



Australian Government

Australian Radiation Protection and Nuclear Safety Agency

CODE OF PRACTICE

**Exposure of Human Subjects to
Ionizing Radiation for Medical
Research Purposes
(2004)**

Radiation Protection Series Publication No. ??

Public Comment Version: February 2004

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.



Australian Government

Australian Radiation Protection and Nuclear Safety Agency

CODE OF PRACTICE

Exposure of Human Subjects to Ionizing Radiation for Medical Research Purposes

Radiation Protection Series Publication No. ??

Public Comment Version: February 2004

This publication was approved by the Radiation Health Committee on dd mmmm yyyy, and the Radiation Health & Safety Advisory Council, at its meeting on dd mmmm yyyy, advised the CEO to adopt the Code of Practice.

NOTICE

© Commonwealth of Australia 2004

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Commonwealth available from the Department of Communications, Information Technology and the Arts. Requests and inquiries concerning reproduction and rights should be addressed to Commonwealth Copyright Administration, Intellectual Property Branch, Department of Communications, Information Technology and the Arts, GPO Box 2154, Canberra ACT 2601.

Requests for information about the content of this publication should be addressed to the Secretariat, ARPANSA, 619 Lower Plenty Road, Yallambie, Victoria, 3085 or by e-mail secretariat@arpansa.gov.au.

ISBN ? ??? ????? ?

ISSN 1445-9760

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 [month yyyy]

Foreword

This *Code of Practice for the Exposure of Human Subjects to Ionizing Radiation for Medical Research Purposes* establishes requirements for adoption by Commonwealth, State and Territory jurisdictions that will provide a system to ensure human subjects and ethics committees are accurately informed of radiation dose and the associated risks, indicate the boundaries above which radiation doses from medical research are unlikely to be acceptable, and to promote uniformity in the supervision of the exposure of human subjects to ionizing radiation for medical research purposes.

Researchers typically use ionizing radiation with human subjects to investigate medical conditions and the effectiveness of possible treatments. Although research may involve volunteers with pre-existing conditions, there is often no known direct benefit to the volunteer from the research and it is not part of the medical management for their condition. In some instances, research involves the administration of ionizing radiation to healthy subjects.

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

Since 1984, developments in advice from the International Commission for Radiological Protection (ICRP) have provided an increased understanding of the effects of ionizing radiation on specific organs and tissues and there now exists a much more extensive list of tissue weighting factors for the evaluation of risks from exposure to radiation. In addition, the classification of research projects by the ICRP has been modified to take into account changes in the assessment of radiation risk and the introduction of a corresponding categorisation of the level of societal benefit. This categorisation should be one of the matters considered in approving the level of dose. This new information has been included in this Code of Practice.

The main changes in this Code of Practice are in terms of dose constraints which now include further age-related and organ and tissue controls. The Code of Practice applies to therapeutic clinical trials and clarifies the relative responsibilities of the researchers, human research ethics committees, volunteers and regulators. For example, the Code of Practice requires researchers to ensure dose calculations and associated risk information provided to human research ethics committees have been checked by a medical physicist. New guidance in the selection of subjects and the provision of information to and from subjects has also been added.

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 the final Code of Practice was approved by the Radiation Health Committee on DD MMMMM

2004. The Radiation health and Safety Advisory Council advised the CEO to adopt the Code of Practice at their meeting on DD MMMMM 2004.

The Code will be revised and updated from time to time to ensure that it continues to be in accordance with international advice in radiation protection in medical research.

[signature]

John Loy
CEO of ARPANSA

Contents

Forewordi

1. Introduction 1

 1.1 CITATION 1

 1.2 BACKGROUND..... 1

 1.3 PURPOSE 1

 1.4 SCOPE 1

2. Responsibilities3

 2.1 RESEARCHER.....3

 2.2 SUBJECTS OR GUARDIANS OF SUBJECTS 6

 2.3 HUMAN RESEARCH ETHICS COMMITTEE..... 7

 2.4 THE RESPONSIBLE PERSON..... 7

 2.5 THE REGULATORY AUTHORITY8

3. Radiation Dose Constraints for Subjects9

Annex 1 ASSESSMENT OF RISK VERSUS BENEFIT 10

**Annex 2 DOSE LIMITS FOR MEMBERS OF THE PUBLIC AND FOR
OCCUPATIONALLY EXPOSED PERSONS..... 12**

**Annex 3 HEALTH EFFECTS OF IONIZING RADIATION AND
STANDARDS FOR CONTROL OF EXPOSURE 13**

Annex 4 REGULATORY AUTHORITIES..... 17

**Annex 5 ARPANSA RADIATION PROTECTION SERIES
PUBLICATIONS 18**

Glossary20

References24

Contributors to Drafting and Review..... 25

Index26

1. Introduction

1.1 CITATION

This Code may be cited as the *Code of Practice for the Exposure of Human Subjects to Ionizing Radiation for Medical Research Purposes (2004)*.

