



Australian Government

Australian Radiation Protection and Nuclear Safety Agency

Regulatory Impact Statement

Code of Practice

**Exposure of Humans to Ionizing Radiation for Research
Purposes**

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This Regulatory Impact Statement (RIS) has been prepared in line with COAG's *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies* (COAG 2004). COAG requires the preparation of a RIS at two stages in the development of a regulatory proposal. The first stage RIS is used as part of community consultation on the proposal and the second or final RIS, reflecting feedback from the community, assists the decision-making body. The Office of Regulation Review (ORR) assesses the adequacy of the RIS at each stage, and advises the decision-making body of its assessment. The ORR assesses this RIS as adequate for consultation.

Background

Ionizing radiation and medical research

1. Researchers typically use ionizing radiation with humans to investigate medical conditions such as osteoporosis, cancer, Alzheimer's disease, deep vein thrombosis, coronary disease, diabetes, arthritis and chronic pulmonary disease. Although research usually involves volunteers with pre-existing conditions, such as those listed, there is often no known direct benefit to the research participant from the research and it is not part of the medical management for the condition. In some instances the research may also involve the administration of ionizing radiation to healthy participants.
2. Most medical research is carried out in teaching hospitals and universities in capital cities. The majority of studies involve bone density studies, extremity radiographs, the use of radiopharmaceuticals and Computed Tomography (CT) scans for screening and monitoring aspects of the research. Many research projects involve drug trials where the effects are monitored using ionizing radiation. Drug trials are often carried out on a multi-centre, worldwide basis.
3. Almost all x-rays, sealed and unsealed sources of ionizing radiation used in research are also used in medical management of patients and are therefore regulated through licensing systems directed at the control of sources of radiation.
4. Although no published data is available on the number of research projects using ionizing radiation and research participants, an estimate based on available Victorian data has been calculated by consulting the four main licensees¹ in Victoria. It was found that between three and seven per cent of total projects initiated in 2002 involved the exposure of research participants to ionizing radiation and were referred to the Victorian regulator.
5. Limited data is available to quantify the economic impact of research projects specifically using ionizing radiation with human participants. Estimates based on ethics committee or regulatory authority approval of the relevant projects is complicated due to simultaneous but mostly separate processes to access funding. For instance, some projects may obtain all the necessary regulatory approvals but do not proceed due to inadequate funding. In accordance with this finding, the Industry Commission acknowledged in 1995² that '*attempts to quantify economic impacts of R&D have been plagued by data problems, which are compounded by the complexity of the task.*' However, general figures for funding of medical research and Commonwealth funding of all types of research are available.
6. The Australian Bureau of Statistics (ABS) reports³ that the Commonwealth was the source of 38.3% (\$3,923 million) of the total research and development (R&D) expenditure of \$10,251 million across sectors⁴. In 2000-01, \$1,490 million was spent in Australia on R&D for the

¹ Royal Melbourne Hospital, Austin & Repatriation Medical Centre, St Vincent's Hospital and Barwon Health

² Industry Commission Report 44, Research and Development, 1995

³ ABS Report 8112.0 for 2000-01

⁴ Business, Commonwealth and State/Territory Government, Higher Education, Private non-profit

socio-economic objective of health⁵. Using the Victorian estimate that between 4 and 7 per cent of research projects involve the exposure of research participants to ionizing radiation, it is estimated that the relevant research projects in Australia were associated with R&D funding of between \$59 million and \$104 million for 2000-01.

