Radiation Protection Guidance for the United States (2018)

Lawrence T. Dauer

National Council on Radiation Protection and Measurements

Radiation Protection Guidance for U.S.

- **NCRP Council Committee 1** (CC-1)
  - Update NCRP Guidance for Radiation Protection in the U.S.
- **NCRP Scientific Committee 1-25** (SC 1-25)
  - Evaluate current science for Linear-Nonthreshold (LNT) as model for radiation protection applications.
- **NCRP Scientific Committee 1-23** (SC 1-23)
  - Guidance on Radiation Dose Limits for the Lens of the Eye.
- See ncrponline.org for ongoing status updates.

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NCRP Council Committee 1

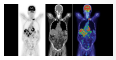
- CC-1 will update NCRP guidance for radiation protection.

- Current draft is early work in progress.
- AAPM input will be crucial for relevance, clarity, and usefulness.
- Chair – Kenneth Kase
  - Co-Chair – John Boice
  - Co-Chair – Don Cool
- Stakeholders
  - Agencies/Regulators
  - Exposed Individuals
  - Public and Private

3

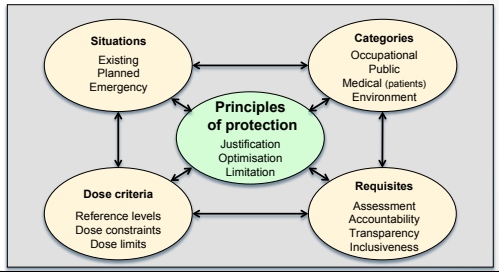
NCRP CC-1 Framework

- Provide framework for appropriate protection against detrimental effects without limiting beneficial uses/results.
- Update the bases of System of Protection for U.S.
- Include sources and exposures not previously addressed:
  - Patients exposed in medical imaging and radiation therapy;
  - Caregivers for such patients;
  - Voluntary participants in medical research; and
  - Exposures of nonhuman species in the environment.
- Prudent guidance for adequate protection.



4

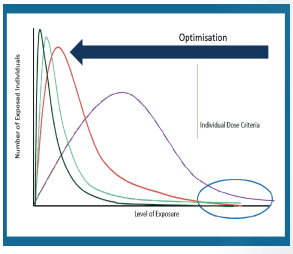
NCRP CC-1 Framework



5

Build a Culture of Protection

- Characterize exposures.
- Establish Dose Criteria and ID exposures that warrant specific attention to reduce magnitude.
- Influence the entire dose distribution and shift exposures towards lower values.
- Reduce inequity.
- Enable stakeholder engagement and action.



6

NCRP CC-1 Science/Ethics/Communication

- Development based upon scientific information, ethics, and expert opinion derived from experience.
- Ethical considerations
  - Provide transparency about the values that underlie the system.
  - Principles:
    - Benificence: provide more good than harm.
    - Non-maleficence: prevent harm.
    - Autonomy: self determination.
    - Justice: act fairly (ensure equity).
- Communicating NCRP system to Stakeholders
  - Establish and maintain Trust and Confidence

7

NCRP CC-1 Considerations

- Adverse Health Outcomes from Radiation Exposure
  - Tissue Reaction (severity increases with dose)
  - Stochastic Effect (probability increases as function of dose)
    - Cancer Incidence and Mortality
      - Site specific, sex/age, special exposure groups, new RERF data, large-scale worker study data coming available.
    - Non-Cancer Detriments
- Significant Uncertainty at low dose and dose rates
  - Require judgment for model selection
  - Radiation protection purposes

8

NCRP CC-1 Recommendations

- Similar, but likely not identical, to those made previously by NCRP and ICRP.
- Restricting dose to skin will be based on NCRP Report #130 and NCRP Statement #9.
- Restricting dose to lens will be based on conclusions of NCRP SC 1-23.
- Restricting dose for emergency exposure will be based on NCRP Report #165 and recommendations of NCRP SC 3-1.

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NCRP CC-1 Recommendations

- Occupational and public exposure categories dose criteria for exposure situations will be similar to NCRP Report #116 and ICRP Publication #103.
- Special considerations for certain medical staff, emergency responders, and the embryo/fetus.
- Dose criteria for comforters/caregivers will be based on recommendations of previous NCRP reports.
- Dose criteria for human research subjects will be based on recommendations of NCRP SC 4-7.

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NCRP CC-1 Schedule and Info

- Draft materials are under review with NCRP PACs.
- Discussions of proposals at IRPA, CRCPD, HPS, AAPM, and other professional societies.
- ICRP Task Group providing consultation.
- Revised draft for Council consideration in 2017.
- For copies of current working draft or other information:
  - Ken Kase: krkase539@gmail.com
  - Marvin Rosenstein: smrmr@msn.com

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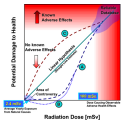
NCRP Scientific Committee 1-25

- SC 1-25 on LNT
- Recent epidemiologic studies and implications for the Linear-Nonthreshold Model for Radiation Protection Purposes



- Chair – Roy Shore
  - Co-Chair – Larry Dauer
- Commentary in support of CC-1 by 2017.

12

NCRP SC 1-25 Purpose

- Prepare a commentary reviewing recent epidemiologic studies and evaluate whether the new observations are strong enough to support or modify the LNT model as used in radiation protection today.
- Will include recent (within ~5y) epidemiologic studies with extensive study and adequate dosimetry. Ecological studies will not be included.
- Studies – Integration of New Findings –

Implications on RP –

Improved communication to broader audiences.

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NCRP SC 1-25 Epidemiological Studies

- **Cancer studies**: atomic bomb survivors, Chernobyl, CT exams, INWORKS, 15 country study(summary), Mayak, other worker studies, Atomic Veterans, Techa River, U.S. Radiologic Technologists, Million Person Study, high natural background, Taiwan.
- **Cardiac/circulatory**: atomic bomb survivors, TB/Fluoro, other worker studies.
- Other considerations – genetics, children, prenatal, noncancer effects (hypothyroidism).
- Assessment of strength of Dosimetry and Statistical models.

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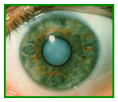
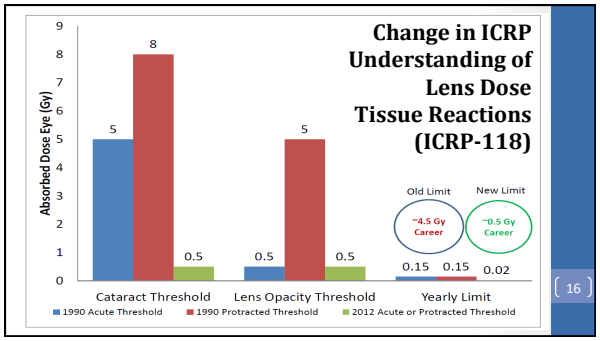
NCRP Scientific Committee 1-23

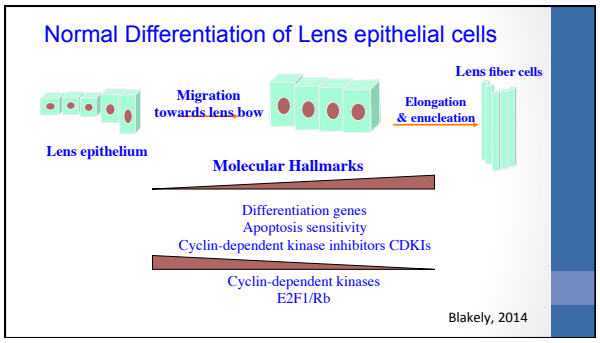
- SC 1-23 Guidance on Radiation Dose Limits for the Lens of the Eye.
- Review radiogenic cataract mechanisms.
- Evaluate epidemiological evidence to date.

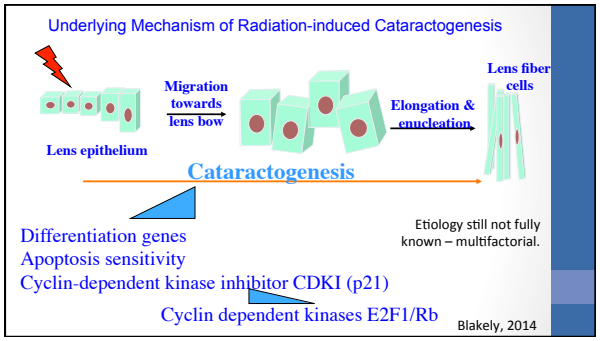


- Chair – Ellie Blakely
  - Co-Chair – Larry Dauer
- Commentary in support of CC-1 by 2016.

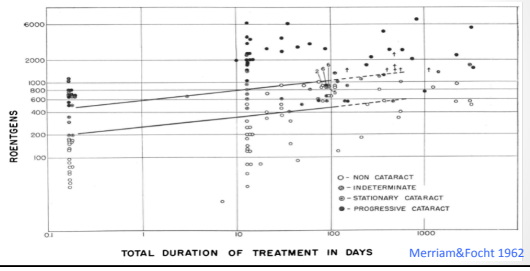
15


Change in ICRP Understanding of Lens Dose Tissue Reactions (ICRP-118)
Absorbed Dose Eye (Gy)
9
8
7
6
5
4
3
2
1
0
5
8
0.5
0.5
5
0.5
Old Limit
New Limit
~4.5 Gy Career
~0.5 Gy Career
0.15
0.15
0.02
Cataract Threshold
Lens Opacity Threshold
Yearly Limit
1990 Acute Threshold
1990 Protracted Threshold
2012 Acute or Protracted Threshold
16


Normal Differentiation of Lens epithelial cells
Lens fiber cells
Migration towards lens bow
Elongation & enucleation
Lens epithelium
Molecular Hallmarks
Differentiation genes
Apoptosis sensitivity
Cyclin-dependent kinase inhibitors CDKIs
Cyclin-dependent kinases
E2F1/Rb
Blakely, 2014


Underlying Mechanism of Radiation-induced Cataractogenesis
Lens fiber cells
Migration towards lens bow
Elongation & enucleation
Lens epithelium
Cataractogenesis
Etiology still not fully known – multifactorial.
Differentiation genes
Apoptosis sensitivity
Cyclin-dependent kinase inhibitor CDKI (p21)
Cyclin dependent kinases E2F1/Rb
Blakely, 2014

Dose and Cataract Progression



Merriam&Focht 1962

19

NCRP SC 1-23 Epidemiology

- Many populations studied to date. Large variations. Only a few investigate low dose effects. Many with poor dosimetry. Method of scoring endpoints differ. Confounders exist.
- General conclusions:
  - Strong likelihood of an association between exposure to ionizing radiation and initiation or development of various opacifications and/or cataracts.
  - Recognize large uncertainty.
  - A lower threshold or no threshold *may* be an appropriate model for radiation cataractogenesis risk.

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NCRP SC 1-23 Draft Conclusions

- Should radiation-induced cataracts be characterized as stochastic or deterministic effects?
  - Best epidemiology still indicates a threshold, not possible to make a specific quantitative estimate with available data.
- Effects of LET, dose rate, acute/protracted dose delivery on cataract induction and progression?
  - Need high-quality epi and mechanistic studies with better dosimetry and scoring to answer.

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NCRP SC 1-23 Draft Conclusions

- How should detriment be evaluated for cataracts?
  - Cataracts not life threatening but may affect individual's ability to carry out their occupations or other daily tasks.
  - SC 1-23 encourages NCRP-168 recommendation to regard eye exposures in much the same way as whole-body exposures. Thus, ensure exposures are consistent with ALARA principles. This includes careful justification and optimization in exposure situations with doses to the lens of the eye.

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NCRP SC 1-23 Draft Conclusions

- Based on current evidence, should NCRP change the recommended limit for the lens of the eye at this time?
  - A threshold model should continue to be used for radiation protection purposes.
  - While some epi evidence points to a threshold for vision-impairing cataracts for doses on the order of 1-2 Gy, a specific quantitative estimate of lens effect thresholds can not be made at this time.
  - **It is prudent to reduce the current recommended annual lens of eye occupational dose limit from 150 mSv to 50 mGy.**

(Note - these considerations are under final review)

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NCRP SC 1-23 Recommendations

- Urgent need for comprehensive evaluation of overall effects of radiation on the eye.
- New RERF studies being initiated for A-Bomb Survivors.
- Need for new, high-quality epidemiology and basic research on mechanisms of action.
- Ongoing opportunity for dose-sparing optimization and dneed for more education and accurate dose assessment.
- Need additional information on pediatric effects.
- Longitudinal studies.
- Stakeholder Workshop on August 29th in NYC.

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  - Evaluate current science for Linear-Nonthreshold (LNT) as model for radiation protection applications.
- **NCRP Scientific Committee 1-23** (SC 1-23)
  - Guidance on Radiation Dose Limits for the Lens of the Eye.
- See ncrponline.org for ongoing status updates and for information on the August 29th Stakeholder Workshop in NYC on Lens of Eye.

25

NCRP DRAFT CC 1 Report

Working Draft (4-12-16)
[Awaiting PACs, ICRP and Member input] … added Fleming (4-10/11-16)

General Comments

Comment [M1]: Preston … I really did not have any major concerns except the usual of length of section not necessarily being representative of relative importance to the task.

Comment [M2]: Bushberg … Suggest robust use of hyperlinks to dentitions in the glossary and (if necessary) the larger NCRP glossary

RADIATION PROTECTION GUIDANCE FOR THE UNITED STATES (2018)

April 2016

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National Council on Radiation Protection and Measurements

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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 the 1993 NCRP 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 1993, substantial advances in radiation effects knowledge, as well as radiation protection understanding and culture, have occurred. New knowledge has been obtained on radiation effects at doses lower than apparent in 1993. Noncancer effects such as cardiovascular disease and cataracts are emerging as potentially important concerns. Discussion of ethical foundations had not been introduced ~~Ethics has not been applied~~ and the severity of health outcomes have not been addressed in a context of radiation protection. The Fukushima nuclear reactor accident and the ever-rising increase in population exposure to radiologic imaging examinations [computed tomography (CT) examinations, positron emission tomography scans, and nuclear medicine procedures] have increased the awareness of the importance of radiation protection guidance in the United States.

Comment [M3]: Fleming edit

Comment [CD4]: Cool … I would change this to "medical use of radiation". I think we must be careful to not just be focused on radiology.

In 2007, the International Commission on Radiological Protection (ICRP) published an update of their recommendations (Publication 103) (ICRP, 2007). Subsequently an important ICRP report on tissue reactions (previously called deterministic effects) and noncancer effects was published in 2013 (Publication 118) (ICRP, 2013). 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 obtain~~ing~~ these goals {i.e., in implementing the three pillars of radiation protection of justification, optimization [the as low as reasonably achievable (ALARA) principle}, and dose limitation] (Kase, 2016). These differences will be discussed in this Report.

A review of recent radiation epidemiologic studies by NCRP Scientific Committee SC 1-25 (in progress) will address dose-response models in general, including threshold models, and their applicability to radiation protection guidance.

CC 1 considered numerous radiation protection issues. It was particularly important that this Report point out where there is consistency with current U.S. and international radiation protection guidance and where there are other points of view for issues where the NCRP guidance is unique for the United States and the rationale for such differences. This Report represents the guidance for the United States at the time of publication of this Report, which is projected to be completed and published in 2018. An illustrative listing of issues is given below whose roles in the overall radiation protection system were examined. However, it should be recognized that all relevant areas (more than those listed below) were reviewed and that the listing below is only a partial illustrative list.

- Noncancer effects such as cardiovascular disease and cataracts
- Effect of age at exposure
- Effect of sex
- Genetic susceptibility
- Severity of the radiation effect
- Treatability of the radiation effect
- The ethical bases for justification, ALARA (optimization), and dose limits

Comment [M5]: Fleming addition

- The ALARA principle
- A risk-based versus a dose-based system
- The appropriate situations when the effect has a threshold
- Dose and dose-rate effectiveness factor (DDREF), dose-rate effectiveness factor (DREF), and low-dose effectiveness factor (LDEF)
- Biologically-based dose-response models
- Risk assessment for U.S. radiation-exposed populations
- Energy-dependent radiation weighting factors for low linear-energy transfer radiation
- Weighting factors for specific radionuclides or classes of radionuclide emitters

- Clarity of radiation quantities and units
- Reporting and recording doses and units
- Skin dose and hot particles
- Patient protection in medical practice
- Revision or reassessment of NCRP Report No. 115 (Risk Estimates for Radiation Protection) (NCRP, 1993b): two Scientific Committees were formed to assist this process, one on Guidance on Radiation Dose Limits for the Lens of the Eye (SC 1-23) and the other on Recent Epidemiologic Studies and Implications for the Linear Non-Threshold Model (SC 1-25)
- Radiation protection for nonhuman species
- Clarification of the philosophical basis for radiation protection (e.g., anthropomorphism)

Comment [M6]: Fleming addition

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

- It was the first Committee formed under the direct oversight of the 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 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 Medical Physics (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:

[bios (to be added at the end) will include other relevant NCRP and radiation organization roles]

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Laura J. Atwell, Office Manager
David A. Smith, Executive Director

The Council 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

References (Preface)

Cool (2016). Health Phys. 110(2):233-7.
ICRP (2007a). ICRP Publication 103
ICRP (2013). ICRP Publication 118
Kase (2016). Health Phys. 110(2):127-45.
NCRP (1993a). NCRP Report No. 116, Radiation Protection Guidance for the United States
NCRP (1993b). NCRP Report No. 115 (Risk Estimates for Radiation Protection)

Contents

1. Introduction

1.1 Goals

The primary goal of the NCRP recommendations is to provide a framework for an appropriate level of protection for people and the environment against the detrimental effects of radiation exposure without unnecessarily limiting the beneficial human actions that may result in or from such exposure. Thus, the recommendations are designed to prevent the occurrence of serious radiation-induced injuries (both acute and chronic) in exposed persons and to reduce the probability of stochastic effects in exposed persons to a degree that is ethically appropriate in relation to the benefits to the individual and to society from the activities that generate such exposures.

This Report updates the bases of the System for Radiation Protection for the United States (these updated recommendations are referred to as The NCRP System in the rest of this Report) and the fundamental recommendations to limit exposures and their subsequent consequences. Its purpose is to inform the reader about all sources of ionizing radiation exposure. It adds to previous recommendations by NCRP (1993a) and ICRP (2007a) by including sources and exposures that have not been specifically addressed. These include patients exposed in medical imaging procedures and radiation therapy, caregivers for patients during medical imaging procedures or treated with radioactive materials, voluntary participants who may be exposed to ionizing radiation in medical research, workers and the general public exposed to naturally occurring radiation sources including those enhanced by technology, and exposure of nonhuman species in the environment.

The National Council on Radiation Protection and Measurements (NCRP) published its last complete set of basic recommendations on exposure to ionizing radiation in 1993 (NCRP, 1993a). The International Commission on Radiological Protection (ICRP) published its most recent recommendations for a system of radiological protection[1] in 2007 (ICRP, 2007a). It is now almost 10 y since the publication of the ICRP report and biological research continues to reveal information that adds to our understanding of radiation effects. Recent epidemiologic studies have also added to the understanding of the relationship of radiation dose to the risk of harm. This additional information and understanding leads to the need to consider a clear rationalization of the concept of detriment and its application in The NCRP System. Moreover, NCRP has identified portions of the previous recommendations that would benefit from further explanation and additional clarity. It is important to emphasize that The NCRP System recommended is prospective and designed for protection of the population of the United States. Because the risk estimates for various health effects are based on averages over a specific population, the calculated detriment values cannot apply to any single individual. Thus, The NCRP System is not intended for retrospective risk analysis for individuals, or for diverse or undefined populations (Figure 1.1).

Comment [M7]: Fleming
Will they not publish a new report by the time this report is out. If so cite it. I believe Cool sent me an earlier version of an ethics chapter for that report.

Cool

Comment [PF8]: Fleming … Is this true in medical therapy? (We seem to be doing this in SC 4-7)

[1] The term "radiological protection" is used when quoting from or referring specifically to the ICRP or the ICRP system. Otherwise, the term "radiation protection" is used in this Report on NCRP recommendations. The term "radiologic" is used as a general adjective.

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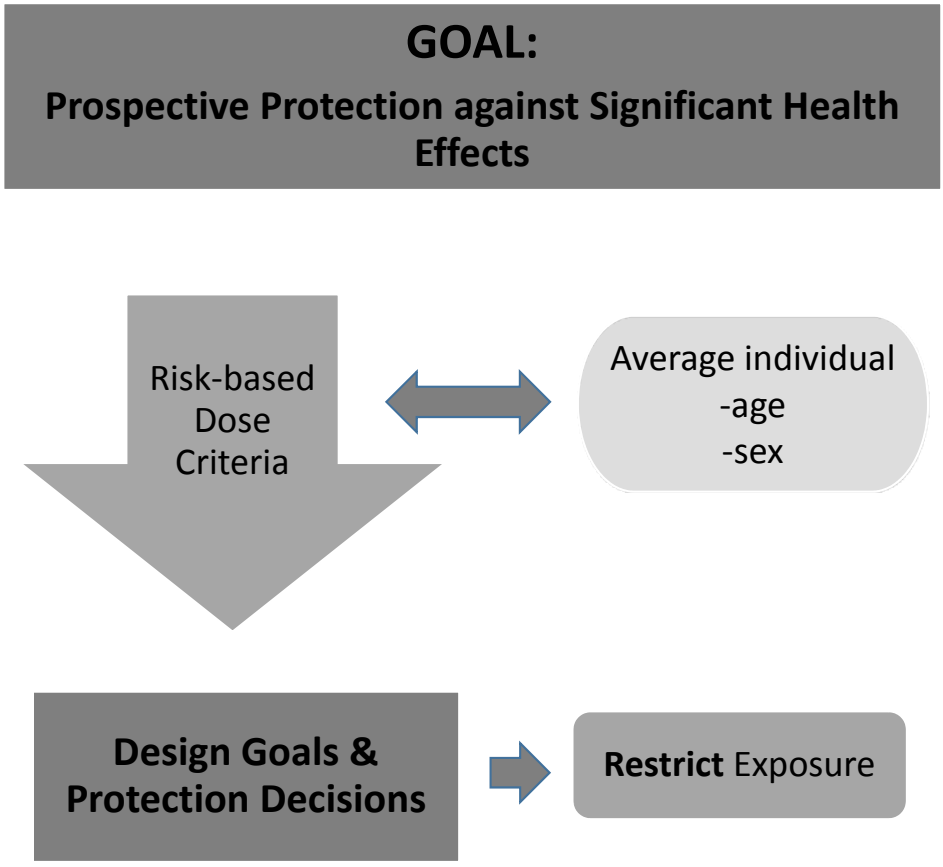

369

370

371 **Fig. 1.1.** Prospective Radiation Protection

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Comment [M9]: Irwin … I am not sure that the figure adds clarity.

Kase

This Report also explains the need for the development of a Safety Culture that engages workers who may be exposed to radiation, as well as members of the public, in the control of their individual exposure.

It is important to be clear about the relationship among scientific, advisory and regulatory bodies and their respective responsibilities for radiation protection. Scientific bodies conduct and analyze studies that provide information on the effects of radiation exposure, and test radiation exposure and protection hypotheses. Advisory bodies interpret the scientific data and establish radiation protection guidance. Regulatory bodies use guidance to promulgate rules for programs that help control exposures to radiation. NCRP has evaluated the current status of this information, guidance and rules and has concluded that an updated NCRP report on basic recommendations for radiation protection for the United States is timely.

This Report updates the basic recommendations of the NCRP that were published in NCRP (1993a), as applicable to the current needs in the United States. NCRP agrees with ICRP statements in the Preface to Publication 103 (ICRP, 2007a) that while the biological and physical assumptions and concepts underlying the basic recommendations remain robust, some updating is required. The overall estimates of cancer risk attributable to radiation exposure have not changed greatly in the past 25 y. Conversely, the estimated risk of heritable effects is currently lower than that previously determined. The overall estimates of tissue reactions (formerly deterministic effects)[2] and stochastic risk remain fundamentally the same. Also as ICRP noted, "It has also become apparent that the radiological protection of the environment should receive more emphasis than in the past".

The recommendations and concepts provided in ICRP Publication 103 (ICRP, 2007a) have been carefully reviewed and in the interest of a uniform international approach to radiation protection have, in general, been incorporated in this Report. The NCRP System remains based on the three principles of Justification, Optimization of Protection (the ALARA principle), and Application of Dose Limits (now termed Dose Criteria by NCRP). However, NCRP recommends some notable additions to the principles. These are:

1. Emphasize the need to justify the removal of a radiation source as well as the addition of a source.
2. Include in the justification of specific medical procedures that use radiation the qualification that the process should minimize harm in addition to maximizing benefit through selection of the most appropriate medical procedure.
3. Add the concept of engaging the affected individuals (stakeholders) in the process.
4. NCRP has also added a section on the ethical considerations that underlie The NCRP System, such as the extension of radiation protection of the environment and the ethical principles that inform the justification, optimization, and restriction of dose.

Comment [PF10]: Fleming … This should be communicated to SC 4-7 and other committees who are using dose limits or the principle of dose limitation.

[2] In the Report, NCRP has adopted the term tissue reaction in place of deterministic effect.

Finally it is important to emphasize that in this Report NCRP makes no recommendations for dose limits. Instead the recommendations are stated as individual dose criteria for optimization during the planning and design process or individual dose criteria for control to restrict dose during operations, to establish values adequate for protection. The approach emphasizes the role of optimization (ALARA) in radiation protection, and the inherent difficulty in specifying an absolute value for a limit that is applicable in all circumstances. It ~~This~~ also allows regulators and other users more flexibility in designing radiation protection programs while still providing protection to workers, medical patients and the public.

In addition to furthering an international harmonization of radiation protection recommendations and standards, this Report aims to:

- Clearly explain the basis for its recommendations and the reasons for any changes from NCRP (1993a) as well as any differences from ICRP (2007a).
- Clearly state what is known and what is unknown about biological response to radiation rationalized with new epidemiologic information and the significance relative to the recommendations.
- Clearly explain the limitations of epidemiologic studies of radiation effects.
- Clearly identify the uncertainties involved in assessing the risks and detriment of radiation injuries.
- Consider the ease of implementation of the recommendations.
- Rationalize The NCRP System for all sources and applications of radiation.
- Specify the rationale for the recommended dose criteria.

1.2 Effects of Concern in Radiation Protection

Ionizing radiation, like any other toxin, can damage or kill cells and thus harm bodily tissues and organs. The number of cells affected depends on the dose of toxin absorbed by the body and the sensitivity of the cells affected. In the case of ionizing radiation the cells damaged by the radiation are those in which some of the energy carried by the radiation is deposited, or for some cases nearby cells. If a large number of cells in a body organ are killed, the function of that organ will be impaired or destroyed. Damaged cells may be repaired by natural body processes and returned to their normal function. In some cases the cell repair process may result in an error, which could change the function of the cell. This could result in the weakening of organ function or growth of new tissue, such as with cancer development.

The serious radiation-induced adverse health effects of concern in radiation protection fall into two general categories: tissue reactions and stochastic effects. An adverse tissue reaction is defined in a general sense as an injury to a tissue or organ that increases in severity with increasing radiation absorbed dose, presumably above a certain threshold absorbed dose. Examples of acute or early adverse tissue reactions are erythema and other skin damage. Chronic or late adverse tissue reactions include fibrosis, organ atrophy and a decrease in the number of germ cells that may result in sterility or a reduction in fertility.

Comment [PF11]: Fleming … So, the recommendations are individual dose criteria based on averages over specific populations? I can bet the public doesn't understand this. I can not recall if we emphasize this in the chapter on communication.

Comment [M12]: Cool edit

A stochastic effect is one in which the probability of the effect occurring increases continuously with increasing absorbed dose while the severity of the effect, in affected individuals, is independent of the magnitude of the absorbed dose. The probability of a specific effect for a given absorbed dose is dependent on individual factors such as age and sex. The stochastic effect of most concern for radiation protection is the induction of cancer.

1.3 Determination of Radiation Effects

1.3.1 Introduction

The amount of cell killing or damage caused by a specific absorbed dose depends on the sensitivity of the cells affected. Consequently, some body organs will be more seriously affected than others. For example, blood cells forming in the bone marrow are more sensitive than most other cells in the body while the cells in the central nervous system and brain are less sensitive. Therefore, serious damage to the body's ability to produce new blood cells will result at a lower absorbed dose than is required to seriously affect the brain.

The immediate and long-term effects of radiation exposure have been determined from fundamental biological studies, epidemiology studies on exposed human populations and by observing the results of exposure of humans to very high absorbed doses. Immediate effects are observed only after an exposure that is 100 to 1,000 times the exposure an individual will receive from the naturally occurring radiation sources in the living environment. The actual effect, which could be skin damage (burns), temporary or permanent sterilization, loss of hair, or in the extreme, death, will depend on the organs exposed and the absorbed dose received. Partial shielding of a sensitive organ such as bone marrow could significantly mitigate the resulting effect.

Long-term effects are more complex. The most serious of these appears to be cancer, which will be detected many years after exposure, if at all. Cellular changes that could lead to cancer have been detected in fundamental biological studies, but many of these cellular changes can be repaired or mitigated and therefore may not be expressed clinically. Other observed cellular changes following radiation exposure can produce an increased transient resistance to subsequent exposures to radiation. However, studies of radiation exposure in animals have shown that the incidence of cancer increases with absorbed dose in almost all cases. These studies expose the animals to radiation doses that are significantly higher than the exposure an individual could receive from the naturally occurring radiation sources in the living environment.

Studies of radiation effects on human populations at absorbed doses similar to those received from naturally occurring radiation sources ("normal" exposure) are much more difficult to perform and less conclusive. However, epidemiologic studies on human populations that have received exposures ranging from 30 to 1,000 times "normal" exposures reveal an increase in cancer mortality with increasing radiation dose. This increase can be described as linear until the dose is very high, but the uncertainty is large and increases as the dose becomes smaller. At the lowest doses the probability for observing excess cancer includes zero (i.e., there may be no observed cancer related to a radiation dose that is as much as 30 times the "normal" exposure).

When excess cancer can be observed and related to radiation exposure, the dependence on absorbed dose depends on the organ in which the cancer appears. Some organs, such as the active (red) bone marrow, colon and lung, are about three times more sensitive than others, such as the bladder, liver and thyroid. Others such as brain, skin and kidneys are even less sensitive.

Radiation sensitivity also depends on the age of the individual at the time of exposure. Sensitivity to the effects of radiation exposure decreases with age. There is also a dependence on sex with females somewhat more sensitive than males overall. However, the sex dependence differs with the organ affected. Finally, there are also differences in radiation sensitivity among individuals and populations.

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, elimination of bias, and other physical and biological confounding factors. When a detailed analysis for a specific situation 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. ~~Within this framework, the Committee has used the available scientific information and its judgment to arrive at nominal detriment values and control values to be used in radiation protection.~~ These are expressed without uncertainty even though there are somewhat similar but alternative values which might have been chosen.

Comment [M13]: Cool edit

1.3.2 Epidemiologic Studies of Radiation Effects

The bulk of the scientific evidence used by the Committee in forming its judgments comes from epidemiologic studies supplemented by animal and cellular mechanistic studies. Well-designed epidemiologic studies are the gold standard for risk estimation because they provide direct information about effects on humans, but there are some well-recognized limitations and uncertainties.

1.3.2.1 Types of Studies. There are three main types of radiation effect epidemiologic studies. These vary in their strengths and weaknesses. The strongest type of study regarding causality 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. These studies may be done either prospectively or retrospectively. The Life Span Study of the atomic-bomb survivors is a cohort study. A "correlation" study is a particular type of cohort study that is based on data averaged over groups. A randomized control study is also a type of cohort study in which people are assigned at random to a group prior to a planned radiation exposure.

Comment [M14]: Miller ... Needs a reference to a recent LSS paper.

Boice

The second most common type of epidemiologic study is the "case-control" study. In this type of study, persons with some specified disease (such as cancer) are matched (for example for age and sex) with a set of persons who do not have the disease. The groups are then compared to assess differences in 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 disease. However, case-control studies are prone to more types of bias (e.g. recall

bias and investigation bias). Subtypes of the case-control studies include the "case-cohort" and "case-base" design.

The third type of study is the "ecological" study. 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 at the individual level it is the weakest type of study for determining causality, but it can be used to formulate hypotheses.

1.3.2.2 Limitations. All epidemiologic studies have limitations due to a number of factors. Biases result in conclusions that differ from the truth. Some examples are given:

- Follow-up bias: If not followed long enough, a population may not yet have developed the disease, resulting in the suggestion that the disease does not occur or occurs at a lower than true rate. Follow-up bias also occurs when exposed people move from the area without notifying the investigator. This type of bias can occur in both cohort and case-control studies.
- Ascertainment bias: Also known as selection bias this occurs when there is variation in ascertainment of disease with varying exposure levels. An example would be if more medical examinations occur in persons with higher exposures. Unless corrected this can bias the slope of the dose-response curve upwards. This type of bias also can occur in both cohort and case-control studies.
- Recall bias: This bias arises when information is collected retrospectively from individuals who have a disease they believe is due to radiation exposure. They may tend to "recall" more radiation exposures than those who do not have the disease. This is more common in case-control studies.

Comment [M15]: Cool edit

Confounding factors also limit the results and application of epidemiologic studies. As an example, confounding "by indication" can result when a person with early symptoms of a disease has a diagnostic radiation procedure and then later when the disease is actually diagnosed, it is erroneously attributed to the diagnostic exposure. Tobacco use is perhaps the most serious confounding factor as it is 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.

There are limitations on the statistical power of epidemiologic studies as a result of both dose level and sample size. Land et al. (1980)) pointed out that using the assumption of a linear association between radiation 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. Thus, assuming that a sample size of 1,000 is needed to detect an effect at an absorbed dose of 1 Gy, a sample size of 10,000,000 would be needed if the absorbed dose were 0.01 Gy. Consequently, for epidemiologic studies in the dose range of 0.01 to 0.1 Gy, a population of about a million persons is needed. It is clear that to demonstrate a radiation effect for doses in the normal (background) exposure range below 0.02 Gy would require epidemiologic studies involving several million exposed persons with suitable controls and

subject to similar risk factors who are followed for decades. This is virtually impossible to accomplish and statistically significant risk estimates in the very low dose range are not likely to be obtainable from epidemiologic studies. If the dose response is linear-quadratic and not linear, even larger population sizes would be needed.

1.4 Developing the System for Radiation Protection

The combination of differing responses in individuals together with the overall uncertainty in the risk of radiation effects in the low-dose range of "normal" exposure makes it difficult to develop a practical system of radiation protection that is applicable and consistent for all populations world-wide. The system for radiation protection that has been in place for almost 50 y was developed by ICRP and NCRP to protect people who might be exposed to radiation doses greater than those received from naturally occurring radiation sources ("normal" exposure). That system was designed to "prevent the occurrence of serious radiation-induced conditions (acute and chronic tissue reactions in exposed persons and to reduce stochastic effects in exposed persons to a degree that is appropriate in relation to the benefits to the individual and to society from the activities that generate such exposures" (NCRP, 1993a). From the results of the many epidemiologic studies that have been conducted in the past 50 y, this expectation for the radiation protection system has, in a general sense, been achieved.

The Committee also realizes that while there may be small changes in estimates of risk from those given in prior NCRP reports, if these new changes fall within a small percentage of total uncertainty, as a precaution, it may be better to continue with current values thereby minimizing disruption of the current radiation protection system. Alternatively, if new significantly changed risks are estimated then new values for radiation risk and detriment should be recommended regardless of the consequence of substantial or disruptive changes in the current system.

Comment [M16]: Fleming edit

As explained by ICRP in its most recent recommendations on radiological protection (ICRP, 2007a) the system of protection takes into account the uncertainties and differences in response to radiation exposure as discussed above. In view of the uncertainties in both the absorbed dose response and the estimate of detriment, primarily resulting from cancer induction, it is appropriate for radiation protection purposes to use age- and sex-averaged tissue response factors and numerical risk estimates. In addition, the ICRP and NCRP agree that the linear non-threshold model remains a prudent basis for radiation protection at low doses and low dose rates, an approach supported by the precautionary principle (Section 3.1). However, for NCRP this does not imply that a linear dose response is the correct biological model to describe the induction of all malignant tumors or other stochastic effects. For practical purposes a linear model is the only way to add doses received at different times and using different dose quantities. This is necessary for the prospective system of protection as constructed and allows the system of protection to be sufficiently robust to achieve adequate protection for all ages and both sexes.

