



**Australian Government**

**Australian Radiation Protection  
and Nuclear Safety Agency**

CODE OF PRACTICE

# Exposure of Humans to Ionizing Radiation for Research Purposes

RADIATION PROTECTION SERIES No. 8

# Radiation Protection Series

The ***Radiation Protection Series*** is published by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) to promote practices which protect human health and the environment from the possible harmful effects of radiation. ARPANSA is assisted in this task by its Radiation Health and Safety Advisory Council, which reviews the publication program for the ***Series*** and endorses documents for publication, and by its Radiation Health Committee, which oversees the preparation of draft documents and recommends publication.

There are four categories of publication in the ***Series***:

**Radiation Protection Standards** set fundamental requirements for safety. They are prescriptive in style and may be referenced by regulatory instruments in State, Territory or Commonwealth jurisdictions. They may contain key procedural requirements regarded as essential for best international practice in radiation protection, and fundamental quantitative requirements, such as exposure limits.

**Codes of Practice** are also prescriptive in style and may be referenced by regulations or conditions of licence. They contain practice-specific requirements that must be satisfied to ensure an acceptable level of safety in dealings involving exposure to radiation. Requirements are expressed in ‘must’ statements.

**Recommendations** provide guidance on fundamental principles for radiation protection. They are written in an explanatory and non-regulatory style and describe the basic concepts and objectives of best international practice. Where there are related **Radiation Protection Standards** and **Codes of Practice**, they are based on the fundamental principles in the **Recommendations**.

**Safety Guides** provide practice-specific guidance on achieving the requirements set out in **Radiation Protection Standards** and **Codes of Practice**. They are non-prescriptive in style, but may recommend good practices. Guidance is expressed in ‘should’ statements, indicating that the measures recommended, or equivalent alternatives, are normally necessary in order to comply with the requirements of the **Radiation Protection Standards** and **Codes of Practice**.

In many cases, for practical convenience, prescriptive and guidance documents which are related to each other may be published together. A **Code of Practice** and a corresponding **Safety Guide** may be published within a single set of covers.

All publications in the ***Radiation Protection Series*** are informed by public comment during drafting, and **Radiation Protection Standards** and **Codes of Practice**, which may serve a regulatory function, are subject to a process of regulatory review. Further information on these consultation processes may be obtained by contacting ARPANSA.



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# Exposure of Humans to Ionizing Radiation for Research Purposes

Radiation Protection Series Publication No. 8

May 2005

This publication was approved by the Radiation Health Committee on 6 May 2005,  
and on 26 May 2005 the Radiation Health & Safety Advisory Council  
advised the CEO to adopt the Code of Practice.

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The mission of ARPANSA is to provide the scientific expertise and infrastructure necessary to support the objective of the ARPANS Act – to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation.

Published by the Chief Executive Officer of ARPANSA in May 2005

## Foreword

This *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes* establishes requirements for adoption by Commonwealth, State and Territory jurisdictions.

Research involving humans in Australia takes place within the context of adherence to the *National Statement on Ethical Conduct in Research Involving Humans*. The *National Statement* requires that research projects involving humans must be reviewed by a Human Research Ethics Committee (HREC) and must not be undertaken or funded unless and until approval has been granted. It also makes clear that the consent of research participants is required and that obtaining consent requires the provision of knowledge about the research.

The *Code of Practice* is designed to ensure that researchers proposing to expose research participants to ionizing radiation provide the participants and the Human Research Ethics Committees with information that allows consent to be properly considered by the research participants and approval considered by the HREC.

The consideration of consent and ethical assessment of the proposed research are likely to be particularly affected by knowledge of the dose of ionizing radiation that is likely to arise from the research as this determines the risk to the human participant. The *Code of Practice* requires researchers to have dose calculations and associated risk information provided to participants and HRECs checked by an independent medical physicist in the relevant field. In the case of doses in excess of certain dose constraints, verification by a second medical physicist must also be obtained.


The *Code of Practice* draws upon the publication by the International Commission on Radiological Protection: *Radiological Protection in Biomedical Research* (ICRP 62). In particular it draws upon a suggested categorisation of risk and corresponding levels of societal benefit. This categorisation should be one of the matters considered in informing research participants and human research ethics committees. This information has been included in Annex 1, along with advice regarding the communication of risk to the participant in Annex 2 of the Code.

The Code replaces the NHMRC 1984 Radiation Health Series publication number 12, *Administration of ionizing radiation to human subjects in medical research*.

This Code will be put forward to be adopted nationally into regulatory frameworks by its inclusion in Schedule 11 of the National Directory of Radiation Protection (NDRP). The NDRP provides an agreed framework for radiation safety to be adopted by the Commonwealth, States and Territories. Section 5.1 of the National Directory states that adoption by jurisdictions can occur by direct reference in the regulations of an Authority or through their use as conditions of licence and/or registration by an Authority.

The Code was released for a public comment period from 11 February 2004 to 26 March 2004 with a Regulatory Impact Statement, to meet the requirements of the Principles and Guidelines for National Standard-setting and Regulatory Action by Ministerial Councils and Standard-setting Bodies published by the Council of Australian Governments in November 1997. The comments received were reviewed

by the working group, and a revised draft Code was released for comment to those individuals and organisations who had provided comments on the earlier draft. The additional comments were reviewed by the working group and the final *Code of Practice* was approved by the Radiation Health Committee on 6 May 2005. The Radiation Health and Safety Advisory Council advised the CEO to adopt the Code of Practice on 26 May 2005.

A handwritten signature in black ink, appearing to read 'John Loy', with a stylized flourish at the end.

**John Loy**  
**CEO of ARPANSA**

27 May 2005

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# 1. Introduction

## 1.1 CITATION

This Code may be cited as the *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005)*.