7. Human resources devoted to R&D are also available from ABS. In 2000-01, a total of 91,784 person years contributed to R&D in Australia. Researchers contributed 69% of this total, followed by 16% by technicians and 15% by other support staff. A total of 16,706 person years were used in research directed at the socio-economic objective of health. Using the Victorian estimate of the proportion of relevant research projects, between 669 and 1,170 person years were directed towards projects relevant to this analysis.
8. Although the proportion of Commonwealth funding directed towards the socio-economic objective of health is not available, grants from the National Health and Medical Research Council (NHMRC) for health and medical research⁶ in 2001 totalled \$216 million. This represents 5.5% of total Commonwealth funding for R&D. The distribution of NHMRC funding approximately reflects the amount of medical research being carried out in Australian jurisdictions. In 2001, forty percent (\$87.2 million) of NHMRC funding went to Victorian researchers, twenty-four percent (\$51 million) went to NSW researchers and thirteen percent (\$28 million) went to QLD researchers, followed by 10.2% (\$22 million) to SA researchers, 8.7% (\$18.9 million) to WA researchers, 2.2% (\$4.8 million) to ACT researchers and just over \$2 million to researchers in NT and Tasmania combined.
9. The NHMRC reports⁷ that '*Victoria receives more than 40% of NHMRC funding because it is home to four of the major medical research institutes and two of the largest and most active health research universities, each with a large number of active and high quality researchers*'. This pattern is reflected in the following description of research projects reported to regulatory authorities and using ionizing radiation on research participants.
10. During 2002⁸, the Victorian regulator approved 36 projects involving 20,543 research participants (Attachment A). These research participants were given effective doses between 0.002 and 13 millisievert (mSv) with 44% of research participants from 14 projects receiving an effective dose of less than or equal to 0.1 mSv, and 52% of research participants from 13 projects receiving between 1.0 to 4.9 mSv. In addition, an average of thirty projects a year using Dual Energy X-ray Absorptiometry (DEXA) scans are conducted in Victoria. These projects are approved directly by the regulator without being reviewed by the Victorian Radiation Advisory Committee and involve the exposure of approximately 50 research participants to between 0.002 to 0.15 mSv.

⁵ The area of expected national benefit rather than the immediate objectives of the researcher. The SEO classification defines the main areas of Australian economic and social activity to which the results of research programs are applied. it describes the purpose of the research, ie why the research is being performed

⁶ NHMRC Grants Book 2001

⁷ NHMRC 'A Report on the Performance of the National Health and Medical Research Council 2000-2003

⁸ In 2003, 31 projects were approved and nine projects were referred to the regulator that did not require approval. In 2004, 48 projects were approved and nine projects were referred to the regulator that did not require approval.

11. Only two of the Victorian research projects approved in 2002 used effective doses above 5 mSv. In other jurisdictions, 5mSv is the current NHMRC effective dose level before approval of the regulator is required. Most research exceeding 5 mSv involves the use of CT scans and radiotherapy techniques often with volunteers with cancer, where the research is being undertaken in addition to treatment for the disease. In Victoria, 140 research participants received an effective dose of greater than or equal to 10 mSv.
12. In NSW, regulatory approval is only required where the effective dose exceeds 5 mSv. As a result of this approach, the regulator approved five research projects that used ionizing radiation on research participants in 2002. In addition, data from a Sydney teaching hospital (Attachment B) over a 3-year period demonstrates a similar pattern to the data obtained for research in Victoria; most research involved research participants receiving doses either less than 0.1 mSv or doses between 1.0 and 4.9 mSv. Research projects where 10 or more millisievert was used mostly involved CT scans to monitor cancer trials.
13. In 2002, 337 South Australian research participants were exposed to ionizing radiation in 13 projects. About half of SA research participants (174) were exposed to less than 5 mSv through their involvement in 6 projects. As elsewhere, higher exposures (> 10.9 mSv) involved research participants with cancer. More than half the projects were drug trials involving diagnostic X-rays, Computed Tomography (CT) scans, Multiple Gated Acquisition (MUGA) scans and Dual Energy X-ray Absorptiometry (DEXA) scans to monitor the effects of the drugs being trialed. Projects included research with thrombosis, post-traumatic stress, gene therapy, Hunter syndrome, osteoporosis, diabetes and various types of cancer.
14. During 2001-2003, the West Australian regulator approved 6 projects with 101 research participants where doses were in excess of WA regulations. All of the projects used radiation for diagnostic purposes with effective doses between 1.7 and 72 mSv.
15. In Queensland, due to the absence of any project specific approval process, details regarding the number of research participants and projects are not available. However, only a few institutions within the State are involved in research with research participants.
16. Very few research projects involving research participants have been carried out in Tasmania. No research using ionizing radiation on research participants has been undertaken in the Northern Territory over the past two years. The Australian Capital Territory has had 3 clinical trials involving diagnostic radiation during 2002 and 2003 (further details were lost during Canberra bushfires of 2003).
17. In Victoria, the regulator approved two projects using volunteers under 18 years of age in 2002. In total, these projects involved about 400 research participants with each participant receiving an effective dose of up to 0.1 mSv. In 2001, six research projects were reviewed involving the exposure of 2893 research participants under the age of 18 to between 0.01 to 0.4 mSv. Most of these projects involved bone density assessments.
18. A graph of the number of projects across jurisdictions above and below the regulatory limit of 5 mSv is at Attachment C. It should be noted that the graph is not entirely representative of research activity relevant to the subject of this analysis, due to the differences in regulatory requirements across jurisdictions. These differences are discussed below.