Comment [M17]: Fleming edit

1.5 The Basis and Structure of the System for Radiation Protection

Because of the variety of radiation exposure situations and of the need to achieve a consistency across a wide range of applications, the Council has now adopted a formal system of radiation

protection aimed at encouraging a structured and feasible approach to protection. The NCRP System has to deal with a number of sources of exposure, some that are already in place, and others that may be introduced deliberately as a matter of choice by society or as a result of emergencies. These sources may be linked by a variety of interconnected events and situations leading to exposure of individuals, groups, or entire populations, both in the present and in the future. The NCRP System has been developed to allow this complex network to be treated within a logical structure.

The NCRP System has 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; it also encompasses our knowledge of advanced biology and mechanistic studies of radiation effects at the molecular and cellular levels. As described in Section 1.2 comprehensive studies in the radiation-effects literature describe short-term and late-term adverse tissue reactions as well as late-term stochastic effects (cancer and hereditary changes). For adverse tissue reactions, important information is available from controlled experimental studies in animals. 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 detailed epidemiology of radiation effects on Hiroshima and Nagasaki atomic-bomb survivors provides the principal risk coefficient data on which current standards for radiation protection are based. The NCRP System accommodates potential exposures from both external sources and internally deposited radionuclides. It accounts for environmental exposures, emergency exposures, workplace exposures, and medically administered radiation.

Protection against the harmful effects of radiation requires a well-defined, coherent system of quantities and units. The fundamental unit for dosimetry is the organ or tissue absorbed dose. Weighting factors applied to absorbed dose yield equivalent dose and effective dose as measures of stochastic risk. In view of uncertainties associated with the assigned values of tissue weighting factors and risk coefficients used to define overall health detriment, The NCRP System has incorporated age- and sex-averaged tissue weighting factors and numerical risk coefficients. The basic protection criteria are sufficiently robust to protect both males and females (Figure 1.1). Further refinements have been applied to protect the developing embryo and fetus.

The doubly weighted unit of effective dose may be applied for radiation protection purposes (exposure controls, criteria, and secondary criteria for measurable quantities such as ~~setting primary dose criteria and assigning secondary restrictions on~~ radionuclide concentrations in air and water), but, as a caution, is not defined as a reliable measure for estimating future cancer risk.

Comment [M18]: Cool edit

Comment [M19]: Fleming edit

1.6 Summary

There are four important points about the design and use of recommended protection values and their associated underlying scientific uncertainties.

1) The power and statistical significance of epidemiologic studies depends upon the size of the studied population, the risk of the radiogenic effect, the background or spontaneous rate of the effect and a range of confounding factors. Cancer incidence has been shown to be clearly increased in a general population at absorbed doses greater than about 100 mGy. At lower doses and dose rates the dose response is not clearly defined by epidemiologic studies. *Ad ignoratium* is~~f~~ avoided by realizing that at very low doses, ~~At very low doses,~~ absence of a finding of an increase in cancer does not mean that there is no risk, nor does it imply that there is a risk. Radiation protection programs must deal with dose levels below which there is no evidence of a statistically significant increase in cancer rates. Consequently, a model is needed to estimate the risk of cancer incidence as the radiation dose approaches the normal natural background dose. A number of radiation dose-response relationships can be supported by the results of studies using selective adverse outcomes. However, together with ICRP, NCRP continues to use the linear non-threshold model for the purpose of developing radiation protection recommendations for the general population.
2) The recommended radiation protection values provided in this Report do not constitute a threshold between "safe" and "unsafe." The risk of stochastic effects is the largest concern for public and occupational exposures. The proper understanding is that the probability of an effect increases with dose, but it does not have any relationship to a specific dose or control level.
3) Even though there are specific recommended values for individual dose criteria for optimization and control, a radiation protection system cannot be rigid. It needs to provide for some flexibility in application depending upon other factors and the current conditions (especially during emergencies).
4) The Council recognizes that there are uncertainties in multiplying a very low effective dose by a large number of individuals to estimate the number of radiation-induced adverse health effects in an exposed population. As a result, NCRP recommends against this practice.

However, for the purposes of retrospective evaluation of radiation related risks, such as in epidemiologic studies and retrospective risk analysis, it is appropriate to use sex- and age-specific data and calculate sex- and age-specific risks.

The following portions of the Report attempt to build on the above constructs.

For purposes of radiation protection it is useful to organize the exposures into various exposure situations, and among categories of individuals who receive the exposures. Section 2 explains the three exposure situations and three categories of exposure to which The NCRP System applies.

Section 3 discusses the ethical foundations (i.e., theories and principles) and philosophical considerations of moral significance that impact on The NCRP System. This discussion ~~Understanding the ethical foundation of The NCRP System~~ helps to ground specific claims about

Comment [PF20]: Fleming … Define this fallacy in the glossary

radiation protection in a widely adopted system of values that~~, in fact,~~ are believed to be held universally by members of disparate cultures. ~~This Report considers the ethical foundation for a system of radiation protection and identifies ethical theories and principles in which these values are embedded.~~

The NCRP System has been developed based upon scientific information on the effects of radiation, ethics, and expert opinion derived from experience with radiation sources and events. Ethicists have specified the theoretical underpinnings of the system of radiation protection (Gonzalez, 2011; Hansson, 2007). This Report provides a finer-grade approach in specifying the ethical principles which underlie justification, optimization (the ALARA principle) and dose limits (criteria).The national and international aspects of The NCRP System itself are specified in Section 4.

Protection against the harmful effects of radiation requires a well-defined, coherent system of quantities and units. Radiation protection quantities and units must be generally applicable to occupational, environmental, and medical exposure to ionizing radiation. In Section 5 the quantities and units used in The NCRP System are defined and briefly discussed.

Section 6 describes the potential adverse health outcomes from ionizing radiation. These include adverse tissue reactions, cancer and noncancer effects and adverse psycho-social effects.

The means for assessing the risk of radiation exposure and its health detriment are discussed in Section 7. ICRP has utilized the concept of health detriment as an expansion of the overall adverse health impact of radiation beyond cancer and noncancer risks. The calculation of detriment is complex and has a number of associated uncertainties and assumptions. Section 7 provides an overview of this concept and discusses NCRP's recommendations for its application in the recommended dose criteria.

Section 8 provides the NCRP's recommendations for controlling radiation exposure in the United States for specific situations.

Section 9 introduces and proposes an approach for screening dose criteria for nonhuman species below which no consideration is needed, and the protection of the environment for the United States. The principal aim is to provide both a factual basis and coherent ethic from which to establish a framework for an appropriate level of protection of the environment against the detrimental effects of radiation exposure. These recommendations are consistent with NCRP's other radiation protection recommendations in that they are intended to prevent the occurrence of adverse radiation-induced effects while still enabling those activities which provide benefit to society from such exposures. NCRP adopts an anthropocentric extensionism (Section 3.1) in its approach to protection of the environment, while supporting protection of the environment when the needs humans are not in conflict with those of the environment.

Finally, Section 10 provides guidance for effective communication of the NCRP recommendations in this Report to all stakeholders. Stakeholders in this context are defined as all parties that would have an interest in the recommendations. Suggestions for communication of

Comment [M21]: Fleming revisions

Comment [M22]: Fleming revisions

Comment [M23]: Fleming addition

MR … needs to be edited … currently is somewhat garbled

these recommendations to professionals, stakeholders, media, and the public are presented. Underlying this guidance ~~these suggestions~~ is the importance of enhancing a stakeholder's autonomy. The Council believes this topic is critical to the understanding, acceptance, and implementation of these recommendations.

References (Section 1)

ICRP, 2007a
Land et.al. (1980) (Science 1980. 209 (4462):1197-1203)
NCRP 1993a
Hansson, S, 2007
Gonzalez, A.J. (2011). The Argentine Approach to Radiation Safety: Its Ethical Basis, in Science and Technology of Nuclear Installations, Volume 2011, Article ID 910718, 15 pages http://dx.doi.org/10.1155/2011/910718, Review Article.

Comment [M24]: Cool edit

Comment [M25]: Fleming additions

2. Exposure Situations and Categories of Exposure

For purposes of radiation protection it is useful to organize exposures into various exposure situations, and categories based on the individuals who are receiving the exposures.

Recommendation: Three exposure situations, Planned, Emergency and Existing, be used as a general approach for applying The NCRP System.

Recommendation: Three categories of exposure, Occupational, Public, and Medical, be used as a method for identifying the individuals receiving exposures and the protection criteria to be applied.

2.1 Exposure Situations

An exposure situation is a circumstance by which a source of radiation, through various pathways, causes the exposure of an individual. Sources may be either radioactive materials, or machines which emit radiation, and may be of natural origin, or man-made. Protection of the individual can be achieved by taking action at the source, or at points in the exposure pathways, and occasionally by modifying the location or characteristics of the exposed individuals. The specific opportunities for protection depend upon the prevailing circumstances that exist for that situation.

As described in Sections 2.1.1, 2.1.2 and 2.1.3, three exposure situations can be used to describe radiation exposures, and are useful in organizing The NCRP System. This NCRP recommendation follows the recommendations of ICRP in Publication 103 (ICRP, 2007a). However, NCRP does not regard the boundaries defining these situations to be rigid demarcations. There may be occasions when the situation is not well defined and the application of The NCRP System must allow some flexibility for informed judgment.

2.1.1 Planned Exposure Situations

Planned Exposure Situations encompass all those instances in which the source of exposure is deliberately introduced into an individual's environment for some purpose, thereby causing exposure. Such situations are characterized by the fact that protection decisions can be made, at least in principle, before the introduction of the source, and protective actions may be taken on the source as well as the pathways leading to the exposure of the individual.

Planned Exposure Situations include all of the man-made uses of radioactive material and radiation, ranging from applications in power generation to industrial, academic, and medical uses. Naturally occurring radioactive materials may present a planned exposure situation, when the material is obtained, processed, and used with forethought to accomplish some particular purpose. In this case, the process and disposition of the materials would be planned in advance, just as with any other radioactive material.

2.1.2 Emergency Exposure Situations

Emergency Exposure Situations are those in which a source of exposure is suddenly present in an individual's environment, and the levels of exposure warrant urgent actions to achieve the objectives of radiation protection. This is the case in an accident or malicious event, and is often characterized by the fact that the source is not well understood, may be rapidly changing, and is not under any controls. In an emergency, there may be only limited means to take any protective actions based on modifying the source, and protection is based upon controls that may be placed on individuals.

2.1.3 Existing Exposure Situations

Existing Exposure Situations are so named because the source of exposure, often of natural origin, but occasionally as a result of previous human activities or events, exists in the individual's environment, and through various pathways causes exposure. Such situations are characterized by the fact that the source was not intentionally introduced for some purpose, that there may be limited means to take any protective actions based on modifying the source itself, and that the levels of exposure do not warrant urgent actions to achieve the objectives of radiation protection (otherwise the situation would be considered an emergency).

Existing Exposure Situations include, in general terms, both natural background in the human environment, and residual contamination that may be present in the environment due to past activities, including those from accidents or previously controlled activities that were not properly remediated. From a radiation protection standpoint, once the situation is recognized and characterized, actions can be undertaken to reduce exposures. Depending on the circumstances, actions make take a short or a very long period of time. An example of a short time period would be the recognition of excessive radon in a home, which can often be significantly reduced by various abatement technologies. Long time periods may be needed for remediation of large areas of contamination, and radiation protection may be heavily dependent upon development of awareness and actions on the part of the individuals themselves. Further, the level of individual exposures may be highly variable, and some levels may be greater than the nominal expectation for individual dose restriction when radiation protection actions are first considered.

2.2 Categories of Exposure

2.2.1 Occupational Exposure

Occupational exposure involves the exposure of individuals in the course of their work. Occupational exposure does not include exposure to medical procedures as a patient, research subject, or comforter or caregiver, nor exposure to naturally occurring radioactive materials outside of the work environment. 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 workers' employer to have responsibility for exercising controls. Occupational exposure can occur in any of the exposure situations, and needs to be treated appropriately in

each circumstance. In some cases, for example in the early phases of an emergency exposure situation, responders, whether or not normally occupationally exposed, are likely to be faced with radiation and other hazards that are much different from those usually expected in their usual work environment. The radiation protection criteria for occupational exposure are described in Section 8.

2.2.2 Public Exposure

Public exposure comprises any exposure of individuals outside of the described occupational and medical categories. Public exposure can occur in all three of the exposure situations. Further, individuals who would be considered as occupationally exposed at their work place, would be considered to be publically exposed at other times. The radiation protection criteria for various aspects of public exposure are described in Section 8.

2.2.3 Medical Exposure

Medical exposures of patients are dealt with separately in The NCRP System because the planned exposure for purposes of diagnosis or therapy of disease provides a direct benefit to the individual exposed. NCRP also uses the category of medical exposure to cover those individuals who may voluntarily be participating in research that results in their exposure to radiation, and to individuals who may be engaged in the comfort and care of a patient who has received radioactive material. 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. The radiation protection criteria for medical exposure are described in Section 8.

Reference (Section 2)

ICRP (2007a). International Commission on Radiological Protection. Recommendations of the ICRP, ICRP Publication 103, Ann. ICRP 37(2–4) (Elsevier, New York).

3. The Ethical Foundations of the System for Radiation Protection (as of 2-28-16) (Additional comments received from CC 1 members since 2-28-16 are under review)

Understanding the ethical foundation of The NCRP System helps to ground specific claims about radiation protection in a widely adopted system of values~~, ones that, in fact, are believed to be held universally by members of disparate cultures~~. Like ICRP (1959), NCRP mentioned early on the need for an ethical approach to radiation protection (Taylor, 1957). More recently, we see this commitment to ethical~~s~~ considerations in such matters as radiation risk for astronauts (NCRP Report No. 167), spaceflights to Mars (NCRP Commentary 23), treatment of human subjects of research using radiation (SC 4-7), and protection of the environment (XXX).

Section 3 considers the ethical foundation for a system of radiation protection. Such considerations provide transparency about the values which underlie such a system, they identify ethical theories and principles in which these values are embedded and they clarify the ethical duties associated with such protection. .

The ethical components of The NCRP System included a set of interrelated components comprised of moral significance, ethical theory and specific renditions of those theories, and key ethical principles and the principles.

3.1 Moral Significance

While much of this Report deals with how and whether radiation protection is possible, questions about who and what should be protected are paramount, particularly as more attention is being paid to repercussions of human activity on the environment. Radiation protection is normally thought to apply to humans and, by extension, to the environment in which humans reside. Is this approach adequate? Does it include fetuses and future generations or only those humans presently living? If inadequate in protecting the environment, should it be revised to do so, thereby extending to nonhuman but sentient species, such as mammals, birds, insects and fish? Or, should it also include non-sentient entities such as rock bodies, forests, deserts, and bodies of water? Does any direct ethical relationship exist between humans and the natural environment? Answers have been given to these questions based on certain assumption about whom to accord moral significance, paralleling the concept of legal standing which answers the question, "to whom or what does the law apply?" To whom or what does a system of radiation protection apply?

3.1.1 Anthropocentrism

The claim that only humans have moral significance is based on their capability to think and to choose. This view does not ignore the environment, including sentient species and non-sentient entities, in considering the effects of radiation. However, the justification of any concerns is rooted in human needs and interests. Ethical concern for deleterious effects to the environment and the biota therein, is based on the value that currently-living humans place on them. ~~Humans are viewed as stewards of nature.~~

3.1.2 Anthropomorphic Extensionism

Comment [M26]: Andersen – At this point, I don't have any specific comments on this section as written –which is very informative. My suggestion is that it be moved to an appendix in the report and/or captured in a separate NCRP document to serve as background and a reference for a more succinct statement of NCRP's view on the appropriate ethical foundations or principles for radiation protection.

MR … see also Adelstein comments at 3.1.1 to .3.1.3, and at 3.2 to 3.2.2.

Fleming/Kase

Comment [M27]: Shows a number of Fleming edits (4-10-16) throughout Section 3

Comment [M28]: Fleming … K. Higley would know if something exists in NCRP publications that appeals to environmental ethics

Higley

Arguments are offered to extend the reach of moral significance backward to unborn fetuses and forward to future generations based on either the needs and interests of currently-living humans (e.g., their desire to bond, to care for their lineage) or on the fact that they are already human (fetuses) or will ~~likely~~ be human (future generations). This is an anthropocentric extensionism. Whether extended beyond existing humans or not, the anthropocentric view claims that humans have ethical duties *regarding* the natural world but not directly *to* the natural world (Desjardins, XXXX).

Comment [AA(29)]: Ansari … Do we need this qualifier?

Fleming … No, it is removed.

~~Non-anthropomorphic extensions of ethics emerged in the last century although some will date it back to the Stoics. Ethicists differ as to whether moral significance should be aligned so narrowly with humans. Some reason that other sentient beings should be taken into consideration because those beings can experience pleasure and pain. This viewed has informed the belief that nonhuman animals have rights which need protection by humans (Reagan, XXXX). Another view is based in interests. Being sentient, nonhuman animals are capable of having interests. To only protect human interests and not the interest of these creatures to avoid pain is described as speciesism (Singer, XXXX).~~

3.1.2 Biocentrism

Non-anthropomorphic extensions of ethics emerged in the last century although some will date them back to the Stoics. Some ethicists point to the limits of anthropocentric extensionism (e.g., that it favors beings that are like humans, that it fails to consider the concerns that are beyond individuals, such as systems and their interconnectedness, and it is not a comprehensive ethic). While biocentricism extends moral standing beyond animals to all living beings it does so through a systematic environmental philosophy, that accounts for more than ethical considerations and considers what has *value*. The value of living beings is not only instrumental but also intrinsic. ~~The biocentrist asserts that all living entities has intrinsic value. Unexplored landscapes and living beings hidden to human view are valued whether or not they are useful to humans. This biocentricism values not only any living being's needs and interests but also the fact the living beings have an objective good of their own or, in Paul Taylor's words "are teleological centers of life (Taylor, 1986).~~ This gives living beings inherent worth. Unexplored landscapes and living beings hidden to human view are valued whether or not they are useful to humans. On this view, radiation protection should extend to all living beings; humans have duties *to* them not just *regarding* them (Desjardins, XXXX). Also, on this view, the protection of certain biota may trump the interest of humans.

3.1.3 Ecocentrism

Still others argue that holding the capacity to reason, and the ability to experience pain and pleasure is too anthropocentric~~antrhropocentrie~~. In addition, having an objective good of one's own is limited to living beings. There are aspects of natural world which may not have a good of their own but are interconnected to an ecology that must be protected. Ecocentrists argue that ~~it is~~ the ecological whole that should be the basis of value and concomitantly the basis of our ethical duties. Both anthropocentrism and biocentrism needs to be replaced with an ecocentrism

that values the interconnectedness of the whole. We have duties, on this view, not only to living beings but also to nonliving natural objects and ecological systems. ~~Biocentrists often, according to this view, literally fail to see the forest for the trees.~~ Wetlands, prairies, and rivers ~~is~~are valuable in ~~its~~ their own right and should be accorded ~~desires~~ moral consideration (Desjardins, XXXX). The Wilderness Act of 1964 to an extent represents ecocentrism. This view raises interesting challenges regarding radiation protection. This is a view that is increasingly common among stakeholders in the public. ~~including the very existence of background radiation. Using background radiation as a norm for radiation protection limits, borrows to some extent on ecocentrism.~~

~~It's fair to say that the~~ The NCRP System has been primarily constructed from ~~has implicitly adopted~~ an anthropocentric extensionism. ~~view.~~ It is prospective and considers fetuses among the populations it protects. The radiation community has long believed that standards for protection of humans often provide an adequate level of protection for nonhuman biota. Section 9 points out~~notes~~ that this view has been challenged, noting that there are circumstances where this is not the case.

~~However, r~~Rectifying the gap that exists because of the inadequacy of human-only based radiation standards need not necessarily commit one to biocentrism or ecocentrism. In fact, similar sets of duties may be deduced from all of them~~anthropocentrism, biocentrism, and ecocentrism~~. In other words, some consensus can be found among these views on moral standing.

At times ~~All of these positions on moral significance~~ one may consistently apply all these views to the protection of the environment. As individuals, we might sometimes act as moral pluralists using all these views in the attempt to fulfill our duties of radiation protection. Prudence may recommend that we do so.

However, among these differing views on moral significance, there are important differences~~will be a variety ofdiscriminations~~. For example, the extent of protection may differ. Stronger duties to all biota or the ecological whole than those required of anthropocentr~~ism~~ extensionism will exist. Resolution of conflicts created by competing needs for protection among humans, all biota, and the ecological whole may differ as well, resulting in human needs receiving higher or lower priority over other needs.

3.2 Ethical Theories~~Foundations~~ and Ethical ~~Theories~~Principles

Specific ethical theories about right and wrong generally can be categorized by one of three foundations: teleological, deontological, or virtue-based.

3.2.1 Ethical Theories

Teleological foundations refer to ends or purposes. For those that adopt this approach, consequences matter, hence the name "consequentialism." Utilitarianism (Bentham (XXX) Mill (XXX)) is grounded in the claim that the consequences of an action determine its ethical

Comment [M30]: Adelstein … One thing about the current version. I believe the emphasis on the moral dimension of radiation protection is important, But I am concerned with sections 3.1 and 3.2, which contain standard presentations on medical ethics. For those who are familiar with ethical principles, the sections are a bit text-book. Just as we do not present the principles of health physics to readers of this report, we might assume readers (at least some of them) do not have to be instructed in medical ethics. On the other hand, I appreciate that others will not be familiar with the material. So, my recommendation is to put the text noted here into an appendix or, at least, put the terms such as anthropocentric, biocentric, ecocentric etc. into a glossary.

Fleming … This should primarily be a Council decision. In almost every committee I have served on for the NCRP this same issue arises, i.e. where to put the ethics. at the beginning, at the end, or in an appendix. In all cases it has remained in the body of the text. These views of moral significance are generally not known. They are not treated in medical ethics.

Comment [DLM31]: Miller We should state explicitly what view we have adopted, without qualification ("It's fair to say…").

Fleming

Comment [M32]: Cool edit

Comment [M33]: MR … something was missing here, should "one" or some other word be added?

Comment [AA(34)]: Ansari … Should this word be "Principles"? Below discussion is about ethical foundations and ethical principles

Fleming.

permissibility The principle of utility, ("Actions are right in proportion as they tend to promote happiness," Mill, p. 55) when applied to a situation (or rule) will help us know what is right or wrong. ~~Natural Law is another teleological view that uses ends or purpose to establish right from wrong (Aquinas, XXXX).~~

Deontology (root "deon", meaning duty) emphasizes the determination of one's duties without referring to consequences. Immanuel Kant, anticipating the use of consequences as the determiner of right and wrong, argued that ethical duties should not be based in hypothetical imperatives. Rather, a categorical imperative determines our duties. "Respect persons as an end only, never as a means" is one accessible formulation of the categorical imperative. Kant relied on logic to help sort out the foundation for ethics. He claimed that one would never will for another what one would not will for oneself (e.g., one would not be willing to impose extreme harm on another since he or she would not be willing to have extreme harm imposed on themselves).

~~**3.2.1** Virtue~~

A virtue-based approach to the ethics, found prominently in the work of Aristotle (Aristotle, Nicomachean Ethics, XXXX) and given a rebirth in modern times, is less inclined to create rules and instead emphasizes a way of being or living. Virtuous behavior involves living in the mean and not at the extremes. As noted below, the virtue of prudence leads to precautionary actions.

3.2.2 Ethical Principles

Ethical principles allow us to note important differences among values and they also aid in identifying ethical duties. Principles are not merely descriptive of value differences. They are prescriptive statements about which values we should or *should* or *ought* to hold. Curiously, both deontological (Kant, 1785) and teleological (Mill, 1879) foundations may support the same ethical principles. When they are applied, however, they will sometimes support differ duties regarding the same event.

One helpful approach focuses on four ethical principles (Beauchamp and Childress, 2012):

1. Provide good (beneficence): The value expressed is that of well-being.
2. Prevent harm (non-maleficence): This value expressed is protection and the duty to refrain from causing a loss.
3. Respect an individual's autonomy (autonomy): the value expressed is freedom or liberty of action and our duty to not interfere in another's self-determination.
4. Act fairly (justice): The value expressed is fairness and the duty to ensure equity (not merely equality).

Three of these principles were used in the Belmont Report (DHHS, 1979) in addressing ethical issues in research on human subjects. Non-maleficence, a fourth principle, was subsumed under beneficence in that document.

A fifth principle, the precautionary principle, has been introduced into the parlance of radiation protection, notably by the European Union and internal law and is taken up by the ICRP. ~~(i.e~~

Comment [DLM35]: Miller … I have to say that this is not at all clear to me.

Fleming … Does the e.g. help?

Comment [AA(36]: Ansari … We probably don't need to make this a separate subsection. For the other two ethical foundations discussed above, teleogical and deontological, we didn' break the text into subsections.

Fleming

Comment [M37]: Fleming … need an example here

Fleming

The principle states that, in the face of significant uncertainty or ignorance about the extent of a harm, one should act in just a way that the public should be afforded greater protection from exposure to the harm. Sound evidence can ameliorate this duty but in the meantime, precaution should be taken and protections should not be relaxed.

In ethical thought, precaution is a form of prudence in the exercise of practical wisdom (Aristotle Nicomachean Ethics XX). It has been abstracted into a principle by those who invoke it as a guide. Being practically wise comes from the experience of making difficult decisions on practical matters. It is often described as more art than science.

These principles are normally thought to be non-reducible. Autonomy is not merely a form of non-maleficence, since a consequence of respecting autonomy could result in harming self or others. Non-maleficence involves preventing harm, whereas beneficence emphasizes providing a good. In order to provide good, one might, indeed, need to allow harm to occur, whether or not they are balanced against each other. Those who collapse the differences among these principles run into difficulty when their distinction makes the difference in realizing right and wrong in a particular situation.

Furthermore, these ~~four~~ five principles may sometimes conflict. In those cases, a ranking needs to be established. Individuals and groups may differ on which principle or duty outweighs another (NCRP, 2010a). Ethical disagreements are resolved between parties when they realize they share the same values. Nevertheless, individuals and groups may differ on fundamental values or on the weight to be placed on the ethical duties these values represent. They may disagree not only with respect to how to fulfill ones duties but also to whom and what, depending on moral significance as noted above, those duties apply. Resolving these differences can be difficult because it is often the case that the *weight* one puts on a principle's role in relation to another can be relative to the values of the culture with which one associates. In the United States, for example, autonomy as expressed in self-determination often holds sway over other principles. Yet~~, in its subcultures,~~ non-maleficence may outweigh autonomy (employers are required to protect workers~~versus workers~~). The precautionary principle has taken hold in the European community. Determining which ethical principle properly guides the choice of alternative courses of action can be quite challenging.

~~A fifth principle has been introduced into the parlance of radiation protection, notably by the ICRP (i.e., the precautionary principle). "The precautionary principle or precautionary approach to risk management states that if an action or policy has a suspected risk of causing harm to the public or to the environment, in the absence of scientific consensus that the action or policy is not harmful, the burden of proof that it is *not* harmful falls on those taking an action." (Wikipedia, https://en.wikipedia.org/wiki/Precautionary_principle)~~

~~The principle states that, in the face of significant uncertainty or ignorance about the extent of a harm, one should act in just a way that the public should be afforded greater protection from exposure to the harm. Sound evidence can ameliorate this duty but in the meantime, precaution should be taken and protections should not be relaxed.~~

Comment [DLM38]: Miller … In whose subcultures? The nation's?

Fleming

Comment [M39]: Cool edit

Comment [M40]: Miller … The precautionary principle needs to be stated and explained. Also, it is in international and EU law, not just ICRP recommendations, and applies to much besides radiation protection.

COMMUNICATION FROM THE COMMISSION on the precautionary principle. COMMISSION OF THE EUROPEAN COMMUNITIES. Brussels, 2.2.2000 COM(2000) 1 final.

(I have a PDF.)

Fleming

~~In ethical thought, precaution may be a form of prudence or state of practical wisdom, in this case, between the extremes (Aristotle Nicomachean Ethics XX). It has been abstracted into a principle by those who invoke it as a guide. Prudence is abstracted from prudential judgment or phronesis. Being prudent comes with the experience of making difficult decisions on practical matters. It is described as more art than science.~~

3.2.3 Ethics and the Fundamental Principles of Radiation Protection

Not all principles to which members of the radiation community appeal are principles of ethics. The international and U.S. radiation protection communities have established three principles of radiation protection. Kase notes that historically "…the fundamental principles of justification, optimization, and dose limitation as initially stated in ICRP Publication 26 have been adopted and applied by the NCRP in its recommendations (NCRP, 1993a). ICRP and NCRP recommendations on dose limitation for the general public and for occupationally exposed individuals are based on the same analyses of radiation risk, and, while similar, there are differences reflecting the aspects of radiation application and exposure circumstances unique to the United States" (Kase, 2004).

These radiation protection principles function as norms of practice. They do express commitments to certain values and to the relationship among the values. As norms of practice they clarify for the radiation protection community the weight to be placed on some values over others. While not identical to norms of practice, the ethical principles mentioned above ~~can be detected as underlying~~underlie these ~~norms of practice~~radiation protection principles. Ethicists have explored the relationship between the major ethical theories mentioned above and justification, optimization (the ALARA principle), and dose limitation (criteria) (Gonzalez, 2011; Hansson, 2007). In Section 4 a different analysis is offered, one that closely examines these norms of practice, demonstrating ~~at the same time~~ their ties to the ethical principles mentioned in this section.

Comment [M41]: Adelstein … One thing about the current version. I believe the emphasis on the moral dimension of radiation protection is important, But I am concerned with sections 3.1 and 3.2, which contain standard presentations on medical ethics. For those who are familiar with ethical principles, the sections are a bit text-book. Just as we do not present the principles of health physics to readers of this report, we might assume readers (at least some of them) do not have to be instructed in medical ethics. On the other hand, I appreciate that others will not be familiar with the material. So, my recommendation is to put the text noted here into an appendix or, at least, put the terms such as anthropocentric, biocentric, ecocentric etc. into a glossary.

Fleming

Comment [KK42]: Cool
This is confusing. What do we mean by "detected"

Fleming

Comment [M43]: Cool edit

Formatted: Highlight

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SC 4-7
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Comment [M44]: MR … Need to check and complete the references

Fleming

Comment [M45]: Fleming … K. Higley would know if something exists in NCRP publications that appeals to environmental ethics

Higley

Comment [M46]: Not yet cited in the text

Comment [M47]: Fleming additions

4. The NCRP System for Radiation Protection

Recommendation: Use a system of protection to control exposure to radiation and radioactive materials to ensure adequate protection of people and the environment while allowing for activities that are beneficial for human development.

The NCRP System has been developed based upon scientific information on the effects of radiation, ethics, and expert opinion derived from experience with radiation sources and events. The NCRP System is composed of a set of interrelated components comprising the principles of protection (Sections 4.1, 4.2 and 4.3), exposure situations (Section 2), categories of exposures (Section 2), and key requisites for implementation (Section 8).

Recommendation: Apply the principles of justification, optimization (the ALARA principle), and restriction of individual dose in all exposure situations.

The three principles of protection, namely justification, optimization (the ALARA principle), and restriction of individual dose, provide a coherent and systematic approach to addressing exposure. The principles of radiation protection are applicable in each of the exposure situations, and can be applied in essentially the same manner in any situation, except for exposure to patients during imaging and radiation therapy procedures. Specifically, it must first be determined that taking action(s) is justified, and then protection should be optimized within appropriate dose criteria for individual exposure. Decisions in a particular circumstance will involve decisions that may need to weigh the ethical principles described in Section 3, and are best taken with the involvement of stakeholders. Implementation then relies upon the use of a set of requisites, including assessment of the exposure, accountability for protection, transparency in communications regarding the exposure, and inclusiveness of all relevant stakeholders. Each radiation protection principle is described in the following sections.

4.1 Justification

Recommendation: Any action to add, increase, reduce, or remove a source of exposure to people or the environment be justified.

Recommendation: All factors, both radiologic and nonradiologic, and particularly the economic, social and psychological implications, be included in the justification ~~and understanding~~ of the implications of an action.

Comment [M48]: Fleming … I suggest we keep the focus on justification

The principle of justification of radiation exposure requires benefits of taking action to outweigh the harm that may result from the action. This means taking an informed decision, at an appropriate decision-making level, that the benefit gained by the introduction or removal of the source, action on exposure pathways, and action on individuals is, overall, beneficial [i.e., whether the benefits to individuals and to society outweigh the resulting harm (including radiation detriment)].

Two ethical principles discussed in Section 3 are key in decisions on justification. ~~It is supported by the principle of~~ non-maleficence and ~~the principle of~~ beneficence, with the latter outweighing the former, insofar as the benefit created must exceed any harms that may result.

Comment [M49]: Fleming edits

The principle of justice also comes into play, in that there should be a commitment to ensuring that benefits be fairly distributed or, minimally, that harms be equitably shared. However, the principle of justification does not guarantee justice plays the primary role. When considering benefits and harm, consideration must 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 benefits and harm, which include social 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 nonradiological impacts. Except in medical patient exposure, the radiation exposure to an individual would be considered a potential harm; however, there may be other nonradiological hazards that would cause harm that significantly outweigh the radiation exposure. Benefits may accrue in various ways, such as economic benefits of working at a particular job, assurance that a piece of equipment will function as intended by verifying integrity through nondestructive testing, or receiving safe and reliable supply of goods such as energy or sterilized medical products. Another important consideration is the social and psychological implications of exposure, such as stress, disruption, and stigma directed as those exposed. While difficult to consider, these factors must be included in deciding what the appropriate course of action might be. Thus it is particularly important to involve relevant stakeholders and interested parties in the process of justification. Doing so ~~as to~~ respects the autonomy of individuals, and provide the most complete insights into the implications of taking an action.

Comment [M50]: Fleming edits

4.1.1 Addition or Removal of a Source

In a Planned Exposure Situation, the introduction of a new source of exposure can be considered before any exposures occur, and a determination made as to whether such an introduction is justified. For Emergency and Existing Exposure Situations, the decision is not whether to introduce the source, but rather to decide what should be done with a source that is causing exposure. Both occupational and public exposure to humans must be considered, as well as exposures in the environment that are in keeping with human interests. In each case, the decision is whether actions to reduce or eliminate the exposure have an overall beneficial effect, particularly in prevailing circumstances in which the actions may be hazardous to those performing them or significantly intrusive to individuals, society, or the environment. It is these types of decisions where the social and psychological factors play a particularly important role.

Comment [CD51]: Cool … Phrasing here will have to be aligned with Section on Environmental Exposure, and whatever term we use.

MR

Comment [M52]: Fleming edits

The range of options that are possible, particularly the degree to which action can be taken to control the source of exposure, will be broad when considering introduction of a new source. Further, decisions can be taken before the source is introduced, and can be fully implemented before any exposure occurs. All of these factors should be taken into account in deciding if the introduction of the source is justified. When the source of exposure is already existing and a decision is needed on radiation protection, there may be more limited options for control, and it may not be possible to exercise all controls on the source. When the source exists, and poses significant implications for individuals or the environment (an emergency), then decisions and actions must be taken urgently to ensure adequate radiation protection. Thus, it is important to

consider, and justify, when actions would be taken before emergencies occur in order to facilitate rapid actions to provide radiation protection.

4.1.2 Medical Exposure

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. Note that occupational and public exposure that may result from medical use of radiation are considered as if they were the addition of another source of exposure for individuals other than the patient.

The benefit-to-harm considerations in medical exposures are different from those used for occupational and public protection. 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.