## 1.2 BACKGROUND

This Code supersedes the NHMRC's statement on *Administration of Ionizing Radiation to Human Subjects in Medical Research (1984)* published as Appendix XXXIX to the Report of the Ninety-eighth Session of the Council, October 1984. It takes into account recommendations of the International Commission on Radiological Protection (ICRP) and the recommendations of ARPANSA and the National Occupational Health and Safety Commission, published as ARPANSA Radiation Protection Series No. 1 (ARPANSA/NOHSC, 2002).

## 1.3 PURPOSE

The purpose of this Code is to provide requirements which must be met for the exposure of humans to ionizing radiation for the purpose of research. This Code contains additional advice to that contained in the *National Statement on Ethical Conduct in Research Involving Humans* (NHMRC, 1999) which addresses the ethical principles and values which govern research involving humans.

## 1.4 SCOPE

This Code applies to research involving humans who are exposed to radiation which is additional to that received as part of their normal clinical management. Thus, this Code applies to research involving healthy volunteers and/or patients and includes, but is not restricted to, research with diagnostic/therapeutic agents and procedures, including Phase I, II, III and IV clinical trials and novel procedures on selected groups of research participants. This Code does not apply to the use of radiation outside a research project even if it involves the use of a novel procedure.

This Code outlines the roles and responsibilities of the following:

- the researcher who proposes to undertake a project involving administration of ionizing radiation to research participants;
- the medical physicist verifying or assessing the total effective dose, organ doses and undertaking the radiation risk assessment;
- the Human Research Ethics Committee, constituted in accordance with the *National Statement on Ethical Conduct in Research Involving Humans* (NHMRC, 1999), which is an advisory body independent of the teams of researchers; and
- The Responsible Person for the radioactive material, radiation apparatus, facility or premises.

Advice on radiation dose constraints for research participants is given in Section 3. The assessment of risk/benefit of research projects is given in Annex 1.

## **1.5 INTERPRETATION**

In interpreting the provisions of the Code, the words ‘must’ and ‘should’ have particular meanings. The presence of the word ‘must’ indicates that the requirement to which it refers is mandatory. The presence of the word ‘should’ indicates a recommendation – that is, a requirement that is to be applied as far as practicable in the interests of reducing risk.

Annexes to the Code provide information supplementary to the requirements embodied in the Code. Annexes provide material that will help in interpretation of the Code, and background information relevant to the development of the Code.

## 2. Responsibilities

### 2.1 RESEARCHER

2.1.1 The researcher must obtain the approval of the Human Research Ethics Committee of the relevant institution for the research.

2.1.2 The researcher must ensure that the selection of the participants is conducted according to the requirements of the Human Research Ethics Committee. Due to the long latent period associated with certain carcinogenic effects of radiation and the possibility of genetic effects, special consideration must be given to the following items;

(a) **Age of the research participants;**

the research participants should, where practicable, be over 40 years of age, and preferably over 50; and

exposure of children must only be permitted if the condition under study is related to the age of the participants and the information sought cannot be obtained using adult participants.

(b) **Pregnancy in the research participants;**

pregnant women must be excluded except when conditions specific to this group are being investigated;

in studies on pregnant women, the dose to the fetus must also be evaluated and advice provided to the Human Research Ethics Committee on the associated risks;

where some participants are women of reproductive age, the possibility that a woman may be pregnant must be taken into account; and

where the pregnancy status is uncertain and the radiation dose to the uterus is likely to exceed 0.1 mSv, premenopausal women should have a biochemical pregnancy test to exclude pregnancy before the radiation exposure.

(c) **Research participants who are breastfeeding;**

In the case of studies involving the administration of radioactive substances, research participants who are breastfeeding must be excluded unless conditions specific to this group are being investigated.

2.1.3 The researcher must provide the research participant with sufficient written information about the purpose, methods, radiation dose, associated risks and any discomforts of the radiation exposure to enable the research participant to give informed consent.

- 2.1.4 Where the research participant cannot give informed consent, including the case of a child, the researcher must provide the parent or guardian with sufficient written information about the purpose, methods, radiation dose, associated risks and any discomforts of the radiation exposure, and obtain the parent or guardian's informed consent.
- 2.1.5 The researcher must:
- (a) keep the radiation dose to research participants to the minimum level practicable; and
  - (b) whenever possible in the case of research involving the radiation exposure of healthy research participants, select persons who have not previously been or who are not currently exposed to radiation from research unless it can be demonstrated that the dose constraints in this Code will be met when those previous and current exposures are taken into account.
- 2.1.6 The researcher must obtain an independent assessment or verification by a medical physicist of:
- (a) the total effective dose<sup>1</sup> and relevant organ doses for those radiological procedures that are performed specifically for the research protocol and which are additional to those received as a part of the research participant's normal clinical management;
  - (b) whether these will exceed the dose constraints in Table 1; and
  - (c) the risks associated with the radiation exposure in accordance with Annex 1.
- 2.1.7 The researcher must prepare a submission to the Human Research Ethics Committee in accordance with its requirements. The submission must include the following information regarding radiation exposure:
- (a) the reasons why it is necessary to expose research participants to ionizing radiation for the purpose of the research;
  - (b) the radiation dose assessment and risk assessment obtained in accordance with clause 2.1.6;
  - (c) a statement confirming that the site at which the examination or procedure will be performed is actively involved in a relevant quality assurance program such as the programs of the Royal Australian and New Zealand College of Radiologists or of the Australian and New Zealand Association of Physicians in Nuclear Medicine;
  - (d) the precautions to be taken to keep radiation exposure to a minimum;

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<sup>1</sup> In radiation therapy research the effective dose is not an appropriate quantity for risk assessment.

- (e) the written information to be given to research participants relating to the doses and risks associated with the radiation exposure; and
- (f) for novel uses of radiation<sup>2</sup>, the arrangements for a review of radiation doses actually received and the arrangements for retention of dose records.

2.1.8 The researcher must advise the research participant to retain the information about the procedure including the radiation dose for at least five years in the case of an adult or, in the case of a child, to age 18 or for five years whichever is the longer period, so that it can be provided to researchers in any future research project involving exposure to ionizing radiation.