Current regulatory processes

19. In 1977, the World Health Organisation published Technical Report Series 611 *Use of Ionising Radiation and radionuclides on Human Beings for Medical Research, Training and Non-Medical Purposes* which divided research projects into categories depending on the radiation doses received by research participants. This formed the basis for the 1984 NHMRC publication RHS 12.
20. In 1993, the International Commission for Radiological Protection (ICRP) modified the classification taking into account changes in the assessment of radiation risk and introduced a corresponding categorisation of the ‘level of societal benefit’ which can be considered as a basis for approval of the level of dose. The type or level of benefit that will result from the research, to participants or society at large, is evaluated to justify the need to expose research participants to ionizing radiation. The likely risk of harm to the research participants is assessed based on the best quantification of doses available and also taking account of the characteristics (age, gender, health) of the participants that may affect the risk from the proposed exposure. It should be noted that in the case of terminally ill patients, long-term risks of radiation are not relevant. The categories of risk and corresponding levels of benefit to society from radiation exposure produced by the ICRP was modified for inclusion in the annexes of the Code of Practice following consideration of public comments regarding the alignment of risk categories and the corresponding risk statements. The modified table is reproduced below:

Table 1: Table 3 in Annex 1 of the proposed Code

Level of Risk	Risk Category	Effective Dose Range (adults) (mSv)	Level of Societal Benefit Expected
Minimal	Category I (10^{-5} or less)	< 0.2	Minor
Very low	Category IIa ($\sim 10^{-5}$ to 10^{-4})	0.2 to 2	Intermediate
Minor to intermediate	Category IIb ($\sim 10^{-4}$ to 10^{-3})	2 to 20	Moderate
Moderate	Category III (10^{-3} or more)	> 20 ^a	Substantial

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

21. With Category I, where risks of total detriment⁹ are of the order of 1 in 100,000, the level of benefit needed as the basis for approval of research with doses less than 0.2mSv will be minor and will include investigations expected to only increase knowledge. With Category IIa,

⁹ 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.

where the risks of total detriment are between 1 in 100,000 and 1 in 10,000, the benefit is related to increases in knowledge leading to health benefit. With Category IIb, the risks of total detriment are between 1 in 10,000 and 1 in 1,000, the benefit will be directly aimed at the diagnosis, cure or prevention of disease. With Category III, where risk of total detriment is 1 in 1,000 or greater, the benefit has to be substantial and usually directly related to the saving of life or the prevention or mitigation of serious disease.

22. Underlying the above assessment is the fundamental regulatory philosophy of regulators expressed in three principles based on the recommendations of the ICRP¹⁰ which are 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.
23. In order to remain in step with developments, additional guidance for researchers and regulators was included in the NHMRC 1995 *Recommendations for limiting exposure to ionizing radiation* (republished as ARPANSA's RPS1).
24. In most jurisdictions, researchers are required to obtain advice and approval from internal and external authorities for the use of ionizing radiation on research participants. These authorities include the institution's radiation safety committee, the institutional human research ethics committee, and, in some cases, the State/Territory regulator.
25. Some institutions have a radiation safety committee consisting of representatives from areas of the institution involved in the use of radiation, external radiation experts and the institution's radiation safety officer. These committees consider all radiation safety related issues including research projects that use ionizing radiation on research participants. The committee's approval of the researcher's use of ionizing radiation may be required by the institution. In other institutions, the researcher is required to consult the radiation safety officer to verify the radiation dose described in documentation submitted to the human research ethics committee and the regulatory authority.
26. Each institution engaged in research with research participants has a Human Research Ethics Committee (HREC). Researchers are required to seek approval for projects from the HREC within the institution. In almost all jurisdictions, the HRECs approval includes the consideration of the existing regulatory requirements of the jurisdiction.
27. Radiation protection regulators do not license HRECs. HRECs are required to operate in accordance with the NHMRC 1999 *National Statement on Ethical Conduct in Research Involving Humans* and must report to the NHMRC Australian Health Ethics Committee

¹⁰ Adopted by Australia in ARPANSA's Recommendations for limiting exposure to ionizing radiation (1995), and National Occupational Health and Safety Commission (NOHSC) National standard for limiting occupational exposure to ionizing radiation (1995) (Radiation Protection Series 1, (RPS 1))

(AHEC) to ensure compliance with the *National Statement*. This compliance reporting is focussed on overall operation of the HRECs. The NHMRC AHEC also provides advice, guidance and support to HRECs through handbooks, bulletins, workshops and an ad hoc advisory service.