There are three levels of justification of a radiologic 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 radiologic 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 characteristics 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. In this case, the principle of autonomy takes precedence over the principles of beneficence and non-maleficence. 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 benefits and harms, so emphasis should be placed on a full and complete interaction between the medical personnel and the patient to provide information and facilitate understanding of the implications of having, or not having, the examination or treatment. ICRP Publication 105 (paragraph 57) (ICRP, 2007b) notes that "The harm, more strictly the detriment, to be considered is not confined to that associated with the radiation; it includes other detriments and the economic and societal costs of the practice. Often, the radiation detriment will be only a small part of the total." NCRP recommends that 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 procedure. This determination will depend on the patient, the indication for the examination, and other factors (e.g., availability, local expertise, cost). These determinants should be considered separately. 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 procedure and should be used when applicable. Clinical decision support should ideally include an indication of the relative radiation exposure from the available imaging procedures.

Recommendation: 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 procedure.

Justification of screening examinations is a separate issue. There are situations where it is reasonable to protect patients from themselves with regard to patient-initiated screening examinations (also called individual health assessments), but that protection is principally medical (the consequences of false-positive, true-negative and false-negative examinations can be a deterioration in health) and economic (screening examinations cost money). Certain screening programs have been demonstrated to have significant clinical value. Criteria for selection of screening programs have been suggested in Europe by the Heads of the European Radiological Protection Competent Authorities (HERCA, 2012). Protecting individuals from excessive screening is supported by the primary exercise of the principle of non-maleficence and, depending on a patient's knowledge, may not really involve the secondary interference in the patient's autonomy.

4.2 Optimization (the ALARA Principle)

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

Optimization of protection is the process of determining what level of protection and safety makes exposures, and the probability and magnitude of potential exposures, as low as reasonably achievable (ALARA), economic and societal factors being taken into account (the ALARA principle). This means that the level of protection should be the best under the prevailing circumstances, maximizing the margin of benefit over harm. In order to avoid severely inequitable outcomes from this optimization process, there should be restrictions on the doses or risks to the individuals from a particular source. The term optimization is used internationally, and is adopted in these NCRP recommendations for the purposes of fostering a common framework and approach throughout the world. In all cases it refers to the application of the ALARA principle.

Optimization is clearly supported by the principle of non-maleficence. The expectation that radiation exposure should meet the ALARA principle is a direct appeal to prevent harm or the

risk of harm. Optimization is contextualized, however, by economic and societal 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.

Recommendation: Optimization be applied in all exposure situations when the potential dose to an individual exceeds the NID.

Optimization of protection is the key component of radiation protection in any exposure situation. Optimization should be applied in all exposure situations consistent with the individual dose criteria for optimization as stated in Section 8. In circumstances such as an Emergency or Existing Exposure Situation where individual exposure levels may be greater than ~~the~~ an appropriate individual dose criterion for ~~control,~~ optimization, actions would first seek to reduce these exposures, but then continue to reduce exposures using the ALARA principle. This is in contrast to previous paradigms where efforts were simply focused on reducing exposures below some intervention level. Thus the NCRP recommendation goes beyond previous recommendations, requiring optimization in all situations and circumstances.

Comment [M53]: Cool edit

4.2.1 Public

Optimization for public exposure is intended to reduce the exposure from a source to various members of the public. NCRP recognizes that optimization can only effectively be undertaken for a particular source that has an accountable party responsible for radiation protection. Account should be taken for other sources which may expose particular individuals in the selection of the relevant individual dose criteria (Section 4.3).

Exposures may take place via any pathway, including direct radiation, inhalation and ingestion. Sources in Planned Exposure Situations should be controlled at the source, reducing direct radiation and the release of effluents, and not be directly dependent upon actions of the individuals. For Emergency and Existing Exposure Situations, it may not be possible to take actions directly on the source, such as the wide distribution of deposited radionuclides on the ground. Actions may, however, be possible on some of the pathways, such as food and water, and upon the location and habits of individuals.

Comment [M54]: Cool edit

For many Existing Exposure Situations, the responsible individuals may be the exposed individuals themselves, such as in the case of radon exposure in the home. In this case, the individuals would be responsible for obtaining an assessment of radon in their home, and if necessary, for enlisting a qualified remediation contractor to consider the best options for effectively reducing the radon concentration.

4.2.2 Occupational

Optimization of protection for occupational exposure focuses upon workers in the particular circumstance, be it in Planned, Existing, or Emergency Exposure Situations. In theory, any individual at work will be receiving some exposure from natural background. To avoid

confusion, NCRP focuses its attention upon exposures from sources that are reasonably under the control of the individual's employer or the specific user of the source.

Optimization is to include all the contributions to the occupational exposure of the individual. Individuals are specifically identified, monitored as appropriate, and records of exposure can 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 to the lowest achievable level.

In many ongoing applications, optimization is simply the continuation of good radiation protection programs and practices which traditionally have been effective in keeping the average and individual exposures for monitored workers well below the limits (NCRP, 2009. Approaches employing quantitative estimates of total radiation detriment and costs of protection have been developed by the ICRP (1983; 1990). ICRP has broadened the optimization concept to a multi-attribute consideration (ICRP, 2006). Application of these and other quantitative approaches to the making of decisions for meeting the ALARA principle have been presented in various NCRP reports.

The ALARA principle is also qualitative, and is fueled by a fundamental mindset of always asking the question about whether there are ways to improve protection. NCRP recognizes that there is a strong connection between a robust radiation protection program and effective use of the ALARA principle with concepts of safety culture which have emerged in recent years.

In Emergency and Existing Exposure Situations the ability to monitor and control exposure may be reduced. Nevertheless, every attempt should be made to characterize the working circumstances, and provide protection that meets the ALARA principle.

4.2.3 Medical

Optimization in a medical exposure of a patient has an entirely different purpose from optimization of occupational or public exposure. In medical exposure, the intention is to achieve the necessary diagnostic or therapeutic outcome, and thus the ALARA principle means as low as reasonably achievable to achieve the intended outcome, and is best described as management of the radiation dose to the patient to be commensurate with the medical purpose.

The medical purpose is to provide benefit to the patient, not merely to prevent harm, so beneficence may outweigh non-maleficence even though the exposure necessary in the medical context in order to achieve the benefit may be significantly greater than exposures in the nonmedical arena. Commensurability is sought, not with harms but with the medical purpose or the benefit.

Optimization is a multidisciplinary task involving the technologist, medical and health physicist, medical or dental practitioner, quality assurance and quality control committees and, to some extent, the equipment manufacturer and the professional radiologic societies. The objective is to design and use the equipment in such a way that an appropriate dose to obtain the desired image

Comment [PF55]: Fleming … Do we need to make it clear that this is not necessarily the cumulative dose an individual may have gotten but only the occupational exposure

Comment [M56]: MR … probably should give the references to the NCRP reports

Cool

or desired therapy is consistently achieved. NCRP Report No. 172 (NCRP, 2012a) provides specific recommendations for optimization of protection in imaging, and the use of diagnostic reference levels (DRLs) and achievable doses as a tool to optimize image quality and the radiation delivered to patients for imaging examinations. DRLs and achievable doses do not apply to radiation therapy. NCRP confirms the recommendations in NCRP (2012a):

Recommendation:
DRLs not be viewed as absolute determinants of appropriate use of medical radiation. Optimization must take into account both patient dose and clinical utility, based on image quality.
DRLs not be used for regulatory or commercial purposes or to establish legal standards of care.

DRLs and achievable doses are tools used to help reduce the risk of stochastic effects. Optimization of protection with respect to the risk of adverse tissue reactions, in particular from interventional medical procedures, was addressed in NCRP Report No. 168 (NCRP, 2010b) and Statement No. 11 (NCRP, 2014a). NCRP (2010b) emphasizes that the safe performance of fluoroscopically-guided interventional (FGI) procedures requires controlling radiation 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. NCRP (2014a) provides an administrative approach to managing radiation dose 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."

4.3 Restriction of Individual Dose

Recommendation: The dose to individuals be restricted by both dose criteria for optimization and dose criteria for control in specific exposure situations.

The radiation protection principle of restricting an individual's dose is fundamental and is intended to ensure adequate protection. It also is intended to ensure that optimization does not result in individuals or groups of individuals receiving an exposure that is inappropriate under the prevailing circumstances. Although historically the principle of limitation has been focused upon the definition of dose limits, the principle is, in fact, broader, and encompasses all individual dose criteria. This principle receives its support from the ethical principle of non-maleficence, placing a boundary on harm for a particular individual irrespective of the balancing of benefit, and from the principle of justice, to ensure that the distribution of doses in an optimized situation is equitable.

Although many factors may set restrictions on the range of options in an optimization process, from a radiation protection standpoint the most significant is the selection of an individual dose criterion for optimization that adequately protects the individual and which, from a protection

Comment [PF57]: Fleming … I find this connection of the second and third principle of radiation protection interesting. Is there ever the case that one might appeal to the third principle independently of the second. Another way of putting this is, "Is this third principle always subservient to optimization. What is there is a conflict between ALARA and individual dose limits?

standpoint, ought not to be exceeded in planning the protection strategy. In the United States, and internationally, a plethora of terms have been used to describe individual dose criteria, creating much discussion and confusion. NCRP believes it is better to focus on the specific use of individual dose criteria for optimization and individual dose criteria for control when specifying adequate protection in the exposure situation and prevailing circumstance, rather than the different terms that have been used or are being used in other recommendations, and by various users of radiation.

Restrictions take two general forms in these recommendations. First is the application of individual dose criteria in the optimization process to ensure an equitable outcome and to focus resources on individuals who are receiving the highest exposure. These will be referred to as the individual dose criteria for optimization, recognizing that ICRP has termed them constraints or reference levels depending on the exposure situation, that in the United States the Federal Guidance for Occupational Exposure uses the term Administrative Control Level, and that radiation source users employ a variety of terms such as "planning value". These individual dose criteria for optimization are established by the user or entity responsible for the source in the planning for protection. (NCRP recommendations for dose criteria are given in Section 8.) They are a guide to the process, and the numeric value should be set to challenge the system to improve safety. If the resultant doses are found to approach or be greater than the previously established individual dose criteria for optimization, this would be an indication that the protection strategies need to be examined, and changes considered. Exceeding the numerical value of the individual dose criteria for optimization should not be considered a violation. However, a regulatory authority may choose to require that the responsible entity establish such values, and to take certain actions, such as review of the program, as a part of the radiation control program. A regulatory authority may also choose to require that individual dose criteria for optimization be reviewed as part of the regulatory review process, to ensure that the broader goals of adequate protection are achieved.

Second is the application of individual dose criteria in the control process to restrict the dose to individuals living or working in a radiation environment that exceeds the normal ubiquitous radiation background. NCRP recommendations for individual dose criteria for control are given in Section 8 and define adequate protection for an individual in a specified exposure situation and prevailing circumstance. This form of restriction on individual dose has often been referred to as the dose limit. The term "dose limit" denotes a specific and absolute value of individual dose from all sources of exposure to that individual. Regulatory authorities establish dose limits as the basis for judging the adequacy of radiation protection for an individual and appropriate functioning of the radiation protection program to ensure adequate protection. From the standpoint of accountability and responsibility, exceeding the numerical value of a dose limit is automatically a violation. The NCRP leaves to regulatory authorities the prerogative to establish such values in regulations when appropriate.

NCRP believes that great care is needed in deciding what type of individual dose restriction is appropriate for a particular exposure situation and prevailing circumstance. The term dose limit has in too many cases been used in contexts when an individual dose criterion for optimization is the preferred approach to achieving protection. Likewise, various other terms have been used on

Comment [M58]: Ansari … We state (lines 1468 and 1490 of the PDF version) that our individual dose criteria for optimization is similar to "dose constraint" and criteria for control is somewhat analogous to "dose limit". One would expect then that criterion for optimization be less than criterion for control, and we would use the latter to restrict individual dose not the former.

Comment [PF59]: Fleming … Why is this not a violation of the third principle? See my earlier remarks.

Comment [M60]: Ansari … We state (lines 1468 and 1490 of the PDF version) that our individual dose criteria for optimization is similar to "dose constraint" and criteria for control is somewhat analogous to "dose limit". One would expect then that criterion for optimization be less than criterion for control, and we would use the latter to restrict individual dose not the former.

Comment [M61]: Cool edit

occasion when, in actuality, a dose limit is being imposed because exceeding the absolute value of dose constitutes a violation. This has caused confusion on the part of both regulatory agencies and entities using radiation, sometimes to the detriment of establishing a robust radiation protection program.

Recommendation: The phrase "individual dose criteria for optimization" be used in planning and design of a radiation protection program as a restriction in the process of optimization of protection.

Recommendation: The phrase "individual dose criteria for control" be used to establish a value for adequate protection in a particular exposure situation and prevailing circumstance.

4.3.1 Occupational

Individual dose criteria for optimization for occupationally exposed individuals are applied to specific identified individuals, and may be of the form of an annual value, or shorter time frames (including specific tasks or events) as may be appropriate for effective planning of radiation protection. It is often better to pursue optimization around certain tasks, in addition to looking at the overall optimization of protection for an individual.

Individual dose criteria for control for occupationally exposed individuals are applied to the doses received by specific identified individuals in their work environment. Comparison of doses received with the individual dose criteria for control provides an assessment of the effectiveness of the radiation protection program as well as providing a means for restricting individual doses. It is incumbent upon licensees, employers, and other responsible entities to provide proper 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 any exposure situation. As such, the use of dose criteria will dependent upon whether it is possible to have sound, ongoing controls, assessment, and recording of exposures. This will always be the case for Planned Exposure Situations, and may often be the case in Existing Exposure Situations. However, such prospective controls are often not available in Emergency Exposure Situations, and may not be available in some Existing Exposure Situations. In these cases, reliance must be placed on the ALARA principle guided by individual dose criteria that are appropriate for the prevailing circumstances.

4.3.2 Public

In a Planned Exposure Situation, a dose limit for a member of the public can only be established in the context of the contribution from particular licensee or other responsible entity because it is not possible to accurately account for all of the possible contributors of exposure to which any single individual may be exposed. For Emergency and Existing Exposure Situations, the concept

Comment [PF62]: Fleming … Without any consideration of cumulative doses, particularly for those members of the public whose occupation or natural environment or medical status suggests the other sources should be considered… is there another alternative, e .g the licensee and, if it is the case, the specific features of a environment, occupation, or medical status of the member of the public.

of a limit cannot be effectively applied in public exposure, and reliance should be placed upon the ALARA principle guided by individual dose criteria for optimization.

Individual dose criteria for optimization for members of the public are established by entities responsible for a source to ensure that the dose contributed from their activities meets the ALARA principle. In Planned Exposure Situations, the criteria should be established in advance and used in the planning and design of the radiation source control. Appropriate monitoring should be conducted to assure adequate protection within the individual dose criteria for control.

In an Emergency Exposure Situation, actions will need to be taken urgently to protect public health and safety, usually based on facility conditions or limited information. As such, the individual dose criteria for optimization must be established in advance, and can be later refined when assessments of dose can be made for the circumstances. Meanwhile, individual dose criteria for control should be applied to assure adequate radiation protection for the exposed individuals.

In Existing Exposure Situations, an assessment is needed of the potential exposures that may be received, or are being received by individuals. The individual dose criteria for optimization are used to guide application of the ALARA principle in planning and designing any remedial action. Individual dose criteria for control would be used to control access and to assure adequate protection for individuals accessing or residing in the affected area. Adjustment of these criteria during a remediation activity may be a rather long and continuous process, depending on the circumstances, as described in NCRP Report No. 175 (NCRP, 2014b).

In Emergency and Existing Exposure Situations, the numeric values of the individual dose criteria may be selected from within a relatively broad band of dose, as described in Section 8. Optimization to achieve the ALARA principle is to be pursued irrespective of whether the assessed individual doses are greater than or less than the established individual dose criteria for optimization, with priority being given to reducing exposures of any individuals that may be receiving doses greater than the individual dose criteria for control.

In public exposure, the individual dose criteria for optimization are generally not specific to any particular individual, and instead are applied to a representative individual, defined to be representative of the more highly-exposed individuals in the population (ICRP Publication 101) (ICRP, 2006). This term is the equivalent of, and replaces~~,~~ ~~'~~average member of the critical group~~'~~. ~~described in previous ICRP and NCRP recommendations~~.

4.3.3 Medical

Individual dose criteria for optimization take an entirely different form in the context of medical patient exposures. This is because the goal of optimization in medical exposure is to achieve the necessary diagnostic or therapeutic outcome while avoiding unnecessary radiation, and thus the ALARA principle means as low as reasonably achievable to achieve the intended clinical purpose. Medical exposures include exposures of patients in the course of their medical examination and treatment, exposure of individuals who may voluntarily take part in medical

Comment [PF63]: Fleming ... Optimization trumps the dose limit principle?

Comment [M64]: MR ... probably should give the references to the previous ICRP and NCRP reports

Cool

Comment [M65]: Cool edit

research, and exposure of individuals (other than those who are occupationally exposed) who are specifically engaged in the comfort or care of a patient (refer to SC 4-7 report when it is completed). The concept of a dose limit does not apply to medical exposures for patients undergoing diagnostic or therapeutic procedures. From an ethical perspective, in medical exposure beneficence is seen to outweigh non-maleficence, but is unlikely to outweigh autonomy.

Public and occupational exposure that may be concurrent with medical treatment is handled in accordance with the provisions described in Sections 4.3.1 and 4.3.2, respectively. For occupational exposure, NCRP Report 168 (NCRP, 2010a) provides recommendations for certain cohorts, such as those involved in certain 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 individual 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 an occupational dose limit. The recommendations in this Report reaffirm the recommendations in NCRP (2010a).

4.3.3.1 Imaging Procedures. An appropriate process for management of the risk of stochastic effects is the use of diagnostic reference levels (DRLs) and achievable doses NCRP supports the use of diagnostic reference levels (DRLs) and achievable doses as tools for optimization of protection and as guides to promoting safe practices (Brink and Miller, 2015; NCRP, 2012a; ICRP, 2007b). This Report reaffirms the recommendations in NCRP (2012a).

Screening imaging procedures are performed on asymptomatic patients and may be performed on multiple occasions. Against the benefit of early detection are the risk of radiation exposure, the adverse effects of true negative, false-negative and false-positive examinations, and the economic cost. A discussion of the nonradiation adverse effects of screening for breast cancer can be found in Lauby-Secretan et al. (2015). In order to optimize radiation exposure, particular care should be taken to monitor the output of radiologic devices used for screening, especially computed tomography (CT) scanners.

4.3.3.2 Radiation Oncology. Localized high absorbed doses of radiation are employed in treating some cancers and other diseases. Adverse tissue reactions and carcinogenic effects are expected and considered in the risk/benefit calculation. For radionuclide therapy, there is a concomitant whole or partial-body exposure. The resulting toxicity, generally to active bone marrow, often limits the administered activity. In addition, the exposure of caregivers and comforters needs to be taken into account when significant gamma rays escape from the body (NCRP, 1995; 2006a). As noted in Section 4.3.3, dose limits do not apply to radiation therapy treatments, and DRLs are not an appropriate means for optimization, since the intent is to deliver a tumoricidal dose to cancerous tissues.

Comment [JTB66]: Bushberg Insert reference to SC 4-7 NCRP Report when completed

MR

Comment [KK67]: Bushberg Define.

MR … check Report No. 172

References (Section 4)

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~~NCRP reports…. that give approaches to the making decisions for meeting the ALARA principle~~

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5. Quantities, Units, and Measurements

(This section is currently under further review)

5.1 Introduction

Radiation protection is a physical science. When a living organism is irradiated by external or internal radiation sources, discrete amounts of energy are imparted to organs and tissues of the body. The absorbed dose, or quantity of energy imparted per unit mass of an absorbing medium, may be measured or calculated. Radiation dose and dose rate are thus expressed using well-defined quantities and units.

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, and charged-particle recoil ions. Each radiation type differs spatially in localized energy deposition patterns produced and density of localized chemistry changes, such as formation 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- and double-strand DNA breaks. Radiations differ in their relative biological effectiveness (RBE) per unit of absorbed dose.

Biological systems may also vary widely in their response to a constant radiation absorbed dose. Tissue radiosensitivity differs among the organs in the body. Biological response may be expressed as whole-organ effects or cellular-level effects, as near-term adverse tissue reactions or as long-term late effects. The interpretation of dose and dose rate in terms of consequences or effects on living systems is a radiobiological science that takes localized energy depositions into account. The study of biological response to ionizing radiation requires rational systems for relating absorbed dose and absorbed dose rate to observed changes after radiation exposure. Thus, the foundational systems for expressing dose and dose-response relationships, dose-rate effects, and radiobiological responses must accommodate many different radiation types and qualities within a complex biological environment for general application to radiation protection.

Protection against the harmful effects of radiation requires a well-defined, coherent system of quantities and units. Radiation protection quantities and units must be generally applicable to occupational, environmental, and medical exposure to ionizing radiation. The radiation dose quantities and units appropriate for use in radiation protection are discussed in this Section.

5.2 Base Quantities

The concept of radiation dose incorporates the integral of all energy-deposition events within a defined volume over a specified period of time for a 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 density, tissue type and radiation sensitivity for a defined endpoint. The ability to determine, quantify, and express dose and dose rate for radiation exposure is fundamental to the science of radiation protection.

Comment [M68]: MR … I think this section needs to be replaced by a simpler version (like the section in Report No. 160) that simply states and defines only the quantities and units used in this Report. For now, I have just retained Darrell's text and the members comments.

The standard ICRP or other technical definitions would appear in the usual style NCRP Glossary.

Fisher … I disagree that this section should be deleted in favor of a simple glossary, because Section 5 is much more than a glossary. It stands as a complete section; it corrects errors and misperceptions, and provides updated clarification and notation for consistency with the evolving terminology, philosophy, notations and symbols used by ICRP. The issues are generally confusing among professionals, and among members of CC-1 (myself included!). THEREFORE, to sort things out, I have put in a substantial effort after many discussions with Wes Bolch (and others) to ensure that this NCRP Report is fully up-to-date. In radiation protection, there is considerable confusion, and some of this confusion is even reflected in your collective comments on the current draft.

MR … There should be a Section 5 (not deleted, but its content to be discussed), and there usually is a separate Glossary in NCRP reports of which brief definitions of quantities and units are only one set of entries.

Comment [M69]: Fisher … I have found a few key sentences from NCRP Report 155, especially well written, that I would like to borrow and incorporate into the current draft of Section 5. In revision, these would represent only minor changes to the current draft.

Comment [KK70]: Kase – I am not sure that this is the place for recommendations. I think that we must be clear that the quantities and units we present in Section 5 are the appropriate ones to use for radiation protection.

Cool
Do we have any recommendations?

5.2.1 Energy Imparted by Ionizing Radiation

Quanta of energy (ε) in definable amounts (joule) are deposited in matter by ionizing radiation when charged and uncharged ionizing particles interact with atoms and molecules in the absorbing medium. These energy depositions represent discrete ionization events.

5.2.2 Absorbed Dose

The basic unit of radiation energy deposition by ionizing radiation is absorbed dose $D(r_T)$ to an absorbing tissue or target region (T) due to radiation of type R ~~(r_T)~~. 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.

Comment [AA(71]:
Ansarai…
In NCRP 116 and ICRP 103, the notation D(T,R) is used. We should use the same notation to avoid confusion.

Kasel believe that Darrell is using the ICRU notation.

Since the actual amount of radiation energy imparted at the microscopic scale may be highly variable, due either to non-uniform distribution of radionuclides in tissues, or due to densely ionizing particle tracks, the definition of the absorbed dose is given as a point function, which allows for specification of dose in terms of spatial distributions and linear energy transfer. Thus, absorbed dose is the mean of all energy deposition events (ε/m) in specified microscopic target volumes (cells and cell nuclei).

In its simplest constitution, the absorbed dose $D(r_T) = \varepsilon/m$, where ε is the energy imparted to a specified target region and m is the mass of the absorbing medium. The units of absorbed dose are joule per kilogram (J kg^{-1}) in the International System of Units (SI), where the special name for the unit of absorbed dose is gray (Gy), and 1 Gy equals exactly 1.0 J kg^{-1}.

Absorbed dose is proportional to the number of ionization events in the target region, which is proportional to the amount of physical damage produced. Therefore, absorbed dose is directly relevant to observed organ, tissue, and tumor cell killing (immediate) effects. Absorbed dose may also be related to delayed effects, cumulative effects, and stochastic effects such as the probability of cancer induction as a function of dose.

5.2.3 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:

$$D(r_T, \tau) = \int_0^\tau \dot{D}(r_T, t)dt \qquad (5.1)$$

5.2.4 Exposure (External Radiation Fields)

Radiation detectors in air serve as surrogate measures of radiation exposure to persons or objects in the same radiation field; that is, the kerma or kerma rate for an absorbing material in free

space (such as a radiation detector) may be directly related to the kerma or kerma rate for another material (such as a living organism) for which it may not be convenient or possible to measure the radiation field directly. The concept of exposure has been used as a measure of the ability of photon (x-ray or gamma-ray) fields to ionize air molecules. Exposure is the term given to irradiation of matter in air by x rays or gamma rays, where exposure is the quotient of (the absolute value) of the total charge of the ions of one sign (+ or -) produced in air (Q, when all of the electrons liberated by photons in a defined volume of dry air are completely stopped in air, in coulombs, C) and the mass of the volume of air; thus $X = Q/m_{air}$ in units of C kg^{-1}.

The traditional unit of exposure is the roentgen (R), and of exposure rate is roentgen per hour (R h^{-1}), where 1 R = 2.58 x 10^{-4} C kg^{-1} (exactly). The SI unit is gray, where 1 R = 8.69 x 10^{-3} J kg^{-1} = 8.69 x 10^{-3} Gy (kerma in air).

5.2.5 Exposure Rate

Exposure rate is exposure per unit time, or $\dot{X} = \dot{Q}/m_{air}$ t (C kg^{-1} s^{-1}), for t in seconds or hours. Exposure rate meters used in radiation protection measure and display the exposure rate per unit time (commonly µR h^{-1}, mR h-1), or in units of a derived operational quantity based on an organ, tissue, or whole-body dose equivalent (µSv h^{-1}, mSv h^{-1}; see Section 5.4). The terms exposure and exposure rate do not apply to irradiation by charged particles or to radiation from internally deposited radionuclides.

5.3 Derived Quantities

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 end point, cellular-level repair mechanisms, and other modifying factors. Therefore, The NCRP System takes many such factors into account.

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. Derived quantities account for the relative biological effectiveness (RBE) 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.

5.3.1 Relative Biological Effectiveness

The relative biological effectiveness (RBE) of any given radiation may be compared to a reference radiation that produces the same level of response (by tissue and end point) per unit absorbed dose. By definition, the 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 = $D_{reference}/D_{test}$. Typical reference radiations are ^{60}Co gamma

rays and ~~200 or~~ 250 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. The RBE is commonly used in radiobiology research for comparing the effects from radiation of different qualities or energies. The RBE may also be used for radiation protection purposes when it is necessary to infer a radiation-weighted absorbed dose to an organ or tissue (Section 8.2.1).

5.3.2 Radiation Weighting Factors

In radiation protection, dimensionless weighting factors (w_R) may be assigned to radiations of different qualities and energies (such as 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 detriment produced by each for a constant radiation absorbed dose. Radiation weighting factors are used to derive the equivalent dose from the absorbed dose (averaged over an organ or tissue). Values of radiation weighting factor for charged particles and neutrons allow for differences in energy deposition among various radiations; the factors are set by committee relative to baseline for x- or gamma radiation ($w_R = 1.0$), apply only to stochastic effects, and usually represent conservative or upper limits on experimentally observed values. Radiation weighting factors should not be used to predict short-term tissue reactions, and should not be applied to individual subjects. Currently accepted radiation weighting factors for radiation protection were established by ICRP Publication 103 (ICRP, 2007a), and recommended values of w_R are given in Table 7.1.

5.3.3 Equivalent Dose

The equivalent dose $H(r_T, \tau)$ to an organ or tissue r_T is a derived radiation protection quantity for relating absorbed dose to the probability of a future stochastic radiation effect (cancer induction and hereditary changes, if any) in that organ or tissue. The equivalent dose represents the sum of all the contributions from radiations of different types $D_R(r_T, \tau)$ multiplied by their respective radiation qualities w_R:

$$H(r_T, \tau) = \sum_R W_R \, D_R(r_T, \tau) \qquad (5.2)$$

$$H_T = \sum_R w_R D_{T,R}$$

The units of equivalent dose are also joule per kilogram (J kg^{-1}), where the special name for the unit of equivalent dose is sievert (Sv), and 1 Sv equals exactly 1.0 J kg^{-1}. However, equivalent dose is not purely a physical quantity, but rather a surrogate of dose representing a numerical entity of radiation damage ~~risk~~ based on the physical quantity absorbed dose. In practice, the unit of equivalent dose should not be used to predict individual risk of cancer or hereditary effects in workers or medical patients. The concept of equivalent dose applies only to population group averages (reference models) for radiation protection planning, and not to individual subjects for risk assessment.

Comment [AA(72]: Ansari ... I think we should only list 250 kVp x rays here.

Fisher ... I agree that 200 kVp may be deleted as a reference radiation for RBE calculations.

Comment [M73]: Ansari ...This notation looks unnecessarily complicated.
We should use the same notation used in other NCRP reports and by ICRP.

Fisher ... Armin, please note that the symbols and nomenclature given are completely current with ICRP (ICRP has been evolving). ICRP has adopted these new symbols. The use of equations and notation has been reduced to the simplest forms (minimalism).

MR ... whatever we decide to use, the symbols need to be defined (i.e., r_T, and τ are not yet explained], and the source of this equation needs to be referenced, since this is not what is in ICRP Publications 103 or 110. Are these in later ICRP publications or in ICRP works-in-progress and not yet published? [see also Equation (5.3)]

Comment [M74]: MR ... this is the basic equation for equivalent dose given in ICRP Publications 103 and 110.

Comment [M75]: Cool edit

Since the radiation-weighting factors were developed only for stochastic effects, the equivalent dose is not applicable to tissue reactions, and equivalent dose should not be used for evaluating organ or tissue toxicity from radiation. Instead, the absorbed dose $D(r_T)$ is the quantity relevant for evaluating biological effects in tissue.

5.3.4 Tissue Weighting Factors

Organs and tissues vary in radiation sensitivity and propensity to undergo radiation-induced changes that could lead to cancer induction and hereditary effects. Tissue weighting factors (w_T) have been selected by committee (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 7.2).

Comment [AA(76]:
Ansari ... This should be just T not rt? The R is for type of radiation.

The tissue weighting factors (w_T) are independent of radiation quality, and apply only to population groups and not to individuals. The choice of tissue weighting factors as measures of relative detriment representing all population groups implies and acknowledges a high degree of uncertainty in the individual values for each organ or tissue.

The scientific basis for selecting tissue weighting factors is the observed cancer incidence among Japanese atomic-bomb survivors; thus, the organ and tissue weighting factors are stipulated only as a measure of relative cancer risk, and do not apply to short-term tissue reactions. The tissue weighting factors (w_T) consider the mortality and morbidity risks of cancer, the risk of severe hereditary effects for all generations, and the length of life lost due to these effects (Section 7), apportioned by organ or tissue.

The tissue weighting factors are used for calculating effective dose for radiation protection purposes and comparing an individual worker's dose against applicable protection criteria. The weighting factors apply to both external sources and internal emitters. The current practice is to apply age- and gender-averaged tissue weighting factors specified by the ICRP (2007a) that represent mean values for humans averaged over both sexes and all ages.

5.3.5 Effective Dose

Effective dose E is the quantity used in radiation protection for establishing individual dose criteria for workers and members of the general public exposed to radiation and radionuclide intakes. The units of effective dose E are joule per kilogram (J kg^{-1}), and the special named unit for effective dose is the sievert (Sv), where 1 Sv = 1.0 J kg^{-1}. However, the effective dose is merely a construct or surrogate of risk and not a purely physical quantity. Instead, effective dose represents an overall risk of observed detriment attributable to stochastic effects of radiation.

By definition, effective dose is a hypothetical, population-average construct, based on absorbed dose that is associated with biological response to organ equivalent dose weighted according to estimates of detriment from exposure to radiation or intake of radionuclides. The concept of

effective dose applies to groups of subjects (reference models) only, and does not apply specifically to any one individual.

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:

$$E = \sum_T W_T \left[\frac{H(r_T,\tau)^{male} + H(r_T,\tau)^{female}}{2}\right] \quad (5.3)$$

$$E = \sum_T w_T H_T$$

Since effective dose is not directly predictive of cancer incidence in a particular individual, values of effective dose should not be used to estimate future cancer risk from specific sources of radiation exposure. Individual assessments of potential detriment should only be based on organ or tissue radiation absorbed dose $D(r_T)$.

In occupational radiation safety, effective dose should be determined for comparing exposure scenarios to the individual dose criteria.

Calculated values of effective dose may be useful for radiation protection planning to compare exposures that could result from different work activities. For example, the relative exposures associated with different diagnostic or fluoroscopically-guided interventional procedures may be nominally compared using effective dose. In this context, effective dose might be appropriate for use by institutional review boards and radiation safety committees.

5.3.6 Committed Effective Dose

The committed effective dose represents an estimated future equivalent dose or a future effective dose that could be received from an intake of a long-lived, long-retained radionuclide that will continue to irradiate the body for a time period greater than one year after intake. The committed equivalent dose is the time integral of the equivalent dose rate in an organ or tissue that will be received by an individual, represented as a standard anthropomorphic reference person. The time integral for calculating a committed equivalent dose is 50 years for adults, and to age 70 years for children. The committed effective dose represents the sum of the products of the committed equivalent doses and the appropriate tissue weighting factors (w_T), where the integration time is 50 y (adults) or to age 70 y (for children) following the radionuclide intake.

By definition, the committed effective dose is a quantity used in radiation protection for establishing individual dose criteria for workers from exposure to internally deposited radionuclides. Use of the committed internal effective dose infers substantial uncertainties. The committed effective dose is not purely a physical or measureable quantity, but rather a surrogate of potential future effective dose representing a numerical entity of *risk* based on the physical

Comment [M77]: Ansari ...This notation looks unnecessarily complicated.
We should use the same notation used in other NCRP reports and by ICRP.

Fisher ... Armin, please note that the symbols and nomenclature given are completely current with ICRP (ICRP has been evolving). ICRP has adopted these new symbols. The use of equations and notation has been reduced to the simplest forms (minimalism).

MR ... whatever we decide to use, the symbols need to be defined (i.e., r_T, and τ are not yet explained], and the source of this equation needs to be referenced, since this is not what is in ICRP Publications 103 or 110. Are these in later ICRP publications or in ICRP works-in-progress and not yet published? [see also Equation (5.2)]

Comment [M78]: MR ... this is the basic equation for effective dose given in ICRP Publications 103 and 110.

Comment [M79]: MR ... need to be very careful how this is worded. There is more precise wording for this point in ICRP Publications 103 and 105 that should replace the current wording if this point is retained. I have reworded this sentence.

Comment [M80]: MR ... This quantity is not mentioned anywhere in the main text of the document.

Fisher ... The section includes committed effective dose, collective population dose, and operational quantities because they need to be included (keeping 5.0 as a main section) for completeness. If you think their mention is missing elsewhere in the report, we might ask ourselves why, and what needs to be done for the other sections. These are significant concept in national radiation protection.

MR ... NCRP reports usually only discuss quantities and units used in the particular report. I can see a couple of outcomes:

- Delete the terms since they do not appear in the body of the report ... although committed effective dose is part of effective dose (i.e., for intakes of radionuclides)
- Alter the content of the body of the report such that the terms are needed and thus are included ... that would likely require saying more in the text about implementation of the recommendations and the role of these quantities in implementation.

quantity absorbed dose. In common practice, the committed equivalent dose to an organ or tissue represents an appropriate quantity for recording and tracking the potential future cumulative internal equivalent dose to radiation workers from internally deposited, long-lived radionuclides. Calculated values of committed effective dose may be used for radiation protection planning to compare exposures that could result from different work activities involving long-lived, long-retained internally deposited radionuclides. In practice, the committed effective dose should not be used for predicting adverse tissue reactions, for epidemiologic studies, or for predicting individual risk of cancer or hereditary effects.