## **2.2 MEDICAL PHYSICIST**

2.2.1 The medical physicist must:

- (a) independently verify the total effective dose and organ doses and radiation risk assessment which have been provided by the researcher; or
- (b) assess the expected total effective dose and organ doses which will be received by the research participant as a result of their participation in the research and the corresponding radiation risks; and
- (c) where the dose constraints are exceeded, obtain verification of the dose assessment by a second medical physicist who must be independent of the researcher.

2.2.2 When undertaking the dose assessment or verification, the medical physicist must:

- (a) assess only those radiological procedures which are performed specifically for the research protocol and which would not form part of the research participant's normal clinical management; and
- (b) take into account the technical specifications of the radiological procedures as detailed in the research protocol.

2.2.3 The medical physicist must prepare a written report, which includes:

- (a) the assessed or verified expected total effective dose and relevant organ doses;
- (b) a statement as to whether the dose constraints in Table 1 are likely to be exceeded;
- (c) an assessment of the risks associated with the expected radiation exposure; and

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<sup>2</sup> As defined in Annex 3.

- (d) the proposed text on the radiation doses and risks to be included in the information provided to the research participants, consistent with Annex 2.

### **2.3 HUMAN RESEARCH ETHICS COMMITTEE**

2.3.1 When assessing research proposals involving ionizing radiation the Human Research Ethics Committee should consider the balance between the likely benefits and risks associated with any radiation exposure including consideration of the advice provided in Annex 1.

2.3.2 The Human Research Ethics Committee should pay particular attention to:

- (a) the estimates of expected radiation doses and associated risks, which must have been calculated or verified by a medical physicist;
- (b) the dose estimates and radiation risk assessments and opinion of an independent medical physicist where the dose constraints are exceeded;
- (c) the manner in which the radiation doses and risks are provided to the research participants in the information sheet;
- (d) the justification for the radiation exposure particularly if the radiation dose exceeds the dose constraints in Table 1; and
- (e) the measures to be taken during the project to assess the radiation doses actually received from novel uses of radiation where these may differ from the expected radiation doses and the arrangements for the retention of records of these doses.

### **2.4 THE RESPONSIBLE PERSON**

The Responsible Person as defined in the glossary of this Code is responsible for establishing systems that ensure the overall observance of this Code and its implementation. In addition to the requirements of this Code, the Responsible Person is responsible for compliance with regulatory requirements for radioactive materials and radiation apparatus at the facility.

### 3. Radiation Dose Constraints for Participants

The radiation doses to the research participants must be kept to the minimum level practicable and assessed or independently verified by a medical physicist. Wherever possible, the total effective doses and organ doses to adults and children should conform with the dose constraints as tabulated below. If these dose constraints are exceeded the Human Research Ethics Committee should give particular attention to the justification for the radiation exposure, and if necessary, seek further independent authoritative advice before approving the proposal.

For comparison purposes, the dose limits for occupational and public exposure are given in Annex 4.

**Table 1. Dose Constraints for Participants in Research<sup>a</sup>**

Participant Category	Dose Constraint <sup>b</sup>
<b>Adults</b>	
total effective dose	– in any year 5 mSv <sup>c</sup> – over 5 years 10 mSv
total effective dose in adult with life expectancy less than five years	– in any year 50 mSv
equivalent dose to skin averaged over 1 cm <sup>2</sup>	– in any year 200 mSv <sup>d</sup>
equivalent dose to any other organ or tissue	– in any year 100 mSv <sup>e</sup>
<b>Children and fetuses</b>	
Total effective dose to age 18 years, – Subject to:	5 mSv
• Effective dose from conception to birth; and	0.1 mSv
• Effective dose in any year from birth to 18 years.	0.5 mSv
Total equivalent dose to age 18 years to any organ or tissue	100 mSv

<sup>a</sup> A dose constraint for research participants specifies a maximum dose with which it should be possible to comply in normal circumstances and it is intended to apply to radiation which is in addition to that received as part of normal clinical management. Dose constraints apply to diagnostic investigations not radiation therapy.

<sup>b</sup> The dose constraint applies to the sum, over the relevant period, of doses received from external exposure and the 50-year committed dose (to age 70 years for children) from intakes over the same period.

<sup>c</sup> When all the research participants are within the following specified age limits, the following total effective dose constraints apply:  
– for adult 60 years or more – in any year – 8 mSv and  
– for adult 70 years or more – in any year – 12 mSv.

<sup>d</sup> Derived from Table 3.1 of ICRP85 – factor of 10 below the threshold of 2 Sv for early transient erythema.

<sup>e</sup> Derived from Table 3.1 of ICRP85 – factor of 10 below the threshold of 1 Sv for detectable lens opacity.

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## **Glossary**

### **Absorbed dose**

the energy absorbed per unit mass by matter from ionizing radiation which impinges upon it. The unit of absorbed dose is the gray (Gy).

### **Approved**

when applied to a plan or proposal, one which has received approval from the appropriate authority.

### **Clinical trial**

a planned study in humans designed to investigate and report upon the effectiveness and/or safety of a therapeutic good. Clinical trials are generally classified according to the phase of development of the therapeutic goods (TGA 2004).

### **Code of practice for radiation protection**

a document prescribing specific requirements for radiation protection in a particular application.

### **Committed effective dose**

the effective dose which a person is committed to receive from an intake of radioactive material.

### **Detriment**

a measure, or measures, of harm caused by exposure to radiation and usually taken to mean health detriment; it has no single definition, but can be taken to be an attribute or a collection of attributes which measure harm, such as attributable probability of death and reduction of life expectancy.

### **Diagnostic Reference Levels (DRL)**

a reference level of dose likely to be appropriate for average-sized patients undergoing medical diagnosis and treatment. If a survey of doses indicates substantial departures from DRLs, the causes should be investigated.

