

image quality: The overall clarity of a radiographic image. Image sharpness, image contrast, and image noise are three common measures of image quality.

internal dose: Dose to organs or tissues of an organism due to intakes of radionuclides (*e.g.*, by ingestion, inhalation, or dermal absorption).

internal exposure: Exposure to radiation originating from a source within the body (*e.g.*, as a result of intakes of radionuclides into the body by inhalation or ingestion).

International System of Quantities and Units [Systeme Internationale (SI**)]:** The International System of Quantities and Units as defined by the General Conference of Weights and Measures in 1960 and periodically revised since. These units are generally based on the meter/kilogram/second units, with special quantities for radiation including the becquerel, gray and sievert.

ionizing radiation: Particulate or electromagnetic radiation that is capable of removing electrons from a neutral atom or molecule either directly or indirectly, resulting in an excess charge.

irradiation: The process of exposure to radiation.

mean: Sum of the measured values divided by the number of measurements. The mean value is also often called the (arithmetic) average value. The mean of a distribution is the weighted average of the possi-

ble values of the random variable.

mean absorbed dose: The mean absorbed dose in an organ or tissue, obtained by integrating or averaging absorbed doses at points in the organ or tissue.

median: Of a set of *n* values, the median is the value that is as frequently exceeded (by other values in the set) as not. The median value of a distribution is the 50th percentile.

medical facility: A hospital, clinic or other facility that provides medical services.

member of the public: An individual who is not already considered occupationally exposed by a radiation source or practice under consideration. When being irradiated as apart of medical care, patients are a separate category.

model: Mathematical or physical representation of an environmental or biological system, sometimes including specific numerical values for parameters of the system.

monitor: To determine the level of ionizing radiation or radioactive contamination. Also, a device used for this purpose.

monitoring: Periodic or continuous determination of exposure rate or dose rate in an area (area monitoring), or of the exposure received by a person (personal monitoring), or the measurement of contamination levels.

naturally-occurring radioactive material (NORM): Materials found in the natural environment containing inherent concentrations of radionuclides. Examples include materials containing long-lived radioactive isotopes of the elements uranium, thorium and potassium, and of their decay products (*e.g.*, the elements radium and radon) that have always been present in Earth's crust. Technologically-enhanced naturally-occurring radioactive material is NORM whose concentrations of radionuclides are increased by or as a result of past or present human practices.

negligible individual dose: A level of effective dose to an individual per source or practice at which efforts to reduce radiation exposure to the individual may not be warranted. This term was introduced in Report No. 116 (NCRP, 1993a) and its recommended value is 0.01 mSv.

neutron: An uncharged elementary particle having a mass slightly greater than a proton that is usually stable when within the nucleus but is unstable otherwise.

nominal risk coefficient: Refers to risk coefficients derived by averaging sex and age-at-exposure lifetime risk estimates for stochastic effects obtained from studies with adequate dose-response data. By definition, nominal risk coefficients are expressed per sievert (Sv^{-1}) without uncertainty. Nominal risk coefficients are for use in radiation protection and are not actual or real specifications of risk for an individual.

nonhuman biota: Animal and plant life.

nuclide: A species of atom having specied numbers of neutrons and protons in its nucleus.

occupational exposure: Radiation exposure to individuals that are incurred in the workplace as a result of situations that can reasonably be regarded as being the responsibility of management (radiation exposures associated with medical diagnosis or treatment for the individual are excluded).

pathway: Route or mechanism of transport of contaminants in the environment, the means of release of contaminants from a facility, or the means of exposure of humans or other organisms.

photon: Quantum of electromagnetic radiation, having no charge or mass, that exhibits both particle and wave behavior, such as a gamma or x ray.

positron: An antiparticle equal in mass to an electron and having an equal but positive charge.

positron emission tomography: An imaging technique using radionuclides that emit positrons (positively charged electrons), whose annihilation photons are imaged in coincidence to form tomographic views of the body.

practicable: Likely to meet a need, but not yet tested in practice or proved in service or use (implies an expectation).

practical: Proven effective in use (implies an actual established usefulness).

precision: Acceptable degree of uncertainty of an estimate with respect to an actual event or outcome (result).

prevailing exposure situation: The prevailing conditions of exposure (*i.e.*, the particular conditions of exposure occurring at the time) from a source of ionizing radiation that is characterized by: the nature of the source; the individuals exposed; the circumstances of exposure; and the ability of those with authority to control the source of radiation and the actions of the persons at risk of exposure.

probability of causation: A term that expresses the probability that a given cancer in an individual has been caused by a previous exposure to radiation. The probability of causation method applies epidemiologic and demographic data to the individual. The calculated probabilities thus pertain to populations rather than individuals and as such are not probabilities in the usual sense, but are properties of the group to which a person belongs.

proton: An elementary nuclear particle with a positive charge equal to the charge of an electron and a mass equal to the nucleus of the ^{1}H atom.

quality assurance: Process of ensuring proper documentation of data, interpretations of data, which are embodied in assumptions, and computer codes.

quality control: The routine performance of tests and tasks and the interpretation of data from the tests of equipment function and the corrective actions taken.

radiation (ionizing): Electromagnetic radiation (x or gamma rays) or particulate radiation (alpha

4436 particles, beta particles, electrons, positrons, protons, neutrons, and heavy charged particles) capable
4437 of producing ions by direct or secondary processes in passage through matter.
4438 **radiation detriment:** Measure of stochastic effects from exposure to ionizing radiation that takes into
4439 account the probability of fatal cancers, probability of severe heritable effects in future generations,
4440 probability of nonfatal cancers weighted by the lethality fraction, and relative years of life lost per
4441 fatal health effect.
4442 **radiation weighting factor (w_R):** (see Section A.3.2).
4443 **radioactive decay:** The spontaneous transformation of one nuclide into a different nuclide or into a
4444 different energy state of the same nuclide. The process results in a decrease, with time, of the number
4445 of original radioactive atoms in a sample. Decay generally involves the emission from the nucleus of
4446 alpha particles, beta particles, or gamma rays.
4447 **radioactive series:** A succession of nuclides, each of which transforms by radioactive decay into the next
4448 until a stable nuclide results. The first member is called the parent and the subsequent members of the
4449 series are called progeny, daughters or decay products.
4450 **radioactive waste:** Solid, liquid or gaseous materials of no value that contain radionuclides, either
4451 anthropogenic or naturally-occurring, and are regulated as hazardous material due to the presence of
4452 radionuclides.
4453 **radiograph:** A film or other record produced by the action of x rays on a sensitized surface.
4454 **radiography:** The production of images on film or other media by the action of x rays transmitted
4455 through a patient.
4456 **radiology:** That branch of healing arts and sciences that deals with the use of images in the diagnosis and
4457 treatment of disease.
4458 **radionuclide:** An unstable (radioactive) nuclide. A nuclide is a species of atom characterized by the
4459 constitution of its nucleus (*i.e.*, the number of protons and neutrons, and the energy content).
4460 **radon (and radon progeny):** Radon is a colorless, odorless, naturally-occurring, and gaseous element
4461 resulting from radioactive decay of isotopes of radium. Radon is also the common name for the
4462 specific radionuclide ^{222}Rn and is used throughout this Report in that context. Radon progeny are
4463 short-lived decay products of ^{222}Rn (*i.e.*, ^{218}Po, ^{214}Pb, ^{214}Bi, and ^{214}Po).
4464 **relative biological effectiveness (RBE):** (see Section A.3.1).
4465 **residual (contamination or dose):** Radioactive material in structures, materials, soils, groundwater, and
4466 other media at a site resulting from activities under the site operator's control, especially radioactive
4467 material remaining at a site after decommissioning and remediation. Residual radioactive material
4468 does not include naturally-occurring radioactive material in its undisturbed state.