1.2 BACKGROUND

This Code of Practice 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)¹ and the recommendations of the ARPANSA and the National Occupational Health and Safety Commission (ARPANSA/NOHSC, 2002).

1.3 PURPOSE

The purpose of this Code of Practice is to provide requirements on the conditions which must be met for the exposure of human subjects to ionizing radiation for the purpose of medical research.

1.4 SCOPE

This Code of Practice applies to the exposure of human research subjects who do not receive a direct medical benefit, or where although there may be a benefit, this has not been established. It also applies to radiological diagnostic studies used to monitor the outcome of therapeutic clinical trials.

It does not apply where the patient receives a direct medical benefit from the administration of ionizing radiation or where procedures are performed as part of the normal clinical management.

Thus the types of clinical research to which this Code of Practice applies includes but is not restricted to; clinical research with diagnostic/therapeutic agents and procedures, Phase I, II and III clinical trials and novel procedures on selected groups of human subjects. Further, this Code of Practice does not apply to the use of pharmaceuticals or medical devices which have been approved by the Therapeutic Goods Administration for routine clinical use in Australia, nor to the use of a novel procedure involving ionizing radiation on an individual patient requested by a medical practitioner as part of the patient's medical management.

This Code of Practice outlines the roles and responsibilities of the following:

- the researcher who proposes to undertake a project involving administration of ionizing radiation to human subjects

- 41 • the subject, or the guardian of the subject, who is exposed to ionizing
42 radiation for research purposes
- 43 • the Human Research Ethics Committee (constituted in accordance
44 with the national Statement on Ethical Conduct in Research Involving
45 Humans (NHMRC, 1999) (issued by the NHMRC in accordance with
46 the NHMRC Act, 1992), which is an advisory body independent of the
47 teams of researchers
- 48 • the responsible person for the radioactive source, apparatus, facility or
49 premises, and
- 50 • the relevant regulatory authority (see Annexe 4) which is responsible
51 for ionizing radiation control.

52 Advice on radiation dose constraints for human subjects in medical
53 research are given in Section 3. The assessment of risk/benefit of research
54 projects is given in Annex 1.

55 **1.5 INTERPRETATION**

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

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

2. Responsibilities

2.1 RESEARCHER

2.1.1 The researcher must:

- (a) consider the requirements of the relevant regulatory authority¹ regarding exposure of human subjects to ionizing radiation for medical research;
- (b) obtain the approval of the Human Research Ethics Committee of the relevant institution for the research; and
- (c) comply with all requirements of the relevant regulatory authority and the Human Research Ethics Committee.

2.1.2 The researcher must prepare a submission to the Human Research Ethics Committee (a '**research proposal**') in accordance with its requirements which should include the following information:

- (a) a detailed protocol for the proposed research;
- (b) the reasons why it is necessary to expose human subjects to ionizing radiation for the purpose of the research;
- (c) the number, age range and gender of the subjects to be exposed;
- (d) an estimate, in the form of a written report from a medical physicist, of the radiation dose (effective dose and relevant organ doses) to be received by each subject together with the associated estimate of risk.
- (e) the anticipated benefits that might reasonably be expected to result to society from the research as advised in Annex 1;
- (f) a statement confirming that:
 - (i) the site(s) at which the examination(s) or procedure(s) will be performed is actively involved in a relevant quality assurance program of either the Royal Australian and New Zealand College of Radiologists or the Australian and New Zealand Society of Nuclear Medicine, or as approved by the relevant regulatory authority; and
 - (ii) any irradiating apparatus to be used complies with requirements of the relevant regulatory authority.
- (g) the precautions to be taken to keep radiation exposure to a minimum;
- (h) details of information to be given to the subjects and the consent form to be used; and

¹ A list of such authorities is provided at Annex 4.

Radiation
Protection
Series
No. ##

Code of Practice
Exposure of Human Subjects to Ionizing Radiation for Medical Research Purposes