28. The NHMRC 1999 *National Statement on Ethical Conduct in Research Involving Humans* requires researchers and Human Research Ethics Committees to follow relevant State and Territory legislation, consult the ARPANSA *Recommendations for Limiting Exposure to Ionising Radiation (1995)* (RPS1) and seek additional advice from ARPANSA.
29. In 1984, the NHMRC published, as part of its Radiation Health Series, an '*Administration of Ionizing Radiation to Human Subjects in Medical Research (1984)*' (RHS 12). The statement is widely used by regulators. NHMRC handed responsibility for the Series to ARPANSA. RHS 12 was rescinded by NHMRC at their 141st session in March 2002.
30. The ICRP system of radiological protection was adopted by Australia for ARPANSA's *Recommendations for limiting exposure to ionizing radiation (1995)*, and *National Occupational Health and Safety Commission (NOHSC) National standard for limiting occupational exposure to ionizing radiation (1995)* (Radiation Protection Series 1, (RPS 1)). This publication is used by State, Territory and Commonwealth governments to form the basis of the radiation protection requirements adopted in legislation, regulations and/or conditions of licence.
31. In 1995, the NHMRC *Recommendations for limiting exposure to ionizing radiation* (now re-published as ARPANSA RPS 1) supplemented RHS 12 through:
 - the description of doses as constraints;
 - the addition of a 5 year averaging period constraint consistent with RPS 1; and
 - a cumulative effective dose constraint of 5 mSv for children to 18 years.
32. Regulators have different approaches to applying the guidance and constraints documented in the NHMRC RHS 12 and the ARPANSA RPS 1:
 - a) In Victoria, due to incidents arising from a lack of sufficient regulatory control over individual researchers in the 1959 regulations, licences at both the researcher and institutional level were introduced in 1984. As a result, all medical research projects involving exposure of research participants to ionizing radiation must be submitted to the Victorian Radiation Advisory Committee (RAC) before an approval is given by the regulator. In order for the RAC to consider approval, researchers must provide:
 - copies of the research protocol,
 - the participant information sheet, that includes an explanation of the risks
 - estimates of radiation doses to participants,
 - evidence of approval by the institution's ethics committee,
 - evidence of the approval of their institution's Human Research Ethics Committee.

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- b) In NSW, only those projects exceeding the constraints in the ARPANSA RPS 1 (greater than 5mSv) require the approval of the NSW Radiation Advisory Council. The institutional HRECs oversee adherence to the dose constraints for projects where the effective dose does not exceed 5 mSv.
- c) Regulatory approval in South Australia is required for any research involving the exposure of research participants to ionizing radiation which would not have been received but for the purpose of research. An exemption under s. 44 of the *Radiation Protection and Control Act 1982* (SA) can be granted that provides approval on an institutional basis, so that the regulator does not review individual research projects. However, all research projects involving the exposure of research participants to ionizing radiation must be reported to the regulator. Exemption from regulator approval includes all research except:
- where the effective dose to the research participant in any one year exceeds 5 mSv;
 - where the research participant is less than 2 years of age and the effective dose in any year is more than 0.1 mSv; and
 - where the research participant is between 2 and 18 years of age and the effective dose in any year is greater than 0.5 mSv.
- d) In Queensland, there is no specific approval for the conduct of research on humans; rather any person who intentionally irradiates a person is required to hold a licence permitting such a practice. The licence permits use of the radiation source for a specific purpose and in accordance with an approved radiation safety and protection plan. Section 9 (1) (c) of the *Radiation Safety Regulation 1999 (QLD)* makes it a condition that a person using an ionizing radiation source for conducting health-related research on persons must comply with the NHMRC RHS 12. Institutions are also licensed and any additional regulatory guidance, such as what information should be presented to ethics committees and who should prepare the information, is exerted through this avenue.
- e) In Western Australia, in addition to the NHMRC RHS 12, regulation 1 (3)(a) of Schedule 1 of the Regulations under the *Radiation Safety Act (1975) (WA)* also applies so that regulator approval for projects in Western Australia involving the exposure of research participants to ionizing radiation is required where:
- the effective dose to an adult exceeds 5 mSv;
 - the effective dose to children or other persons incapable of giving informed consent exceeds 0.5 mSv;
 - the effective dose to infants, babies or foetuses exceeds 0.1 mSv; and
 - the radiation dose to any individual in any 5 year period exceeds an average effective dose of 1 mSv per year.
- f) In Tasmania, there is no formal process for assessment of research projects involving the use of ionizing radiation on research participants. However, licence conditions require compliance with RPS 1 *Recommendations for limiting exposure to ionizing radiation (1995)*, and *National standard for limiting occupational exposure to ionizing radiation*.