roentgen (R**):** The special name for the unit of exposure. Exposure is a specific quantity of ionization (charge) produced by the absorption of x-ray or gamma-ray energy in a specified mass of air under standard conditions. 1 R = 2.58×10^{-4} coulomb per kilogram (C kg^{-1}).

risk coefficient: (see *nominal risk coefficient*).

safety culture: The environment within which individual safety attitudes develop and persist and safety behaviors are promoted.

radiation protection culture: Includes the core values and behaviors resulting from a collective commitment by leaders and individuals within an organization to emphasize radiation protection over competing goals to ensure protection of people and the environment. The overriding principle is to "put safety first."

sievert (Sv**):** The special name (in the SI system) for the unit of equivalent dose and effective dose; 1 Sv = 1 J kg^{-1}.

source (or radiation source): Radiation-producing equipment or an aggregate of radioactive nuclei.

stochastic: Of, pertaining to, or arising from chance; involving probability; random.

stochastic effects: Effects, the probability of which, rather than their severity, is assumed to be a function of dose without a threshold. For example, cancer and heritable effects of radiation are regarded as being stochastic.

the ALARA principle: (see *ALARA principle*).

threshold dose: (see *tissue reaction*).

tissue reaction: Injury in a population of cells, characterized by a threshold dose and an increase in the severity of the reaction as the dose is increased further. Previously referred to as deterministic effect.

tissue weighting factor (w_T**):** A (see Section A.3.4).

ubiquitous background radiation: As used in this Report, includes external exposure from space radiation (solar particles and cosmic rays), external exposure from terrestrial radiation (primarily ^{40}K and the ^{238}U and ^{232}Th decay series), internal exposure from inhalation of radon and thoron and their progeny, and internal exposure from radionuclides in the body.

uncertainty: Lack of sureness or confidence in predictions of models or results of measurements. Uncertainties may be categorized as Type A, which are those due to stochastic variation, or Type B, which are those due to lack of knowledge founded on an incomplete characterization, understanding or measurement of a system.

variability: A heterogeneity, diversity or range that characterizes a measured value or parameter (*e.g.*, differences in body weight in a population). Further study cannot reduce variability but may provide

greater confidence in quantitative characterizations of variability (see *uncertainty*).

x rays: Penetrating electromagnetic radiation having a range of wavelengths (energies) that are similar to those of gamma photons. X rays are usually produced by interaction of the electron field around certain nuclei or by the slowing down of energetic electrons. Once formed, there is no physical difference between x- and gamma-ray photons; however, there is a difference in their origin.

Abbreviations, Acronyms and Symbols

AHS	Adult Health Study
ALARA	as low as reasonably achievable (the ALARA principle)
CI	confidence interval
CNS	central nervous system
CT	computed tomography
CVD	cardiovascular disease
DCRL	derived consideration reference level
DDREF	dose and dose-rate effectiveness factor
DREF	dose-rate effectiveness factor
DRL	diagnostic reference level
E	effective dose
EAR	excess absolute risk
ERR	excess relative risk
FGI	fluoroscopically-guided interventional (procedure)
H_T	equivalent dose
REID	risk of exposure-induced death (for cancer)
SI	Systeme Internationale (International System of Quantities and Units)
LDEF	low-dose effectiveness factor
LET	linear energy transfer
LNT	linear non-threshold
LSS	Life Span Study
NORM	naturally-occurring radioactive material
RBE	relative biological effectiveness
w_R	radiation weighting factor
$\underline{w}_T$	tissue weighting factor

References

Acevedo-Whitehouse, Karina, and Amanda LJ Duffus. (2009). "Effects of environmental change on wildlife health." *Philosophical Transactions of the Royal Society B: Biological Sciences* 364.1534: 3429-3438.

Albitar M, Manshouri T, Shen Y, Liu D, Beran M, Kantarjian HM, Rogers A, Jilani I, Lin CW, Pierce S, Freireich EJ, Estey EH. (2002). Myelodysplastic syndrome is not merely "preleukemia". Blood. Aug 1;100(3):791-8.

Amiro B.D. (1994). Response of Boreal Forest tree Canopy Cover to Chronic Gamma Irradiation. J. Environ. Radioactivity 24: 181-197.

ANDERSSON, P., BEAUGELIN-SEILLER, K., BERESFORD, N., COPPLESTONE, D., DELLA VEDOVA, C., GARNIER-LAPLACE, J., HOWARD, B., HOWE, P., OUGHTON, D. & WELLS, C. 2008. Numerical benchmarks for protecting biota against radiation in the environment: proposed levels, underlying reasoning and recommendations.

ANDERSSON, P., GARNIER-LAPLACE, J., BERESFORD, N. A., COPPLESTONE, D., HOWARD, B. J., HOWE, P., OUGHTON, D. & WHITEHOUSE, P. 2009. Protection of the environment from ionising radiation in a regulatory context (PROTECT): proposed numerical benchmark values. *Journal of Environmental Radioactivity,* 100**,** 1100-1108.

Aristotle (1999). *Nicomachean Ethics*, Terence Irwin (Translator) Hackett Publishing Company, Inc.; 2nd edition (December 1, 1999)

BEAUCHAMP, T.L. and CHILDRESS, J.F. (2013). *Principles of Biomedical Ethics*, 7th ed. (Oxford University Press, New York).

Beck HL, Till JE, Grogan HA, Aanenson JW, Mohler HJ, Mohler SS, Voillequé PG. (2017). Red Bone Marrow and Male Breast Doses for a Cohort of Atomic Veterans. Radiat Res. 187(2):221-228.

Beresford, N.A., C.L. Barnett, D.G. Jones, M.D. Wood, J.D. Appleton, N. Breward, D. Copplestone, Background exposure rates of terrestrial wildlife in England and Wales, Journal of Environmental Radioactivity, Volume 99, Issue 9, September 2008, Pages 1430-1439, ISSN 0265-931X, http://dx.doi.org/10.1016/j.jenvrad.2008.03.003. (//www.sciencedirect.com/science/article/pii/S0265931X08000489)

Bernstein JL, Haile RW, Stovall M, Boice JD Jr, Shore RE, Langholz B, Thomas DC, Bernstein L, Lynch CF, Olsen JH, Malone KE, Mellemkjaer L, Borresen-Dale AL, Rosenstein BS, Teraoka SN, Diep AT, Smith SA, Capanu M, Reiner AS, Liang X, Gatti RA, Concannon P (2010). WECARE Study Collaborative Group. Radiation exposure, the ATM Gene, and contralateral breast cancer in the

women's environmental cancer and radiation epidemiology study. J Natl Cancer Inst. 2010 Apr 7;102(7):475-83.

Bernstein JL, Thomas DC, Shore RE, Robson M, Boice JD Jr, Stovall M, Andersson M, Bernstein L, Malone KE, Reiner AS, Lynch CF, Capanu M, Smith SA, Tellhed L, Teraoka SN, Begg CB, Olsen JH, Mellemkjaer L, Liang X, Diep AT, Borg A, Concannon P, Haile RW (2013). WECARE Study Collaborative Group Contralateral breast cancer after radiotherapy among BRCA1 and BRCA2 mutation carriers: a WECARE study report. Eur J Cancer. 2013 Sep;49(14):2979-85.