5.3.7 Collective Population Dose

Collective population dose, S, or collective effective dose, refers to the product of the average effective dose for a population subgroup *i* and the number of persons in the subgroup over a specified period of time; $S = \sum_i E_i N_i$, where E_i is the average effective dose and N_i is the number of persons in the subgroup. The unit of the collective effective dose is joule per kilogram (J kg^{-1}), and its special name is person-sievert (ICRP, 2007a).

Collective dose represents a measure of the total dose impact on a community affected by a radiation-generating activity. Collective dose applies only to populations with individual effective dose values that are substantially greater than environmental background levels plus contributions from beneficial medical exposures. This is useful for comparing the radiological impact of competing plans for introducing or removing a source of radiation exposure.

Sometimes collective dose is used in epidemiologic studies. Since there are significant dosimetry uncertainties in epidemiologic studies, and since individual responses to radiation are highly variable, the collective dose is not intended as a tool for epidemiologic research.

Computation of collective dose to prospectively predict future risk to an exposed population by multiplying small risk coefficients by large population numbers is biologically and statistically uncertain and leads inevitably to unsupportable claims of adverse health effects from ionizing radiation (NCRP 1997; 2012). Therefore, calculation of the number of adverse health effects expected, based on collective effective doses representing trivial individual doses, should be avoided (ICRP 2007).

5.4 Direct Measurements of Radiation Dose

Radiation doses from external sources are estimated using measurements from area-monitoring instruments and personal dosimeters. It is not possible to directly measure radiation doses to internal organs of the body from external gamma-ray, beta-particle, or neutron radiation sources. Therefore, the information obtained from personal dosimeters and area-monitoring instruments must be converted to operational quantities that may be used to compare an individual's radiation exposure against established dose criteria.

The measurement of radiation quantities corresponding to an estimate of whole-body effective dose requires calibration and correction factors unique to each dosimeter, device, and instrument to account for and record an individual's exposure. Radiation survey instruments are calibrated

Comment [KK81]: Kase ... Except for this sentence the paragraph discusses committed effective dose. The purpose of this sentence is not clear to me.

Comment [M82]: MR ... This quantity is not mentioned anywhere in the main text of the document.

Fisher ... The section includes committed effective dose, collective population dose, and operational quantities because they need to be included (keeping 5.0 as a main section) for completeness. If you think their mention is missing elsewhere in the report, we might ask ourselves why, and what needs to be done for the other sections. These are significant concept in national radiation protection.

MR ... NCRP reports usually only discuss quantities and units used in the particular report. I can see a couple of outcomes:

- Delete the terms since they do not appear in the body of the report ... although committed effective dose is part of effective dose (i.e., for intakes of radionuclides)
- Alter the content of the body of the report such that the terms are needed and thus are included ... that would likely require saying more in the text about implementation of the recommendations and the role of these quantities in implementation.

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 radiation scatter. Therefore, appropriate correction factors are needed to relate field instrument readings to laboratory-controlled calibration conditions.

Modern radiation detectors, personal dosimeters, and associated electronic instrumentation provide direct measurements of external penetrating (gamma, 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. The absorbed dose related to this exposure can be determined 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 instruments do not measure equivalent dose $H(r_T,T_D)$ or effective dose E.

Conversion from a radiation measurement in air to absorbed dose in the body requires an anatomical model to represent the human body and the location of various organs within that body. The absorbed dose in 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 and irradiation geometries, the organ absorbed dose may only be estimated, and the overall uncertainties in translating the air-measurement to organ dose may be great (NCRP, 2015a).

Neutron fields are detected by measuring nuclear reactions that produce energetic charged recoil nuclei, protons, alpha particles, and fission fragments. Since neutron interactions with matter depend on neutron energy, a number of different methods are needed to detect and measure the neutron field over a broad energy spectrum (10^{-2} to 10^{7} eV). Several different materials are appropriate for neutron detection. For slow neutrons, the most common neutron detector measures the conversion of boron-10 to lithium-7, or conversion of lithium-6 to hydrogen-3 (tritium) with release of a detectable alpha particle. For medium energy neutrons, the detection medium helium-3 is converted to hydrogen-3 with release of a detectable proton. For fast neutron detection, a moderator rich in hydrogen, such as polypropylene, is used to thermalize fast neutrons by elastic neutron scattering. These instruments provide estimates of dose equivalent to the worker.

5.4.1 Operational Quantities

Radiation protection guidelines, standards and limits are nominally specified in units of equivalent dose and effective dose, which cannot be measured directly. Thus, operational quantities have been developed for radiation protection purposes to relate measured quantities to applicable dose criteria. "Operational quantities" represent derived quantities based on measurements using personal dosimeters or area radiation field instruments for assigning worker doses and for demonstrating compliance with radiation exposure guidelines, standards, and limits.

Comment [AA(83]: Ansari … It may be better to cite a reference for this and not include the details here.

Comment [M84]: Kase … Is the specification of dose equivalent here necessary because these instruments do not use the radiation weighting factors appropriate for equivalent dose? If so, this needs to be explained.

Fisher … I agree with your comment on dose equivalent and equivalent dose…yes, further explanation is needed because measuring instruments do not incorporate radiation weighting factors and most people don't know the difference.

Comment [M85]: MR … This quantity is not mentioned anywhere in the main text of the document.

Fisher … The section includes committed effective dose, collective population dose, and operational quantities because they need to be included (keeping 5.0 as a main section) for completeness. If you think their mention is missing elsewhere in the report, we might ask ourselves why, and what needs to be done for the other sections. These are significant concept in national radiation protection.

MR … NCRP reports usually only discuss quantities and units used in the particular report. I can see a couple of outcomes:

- Delete the terms since they do not appear in the body of the report … although committed effective dose is part of effective dose (i.e., for intakes of radionuclides)
- Alter the content of the body of the report such that the terms are needed and thus are included … that would likely require saying more in the text about implementation of the recommendations and the role of these quantities in implementation.

The operational quantities are based on the concept of radiation absorbed dose $D(r_T)$ at a specific point in an organ or tissue (or tissue equivalent material). The absorbed dose $D(r_T)$ to an organ or tissue in a radiation worker from external radiation sources cannot be measured directly, but can be related to the operational quantities by comparing radiation fields with dosimeters measured in tissue-equivalent phantoms.

Three operational dose-equivalent quantities have been defined: ambient dose equivalent, directional dose equivalent, and personal dose equivalent. Each of these quantities is derived from the product of the absorbed dose $D(r_T)$ at a specific point in an organ or tissue-equivalent phantom and a radiation quality factor Q, based on the linear energy transfer (LET) value assigned to the incident radiation, where the dose equivalent $H = D(r_T)\, Q$. Further, it is assumed that the operational value H (in Sv) may be compared for radiation protection purposes to the time-integrated equivalent dose $H(r_T, \tau)$.

5.5 Summary

The basic radiation dose quantities and units, and their applications in radiation protection are summarized in Table 5.1.

- **Absorbed dose** is the basic physical dose quantity that is 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 the quantity relevant to adverse tissue reactions and future stochastic effects.
- **Equivalent dose** to an organ or tissue is a radiation protection quantity derived from absorbed dose related to the probability of a future stochastic radiation effect (cancer induction and hereditary changes, if any) in that organ or tissue. Equivalent dose is not purely a physical quantity, but rather a surrogate of dose that expresses a measure of future cancer risk. Equivalent dose is used in the calculation of effective dose.
- **Effective dose** to the whole body is the quantity used in radiation protection for establishing dose criteria for workers and members of the general public exposed to radiation and radionuclide intakes. Effective dose represents an overall risk of detriment attributable to stochastic effects of radiation. Estimates of effective dose may be used to evaluate the relative radiological impact of exposure to a work activity but should not be used for predicting future cancer risk for individuals or population groups.
- **Collective effective dose** represents the product of the average effective dose for a population subgroup and the number of persons in the subgroup over a specified period of time. Collective effective dose applies only to effective doses that are substantially greater than background. Collective effective dose is not an appropriate quantity for epidemiologic studies or to project future cancer risk in an exposed population, particularly at low doses.

Comment [M86]: MR … This statement (last sentence) is incorrect. For example, the personal dose equivalent $H_p(10)$] is the surrogate for effective dose when comparing recorded doses to an effective dose criteria.

Fisher … Your comment on the operational value H (Sv) and equivalent dose is interesting…. The new text is verbatim, as recommended and written by Wes Bolch for consistency with ICRP. Remember your goal for consistency with ICRP (not the out-of-date ICRP of years past).

MR … This whole paragraph is confusing … is ICRU completely revising its definitions of these three operational quantities? And has it published a new report on this yet? ICRU is the body that defines the operational quantities, and ICRP jointly with ICRU have done the Monte Carlo calculations to relate these operational quantities to quantities like air kerma, fluence and specific organ/tissue doses, and the radiation protection quantity effective dose. Equivalent dose is only relevant as an intermediate step to get to effective dose.

Dose equivalent is a separately quantity (defined at a point); the one defined as H = D Q.

Comment [M87]: Kase … Here we are again using dose equivalent. The implication in the last sentence is that there is no difference between dose equivalent and equivalent dose. I think that this paragraph needs to be rewritten.

Comment [M88]: MR … This quantity is not mentioned anywhere in the main text of the document.

2122 **Table 5.1** --- Summary of basic radiation dose quantities and units.

2123

Quantity	Symbol	Applicable To	Special Name
Absorbed dose	$D(r_T)$	Individual organ and tissue dosimetry, whole-body dose, and tumor dosimetry Organ or tissue sub-regions and multi-cellular dosimetry Cellular and nucleus dosimetry Derived risk coefficients for stochastic effects and adverse tissue reactions Individual patients for medically administered radionuclides	Gray (Gy)
Equivalent dose	$H(r_T, \tau)$	Population organ and tissue dosimetry Stochastic effects Calculating effective dose	Sievert (Sv)
Effective dose	E	Age and sex-averaged population groups Stochastic effects Establishing primary radiation limits Establishing secondary limits for radionuclides in air and water	Sievert (Sv)

2124

Comment [M89]: Miller … I think the column 'Not Applicable to" will confuse many people.

Kase/MR … agree, that column was deleted

Fisher … I think Table 5.1 has lost some value in revision.

MR … Darrell is referring to the deletion of the 'Not Applicable to" column.

References (Section 5)

ICRP (2007a). International Commission on Radiological Protection. Recommendations of the ICRP, ICRP Publication 103, Ann. ICRP 37(2–4) (Elsevier, New York).

NCRP (1997). Uncertainties in fatal cancer risk estimates used in radiation protection. Bethesda, MD: National Council on Radiation Protection and Measurements; NCRP Report No. 126.

NCRP (2012). Uncertainties in the estimation of radiation risks and probability of disease causation. Bethesda, MD: National Council on Radiation Protection and Measurements; NCRP Report No. 171.

NCRP (2015a). 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).

6. Adverse Health Outcomes from Radiation Exposures

6.1 Categories of Adverse Health Outcomes

For many years, it has been the common practice in the development of radiation protection standards to categorize radiation-induced adverse health effects into stochastic effects and tissue reactions. This was based on the accepted general mechanism of formation of these types of adverse outcomes.

Stochastic effects are cancer and heritable (genetic) effects that occur by chance, can occur at any absorbed dose and have no observable threshold. (Note that in Section 6 the term dose will refer to absorbed dose unless otherwise specified.) The effects are initiated in single cells. Cancer and heritable mutation frequencies increase with dose but the severity of the effect is not dose-dependent. Stochastic effects generally have a very long latency period, being observed in mice to occur in the next generation for heritable effects and, in humans, after 20+ y for solid cancers following radiation exposure.

The other major class of adverse health outcomes is tissue reactions. The classification stems from the assumption that these were determined directly by the radiation exposure. In addition, the severity of the disease increases with increasing dose. These outcomes were renamed as tissue reactions in the ICRP 2007 Recommendations (ICRP, 2007a) because of the enhanced evidence that such responses could be modified after irradiation rather than being determined at the time of radiation. Tissue reactions can occur at early or late times after irradiation. In addition, they typically exhibit a threshold response that has been the basis historically for establishing recommended dose limits. The underlying mechanism for the early effects involves cell killing whereas the later effects involve modifications of the tissue involved. Such tissue reactions include cataracts, circulatory disease, respiratory disease and neurocognitive damage. Threshold doses have been set by ICRP at a 1 % incidence of an effect (ICRP, 2007a). Recent studies have indicated that for circulatory disease and lens cataracts the threshold dose is lower than previously observed and differences between acute and protracted exposures are not entirely clear. The conflicting recent human evidence of effects at low doses tempers the conclusions that can be drawn and their applicability to radiation protection guidance at this time (Little et al., 2015; NCRP, 2016a).

Given that there is not necessarily a clear distinction between the two major classes of adverse health outcomes and that this will lead to some confusion as to what might be included in the calculation of detriment, it is appropriate at this time to consider all radiation-induced diseases under the single category of "adverse health outcomes."

When a clear threshold is apparent for a particular outcome, this threshold dose can be used in protection practice to establish an appropriate dose criterion. This dose criterion will be significantly higher than that for any adverse health outcome that is characterized as stochastic. However, a decision might need to be made as to whether some specific tissue reactions (e.g., circulatory diseases or cataracts) should be considered for inclusion in a detriment calculation, bearing in mind what impact this can have on the overall development and use of detriment.

Recommendation: The term "tissue reactions" be used instead of deterministic effects.

Recommendation: The review of the mechanism of formation and dose-response characteristics of the major classes of tissue reactions continue with a view to considering if they should be incorporated into the detriment calculation, and if so, how they should be incorporated.

Reference (Section 6.1)

ICRP (2007a). The 2007 Recommendations of the International Commission on Radiological Protection. ICRP publication 103 *Annals of the ICRP*, 37**,** 1-332

Little MP, Zablotska LB, Brenner AV, Lipshultz SE (2015). Circulatory disease mortality in the Massachusetts tuberculosis fluoroscopy cohort study. Eur J Epidemiol. 2015 Aug 9. Epub ahead of print]

NCRP (2016a). National Council for Radiation Protection and Measurements. Guidance on Radiation Dose Limits for the Lens of the Eye. NCRP Commentary No. 2x (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

6.2 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. The Japanese Life Span Study (LSS) has been relied upon for these computations, 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 natural background radiation. Pooled analyses of selective studies for specific cancers, such as breast cancer, have also been informative. Incidence data tend to have less diagnostic misclassification than mortality data and provide better estimates for cancers that have relatively low lethality such as the thyroid.

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),
- organ or tissue exposed,
- population characteristics (such as age-at-exposure, 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.

A comprehensive review of radiation epidemiology is beyond the scope of this Report. The Committee considered the comprehensive reviews of radiation studies published by UNSCEAR (2008), the BEIR VII Committee (NA/NRC, 2006) and EPA (2011), recent data from the LSS (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 NCRP Report No. 171 (NCRP, 2012), and the 2013 NCRP Annual Meeting reviewed exposed populations that have contributed to our understanding of radiation effects (Boice, 2014). As of 2016, Scientific Committee 1-25 is preparing a Commentary on recent epidemiologic studies conducted over the past 10 or so years to provide guidance on the dose-response relationships that might be considered for radiation protection.

A brief review of selected site-specific radiation effects (Section 6.2.1) is followed by a more in depth look at age-specific (Section 6.2.2) and sex-specific (Section 6.2.3) differences in cancer risks.

6.2.1 Site-Specific Risk Estimates

Cancers not convincingly linked to radiation. Not every cancer has been consistently seen to be increased following radiation exposure. For example, there is little evidence for an association with radiation for induction of chronic lymphocytic leukemia (CLL), pancreatic cancer, prostate cancer, cervical cancer, testicular cancer, non-Hodgkin's lymphoma, Hodgkin's disease or multiple myeloma (UNSCEAR, 2008). For some cancers, an excess risk has only been seen following very high (radiotherapeutic) doses (e.g., cancers of the small intestine, rectum, uterus and kidney) (NCRP, 2011). Thus, for a number of cancers the risk following low doses of radiation either do not exist or are highly uncertain.

Leukemia. Radiation-induced leukemia is the most prominent stochastic radiation effect. It is seen most frequently in 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-fetus is not considered more vulnerable than young infants. Risk varies by cell type with acute myelogenous leukemia (AML) predominating in most studies. CLL is not 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 should not be considered an early phase of AML (Albitar et al., 2002). MDS should be considered a discrete entity and not combined with leukemia for risk estimation.

Breast cancer. Radiation-induced breast cancer has been observed in many cohorts of exposed women. Excess risk is seen to decrease with increasing age at exposure and there is little evidence for a risk following exposures around the menopausal ages, over 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 is long and inversely related to age at exposure (i.e., it takes a young girl many years for a radiogenic cancer to develop and a shorter time for an older woman). Excess absolute risks are more similar than excess relative risks across different populations. 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.

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 is 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 other comprehensive studies, however, find little evidence for an increase in thyroid cancer or disease following intakes of radioactive ^{131}I.

Lung cancer. Radiation-induced lung cancer is a major consequence of exposure to the atomic bombs among Japanese survivors. Excesses are clearly linked to radon progeny exposure among underground miners and following high and prolonged exposure to residentiallevels. 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 radiations. Most notable is the absence of increased lung cancer risks among tuberculosis patients who received up to several hundred chest fluoroscopic examinations and among patients with severe scoliosis who received up to 160 spinal x-ray examinations. These patient populations are notable because significant increases in breast cancer were clearly evident. Occupational studies are difficult to interpret because of the inability to adequately control for the effect of cigarette smoking on lung cancer risk.

Comment [KK90]: From Irwin
Irwin It would be useful to put the residential level into perspective. Could the residential level be "in excess of EPA guidelines" or "an order of magnitude greater than average outdoor air levels"?

Boice

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 ongoing large-scale worker studies in Europe and the United States should be able to provide quantitate estimates of risk following exposures received gradually over time that cumulate to a level where excesses should be observed. Until recently, the dose ranges were too narrow and the number of excess cancers too small to be informative.

Other cancers. The other cancers that are reported to be significantly elevated among Japanese atomic-bomb survivors include cancers of the esophagus, colon, liver, gallbladder, ovary, bladder, non-melanoma skin cancer, renal pelvis and ureters. The most recent cancer incidence data confirm these increases as well as the previously mentioned cancers that were not significantly elevated: there was no indication of a statistically significant dose response for cancers of the pancreas, prostate, kidney, cancers of the rectum, gallbladder and uterus.

Mortality from radiation-induced brain cancer is not significantly elevated and the incidence data are not clearly interpretable since benign conditions were included in the analysis: there was a clear increase in brain and central nervous system (CNS) conditions but this appeared to be due to an unusually high risk of schwannoma; glioma and meningioma were not significantly increased.

Combined solid cancers. The brief descriptions above of site-specific cancers indicate that a single dose-response model does not fit all individual cancers: rates of some cancers are not significantly or consistently elevated (e.g., pancreas), some are elevated only after large doses (e.g., rectum), some depend entirely on a young age at exposure (e.g., thyroid), and some are sex-specific (e.g., breast).

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 somewhat 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). For example, 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. Combining all cancers together increases statistical precision but lacks biological plausibility, so interpretation and application to radiation protection circumstances should be done cautiously.

Studies that have combined all cancers together with an aim to investigate the shape of the dose-response relationship include the Japanese atomic-bomb survivor studies, the U.K. worker study, the 15-country study, U.S. worker studies, and the recent INWORKS study (Ozasa et al., 2012; Preston et al., 2007; Muirhead et al., 2009; Cardis et al., 2005; Schubauer-Berigan et al., 2015; Richardson et al., 2015). The data are not entirely consistent. While linearity is consistent with the Japanese atomic-bomb survivor data, a linear-quadratic shape shows a statistically significant fit for the first time. The 15-country study is difficult to interpret because of acknowledged biases in the Canadian dosimetry data and the likely confounding by cigarette smoking (i.e., lung cancer was the only significantly elevated site). The U.K. and INWORKS results were influenced by likely confounding due to asbestos exposure since pleural cancer was significantly elevated. The U.S. study is not independent of the INWORKS study, but results were not significantly elevated. It is envisioned that the U.S. Million Person Study will be sufficiently advanced that preliminary results will be available for consideration (Bouville et al., 2015).

[NOTE: CC-1 AWAITS THE NCRP SC 1-25 COMMENTARY ON EPIDEMIOLOGIC STUDIES AND IMPLICATIONS ON THE LNT MODEL AS USED IN RADIATION PROTECTION. THUS A SECTION IS ENVISIONED ON THE LATEST ESTIMATES OF LIFETIME RISK AND DOSE-RESPONSE MODELS WILL BE FORTHCOMING.]

Comment [KK91]: Kase ... Incidence rates?

Boice

Comment [KK92]: Kase ... References?

Boice

Comment [DLM93]: Miller What results? The paragraph starts of talking about the shape of the dose-response curve, but by the end of the paragraph you are talking about specific organs and cancers.

Boice

Comment [DLM94]: Miller I don't understand. By when? Who will be doing the considering, and when will that happen? Perhaps it would be better to say that, when completed and published, data from the million worker study will likely provide additional valuable data.

Kase
This will be revised when the SC 1-25 Commentary is incorporated.

Comment [KK95]: Kase New text pending SC 1-25 Commentary.

Boice

6.2.2 Effect of Age at Exposure

Radiation protection of a population typically uses recommended dose criteria that are the same for all persons. 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. One obvious reason for this is that those exposed at young ages are likely to live longer and have more time to express risk and detriment. At the other end of the scale persons exposed at very old ages are at lower risk since they generally die from other causes before radiogenic cancer can develop. In addition, tissue sensitivity for a given absorbed dose may vary with age. An additional complication is that depending upon the model used (age-at-exposure versus attained age) differing conclusions are reached regarding the effect of age (Figure 6.1 from Ozasa et al., 2012).

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, (Figure 6.1, left-hand panel), and in several other exposed groups (e.g., radiation therapy patients). For leukemia, ERRs also generally diminish with increasing age at exposure. The pattern of variation of excess absolute risks (EARs) with age at exposure is generally the reverse. For constant attained age the EAR for solid cancers increases with increasing age at exposure, as seen in the LSS (Figure 6.1, right-hand panel). While these differences in models that describe excess cancer risks over time may seem academic, they can lead to substantially different risk projections, especially if applied to populations with different baseline rates of cancer. In attempting to estimate lifetime population cancer risks, it is important to predict how risks might vary as a function of time after radiation exposure, and in particular for individuals for whom the uncertainties in projecting risk to the end of life are most uncertain, (i.e., persons who were exposed in childhood).

Lifetime risk projection models therefore must account for the modifying effects of sex, age-at-exposure and attained age. In general, the parameters in these ERR and EAR risk models have been estimated using incidence data from the studies of the Japanese atomic-bomb survivors with follow-up from 1958 through to 1998 for solid cancers (Preston et al., 2007).
[Note: New incidence data is forthcoming; should be available before Report is complete.]

Another example of age-dependence comes from the U.K. Health Protection Agency Report HPA-CRCE-028, "Radiation Risks from Medical X-ray Examinations as a Function of the Age and Sex of the Patient" (Wall et al., 2011). Table 6.1 indicates that children have a higher absolute risk than adults, that the risk, related to effective dose, for a general population is 5.5 % per sievert, including children and that for an adult population it is 4.0 % per sievert.

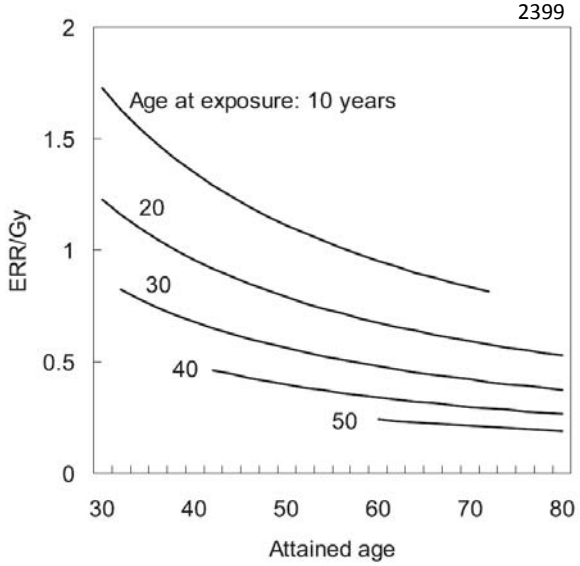

FIG. 2. Modification of the excess relative risk (ERR) for all solid cancer by age at exposure and attained age.

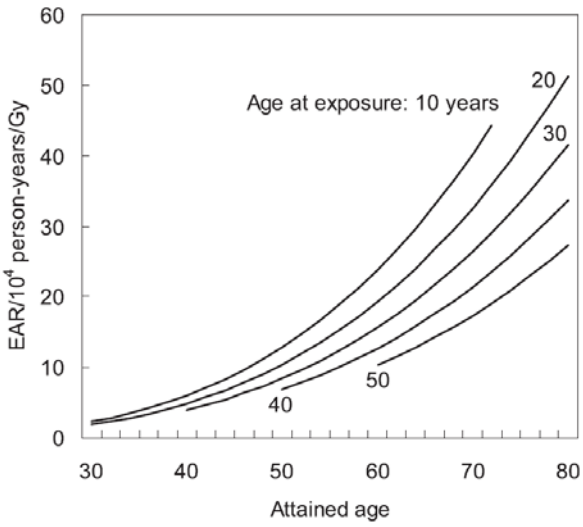

FIG. 3. Modification of the excess absolute risk (EAR) for all solid cancer by age at exposure and attained age.

Fig. 6.1. Modification of excess relative risk (ERR) (left-hand panel) and excess absolute risk (EAR) (right-hand panel) for all solid cancer by age-at-exposure and attained age.
(Captions on the original "Figs. 2 and 3" will be removed)

Table 6.1 --- Comparison between age and sex-specific risk coefficients for cancer incidence for x-ray examinations (Wall et al., 2011) and ICRP nominal risk coefficients for detriment-adjusted cancer (ICRP, 2007a).

(Table 23 title on the original will be removed)

TABLE 23 Comparison between age and sex specific risk coefficients for cancer incidence for x-ray examinations (present work) and ICRP nominal risk coefficients for detriment-adjusted cancer (ICRP, 2007)

Source of data	Scope of data	Population	Risk/E
Present work (Table 22)	Range in risk/E for both sexes and all examinations	0 – 9 y	7.8 – 20 % per Sv
		30 - 39 y	2.8 – 9.2 % per Sv
		60 – 69 y	0.8 – 6.8 % per Sv
ICRP Publication 103 (ICRP, 2007)	Nominal risk coefficient for detriment-adjusted cancer	Whole	5.5 % per Sv
		Adult	4.0 % per Sv

6.2.3 Effect of Sex

Females are at a greater risk for radiation induced cancer than are males for a given absorbed dose (NCRP, 1989; 2000; EPA, 2011). 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 is primarily related to the cancer induction in organs unique to each sex (Table 6.2); also noted in NCRP Commentary No. 23 (NCRP, 2014). 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 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 per gray for females and 0.31 per gray for males (Ozasa et al., 2012). The female/male ratio for all solid cancers is 1.65 (95 % CI: 1.4, 3.1). The difference is less using an EAR model with the female/male ratio being 1.1 (95 % CI: 0.80, 1.74). The cancer incidence data are similar with the ERR per gray female/male ratio for all solid cancers being 1.6 and the EAR per gray 1.4 (Preston et al., 2007). Thus females are at about 20 to 30 % higher risk than the sex-averaged risk and males are at about 20 to 30 % lower risk than the sex-averaged values. These differences are comparable with the range of other uncertainties that occur in the process of risk estimation. The recommended dose criteria of ICRP (and NCRP) are based upon sex-averaged nominal risks and detriment (ICRP, 2007a).

Comment [KK96]: Kase ... Assuming that the first ratio given, 1.65, is for ERR, what is the difference between the first of these statements and the second? Both seem to be referring to cancer incidence.

Boice

Recommendation: We'll wait until the new RERF cancer incidence data is published. It will include age, sex and site-specific risk estimates. It has been submitted for publication and should be forthcoming.

[Specifically and FYI: The Life Span Study (LSS) of 120,321 atomic-bomb survivors is a prospective cohort study with continuous cancer incidence surveillance since 1958. There have been two comprehensive reports (1994 and 2007) on the risks of solid cancer incidence following radiation exposure. A new report is now ready for publication. The current data have been updated through 2009 representing 11 additional years of follow-up since the 2007 report. In addition to the longer follow-up period, a number of comprehensive changes have been incorporated. They are, the inclusion of lifestyle data (smoking, drinking, and reproductive factors) collected from mail surveys and clinical interviews, updated doses, and updated migration coefficients to account for migration of cohort members into and out of the cancer registries' catchment areas. The 2009 update contains a total of 3.3 million person-years of follow-up and 24,096 incident cases, which represent roughly an additional 0.5 million person-years and 7,000 additional cancers since the 2007 report. Nearly 38 % of the LSS cohort was alive at the end of 2009. The Dosimetry System 2002 has not been altered, however, survivor input data used to calculate doses have been reviewed and updated. Changes include restoration of map coordinate precision that was lost due to memory constraints in early computer systems; corrections for distortion in WWII-era maps, use of geographical information systems to accurately determine ground distance for those with detailed shielding drawings; accounting for terrain shielding using digital terrain elevation data now available for all survivors, at their re-estimated locations. Results include the shape of the dose response, risks at low doses, and the effect of adjusting for smoking, and modification of the dose response by sex, attained age and age at exposure. (Grant et al., RRS, 2012 abstract)]

Table 6.2 --- Sex-specific differences in the excess relative risk (ERR) per gray for major cancers (adapted from Ozasa et al., 2012).

[Note: The table might be improved by including the individual sex-specific ERRs in addition to the sex-averaged ERRs.]

Cancer Type	ERR Gy^{-1} (averaged over both sexes)[a]	Female to Male Ratio (sex-specific ERR Gy^{-1} estimates)
All solid cancers	0.42	2.1[b]
Esophagus	0.60	4.3
Stomach	0.33	3.7
Colon	0.34	1.4
Liver	0.38	1.6
Gallbladder	0.48	0.43
Lung	0.75	2.7
Bladder	1.19	1.7
Cancer Type (sex-specific organs)	ERR Gy^{-1} (age averaged)	Not Applicable
Female breast	1.5	
Ovary	0.79	
Prostate	Little evidence for an association with radiation (UNSCEAR, 2008)	
Testicular	Little evidence for an association with radiation (UNSCEAR, 2008)	

[a]The sex-averaged ERR Gy^{-1} is shown for subjects at the attained age of 70 y after exposure at age 30 y.
[b]A ratio of 2.1 can be interpreted as females having a risk of radiation-induced cancer death that is 2.1 times that of males. These patterns generally hold when estimates are based on excess absolute risk per gray and for cancer incidence data as well (Preston *et al.*, 2007).

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6.2.4 Special Exposure Groups

There are several exposure groups that require special attention: infants, children, the embryo and fetus, and the pregnant woman. This is because of radiation sensitivity, vulnerability and ethical considerations. Justice, and equity particular, would have us treat these populations in such a way that they are protected because of their differences with adults.

Comment [M97]: Fleming addition

6.2.4.1 Infants and Children. Radiation exposure of infants and children is of fundamental concern. This is true whether the exposure is accidental, natural background, or due to medical or industrial sources. Children represent the largest group of what are often considered to be populations 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 age 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. Specific differences in age at exposure risk estimates are discussed elsewhere in this Report. It is commonly assumed that children might be 2 to 3 fold more sensitive to cancer than are adults. This generality is not strictly applicable for all tumor types. UNSCEAR (2013) has conducted a rigorous scientific review of the literature regarding 23 specific tumor types and concluded that for about 25 % of these 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's disease, prostate, rectum and uterine cancer) there is only 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 public exposure dose criteria for infants and children are the same as for the general public. At present, projections of lifetime risk for specific cancer types following exposure at young ages are statistically insufficient.

The annual dose limit for the public recommended in ICRP (1977) was 5 mSv. This was reduced five-fold to 1 mSv in the 1990 recommendations of the ICRP (ICRP, 1991b), essentially driven by the new Japanese data on exposure at young age and the realization that young age at exposure was associated with approximately a 2 to 3 fold higher risk of radiation-induced cancer. (See paras 64, 191 and B84 of ICRP, 1991b). In addition, the detriment model used was based upon annual conditional death probability of fatal radiation-induced cancer, and the observation that exposure at young ages confers a risk over a much longer time than exposure at older ages. A very complex and detailed analysis is contained in Annex C and table C5 of ICRP (1991b). The ICRP (1991b) reduction in public dose limits from 5 to 1 mSv was proportionally greater

than that recommended for occupational exposure (from 50 to 20 mSv) because the risk to children was the driving factor in risk when public exposure was considered.

The data regarding potential radiation effects on children has become clearer over the last decade, especially with regard to specific tumor types and the temporal pattern of risk expression for different tumors. However, the overall risk coefficient has not changed significantly since the Council's prior recommendation (NCRP, 1993a). The greater sensitivity of children was already factored into that recommendation which followed the ICRP (1991b) 1 mSv public dose limit. 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 is supported by both the principle of non-malificience as well as the principle of justice which requires unequal treatment to achieve an equitable situation.

Comment [PF98]: Fleming ... This can probably said more elegantly and perhaps early on when looking at special populations.

Recommendation: The public dose criteria should continue to incorporate the sensitivity of infants and children.

6.2.4.2 Embryo and Fetus. Insofar as the the embryo and fetus are considered morally significant (Section 3.2), NCRP extends radiation protection to them. ~~The embryo and fetus~~ They are highly sensitive to radiation. The nature and severity of effects depend upon absorbed dose and the stage of development. Recent extensive reviews of the effects of in utero exposure have been published by both NCRP (2013) and ICRP (2003).

There are a number of potential radiation induced-effects on the embryo/fetus.

Embryonic loss. Doses above about 0.15 to 0.2 Gy may cause pre-implantation and pre-somite embryonic loss but there does not appear to be a significant risk to health expressed after birth.

Malformations. The background rate for major congenital malformations in the absence of ionizing radiation exposure is about 3 %. Minor malformations occur in an additional 4 % of births (NCRP, 2013). There appears to be greater sensitivity to radiation-induced malformations during major organogenesis (3 to 7 weeks post conception). There appears to be a true dose threshold at about 0.2 Gy absorbed dose to the fetus.

CNS effects include potential severe mental retardation and/or reduction in intelligence quotient (IQ). CNS effects are greatest at 8 to16 weeks post-conception and to a lesser extent at 16 to 25 weeks post conception. Atomic-bomb survivor data for severe mental retardation indicate a lower confidence bound on the threshold of about 0.3 Gy. A radiation dose of 1 Gy would increase the risk of severe mental retardation by about 40 %. There does not appear to be a risk of radiation-induced severe mental retardation at low doses such as those typically associated with radiation protection. A linear dose-response model fit the Japanese data for IQ loss during the sensitive period (8 to 15 weeks post conception and with an IQ loss of around 25 points per gray. A threshold dose was not apparent, however at doses of <0.10 Gy effects were essentially undetectable and considered negligible.

Data on induction of neoplasms following in utero exposure is somewhat contradictory and has been debated for years. The case-control Oxford study following diagnostic radiology pelvimetry examination indicated an increased risk of childhood neoplasms but with the same risk for all types of neoplasms. 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 range of composite increase ranged from 0 to 30 %. 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. Overall, doses to the embryo/fetus above 0.5 Gy will increase the risk of cancer but the risk of cancer at doses <0.1 Gy has not been fully resolved. A detailed discussion and analysis of the epidemiologic studies is contained in NCRP (2013).

Recent publications and analyses of the Japanese atomic-bomb survivor data indicate that the lifetime risk may be lower for the irradiated embryo/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 (Section 6.2.4.1).

In summary, the sensitivity of the embryo/fetus for both mental retardation and cancer should be considered when making protective guidance.

References (Section 6.2.4)

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Comment [M99]: Miller … Is all this material necessary? The reader could just be referred to NCRP Report No. 174, which treats it exhaustively.