### **Dose**

a generic term which may mean absorbed dose, equivalent dose or effective dose depending on context.

### **Dose constraint**

a prospective restriction on anticipated dose, primarily intended to be used to discard undesirable options in an optimisation calculation.

in occupational exposure, a dose constraint may be used to restrict the options considered in the design of the working environment for a particular category of employee.

in research, a dose constraint for participants may be used to restrict the options considered in the design of an experimental protocol in order to minimise the exposure of participants.

in public exposure, a dose constraint may be used to restrict the exposure of the critical group from a particular source of radiation.

### **Effective dose**

a measure of dose which takes into account both the type of radiation involved and the radiological sensitivities of the organs and tissues irradiated. The unit of effective dose is the sievert (Sv).

### **Equivalent dose**

a measure of dose in organs and tissues which takes into account the type of radiation involved. The unit of equivalent dose is the sievert (Sv).

### **Exposure**

either: the circumstance of being exposed to radiation,  
or: a defined dosimetric quantity now no longer used for radiation protection purposes.

(The context in which the word is used should help avoid any ambiguity)

### **Human Research Ethics Committee (HREC)**

advises an institution or organisation regarding ethical approval for research projects which is constituted in accordance with, and acting in compliance with, the *National Statement on Ethical Conduct in Research Involving Humans* (NHMRC, 1999), as amended from time to time.

### **Ionization**

the process by which one or more electrons are removed from, or sometimes added to, an atom leaving the atom in a charged state.

### **Ionizing radiation**

radiation which is capable of causing ionization, either directly (for example: for radiation in the form of gamma rays and charged particles) or, indirectly (for example: for radiation in the form of neutrons).

### **Justification**

the notion that human activities which lead to exposure to radiation should be justified, before they are permitted to take place, by showing that they are likely to do more good than harm.

### **Licence**

a written authorisation issued by the relevant regulatory authority to an operator which allows the operator to carry out an operation legally.

### **Limitation**

the requirement that radiation doses and risks should not exceed a value regarded as unacceptable.

### **Medical exposure**

exposure of a person to radiation received as a patient undergoing medical diagnosis or therapy, or as a volunteer in medical research, or non-occupational exposure received as a consequence of assisting an exposed patient.

### **Medical physicist**

for the purpose of this Code, is a person who is qualified to perform the necessary dosimetric calculations, measurements and monitoring and has been approved by the regulatory authority to make estimates in the specialty relevant to the research project.

the medical physicist must be accredited by the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) or have an equivalent level of training as determined by the relevant regulatory authority.

### **Occupational exposure**

exposure of a person to radiation which occurs in the course of that person's work and which is not excluded exposure.

### **Optimisation**

the process of maximising the net benefit arising from human activities which lead to exposure to radiation.

### **Public exposure**

exposure of a person, or persons, to radiation which is neither occupational nor medical exposure.

### **Quality Assurance Program**

all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy the given requirements for quality.

### **Radiation**

electromagnetic waves or quanta, and atomic or sub-atomic particles, propagated through space or through a material medium.

### **Radioactive material**

material which spontaneously emits ionizing radiation as a consequence of radioactive decay.

### **Radionuclide**

a species of atomic nucleus which undergoes radioactive decay.

### **Registration**

means an authorisation by the relevant regulatory authority for a radiation apparatus or radioactive material, or for premises in which radioactive material is stored or used.

### **Relevant regulatory authority**

a statutory or regulatory authority having responsibility for implementing radiation control legislation or any other regulatory instrument which makes use of or refers to the *Code of Practice*.

### **Research participant**

individual about whom a researcher conducting research obtains data through intervention with the person.

### **Responsible person**

in relation to any radioactive material, radiation apparatus, prescribed radiation facility or premises in which radioactive material is stored or used means the person:

- (a) having overall management responsibility including responsibility for the security and maintenance of the radioactive material, apparatus, or facility;
- (b) having overall control over who may use the radioactive material or apparatus or facility; and

(c) in whose name the radioactive material, apparatus, or facility would be registered if this is required.

**Stochastic effect**

cancer development in exposed individuals and heritable disease in their offspring due to mutation of somatic and reproductive (germ) cells respectively as a consequence of exposure to radiation, but which may or may not be expressed in a particular exposed person, the likelihood of the effect occurring being a function of the dose received.

**Tissue reaction**

an effect, such as partial loss of function of an organ or tissue, caused by radiation and is manifested only above some threshold of dose, the severity of the effect depending upon the dose received. These reactions were previously known as deterministic effects.

**Total effective dose**

is the sum of the effective dose from all external exposures and the committed effective dose from all radionuclide administrations received from those radiological procedures performed specifically for the research protocol.

**X-ray**

ionizing electromagnetic radiation emitted during the transition of an atomic electron to a lower energy state or during the rapid deceleration of a charged particle.

## Annex 1

### ASSESSMENT OF RISK ASSOCIATED WITH THE RADIATION EXPOSURE

All research proposals must be designed to ensure that any risks of discomfort or harm to participants are balanced by the likely benefit to be gained to the community.

The level of risk for stochastic effects can be estimated from the effective dose. The risk refers to the total detriment from the radiation exposure: namely the sum of the probability of fatal cancers, the weighted probability of non-fatal cancers and the probability over all succeeding generations of serious hereditary disease resulting from the dose. This risk estimate to the general population is averaged over the full age distribution. However, for a given exposure, the risk is greater for children and decreases with age. The risk of radiogenic cancer is given in Table 2 using age- and sex-specific risk factors<sup>3</sup>.