- 101 (i) arrangements for review of radiation doses delivered and for
102 keeping of dose records for the project.
- 103 2.1.3 The researcher must ensure that the selection of the subjects is
104 conducted according to the requirements of the Human Research Ethics
105 Committee and the following criteria:
- 106 (a) **Age;**
- 107 (i) partly because of the possibility of genetic effects and partly
108 because of the long latent period associated with certain
109 somatic effects of radiation, the human subject should, where
110 practicable, be over 40 years of age, and preferably over 50;
- 111 (ii) exposure of children must only be permitted if the condition
112 under study is related to the age of the participants and the
113 information sought cannot be obtained using adult subjects;
114 and
- 115 (iii) fetuses must not be exposed to ionizing radiation for the
116 purposes of medical research unless the appropriate health
117 or medical authority, with the permission of the parents,
118 grants an exceptional approval in circumstances where the
119 information sought is essential and cannot be obtained by
120 other means.
- 121 (b) **Pregnancy;**
- 122 (i) pregnant women must be excluded except when problems
123 specific to this group are being investigated;
- 124 (ii) research involving irradiation of pregnant women must be
125 performed only when the information sought cannot be
126 obtained by other means, and the risks are minimal;
- 127 (iii) in studies on pregnant women, the dose to the fetus must
128 also be assessed and taken into account;
- 129 (iv) in considering the choice of women of reproductive age as
130 subjects, the possibility that a woman may be pregnant must
131 be taken into account².
- 132 (c) **Number of Subjects;**
- 133 The number of subjects exposed must be restricted to the minimum
134 necessary to acquire the information needed with sufficient statistical
135 power.

² Premenopausal potentially fertile women should have a serum pregnancy test to exclude pregnancy before commencement of the radiological investigation.

136 2.1.4 The researcher must provide the subject with sufficient
137 information about the purpose, methods, radiation dose, associated risks
138 and any discomforts of the research to enable the subject to give informed
139 consent.

140 2.1.5 Where the research subject cannot give informed consent,
141 including the case of irradiation of a child, the researcher must provide the
142 parent or guardian with sufficient information about the purpose,
143 methods, radiation dose, associated risks and any discomforts of the
144 research and obtain consent.

145 2.1.6 The researcher must inform the subject that they have the right to
146 terminate participation at any time.

147 2.1.7 The researcher must;

148 (a) Whenever possible, select subjects who have not previously or are
149 not currently exposed to radiation from research projects, as it is
150 undesirable for the same subject to participate in multiple research
151 protocols involving ionizing radiation; and

152 (b) consider whether to exclude subjects whose past radiation history
153 cannot be verified;

154 (c) keep the radiation dose to subjects to the minimum level
155 practicable; and

156 (d) ensure that an estimate is obtained of the absorbed dose to the skin
157 if the research protocol requires multiple CT scans or prolonged
158 fluoroscopic screening (greater than 10 minutes in normal dose rate
159 mode, or greater than one minute in high dose rate mode).

160 2.1.8 The researcher must assess whether the total cumulative dose to
161 each subject will exceed the dose constraints in Table 1.

162 2.1.9 The researcher must ensure that the Human Research Ethics
163 Committee is provided with specific advice from the relevant regulatory
164 authority about the proposed doses to subjects if the proposal indicates
165 that doses to subjects will exceed the dose constraints in Table 1.

166 2.1.10 The researcher must make arrangements to maintain records of
167 the subjects' signed consent forms, radiation doses and details of the
168 research undertaken.

169 2.1.11 The researcher must state in the proposal the period of time that
170 records will be kept.

171 2.1.12 The researcher must seek and obtain for submission to the Human
172 Research Ethics Committee for consideration as part of the research
173 proposal, verification or specific authorisation from the relevant regulatory
174 authority, or a medical physicist, that the following information to be
175 provided to the Committee is adequate and correct:

Radiation
Protection
Series
No. ##

- 176 (a) estimates of radiation doses to subjects (refer to 2.1.2(d));
177 (b) the radiological aspects of the quality assurance program for the
178 project (refer to 2.1.2(f));
179 (c) precautions to keep radiation exposure to a minimum (refer to
180 2.1.2(g));
181 (d) the information on the radiation exposure and associated risks to be
182 given to subjects and the radiation-related aspects of the consent
183 form to be used (refer to 2.1.2(h));
184 (e) proposals for review of the radiation doses delivered (refer to
185 2.1.2(i)); and
186 (f) proposals in relation to the keeping of dose records and consent
187 forms for the project (refer to 2.1.10 and 2.1.11).

188 2.1.13 The researcher must give the subject a record of the radiation dose
189 received during the project, with instructions to retain the record for
190 reference prior to participation in any future research project involving
191 exposure to ionizing radiation.

192 **2.2 SUBJECTS OR GUARDIANS OF SUBJECTS**

193 2.2.1 A person must not participate in a research project involving
194 exposure to ionizing radiation until the nature and the objects of the
195 project have been explained to that person (or guardian) by the researcher.
196 The person (or guardian) must have understood the risks and must
197 demonstrate willing participation by signing the consent form.

198 2.2.2 In a case where the research subject cannot give informed consent,
199 including the case of irradiation of a child, the information must be
200 explained to his/her parent or guardian and consent obtained from the
201 parent or guardian.

202 2.2.3 The subject or the guardian should retain records of participation
203 in investigations with radiation doses received, and provide this dose
204 history to any researcher before consenting to any further radiation
205 exposure for research purposes.

206 2.2.4 The subject or the guardian has the right to terminate
207 participation in the project at any time.