Boice

6.3 Heritable (Genetic) Effects

Over the past 60 or so years, there have been a range of studies conducted to establish whether or not there are risks of heritable disease to offspring of parents exposed to ionizing radiation as a result of accidents or medical exposures. Studies of atomic-bomb survivors and to a lesser extent of those exposed as a result of the Chernobyl accident are quite comprehensive. The overall conclusion is that there is no direct evidence that parental exposure results in excess heritable disease in offspring. In addition, there have been a number of studies on genetic disease in the offspring of long-term survivors of childhood cancer. Two such studies were reviewed by UNSCEAR (UNSCEAR, 2001) and as with adults, there is no evidence that radiation exposure in childhood confers any measurable risk of heritable effects in offspring. Over the past decade, there have been additional studies that have focused on survivors of childhood and adolescent cancer (UNSCEAR, 2013). Gonadal doses from radiation therapy often range from tenths of a gray up to 20 Gy. There has been no consistent evidence of chromosomal instability, minisatellite mutations, transgenerational genomic instability, change in sex ratio of offspring or congenital anomalies after these childhood exposures, This conclusion is supported by a number of national and international organizations (e.g., ICRP, 2007a; NAS/NRC, 2006; NCRP; 2005; UNSCEAR, 2001).

However, because there are clearly heritable effects observable in the offspring of mice and other mammalian and non-mammalian species (UNSCEAR, 2001), it has long been deemed necessary to develop a risk estimate for human exposures based on mouse data. The most recent approach has taken advantage of recent data on the genetics of human genetic diseases by basing the heritable risk on human background mutation data and mouse radiation-induced mutation data (ICRP 2007a; UNSCEAR 2001). 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), and for radiation protection purposes this value for heritable risk is included with cancer in the overall risk for gonads (ICRP, 2007a).

Recommendation: The heritable risk estimate of 0.2 % per gray developed for UNSCEAR and ICRP be accepted in health detriment evaluations.

References (Section 6.3)

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6.4 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). For example, for so-called high penetrance genes, excess spontaneous cancers are expressed in a large proportion of carriers. In addition, there are gene-gene and gene-environment interactions that can lead to variations in the likelihood of cancer across the population. How such information might convert into inter-individual differences in susceptibility to radiation-induced cancer has been quite extensively discussed by ICRP (1998), NAS/NRC (2006), and UNSCEAR (2001; 2006). 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.

Sankaranarayanan and Chakraborty (2001) conducted an extensive analysis of potential impacts at the individual and population levels. They used a Mendelian one-locus, two allele autosomal dominant model for predicting the impact of cancer predisposition and increased radiosensitivity on the risk of radiation-induced cancers in the population and in relatives of affected individuals using breast cancer due to BRCA1[3] mutations. The general conclusions from their study were that, when the proportion of cancers due to the susceptible genotype is small (<10 %), the attributable risks are small. On the other hand, when the proportion of cancers resulting from the susceptible genotypes is large (10 %), there can be significant increases in attributable risk for relatively small increases in cancer susceptibility (>10-fold) and radiosensitivity (>100-fold) in the susceptible populations. This means 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 small. 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, dose criteria for the public will not be significantly influenced by genetic radiosensitivity whereas they certainly could be influenced in some occupational settings and for individual assessments for defined medical exposures.

In this context, progress is being made in demonstrating experimentally that there are complex interactions that underlie the expression of cancer-predisposing genes of lower penetrance (NAS/NRC, 2006). This knowledge highlights the difficulty that will be encountered in trying to incorporate facets of genetic radiosensitivity into the radiation risk assessment process, especially at low doses and doses rates.

Recommendation: That specific genetic sensitivities not be incorporated into radiation risk estimates for populations.

[3] A gene on chromosome 17 that normally helps to suppress cell growth. A person who inherits certain mutations (changes) in a BRCA1 gene has a higher risk of getting breast, ovarian, prostate, and other types of cancer.

Recommendation: Where specific genetic sensitivities can be identified at the individual level, consideration be given to appropriate dose levels for treatment or imaging regimes for that individual.

References (Section 6.4)

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6.5 Cardiovascular Effects

The literature regarding cardiovascular disease (CVD) after radiation exposure is complicated by a number of important factors.

First, CVD is not a single entity and is a term used to describe a myriad of very disparate conditions with different causes. Even the division of CVD into heart disease or stroke is inadequate. As an example, heart disease includes disorders such as valvular abnormalities, capillary and blood vessel lesions, aneurysms, effusions, muscle abnormalities, arrhythmia, endocarditis, and malformations. Stroke can either be hemorrhagic or ischemic and both have multiple different causes. Hypertension is often included in the category CVD but generally has no etiological relationship to the heart itself.

The second issue that must be considered is the large number of confounding causes of CVD. These include smoking, hereditary or genetic factors, and dietary factors. Concurrent diseases and conditions also raise the risk of CVD (particularly diabetes and obesity).

Third is the issue of disease diagnosis and classification. There are clear examples of death certificates which list the cause of death as “cardiac failure” when a person is found dead with no other apparent cause. The criteria used to diagnose hypertension also vary widely among different medical practices, in different countries and over time causing additional confusion in interpretation of results. Unless all these issues are carefully spelled out and controlled for, results of published studies about low-dose radiation and CVD can be misleading.

The fourth issue is that while there are a number of hypotheses, at present there is no clear understanding of the biological mechanisms for cardiovascular diseases at low doses and there is no clear understanding of the target cells or tissue. Without this, application of a linear dose-

response model at low doses or the assumption that this is a stochastic or deterministic process remains debatable.

Increased risk of CVD (including myocardial infarction, coronary artery disease and stroke) are well documented effects after high radiation doses (>30 Gy) to the heart or neck that may occur with radiation therapy.

There are several reports of increased risk of CVD in atomic-bomb survivors. In the Life Span Study (LSS) cohort (Shimizu et al., 2010) researchers found an approximately linear dose response over the dose range 0 to ~3 Gy. The dose response over the dose range 0 to 1 Gy was statistically significant but over the range 0 to 0.5 Gy it was not. Excess relative risk was only clear above ~5 Gy. The nature and magnitude of the risk at acute doses <0.5 Gy is unresolved (Takahashi et al., 2013).

Interestingly, it is only the mortality data that shows a possible linear association with heart disease, whereas the incidence data as reflected in the adult health study is more consistent with a quadratic dose-response model for myocardial infarction and hypertension (Yamada, 2004). The high proportion of ill-defined heart conditions is problematic. A change in coding practices for causes of death in 1995 may have resulted in misclassifications of heart disease as "heart failure" being avoided as an underlying cause of death; cerebral infarction and acute myocardial infarction causes of death jumped dramatically.
(Note: A new follow-up of the atomic-bomb survivor population from 1950 to 2008 has been completed and should be available shortly. These new data will be considered in the next Report revision.)

The vast majority of occupational studies are either nonsignificant or marginally significant with regard to CVD (Little, 2013). For U.K. radiologists who worked from 1987-1997 the mortality from circulatory disease was lower compared with other medical practitioners (Berrington et al., 2001).

There are many studies of nuclear workers that have examined the issues of mortality from heart disease and stroke. The vast majority of these have standardized mortality ratios (SMRs) below that of the general population (perhaps due to the healthy worker effect) as well as a number that have SMRs below 100 when comparing radiation workers to nonradiation workers or when comparing high-dose to low-dose groups (Boice et al., 2016; Howe, et al., 2004). Studies of nuclear workers showing a statistically significant increase in CVD are very rare.

There are a number of studies of CVD in populations around nuclear facilities. These do not show a relationship to radiation exposure and typically have SMRs that reflect those in the regional or national population (Boice et al., 2007; 2010). Positive results would not be expected on the basis of the very low doses and the nuclear worker literature.

There are very few studies concerning natural background radiation and correlation with CVD. Those studies that do exist do not show a relationship and some even show a negative trend, likely due to population age differences and lifestyles. Similar results are found for studies of airline crews exposed to higher than normal levels of cosmic radiation (Blettner et al., 2003).

A recent study of tuberculosis patients in Massachusetts who received up to several hundred chest fluoroscopic examinations over a period of several years failed to reveal an overall increase in radiation-related circulatory disease (Little et al. 2015). These findings were consistent with an earlier report for the same population (Davis et al. 1989). A similar but larger study of Canadian tuberculosis patients also did not find a significant association between estimated radiation doses to lung and all cardiovascular disease although subgroup analyses indicated significant associations with ischemic heart disease, a condition not increased in studies of Japanese atomic-bomb survivors (Zablotska et al 2014).

Recommendation: The literature is insufficient to derive an estimate of any potential cardiovascular detriment at the low doses typically associated with occupational and public exposure.

Recommendation: Close attention to the results of research related to CVD at low and moderate doses is warranted.

References (Section 6.5)

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Comment [M100]: MR and Mettler … This is a placeholder. Boice says it is true and in the process of publication.

Boice

with significant dose fractionation in the Canadian fluoroscopy cohort study. Am J Epidemiol. 2014;179(1):120–31.

6.6 Central Nervous System Effects

The central nervous system (CNS) is very 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). For reasons that are unclear (possibly due to hormonal effects or sexual dimorphism in brain development) cognitive decline after radiation therapy is greater in females. The above mentioned changes have not been observed at doses below about 12 to 20 Gy.

There is known to be an increase in the incidence of certain brain tumors after cranial irradiation, but again this is seen only after high absorbed doses and typically when those doses are received during childhood. There are a few scattered reports of changes in mental function at lower doses from low linear energy transfer (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 and do not meet most of the Bradford-Hill criteria for causality. The incidence of dementia was examined among atomic-bomb survivors within the Adult Health Study cohort (Yamada et al., 2009), but no association with radiation exposure was found.

Recent experiments have shown a number of early and delayed deleterious effects in animals exposed to high atomic number, high-energy (HZE) 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), NCRP Report No. 153 (NCRP, 2006b), and NCRP Commentary No. 23 (NCRP, 2014d). 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 are 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 (2016b). A NASA exposure standard based on cancer and certain noncancer effects is in place (NASA REF). In utero exposure and CNS effects are discussed in the Special Exposure Group section on the embryo and fetus (Section 6.2.4.2).

Recommendation: Radiation effects on the CNS not be considered a major factor in evaluation of radiation protection for workers and the public with the possible exception for exposure to HZE particles.

References (Section 6.6)

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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.

6.7 Thyroid (Noncancer Effects)

This section refers to tissue reactions on thyroid function and possible thyroiditis. Thyroid cancer and nodules are discussed elsewhere (Section 6.2.1). 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 doses the issue of thyroiditis is of greater concern.

Studies of atomic-bomb survivors showed a questionable increase in hypothyroidism in the 0.01 to 0.49 Gy group but not in the 0.05 to 0.99 Gy group (Nagataki et al., 1994). Morimoto et al., (1987) reported that in survivors under the age of 20 y at exposure and with doses 1 Gy or more there was no increase in either hypothyroidism or autoimmune thyroiditis.

Fallout from nuclear testing resulted in significant deposition of radioiodine in the Marshall Islands and caused subclinical hypothyroidism in about 30 % of children who received thyroid doses of >2 Gy.(Lessard et al., 1985). Long-term follow-up of those with thyroid doses up to 4 Gy did not show an increase in autoimmune thyroiditis. Conflicting results have been reported in the United States for fallout from atomic tests in Nevada. Rallison et al. (1991) reported an increase in thyroiditis but a later study by Kerber et al. (1993) did not find any thyroid effects.

There are quite a number of studies related to Chernobyl with various methodologies, different dose sources and often with conflicting results. The studies of thyroiditis are also complicated by the availability of nonradioactive iodine. A study by Ostroumova et al. (2013) reported an increase in hypothyroidism (based on thyroid-stimulating hormone not thyroxine levels) but no evidence of autoimmune thyroiditis, based on a linear model even though the best fit to the data was not linear and there was no statistical significance at doses <4 Gy. 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). The study included 160,000 children and did not find any increase in thyroid antibodies, hypothyroidism or hyperthyroidism that could be related to ionizing radiation. In an analysis of fallout from Hanford, Davis et.al. (2002) found a negative dose-response curve for both hypothyroidism and autoimmune thyroiditis.

Clinical and subclinical hypothyroidism are well-documented complications after external beam radiation therapy to the head, neck and upper chest for malignancies. Reports of the doses needed to cause hypothyroidism from fractionated exposures range from 20 to 50 Gy. The risk of subclinical (or biochemical hypothyroidism is about 40 % 20 y after receiving 10 to 30 Gy.

Iodine-131 has been used for over half a century to treat hyperthyroidism. With high administered activities (typically 100 to 600 MBq), hypothyroidism can be evident within months. Considering the high uptake of ^{131}I in a hyperfunctioning gland the absorbed dose is usually in excess of 100 Gy.

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In summary, fractionated thyroid doses above a few gray can induce subclinical hypothyroidism and at doses >20 Gy clinical hypothyroidism may occur. The incidence increases with time and is quite variable among individuals. Autoimmune thyroiditis and hypothyroidism are not likely to increase to any significant extent at dose criteria recommended for occupational or public exposure.

References (Section 6.7)

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Rallison, M.L., B.M. Dobyns, A.W. Meikle et al. (1991). Natural history of thyroid abnormalities: prevalence, incidence, and regression of thyroid diseases in adolescents and young adults. Am J Med 91(4): 363-370.

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.

6.8 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 doses > 5 Gy in a single 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.

Vision-impairing cataracts occurring after high doses to the lens of the eye have been known for many decades. Acute, fractionated doses over weeks that exceed several gray can cause obvious cataracts within a few years. Radiation induced cataracts have been reported following radiation therapy with doses of 10 to 18 Gy (Merriam and Focht, 1957). More recently, with more sophisticated technology, it has become apparent that lens opacities can be seen after doses as low as 0.5 Gy.

However,, there is still considerable uncertainty surrounding the relationship between dose and radiation cataract development (ICRP, 2012). Consequently, several reviews of recent radiation cataractogenesis epidemiologic studies have been published [see NCRP (2016a) for detailed review of this literature]. In general, these reviews have concluded that there is a strong likelihood of an association between exposure to ionizing radiation and initiation or development of various cataracts (NCRP, 2016a). Overall, the data were consistent with an association between exposure to ionizing radiation at 1 Gy 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 reviews of mechanistic studies by several authors as summarized by NCRP (2016a) suggests that radiation-induced opacities could be stochastic in nature and perhaps not a tissue reaction, as long thought. However, the link between the induction of any, even minor, opacities in animal models and the occurrence of clinically-relevant, vision-impairing cataracts in humans is still far from clear. Because of the incoherence of the mechanistic and epidemiologic evidence, it is not yet known if radiation cataractogenesis can be classified as strictly a stochastic effect or a tissue reaction in nature. The epidemiologic evidence to date indicates a threshold model, and NCRP has determined that this model should continue to be used for radiation protection purposes at this time. The specific value of the threshold for detectable opacities or vision-impairing cataracts is less clear. The epidemiologic evidence has large associated uncertainties, but currently indicates a threshold dose in the region of 1 to 2 Gy for vision-impairing cataracts. . However, NCRP has concluded that it is not possible to make a specific quantitative estimate of lens effect thresholds at this time.

Recommendation: A threshold model for formation of lens opacities continue to be used for radiation protection purposes.

Recommendation: An absorbed dose threshold for detectable lens opacities or vision impairing cataracts not be specified at this time.

The effects of LET, dose rate, acute or protracted dose delivery on cataract induction and progression are not clear. Vision-impairing cataracts could be considered the endpoint of greatest concern in terms of lens radiation protection. Cataracts are not life threatening but may affect individuals' ability to carry out their occupations or other daily tasks.

Epidemiologic studies of the effect of radiation on the lens of the eye indicate that there is an association between exposure to ionizing radiation and initiation or development of post-sub-capsular cataracts, mixed and cortical vision-impairing cataracts in humans for various exposure situations. The systematic review of the current eye epidemiology data has shown that the probable risks for vision-impairing cataracts are likely increased for doses in the region of 1 to 2 Gy. However, the preponderance of evidence appears to suggest the possibility that effects (e.g., lens opacities and/or cataracts) could occur at lower doses.

Therefore, NCRP has determined that it is prudent for lens of the eye to recommend an annual occupational individual absorbed dose criterion for control of 50 mGy. Prudence, in this case, refers to the selection of an annual dose criterion that would not result in an individual accumulating an exposure in excess of the likely range of threshold values.

The annual absorbed dose criterion for control of lens of the eye exposure recommended for members of the public at should be 15 mGy and is adequately protective.

Recommendation: The annual absorbed dose criterion for occupational exposures for the lens of the eye be set at 50 mGy.

Recommendation: The annual absorbed dose criterion for the public for exposure to the lens of the eye be set at 15 mGy.

Recommendation: Evaluation and additional research should continue in the following areas: 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).

References (Section 6.8)

ICRP (2012). International Commission on Radiological Protection. ICRP Statement on Tissue Reactions and Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context, ICRP Publication 118, Annals of the ICRP **41 (1/2)** (Elsevier Science, New York).

NCRP (2016a). National Council for Radiation Protection and Measurements. Guidance on Radiation Dose Limits for the Lens of the Eye. NCRP Commentary No. 2x (National Council on Radiation Protection and Measurements, Bethesda, Maryland).
Merriam, G.R. and E.F. Focht, (1957). *A clinical study of radiation cataracts and the relationship dose.* AJR, 1957. 77: p. 759-785.

6.9 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 the ICRP (1991a).

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 are anatomic differences with basal cell cancers occurring on the face and neck and squamous cell cancer more commonly on the hands. For basal cell cancer the relative risk decreases with increasing age at exposure. The interaction with ultraviolet and ionizing radiation for induction of skin cancers appears more than additive and there is a clear increase in skin cancers after ionizing radiation exposure in skin areas exposed to sunlight and in persons with faulty DNA repair (e.g., xeroderma pigmentosa). There is no significant evidence that melanoma is induced by ionizing radiation.

The normal incidence of non-melanoma skin cancer is difficult to assess since these cancers are commonly removed by dermatologists and are often not reported to tumor registries. The mortality rate of both types is low (usually <0.3 %). The incidence of non-melanoma skin cancers after irradiation has been assessed in atomic-bomb survivors, occupationally exposed groups and after medical exposures. In the atomic-bomb survivors the ERR of basal cell carcinoma was significantly elevated at 0.74 Gy^{-1} [95 % confidence interval (CI) 0.26 to 1.6] and for squamous cell carcinoma the ERR was 0.71 Gy^{-1} (95 % CI 0.063 to 1.9) (Sugiyama et al., 2014). There was no significant dose response for melanoma. There are major variations in the skin cancer risk reported among epidemiologic studies particularly regarding age at exposure as well as excess absolute risk (EAR). These differences may be due to variation in ascertainment of the cancers, variation in genetic makeup of the populations, whole-body acute exposures versus partial-body fractionated exposures, lack of suitable controls in some studies, increased detection in groups with increased dermatological surveillance, and variations in handling of the latent period.

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 effective dose restriction provides sufficient protection against stochastic skin effects.

The tissue reactions from ionizing radiation on the skin include a number of different effects due to the various layers of skin which have different cell types, functions and radiosensitivities (ICRP, 2013).

The threshold doses for these effects are shown in Table 6.3 (ICRP, 2012). Note however that the thresholds and time course for these effects are better shown as ranges than as specific values (ICRP, 2013). Table 6.3 is for single acute exposures, however a number of these effects (such as skin atrophy) can be seen with significantly higher but fractionated or chronic exposures. Field size is also a crucial factor in determining outcome with smaller fields tolerating higher doses. For a small (6 x 4 cm) field the dose of x-rays required for an effect may be twice as high as that for a large field (15 x 20 cm).

Recommendation: For radiation protection purposes the dose criteria for skin exposure is designed to avoid significant 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 which develops over 2 weeks, has a bullseye appearance and can heal to a small dimple.. 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).

6.10 Psycho-Social Effects (Pending)

6.11 Summary and Recommendations [Pending (if a summary of Section 6 is wanted)]

Table 6.3 --- 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
Ischaemic 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

References (Section 6.9)

ICRP (1991a). The biological basis for dose limitation in the skin, Publication 59, Annals of the ICRP Vol 22 No.2.

ICRP (2012). International Commission on Radiological Protection. ICRP Statement on Tissue Reactions and Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context, ICRP Publication 118, Annals of the ICRP **41 (1/2)** (Elsevier Science, New York).

ICRP (2013). Radiological protection in cardiology. ICRP Publication 120. Annals of the ICRP 42(1), 1-125.

Sugiyama et.al. (2014). Skin cancer incidence among atomic bomb survivors from 1958 to 1996, Rad Res.181:531-539.

7. Radiation Risk Estimates, Detriment and Uncertainties

7.1 Measure of Detriment

7.1.1 Introduction

The concept of detriment for radiation protection purposes was originally introduced by ICRP in Publication 26 (ICRP, 1977) where it was defined as the mathematical 'expectation' of the harm incurred from an exposure to radiation. The effects included in harm were cancer and hereditary effects. This harm included not only the probability of each type of deleterious effect but also the adjudged severity of the effect. In ICRP Publication 60 (ICRP, 1991b), the definition of detriment was reconsidered to include fatal cancer risk for a specific organ, a weighted allowance for nonfatal cancers plus an estimate of severe hereditary effects, all of which were also weighted for the relative length of life lost. The primary use of detriment estimates from Publication 26 (ICRP, 1977) onwards is for producing tissue weighting factors (Section 7.2.5) for use in calculating nominal risk estimates and ultimately effective dose and dose criteria for radiation protection purposes. This general concept of detriment was continued in ICRP Publication 103 (ICRP, 2007a). However, the use of cancer incidence values and the inclusion of new epidemiologic data resulted in revised values for radiation detriment and tissue weighting factors. The resulting detriment adjusted nominal risk coefficients for cancer were very similar to those in ICRP Publication 60 (ICRP, 1991b), namely, 5.5 x 10^{-2} Sv^{-1} for the whole population and 4.1 x 10^{-2} Sv^{-1} for adult workers [compared to 6.0 x 10^{-2} Sv^{-1} and 4.8 x 10^{-2} Sv^{-1}, respectively, in Publication 60 (ICRP, 1991b)]. The overall measure of relative detriment is almost exclusively for cancer with heritable effects being a very minor component based on relative risk. The detriment for heritable effects is included in the tissue weighting factor for the gonads.

Thus, for radiation protection purposes, ICRP has utilized the concept of health detriment as an expansion of overall health impact of radiation beyond cancer and noncancer risks. The calculation of detriment is both complex and has a number of associated uncertainties and assumptions. Section 7.1 provides an overview of this usage and discusses NCRP's recommendations for its application in their dose criteria.

7.1.2 Risk of Effect

For radiation protection purposes as recommended by ICRP, cancer risks are converted to nominal risk coefficients, based upon sex-averaged risk values and averaging over the range in age at the time of exposure.. Clearly this in itself leads to uncertainty in the risk coefficients (hence the designation as "nominal"). The first step in the development of these nominal risk coefficients is to determine lifetime cancer incidence risk estimates for radiation-associated cancers, largely based on the atomic-bomb survivor cohort. Excess relative risk (ERR) and excess absolute risk (EAR) models were used to estimate male and female lifetime excess cancer risks for 14 tissues or organs. These values were then averaged across sexes. These lifetime risk estimates were adjusted downward by a dose and dose-rate effectiveness factor (DDREF) (a value of 2 was selected by ICRP). The risk estimate for leukemia is not adjusted for DDREF

because the linear-quadratic (LQ) model for risk accounts for any DDREF. A discussion of the uncertainty in the value of DDREF is provided in Section 7.2.3.

These lifetime risk estimates, as mentioned, rely on atomic-bomb survivor data for a Japanese population, but background cancer rates differ across different populations. Thus, the risk estimates need to be adjusted when being transported across populations. ICRP Publication 103 (ICRP, 2007a) states that for risk transfer across populations for each cancer site a weighting factor of the ERR and 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 in their calculation of radiation detriment.

7.1.3 Lethality of Effect

The ICRP nominal risk coefficients for each cancer site were based on lifetime risks of cancer incidence, whereas detriment is based on the risk of fatal cancer. The excess cancer incidence values were converted to fatal cancer risks by multiplying by the appropriate lethality fraction derived from selected national cancer survival data. The uncertainty for this adjustment is largely in the accuracy of the lethality fractions used and is relatively large.

7.1.4 Reduction in Quality of Life

The ICRP judged that cancers should be weighted not only by lethality but for cancer survivors also for pain, suffering and any adverse effects of cancer treatment. By a somewhat complex process, the nonlethal fraction of cancers is adjusted by a factor to account for the quality of life loss to give an adjusted lethality fraction. In practice, a value of 0.1 was chosen for all sites, so that in effect the greatest impact would be on relatively nonlethal cancers, such as breast or thyroid. The nominal risk coefficients were adjusted for the quality of life reduction.

7.1.5 Life Shortening (Years of Life Lost)

The nominal risk coefficients were also adjusted for the adjudged "harm" from years of life lost. The age distribution differs for the different cancer types used in the calculation of detriment. Thus, years of life lost can vary with cancer type. To account for this, the average ages at death for several types of cancer were estimated from national cancer data and converted to average years of life lost from when a cancer is diagnosed. These averaged values were applied to the nominal risk coefficients that had been adjusted for lethality and quality of life, as above.

The result of adjusting the nominal cancer risk coefficients for lethality, quality of life and years of life lost is an estimate of radiation detriment associated with each type of radiogenic cancer. These values were normalized to sum to unity for deriving a set of relative radiation detriment values.

References (Section 7.1)

ICRP (1977). Recommendations of the International Commission on Radiological Protection, ICRP Publication 26. *Annals of the ICRP,* 1.
ICRP (1991b). *ICRP Publication 60: 1990 Recommendations of the International Commission on Radiological Protection*, Elsevier Health Sciences.
ICRP (2007a). ICRP publication 103. *Annals of the ICRP,* 37**,** 1-332.

7.2 Risk Estimates and Uncertainty: Addressing the Issue

7.2.1 Introduction

For setting radiation protection dose criteria, there are several essential, and linked, factors that are currently considered to be quite uncertain. The quantitation of adverse health effects at low doses and low dose rates uses the DDREF for which there is a significant uncertainty. The adverse outcomes that are used (other than acute radiation syndromes) are phenotypically the same whether they are radiation induced or assumed to be part of the background, making it impossible to separate them for assessing low-dose effects through epidemiologic studies. To be able to attribute a specific outcome to radiation there is a need to develop some form of radiation-specific disease signature or bio-indicator. NCRP Commentary No. 24 (NCRP, 2015b) describes one such approach based on key events and adverse outcome pathways. The low dose and low dose-rate risk estimate is proposed to be based on the use of biologically-based dose-response (BBDR) models that utilize key events as parameters. This approach is potentially viable as indicated by recent publications describing risk assessments for environmental chemicals (e.g., Adeleye et al., 2015; Preston, 2015). As part of this approach, it is proposed that key events can be selected as radiation-specific signatures in the process of attribution. The issues associated with attributability together with considerations of the use of DDREF and weighting factors in risk estimation are discussed in Sections 7.2.2 and 7.2.3, respectively. Possible approaches for addressing the uncertainties associated with low dose and low dose-rate risk estimates are discussed in Section 7.2.6.

References (Section 7.2.1)

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PRESTON, R.J. (2015). "Integrating basic radiobiological science and epidemiological studies: Why and how," Health Phys. **108**(2), 125–130.

7.2.2 Attributability

For purposes of radiation protection and establishing public and occupational dose criteria 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 in UNSCEAR (2012).

For purposes of this document on radiation protection and for absorbed doses of <1 Gy, the discussion of attribution, inferring risks and uncertainties is limited to radiation-induced cancer. 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 significant increase in cancer incidence in those tissues known to be radiosensitive following a significant radiation exposure then attribution is plausible. The probability of causation depends upon the type of cancer, organ equivalent dose (not effective dose), radiation type and quality, age at exposure, latent period and other risk factors. In general, an increase in health effects in an individual or population cannot reliably be attributed to chronic low-LET doses in the range of average natural background radiation. This is due to uncertainties in dose assessment, insufficient statistical power of most epidemiologic studies at low doses and lack of radiation-specific biomarkers. There does appear to be an increased cancer risk from radon at or near background levels, but this is high -LET radiation.

Future risks from radiation exposure of an individual or population cannot and should not be inferred from effective doses that are above or below effective dose criteria for radiation protection. Effective dose criteria are not threshold levels at which stochastic health effects may or may not occur, nor are they a designated “safe” versus “unsafe” criteria. The Council understands that there are substantial uncertainties in multiplying very low doses by large numbers of individuals to estimate numbers of radiation-induced health effects in an exposed population. The Council understands that such projections have been made to allocate resources or to compare potential risks from various practices.

Recommendation: Future risks from radiation exposure of an individual or population not be inferred from effective doses that are above or below effective dose criteria for radiation protection.

Recommendation: Effective dose criteria not be interpreted as threshold levels at which stochastic health effects may or may not occur, nor as a designated “safe” versus “unsafe” criteria.

Uncertainties in risk estimates can be classified as random nonsystematic (aleatory) or as due to lack of knowledge about true, but unknown, variables that are constants shared by members of cohort subgroups (epistemic). For estimation of radiation-induced cancers, the major uncertainties arise from dosimetry, transfer across populations, effect of low dose and low dose

rate, radiation quality and other physical and biological confounding factors. When a detailed analysis for a specific situation is performed, the 95 % CI is generally a factor of about 2 to 3 about a central estimate of risk based on a uniform whole-body exposure.

References (Section 7.2.2)

Berrington, Gonzales et al 2012 (not yet cited in text)
NAS/NRC (2006). BEIR VII (not yet cited in text)
NCI RadRAT (not yet cited in text)
NCRP (1992). Statement No. 7
UNSCEAR (2012). 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 2015.

Comment [M102]: MR … need to indicate where these **three** references should be called out in the text of Section 7.2.2. Also need full citations for Berrington et al. (2012) and NCI RadRAT.

Mettler

7.2.3 Dose and Dose-Rate Effectiveness Factor

It has been considered necessary, based on a range of biological studies and selected epidemiologic studies, to include a DDREF for converting cancer risks obtained at relatively high absorbed doses and absorbed dose rates for predicting risks at low doses (<100 mGy) and low dose rates (<5 mGy h^{-1}). The use of DDREF has been restricted to the development of low-dose and low dose-rate cancer risk estimates for calculating detriment values to be used in establishing recommendations for dose criteria for radiation protection purposes. It is not a definitive, measured value but rather a derived one based upon a selected data set that varies according to the organization making the recommendations. For example, after considering various human and experimental data, a value of 2 was selected by ICRP in Publication 60 (ICRP, 1991b). A considerable amount of discussion has ensued since this time on what are the appropriate data sets upon which to base a selection of DDREF and the methods for calculating a specific value. ICRP in its most recent set of recommendations (ICRP, 2007a) retained a value of 2; BEIR VII (NAS/NRC, 2006) using a Bayesian approach for data analysis selected a value of 1.5; and UNSCEAR (2006) 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 NCRP Report No.171 (NCRP, 2012b)].

It has been proposed by a number of sources that it is more appropriate and more correct, based on the available literature, 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).

Recommendation: Separate LDEF **and** DREF values be used **once the necessary data are available for accurately establishing values.**

These two quantities (LDEF and DREF) represent outcomes of different underlying processes and rely upon quite different data sets for their calculation. These aspects are considered below in Sections 7.2.3.1 and 7.2.3.2. Both of these factors must be determined for use in radiation protection. Targeted research is needed to obtain the required data set (human, laboratory animal or cellular). There are international (e.g., ICRP, Multidisciplinary European Low Dose Initiative, and UNSCEAR) and national organizations (e.g., Public Health England, NCRP, and Electric Power Research Institute) that are currently addressing this issue and the associated necessary data sets.

7.2.3.1 Low-Dose Effectiveness Factor. A LDEF is necessary when extrapolating linearly from high-dose to low-dose effects for an adverse health effect dose-response curve that is essentially linear-quadratic (LQ). The LDEF is calculated as the ratio of the slope of the linear extrapolation from a point on the LQ curve and the slope of the linear component of this LQ curve. For acceptance of this approach, the need is to establish if, for example, the dose-response for radiation-induced cancer (particularly that for the atomic-bomb survivors) is described by an LQ curve. There has been an active discussion on this topic with opinions for and against an LQ curve for all solid cancers for the atomic-bomb survivor cohort. While it is difficult to reach a definitive conclusion because of the uncertainties associated with effects at low doses, the recent report by Ozasa et al. (2012) provides a convincing argument that there is no threshold for all solid cancers.

Recommendation: At this time, the use of a separate LDEF for radiation protection purposes does not appear to be warranted.

7.2.3.2 Dose-Rate Effectiveness Factor. The DREF is calculated as the ratio of the slope of the dose response at low acute doses to that at low doses and low dose rates. For a linear non-threshold model application, the slope for acute doses is described by the slope of the curve over the entire dose range of epidemiologic assessment. If the dose-response curve is best described by an LQ application, then the low-dose slope is that for the linear component of the LQ curve. The greatest uncertainty in calculating a DREF arises from the relative lack of epidemiologic data for low-dose and low dose-rate exposures. The data for occupational and environmental low dose-rate exposures of human populations together with the associated uncertainties were reviewed in NCRP Report 171 (NCRP, 2012b). The general conclusion was that a (D)DREF of 1 is feasible but that higher values cannot be excluded. Thus, to help reduce this uncertainty, additional reliance has to be placed on animal and cellular data. A concern is that there is a lack of direct association between the non-epidemiologic data and human cancer induction. It might well be possible to strengthen this relationship through the design of research to develop data bases that more directly address this relationship (NCRP, 2015b). Given these uncertainties, the selection of a DREF for radiation protection purposes is somewhat subjective and values of 1, 1.5, 2 or greater can be defended.

Recommendation: NCRP adopt the existing ICRP recommendation for a (D)DREF of 2 for radiation protection purposes.

Comment [M103]: Bushberg … Below what dose is dose rate not a factor? Medical exposure low dose but very high dose rate

Preston … Tricky – if response is linear quadratic then dose at which essentially no quadratic component would be independent of dose rate. However, for LNT hypothesis used for radiation protection, dose rate is included by reducing slope and so there is no dose at which there would be no theoretical dose rate effect. This is intended to have been addressed in the text. Changes if needed.

References (Section 7.2.3)

NAS/NRC (2006). BEIR VII
NCRP (2012b). NCRP Report No.171
NCRP (2015b). NCRP Commentary No. 24
ICRP (1991b). *ICRP Publication 60: 1990 Recommendations of the International Commission on Radiological Protection*, Elsevier Health Sciences.
ICRP (2007a). ICRP publication 103. *Annals of the ICRP,* 37**,** 1-332.
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.
Rühm 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.
UNSCEAR (2006). Effects of ionizing radiation, Volume I, UNSCEAR 2006 report to the General Assembly, Annex A: Epidemiological studies of radiation and cancer.

7.2.4 Radiation Weighting Factors

In the definition and calculation of equivalent dose, the recommended radiation weighting factors (w_R) allow for the differences in the effect of various radiations in causing stochastic effects. The w_R values for high-LET radiation are derived for stochastic effects at low doses. ICRP (2007a) updated the previously recommended w_R values (ICRP, 1991b) for neutrons and protons. The changes were based on reviews of the range of available data on the RBE of different radiations, together with biophysical consideration. Values for neutrons were given as a continuous function of neutron energy (Equation. 7.1), and include a value for charged pions.

$$w_R = \begin{cases} 2.5 + 18.2\ exp\text{-}\{[\ln (E_n)]^2/6\}; & E_n < 1 \text{ MeV} \\ 5.0 + 17.0\ exp\text{-}\{[\ln (2\ E_n)]^2/6\}; & 1 \text{ MeV} \le E_n \le 50 \text{ MeV} \\ 2.5 + 3.25\ exp\text{-}\{[\ln (0.04\ E_n)]^2/6\}; & E_n > 50 \text{ MeV} \end{cases} \quad (7.1)$$

The w_R values are selected to give a representative value for the known data and to be sufficiently accurate for application in radiation protection. The values of w_R are selected by judgment for use in the determination of radiation protection quantities; as such they have fixed values and are not associated with any uncertainty.