**Table 2. Estimates of the risks of late radiation effects**

Age at exposure (years)	Deaths ( $10^{-2} \text{ Sv}^{-1}$ )	
	Male	Female
0-9	10.3	12.0
10-19	9.0	10.8
20-29	6.1	7.0
30-39	4.3	4.6
40-49	4.2	4.2
50-59	4.2	3.8
60-69	3.3	2.9
70-79	1.7	1.6
80+	0.8	0.7
Population weighted average	5.8	5.9

The World Health Organization (WHO, 1977) divided research projects into categories depending on the radiation doses received by research participants. The ICRP modified this classification taking into account changes in the assessment of radiation risk, and has introduced a corresponding categorisation of the 'level of societal benefit' which might be considered as a basis for approval of that level of dose. The type or level of benefit that will result from the research, to the participants or to society at large, has to be evaluated to justify the need to expose research participants to ionizing radiation. The risk of harm to the research participants has to be assessed based on the best quantification of doses available and also taking account of the characteristics (eg. age, gender and state of health) of the participants that might affect the risk resulting from the exposure. The long-term risks from radiation exposure are minimal in patients who have a very short life expectancy; however in research involving therapeutic radiation, acute effects are important and must be assessed.

<sup>3</sup> Lifetime projection for exposure to low doses or at low dose rates, based on a dose and dose rate effectiveness factor (DDREF) of 2. From *Estimates of late radiation risks to the UK population*. Documents of the NRPB 4(4), 1993: Table 4.8: Estimates of radiation-induced fatal cancer risks in a UK population.

The categories of risk and the corresponding levels of benefit to society expected from the radiation exposure are given in the following table, which is modified from that published by the ICRP (ICRP 1991) and incorporates the risk terminology recommended by Calman (1996)<sup>4</sup>:

**Table 3. Categories of risk, corresponding levels of dose and corresponding levels of benefit to society**

<b>Level of Risk</b>	<b>Risk Category</b>	<b>Effective Dose Range (adults) (mSv)</b>	<b>Level of Societal Benefit Expected</b>
Minimal	Category I (~10 <sup>-5</sup> or less)	< 0.2	Minor
Very Low	Category IIa (~10 <sup>-5</sup> to 10 <sup>-4</sup> )	≥ 0.2 and < 2	Intermediate
Low	Category IIb (~10 <sup>-4</sup> to 10 <sup>-3</sup> )	≥ 2 and ≤ 20	Moderate
Moderate	Category III (~10 <sup>-3</sup> or more)	> 20 <sup>a</sup>	Substantial

<sup>a</sup> *To be kept below deterministic thresholds except where therapeutic procedures involving radiation are being investigated.*

The risk categories, differing from one to the next by an order of magnitude of effective dose, and associated information are given below:

**Category I (risk less than 1 in 100,000)**

The dose range for this project category is less than 0.2 mSv which is the dose delivered by natural background radiation in a few weeks. It is considerably less than the variations in annual dose from natural background radiation to persons living in different locations, and the risk level is considered minimal. The level of benefit needed as the basis for approval of research with doses in this category will be minor and will include those investigations expected only to increase knowledge.

**Category II**

The dose range for this category includes the annual doses received by essentially all radiation workers in the course of their employment and the annual doses received by members of the public from the totality of naturally occurring sources to which they are exposed, apart from some of the doses from radon where the radon contribution to the annual doses is somewhat higher.

**Category IIa (risk less than 1 in 10,000)** represents a very low level of risk. The dose range of 0.2 to 2 mSv covers the allowable annual dose to the public from controlled sources. To justify risks in this category the benefit will probably be related to increases in knowledge leading to health benefit.

<sup>4</sup> Calman KC. *Cancer: science and society and the communication of risk.* BMJ 1996; 313: 799-802.

**Category IIb (risk less than 1 in 1,000)** represents a low level of risk. The dose range of 2 to 20 mSv covers the annual doses received by most radiation workers in the course of their employment, and most diagnostic radiological procedures. To justify the risks a moderate benefit will be needed. The benefit will be more directly aimed at the diagnosis, cure or prevention of disease.

**Category III (risk greater than 1 in 1,000)**

The dose range for this category is tens of mSv or more which is greater than the annual dose limit of 20 mSv for occupational exposure and is comparable to that received from several CT procedures together. To justify research involving doses or risks in this category, the benefit will have to be substantial and usually directly related to the saving of life or the prevention or mitigation of serious disease.

## Annex 2

### COMMUNICATION OF THE RISK TO THE RESEARCH PARTICIPANT

The main risk from low levels of ionizing radiation is the induction of cancer some time in the future. It is particularly important that information about this risk and other risks are communicated in a manner that will be understood by the research participant. It is recommended that a consistent approach is used by researchers for the 'lay language' description of risk. Strategies to help researchers communicate risks to research participants can be found in the publications of Alaszewski & Horlick-Jones, Gigerenzer & Edwards and Paling.

To assist researchers, the medical physicist and the Human Research Ethics Committee, four different versions of a passage suitable for inclusion in an Information Statement for Participants are given below. Each version is applicable to the level of exposure indicated, and is in keeping with the risk categories described in Annex 1. Sometimes it may be helpful to use a comparator of risk<sup>5</sup>. As the long-term risks from radiation exposure are minimal in patients who have a very short life expectancy, these statements of risk are inappropriate and are not required for research studies involving such patients.

#### A Effective dose less than 2 mSv

*This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about... mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be minimal (if dose < 0.2 mSv) or very low (if 0.2 mSv ≤ dose < 2 mSv).*

#### B Effective dose in range 2 to 20 mSv

*This research study involves exposure to a small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about... mSv. The dose from this study is comparable to that received from many diagnostic medical x-ray and nuclear medicine procedures. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be low and theoretically is approximately equivalent to....(insert risk comparator).*

#### C Effective dose greater than 20 and up to 50 mSv

*This research study involves exposure to a small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about .... mSv. The dose from this study is comparable to that received from several computed tomography x-ray (CT) and nuclear medicine procedures. The benefits from the study should be weighed against the possible detrimental effects of radiation, including an increased risk of fatal cancer. In this particular study, the risk is moderate and the estimated risk of such harm is about 1 in .... (Calculate using the ICRP risk coefficient for fatal cancer in the general*