208 2.3 HUMAN RESEARCH ETHICS COMMITTEE

209 2.3.1 Research proposals must be assessed by a Human Research Ethics
210 Committee to ensure an independent and impartial opinion of the
211 necessity for the investigation and the balance between the likely benefits
212 and risks involved including consideration of the advice provided in
213 Annex 1.

214 2.3.2 In evaluating each research project before approval, the Human
215 Research Ethics Committee must consider the information submitted by
216 the researcher. Particular attention should be given to:

- 217 (a) the manner in which the project is to be explained to the subject
218 and the informed consent obtained;
- 219 (b) the estimates of expected radiation doses and associated risks,
220 which must be calculated or verified by a medical physicist;
- 221 (c) any statements from the relevant regulatory authority, or a medical
222 physicist, about the adequacy and correctness of the radiation
223 related information in the research proposal;
- 224 (d) any specific advice from, or requirements of, the relevant regulatory
225 authority about the proposed doses to subjects if the proposal
226 indicates that doses to subjects will exceed the dose constraints in
227 Table 1;
- 228 (e) the measures to be taken during the project to assess the radiation
229 doses delivered, and to keep them to a minimum;
- 230 (f) the arrangements for keeping records of the subjects' doses;
- 231 (g) legal requirements for the use of ionizing radiation in the project.

232 2.3.3 A recommendation from, or an approval issued by, a Human
233 Research Ethics Committee indicating that the proposed research meets
234 ethical requirements carries the implication that the Human Research
235 Ethics Committee has considered the radiation related risks of the
236 proposed research. Human Research Ethics Committees must therefore
237 ensure that they have access to appropriate radiation advice sufficient to
238 permit a full understanding of the radiation aspects of the proposed
239 research prior to recommending that such research proceeds.

240 2.4 THE RESPONSIBLE PERSON

241 The responsible person as defined in the glossary of this Code is
242 responsible for monitoring the overall observance of this Code and its
243 implementation in relation to the radioactive source, radiation apparatus,
244 facility or premises.

**Radiation
Protection
Series
No. ##**

245
246
247
248
249
250
251

Code of Practice
Exposure of Human Subjects to Ionizing Radiation for Medical Research Purposes

2.5 THE REGULATORY AUTHORITY

The role of the regulatory authority is to provide advice to the researcher and the Human Research Ethics Committee regarding the legislative requirements for the use of ionizing radiation, including the circumstances when researchers must seek the opinion of, or specific advice/requirements of the relevant regulatory authority in relation to the research.

3. Radiation Dose Constraints for Subjects

The radiation dose to the subjects must be kept to the minimum level practicable, and the cumulative effective dose to adults and children must conform with the dose constraints as tabulated below unless the Human Research Ethics Committee is provided with specific advice/approval from the relevant regulatory authority in relation to any proposal to exceed these dose constraints. In addition, the equivalent dose to any organ or portion of an organ should conform to the dose constraints. For comparison purposes, the dose limits for occupational and public exposure are at Annex 2.

Table 1. Dose Constraints for Subjects in Medical Research^a

Volunteer Category	Dose Constraint ^{b,c}
Adult subjects in biomedical research	
Cumulative effective dose ³	
– in any year	5 mSv ^d
– over 5 years	10 mSv
Equivalent dose to any organ or tissue, or a portion of any organ or tissue	
– in any year	200 mSv ^e
Children exposed in biomedical research	
Cumulative effective dose to age 18 years,	5 mSv
– Subject to:	
• effective dose in any year, from conception to age 2 years; and	0.1 mSv
• effective dose in any year for age 2 to 18 years.	0.5 mSv
Cumulative equivalent dose to age 18 years to any organ or tissue, or a portion of any organ or tissue	200 mSv

^a A dose constraint for subjects in medical research specifies a maximum dose with which it should be possible to comply in normal circumstances and it is intended to apply to subjects who do not themselves benefit from the exposure.

^b 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.

^c Any proposal to exceed these values must be referred to the regulatory authority.

^d mSv = millisievert.

^e Derived from Table 3.1 of ICRP85 - factor of 10 below the threshold of 2 Gray for early transient erythema and detectable lens opacity.

³ From ARPANSA/NOHSC 2002

Annex 1**ASSESSMENT OF RISK VERSUS BENEFIT**

The level of risk 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, the risk is significantly greater for children and decreases with age.

The World Health Organisation (WHO, 1977) divided research projects into categories depending on the radiation doses received by human subjects. The ICRP has recently 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 subjects or to society at large, has to be evaluated to justify the need to expose human subjects to ionizing radiation. The likely risk of harm to the human subjects 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 subjects that might affect the risk resulting from the exposure. It should also be noted that in the case of terminally ill patients, long-term risks of radiation are not relevant.