Values of w_R for photons, electrons, muons, and alpha particles remained unchanged. All w_R values relate to the radiation incident on the body or, for internal radiation sources, emitted from the incorporated radionuclide(s).

Over the years there has been a concern that the RBE for very low-energy photons and electrons may be greater than that for higher-energy photons such as the gamma rays from ^{60}Co or ^{137}Cs.

(NCRP Scientific Committee 1-20 has been reviewing the available scientific information on this issue and is developing a report of their findings. The Council recommendations on the biological effectiveness of these lower-energy radiations will be based on the conclusions of that report.)

Recommendation: NCRP adopt the w_R values in Table 7.1 provided by ICRP (2007a).

7.2.5 Tissue Weighting Factors

In the definition and calculation of effective dose, tissue weighting factors (w_T) allow for the variations in radiation sensitivity of different organs and tissues to the induction of stochastic effects. Effective dose is calculated using age- and sex-averaged w_T values.

ICRP (2007a) advanced the concept of w_T and recommended basing values of w_T primarily on the incidence of radiation-induced cancer rather than on mortality, as well as on the risk of heritable disease over the first two generations. The values of w_T, are based on epidemiologic studies of cancer induction as well as on experimental genetic data after radiation exposure, and on expert judgment. The w_T values represent mean values for humans, averaged over both sexes and all ages. Effective dose is calculated for a Reference Person and not for an individual (ICRP 2007a).

The tissue weighting factors recommended by ICRP (2007a) (Table 7.2) are sex- and age-averaged values for all organs and tissues, including the male and female breasts, the testes, and the ovaries. This averaging implies that the application of this approach is restricted to the determination of effective dose in radiation protection and, in particular, cannot be used for the assessment of individual risk.

Recommendation: NCRP adopt the w_T values in Table 7.2 provided by ICRP (2007a).

Table 7.1. --- 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 (Equation 7.1)

Table 7.2 --- 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
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 (ET) region, gall bladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate (male), small intestine, spleen, thymus, uterus/cervix (female).

References (Section 7.2.4 and 7.2.5)

ICRP (1991b). *ICRP Publication 60: 1990 Recommendations of the International Commission on Radiological Protection*, Elsevier Health Sciences.
ICRP (2007a). ICRP publication 103. *Annals of the ICRP*, 37**,** 1-332.
NCRP Scientific Committee 1-20 Report (in progress)

7.2.6 Biologically-Based Dose-Response Models

There are well-documented limitations to the reliance on epidemiologic data for estimating cancer and noncancer risks at low radiation doses and dose rates (NCRP, 2012b). In cases where such direct use has been presented (e.g., Kendall et al., 2013; Pearce et al., 2012), it is clear that low statistical power, possible confounders and uncertainties in dose and assessed health outcome make any conclusion quite preliminary. A way forward is to develop and utilize approaches that integrate radiation biology data into available or proposed radiation epidemiologic studies in support of a risk assessment process. The specific application is to enhance the extrapolation from available high or medium dose epidemiologic data to the dose levels and dose rates relevant for radiation protection purposes. In this regard, it has been proposed that some form of BBDR modeling could meet this need (e.g., Conolly et al., 2004;

Curtis et al., 2002; Little et al., 2008; NCRP, 2012b; Shuryak et al., 2010). However, modeling on such a biological basis is also uncertain outside the range of the available data that are used as input parameters to a biologically-based model. For risk assessment for environmental chemicals, because of the paucity of epidemiologic data, it has been proposed that a BBDR model approach be used for predicting adverse health outcomes under low-dose chronic exposure scenarios (EPA, 2005). However, the approach has been used very sparingly in the regulatory arena itself, largely because of the lack of availability of the appropriate data sets to provide input parameters to a BBDR model. The need for expanded use of BBDR models has been concisely expressed in NCRP Report No. 171 (NCRP, 2012b):

"The challenge of developing a biologically-based computational model to minimize uncertainty in dose-response modeling can be summarized as: understanding a sufficient amount of the relevant biology; acquiring enough data to parameterize the model; and developing the computational model."

Of course, this simple statement hides a degree of complexity that must be addressed. For example, how much of the detailed biology do we need to know and when are there sufficient data to sustain model development? This situation can be significantly alleviated if research is directed towards the data requirements identified by BBDR models; research targeted to the risk assessment process is needed.

It is to be noted that no viable BBDR model has been proposed and applied to radiation risk assessment, with the possible exception of the multistage model developed by Shuryak et al. (2010) for the analysis of cancer risk patterns as a function of age-at-exposure in Japan atomic-bomb survivors.

The development of realistic BBDR models is a viable goal for enhancing the current risk assessment approach for radiation-induced cancer and quite possibly for noncancer diseases. The rapid advancements in our understanding of the basis of a range of adverse health outcomes (cancer and noncancer) and the equally rapid technological advances (whole genome analysis; proteomics, systems biology) make the enhanced use of BBDR models a realistic goal.

References (Section 7.2.6)

Conolly RB, Kimbell JS, Janszen D, Schlosser PM, Kalisak D, Preston J, Miller FJ 2004. Human respiratory tract cancer risks of inhaled formaldehyde: dose-response predictions derived from biologically-motivated computational modeling of a combined rodent and human dataset. Toxicol Sci 82: 279-296.

Curtis SB, Luebeck EG, Hazelton WD, Moolgavkar SH. 2002. A new perspective of carcinogenesis from protracted high-LET radiation arises from the two-stage clonal expansion model. Adv Space Res 30: 937-944.

EPA (US Environmental Protection Agency) 2005. Guidelines for carcinogen risk assessment. In: EPA/630/P 03/001F Washington, DC: US Environmental Protection Agency, 1-166.

Kendall GM, Little MP, Wakeford R, Bunch KJ, Miles JC, Vincent TJ, Meara JR, Murphy MF 2013. A record-based case-control study of natural background radiation and the incidence of childhood leukaemia and other cancers in Great Britain during 1980-2006. Leukemia 27: 3-9

Little MP, Vineis P, Li GQ. 2008. A stochastic carcinogenesis model incorporating multiple types of genomic instability fitted to colon cancer data (vol 254, pg 229, 2008). Journal of Theoretical Biology 255: 268.

NCRP (2012b). NCRP Report No. 171

Pearce MS, Salotti JA, Little MP, McHugh K, Lee C, Kim KP, Lee C, Craft AW, Berrington de Gonzalez A, Parker L 2012. Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. Lancet 380: 499-505.

Shuryak I, Sachs RK, Brenner DJ. 2010. Cancer risks after radiation exposure in middle age. J Natl Cancer Inst 102: 1628-1636.

8. Recommendations

8.1 Introduction

NCRP published its most recent complete set of recommendations for the limitation of exposure to ionizing radiation as NCRP Report No. 116 (NCRP, 1993a). ICRP published its most recent set of recommendations for a system of radiological protection as ICRP Publications 103 and 118 (ICRP, 2007a; 2012). The recommendations made in this Report are similar to those made previously by NCRP and ICRP. However, some changes have been made for clarity in language and terminology, and in some cases the dose values recommended for control of exposure have been changed.

8.1.1 Principles of Radiation Protection

Historically the System of Radiation Protection (the NCRP System) has incorporated the three principles of justification, optimization (the ALARA principle) and dose limitation. In this Report, NCRP has restated the principle of dose limitation as restriction of individual dose. Consequently, NCRP recommends Dose Criteria for optimization and control (Section 4.3). The NCRP System is applied here to the three exposure situations (Section 2.1) and exposure categories (Section 2.2).

Recommendation: NCRP reaffirms the Principles of radiation protection stated as justification, optimization (the ALARA principle), and restriction of individual dose.

ICRP (2007a) applied its concepts of dose constraint and reference level in conjunction with the optimization of protection (the ALARA principle) to restrict individual doses. NCRP does not use the dose constraint and reference level terminology in this context. Instead NCRP has recommended that individual Dose Criteria be used in optimization of planning and exposure control. The similarities and differences are discussed in the subsections of Section 8, and are summarized in Tables 8.1 and 8.2.

Recommendation: Restriction of individual dose be stated as individual Dose Criteria for optimization.

The dose recommendations in Table 8.1 are subject to various conditions as stated in the footnotes to Table 8.1. It is also expected that the ALARA principle will be applied to reduce the actual dose received to as low a value as is reasonably achievable. However, in NCRP Report No. 116 (NCRP, 1993a) the Council also recommended that an annual effective dose of 0.01 mSv be considered a Negligible Individual Dose (NID) per source or practice. This recommendation is reaffirmed in this Report. The NID corresponds to a risk for adverse health effects of less than 5 in 10 million. The recommendations in this Report are related to the broader recommendations as given in Table 8.3.

Dose Criteria are recommended to restrict dose based on two adverse health outcomes, tissue reactions and stochastic effects (primarily cancer mortality). The Council no longer recommends

Comment [M104]: Ansari … see Ansari comments at Table 8.2 and Section 4.3.

Cool (refer to Table 8.2 and Section 4.3) … Good question. One of the many places where we need to be clear, and as yet are not.

I think we are recommending two things. The recommendation here refers to ALARA, and so rightfully use the dose criteria for optimization. We also have recommended dose criteria for control, which is related to "limits" that all us regulators (past and present) refer to. As the draft developed the two terms have become very similar, which is no doubt contributing to potential confusions.

Table 8.1 --- Summary of recommendations for occupational exposure (adverse tissue reactions).

Tissue or Organ	NCRP (1993a) Annual Equivalent Dose (mSv)	ICRP (2012) and ICRP (2007a) Annual Equivalent Dose (mSv)	This Report Annual Absorbed Dose (mGy)
Crystalline lens of the eye.	150	20 (average over 5 y)[a] 50 (single year)[a]	50
Skin	500 (localized areas)	500 (at a depth of 70 μm averaged over 1 cm^2)[b]	500 (at a depth of 70 μm from any external source of irradiation and averaged over the most highly exposed 10 cm^2 of skin.)
Hands and feet.	500 (localised areas)	500 (at a depth of 70 μm)[b]	500 (at a depth of 70 μm averaged over area exposed.)

[a] From ICRP (2012).
[b] From ICRP (2007a).

Table 8.2 --- Summary of basic recommendations (adverse stochastic health effects).

Situation[a] → / Category	Planned Annual (Effective Dose, mSv)			Emergency Exposure (Effective Dose, mSv)			Existing Annual (Effective Dose, mSv)		
	NCRP (1993a)	ICRP (2007a)	This Report	NCRP (1993a)	ICRP (2007a)	This Report	NCRP (1993a)	ICRP (2007a)	This Report
Occupational	50[b]	20[c]	50[d]	500[e]	None[e] 1,000 or 500	500[f]	none	none	50[d]
Public	1[g]	1[h]	1[i]	5[j]	20-100[k]	20[i]	none	1-20	5[i]

[a] These situations were defined in ICRP (2007a) and are not strictly applicable to the recommendations in NCRP (1993a).
[b] Subject to a cumulative dose not to exceed 10 mSv times age.
[c] Averaged over 5 y, not to exceed 50 mSv in any one year.
[d] Dose Criterion for optimization with a Dose Criterion for control of 20 mSv annually.
[e] For life saving or equivalent purposes.
[f] Dose Criterion for optimization with a Dose Criterion for control of 50 mSv annually.
[g] Continuous or frequent exposure.
[h] Recommended limit.
[i] Dose Criterion for control.
[j] Intended for infrequent exposure.
[k] Reference level

Comment [M105]: Ansari … criterion for optimization is 50 mSv/y while criterion for control is 20 mSv/y. I found that confusing and would have thought them to be the other way around.

Comment [M106]: Ansari … the comment above may apply here also.

Comment [M107]: Ansari … the comment above may apply here also.

Table 8.3 --- Framework for source-related effective dose criteria with examples for single dominant sources for all exposure situations that can be controlled. (Adapted from Table 5, ICRP, 2007a).

Dose criteria [a] (mSv)	Characteristics of the Exposure Situation	Radiological Protection Requirements	Examples
Greater than 20 to 100[b,c]	Individuals exposed by sources that are not controllable, or where actions to reduce doses would be disproportionately disruptive. Exposures are usually controlled by action on the exposure pathways.	Consideration should be given to reducing doses. Increasing efforts should be made to reduce doses as they approach 100 mSv. Individuals should receive information on radiation risk and on the actions to reduce doses. Assessment of individual doses should be undertaken.	Dose criterion set for the highest planned residual dose from a radiological emergency.
Greater than 1 to 20	Individuals will usually receive benefit from the exposure situation but not necessarily from the exposure itself. Exposures may be controlled at source or, alternatively, by action in the exposure pathways.	Where possible, general information should be made available to enable individuals to reduce their doses. For planned situations, individual assessment of exposure and training should take place.	Dose criteria set for occupational exposure in planned situations. Dose criteria set for comforters and caregivers of patients treated with radiopharmaceuticals. Dose criterion for the highest planned residual dose from radon in dwellings.
1 or less	Individuals are exposed to a source that gives them little or no individual benefit but benefits society in general. Exposures are usually controlled by action taken directly on the source for which radiological protection requirements can be planned in advance.	General information on the level of exposure should be made available. Periodic checks should be made on the exposure pathways as to the level of exposure.	Dose criteria set for public exposure in planned situations.

[a] Acute or annual dose.
[b] In exceptional situations, informed volunteer workers may receive doses above this band to save lives, prevent severe radiation-induced health effects, or prevent the development of catastrophic conditions.
[c] Situations in which the dose threshold for tissue reactions in relevant organs or tissues could be exceeded should always require action.

the use of dose equivalent or equivalent dose for assessing adverse tissue reactions because these quantities were developed for stochastic (no threshold dose) effects. The Dose Criteria for tissue effects is now stated as absorbed dose. Dose Criteria for stochastic effects continue to be given as effective dose or equivalent dose to a specific organ.

8.1.2 Ethical principles

The NCRP System is based primarily on the ethical principles (Section 3):

- beneficence,
- non-maleficence,
- autonomy, and
- justice.

The uncertainties associated with establishing the relationship between radiation dose and adverse stochastic health effects at radiation doses approaching those delivered by the ubiquitous natural background radiation have resulted in a fifth principle, that of precaution, being added to the NCRP System. Thus, the recommendations continue to be based on the radiation dose-effect model termed linear-no-threshold (LNT) for exposure to doses above approximately 1 mSv.

Recommendation: The NCRP System continue to be based on the LNT model to describe the dose-effect relationship for stochastic adverse health effects.

8.2 Tissue Reactions

Recommendations are given in this section for Dose Criteria related to exposure of the skin and extremities, and the lens of the eye for planned and existing exposure situations (Sections 8.2.1 and 8.2.2). Special considerations are necessary for occupational exposures during emergency situations, which are covered in Section 8.2.3.

8.2.1 Skin, Including Extremities

Both NCRP (1993) and ICRP (2007a) have stated that discrete limits are necessary to protect localized areas of skin including the extremities against tissue reactions because these tissues will not necessarily be protected by limits on effective dose. The recommended limits were given in equivalent dose because, as explained by ICRP (2007a), "the relevant RBE values for the deterministic effects are always lower than w_R values for stochastic effects. It is, thus, safely inferred that the dose limits provide at least as much protection against high-LET radiation as against low-LET radiation". NCRP (1993a) and ICRP (1991b) recommended that for occupational exposure the annual limit be set at 500 mSv. This recommendation was reaffirmed by ICRP in Publication 103 (ICRP, 2007a), which specified that the limit applied to the equivalent dose averaged over 1 cm^2 area of skin regardless of the area exposed. ICRP (2007a) also provided a recommended annual limit for public exposure of 50 mSv.

NCRP (2001b) has recommended a somewhat different approach to assessing skin dose relevant to radiation protection. Following a detailed report on biological effects for "hot particles" on the skin (NCRP, 1999) the Council reassessed its recommendation for skin exposures.

The Council then made the following recommendation (NCRP, 2001b):

> "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 (500 mGy) 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 the skin limit to high-LET radiations, the Council recommends the approach taken in NCRP Report No. 132 (NCRP, 2000) in which the absorbed dose is multiplied by the biological effectiveness of the radiation to obtain a radiation-weighted absorbed dose (in gray). This may then be compared to the limit expressed in gray. Values of biological effectiveness for the various high-LET radiations are given in Table 8.4.

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 6.3. Consequently NCRP makes no recommendation of Dose Criteria related to exposure of the skin and extremities for members of the public.

Recommendation: For planning and dose control during operations the absorbed Dose Criterion in skin at a depth of 70 μm from any external source of irradiation be 0.5 Gy (500 mGy) averaged over the most highly exposed 10 cm^2 of skin.

Recommendation: There be no Dose Criteria recommended for the skin for exposure of the public.

8.2.2 Lens of the Eye

NCRP has determined that it is prudent to reduce the current recommended annual lens of the eye occupational absorbed Dose Criterion to 50 mGy (NCRP, 2016a). If it is necessary to apply the recommended lens Dose Criterion to high-LET radiation, NCRP recommends the approach described in Section 8.2.1 for skin exposures.

Recommendation: The annual absorbed Dose Criterion for occupational exposure to the lens of the eye be 50 mGy.

Recommendation: The annual absorbed Dose Criterion for members of the public lens of the eye exposure be 15 mGy.

Table 8.4 --- Biological effectiveness values for converting absorbed dose in tissue (gray) to radiation-weighted absorbed dose in tissue (gray) for tissue reactions (adapted from ICRP, 1989).[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)
Proton >2 MeV	1.5	----

[a]RBE values for late tissue reactions are higher than for early effects in some tissues and are influenced by the doses used to determine the RBE.
[b]There are not sufficient data on which to base RBE 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 kVp x rays as the reference radiation, the RBE for neutrons <1 MeV are comparable to those for fission spectrum neutrons. It is reasonable to assume that the RBE values for >50 MeV will be equal to or less than those for neutrons in the 5 to 50 MeV range.
[c]There are few data for the tissue reactions of ions with a $Z > 18$ but the RBE values for iron ions ($Z = 26$) are comparable to those for argon. Based on the available data a value of 2.5 for the RBE of heavy ions is reasonable. One possible exception is cataract of the lens of the eye because high RBE values for cataracts in mice have been reported.

8.2.3 Acute Organ Effects

The principal organ effects that could lead to serious injury or death from radiation exposure are given in Table 8.5. ICRP has established a maximum value for its reference level of 100 mSv. Further ICRP stated, "Exposures above 100 mSv incurred either acutely or in a year would be justified only under extreme circumstances, either because the exposure is unavoidable or in exceptional situations such as the saving of life or the prevention of a serious disaster" (ICRP, 2007a). Nevertheless, in footnotes b and c associated with Table 8.3 ICRP 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." and, "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.

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

Recommendation: For planning and dose control during operations the absorbed Dose Criterion for exposure to a significant portion of a critical organ, such as active bone marrow, be 1 Gy.

Recommendation: For dose control during operations the absorbed Dose Criterion for exposure of the whole body be 0.5 Gy for occupationally exposed individuals engaged in critical emergency situations.

Recommendation: For planning and dose control during operations the absorbed Dose Criteria for exposure of the lens of the eye and skin be adjusted accordingly.

Recommendation: In exceptional situations, informed volunteer workers may receive doses above these Dose Criteria to save lives, prevent severe radiation-induced health effects, or prevent the development of catastrophic conditions.

The recommendations for annual occupational absorbed Dose Criteria for the various tissue reactions for planned, emergency and existing exposure situations are summarized in Table 8.6.

Table 8.5. --- 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; ranges indicate area dependence for skin and differing medical support for bone marrow.

Table 8.6 --- Recommendations for annual occupational absorbed Dose Criteria for tissue reactions (Gy).

Exposure Situation [Absorbed Dose (Gy)]			
Planned	Emergency	Existing	Critical Organ
0.05	1.0	0.05	Active bone marrow
0.05	0.5	0.05	Total body
0.05	1.0	0.05	Crystalline lens of the eye
0.5	1.0	0.5	Localized areas of the skin
0.5	1.0	0.5	Hands and feet

8.3 Stochastic Effects

The Council has reviewed the estimated risks for radiation exposure and the uncertainties in these risk estimates. As a result the Council has determined that there is no basis for changing the fundamental ICRP (2007a) recommendations for controlling doses (based on stochastic effects) as expressed in Table 8.3. The differences are that the Council does not use the ICRP terminology of dose constraints and reference levels, but has established a single general term, individual effective Dose Criteria, for optimization and control to apply adequate protection for various situations. The Council has retained its basic recommendations for restriction of annual effective dose (NCRP, 1993a), but has placed those recommendations within the three exposure situations (planned, emergency and existing.) using the flexibility provided by ICRP (2007a) as stated in footnotes b and c to Table 8.3.

It should be noted that the recommended dose criteria depend upon the exposure situation. When the exposure can be reasonably expected to be under the control of the party responsible for the radiation source causing the exposure, the recommended dose criteria are more restrictive than in emergency or existing exposure situations in which the source of the exposure is not controllable. However, in all situations the recommended dose criteria represent adequate protection within the NCRP System.

The dose recommendations, based on the health detriment related to stochastic effects, for occupational, public and medical exposures are discussed for each of the three exposure situations in Sections 8.4 through 8.6. Summaries of the recommended dose criteria for occupational exposure are given in Table 8.7, and for exposure to members of the public, to comforters and caregivers, and to medical research volunteers are given in Table 8.8.

8.4 Planned Exposure Situation

8.4.1 Occupationally Exposed Individuals.

Occupational exposure is discussed in Section 2.2.1. The Council continues to endorse the annual effective dose recommendation of 50 mSv for occupationally exposed individuals stated in NCRP Publication No.116 (NCRP, 1993a) for planned occupational exposure.

Recommendation: For planning and design of radiation protection the annual effective Dose Criterion for optimization be 50 mSv.

Previously NCRP (1993a) recommended that the cumulative lifetime dose for an individual not exceed 10 mSv multiplied by the individual's age. The Council no longer recommends a limit on the cumulative lifetime dose for an individual. Instead the Council recommends that for occupational exposure the average annual effective Dose Criterion for control for an individual be 20 mSv over any consecutive 5 y period.

Recommendation: During operations the Council recommends the average annual effective Dose Criterion for control for an individual be 20 mSv.

3946 Table 8.7 --- Recommendations for occupational exposure.

3947

Exposure Situation	Purpose	Individual Effective Dose Criteria (mSv)		
		Planned	Emergency	Existing
General				
Annual	Optimization	50	500	50
	Control	20	50	20
Pregnancy				
Annual	Control (during pregnancy)	5	5	5
Minors under 18 y				
Annual	Control	1	20	5
Negligible individual dose				
Annual	Optimization	0.01	0.01	0.01

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Table 8.8 --- Recommendations for exposure to members of the public, to comforters and caregivers, and to medical research volunteers.

Exposure Situation	Purpose	Individual Effective Dose Criteria (mSv)		
		Planned	Emergency	Existing
General				
Annual	Optimization	5	20	-
	For the first year of occupancy (existing)			20
	Control	1	20	-
	For continued occupancy (existing)			5
Comforters and caregivers				
Annual-adults (not pregnant)	Optimization	5	-	-
Annual-adults (pregnant)	Optimization	1	-	-
Medical research volunteers				
Societal benefit			-	-
minor	Optimization	<0.1		
intermediate	Optimization	0.10-01	-	-
moderate	Optimization	1 – 10	-	-
substantial	Optimization	>10	-	-
Negligible individual dose				
Annual	Optimization	0.01	0.01	0.01

As in the past, the Council continues to recommend that minors who are employed in an occupation in which exposure to radiation is possible be treated as members of the public for radiation protection purposes.

Recommendation: For dose control during operations the annual effective Dose Criterion for individuals under the age of 18 y be guided by the recommendations for exposure to the public.

As discussed in Section 8.1 the Council reaffirms its NID as the effective dose at which efforts to reduce radiation exposure to the individual may not be warranted (NCRP, 1993a).

Recommendation: An annual effective dose of 0.01 mSv be considered a Negligible Individual Dose (NID) per source or practice

8.4.1.1 Special Considerations and Dose Criteria for Medical Staff. In some circumstances it may be necessary for a health care worker to exceed the recommended annual effective Dose Criterion 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 (2010) describes situations where this may be necessary in fluoroscopically guided interventional procedures.

In such situations policies and procedures should be in place so that in the event of a reasonably foreseeable time-critical urgent or emergent situation, advanced provision exists for exceeding the annual occupational effective Dose Criterion. However, the average annual effective Dose Criterion for an individual of 20 mSv over any consecutive 5 y period still applies.

8.4.1.2 Embryo and Fetus. The sensitivity of the embryo and fetus for both mental retardation and cancer should be considered in all situations involving irradiation of an embryo or fetus (NCRP, 1993a). This is a special consideration for occupationally exposed pregnant workers.

For the risk of cancer induction from prenatal exposure, ICRP (2007a) indicates that it is prudent to assume that the risk of induction of childhood solid tumors is similar to that of leukemia and the risk of cancer later in life is similar to that of childhood irradiation and is, at most, about three times that of a population as a whole (ICRP, 2007a). ICRP (1991b) indicated that while there is no need to differentiate between male and female occupational exposure, when a worker is known to be pregnant, it is appropriate that a higher more stringent standard of protection is afforded to the fetus. ICRP (2007a) also indicated in the 2007 recommendations (Publication 103, paragraph 299) that "prenatal exposure would not be a specific protection case, i.e. would not require protective actions other than those aimed at the general population".

This situation can be thought of as occupational exposure to the mother while the unborn child is treated as a member of the public. In the context of occupational exposure consideration must be given to the right of the mother to retain her job. The ethical principles of autonomy and justice (Section 3.2.2) permit the mother to accept risks for her unborn child. In the context of exposure to a member of the public, exposure to the unborn child would normally be governed by the Dose Control criteria for planned exposure (Section 8.4.2). Within the framework presented in

Table 8.3, a reasonable compromise would be to consider the exposure to the unborn child as an infrequent occurrence and establish the Dose Criterion for the pregnant worker at 5 mSv for the period of her pregnancy. This is a slight change from the previous NCRP (1993a) recommendation of an equivalent dose equal to 0.5 mSv per month to the developing embryo and fetus, once the pregnancy is declared.

Recommendation: For planning and dose control during operations the annual effective Dose Criterion for an occupationally-exposed pregnant worker be 5 mSv for the period of her pregnancy. Exposure control based on this Dose Criterion should begin when the pregnancy is declared

This recommendation reflects the need to limit the total lifetime risk of leukemia and other cancers in individuals exposed in utero. At doses below the recommended Dose Criterion the risk of all tissue reactions is expected to be negligible. It also reflects the fact that monitoring the dose to the mother during her pregnancy is more practical than attempting to determine the dose to the embryo/fetus.

8.4.2 Exposure of the Public

The public is familiar with the effective dose value of 1 mSv as the annual dose limit under current regulations. NCRP (1993a) recommended this value as a public dose limit for continuous or frequent exposures. However, NCRP also recommended a maximum annual effective dose limit of 5 mSv for infrequent exposures. ICRP (2007a) establishes an upper dose constraint of 20 mSv for members of the public under certain circumstances.

It is prudent and practical for NCRP to establish the effective Dose Criterion for control for planned exposure situations at 1 mSv y^{-1} for members of the public. In all situations a process of optimization shall be applied to reduce the actual exposures below the recommended Dose Criterion consistent with the ALARA principle.

The Dose Criterion for control for a planned exposure situation should be the design objective for any individual source of radiation exposure. The design objective may be reduced below 1 mSv y^{-1} based on the application of the ALARA principle. Periodic estimates of exposures to members of the public should be made to confirm that the design objective is being met. This should assure that for possible exposure to multiple sources, the exposure of any individual would likely not exceed the Dose Criterion for optimization of 5 mSv in any one year.

Recommendation: For planning and design of radiation protection systems the annual effective Dose Criterion for optimization be 5 mSv.

Recommendation: For dose control during operations the annual effective Dose Criterion for control related to any individual source of radiation be 1 mSv.

Information regarding potential radiation effects on children has become clearer over the last decade, especially with regard to specific tumor types and the temporal pattern of risk expression for different tumors (Section 6.2). However, the overall risk coefficient has not changed significantly since the Council's prior recommendation (NCRP, 1993a). The greater sensitivity of children was already factored into that recommendation. The Dose Criteria for public exposure provide responsible consideration for the sensitivity of infants and children, as well as the developing fetus for all exposure situations.

8.4.3 Exposure Related to Certain Medical Activities

Certain medical procedures and research activities involve radiation exposure to individuals who are not patients, but rather members of the public. Because of the benefits of these exposures and the possibility that they could expose an individual to an effective dose that exceeds the Dose Criteria for control for planned exposures, special consideration is required. These individuals can be grouped into two classifications: Comforters and Caregivers, and Human Studies Research subjects. ICRP (2007a) recommended that the dose constraint for caregivers be 5 mSv per episode. The recommendation for the dose constraint for volunteers for biomedical research is based on the expected benefit to society and ranges from less than 0.1 mSv to greater than 10 mSv.

8.4.3.1 Comforters and Caregivers. ICRP (2007a) and NCRP (2006) addressed radiation exposure to comforters and caregivers, particularly family members. 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 FGI procedure. This is generally permissible for a family member. Appropriate radiation protection measures shall 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. These exposures occur infrequently and merit special consideration. ICRP (2007a) recommends a dose constraint of 5 mSv per episode. Based on NCRP (2006) the Council recommends an annual effective Dose Criterion of 5 mSv be applied for adult members of the family of a patient, other than pregnant women. An annual effective Dose Criterion equal to 1 mSv is recommended for pregnant women and children.

Recommendation: For planning the annual effective Dose Criterion for control be 5 mSv for adult members of the family of a patient, other than pregnant women, and 1 mSv for pregnant women and children. .

Hired caregivers such as healthcare aides or nurses are not generally considered to be occupationally exposed. The radiation exposure they receive in the course of caring for their patients should reflect effective Dose Criteria recommended for members of the public in planned exposure situations.

For the purpose of applying radiation exposure Dose Criteria, other patients, visitors to the medical facility, and staff who are not specifically trained in radiation safety should be

considered members of the public and their dose restricted within the recommended effective Dose Criteria for planned exposure.

Recommendation: The effective Dose Criteria for hired caregivers, other patients, visitors to the medical facility, and staff who are not specifically trained in radiation safety reflect Dose Criteria recommended for members of the public in planned exposure situations.

8.4.3.2 Human Studies Research. The radiation dose a human subject receives specifically through participation in a research protocol, which would not have been received otherwise, is considered separately from that received in the normal course of medical treatment.

Comment [KK108]: NCRP recommendations will be based on the report of SC 4.7 and PAC 4.

The use of ionizing radiation modalities must be justified and should be assessed against the potential use of other modalities that utilize nonionizing radiation (such as ultrasound and magnetic resonance imaging), to minimize radiation exposure to the human subject. A key consideration in the process of justification is whether or not the radiation study adequately assesses a given clinical trial measure, and whether it does so while delivering the lowest reasonable radiation dose.

As in standard medical care, imaging studies in a research protocol should be optimized, to ensure adequate image quality with the lowest possible radiation absorbed dose. Protocol designers and Institutional Review Board reviewers must consider:

- whether or not the clinical trial measures are appropriate and are effectively obtained;
- whether or not the clinical trial measures are obtained using the lowest radiation dose that is reasonably achievable; and
- whether the estimated radiation risk is appropriate within the context of other protocol risks and any potential benefits.

ICRP (2007a) recommends effective doses to volunteers from biomedical research, if the research is a benefit to society be restricted to a range from <0.1 mSv for minor benefit to >10 mSv for substantial benefit. Table 8.8 contains recommendations based on ICRP (2007a) Table 8.

In the United States, for clinical research involving radioactive drugs conducted under the auspices of a Radioactive Drug Research Committee, specific limitations apply under Federal Regulations [21 CFR 361.1(b)(3)] (FDA, 2015). Subjects must receive the smallest radiation dose with which it is practical to perform the study without jeopardizing the scientific benefits of the study. Under no circumstances can the radiation dose to an adult subject from a single study, or cumulatively from a number of studies conducted within 1 y, exceed the limits shown in Table 8.9. For subjects under 18 y of age, the radiation dose cannot exceed 10 % of the adult values. (NCRP recommendations will be based on the report of SC 4.7 and PAC 4.)

Table 8.9 --- Limits for conducting Radioactive Drug Research Committee studies on adult research subjects.[a]

Portion of Body	Dosing	Dose
Whole body	Single dose	30 mSv (effective dose)
	Annual and total dose commitment	50 mSv (effective dose)
Active blood-forming organs, lens of the eye, gonads	Single dose	30 mGy (organ dose)
	Annual and total dose commitment	50 mGy (organ dose)
Other organs	Single dose	50 mGy (organ dose)
	Annual and total dose commitment	150 mGy (organ dose)

[a]Adapted from 21 CFR 361.1(b)(3) (FDA, 2015), separating specific organ dose from the whole-body dose and basing the organ dose limits on the tissue reactions (Section 8.2).

8.5 Emergency Exposure Situation

Following an accident or malicious event that introduces a source of radiation, the radiation dose may be rapidly changing and is not under any controls. Protection may be based upon controls placed on individuals and individual actions.

8.5.1 Occupationally Exposed Individuals

The first responders to an emergency must be considered as occupationally exposed. They may be exposed to radiation dose rates that are much greater than those typically encountered in an occupational setting. Consequently there is a potential for accumulating a high dose in a short time. Under these conditions special considerations should be given to the Dose Criteria. Guidance for dose control for first responders is given in NCRP Report No. 165 (NCRP, 2010a).

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. Dose Criteria that are higher than those recommended for planned 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 (2010a) 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 of 0.5 Gy as a decision point at which the benefit of further exposure is evaluated.

Dose control for life-saving 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. This can be done by selectively shielding a portion of the active bone marrow and by controlling the absorbed dose to the total body. For this purpose the Dose Criteria for avoiding adverse tissue reactions (Table 8.6) should be applied.

Recommendation: For operations in life-saving and other urgent rescue activities the effective Dose Criterion be 500 mSv.

For activities that do not involve life-saving and other urgent rescue actions, NCRP recommends that the Dose Criteria be based on adverse health outcomes of a stochastic nature and that the effective Dose Criterion be 0.5 Sv.

Recommendation: During activities that do not involve life-saving and other urgent rescue activities the effective Dose Criterion be 0.5 Sv.

Following the immediate response, emergency operations may continue for some time. During this period the Dose Criteria should be based on those for a planned exposure situation and the recommended effective Dose Criterion is 50 mSv.

Recommendation: For dose control the effective Dose Criterion be 50 mSv for extended activities during the emergency.

8.5.2 Members of the Public

During the emergency there is likely to be some possibility of controlling dose to members of the public by certain actions. These actions could include sheltering in place, evacuation, or distribution of radioprotective drugs. The beneficial effects of applying any of these controls should be evaluated and justified as quickly and completely as possible. Guidance for protection of the public in emergency situations is given in NCRP Report Nos. 138 (NCRP, 2001a) and 165 (NCRP, 2010a). No dose limits are recommended.

NCRP (1993a) made no specific recommendation related to exposure to the public in emergency situations, or when the dose to individual members of the public might exceed the normal dose limits. Presumably the applicable limit was understood to be 5 mSv because the exposure would be infrequent. ICRP (2007a) states, "Reference levels for the highest planned residual doses in emergency situations are typically in the 20 mSv to 100 mSv band of projected dose."

During the early stages of an emergency it will be extremely difficult to control and assess the dose to any individual member of the public. The Council accepts the statement of ICRP (2007a) concerning the range of doses estimated in emergency situations and recommends that the effective Dose Criterion for a member of the public be 20 mSv during the period of the emergency.

Recommendation: For planning and dose control during emergency situations the effective Dose Criterion for optimization and control be 20 mSv for a member of the public.