Bithell JF, Stewart AM. (1975). Pre-natal irradiation and childhood malignancy: a review of British data from the Oxford Survey. Br J Cancer. 1975 Mar;31(3):271-87.

Boice JD Jr (2014). Implications of radiation dose and exposed populations on radiation protection in the 21st century. Health Phys. 106(2):313-328; 2014

Boice JD Jr. (2015a). Radiation epidemiology and recent paediatric computed tomography studies. Ann ICRP. 2015;44(1 Suppl):236-248.

Boice JD Jr. (2015b). LNT 101. Health Phys News XLIII(9):25-26. Available at http://ncrponline.org/wp-content/themes/ncrp/PDFs/BOICE-HPnews/40_LNT_Sept2015.pdf

Boice JD Jr. (2015c). Human health studies and radiation protection. Health Phys News XLIII(11):19-20. Available at http://ncrponline.org/wp-content/themes/ncrp/PDFs/BOICE-HPnews/42_HumanHlthStudies_11-2015.pdf

Boice JD Jr. (2017a). Space: the final frontier-research relevant to Mars. Health Phys 112(4):392–397.

Boice JD Jr. (2017b). The linear-nonthreshold (LNT) model as used in radiation protection: An NCRP update. Int J Radiat Biol (in press).

Boice JD Jr, Preston D, Davis FG, Monson RR. (1991). Frequent chest X-ray fluoroscopy and breast cancer incidence among tuberculosis patients in Massachusetts. Radiat Res. 1991 Feb;125(2):214-22.

BOICE JD Jr, Leggett RW, Ellis ED, Wallace PW, Mumma M, Cohen SS, Brill AB, Chadda B, Boecker BB, Yoder RC, Eckerman KF (2006). A comprehensive dose reconstruction methodology for former Rocketdyne/Atomics International radiation workers. *Health Phys* 90:409–430, 2006

BOICE, J.D., JR., COHEN, S.S., MUMMA, M.T., ELLIS, E.D., ECKERMAN, K.F., LEGGETT, R.W., BOECKER, B.B., BRILL, A.B. and HENDERSON, B.E. (2011). "Updated mortality analysis of radiation workers at Rocketdyne (Atomics International), 1948–2008." Radiat. Res. **176**(2), 244–258.

BOICE, J.D., JR., COHEN, S.S., MUMMA, M.T., ELLIS, E.D., CRAGLE, D.L., ECKERMAN, K.F., WALLACE, P.W., CHADDA, B., SONDERMAN, J.S., WIGGS, L.D., RICHTER, B.S. and LEGGETT, R.W. (2014). "Mortality among Mound workers exposed to polonium-210 and other sources of radiation, 1944–1979," Radiat. Res. **181**(2), 208–228.

BOICE, J.D. Jr. *et al.* (2017a). PENDING (Section 5.3.2)

BOICE, J.D. Jr. *et al.* (2017b). PENDING (Section B.4)

BOUVILLE, A., TOOHEY, R.E., BOICE, J.D., JR., BECK, H.L., DAUER, L.T., ECKERMAN, K.F., HAGEMEYER, D., LEGGETT, R.W., MUMMA, M.T., NAPIER, B., PRYOR, K.H., ROSENSTEIN, M., SCHAUER, D.A., SHERBINI, S., STRAM, D.O., THOMPSON, J.L., TILL, J.E., YODER, C. and ZEITLIN, C. (2015). "Dose reconstruction for the Million Worker Study: Status and guidelines," Health Phys. **108**(2), 206–220.

BOX, G.E.P. (1979). Robustness in the strategy of scientific model building. In: LAUNER, R.L. and WILKINSON, G.N. (eds) Robustness in Statistics. Academic Press, New York, pp 201-236

Bradshaw, Clare, Lawrence Kapustka, Lawrence Barnthouse, Justin Brown, Philippe Ciffroy, Valery Forbes, Stanislav Geras' kin, Ulrik Kautsky, and François Bréchignac. "Using an Ecosystem Approach to complement protection schemes based on organism-level endpoints." *Journal of environmental radioactivity* 136 (2014): 98-104.

Brenner *et al.* (2011). PENDING (Section B.4.2)

Bromet E J (2012). Mental health consequences of the Chernobyl disaster J. Radiol. Prot. 32 N71

Bromet E J, Havenaar J M and Guey L T (2011). Growing up in the shadow of Chornobyl: adolescents' risk perceptions and mental health. A 25 year retrospective review of the psychological consequences of the Chernobyl accident Clin. Oncol. [R. Coll. Radiol.] 23 297–305

Brown, J.E., S.R. Jones, R. Saxén et al. Radiation doses to aquatic organisms from natural radionuclides. J. Radiol. Prot. 24(4A): A63-A77 (2004).

BROWN, J., ALFONSO, B., AVILA, R., BERESFORD, N. A., COPPLESTONE, D., PRÖHL, G. & ULANOVSKY, A. 2008. The ERICA tool. *J. Environmental Radioactivity,* 99(9)**,** 1371-1383.

Browning, H. M., Gulland, F. M., Hammond, J. A., Colegrove, K. M., & Hall, A. J. (2015). Common cancer in a wild animal: the California sea lion (Zalophus californianus) as an emerging model for carcinogenesis. *Phil. Trans. R. Soc. B*, *370*(1673), 20140228.

Cahoon EK, Preston DL, Pierce DA, Grant E, Brenner AV, Mabuchi K, Utada M, Ozasa K. (2017). Lung, Laryngeal and Other Respiratory Cancer Incidence among Japanese Atomic Bomb Survivors: An Updated Analysis from 1958 through 2009. Radiat Res. 2017 Mar 21. doi: 10.1667/RR14583.1. [Epub ahead of print]

Cardis E1, Kesminiene A, Ivanov V, Malakhova I, Shibata Y, Khrouch V, Drozdovitch V, Maceika E, Zvonova I, Vlassov O, Bouville A, Goulko G, Hoshi M, Abrosimov A, Anoshko J, Astakhova L, Chekin S, Demidchik E, Galanti R, Ito M, Korobova E, Lushnikov E, Maksioutov M, Masyakin V, Nerovnia A, Parshin V, Parshkov E, Piliptsevich N, Pinchera A, Polyakov S, Shabeka N, Suonio E,

Tenet V, Tsyb A, Yamashita S, Williams D. (2005a). Risk of thyroid cancer after exposure to 131I in childhood. J Natl Cancer Inst. 2005 May 18;97(10):724-32.

CARDIS, E., VRIJHEID, M., BLETTNER, M., GILBERT, E., HAKAMA, M., HILL, C., HOWE, G., KALDOR, J., MUIRHEAD, C.R., SCHUBAUER-BERIGAN, M., YOSHIMURA, T., BERMANN, F., COWPER, G., FIX, J., HACKER, C., HEINMILLER, B., MARSHALL, M., THIERRY-CHEF, I., UTTERBACK, D., AHN, Y.O., AMOROS, E., ASHMORE, P., AUVINEN, A., BAE, J.M., SOLANO, J.B., BIAU, A., COMBALOT, E., DEBOODT, P., DIEZ SACRISTAN, A., EKLOF, M., ENGELS, H., ENGHOLM, G., GULIS, G., HABIB, R., HOLAN, K., HYVONEN, H., KEREKES, A., KURTINAITIS, J., MALKER, H., MARTUZZI, M., MASTAUSKAS, A., MONNET, A., MOSER, M., PEARCE, M.S., RICHARDSON, D.B., RODRIGUEZ-ARTALEJO, F., ROGEL, A., TARDY, H., TELLE-LAMBERTON, M., TURAI, I., USEL, M. and VERESS, K. (2005b). "Risk of cancer after low doses of ionising radiation: Retrospective cohort study in 15 countries," Br. Med. J. 331(7508), 77.