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 adapted, with permission, from ICRP (ICRP 1993):

Categories of risk and corresponding levels of benefit

Level of Risk	Risk Category	Effective Dose Range (adults) (mSv)	Level of Societal Benefit Expected
Minimal	Category I (10^{-6} or less)	< 0.1	Minor
Minor to intermediate	Category II IIa (10^{-5}) IIb (10^{-4})	0.1-1 1-10	Intermediate to moderate
Moderate	Category III (10^{-3} or more)	> 10^a	Substantial

^a *To be kept below deterministic thresholds except where therapeutic procedures involving radiation are being investigated.*

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

311 **Category I (risk of the order of 1 in 1,000,000)**

312 The dose range for this project category is less than 0.1 mSv which is the dose
313 delivered by natural background radiation in a few weeks. It is considerably
314 less than the variations in annual dose from natural background to persons
315 living in different locations, and the risk level is considered minimal. The level
316 of benefit needed as the basis for approval of research with doses in this
317 category will be minor and will include those investigations expected only to
318 increase knowledge.

319 **Category II**

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

325 **Category IIa (risk of the order of 1 in 100,000)** represents a
326 minor level of risk, and covers doses (in the range of 0.1-1 mSv) to the
327 public from controlled sources; nevertheless, an intermediate benefit
328 will be required. To justify risks in this category the benefit will probably
329 be related to increases in knowledge leading to health benefit.

330 **Category IIb (risk of the order of 1 in 10,000)** represents an
331 intermediate level of risk, and covers doses (in the range of 1-10 mSv)
332 received by workers in some radiation areas each year, and a moderate
333 benefit will be needed. The benefit will be more directly aimed at the
334 cure or prevention of disease.

335 **Category III (risk of the order of 1 in 1,000 or greater)**

336 The dose range for this category is tens of mSv or more which may be greater
337 than the annual dose limit of 20 mSv for occupational exposure. It covers the
338 higher part of the range of annual doses from natural background radiation
339 (including radon), a range in which remedial measures to reduce dose is
340 usually recommended. To justify research involving doses or risks in this
341 category, the benefit will have to be substantial and usually directly related to
342 the saving of life or the prevention or mitigation of serious disease.

Radiation
Protection
Series
No. ##
343
344
345
346
347

Code of Practice
Exposure of Human Subjects to Ionizing Radiation for Medical Research Purposes

Annex 2

DOSE LIMITS FOR MEMBERS OF THE PUBLIC AND FOR OCCUPATIONALLY EXPOSED PERSONS

Application	Dose Limits ¹	
	Occupational	Public
Effective dose	20 mSv per year, averaged over a period of 5 consecutive calendar years ^{2,3}	1 mSv in a year ⁴
Annual equivalent dose in:		
the lens of the eye	150 mSv	15 mSv
the skin ⁵	500 mSv	50 mSv
the hands and feet	500 mSv	–

1. The limits must apply to the sum of the relevant doses from external exposure in the specified period and the 50-year committed dose (to age 70 years for children) from intakes in the same period.
2. With the further provision that the effective dose must not exceed 50 mSv in any single year. In addition, when a pregnancy is declared by an employee, the embryo or fetus should be afforded the same level of protection as required for members of the public.
3. When, in exceptional circumstances, a temporary change in the dose limitation requirements is approved by the appropriate authority, one only of the following conditions must apply: (a) the effective dose limit must not exceed 50 mSv per year for the period, which must not exceed 5 years, for which the temporary change is approved, or (b) the period for which the 20 mSv per year average applies must not exceed 10 consecutive years and the effective dose must not exceed 50 mSv in any single year.
4. In special circumstances, a higher value of effective dose could be allowed in a single year, provided that the average over 5 years does not exceed 1 mSv per year.
5. The equivalent dose limit for the skin applies to the dose averaged over any 1 cm² area of skin, regardless of the total area exposed.

NOTE: The above dose limits table is directly extracted from the ARPANSA's *Recommendations for limiting exposure to ionizing radiation (2002)*, however the Radiation Health Committee now advises that the exceptional circumstances clause in note 3 of the table is not recommended for use in Australia.

348
349
350
351
352
353
354
355
356
357
358
359
360
361
362
363
364
365
366
367
368
369
370
371
372
373
374
375
376
377

Annex 3

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 recognize 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 internal organs and tissues of 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, deterministic effects can be prevented entirely.

Doses below the thresholds for deterministic effects 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 unequivocally 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

* The sievert (Sv) is a unit of measurement of radiation dose (ARPANSA's *Recommendations for limiting exposure to ionizing radiation (2002)*).