<sup>5</sup> Such comparators may be found in publications of the Australian Bureau of Statistics, such as *Injuries and deaths due to external causes* published in the Year Book of Australia available at <http://www.abs.gov.au/>.



population of  $5 \times 10^{-2}$  per Sv. For studies in children or for persons over the age of 50, the risk of death from radiogenic cancer should be calculated using age- and sex-specific risk factors given in Table 2 in Annex 1) *For comparison, this risk is about ... times lower than the cancer mortality rate in the general population of about one case in every four people and theoretically is approximately equivalent to.... (insert risk comparator) .*

#### **D Effective dose greater than 50 mSv**

*This research study involves exposure to a significant amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about .... mSv. The benefits from the study should be weighed against the possible detrimental effects of radiation, including an increased risk of fatal cancer. In this particular study, the risk is moderate and the estimated risk of such harm is about 1 in .... (Calculate using the ICRP risk coefficient for fatal cancer in the general population of  $5 \times 10^{-2}$  per Sv. For studies in children or for persons over the age of 50, the risk of death from radiogenic cancer should be calculated using age- and sex-specific risk factors given in Table 2 in Annex 1) For comparison, this risk is about ... times lower than the cancer mortality rate in the general population of about one case in every four people and theoretically is approximately equivalent to..... (insert risk comparator) .*

The above paragraphs apply only to studies in which the equivalent doses to individual tissues are below the thresholds for tissue reactions. If threshold doses may be exceeded, for example in therapeutic trials, a statement on specific radiation risks is required.

## Annex 3

### RECOMMENDATIONS TO ASSIST IN THE IMPLEMENTATION OF THE CODE

#### (a) The Medical Physicist

The medical physicist may use published data of effective dose and organ doses for routine radiographic and nuclear medicine procedures taking into account the age and gender of the research participants as appropriate. As the radiation exposure may vary substantially with the technique factors used between sites, dose calculations should be performed for all studies employing fluoroscopy or CT scans using the technique factors specific to the site(s) at which the research will be performed.

The dosimetry report from the medical physicist should include the absorbed dose to the uterus, the maximum organ dose to any individual organ and the effective dose. For children and young adults, the report should also include the absorbed dose to the bone marrow, thyroid, gonads and the breast.

In circumstances where verification of the dose and risk assessment by an independent medical physicist is required, it may be preferable for the second medical physicist to be affiliated to a different institution from that of the researcher.

#### (b) Sponsored Trials

For sponsored trials, the sponsoring organisation should arrange for a medical physicist to estimate the dose, or range of doses, from the proposed x-ray and/or nuclear medicine studies for verification by the institution's independent medical physicist.

#### (c) Radiation Therapy Trials

Patients who undergo radiation therapy receive radiation doses that are many orders of magnitude higher than those from diagnostic investigations. In radiation therapy the doses are at levels which cause tissue effects, specifically destruction of the cancer with an acceptable level of radiation induced complications. In radiation therapy it is not possible to apply the dose constraints in Table 1 as they are designed for diagnostic investigations and are set at a level to prevent tissue effects and minimise the probability of long term effects such as carcinogenesis. The risk associated with the radiation exposure needs to be outlined to the research participant, but in radiation therapy studies it is not meaningful to assign a risk level category as per Annex 1. The individual patient may receive some potential benefit from the radiation therapy study. In radiation therapy research the effective dose is not an appropriate quantity for risk assessment.

#### (d) Novel Uses of Radiation

In most research, the estimate of the radiation exposure of the research participant determined by the medical physicist will be close to the actual exposure received during the research project. This will not necessarily be the case for *novel uses of radiation*. This type of research will include, for example, the initial use of a new radiopharmaceutical or the initial use of a new radiology imaging device. The dose estimations available to the Human Research Ethics Committee may have been calculated based on the results of animal experiments or derived using anthropomorphic phantoms. In these circumstances, it is essential that the *actual* doses received are calculated or measured, in compliance with clause 2.1.7 (f) of the

Code. These doses should be included in any reports on the project which are prepared by the researcher for the Human Research Ethics Committee.

**(e) Quality Assurance Statement**

Clause 2.1.7(c) of the Code requires the researcher to provide a statement that an appropriate quality assurance program is being followed. The statement should be obtained from the responsible person or the Head of the relevant department.

**(f) Optimisation of the Radiation Exposure**

Clause 2.1.5(a) requires the researcher to keep the radiation dose to the research participants to the minimum level practicable. To achieve this it will be necessary for the researcher to liaise with the Head of the relevant departments, for example, the Radiology and/or Nuclear Medicine Departments. In certain circumstances it will be possible to modify the department's standard protocol to minimise the exposure of the research participants. For example, in radiology it may be possible to further restrict the field of view compared with that normally used, and in nuclear medicine, it may be possible to reduce the administered activity depending on the requirements of the research. It should always be possible to keep the radiation exposures within the Diagnostic Reference Levels specified for the particular procedures.

## Annex 4

### HEALTH EFFECTS OF IONIZING RADIATION AND STANDARDS FOR CONTROL OF EXPOSURE

It is well known that high doses of ionizing radiation can cause harm, but there is continuing scientific uncertainty about effects at low doses. At levels of dose routinely encountered by members of the public and most present-day radiation workers, there is little or no epidemiological evidence of health effects. Radiation protection standards recognise that it is not possible to eliminate all radiation exposure, but they do provide for a system of control to avoid unnecessary exposure and to keep doses in the low dose range.

Extreme doses of radiation to the whole body (around 10 sievert and above), received in a short period, cause so much damage to the body that vital systems cease to function and death may result within days or weeks. Very high doses (between about 1 sievert and 10 sievert), received in a short period, kill large numbers of cells, which can impair the function of vital organs and systems. Acute health effects, such as nausea, vomiting, skin and deep tissue burns, and impairment of the body's ability to fight infection may result within hours, days or weeks. The extent of the damage increases with dose. However, 'deterministic' effects such as these are not observed at doses below certain thresholds. By limiting doses to levels below the thresholds, tissue reactions can be prevented entirely.