Cardis E, Vrijheid M, Blettner M, Gilbert E, Hakama M, Hill, C et al. (2007). The 15-country collaborative study of cancer risk among radiation workers in the nuclear industry: estimates of radiation-related cancer risks. Radiat Res. 167:396-416.

CDC (2011). Centers for Disease Control and Prevention. Risk Communication. 2011. Available at: https://www.cdc.gov/healthcommunication/risks/index.html, Accessed April 28, 2017.

Cool (2016). Health Phys. 110(2):233-7.

Copplestone, D., B.J. Howard and F. Bréchignac. The ecological relevance of current approaches for environmental protection from exposure to ionizing radiation. J. Environ. Radioact. 74(1-3): 31-41 (2004).

COURT BROWN WM, DOLL R, HILL RB. (1960). Incidence of leukaemia after exposure to diagnostic radiation *in utero*. Br Med J. Nov 26;2(5212):1539-45.

Covello, V. (1993). Risk communication, trust, and credibility. J. Occupational Medicine, 35, 18-19.

Covello VT. (2011). Guidance on developing effective radiological risk communication messages [online]. Washington, DC: U.S. Nuclear Regulatory Commission; NUREG/CR-7033; 2011. Available at pbadupws.nrc.gov/docs/ML1104/ML110490120.pdf.

Covello, V. and F. Allen (1988), Seven Cardinal Rules of Risk Communication, Washington, D.C.: U.S. Environmental Protection Agency, Office of Policy Analysis.

CUCINOTTA, F.A., ALP, M., SULZMAN, F.M. and WANG, M. (2014). "Space radiation risks to the central nervous system," Life Sci. Space Res. **2**, 54–69.

DAUER, L.T., BROOKS, A.L., HOEL, D.G., MORGAN, W.F., STRAM, D. and TRAN, P. (2010). "Review and evaluation of updated research on the health effects associated with low-dose ionising radiation," Radiat. Prot. Dosim. 140(2), 103–136.

Daniels RD, Bertke S, Waters KM, Schubauer-Berigan MK. Risk of leukaemia mortality from exposure to ionising radiation in US nuclear workers: a pooled case-control study. Occup Environ Med. 2013;70(1):41-48.Davis, S., K.J. Kopecky and T.E. Hamilton. (2002). Hanford thyroid disease study final report. CDC Contract Number 200-89-0716. Fred Hutchinson Cancer Center.

Davis (1989) PENDING (Section B.7)

Davis FG, Yu KL, Preston D, Epifanova S, Degteva M, Akleyev AV. (2015). Solid cancer incidence in the Techa River Incidence Cohort: 1956–2007. Radiat Res. 2015;184(1):56-65.

DESJARDINS, J.R. (2012). *Environmental Ethics. An Introduction to Environmental Philosophy*, Fifth Edition (Wadsworth, Cengage Learning, Boston).

DHEW (1979). Department of Health, Education and Welfare. *Office of the Secretary. Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/ (accessed January 30 2017) (Department of Health and Human Services, Washington).

DOE, U. S. 2002. A Graded Approach for Evaluating Radiation Doses to Aquatic and Terrestrial Biota. *In:* ENERGY, U. S. D. O. (ed.). Washington, D.C.

EPA (2007). Communicating Radiation Risks. Risk communications for emergency responders. EPA-401-F-07-008, 2007.

EPA (2011). Environmental Protection Agency. *EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population*, EPA-402-R-11-001, https://www.epa.gov/sites/production/files/2015-05/documents/bbfinalversion.pdf (accessed November 27, 2016) (Environmental Protection Agency, Washington).

EPA (2017). Protective Action Guidance Manual. https://www.epa.gov/sites/production/files/2017-01/documents/epa_pag_manual_final_revisions_01-11-2017_cover_disclaimer_8.pdf

Garnier-Laplace, J., et al. "Are radiosensitivity data derived from natural field conditions consistent with data from controlled exposures? A case study of Chernobyl wildlife chronically exposed to low dose rates." *Journal of environmental radioactivity* 121 (2013): 12-21.

GARNIER-LAPLACE, J., BEAUGELIN-SEILLER, K., DELLA-VEDOVA, C., MÉTIVIER, J.-M., RITZ, C., MOUSSEAU, T. A. & MØLLER, A.P. 2015. Radiological dose reconstruction for birds

reconciles outcomes of Fukushima with knowledge of dose-effect relationships. *Scientific Reports,* 5**,** 16594.

GILBERT, E. (2009). "Ionising radiation and cancer risks: What have we learned from epidemiology?" Int. J. Radiat. Biol. 85(6), 467–482.

GONZALEZ, A.J. (2011). "The Argentine approach to radiation safety: Its ethical basis," Science and Technology of Nuclear Installations, **Vol. 2011** (Article ID 910718), 15 pages, http://dx.doi.org/10.1155/2011/910718

González AJ, Akashi M, BOICE JD JR, Chino M, Homma T, Ishigure N, Kai M, Kusumi S, Lee J-K, Menzel H-G, Niwa O, Sakai K, Weiss W, Yamashita S, Yonekura Y. (2013). Radiological protection issues arising during and after the Fukushima nuclear reactor accident. *J Radiol Prot* 33:497–571.

Goto A, Bromet EJ, Ota M, Ohtsuru A, Yasumura S, Fujimori K; (2017). Pregnancy and Birth Survey Group of the Fukushima Health Management Survey. The Fukushima Nuclear Accident Affected Mothers' Depression but Not Maternal Confidence. Asia Pac J Public Health. 2017 Mar;29(2_suppl):139S-150S

Grant EJ, Furukawa K, Sakata R, Sugiyama H, Sadakane A, Takahashi I, Utada M, Shimizu Y, Ozasa K. (2015). Risk of death among children of atomic bomb survivors after 62 years of follow-up: a cohort study. Lancet Oncol. 2015 Oct;16(13):1316-23.

Grant EJ, Brenner A, Sugiyama H, Sakata R, Sadakane A, Utada M, Cahoon EK, Milder CM, Soda M, Cullings HM, Preston DL, Mabuchi K, Ozasa K. (2017). Solid Cancer Incidence among the Life Span Study of Atomic Bomb Survivors: 1958-2009. Radiat Res. 2017 Mar 20. doi: 10.1667/RR14492.1. [Epub ahead of print]

GRIEBEL, J. and EBDON-JACKSON, S. (2012). *Exposure of Asymptomatic Individuals in Health Care – Position Paper on Screening*, http://www.herca.org/documents/HERCA%20Position%20Paper%20on%20screening.pdf (accessed December 29, 2016) (Heads of the European Radiological Protection Competent Authorities, Montrouge, France).

Hamra GB, Richardson DB, Cardis E, Daniels RD, Gillies M, O'Hagan J, et al. 92016). Cohort profile: the International Nuclear Workers Study (INWORKS). Int J Epidemiol. 2016;45(3):693-699.

HANSSON, S.O. (2007). "Ethics and Radiation Protection," J. Radiol. Prot. **27**(2), 147–156.

Harrison, P. T. C., Holmes, P., & Humfrey, C. D. N. (1997). Reproductive health in humans and wildlife: are adverse trends associated with environmental chemical exposure?. *Science of the Total Environment*, *205*(2-3), 97-106.