Radiation 423
Protection 424
Series 425
No. ## 426
427

Code of Practice
Exposure of Human Subjects to Ionizing Radiation for Medical Research Purposes

428
429
430
431
432
433
434
435
436

437
438

439
440
441

442
443

444
445
446
447
448
449
450
451

452

453
454

455
456

457
458

459
460
461

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 optimizing 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 optimization 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 summarized as follows:

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

Optimization 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 Organisation and the International Atomic Energy Agency. Australia's Radiation Health Committee, now established under the ARPANS Act[†], has recommended that the international standards be adopted in Australia. The recommended dose limits are summarized 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:

[†] The Australian Radiation Protection and Nuclear Safety Act (1998).

462

Annual limit on equivalent dose*

463

For occupational
exposure

For members of
the public

464

465

To prevent deterministic effects

466

in the lens of the eye

150 mSv

15 mSv

467

in the skin

500 mSv

50 mSv

468

in the hands and feet

500 mSv

–

469

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

470

**Radiation
Protection
Series
No. ##**

Code of Practice
Exposure of Human Subjects to Ionizing Radiation for Medical Research Purposes

Radiation 471
Protection 472
Series 473
No. ## 474

Code of Practice
Exposure of Human Subjects to Ionizing Radiation for Medical Research Purposes

475
476
477
478
479
480
481

482

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 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* 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).

* The gray (Gy) is a unit of radiation dose. For X-rays and gamma radiation, it is essentially equivalent to the sievert.

483 **Annex 4**

484

485 **REGULATORY AUTHORITIES**

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

COMMONWEALTH, STATE / TERRITORY	CONTACT
Commonwealth	Director, Regulatory Branch ARPANSA PO Box 655 Tel: (02) 9545 8333 Miranda NSW 1490 Fax: (02) 9545 8348 Email: info@arpansa.gov.au
Australian Capital Territory	Director, Radiation Safety Section ACT Health GPO Box 825 Tel: (02) 6207 6946 Canberra ACT 2601 Fax: (02) 6207 6966 Email: radiation.safety@act.gov.au
New South Wales	Director, Radiation Control Section Environment Protection Authority P.O. Box A290 Tel: (02) 9995 5000 Sydney South NSW 1232 Fax: (02) 9995 5925 Email: radiation@epa.nsw.gov.au
Northern Territory	Manager – Radiation Health Radiation Health Section Department of Health and Community Services GPO Box 40596 Tel: (08) 8922 7489 Casuarina NT 0811 Fax: (08) 8922 7334 Email: envirohealth@nt.gov.au
Queensland	Director, Radiation Health Department of Health 450 Gregory Terrace Tel: (07) 3406 8000 Fortitude Valley QLD 4006 Fax: (07) 3406 8030 Email: radiation_health@health.qld.gov.au
South Australia	Director, Radiation Protection Branch Environment Protection Authority PO Box 721 Tel: (08) 8130 0700 Kent Town SA 5071 Fax: (08) 8130 0777 Email: radiationprotection.branch@state.sa.gov.au
Tasmania	Senior Health Physicist, Health Physics Branch Department of Health & Human Services GPO Box 125B Tel: (03) 6222 7256 Hobart TAS 7001 Fax: (03) 6222 7257 Email: health.physics@dhhs.tas.gov.au
Victoria	Manager, Radiation Safety Program Department of Human Services GPO Box 4057 Tel: (03) 9637 4167 Melbourne VIC 3001 Fax: (03) 9637 4508 Email: radiation.safety@dhs.vic.gov.au
Western Australia	Secretary Radiological Council of Western Australia Locked Bag 2006 PO Tel: (08) 9346 2260 Nedlands WA 6009 Fax: (08) 9381 1423 Email: radiation.health@health.wa.gov.au

488 Please note: This table was correct at the time of printing but is subject to change
489 from time to time. For the most up-to-date list, the reader is advised to consult
490 the ARPANSA web site.

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

Annex 5

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 <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 # Code of Practice for the Exposure of Human Subjects to Ionizing Radiation for Medical Research Purposes (2003).

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 11. Code of practice for the safe use of soil density and moisture gauges containing radioactive sources (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)