Doses below the thresholds for tissue reactions may cause cellular damage, but this does not necessarily lead to harm to the individual: the effects are probabilistic or 'stochastic' in nature. It is known that doses above about 100 millisievert, received in a short period, lead to an increased risk of developing cancer later in life. There is good epidemiological evidence – especially from studies of the survivors of the atomic bombings – that, for several types of cancer, the risk increases roughly linearly with dose, and that the risk factor averaged over all ages and cancer types is about 1 in 100 for every 100 millisievert of dose (i.e. 1 in 10,000 per millisievert).

At doses below about 100 millisievert, the evidence of harm is not clear-cut. While some studies indicate evidence of radiation-induced effects, epidemiological research has been unable to establish that there are effects of statistical significance at doses below a few tens of millisieverts. Nevertheless, given that no threshold for stochastic effects has been demonstrated, and in order to be cautious in establishing health standards, the proportionality between risk and dose observed at higher doses is presumed to continue through all lower levels of dose to zero. This is called the linear, no-threshold (LNT) hypothesis and it is made for radiation protection purposes only.

There is evidence that a dose accumulated over a long period carries less risk than the same dose received over a short period. Except for accidents and medical exposures, doses are not normally received over short periods, so that it is appropriate in determining standards for the control of exposure to use a risk factor that takes this into account. While not well quantified, a reduction of the high-dose risk factor by a factor of two has been adopted internationally, so that for radiation protection purposes the risk of radiation-induced fatal cancer (the risk factor) is taken to be about 1 in 20,000 per millisievert of dose for the population as a whole.

If the LNT hypothesis is correct, any dose carries some risk. Therefore, measures for control of exposure for stochastic effects seek to avoid all reasonably avoidable risk. This is called optimising protection. However, risk in this sense may often be assessed in terms of risk to a population, and may not ensure sufficient protection of the individual. Consequently, the optimisation approach is underpinned by

applying dose limits that restrict the risk to individuals to an acceptable level. The fundamental regulatory philosophy is expressed in three principles, based on the recommendations of the International Commission on Radiological Protection (ICRP), which may be summarised as follows:

*Justification:* human activities that cause exposure to radiation may be permitted only if they do more good than harm;

*Optimisation of protection:* exposure to radiation from justified activities should be kept as low as reasonably achievable, social and economic factors being taken into account; and

*Limitation of individual dose:* doses must not exceed the prescribed dose limits.

Determining what is an acceptable risk for regulatory purposes is a complex value judgement. The ICRP reviewed a number of factors in developing its recommendations, which have in general been internationally endorsed, including by the World Health Organization, the International Labour Organization and the International Atomic Energy Agency. Australia's Radiation Health Committee, now established under the ARPANS Act<sup>†</sup>, has recommended that the international standards be adopted in Australia. The recommended dose limits are summarised as follows:

**Limit on effective dose\***

	For occupational exposure	For members of the public
To limit individual risk	20 mSv per year, averaged over 5 years*	1 mSv in a year*

\*for details, see ARPANSA's *Recommendations for limiting exposure to ionizing radiation (2002)*

In most situations, the requirements for limiting individual risk ensure that doses are below deterministic thresholds, but for cases where this does not apply, the recommended limits are as follows:

**Annual limit on equivalent dose\***

	For occupational exposure	For members of the public
To prevent tissue reactions		
in the lens of the eye	150 mSv	15 mSv
in the skin	500 mSv	50 mSv
in the hands and feet	500 mSv	–

\*for details, see ARPANSA's *Recommendations for limiting exposure to ionizing radiation (2002)*

In the case of occupational exposure during pregnancy, the general principle is that the embryo or fetus should be afforded the same level of protection as is required for

<sup>†</sup> The *Australian Radiation Protection and Nuclear Safety Act (1998)*.

a member of the public. For medical workers, the ICRP recommends that there should be a reasonable assurance that fetal dose can be kept below 1 mGy<sup>‡</sup> during the course of the pregnancy. This guidance may be generalised to cover all occupationally exposed pregnant workers by keeping the fetal dose below 1 mSv. A full explanation of radiation protection principles and of the recommended standards for Australia is given in ARPANSA/NOHSC Radiation Protection Series No. 1: *Recommendations for limiting exposure to ionizing radiation (1995)* and *National standard for limiting occupational exposure to ionizing radiation* (both republished in 2002).

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<sup>‡</sup> The gray (Gy) is a unit of radiation dose. For X-rays and gamma radiation, it is numerically equivalent to the sievert.

## Annex 5

### REGULATORY AUTHORITIES

Where advice or assistance is required from the relevant regulatory authority, it may be obtained from the following officers:

COMMONWEALTH, STATE / TERRITORY	CONTACT
Commonwealth	Director, Regulatory Branch ARPANSA PO Box 655 Miranda NSW 1490 Email: info@arpansa.gov.au Tel: (02) 9541 8333 Fax: (02) 9541 8348
Australian Capital Territory	Manager Radiation Safety Radiation Safety Section ACT Health Locked Bag 5 Weston Creek ACT 2611 Email: radiation.safety@act.gov.au Tel: (02) 6207 6946 Fax: (02) 6207 6966
New South Wales	Director Radiation Control Department of Environment and Conservation PO Box A290 Sydney South NSW 1232 Email: radiation@epa.nsw.gov.au Tel: (02) 9995 5000 Fax: (02) 9995 6603
Northern Territory	Manager Radiation Protection Radiation Protection Section Department of Health and Community Services GPO Box 40596 Casuarina NT 0811 Email: envirohealth@nt.gov.au Tel: (08) 8922 7152 Fax: (08) 8922 7334
Queensland	Director, Radiation Health Department of Health 450 Gregory Terrace Fortitude Valley QLD 4006 Email: radiation_health@health.qld.gov.au Tel: (07) 3406 8000 Fax: (07) 3406 8030
South Australia	Director, Radiation Protection Division Environment Protection Authority PO Box 721 Kent Town SA 5071 Email: radiationprotection@state.sa.gov.au Tel: (08) 8130 0700 Fax: (08) 8130 0777
Tasmania	Senior Health Physicist Health Physics Branch Department of Health and Human Services GPO Box 125B Hobart TAS 7001 Email: health.physics@dhhs.tas.gov.au Tel: (03) 6222 7256 Fax: (03) 6222 7257
Victoria	Manager, Radiation Safety Program Department of Human Services GPO Box 4057 Melbourne VIC 3001 Email: radiation.safety@dhs.vic.gov.au Tel: (03) 9637 4167 Fax: (03) 9637 4508
Western Australia	Secretary, Radiological Council Locked Bag 2006 Nedlands WA 6009 Email: radiation.health@health.wa.gov.au Tel: (08) 9346 2260 Fax: (08) 9381 1423