Higley, Kathryn (20XX). "Radiation Protection of the Environment – A Case for US Standards," (in preparation, for submittal to Health Physics, February 2016).

Hunter *et al.* (2013) PENDING (Section B.4.2)

Hsu WL, Preston D, Soda M, Sugiyama H, Funamoto S, Kodama K, et al. (2013). The incidence of leukemia, lymphoma and multiple myeloma among atomic bomb survivors: 1950-2001. Radiat Res. 2013;179:361-382.

Hyer RN, Covello VT. (2007). Effective media communication during public health emergencies: a WHO handbook. Geneva: World Health Organization.

Hyer, Randall N.; Covello, Vincent T. (2017). Breaking Bad News in the High-concern, Low Trust Setting: How to Get Your Story Heard. Health Physics: Volume 112 - Issue 2 - p 111–115

IAEA (1992). International Atomic Energy Agency. Effects of ionizing radiation on plants and animals at levels implied by current radiation protection standards. Technical Reports Series No. 332. IAEA, Vienna.

IAEA 2002. Ethical Considerations in Protection of the Environment from the Effects of Ionizing Radiation: A Report for Discusion. Vienna, Austria.

ICRP (1959). International Commission on Radiological Protection. *Recommendations of the International Commission on Radiological Protection,* ICRP Publication 1 (Sage Publications, Thousand Oaks, California).

ICRP (1977). International Commission on Radiological Protection. *Recommendations of the International Commission on Radiological Protection,* ICRP Publication 26, Ann. ICRP **1**(3) (Sage Publications, Thousand Oaks, California).

ICRP (1983). International Commission on Radiological Protection. *Cost-Benefit Analysis in the Optimization of Radiation Protection*, ICRP Publication 37, Ann. ICRP **10**(2-3) (Sage Publications, Thousand Oaks, California).

ICRP (1990a). International Commission on Radiological Protection. *Optimization and Decision Making in Radiological Protection*, ICRP Publication 55, Ann. ICRP **20**(1) (Sage Publications, Thousand Oaks, California).

ICRP (1990b). International Commission on Radiological Protection. *RBE for Deterministic Effects*, ICRP Publication 58, Ann. ICRP **20**(4) (Sage Publications, Thousand Oaks, California).

ICRP (1991a). International Commission on Radiological Protection. *1990 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 60, Ann. ICRP **21**(1-3) (Sage Publications, Thousand Oaks, California).

ICRP (1991b). International Commission on Radiological Protection. *The Biological Basis for Dose Limitation in the Skin*, ICRP Publication 59, Ann. ICRP **22**(2) (Sage Publications, Thousand Oaks, California).

ICRP (1996). International Commission on Radiological Protection. *Radiological Protection and Safety in Medicine*, ICRP Publication 73, Ann. ICRP **26**(2) (Sage Publications, Thousand Oaks, California).

ICRP (1998). International Commission on Radiological Protection. *Genetic Susceptibility to Cancer*, ICRP Publication 79, Ann. ICRP **28**(1-2) (Sage Publications, Thousand Oaks, California).

ICRP (2003). International Commission on Radiological Protection. *Biological Effects after Prenatal Irradiation (Embryo and Fetus)*, ICRP Publication 90, Ann. ICRP **33**(1-2) (Sage Publications, Thousand Oaks, California).

ICRP (2005). International Commission on Radiological Protection. *Low-Dose Extrapolation of Radiation-Related Cancer Risk*, ICRP Publication 99, Ann. ICRP **35**(4) (Sage Publications, Thousand Oaks, California).

ICRP (2006). International Commission on Radiological Protection. *Assessing Dose of the Representative Person for the Purpose of Radiation Protection of the Public and The Optimisation of Radiological Protection: Broadening the Process*, ICRP Publication 101, Ann. **36**(3) (Sage Publications, Thousand Oaks, California).

ICRP (2007a). International Commission on Radiological Protection. *The 2000 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 103, Ann. ICRP **37**(2-4) (Sage Publications, Thousand Oaks, California).

ICRP (2008). International Commission on Radiological Protection. *Environmental Protection–The Concept and Use of Reference Animals and Plants*, ICRP Publication 108, Ann. ICRP **38**(4-6) (Sage Publications, Thousand Oaks, California).

ICRP (2012). International Commission on Radiological Protection. *ICRP Statement on Tissue Reactions / Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context*, ICRP Publication 118, Ann. ICRP **41**(1/2) (Sage Publications, Thousand Oaks, California).

ICRP (2013). International Commission on Radiological Protection. *Radiological Protection in Cardiology*, ICRP Publication 120. Ann. ICRP **42**(1), (Sage Publications, Thousand Oaks, California).

ICRP (2014a). International Commission on Radiological Protection. *Radiological Protection against Radon Exposure*, ICRP Publication 126, Ann. ICRP **43**(3) (Sage Publications, Thousand Oaks, California).

ICRP (2014b). International Commission on Radiological Protection. *Protection of the Environment under Different Exposure Situations*, ICRP Publication 124, Ann. ICRP **43**(1) (Sage Publications, Thousand Oaks, California).

ICRP (2015). International Commission on Radiological Protection. *Occupational Intakes of Radionuclides: Part 1*, ICRP Publication 130, Ann. ICRP **44**(2) (Sage Publications, Thousand Oaks, California).

ICRU (2011). International Commission on Radiation Units and Measurements. *Fundamental Quantities and Units for Ionizing Radiation*, ICRU Report 85a, revised. J. ICRU **11**(1).

IRPA (2014). IRPA GUIDING PRINCIPLES FOR ESTABLISHING A RADIATION PROTECTION CULTURE, http://www.irpa.net/members/IRPA-Guiding%20Principles%20on%20RP%20Culture%20-2014%20.pdf

Ito, M., et al. (1995). Childhood thyroid diseases around Chernobyl evaluated by ultrasound examination and fine needle aspiration cytology. Thyroid 5(5): p. 365-368.

KANT, I. (1785). *Grundlegung zur Metaphysik der Sitten* (Johann Friedrich Hartfnoch, Riga). (Latest translation: 2011). *Groundwork of the Metaphysics of Morals: A German-English Edition*, Gregor, M. and Timmermann, J., Ed. and Tr. (Cambridge University Press, New York).

KASE, K. R. (2004). "Radiation protection principles of NCRP," Research Gate **87**(3), 251–257.

Kase (2016). Health Phys. 110(2):127-45.

Kashcheev VV, Chekin SY, Maksioutov MA, Tumanov KA, Kochergina EV, Kashcheeva PV, et al. (2015). Incidence and mortality of solid cancer among emergency workers of the Chernobyl accident: assessment of radiation risks for the follow-up period of 1992-2009. Radiat Environ Biophys. 2015;54(1):13-23.

Knowles (1996). Fig. B.1 (reference column) [Pending]

Knowles, J.F. (1999). Long-term irradiation of a marine fish, the plaice Pleuronectes platessa: an assessment of the effects on size and composition of the testes and of possible genotoxic changes in peripheral erythrocytes. Int. J. Radiat. Biol. 75(6): 773-782.

Krestinina LY, Davis FG, Schonfeld S, Preston DL, Degteva M, Epifanova S, Akleyev AV. (2013). Leukaemia incidence in the Techa River Cohort: 1953-2007. Br J Cancer. 2013;109(11):2886-2893.

Krivolutsky D.A. (1987). Radiation ecology of soil animals. Biol. Fertil. Soils 3: 51 [Cited in UNSCEAR, 1996].