- 537 RHS 16. Code of practice for the safe use of short wave (radiofrequency)
538 diathermy units (1985)
- 539 RHS 17. Procedure for testing microwave leakage from microwave ovens (1985)
- 540 RHS 18. Code of practice for the safe handling of corpses containing radioactive
541 materials (1986)
- 542 RHS 19. Code of practice for the safe use of ionizing radiation in secondary
543 schools (1986)
- 544 RHS 20. Code of practice for radiation protection in dentistry (1987)
- 545 RHS 21. Revised statement on cabinet X-ray equipment for examination of
546 letters, packages, baggage, freight and other articles for security,
547 quality control and other purposes (1987)
- 548 RHS 22. Statement on enclosed X-ray equipment for special applications (1987)
- 549 RHS 23. Code of practice for the control and safe handling of radioactive sources
550 used for therapeutic purposes (1988)
- 551 RHS 24. Code of practice for the design and safe operation of non-medical
552 irradiation facilities (1988)
- 553 RHS 25. Recommendations for ionization chamber smoke detectors for
554 commercial and industrial fire protection systems (1988)
- 555 RHS 26. Policy on stable iodine prophylaxis following nuclear reactor accidents
556 (1989)
- 557 RHS 28. Code of practice for the safe use of sealed radioactive sources in
558 bore-hole logging (1989)
- 559 RHS 29. Occupational standard for exposure to ultraviolet radiation (1989)
- 560 RHS 30. Interim guidelines on limits of exposure to 50/60Hz electric and
561 magnetic fields (1989)
- 562 RHS 31. Code of practice for the safe use of industrial radiography equipment
563 (1989)
- 564 RHS 32. Intervention in emergency situations involving radiation exposure
565 (1990)
- 566 RHS 34. Safety guidelines for magnetic resonance diagnostic facilities (1991)
- 567 RHS 35. Code of practice for the near-surface disposal of radioactive waste in
568 Australia (1992)
- 569 RHS 36. Code of practice for the safe use of lasers in schools (1995)
- 570 RHS 37. Code of practice for the safe use of lasers in the entertainment industry
571 (1995)
- 572 RHS 38. Recommended limits on radioactive contamination on surfaces in
573 laboratories (1995)
574
- 575 **ENVIRONMENT PROTECTION (NUCLEAR CODES) ACT SERIES**
- 576 Code of Practice on the Management of Radioactive Wastes from the Mining and
577 Milling of Radioactive Ores 1982
- 578 Code of Practice on Radiation Protection in the Mining and Milling of Radioactive
579 Ores 1987

580

Glossary

581

Absorbed dose

582

the energy absorbed per unit mass by matter from ionizing radiation which impinges upon it (see Annex B).

583

584

Accident

585

an unintended event which causes, or has the potential to cause, employees or members of the public to be exposed to radiation from which the individual doses or collective doses received do not lie within the range of variation which is acceptable for normal operation. An accident may result from human error, equipment failure or other mishap; it may require emergency action to save life or to safeguard health, property or the environment; it requires investigation of its causes and consequences and, possibly, corrective action within the program for control of radiation; and it may require remedial action to mitigate its consequences.

586

587

588

589

590

591

592

593

594

Approval

595

a written agreement by the appropriate authority that a plan or proposal meets the radiation protection requirements of the *Recommendations*.

596

597

Approved

598

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

599

600

Relevant regulatory authority

601

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 *Recommendations*.

602

603

604

Code of practice for radiation protection

605

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

606

607

Constraint

608

either **dose constraint** in the case of exposures anticipated to be received, or **risk constraint** in the case of potential exposures (see **dose constraint** and **risk constraint**).

609

610

611

Deterministic effect

612

an effect, such as partial loss of function of an organ or tissue, caused by radiation and manifest only above some threshold of dose, the severity of the effect depending upon the dose received.

613

614

615

Detriment

616

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.

617

618

619

620

Dose

621

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

622

623

Dose constraint

624

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

625

626

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.

627

628

629 in medical exposure, a dose constraint for subjects in medical research may
630 be used to restrict the options considered in the design of an experimental
631 protocol.

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

634 **Effective dose**

635 a measure of dose which takes into account both the type of radiation
636 involved and the radiological sensitivities of the organs and tissues irradiated
637 (see Annex B).

638 **Employee**

639 a person who works for an employer within an operation.

640 **Employer**

641 an operator who or which engages people to work within an operation; the
642 term employer includes a self-employed person.

643 **Equivalent dose**

644 a measure of dose in organs and tissues which takes into account the type of
645 radiation involved (see Annex B).

646 **Excluded exposure**

647 in the context of occupational exposure, the component of exposure
648 which arises from natural background radiation, provided that any
649 relevant action level, or levels, for the workplace are not exceeded and
650 that the appropriate authority does not prohibit its exclusion.

651 **Exposure**

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

655 (The context in which the word is used should avoid ambiguity.)

656 **Ionization**

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

659 **Ionizing radiation**

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

663 **Justification**

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

667 **Licence**

668 a written authorization issued to an operator which allows the operator to
669 carry out an operation legally.

670 **Limitation**

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

673 **Medical exposure**

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

**Radiation
Protection
Series**

No. ##

**Code of Practice
Exposure of Human Subjects to Ionizing Radiation for Medical Research Purposes**

678
679
680
681
682
683
684
685
686
687
688
689
690
691
692
693
694
695
696
697
698
699
700
701
702
703
704
705
706
707
708
709
710
711
712
713
714
715
716
717
718
719
720
721
722
723
724
725
726
727

Medical physicist

for the purpose of this Code, is a person who is qualified to perform the necessary dosimetric calculations, measurements and monitoring and –

- (a) accredited in Radiological Physics or Nuclear Medicine Physics by the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) and specifically approved by the relevant regulatory authority to make estimates of radiation doses in research projects; or
- (b) has an equivalent level of training, skills, knowledge and expertise to a person accredited in Radiological Physics or Nuclear Medicine Physics by the ACPSEM as determined by the relevant regulatory authority and specifically approved by the relevant regulatory authority to make estimates of radiation doses in research projects.