Please note: This table was correct at the time of printing but is subject to change from time to time. For the most up-to-date list, the reader is advised to consult the ARPANSA web site – [www.arpansa.gov.au](http://www.arpansa.gov.au).

For after hours emergencies only, the police will provide the appropriate emergency contact number.

## Annex 6

### ARPANSA RADIATION PROTECTION SERIES PUBLICATIONS

ARPANSA has taken over responsibility for the administration of the former NHMRC Radiation Health Series of publications and for the codes developed under the *Environment Protection (Nuclear Codes) Act 1978*. The publications are being progressively reviewed and republished as part of the *Radiation Protection Series*. All publications listed below are available in electronic format, and can be downloaded free of charge by visiting ARPANSA's website at [www.arpansa.gov.au/pubs.htm](http://www.arpansa.gov.au/pubs.htm).

Radiation Protection Series publications are available for purchase directly from ARPANSA. Further information can be obtained by telephoning ARPANSA on 1800 022 333 (freecall within Australia) or (03) 9433 2211.

- RPS 1. Recommendations for Limiting Exposure to Ionizing Radiation (1995) and National Standard for Limiting Occupational Exposure to Ionizing Radiation (republished 2002)
- RPS 2. Code of Practice for the Safe Transport of Radioactive Material (2001)
- RPS 3. Radiation Protection Standard for Maximum Exposure Levels to Radiofrequency Fields – 3 kHz to 300 GHz (2002)
- RPS 4. Recommendations for the Discharge of Patients Undergoing Treatment with Radioactive Substances (2002)
- RPS 5. Code of Practice and Safety Guide for Portable Density/Moisture Gauges Containing Radioactive Sources (2004)
- RPS 6. National Directory for Radiation Protection – Edition 1.0 (2004)
- RPS 7. Recommendations for Intervention in Emergency situations Involving Radiation Exposure (2004)
- RPS 8. Code of Practice for the Exposure of Humans to Ionizing Radiation for Medical Research Purposes (2005)

Those publications from the NHMRC Radiation Health Series and the Environment Protection (Nuclear Codes) Act Series that are still current are:

#### RADIATION HEALTH SERIES

- RHS 2. Code of practice for the design of laboratories using radioactive substances for medical purposes (1980)
- RHS 3. Code of practice for the safe use of ionizing radiation in veterinary radiology: Parts 1 and 2 (1982)
- RHS 4. Code of practice for the safe use of radiation gauges (1982)
- RHS 8. Code of nursing practice for staff exposed to ionizing radiation (1984)
- RHS 9. Code of practice for protection against ionizing radiation emitted from X-ray analysis equipment (1984)
- RHS 10. Code of practice for safe use of ionizing radiation in veterinary radiology: part 3-radiotherapy (1984)
- RHS 13. Code of practice for the disposal of radioactive wastes by the user (1985)
- RHS 14. Recommendations for minimising radiological hazards to patients (1985)



- RHS 15. Code of practice for the safe use of microwave diathermy units (1985)
- RHS 16. Code of practice for the safe use of short wave (radiofrequency) diathermy units (1985)
- RHS 18. Code of practice for the safe handling of corpses containing radioactive materials (1986)
- RHS 19. Code of practice for the safe use of ionizing radiation in secondary schools (1986)
- RHS 20. Code of practice for radiation protection in dentistry (1987)
- RHS 21. Revised statement on cabinet X-ray equipment for examination of letters, packages, baggage, freight and other articles for security, quality control and other purposes (1987)
- RHS 22. Statement on enclosed X-ray equipment for special applications (1987)
- RHS 23. Code of practice for the control and safe handling of radioactive sources used for therapeutic purposes (1988)
- RHS 24. Code of practice for the design and safe operation of non-medical irradiation facilities (1988)
- RHS 25. Recommendations for ionization chamber smoke detectors for commercial and industrial fire protection systems (1988)
- RHS 28. Code of practice for the safe use of sealed radioactive sources in bore-hole logging (1989)
- RHS 29. Occupational standard for exposure to ultraviolet radiation (1989)
- RHS 30. Interim guidelines on limits of exposure to 50/60Hz electric and magnetic fields (1989)
- RHS 31. Code of practice for the safe use of industrial radiography equipment (1989)
- RHS 34. Safety guidelines for magnetic resonance diagnostic facilities (1991)
- RHS 35. Code of practice for the near-surface disposal of radioactive waste in Australia (1992)
- RHS 36. Code of practice for the safe use of lasers in schools (1995)
- RHS 37. Code of practice for the safe use of lasers in the entertainment industry (1995)
- RHS 38. Recommended limits on radioactive contamination on surfaces in laboratories (1995)

#### **ENVIRONMENT PROTECTION (NUCLEAR CODES) ACT SERIES**

Code of Practice on the Management of Radioactive Wastes from the Mining and Milling of Radioactive Ores 1982

Code of Practice on Radiation Protection in the Mining and Milling of Radioactive Ores 1987

## **Contributors to Drafting and Review**

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