Kryshev and Sazykina (2011**)**. Fig. B.1 (reference column) [Pending … Sazykina and Kryshev (2011)?]

LAND, C.E. (1980). "Cancer risk from low doses of ionizing radiation," Science **209**, 1197–1203.

LAND, C.E. (1981). "Statistical limitations in relation to sample size," Environ. Health Perspect. **42**, 15–21.

Little (2016). PENDING (Section B.7)

Little MP, Tawn EJ, Tzoulaki I, Wakeford R, Hildebrandt G, Paris F, Tapio S, Elliott P. (2008). A systematic review of epidemiological associations between low and moderate doses of ionizing radiation and late cardiovascular effects, and their possible mechanisms. Radiat Res. 2008 Jan;169(1):99-109

Martineau, D., Lemberger, K., Dallaire, A., Labelle, P., Lipscomb, T. P., Michel, P., & Mikaelian, I. (2002). Cancer in wildlife, a case study: beluga from the St. Lawrence estuary, Quebec, Canada. *Environmental health perspectives*, *110*(3), 285.

McAloose, D., & Newton, A. L. (2009). Wildlife cancer: a conservation perspective. *Nature reviews cancer*, *9*(7), 517-526.

MILL, J.S. (1879). *Utilitarianism*, 7th ed., http://www.gutenberg.org/files/11224/11224-h/11224-h.htm (accessed September 28, 2014) (Frasers Magazine, Longmans, Green and Co., London).

Miller AB, Howe GR, Sherman GJ, Lindsay JP, Yaffe MJ, Dinner PJ, Risch HA, Preston DL. (1989). Mortality from breast cancer after irradiation during fluoroscopic examinations in patients being treated for tuberculosis. N Engl J Med. 1989 Nov 9;321(19):1285-9

Mousseau TA, Møller AP (2013) Elevated Frequency of Cataracts in Birds from Chernobyl. PLoS ONE 8(7): e66939. doi:10.1371/journal.pone.0066939

Muirhead CR, O'Hagan JA, Haylock RG, Phillipson MA, Willcock T, Berridge GL, Zhang W. (2009) Mortality and cancer incidence following occupational radiation exposure: third analysis of the National Registry for Radiation Workers. Br J Cancer. 2009 Jan 13;100(1):206-12.

Nair R, Rajan R, Akiba S, Jayalekshmi P, Nair K, Gangadharan P, et al. (2009). Background radiation and cancer incidence in Kerala, India -- Karunagappally cohort study. Health Phys. 2009;96(1):55-66.

NASA (2009). National Aeronautics and Space Administration. Human Health and Performance Risks of Space Exploration Missions, Evidence Reviewed by the NASA Human Research Program, NASA SP-2009-3405, http://humanresearchroadmap.nasa.gov/Evidence/reports/EvidenceBook.pdf (accessed January 12, 2015) (National Aeronautics and Space Administration, Washington).

NASA (2014). National Aeronautics and Space Administration. *NASA Space Flight Human System Standard. Volume 1, Revision A: Crew Health*, NASA-STD-3001, https://standards.nasa.gov/documents/detail/3315622 (accessed September 28, 2014) (National Aeronautics and Space Administration, Washington).

NA/NRC (2006). National Academies/National Research Council. *Health Risks from Exposure to Low Levels of Ionizing Radiation*, BEIR VII, Phase 2 (National Academies Press, Washington).

NCRP (1980). National Council on Radiation Protection and Measurements. *Influence of Dose and Its Distribution in Time on Dose-Response Relationships for Low-LET Radiations*, NCRP Report No. 64 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (1989). National Council on Radiation Protection and Measurements. *Guidance on Radiation Received in Space Activities*, NCRP Report No. 98 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (1991). National Council for Radiation Protection and Measurements. *Effects of Ionizing Radiation on Aquatic Organisms*, NCRP Report No. 109 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (1992). National Council on Radiation Protection and Measurements. *The Possibility That a Particular Malignancy May Have Been Caused by a Specified Irradiation*, NCRP Statement No. 7 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (1993a). National Council for Radiation Protection and Measurements. *Limitation of Exposure to Ionizing Radiation*, .NCRP Report No. 116 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (1993b). National Council for Radiation Protection and Measurements. *Risk Estimates for Radiation Protection*, NCRP Report No. 115 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (1995). National Council for Radiation Protection and Measurements. *Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients*, NCRP Commentary No. 11 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (1997). National Council for Radiation Protection and Measurements. *Uncertainties in Fatal Cancer Risk Estimates Used in Radiation Protection*, .NCRP Report No. 126 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (1999). National Council on Radiation Protection and Measurements. *Biological Effects and Exposure Limits for "Hot Particles,"* NCRP Report No. 130 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2000). National Council for Radiation Protection and Measurements. *Radiation Protection Guidance for Activities in Low-Earth Orbit*, NCRP Report No. 132 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2001a). National Council on Radiation Protection and Measurements. *Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation*, NCRP Report No. 136 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2001b). National Council on Radiation Protection and Measurements. *Extension of the Skin Dose Limit for Hot Particles to Other External Sources of Skin Irradiation*, NCRP Statement No. 9 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2005). National Council for Radiation Protection and Measurements. *Extrapolation of Radiation-Induced Cancer Risks from Nonhuman Experimental Systems to Humans*, .NCRP Report No. 150 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2006a). National Council for Radiation Protection and Measurements. *Management of Radionuclide Therapy Patients*, NCRP Report No. 155 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2006b). National Council for Radiation Protection and Measurements. *Information Needed to Make Radiation Protection Recommendations for Space Missions Beyond Low-Earth Orbit*, .NCRP Report No. 153 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2009). National Council for Radiation Protection and Measurements. *Ionizing Radiation Exposure of the Population of the United States*, NCRP Report No. 160 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2010a). National Council for Radiation Protection and Measurements. *Potential Impact of Individual Genetic Susceptibility and Previous Radiation Exposure on Radiation Risk for Astronauts*, NCRP Report No. 167 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2010b). National Council for Radiation Protection and Measurements. *Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures,* NCRP Report No. 168 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2010c) National Council on Radiation Protection and Measurements. *Responding to a Radiological or Nuclear Terrorism Incident: A Guide for Decision Makers*, NCRP Report No. 165 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2011a). National Council for Radiation Protection and Measurements. *Second Primary Cancers and Cardiovascular Disease after Radiation Therapy*, NCRP Report No. 170 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2011b). National Council on Radiation Protection and Measurements. Communication of radiation benefits and risks in decision making: proceedings of the 46th annual meeting. Health Phys 101:511–629; 2011.