8.6 Existing Exposure Situation

As discussed in Section 2.1, in an existing exposure situation there may be limited means to take any protective actions based on modifying the source itself, and the levels of exposure may not warrant urgent actions to achieve the objectives of radiation protection.

NCRP (1993a) did not define an existing exposure situation in Report No. 116. However, the Council did provide recommendations for remedial actions for naturally occurring radiation. This is a limited case of an existing exposure situation. 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". ICRP (2007a) recommends that reference levels for existing exposure situations should be set typically in the 1 mSv to 20 mSv band of projected dose.

Naturally Occurring Radioactive Material (NORM) poses unique challenges to The NCRP System because of the ubiquitous nature of the radioactive material, and 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 through optimization (the ALARA principle) with individual dose criteria can, and should be applied.

Because of the widespread nature of NORM in the environment, the exposure is usually considered to be an existing exposure situation. Human activities often change the prevailing circumstances of exposure, in some cases enhancing the concentration of NORM materials. It is these circumstances that warrant particular attention from a radiation protection standpoint.

Recommendation: There be a systematic, graded approach to NORM, based on characterization of the exposure conditions, the level of dose received by individuals, and the possibilities for taking action to reduce exposures.

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. Potential exposure to the public may be elevated over the normal level expected from the ubiquitous background radiation. In situations such as this remedial actions, which may involve active public participation, are taken to reduce this exposure. However, an elevated radiation dose may exist for some time during this process.

8.6.1 Radon and Naturally Occurring Radioactive Material

High levels of radon may be found in both homes and in workplaces. In this situation the equivalent dose to the lung is the important radiation protection quantity. However, it is difficult to determine on an individual basis and is not practicable to use for radiation protection. Consequently, a Criterion has been established for the radon concentration in air at 300 Bq m^{-3} (NCRP, 1993a; ICRP 2014). This represents an annual effective dose of approximately 20 mSv. This criterion applies to both occupational and public exposure.

In almost all cases, radon mitigation actions based on concentration will be sufficient, and further actions are generally not warranted under the optimization principle.

Recommendation: Radon levels be assessed, and the Air Concentration Criterion be 300 Bq m^{-3}

8.6.2 Occupationally Exposed Individuals

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.

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

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, for example, 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 Dose Criteria for planning and control of occupational exposure under planned exposure situations apply.

Comment [M109]: Cool edit

Recommendation: The effective Dose Criteria for optimization and control of occupational exposure under planned exposure situations apply.

Occupational exposure would occur during remedial actions to institute controls on exposure for an existing situation. Previous NCRP (1993a) recommendations imply that the limit for annual occupational dose applies in this situation. ICRP (2007a) applies its reference levels to occupational exposures. The Council recommends that the protection for occupational exposure in planned exposure situations be applied.

Recommendation: For planning and design of a remedial action the annual effective Dose Criterion for optimization be 50 mSv.

Recommendation: For dose control during operations the annual effective Dose Criterion for control **for an individual be 20 mSv.**

8.6.2 Members of the Public

Consistent with previous NCRP recommendations (NCRP, 1993a) and ICRP recommendations (ICRP, 2007a) summarized in Table 8.3, the Council recommends that the effective Dose Criterion be 20 mSv in the first year following identification of the situation. The Council further recommends that the annual effective Dose Criterion be set at 5 mSv for later years.

Recommendation: For planning purposes the effective Dose Criteron for optimization for a member of the public be 20 mSv in the first year following identification of the situation.

Recommendation: For dose control purposes the annual effective Dose Criteron for control for a member of the public be 5 mSv for later years.

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9. Protection of the Environment

The principal aim of NCRP in Section 9 is to provide both a factual basis and coherent philosophy from which to establish a framework for an appropriate level of protection of the environment against the detrimental effects of radiation exposure. These recommendations are consistent with other radiation protection recommendations of NCRP in that they are intended to prevent the occurrence of adverse radiation-induced effects while still enabling those activities which provide benefit to society from such exposures.

Within the United States, radiologic impacts to the environment because of human activities have resulted from past intentional or accidental releases and continue through periodic regulated intentional releases of radioactive substances. These impacts have been modest in almost all cases. However, NCRP in its advisory capacity has an obligation to provide guidance to regulators, industry, and the public on radiation doses and their effects to nonhuman biota. This guidance is intended to provide a defensible technical foundation for those organizations and individuals tasked with the responsibility of assessing radiologic impacts on the environment.

NCRP recognizes that the ultimate determination of what constitutes an appropriate or allowable environmental impact requires much more than adherence to a single numerical value of 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
- inherent value of the environment being evaluated.

Those considerations are, appropriately, outside the purview of NCRP.

9.1 Philosophical Basis of Environmental Radiation Protection

The NCRP has long supported the philosophy that radiation protection is more than simply the development of limits. It requires justification for exposure and optimization of dose such that potential harm is minimized (Lindell, 1966; NCRP, 1993). Radiation protection of the environment readily fits within this philosophical framework (Higley, 2016). In the last 20 y there has been considerable effort expended globally to examine the philosophical basis of environmental protection in an effort to develop a consensus on what constitutes an appropriate framework for protection (Dicus, 2003; Pentreath, 1999; Robinson, 2003). Most recent recommendations focus on environmental endpoints which impact population maintenance, such as reproductive success (Andersson et al., 2008; ICRP, 2007a; UNSCEAR, 2008).

Comment [KK110]: From Andersen
Andersen – General Comment: It seems to me that the most vexing issue in regard to protection of the environment or protection of non-human species, which are not necessarily the same thing, is that we haven't clarified our objective. For human protection, we have been pretty clear that the objective is to prevent deterministic effects and minimize (ALARA) stochastic effects for individuals – sorry for the "old" terminology. Can we be more specific for this section in regard to our views on individual protection versus some collective level of protection (e..g., community, species, or habitat)? I think that this would help convey a better understanding of why dose control targets are not recommended and why the use of screening criteria is practical and protective (i.e., in meeting the defined objective).

9.2 Scientific Basis for Radiation Protection Guidance

Past efforts on environmental radiation protection assumed that humans were the most radiosensitive species, and that by protecting them all other organisms 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 (Rose, 1991).

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 World Health Organization (WHO), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and International Atomic Energy Agency (IAEA). WHO has concluded that the radiation doses received by the Japanese population following the accident, while substantial, are unlikely to result in measurable excesses of cancer in the human population (WHO, 2012). However, in contrast, a recent publication has matched field observations of impacts on birds in the vicinity of Fukushima with a rigorous assessment of dose (Garnier-Laplace et al., 2015). This assessment has concluded that dose rates and doses experienced by numerous avian species at Fukushima were within the range where adverse population level are expected to occur. Because pathways of exposure and dose, even within the same environment, differ markedly amongst organisms, steps taken to limit human exposures may not restrict doses of nonhuman biota to levels that would prevent adverse population effects, particularly in the wild (Higley, 2016).

Radiation protection of the environment, as a concept distinct from protection of people has been vigorously debated for more than 20 y (Higley, 2016). 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 the environment have been widely developed and implemented both within and outside the United States. A comparison of recent recommendations is shown in Table 9.1. 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 has recommended a framework for consideration of environmental radiation protection (ICRP, 2008). ICRP published its derived consideration reference levels (DCRLs) (ICRP, 2007a), dose conversion factors (ICRP, 2008), and guidance for application of the ICRP methodology (ICRP, 2014). 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 radiologic impact.

Table 9.1 --- Comparison of reported effects and absorbed dose-rate screening levels for nonhuman biota.[a]

Organization	Dose Rate (mGy d^{-1})	Criteria	Reference
DOE	1	Recommended dose rate criteria for terrestrial mammals	DOE (2002)
ICRP	0.1	Lower level, DCRL[b], mammals	ICRP (2008)
UNSCEAR	2	Lowest reported value for chronic ecosystem level effects	UNSCEAR (2008)
EU Protect	0.2	Screening level for all species set at a predicted no effects dose rate	Andersson et al. (2009)
UK	0.1	Screening level	
Russia (suggested)	0.07	Long-lived warm blooded mammals	Sazykina and Kryshev (1999)
EU Protect	0.05	Vertebrate screening level	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.
[b] DCRL is derived consideration reference level.

9.3 Recommendations

Dose limits per se are not appropriate in the context of environmental protection, as it is not feasible to monitor individual organism dose against a limit. However, as previously noted, scientific data provide an indication of the levels of absorbed dose rate likely to cause measurable impacts in nonhuman species. Bradshaw et al. (2014) has 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 9.1). Although not shown on Figure 9.1, the DOE recommendations would align with the upper level of the ICRP recommendations.

While dose limits are not appropriate for environmental protection, NCRP believes that establishing screening values is an appropriate task for this advisory body. Consequently, NCRP acknowledges that the current science on radiation impacts on organisms and the environment warrants a screening level of 0.1 mGy d^{-1}. Below this level, no additional analysis should be considered. Conversely, absorbed dose rates exceeding this level may require additional evaluation.

Recommendation: An absorbed dose criterion for screening of 0.1 mGy d^{-1} be established for organisms and the environment.

Comment [AA(111]:
Ansari … It is clear how this section's discussion and this recommended screening level apply to Existing Exposure situations. But do they apply to other exposure situations? If not, we should specify it. But if the principles of protection for non-human species do apply to other exposure situations, it would make this section even more helpful if we can elaborate on how:

- For Emergency Situations, a good example from Fukushima is mentioned in the text – doses to avian species high enough to expect tissue reactions. We also know the dreadful consequences (not directly due to radiation) for mammalian farm animals that were left behind as people were evacuated. Should we comment on how these factors should be balanced in emergency response situations? How do we allocate scarce resources when taking action to reduce dose or assist non-human species may mean taking resources away from humans. [of course related to ethics as well] But in practice, do we have a recommendation for these situations or a practical guide to follow?

- In a Planned Exposure Situation (although I can't think of a good example at this moment), dose rates to non-human species may exceed this screening level for a period of time. Accumulated dose to non-human species can also exceed dose limits for humans because of protection measures humans take and non-humans can't. How should we approach those situations?

Higley

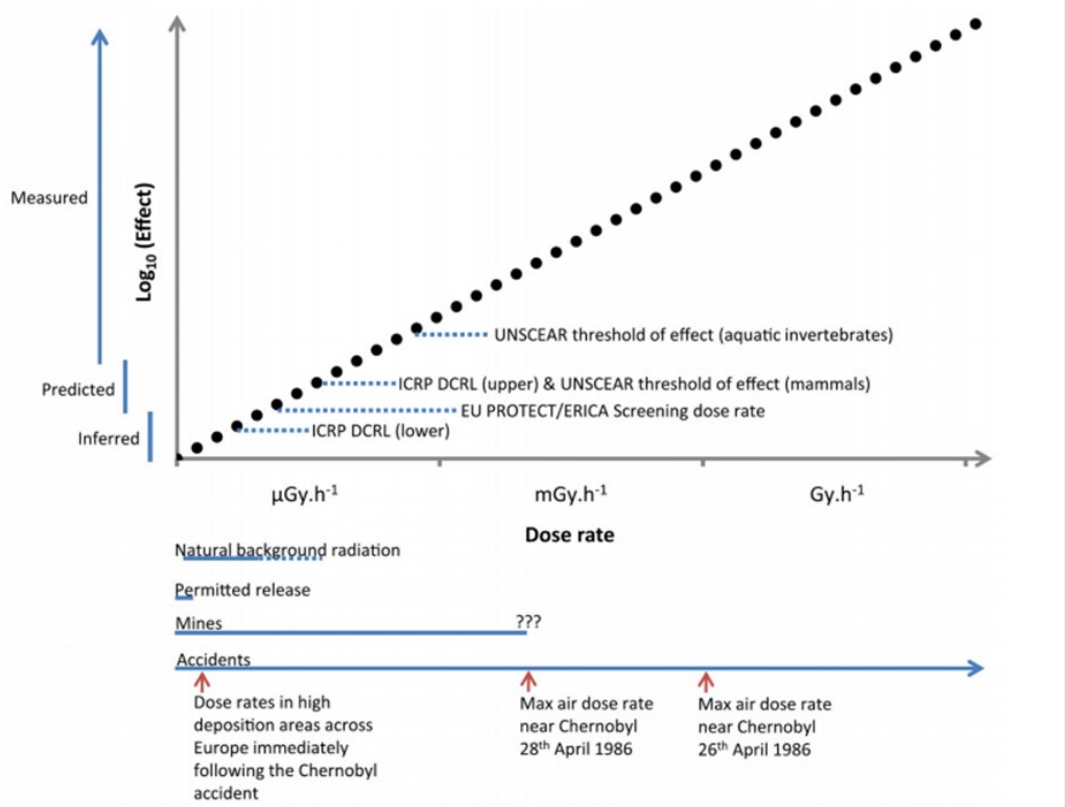

Fig. 9.1. A qualitative comparison of radiation guidance and doses from anthropogenic and natural sources in comparison with measured, predicted and inferred effects (Bradshaw et al., 2014).

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10. Communication of NCRP's System of Radiation Protection to Stakeholders

Comment [M112]: Kase … I read through Section 10 quickly. At this point I think we should include it as is, but eventually I think that it can be condensed somewhat, perhaps by 30% or so.

Hyer et al.

Key Points

- Effectively communicating the guidance is as important as the guidance itself.
- A tangible benefit to open, transparent, and effective communication is the establishment and maintenance of trust and confidence in the system of radiation protection for stakeholders.
- Professionals, patients, the media, and the public have various perceptions of radiation risk and thus different information needs and communication best practices.
- Public perception of radiation risk can evoke some of the highest levels of concern – special risk and crisis communication best practices are needed to effectively deliver key information and encourage helpful behaviors.

Communication has always been an integral part of NCRP's mission as prescribed in its Charter (see below). However, the need for communication of its recommendations has changed dramatically over time and the tools available for communication have evolved rapidly over the past decade. An objective of Section 10 is to clearly articulate NCRP's role in communicating its recommendations and to provide guidance on how this can be accomplished.

Another objective of Section 10 is to provide guidance for the communication of the Council's recommendations encompassed in this Report to all of its stakeholders. Stakeholders in this context are defined as all parties that would have an interest in the Council's recommendations.

A tangible benefit to open, transparent, and effective communication is the establishment and maintenance of trust and confidence in the NCRP system of radiation protection (The NCRP System). Part of this communication effort should be directed to fostering an understanding of The NCRP System, its underlying science and philosophy, and the accompanying regulatory mechanisms. Depending on the type of exposure situation, stakeholders may include the relevant scientific and professional organizations, industry, medical workers, the media, and the general public (including patients and their caregivers). A variety of training, educational, outreach, and collaborative opportunities can promote this understanding among these stakeholders.

The sections below review how communication has been achieved historically, how NCRP currently communicates with its stakeholders, and how to incorporate available new technologies for the future. The section also discusses various types of stakeholders that may have an interest in the Council's recommendations and provides examples of how The NCRP System can be effectively communicated through different degrees of interaction to these stakeholders. Finally, the section provides a general discussion on the challenges of communicating radiation protection and the risks and benefits of the use of radiation in our everyday lives.

Section 10 is not meant to prescribe the details of how to communicate, rather it is a high level view of principles that can be employed, the various groups of stakeholders involved, and new areas to explore in the future. It is clear that NCRP must give more emphasis to communicating its recommendations in the future and this section is meant to provide a guide. The Council believes this topic is critical to the understanding, acceptance, and implementation of these recommendations. Therefore, this section is the beginning of a renewed area of focus for NCRP the future.

10.1 NCRP's responsibility to communicate its System of Radiation Protection

NCRP specifically recommends the following principles when communicating radiation guidance:

- **Inclusiveness** – one should engage all relevant stakeholders in the dialogue and dissemination of information
- **Culture of safety** – an effective culture of safety should be cultivated and maintained to facilitate radiation protection
- **Accountability** – there should be clear accountability for radiation protection responsibilities, including responsiveness to feedback on safety from internal and external stakeholders
- **Transparency** – all communication should be transparent with accurate, open, user-friendly and easily understandable information for the individuals and groups that need to access and use it
- **Use of all channels** – communications should utilize the wide range of mechanisms that are available for reaching all professionals, stakeholders, media, and especially the public; social media outlets can be a key resource to help reach specific populations.

Communication has always been an integral part of NCRP's mission and is clearly stated in the first article of its Congressional Charter (NCRP, 1964). It is to:

> "Collect, analyze, develop, and disseminate in the public interest information and recommendations about (a) protection against radiation (referred to herein as radiation protection) and (b) radiation measurements, quantities and units, particularly those concerned with radiation protection:"

This element of NCRP's Charter has been manifested in many different forms over its existence, including reports, commentaries, annual meetings, topical meetings, media interaction, professional society participation, Congressional testimony, and in many other forms.

Nevertheless, the Council's policies on communication have taken a much more proactive direction over the past decade by including experts on communication as members of the

Council. Knowledge from these professionals is dramatically influencing not only the substance of NCRP products and their clarity but also how the information is disseminated and communicated. Although communication has always been a foundation of NCRP's mission, the Council is moving to strengthen and expand the role of communication of its work in the future. This Report, in particular, is an example of how communication has been incorporated into NCRP's work from the very beginning of the organization of this committee and the evolution of the Report from its earliest draft to the final product.

The Council recognizes its responsibility to communicate to its stakeholders but it also realizes the limitations inherent in this goal. Stakeholders span a broad spectrum of government and private organizations, professionals, and members of the general public. Therefore, the degree to which we can effectively communicate directly with stakeholders and the methods employed differ. Section 10.2 addresses who our stakeholders are and how we plan to strengthen our communication role to each.

The following sub-sections provide a general overview of the comprehensive process involved in the development of NCRP's work products and the communication of these products to a broad scope of interested persons and organizations.

10.1.1 Standards of Scientific Excellence and Quality Required by NCRP

Effective communication begins with the highest standards of science. NCRP recommendations are produced primarily in the form of reports and are the product of a high-standard peer review and publication process. The intensive internal and external peer review process that is required by each NCRP report is one of the most extensive and thorough of any scientific organization. This standard of excellence ensures that the recommendations of the Council are founded on the best available science and are clearly presented. A brief summary of the peer review process is described below along with a discussion of the different types of publications NCRP uses to communicate its recommendations to its stakeholders.

10.1.2 Peer Review Process for NCRP Reports

NCRP reports carry the full weight and authority of the Council. A draft report being prepared by an NCRP committee undergoes essentially continuous review by the committee, but NCRP also employs an extensive review process that begins when the committee has finished its drafting work. When the committee has produced what is deemed to be the penultimate draft, the report is sent to a Program Area Committee (PAC) that is expected to provide suggestions and advice on how the draft publication might be improved prior to submission to the full Council membership. Frequently, the committee identifies expert reviewers outside of the Council membership who could also provide valuable comments. The comments of the PAC and expert reviewers, as well as any comments resulting from review by the committee members are collected, they are made available to the committee, considered, and modified if needed.

With the critical review process completed, the draft publication, as revised on the basis of the comments generated during the PAC and expert review process, is sent to the full Council (100

members), Distinguished Emeritus members, and Collaborating and Special Liaison Organizations for review. The publication may also be sent, as a draft, to other interested and informed individuals and organizations both in the United States and abroad, with requests for comments.

The comments resulting from the review are collected and the process of examination and modification by the committee begins again. The goal of this iteration is to reconcile significant scientific differences between the scientific committee and the reviewers. In the end, NCRP reports require the approval of essentially 100 % of the Council's members. If any differences of opinion between Council members and the scientific committee remain, they are resolved by the Board of Directors.

The rigorous peer review process described above is required for all NCRP reports. However, the Council has other forms of communication of its recommendations available that may be used depending on the circumstances involved.

10.1.3 Other Forms of Communication of NCRP Recommendations to Stakeholders

In addition to NCRP reports, the Council uses other forms of communicating with its stakeholders, each incorporating varying forms of peer review and publication. These publications give NCRP the ability to respond quickly to specific requests or emerging issues. Examples of these forms of communication are described below.

- Commentaries provide preliminary evaluations, critiques, or reviews and results of exploratory studies, and are approved by the Board of Directors rather than the Council membership.
- Supplements, which are approved by the Board of Directors, are additions to existing reports and commentaries, allow new information to be provided on a previously reported topic.
- Statements are concise documents that succinctly address topics of contemporary interest and importance for radiation protection.
- Proceedings of the annual meetings.
- Proceedings of NCRP sponsored symposia.
- Lauriston S. Taylor lectures.
- Presidential Reports, which are documents on specific issues in radiation protection that are developed by a scientific committee, reviewed by members of Council and other subject area experts as needed, and approved for publication by the President and Board of Directors.

In addition to these avenues, supplemental mechanisms (such as presentations at scientific meetings, speaking to public groups, and responses to media requests) are also used to communicate NCRP recommendations with stakeholders. Regardless of the form of communication used, the Council incorporates a rigorous and extensive review process to meet its standards of excellence for communicating The NCRP System.

10.1.4 Recent New Initiatives of NCRP Related to Communication of its Recommendations

(Text pending; some topics listed below)

- Transmission of annual meetings over the web
- PAC-7
- CC-1 report

10.1.5 Future Initiatives in Communication of NCRP Recommendations

NCRP will need to evaluate its communication strategy with respect to newer technologies and practices. It is key that NCRP adapts to these changes to ensure that its quality product and guidance reach their intended audiences.

Radiation is one of the least understood and most frightening matters. The media attention to radiation events and recent large scale disasters, like Fukushima, serve to aggravate these challenges and further weaken trust. Thus the challenge for anyone trying to communicate radiation topics and risk will be to overcome people's concerns, such that correct and accurate information can be exchanged. If knowledgeable authorities do not communicate this information effectively, the information gap will be filled by other sources of information that may or may not serve the public interest.

Today, nearly everyone is inundated with information and it has become increasingly difficult to be heard. These challenges apply almost everywhere. Moreover, the internet and the concept of "Web 2.0" are rapidly changing how people create and receive information. Web 2.0 represents the movement from passive viewing of content (downloading documents, charts, graphs, photographs) to actively viewing and creating content by many users. This is the very nature of social media. Web 2.0 also heralds the movement of the internet from static text to dynamic video. A recent Nielsen report predicts 90 % of web traffic will be video by 2020 and it is expected that 1,000,000 minutes of video will cross the internet every minute!

Change is inevitable and people and organizations either move with change or are at risk for being left behind. The trends in the internet are such that there will be a movement towards quality of message and content. The dominance of video will favor stories, vignettes, personal accounts, and anecdotal reports over statistics and figures.

Sharing ideas and recommendations with others, particularly in high detail, will likely continue to take place in written reports. There has been a long standing trends to make written reports more visually interesting and attractive. Use of tables, graphs, call-out boxes, photographs, and colors can greatly increase reader interest and retention of key materials.

Social media outlets can be very useful in providing users with access to credible, science-based health information when, where and how users want it. One must accept the concept of bringing information to where the end users are. A recent Nielsen study showed that Americans doubled their time spent on social media channels in a single year (Nielsen, 2015). A variety of social media tools can be employed to reinforce and personalize messages, reach new audiences, and

build a communication infrastructure based on open information exchange. There are three key attributes of social media channels that are believed to make them highly effective as health communication tools.

- Personalization: content tailored to individual needs.
- Presentation: timely and relevant content accessible in multiple formats and contexts.
- Participation: partners and the public who contribute content in meaningful ways.

Additionally, many social media channels facilitate social engagement, viral sharing of information and trust (CDC, 2011).

Comment [AA(113]: Ansari ... John, if you have a more recent 2016 version, please substitute. I think you are referring to the Health Communicators' Social Media Toolkit? That is a 2011 reference found here: http://www.cdc.gov/socialmedia/tools/guidelines/pdf/socialmediatoolkit_bm.pdf
I edited the reference list to include this.

Till

NCRP will need to evaluate its communication strategy with respect to newer technologies and practices. It would be challenging to make specific recommendation here. What is known is that how and where people receive and process information is rapidly changing. It is key that NCRP adapts to these changes to ensure that its quality product and guidance reach their intended audiences.

10.2 Communication Strategies for Stakeholders

The stakeholders of The NCRP System include:

- agencies or organizations responsible for regulating radiation exposures of the public, the workers, and the environment;
- individuals or groups of individuals occupationally or accidentally exposed to radiation;
- public or private entities responsible for appropriations or expenditure of funds for control of radiation exposures; and
- anyone interested or otherwise affected by the nation's governing system of radiation protection and its underlying scientific principles.

The information needs of various stakeholders vary. So does the nature of NCRP's relationship and the extent of its direct engagement with each group of stakeholders. Consequently, the content and means of communication to address the information needs of each group need to be examined carefully. In this section, a number of specific NCRP stakeholders and their information needs are briefly described along with communication strategies for each.

Government, legislators and scientific or professional organizations often have direct communication links with the NCRP. Radiation workers and the general public typically have indirect links to the NCRP. While they may go to the NCRP guidance documents for information and to answer their questions, it is more likely that they obtain information about radiation protection from other subject matter experts such as radiation protection agencies, radiation safety trainers, radiological health researchers and educators, radiation protection leadership within organizations for whom they work, and medical professionals providing patient care involving radiation.

10.2.1 Governmental Agencies

To enhance the communications exchange, it is recommended that government agencies have representatives with the expertise and time to evaluate NCRP guidance on the System of Radiological Protection, and translate it into working regulatory practices.

Government agencies, at both the federal and state levels, are responsible for establishing and enforcing the system of radiation protection as it applies in their respective jurisdictions. These agencies include the Nuclear Regulatory Commission (NRC), the Environmental Protection Agency (EPA), the Department of Energy (DOE), the Department of Defense (DOD), the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA), the National Aeronautics and Space Administration (NASA), and each of the state radiation control programs. These government agencies can use the guidance and recommendations of the NCRP as the scientific foundation to inform their regulatory practices. Other federal and state government agencies engaged in protection of the people and the environment including the Centers for Disease Control and Prevention (CDC) and Department of Homeland Security (DHS) can use the guidance and recommendations of the NCRP to inform their activities in promoting public health. As such, the NCRP often has a direct relationship with government agencies and is responsive to specific needs which these agencies may express for scientific guidance and recommendations.

Government organizations in turn need to communicate their findings, practices, and regulations to their stakeholders. It is worth noting that radiation protection regulations may not necessarily reflect the latest NCRP guidance and recommendations. Government agencies consider societal, practical, and other factors to develop new regulations, and the regulatory process by nature takes time.

Government agencies often obtain their knowledge of The NCRP System directly from the reports and commentaries of the NCRP. As described in Section 10.1, members of the NCRP may testify before Congress and other lawmakers. Government agencies also request the NCRP to provide evidence-based recommendations to fill a radiation protection gap. Some representatives from government agencies are members of NCRP committees. In this capacity, they engage in research on radiation protection issues and help formulate new or updated guidance.

10.2.2 Lawmakers

Although the NCRP is a congressionally chartered organization, it receives no appropriations from Congress and the scientific activities it conducts within its Charter are not managed by Congress. However, the NCRP is occasionally called upon to provide information on specific scientific topics to congressional staff or to offer testimony at congressional hearings. These congressional requests may be part of legislative activities, government oversight functions, or response to particular constituents. The NCRP communication with congressional staff is direct, and the content is responsive to specific requests from congressional staff.

NCRP guidance is typically brought to lawmakers by government agencies during rulemaking. It is valuable to both the agency and lawmakers when the objective perspectives of the NCRP are used to support regulations. The agency representative must thoroughly research NCRP perspectives before sharing them with lawmakers. NCRP Report executive summaries provide a brief overview of the findings. The documents also have a comprehensive index which makes finding specific evidence more efficient. The agency representative may have to translate some of the scientific evidence used by the NCRP into more common language. Educating legislative staff assigned to committees or individual representatives is valuable as they may have more time to read and understand technical information for summaries they provide lawmakers.

The scientific findings of the NCRP may also be used to clarify positions of interest to the constituents whom lawmakers represent. There may be debate about a radiation protection issue within a community or in a certain industry that can be improved with recommendations from the NCRP. This Report characterizes these exposures in Section 2. Fact-based guidance to restrict dose for planned, existing and emergency exposure situations is found in Section 8.

The answers to questions about existing situations are often not as straightforward as with planned and even emergency situations. ICRP Publication 103 describes the complexities when high levels of radon or other naturally occurring radioactive materials contribute significantly to public dose, or when an incident at a nuclear facility or other site can cause radiological contamination to the environment (ICRP, 2007a).

As described in NCRP Report No. 175, the circumstances of exposure and criteria for control of that exposure following a radiological or nuclear emergency may not fit neatly into The NCRP System without site-specific optimization (NCRP, 2015). This optimization must be conducted in collaboration with the community members who may be displaced, and with those who may return to once abandoned locations.

> More so than in any other exposure situation, agencies must listen to the concerns and suggestions of the people exposed when radioactive materials and radiation are newly discovered or introduced into a community.

As important as listening is to the communication process, so too are the steps of sharing the initial information so the listener receives the message as intended. The National Library of Medicine provides excellent guidance for readable health materials (https://www.nlm.nih.gov/medlineplus/etr.html). The speaker must know the audience and determine the objectives of the message for each audience. A message can be scored for readability with word processing software. The speaker must also demonstrate proficiency with the science, especially since it is likely he or she will have to answer questions about the initial message. Subject matter expert is a designation more easily lost than gained.

Reading press coverage or other accounts after the message is delivered can provide feedback about message delivery and reception. Effective organizations have public information officers

that perform this and similar tasks to measure the success of communications activities. Should there be misconceptions a clarification should be published to mitigate them.

10.2.3 Scientific and Professional Organizations

Scientific and professional organizations represent a pool of subject matter experts who contribute, directly or indirectly, to development and implementation of the system of radiological protection. Their work practices in areas of radiation research or radiation safety are often influenced by regulatory decisions. Furthermore, senior members of these organizations are often engaged by media outlets to disseminate information on issues of public interest. Representatives of these organizations are consulted by legislative bodies and decision makers at state and federal levels.

As such, these organizations should be regarded as stakeholders themselves and as important partners in the context of communicating The NCRP System to other stakeholders. In the last several decades, the NCRP has fostered close relationships with national and international organizations engaged in science and the practice of radiation protection. These organizations include the Radiation Research Society (RRS), the Health Physics Society (HPS), the Conference of Radiation Control Program Directors (CRCPD), the International Radiation Protection Association (IRPA), the International Commission on Radiological Protection (ICRP), and the International Commission on Radiation Units and Measurements (ICRU), the American Association of Physicists in Medicine (AAPM), the American College of Radiology (ACR), the American Nuclear Society (ANS), Radiological Society of North America (RSNA), and the American Society of Radiation Oncology (ASTRO). Many universities have academic programs that support radiation protection and the industries requiring radiation protection. They also look to the NCRP for guidance and for reference material for teaching and research.

In times of crises and emergencies, the contributions of such organizations become even more vital. Members or representatives of scientific and professional organizations can help inform and explain radiation protection concepts to the public through print, broadcast, or social media. Communication material, especially if developed and coordinated in advance with these organizations, help ensure that clear and consistent messages are available and disseminated using risk communication science and methodology.

These entities often serve as translators. They may engage government lawmakers and radiation protection agencies during rulemaking and try to represent one or many perspectives of the public who are exposed to, or the industries which use, radiation and radioactive materials. This role is important because not every law or government position is necessarily based on facts. The role is so important that many organizations have liaisons with government officials.

> It is important that scientific and professional organizations maintain liaison relationships with the NCRP, so developments in our understanding of The NCRP System can be accurately translated by them for their constituents.

10.2.4 Radiation Workers

As explained below, radiation workers may not be the primary and direct audience of NCRP guidance and recommendations because the immediate information needs of radiation workers, in both industry and medicine, focus on operational and procedural issues and the regulatory radiation protection practices at their specific institutions. However, radiation protection managers, radiation safety officers and instructors can use NCRP guidance and recommendations to guide their practices, procedures, and development of educational material they use to train and inform their workers.

An important pillar of any system of radiological protection is its safety culture in maintaining the safety of workers, the public and the environment (Classic et al., 2014; IAEA, 1991; 2002; 2013; IRPA, 2014).[4] While the radiation protection system is promulgated and subsequently regulated by appropriate state or federal government agencies, the primary responsibility for the safe and secure use of radiation and radioactive materials is with individuals and organizations performing those regulated activities. Both industry and the regulatory community are encouraged to increase the transparency of and communication about their efforts to assess and improve their safety cultures (IAEA, 2013; NA/NRC, 2014).

A model is what is called the nuclear safety culture. It is defined as "the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment" (HPS, 2012; NRC, 2011).

An essential component of a positive safety culture is open and transparent communication with a focus on safety. The focus areas of communication in the context of nuclear safety culture are operational issues and procedures at the workplace, and the concept is primarily for workers in the nuclear industry. However, the concept of safety culture has broader applications and applies to all classes of workers with potential for occupational exposures. Furthermore, free and transparent communication can and should include all aspects of The NCRP System to foster trust and confidence.

Medical care providers comprise a large and important group of workers with potential for radiation exposure. The concept of promoting safety-focused communication toward a positive safety culture applies to the medical exposure situation. Practitioners' understanding of the radiation protection system will help in the implementation of that system and improved safety practices that benefit both the practitioners and the patients. With the growing proportion of medical doses in the overall dose to humans (NCRP, 2009), strengthening the medical worker's knowledge of the radiological protection safety culture, and promoting their discussion and use of its tenets with patients is vital.

[4] The term "safety culture" was first introduced by the International Nuclear Safety Advisory Group (INSAG, 1986) and further expanded on in INSAG (1988).

Under potential emergency exposure situations, workers are likely to encounter conditions different from their routine responsibilities, and they may be asked to undertake critical emergency response tasks with potential radiation exposures beyond applicable routine annual exposure limits (EPA, 2013; FEMA, 2013; IAEA, 2015; NCRP, 2001). Effective communication with workers about safety practices, potential risks, and the system in place to monitor and protect their safety in emergency exposure situations is most effective when included as part of the routine worker training and refresher training. This can have immediate impact in saving lives (e.g., when medical care providers are receiving contaminated or exposed patients with life-threating injuries) (NCRP, 1994; 2001; HHS, 2006a; FEMA, 2013; CDC, 2012; IAEA, 2015).

Radiation workers are among the most important of people with whom NCRP guidance about The NCRP System is shared. They have agreed to earn a living at the expense of radiation dose. For many the cost is modest, a small dose accumulated slowly over a long time. For others, the cost may be much higher. For both, it is critical that fears be attended to with the same facts. This Report provides those facts with the individual Adverse Health Outcomes from Radiation Exposures described in Section 6, accounted for in the Radiation Risk Estimates, Detriment and Uncertainties of Section 7, and controlled by dose criteria in the Recommendations of Section 8.

It is the responsibility of the employer to clearly share the findings in these sections of the Report at multiple opportunities. The first is at the time of employment. At this point a brief summary should be shared with prospective new hires. A common source of such guidance is required by the legal radiation protection authority for the jurisdiction.

> It is recommended that the Nuclear Regulatory Commission, Agreement States, Environmental Protection Agency, Department of Energy, Department of Defense, Occupational Safety and Health Administration, and Conference of Radiation Control Program Directors review the recommendations of this Report and revise their notices, instructions and reports to workers relative to radiation protection.

Once hired, personnel need radiation protection training commensurate with their level of radiation exposure. Administrative staff who work near a radiology suite need not have the same level of training as the radiologic technician in that suite. State and Federal regulations consistently provide guidance about the required level of radiation protection training. Those licensed by these authorities must periodically evaluate the effectiveness of this training. As it is important to verify the message was received as intended, the trainee should be tested for comprehension of key information. NCRP Report 134 provides guidance on radiation protection training programs (NCRP, 2000), and Appendix B of NCRP Report 162 provides a useful tool for verifying the adequacy of training for all scales of radiation protection programs (NCRP, 2009).

Training must continue throughout employment, not simply because regulations require it, but because the science behind radiation protection regulation advances. In this Report, the evidence

for some risks of radiation exposure have been found to be less than measured in the past, and some risks are now understood to be greater than previously reported. Where there is insufficient evidence to change perspectives for other health outcomes, this can illuminate the issue of uncertainty. The components of this uncertainty are described in Section 7.2.