Millisievert (mSv)

One thousandth of a sievert. The sievert (Sv) is the unit for dose equivalent, equal to the joule per kilogram, taking into account the quality factor and other modifying factors.

Occupational exposure

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

Operation

an instance of a practice; a particular human activity which may result in exposure to ionizing radiation and to which a program of radiation protection applies.

Operator

any person or entity responsible for an operation which may lead to exposure to ionizing radiation.

Optimization

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

Practice

a type of human activity; in a radiological context, a human activity which may result in exposure to ionizing radiation and to which a system of radiation protection applies.

Program of radiation protection

an instance of a system of radiation protection, designed for a particular operation.

Public exposure

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

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.

Radon

used generically, all isotopes of the element radon, having atomic number 86, but typically used to refer to the radioactive gas radon-222.

728 **Responsible person**

729 in relation to any radioactive source, radiation apparatus, prescribed
730 radiation facility or premises on which unsealed radioactive sources are
731 stored or used means the person:

- 732 (a) having overall management responsibility including responsibility for
733 the security and maintenance of the source, apparatus, or facility;
- 734 (b) having overall control over who may use the source of apparatus, or
735 facility; and
- 736 (c) in whose name the source, apparatus, or facility would be registered if
737 this is required.

738 **Risk constraint**

739 a restriction applied to potential exposure (see dose constraint).

740 **Stochastic effect**

741 an effect known to occur sometimes as a consequence of exposure to
742 radiation, but which may or may not be expressed in a particular exposed
743 person, the likelihood of the effect occurring being a function of the dose
744 received.

745 **System of radiation protection**

746 a generic process of radiation risk management designed to limit the health
747 risks arising from exposure to radiation to acceptable levels in a manner
748 which takes economic and social considerations into account.

749 **X-ray**

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

753

754
755
756
757
758
759
760
761
762
763
764
765
766
767
768
769
770
771
772
773
774
775
776
777
778

References

- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) 2002^a, *Recommendations for limiting exposure to ionizing radiation (1995), and National Occupational Health and Safety Commission (NOHSC) 2002, National standard for limiting occupational exposure to ionizing radiation, Radiation Protection Series No. 1*, republished 2002, ARPANSA, Yallambie.
- European Commission, *Radiation Protection 99 – Guidance on Medical Exposures in Medical and Biomedical Research*, 1999.
<http://europa.eu.int/comm/environment/radprot/99/99.htm>
<http://europa.eu.int/comm/environment/radprot/99/rp-99-en.pdf>
- International Commission for Radiological Protection (ICRP), 1993 – ICRP Publication 62. *Radiological Protection in Biomedical Research*. Annals of the ICRP Vol.22 No.3. Pergamon Press, Oxford.
- International Commission for Radiological Protection (ICRP), 2000 – ICRP Publication 85. *Avoidance of Radiation Injuries from Medical Interventional Procedures*. Annals of the ICRP Vol. 30 No. 2 Pergamon Press, Oxford.
- National Health and Medical Research Council (NHMRC), 1999 – *National Statement on Ethical Conduct in Research Involving Humans* (Issued by the National Health and Medical Research Council (NHMRC) in accordance with the *NHMRC Act 1992* (Cth).
- World Health Organisation (WHO), 1977 – *Use of Ionising Radiation and Radionuclides on Human Beings for Medical Research, Training and Non-Medical Purposes*. Technical Report Series 611. WHO, Geneva.

779 **Contributors to Drafting and Review**

780 **WORKING GROUP**

781	Dr Nicholas Daunt	Royal College of Australian and New Zealand
782		Radiologists (RANZCR), Radiation Health
783		Committee (Working Group Convenor)
784	Dr Richard Smart	Australasian College of Physical Scientists and
785		Engineers in Medicine (ACPSEM), Radiation Health
786		and Safety Advisory Council
787	Ms Sarah Wong	Radiation Protection Division, Environment
788		Protection Authority, South Australia
789	Ms Rosemary Marcon	Environmental and Radiation Health Branch,
790		ARPANSA

**Radiation
Protection
Series
No. ##**

Code of Practice
Exposure of Human Subjects to Ionizing Radiation for Medical Research Purposes

**Radiation
Protection
Series
No. ##**

791
792
793
794

Code of Practice
Exposure of Human Subjects to Ionizing Radiation for Medical Research Purposes

Index