NCRP (2012a). National Council for Radiation Protection and Measurements. *Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States*, NCRP Report No. 172 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2012b). National Council on Radiation Protection and Measurements. *Uncertainties in the Estimation of Radiation Risks and Probability of Disease Causation*, NCRP Report No. 171 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2013). National Council on Radiation Protection and Measurements. *Preconception and Prenatal Radiation Exposure Health Effects and Protective Guidance*, NCRP Report No. 174 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2014a). National Council for Radiation Protection and Measurements. *Radiation Protection for Space Activities: Supplement to Previous Recommendations*, NCRP Commentary No. 23 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2014b). National Council for Radiation Protection and Measurements. *Outline of Administrative Policies for Quality Assurance and Peer Review of Tissue Reactions Associated with Fluoroscopically-Guided Interventions*, .NCRP Statement No. 11 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2014c). National Council for Radiation Protection and Measurements. *Decision Making for Late-Phase Recovery from Major Nuclear or Radiological Incidents*, NCRP Report No. 175 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2015a). National Council on Radiation Protection and Measurements. *Health Effects of Low Doses of Radiation: Perspectives on Integrating Radiation Biology and Epidemiology*, NCRP Commentary No. 24 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2015b). National Council on Radiation Protection and Measurements. Uncertainties in the Measurement and Dosimetry of External Radiation, NCRP Report No. 158 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2016a). National Council for Radiation Protection and Measurements. *Guidance on Radiation Dose Limits for the Lens of the Eye*. NCRP Commentary No. 26 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2016b). National Council for Radiation Protection and Measurements. *Potential for Central Nervous System Effects from Radiation Exposure during Space Activities, Phase I: Overview*, NCRP Commentary No. 25 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

NCRP (2017a). National Council for Radiation Protection and Measurements. *Implications of Recent Epidemiologic Studies for LNT and Radiation Protection*, NCRP Commentary No. 2x (SC 1-25) (National Council on Radiation Protection and Measurements, Bethesda, Maryland) (work in progress).

NCRP (2017b). National Council for Radiation Protection and Measurements. *Guidance for Emergency Response Dosimetry*, NCRP Report No. 17y (SC 3-1) (National Council on Radiation Protection and Measurements, Bethesda, Maryland) (in publication process).

NCRP (201Y). National Council for Radiation Protection and Measurements. *Evaluating and Communicating Risks for Studies Involving Human Subjects: Guidance for Researchers and Institutional Review Boards*, NCRP Report No. 17x (SC 4-7) (National Council on Radiation Protection and Measurements, Bethesda, Maryland) (work in progress).

NELSON, G.A. (2009). "Neurological effects of space radiation," Gravit. Space Biol. Bull. **22**(2), 33–38.

NEPA (1969). *National Environmental Policy Act*. Public Law 91-190, 40 CFR Part 1500 (U.S. Government Printing Office, Washington).

OUGHTON, D. 2003. Protection of the environment from ionising radiation: ethical issues. *Journal of Environmental Radioactivity,* 66**,** 3-18.

OUGHTON, D. H. & STRAND, P. 2004. The Oslo consensus conference on protection of the environment. *Journal of Environmental Radioactivity,* 74**,** 7-17.

OZASA, K., SHIMIZU, Y., SUYAMA, A., KASAGI, F., SODA, M., GRANT, E.J., SAKATA, R., SUGIYAMA, H. and KODAMA, K. (2012). "Studies of the mortality of atomic bomb survivors, Report 14, 1950–2003: An overview of cancer and noncancer diseases," Radiat. Res. **177**(3), 229–243.

Ozasa K, Takahashi I, Grant EJ. (2016). Radiation-related risks of non-cancer outcomes in the atomic bomb survivors. Ann ICRP. 2016 Jun;45(1 Suppl):253-61.

Ozasa K, Takahashi I, Grant EJ, Kodama K. (2017). Cardiovascular disease among atomic bomb survivors. Int J Radiat Biol. 2017 Feb 24:1-6.

Paquet, F., Bailey, M.R., Leggett, R.W. and Harrison, J.D. (2016). "Assessment and interpretation of internal doses: Uncertainty and variability," Ann ICRP **45**(1 Suppl), 202-214.

Peshkov, S.P., I.A. Shekhanova, G.N. Romanov, B.S. Prister, G.P. Sheyin (1978). Radioecological Problems of Atomic Power Plant Cooling Reservoirs, Urals Scientific Center, USSR Academy of Sciences, Sverdlovsk (1992) as cited in IAEA, 1992

Poston, J.W. (1993) for the MIRD Committee. "Application of the Effective Dose Equivalent to Nuclear Medicine Patients," J. Nucl. Med. **34**, 714-716.

Preston DL, Mattsson A, Holmberg E, Shore R, Hildreth NG, Boice JD Jr. (2002). Radiation effects on breast cancer risk: a pooled analysis of eight cohorts. Radiat Res. 2002;158(2):220-235. Erratum in: Radiat Res. 2002;158(5):666

PRESTON, D.L., RON, E., TOKUOKA, S., FUNAMOTO, S., NISHI, N., SODA, M., MABUCHI, K., and KODAMA, K. (2007). "Solid cancer incidence in atomic bomb survivors: 1958–1998," Radiat. Res. **168**(1), 1–64.

PRESTON, D.L., CULLINGS, H., SUYAMA, A., FUNAMOTO, S., NISHI, N., SODA, M., MABUCHI, K., KODAMA, K., KASAGI, F. and SHORE, R.E. (2008). "Solid cancer incidence in atomic bomb survivors exposed *in utero* or as young children," J. Natl. Cancer Inst. **100**(6), 428–436.

R&D Publication 128, Environment Agency, Bristol, UK (2001) ISBN 1-85705590

RESRAD (2016). RESRAD-BIOTA, part of the RESRAD Family of Codes, https://web.evs.anl.gov/resrad/home2/biota.cfm (accessed January 25, 2016) (Argonne National Laboratory, Argonne, Illinois). [see also http://www.ead.anl.gov/resrad]

Richardson DB, Cardis E, Daniels RD, Gillies M, O'Hagan JA, Hamra GB, Haylock R, Laurier D, Leuraud K, Moissonnier M, Schubauer-Berigan MK, Thierry-Chef I, Kesminiene A.(2015). Risk of cancer from occupational exposure to ionising radiation: retrospective cohort study of workers in France, the United Kingdom, and the United States (INWORKS). BMJ. 2015 Oct 20;351:h5359.

Ron E, Modan B, Preston D, Alfandary E, Stovall M, Boice J. (1989). Thyroid neoplasia following low-dose radiation in childhood. Radiat Res. 1989;120:516-531

Ronckers CM, Land CE, Miller JS, Stovall M, Lonstein JE, Doody MM. (2010). Cancer mortality among women frequently exposed to radiographic examinations for spinal disorders. Radiat Res. 2010;174(1):83-90.

ROSE, K. 1991. Lower limits of radiosensitivity in organisms, excluding man. *Journal of Environmental Radioactivity,* 15**,** 113-133.

Ruhm W, Woloschak GE, Shore RE, Azizova TV, Grosche B, Niwa O, Akiba S, Ono T, Suzuki K, Iwasaki T, Ban N, Kai M, Clement CH, Bouffler S, Toma H, Hamada N. (2015). Dose and dose-rate effects of ionizing radiation: a discussion in the light of radiological protection. Radiat Environ Biophys. 54(4):379-401. doi: 10.1007/s00411-015-0613-6. Epub 2015 Sep 5.

Ruhm W, Azizova TV, Bouffler SD, Little MP, Shore RE, Walsh L, Woloschak GE (2016). Dose-rate effects in radiation biology and radiation protection. Ann ICRP. 2016 Mar 9. pii: 0146645316629336. [Epub ahead of print]

Sazykina, T.G., Kryshev, I.I. (2006). Radiation effects in wild terrestrial vertebrates – the EPIC collection J. Environ. Radioact., 88, pp. 11–48

Sazykina, T. G., & Kryshev, A. I. (2011). Manifestation of radiation effects in cold environment: data review and modeling. *Radiation and environmental biophysics*, *50*(1), 105-114 [Kryshev and Sazykina (2011)? in Fig. B.1 (reference column)]

Schonfeld SJ, Tsareva YV, Preston DL, Okatenko PV, Gilbert ES, Ron E, Sokolnikov ME, Koshurnikova NA. (2012). Cancer mortality following *in utero* exposure among offspring of female Mayak Worker Cohort members. Radiat Res 178: 160-165.