> It is recommended that the findings of this Report be incorporated into radiation worker training programs to ensure the latest findings on risk and detriment are shared with those exposed occupationally to radiation.

10.2.5 The General Public

As was the case with radiation workers, members of the public are not the primary and direct audience of NCRP guidance and recommendations. Information needs of the public vary depending on where they live, where they work, and whether they or members of their family have had medical exposures or other life experiences involving radiation. People living in proximity to a nuclear facility or in communities where construction of new facilities are planned would have specific needs for information on potential risk to their families and their environment.

In an emergency exposure situation, the needs and demands of the public for information are immediate, and require clear, concise, and actionable information (NCRP, 1994; 2001). During the recovery phase of an emergency, however, communication challenges are different. When the transition is made from an emergency exposure to an existing exposure situation, and members of the public are encouraged to return to homes they previously evacuated, they are likely to scrutinize and question the radiological safety criteria supporting those recommendations (ICRP, 2012). Recognizing the concerns of the public and understanding their need for information are necessary for effective communication.

Public perception of radiation risk is often disproportionate to the actual risk. As a result, radiation safety practitioners, managers, and regulators continue to face communication challenges. Furthermore, too often traditional and social media outlets provide inaccurate or exaggerated information that increases apprehension about the subjects of radiation and radioactive materials. These outlets are growing in number, and reliance upon them for the majority of information used by members of the public is accelerating. Leveraging the same means of communication to provide accurate and contextual information is paramount.

In this context, medical patients and caregivers comprise an important sector of the general public. It is common for health care providers to share information with their patients getting diagnostic images or receiving radiation therapy. Radiologists and radiation oncologists can easily explain how the benefits of exposure far outweigh the adverse effects possible. Some patients who have been administered radioactive materials to treat an illness are released to caregivers despite that the materials within their bodies emit radiation. The radiological health

care provider releasing the patient to a caregiver must be capable of providing caregivers a thorough summary of the risks of their personal radiation exposure while helping another.

Public information personnel should have policies and plans to clearly explain the rationale supporting the system of radiation protection. Engagement with the public about The NCRP System, and how it pertains to their real everyday lives and what it means for their future helps build public trust in The NCRP System.

The NCRP communication efforts are not targeted at the general public. However, the guidance and recommendations and the scientific discussions that support NCRP recommendations can be the basis for developing such targeted communication materials.

While the worker has agreed to incorporate some risk from radiation exposure, he or she has also been additionally compensated with specialized training to provide the knowledge and skills to minimize dose, and is provided detailed personal dose information through time. This bargain rarely exists for members of the general public, who may find themselves suddenly and unexpectedly in a radiation exposure situation. Such is the case for homeowners who obtain radon test results that require mitigation or for a whole nation when a disaster includes widespread radioactive material contamination. For the latter, the ICRP identified radiological protection and risk communication problems were important impediments following the reactor releases at Fukushima (ICRP, 2012). The CDC has exceptional guidance that can prevent many communication problems with planning (CDC, 2012).

Because the audience is diverse and obtains information in many ways, communication about the relevant aspects of The NCRP System must be shared in many ways. The means by which people share information change rapidly, and should be understood so accurate information is found efficiently and from those well informed by guidance such as found in this Report. In radiological or nuclear emergencies, testing message templates for effectiveness is useful. FEMA has provided tested messages for an improvised nuclear device (FEMA, 2013). Many jurisdictions have developed similar products for nuclear power plant accidents (CRCPD, 2010).

Social media can be a force multiplier (White, 2012), and important information can reach more people more rapidly using brief comments, a photograph, an attention-grabbing video, and a web link for more details.

> It is recommended that a diverse collection of social media outlets as well as traditional print and broadcast methods be used to communicate critical messages about radiation protection to the general public in brief, effectiveness-tested, written, audio and video formats to accommodate the multiplicity of communication devices.

10.2.6 The Media

The media are an effective mechanism for reaching an audience. Traditional media outlets (television, radio, and print media) together with more modern media outlets (internet and social media) reach large segments of the population and are effective in forming public opinion and perceptions. Establishing and maintaining a professional relationship with members of the media can create opportunities to communicate informational and educational materials for the public regarding radiation issues of national or local concern. This relationship can be cultivated by creating scientific information in templates or formats that members of the media can use. It would be helpful to indeed work with members of the media, on an ongoing basis, to develop communication materials that can be used in short notice when the need arises (e.g., when a medical overexposure occurs or when the news of a new published study generates public interest.)

The NCRP is responsive to requests from the media for information, and in that context, does have a relationship with the media. However, it is prudent for major stakeholders in the nation's radiation protection system, namely government agencies and scientific and professional organizations to work with media on an ongoing basis so they can have credible and accurate information when they need it.

The role of the media becomes more paramount during public health emergencies. While it is important to recognize that the role and function of the media is not the same as a public information officer (CDC, 2012), media professionals can be effective partners, through open and honest communication, to provide timely information to the public and help manage a crisis. Developing media guides with basic background information that members of the media can use during public health emergencies is one such approach (HHS, 2006a). Engaging representative members of the media in the creation of communication templates used for emergencies is another and complimentary approach. For example, FEMA (2013) published an interagency guide that provides such messages for use in the aftermath of an improvised nuclear device detonation. The media professionals' knowledge of what works can be combined with learning about radiation and emergency response. If knowledgeable authorities do not communicate this information effectively, the information gap will be filled by other sources of information that may or may not serve the public interest.

10.3 Challenges of Communicating Concepts of Radiological Protection

Communicating radiation risk is challenge and people react differently to radiation concerns. Since people react to and process information differently in the high-concern setting, communication strategy must adapt as well. Effective communication is key; the better the target audiences are able to understand and process key information, the higher the likelihood of appropriate perception of actual risk and helpful behaviors and attitudes.

Radiation and radiation risk are some of the most complex topics. There are broad applications of radiation from the personal level with medical imaging and cosmic radiation to daily exposure with radiation workers to community concerns with a nuclear power plant. Radiation protection

is, by definition, communicating risk. There is no uniform nor consistent perception of radiation risk. Public perception and acceptance is determined by the context in which the radiation is used. Various intended audiences will have different needs regarding not only technical content but also best practices of communicating risk. Amongst an uninformed and unfamiliar audiences, the inherent risk and unknowns of radiation can trigger some of the highest levels of concern. Amongst professional audiences, familiarity with radiation does reduce the perceived risk.

The very different reactions to different uses provide insight into the nature of perception and the determinants of acceptable risk (Slovic, 1996). In in the setting of high awareness and high trust, such as radiation professionals and some stakeholders, communication and education strategies can be based on conveying data and detailed guidance in a conventional logical and organized fashion. On the contrary, for those uninformed, unfamiliar or with different priorities, a different strategy is often required. In this high-concern, low-trust setting, using best practices of risk and crisis communication is essential. These practices focus on addressing peoples' natural emotional response in a high-concern, low-trust setting.

There are many enhanced challenges for getting balance and useful information about radiation to people. Most situations will be non-crisis or routine. Since radiation remains a high-concern issue, many of the techniques used in risk and crisis communication will still apply in the routine setting. For example, message mapping has proven to help explain complex matters. Message mapping is a strategy to create a set of key messages (usually three) consisting of short statements that are easily understood. The three key messages when said together comprise a soundbite, or easily quoted and memorable phrase. Each key message can have more detailed information available for a more informed response. These layered answers to key questions are very useful to communicate key concepts in the high-concern setting. Once people grasp the key concepts, they are more open for complexity and details.

The message map strategy was developed for the top 60 difficult question for pandemic influenza (HHS, 2006b). For the 2014 Ebola crisis, the 50 State Health Officials developed message maps for the top 60+ questions on Ebola (Covello and Hyer, 2014). The detailed peer-reviewed message maps were published in the middle of intense media coverage. Data from an independent tracking poll of Americans' perception of improved accuracy in media reporting were tightly correlated with the publication and downloading of this document (Frankovic, 2014). A similar effort is now being done for communicating risk and healthy behaviors associated with the Zika virus.

Radiation risk remains a high concern topic for many people. People simply process information differently in the high concern setting and officials must account for this. Effective communication is key; the better the target audiences are able to understand and process key information, the higher the likelihood of appropriate perception of actual risk and helpful behaviors and attitudes.

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Comment [M114]: MR … need full citation

Hyer

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Glossary (These Glossaries are currently under further review)

[Teaching Definitions]

Absorbed dose: Not all the ionizing radiation to which we are exposed actually causes dose. Some is reflected away, some is used up in the dead layer of skin that covers the outer layer of our bodies and some actually passes all the way through our body without interacting at all. That which does cause us dose is the absorbed dose. The absorbed dose in tissue is often a fraction, sometimes a much smaller fraction of the dose in air near our bodies.

Activity: Radioactive materials are made up of atoms that are unstable. In the simplest terms, this instability is a function of the number neutrons relative to the number of protons in the atom's nucleus. Unstable atoms seek to become stable, and they do so by emitting radiation. This radiation is excess nuclear mass converted to energy. The transformation of unstable atoms to stable atoms has been called radioactivity, or more simply, activity. The unit of activity is the becquerel which is equal to one radioactive transformation per second. The more activity, the more radioactive material that exists, the more ionizing radiation that is emitted over time. This ionizing radiation causes dose, so the more activity, the higher the possible dose.

Acute and Chronic Radiation Dose: An acute ionizing radiation dose is a high dose received in a short time. Chronic ionizing radiation doses are accumulated in small increments over a longer time. Acute radiation doses risk immediate effects, while chronic doses increase the risk of effects later in life.

ALARA: As Low As Reasonably Achievable (ALARA) is a radiation protection approach where the objective is to minimize the dose a person gets in a situations like work, medical diagnosis or treatment or from radioactive materials in the environment as with radon exposure in the home. The dose minimization or optimization effort is to as low a level as is practical, generally, to a point where the benefits are equivalent to or greater than the costs to reduce the dose.

ALI and DAC: Doses from radioactive materials we breathe into our bodies are controlled to minimize health effects using the Annual Limit on Intake (ALI) and the Derived Air Concentration (DAC). The ALI is that amount of radioactive materials taken into the body that will result in the person getting a dose of 0.05 sievert, a current limit for occupational exposures. The DAC is used to make it easier to control work exposures. The DAC divides the ALI by the amount of air a worker breathes over the course of a year. The results are in units of radioactive material per volume of air, typically in becquerel per liter. An air sampler can measure the becquerel/liter in a work location, and a worker's dose from the air can be controlled by minimizing the duration of exposure or providing the worker respiratory protection. The ALI must also account for dose from radioactive materials that are ingested, for example from consuming food or water contaminated with radioactive materials. The ALI is also used to limit intakes of radioactive materials from food and water. Calculations using food and water concentrations and human ingestion rates allow comparisons to the ALI. .

Background Radiation: This is the ionizing radiation from sources not related to our

Comment [M115]: MR … we should go with the usual NCRP style Glossary … to be created later … will use these input and as appropriate

MR

Comment [M116]: MR … Need to coordinate with Section 5.
The formal definitions of quantities and units in Section 5 and the Glossary should be exactly the same (and the same as the original source). The additional detail would only be in Section 5.

MR

Comment [CD117]: Cool … I don't think the text makes any reference to ALI and DAC.

occupation. It is from ionizing radiation used to diagnose or treat illness; from the radiations emitted by radioactive materials in our environment, like radon; from radiations entering our atmosphere from outer space, as from the sun; and from the use of ionizing radiation in a host of industrial settings. When we get ionizing radiation exposure at work, records of our dose do not include this background radiation. When we measure ionizing radiation, we typically subtract background radiation to account for that ionizing radiation from the source alone. Efforts to reduce background radiation doses are as important as reducing them from work exposures. Some people get doses from background radiations that are greater than doses from occupational exposures.

Becquerel (Bq): Henri Becquerel discovered natural radioactivity in 1896. He was awarded a Nobel Prize in Physics in 1903 for this. In his honor, the unit of activity, by which the quantity of radioactive materials is measured, is the Becquerel. Its abbreviation is Bq. One Bq is equal to one radioactive transformation per second.

Bioassay: Bioassay is a means to estimate the ionizing radiation dose to an individual, by examining samples from their body (*in vitro* bioassay), or by measuring emissions of radiation from radioactive materials within their body with instruments (*in vivo* bioassay). With *in vitro* bioassay, say with a urine, fecal, blood or hair sample, the amount of radioactive material in the body is calculated based on the amount in the sample. With *in vivo* bioassay, the amount of radioactive material in the person's body is calculated using the number and energy of ionizing radiations emitted by radioactive materials measured with an external detector and instrumentation.

Biodosimetry: We can use changes in our bodies to estimate how much dose we received. For low doses, we may look for subtle changes like those in the exposed person's chromosomes. For higher doses, effects like skin reddening, hair loss and time until the onset of vomiting can help us estimate the dose.

Committed effective dose: This is the dose a person receives from an intake of radioactive materials, and to which he or she is committed based on the time it takes to eliminate the radioactive material from the body. Generally, a maximum period of time is used for the accumulation of this dose, because some radioactive materials take many years to be eliminated. 50 y is the duration recommended in the United States.

Committed equivalent dose: The committed effective dose from internal radioactive materials may impact only a small part of the body. As an example, the thyroid gland is essentially the only part of the body that gets dose when radioactive iodine is inhaled or ingested. The different tissues or organs that may be affected have different tissue weighting factors on the basis of the detriment done to the health of the person as a whole. The thyroid, for example, has a small tissue weighting factor (0.03), because detriment to the thyroid has a small health impact on the human body as a whole. Because harm to it can be more severe as an overall impact to the health of the body, the red bone marrow has a higher tissue weighting factor (0.12).

Deterministic effect (see tissue reaction): A deterministic effect is a dose consequence known to result when the dose exceeds a threshold. The threshold varies somewhat based on the differences among people, but the effect will not occur until that threshold is exceeded. For example, erythema or reddening of the skin by ionizing radiation exposure will not occur at low doses, such as those where the skin dose limit is established. A dose of hundreds of millisieverts is required before the skin reddens.

Detriment: This is the harm possible with exposure to ionizing radiation, especially due to cancer or genetic effects.

Dose and Dose Rate: Dose is the generic term used in radiation protection to account for the amount of radiation a person is exposed to and affected by. Dose is usually measured with an instrument, but it can also be estimated, calculated or reconstructed from facts about the duration of, and types of, radiation exposure. The dose rate tells us how rapidly someone can accumulate a dose. Dose rate is usually measured with an instrument, for example a Geiger counter, in units of radiation per unit time, for example microsievert per hour. If someone is exposed to a radiation field of 0.1 microsievert per hour for 10 hours, their dose would be recorded as 1 microsievert.

Dose coefficient: Radiation causes damage through the ionization of tissues with which radiation interacts. The radiations from different radioactive materials are all different, so the amount of ionization, damage and dose they cause differs. Dose coefficients have been numerically, and often, experimentally, determined for the radiations from different radioactive materials. If you multiply the amount of activity interacting with the tissue by the dose coefficient, you obtain the expected dose to that tissue. This means knowing what type radioactive material emitted the radiation, can be as important as knowing how much is interacting with the tissue.

Dose Limit: Dose limits are used to control exposures, usually at work, to minimize health risks. A common dose limit in the United States is 0.05 sievert whole body for a year. It is common to have different limits for different parts of the body, for example the lens of the eye, the extremities, and the whole body except for the eyes and extremities.

Dose Reconstruction: Sometimes a person's radiation exposure was not recorded by an instrument, and his or her dose is reconstructed from evidence about the exposure. Such evidence includes the radiation type, an estimate of the duration of exposure, an estimate of what the radiation dose rates were or how much radioactive material the person took into his or her body.

Dosimeter: This is a way, usually a device, to measure dose. Common devices used as dosimeters are film badges, thermoluminescent dosimeters or optically stimulated luminescent dosimeters. In each, the radiation alters the material within the dosimeter, and the amount of change is proportional to the amount of radiation to which the device was exposed. A dosimeter of legal record is one that can be used, most often for workers, to record the "official" dose.

Effective dose: Radiation-induced damage to certain tissues, for example the lung tissue, causes more harm to the health of the person as a whole than the same amount of radiation to other

Comment [DLM118]: Miller … Tissue reaction is not defined.

Comment [M119]: MR … see items under "simple definitions" (i.e., deterministic effect and tissue reaction).

Comment [CD120]: Cooll … thought we were getting rid of this term for our recommendations.

Comment [CD121]: Cool … Need to be clear that this is annual occupational exposure if we use an example. To just say "a common…" does not do it.

tissues, for example the bone surfaces. To calculate the effective dose, one must not only know how much total tissue mass has absorbed the radiation energy and the amount of that energy, but also how sensitive the tissue is to radiation and to the overall well-being of the exposed individual. Tissue weighting factors are available, often from empirical testing, to account for these differences.

Equivalent dose: While the effective dose accounts for the different sensitivities of different organs, and the overall detriment to the whole body from the dose using tissue weighting factors, equivalent dose accounts for the fact that certain kinds of radiation are more harmful than others. For example, one milligray of alpha radiation dose to the tissues lining the deep lung tissues will cause roughly twenty times more damage that one milligray absorbed dose from beta radiation tp those same tissues. Radiation weighting factors account for these differences. Multiplying the absorbed dose in gray by the radiation weighting factor yields the equivalent dose. Equivalent dose is measured in the unit Sievert (Sv). Tallying equivalent dose in sievert puts weight on the biological dose consequences in people no matter what type of radiation. With alpha and beta radiation, one milligray of alpha radiation results in an equivalent dose of twenty millisievert, while one milligray of beta radiation results in an equivalent dose of one millisievert.

External and Internal Dose: Radiation dose can be received from radioactive materials that are inside the body, perhaps from breathing in contaminated air or from drinking water with naturally occurring radium or uranium in it. This is called internal dose. When radiation dose is the result of exposure to machine generated radiation, or from radioactive materials outside the body, the dose is an external dose. The effects of a 1 millisievert dose from radioactive materials within the body or of a 1 millisievert dose from sources outside the body are equivalent. Because internal doses accumulate over the entire time it takes for the radioactive material to pass through the body, determining the dose from internal sources is often more complex than for those outside the body.

Genetic, Somatic and Teratogenic Risk: There are risks to health from radiation exposure. Those that affect our own tissues are called somatic risks. If the sex cells within our bodies, the sperm and ova, are exposed to the radiation, those cells may be affected increasing the risk of health effects for children conceived with those sperm or ova. These are genetic risks. If a woman is pregnant when she is exposed to radiation, and the radiation also exposes the embryo or fetus simultaneously, there are risks that the child may be affected, as well as the mother. The risks to the embryo or fetus are teratogenic, and the dose to the embryo or fetus must be considered as well as the dose to the mother.

Gray (Gy): The gray is the unit of absorbed dose, and only for the total amount of radiation absorbed in some medium, for example air or human skin, and the total mass within which it was absorbed. The absorbed dose can be directly measured with instruments.

Half-life, including biological, physical and effective: Because radioactive materials transform over time in a random manner, the time required for them to transform is a statistical term, the half-life. It is the average time required for half the total amount of radioactive material to transform. The time it takes for half the material to transform because of changes in the atomic

nucleus of the radioactive material is called the physical half-life. When radioactive materials are within our bodies, the term half-life is used to measure the time required for biological processes to eliminate half of the radioactive material from the body. This is called the biological half-life. Since radioactive materials in the body are subject to both physical radioactive transformation in the atomic nucleus and biological elimination from the body, the effective half-life is calculated to account for both the physical and the biological half-lives. When internal dose is calculated, the effective half-life must be applied.

Lifetime Risk: From the moment of conception, radiation exposure is a fact of life. Usually, the womb provides protection, but embryo and fetal dose may result in risk of teratogenic effects like microcephaly, smaller than average head size, or reduce the born child's mental function. Throughout life outside the womb, there is constant radiation dose from naturally occurring radioactive materials and from machine-made radiations. Some of us experience more than others, depending on where we live, and, often, the number of medical conditions we experience where diagnostic or therapeutic doses are delivered with the care. There are also people who work with radiation, from health care providers to nuclear power plant workers, and they receive additional radiation dose beyond these "background" exposures. It is important to reduce the risk from all of these radiation doses incurred over our lifetimes. Knowing when and, where you can, to how much radiation you are exposed, for example by testing the air in your home for radon and keeping track of the number and type of radiology procedures you receive, can be as important as getting a record of occupational dose from your employer if you work in a job requiring radiation exposure.

Radiation: Radiation is the term often equated with x-rays from machines and the emissions of alpha, beta and gamma radiations from radioactive materials in our environment and used in various ways in occupations. Sound waves, radio waves and infrared, visible and ultraviolet light are also radiations, they move in a wave form through time and space. These though are called non-ionizing radiation, X, alpha, beta and gamma radiations are ionizing. The dose delivered by non-ionizing radiations is primarily the result of physical disturbances, including some intense enough to increase tissue and whole body temperatures. Ionizing radiations deliver dose imperceptibly, imparting energy to individual atoms and molecules, even the genetic material within the nucleus of atoms. This energy can create charged particles called ions, and it is the dose delivered by these charged particles that we try to manage in traditional radiation protection.

Radiation weighting factor: The different radiation types, for example, alpha, beta, gamma, neutron and proton, cause different amounts of human tissue detriment. Radiation weighting factors account for this. When the absorbed dose from radiation in gray is multiplied by the weighting factor for that radiation, the product is the equivalent dose in sievert.

Radioisotope and Radionuclide: Radioactive materials are unstable atoms that emit radiation to achieve stability. Otherwise, radioactive materials are chemically identical to stable atoms of the same material that do not emit radiation. Chemical identity and behavior is governed by the number of electrons possessed by an atom. The number of neutrons and protons, in simplest terms, defines the stability of the atom. Most atoms have numerous forms, and these are often

Comment [M122]: Higley … the definition of radiation weighting factor uses the word detriment. ICRP defines detriment as" Detriment The total harm to health experienced by an exposed group and its descendants as a result of the group's exposure to a radiation source. Detriment is a multidimensional concept. Its principal components are the stochastic quantities: probability of attributable fatal cancer, weighted probability of attributable non-fatal cancer, weighted probability of severe heritable effects, and length of life lost if the harm occurs." I'm not sure we're using the term appropriately in our definition.

In fact ICRP in 103 describes radiation weighting factor as "Radiation weighting factor, wR A dimensionless factor by which the organ or tissue absorbed dose is multiplied to reflect the higher biological effectiveness of high-LET radiations compared with low-LET radiations. It is used to derive the equivalent dose from the absorbed dose averaged over a tissue or organ."

MR … an example of creating a newly worded definition (that confuses the issue) for a term that is clearly defined by the originating body (in this case ICRP). Section 5 and these "Glossaries" have a number of such cases.

referred to as different radioisotopes of the stable atom. Isotopes of an atom have the same number of protons, but different numbers of neutrons in the nucleus. These different forms of a chemical may also be referred to as radionuclides, radioactive materials with nuclei that are different from isotope to another. Stable atoms deliver no radiation dose, while different radioisotopes may actually deliver different amounts of radiation dose based upon the radiations they emit trying to become stable.

Risk coefficient: When you correlate the radiation dose with the level of risk of an effect from that dose, it yields a risk coefficient. Typically, the risk coefficient is obtained by dividing the numeric level of risk by the radiation dose associated with it. This may yield, for example, a risk coefficient of 0.02 excess fatal cancers per gray of absorbed dose. You can see the varying level of risk with different doses on a graph where dose is plotted on the x-axis and the risk of cancer, for example, is plotted on the y-axis. Different shapes of the curve indicate doses where risk coefficients for cancer are higher or lower than for other doses.

Sievert (Sv): This is the unit of equivalent dose. It account for the absorbed dose as well as the greater or lesser biological effects of that absorbed dose based on the types of radiation delivering the absorbed dose, that is, alpha, beta, gamma, neutron and proton. Radiation weighting factors are used to convert the absorbed dose in gray to equivalent dose for the type of radiation in sievert.

Comment [DLM123]: Miller … And also effective dose.

Stochastic effect: A stochastic effect is one where the level of risk for that effect is random in nature, but it generally increases with increasing dose.

Tissue weighting factor: different human tissues have been shown to affect the overall health of the person to different degrees. Tissue weighting factors are used to account for these differences so the absorbed dose to one tissue can be related to the possible detriment to the person as a whole. This can be seen with the breast tissue weighting factor (0.15). It is higher than, for example, the thyroid tissue weighting factor (0.03) because the health effects from a given dose of radiation will be worse to the overall health of a person when the breast tissue absorbs it as compared to when the thyroid does.

[Simple Definitions]

Absorbed dose: The amount of radiation energy deposited in a unit mass of material such as body tissue. It is expressed in units Gray (Gy) which equals the absorption of one joule of energy per kilogram of material. Absorbed dose is typically used in assessing the severity of tissue reactions due to short term (acute) radiation exposure. Absorbed dose also forms the basis for calculating the probability of stochastic effects after accounting for the type and energy of radiation and affected organ(s) – see "equivalent dose" and "effective dose".

Activity: The rate of transformation (decay) of radioactive materials. Activity is a measure of the amount of radioactive material. It is expressed as the number of atoms breaking down per second and is measured in unit of Becquerel (Bq).

Acute and Chronic Radiation Dose: An acute radiation dose is one where a high dose is received in a short time, and the effects result soon after. Chronic radiation doses are accumulated in small increments over a longer time, and the effects manifest later in life.

ALARA: As Low As Reasonably Achievable is a radiation protection approach where00 dose is reduced to the minimum practical level (such that the costs to reduce the dose are at least equivalent to the benefits).

ALI and DAC: The Annual Limit on Intake (ALI) is that amount of radioactive material (in becquerel) taken into the body that will result in a dose of no more than 0.05 sieverts, the current limit for occupational exposures in the United States. The Derived Air Concentration (DAC) divides the Annual Limit on Intake by the amount of air a worker breathes in over the course of a year to yield the radioactive material per volume of air in bequerels per liter. The Annual Limit on Intake must also account for dose from radioactive materials that are ingested.

Background Radiation: This is the radiation not related to our occupation. It consists of dose from medical uses of radiation, from radioactive materials in our environment, from radiations from outer space, and from the use of radiation in industry. Occupational dose records do not include background radiation. Reducing dose from background radiation doses is as important as reducing them from work exposures.

Becquerel (Bq): The special SI unit for measuring the amount of radioactivity. One Bq is a very small quantity and equals one radioactive atom disintegrating per second. It is more common to use multiples of Bq such as kBq (kilobequerel, or 1,000 Bq), MBq (megabequerel, or $1x10^6$ Bq), GBq (gigabequerel, or $1x10^9$ Bq) or TBq (terabequerel, or $1x10^{12}$ Bq).

Bioassay: An assessment of the amount of radioactive material in the body. Direct bioassay (also called in vivo assay) measures the radiation coming directly from the body. Indirect bioassay (also called in vitro assay) measures the amount of radioactivity in material excreted or otherwise removed from the body such as urine, feces, or hair.

Biodosimetry: Biodosimetry is the use of changes in our bodies, like chromosome aberrations for low doses and skin reddening for high doses, to estimate dose.

Committed effective dose: The sum of the weighted committed equivalent doses to all body organs. The committed equivalent dose to each organ is weighted by that organ's tissue weighting factor. The accumulated dose from radioactive material inside the body is calculated for 50 y to the future for adults and to age 70 for children.

Committed equivalent dose: Accounts for continuing radiation exposure to body organs from radioactive material inside the body. This accumulated dose to each organ is typically calculated for 50 y to the future for adults and to age 70 for children.

Deterministic effect (see tissue reaction): Adverse health effect to an organ or series of organs for which the severity of the effect increases with increasing radiation dose. Typically, there is a dose threshold below which deterministic effects will not occur. Examples of deterministic effects are the development of cataracts due to irradiation of the eye, erythema (reddening) of the skin due to dermal irradiation, cutaneous radiation injury and acute radiation syndrome.

Comment [DLM124]: Miller ... Circular; the definition for tissue reaction is "see deterministic effect"!

Comment [M125]: MR ... see Preston Glossary addition later in this list for tissue reaction. Need to combine these inputs into one entry (under tissue reaction)

Detriment: An overall measure of the probability of occurrence of stochastic effects due to radiation exposure. Detriment is the sum of the probabilities of all stochastic effects (fatal cancer, morbidity from non-fatal cancer, and heritable effects) due to exposure to ionizing radiation.

Dose and Dose Rate: Dose is the term used to account for the amount of radiation a person is effected by. It is usually measured with an instrument, but it can also be estimated, calculated or reconstructed from facts about the time and types of radiation exposure. The dose rate is usually measured with an instrument in units of radiation per unit time, as in microsieverts per hour. The dose equals the dose rate multiplied the time.

Dose coefficient: A factor used to calculate radiation doses from either a) an internal exposure due to radioactive material taken into the body or b) an external exposure due to radioactive material in the environment. Dose coefficients vary depending on the particular radionuclides and the route of intake (e.g., ingestion or inhalation. Furthermore, dose coefficients may be expressed in terms of either equivalent dose or effective dose, and care must be exercised in selection of the appropriate dose coefficients for the desired result.

Dose Limit: Dose limits are used to control occupational exposures. A common dose limit in the United States is no more than 0.05 sieverts whole body for a year. There may be other limits, for example, for the lens of the eye or the extremities.

Dose Reconstruction: This is how a person's radiation exposure is calculate from evidence about the radiation exposure's duration, intensity and type..

Dosimeter: This is usually a device which measures dose, like a film badge or a thermoluminescent or optically stimulated luminescent dosimeter. The radiation alters the material within the dosimeter, and the amount of change is proportional to the amount of

radiation to which the device was exposed. A dosimeter of legal record is one used, mostly for workers, to record the "official" dose.

Effective dose: A quantity used in radiation protection to evaluate the overall health effects of radiation exposure on the whole body. This quantity takes into account the absorbed doses received by various organs and tissues and weighs them according to present knowledge of the sensitivity of each organ to radiation. It also accounts for the type and energy of radiation and the potential for each type to inflict biologic damage. Effective dose is expressed in units of Sievert (Sv) or millisieverts (mSv) where 1 Sv equals 1000 mSv.

Equivalent dose: A quantity used in radiation protection to place all types and energies of radiation on a common scale regarding the stochastic health effects that could result from exposure to such radiations. To calculate equivalent dose, the absorbed dose (in units of Gy) is multiplied by a unit-less factor determined by the type and energy of the radiation (see the "radiation weighting factor"). Equivalent dose is expressed in units of Sievert (Sv) or millisieverts (mSv) where 1 Sv equals 1000 mSv.

External and Internal Dose: Radiation dose received from radioactive materials inside the body is called internal dose. When the radiation dose is the result of exposure to sources outside the body, it is called external dose.

Genetic, Somatic and Teratogenic Risk: Those risks of radiation exposure that affect your own tissues are somatic risks. Genetic risks arise when the sperm cells or ova are exposed to radiation and the effects are seen in children subsequently conceived. If a pregnant woman and her embryo or fetus is exposed simultaneously, there are risks that the child may be affected, as well as the mother. The risks to the embryo or fetus are teratogenic.

Gray (Gy): The SI special unit for absorbed dose. One Gy is equivalent to deposition of 1 joule of radiation energy in 1 kilogram of material such as body tissue. (see "absorbed dose").

Half-life, including biological, physical and effective: The time required for radioactive materials to transform to a stable state is its half-life, the average time required for half the radioactive material to transform. The physical half-life is the time it takes for half the material to transform with changes in the atomic nucleus. When radioactive materials are within the body, the biological half-life accounts for the time for biological processes to eliminate half of them from the body. Since the materials are subject to both physical nuclear transformation and biological elimination, the effective half-life is calculated to account for both. The effective half-life must be applied when internal dose is calculated.

Lifetime Risk: Embryo and fetal dose may result in risk of teratogenic effects like microcephaly or reduced mental function. Throughout life, all of us are subject to the ionizing radiation dose from naturally occurring radioactive materials, and from diagnostic and therapeutic exposure in medical care. Some also receive occupational ionizing radiation dose beyond these "background" exposures. Working from the tenet that any ionizing radiation exposure increases our risk of

adverse health consequences, it is important to reduce all of these ionizing radiation doses incurred over our lifetimes.

Radiation: Radiation is not just the term associated with x-rays from machines and the emissions of alpha, beta and gamma radiations from radioactive materials in our environment and used in various ways in industry. It is also used for sound waves, radio waves and infrared, visible and ultraviolet light. X, alpha, beta and gamma radiations are ionizing radiations. Ionizing radiations impart energy to individual atoms and molecules, even the genetic material within the nucleus of atoms, and it can create charged particles called ions. Ionizing radiation dose is delivered by these charged particles.

Radiation weighting factor: Expresses the biological effectiveness of different ionizing radiations when calculating equivalent doses. It is a unit-less number, and assumed to be independent of the tissue or organ irradiated. For gamma radiation, this multiplier is 1. Some ionizing radiations, such as high-energy beta particles, alpha particles and neutrons, cause more damage per unit of absorbed dose than does gamma radiation, and have radiation weighting factors ranging as high as 20.

Radioisotope and Radionuclide: Radioactive materials are unstable atoms that emit ionizing radiation to achieve stability. The number of neutrons and protons, in simplest terms, defines the stability of the atom. Isotopes of an atom have the same number of protons, but different numbers of neutrons in the nucleus. These different forms of the same chemical may also be referred to as radionuclides, radioactive materials with nuclei that are different from one isotope to another. Stable atoms deliver no ionizing radiation dose. Different radioisotopes may deliver different radiation doses based upon the radiations they emit trying to become stable.

Risk coefficient: is the probability of a stochastic health effect such as cancer per unit of ionizing radiation dose. Risk coefficient may also be expressed as the probability of cancer per unit of radioactivity taken inside the body, or per unit of radioactivity in the environment.

Sievert (Sv): The SI special unit for equivalent dose and effective dose. One Sv equals 1 joule/kilogram absorbed dose, multiplied by one or more multipliers for the organ(s) considered, the type and energy of ionizing radiation, or both.

Stochastic effect: Adverse health effects to an organ or series of organs for which the probability of occurrence increases with increasing ionizing radiation dose. An example of stochastic effects is the development of cancer. The severity of such stochastic (random) effects does not change with increasing dose, and their onset does not typically exhibit a dose threshold.

Tissue reaction: ~~See "deterministic effect".~~ For protection purposes the biological effects of radiation are separated into stochastic effects (cancer, heritable effects) and tissue reactions. The latter had previously been termed deterministic effects but were renamed as tissue reactions in ICRP (2007a) because of the enhanced evidence that these responses could be modified after irradiation rather than being determined at the time of irradiation. Such tissue reactions can occur

at early or late times after irradiation. In addition, they typically exhibit a threshold dose that has been the basis for establishing recommended dose limits.

Comment [M126]: Preston revision

Tissue weighting factor: Expresses the contribution of detriment in a particular organ to total detriment to the body as a whole. It is a unit-less number between 0 and 1, and it is assumed to be independent of the type or energy of ionizing radiation.

Glossary (usual style) (example)

as low as reasonably achievable (ALARA**):** A principle of radiation protection philosophy that requires that exposures to ionizing radiation be kept as low as reasonably achievable, 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.

Abbreviations, Acronyms and Symbols

ALARA	as low as reasonably achievable (the ALARA principle)
BBDR	biologically-based dose-response (model)
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
(D)DREF	dose and dose-rate effectiveness factor (alternate presentation)
DNA	deoxyribonucleic acid
DREF	dose-rate effectiveness factor
$\underline{E}$	effective dose
EAR	excess absolute risk
ERR	excess relative risk
FGI	fluoroscopically-guided interventional (procedure)
HZE	high atomic number, high-energy (particle)
SI	Systeme Internationale (International System of Quantities and Units)
LDEF	low-dose effectiveness factor
LET	linear energy transfer
LQ	linear-quadratic (model or curve)
LSS	Life Span Study
RBE	relative biological effectiveness
SMR	standardized mortality ratio
The NCRP System	the System for Radiation Protection for the United States
w_R	radiation weighting factor
$\underline{w}_T$	tissue weighting factor