Schonfeld SJ, Krestinina LY, Epifanova S, Degteva MO, Akleyev AV, Preston DL. (2013). Solid cancer mortality in the Techa River cohort (1950-2007). Radiat Res. 2013;179(2):183-189.

Schubauer-Berigan MK, Daniels RD, Bertke SJ, Tseng CY, Richardson DB. (2015). Cancer Mortality through 2005 among a Pooled Cohort of U.S. Nuclear Workers Exposed to External Ionizing Radiation. Radiat Res. 2015 Jun;183(6):620-31. Epub 2015 May 26.

SHORE, R.E. (2014). "Radiation impacts on human health: certain, fuzzy, and unknown," Health Phys. 106(2), 196-205.

Siegel RL, Miller KD, Jemal A. Cancer Statistics, 2017. CA Cancer J Clin. 2017 Jan;67(1):7-30.

Signorello L B, Mulvihill J J, Green D M, Munro H M, Stovall M, Weathers R E, Mertens A C, Whitton J A, Robison L L and Boice J D Jr (2010). Stillbirth and neonatal death in relation to radiation exposure before conception: a retrospective cohort study Lancet 376 624–30

STRAM, D.O., PRESTON, D.L., SOKOLNIKOV, M., NAPIER, B., KOPECKY, K.J., BOICE, J., BECK, H., TILL, J. and BOUVILLE, A. (2015). "Shared dosimetry error in epidemiological dose-response analyses," PLOS One **10**(3), e0119418.

Strand, P., Sundell-Bergman, S., Brown, J.E. and Dowdall, M. (2017). On the divergences in assessment of environmental impacts from ionising radiation following the Fukushima accident, Journal of Environmental Radioactivity, Volumes 169–170, Pages 159-173, ISSN 0265-931X, http://dx.doi.org/10.1016/j.jenvrad.2016.12.005.

Peptic ulcer study (reference to be added) PENDING (Section B.4.1.6)

Takahashi I, Shimizu Y, Grant EJ, Cologne J, Ozasa K, Kodama K. (2017). Heart Disease Mortality in the Life Span Study, 1950-2008. Radiat Res. 2017 Mar;187(3):319-332.

Tatsukawa Y, Cologne JB, Hsu WL, Yamada M, Ohishi W, Hida A, Furukawa K, Takahashi N, Nakamura N, Suyama A, Ozasa K, Akahoshi M, Fujiwara S, Shore R. (2013). Radiation risk of individual multifactorial diseases in offspring of the atomic-bomb survivors: a clinical health study. J Radiol Prot. 2013 Jun;33(2):281-93.

Taylor, L.S. (1957). The philosophy underlying radiation protection. American Journal of Roentgenology, 77, 914–919.

TILL, J.E., BECK, H.B., AANENSON, J.W., GROGAN, H.A., MOHLER, H.J., MOHLER, S.S. and VOILLEQUE, P.G. (2014). "Military participants at the U.S. atmospheric nuclear weapons testing—methodology for estimating dose and uncertainty," Radiat. Res. **181**(5), 471–484.

Tran V, Zablotska LB, Brenner AV, Little MP. (2017). Radiation-associated circulatory disease mortality in a pooled analysis of 77,275 patients from the Massachusetts and Canadian tuberculosis fluoroscopy cohorts. Sci Rep. 2017 Mar 13;7:44147. doi: 10.1038/srep44147.

UNSCEAR (2001). United Nations Scientific Committee on the Effects of Atomic Radiation. *Hereditary Effects of radiation. UNSCEAR 2001 Report to the general Assembly, with Scientific Annex*, No. E.01.IX.2 (United Nations Publications, New York).

UNSCEAR (2008). United Nations Scientific Committee on the Effects of Atomic Radiation. Effects of ionizing radiation, Volume I, UNSCEAR 2006 report to the General Assembly, Annex A: Epidemiological studies of radiation and cancer. E.08.IX.6 (United Nations Publications, New York).

UNSCEAR (2011). United Nations Scientific Committee on the Effects of Atomic Radiation. Sources and Effects of Ionizing radiation, 2008 Report to the General Assembly, with scientific annexes; Annex E: Effects of ionizing radiation on non-human biota; United Nations: New York.

UNSCEAR (2013). Sources Effects and Risks of Ionizing Radiation, UNSCEAR 2013 Report, Annex B: Effects of Radiation Exposure of Children, United Nations New York.

UNSCEAR (2015). United Nations Scientific Committee on the Effects of Atomic Radiation, UNSCEAR 2012 Report to the General Assembly, Annex A, Attributing Health Effects to ionizing radiation exposure and inferring risks, Annex B Uncertainties in risk estimates for radiation-induced cancer, United nations New York.

Veiga LHS, Holmberg E, Anderson H, Pottern L, Sadetzki S, Adams MJ, et al. (2016). Thyroid cancer after childhood exposure to external radiation: an updated pooled analysis of 12 studies. Radiat Res. 2016;185(5):473-484.

Vittecoq, M., Roche, B., Daoust, S.P., Ducasse, H., Missé, D., Abadie, J., Labrut, S., Renaud, F., Gauthier-Clerc, M. and Thomas, F., 2013. Cancer: a missing link in ecosystem functioning?. *Trends in ecology & evolution*, *28*(11), pp.628-635.

Walsh L, Shore R, Auvinen A, Jung T, Wakeford R. Risks from CT scans -- what do recent studies tell us? (2014). J Radiol Prot. 2014;34(1):E1-E5.

WEINBERG, R.A. (2013). *The Biology of Cancer* (Garland Science, New York).

WHO (2007). World Health Organization. Effective Media Communication During Public Health Emergencies. Handbook, Field Guide, and Wall Chart. 2007. Available at: http://www.who.int/csr/resources/publications/WHO_CDS_2005_31/en/, Accessed April 28, 2017.

WHO (2012). World Health Organization. Preliminary dose estimation from the nuclear accident after the 2011 Great East Japan Earthquake and Tsunami. Geneva: World Health Organization, pp. 1–120.

Winther J F, Olsen J H, Wu H, Shyr Y, Mulvihill J J, Stovall M, Nielsen A, Schmiegelow M and Boice J D Jr (2012). Genetic disease in the children of Danish survivors of childhood and adolescent cancer J. Clin. Oncol. 30 27–33

Woodwell, G.M. and L.N. Miller. Chronic gamma radiation affects the distribution of radial increment in Pinus rigida stems. Science 139(3551): 222-223 (1963)

YAMADA, M., KASAGI, F., MIMORI, Y., MIYACHI, T., OHSHITA, T. and SASAKI, H. (2009). "Incidence of dementia among atomic-bomb survivors—Radiation Effects Research Foundation Adult Health Study," J. Neurol. Sci. **281**(1–2), 11–14.

Yamashita, S. and Y. Shabita. (1996). Chernobyl: A decade later, in Proceedings of the 5th Chernobyl Sasakawa Medical Cooperation Symposium 1996. Kiev, October 14-15, 1996: Elsevier Science B.V., Amsterdam.

Yoschenko, V., Nanba, K., Yoshida, S., Watanabe, Y., Takase, T., Sato, N., & Keitoku, K. (2016). Morphological abnormalities in Japanese red pine (Pinus densiflora) at the territories contaminated as a result of the accident at Fukushima Dai-Ichi Nuclear Power Plant. *Journal of Environmental Radioactivity*, *165*, 60-67.

Zablotska (2014). PENDING (Section B.7)