- g) In the ACT, where exposure is not part of ‘the normal clinical practice’ of a licence holder, approval to vary the licence and conditions related to the research may be required by the ACT Radiation Council.
- h) In the Northern Territory, research of this nature requires a licence from the Chief Health Officer.

Problem

Outdated information

- 33. The NHMRC RHS 12 draws on the 1977 Technical Report Series 611 by the World Health Organisation (WHO) *Use of Ionising Radiation and radionuclides on Human Beings for Medical Research, Training and Non-Medical Purposes*. Since the WHO report, the International Commission for Radiological Protection (ICRP) produced Publication 62 *Radiological Protection in Biomedical Research* in 1993 which categorised risk and corresponding levels of societal benefit from the exposure of research participants to radiation in the course of research. Additional guidance for researchers was also included in the NHMRC 1995 *Recommendations for limiting exposure to ionizing radiation* (republished as ARPANSA RPS1).
- 34. Understanding of the effects of ionizing radiation on specific organs and tissues has also increased since 1984, with the ICRP producing a much more extensive list of tissue weighting factors for the evaluation of the risks from exposure to radiation in Publication 60, *1990 Recommendations of the International Commission on Radiological Protection*.
- 35. The NHMRC RHS 12 was rescinded by the NHMRC in March 2002 and, as it is more than 10 years since it was published, it is due for a review. However, the NHMRC does not wish to continue publishing the Radiation Health Series (RHS) publications and has handed responsibility for the RHS publications to ARPANSA.
- 36. Members of the working group advise that there is confusion amongst researchers in some jurisdictions as to whether NHMRC RHS 12 applies to their research due to its age and brief nature.
- 37. In Victoria, the common application form used by researchers to make submissions to ethics committees does not include reference to NHMRC RHS 12 because it does not contain the most up to date guidance. Instead, researchers are directed to follow the recommendations of ICRP Publication 62 and ARPANSA RPS 1 in filling out the ionizing radiation form for module five of the application.
- 38. The NHMRC’s 1999 *National Statement on Ethical Conduct in Research Involving Humans* refers to RPS1 and the radiation dose constraints in the NHMRC RHS 12 are not consistent with those in Part 2 of ARPANSA RPS1. See paragraph 40 for radiation protection impact of this disparity.

Radiation Protection Issues

39. The NHMRC RHS 12 does not take account of the possible participation by research participants in multiple projects. Although ARPANSA RPS1 included an additional constraint of 10mSv over 5 years to address this potential exposure, there have been other research applications that the existing guidance does not address. For example, equivalent dose to individual organs of adults and persons under 18 years.
40. The NHMRC RHS 12 has a dose constraint of 0.5 mSv in any year for children and 0.1 mSv in any year for babies, infants and foetuses, whereas ARPANSA RPS1 has a cumulative effective dose constraint of 5 mSv to age 18 years. If the baby and infant stage is taken from birth to 2 years of age, then the ‘baby-infant-foetus’ period covers approximately 3 years and the remaining ‘child’ period covers 16 years. This means that the constraint in the NHMRC RHS 12 allows a maximum cumulative dose of 8.3 mSv to 18 years compared to the 5 mSv allowed in ARPANSA RPS1.
41. The application of the existing guidance for the use of ionizing radiation in research with research participants has been inconsistent across jurisdictions. Variations appear to mostly arise due to uncertainty of the scope of the NHMRC RHS12. The Victorian regulator relies on an advisory committee to decide what projects utilise ionizing radiation for research purposes rather than medical management. The NSW regulator also uses an advisory committee, however research projects are only considered if the 5 mSv constraint is to be exceeded. Further variations in the application of existing guidance are detailed in paragraph 32.
42. The NHMRC 1984 statement applies to ‘any administration of ionizing radiation to human subjects for the purposes of diagnostic or therapeutic research involving either external irradiation of the administration of radionuclides...’. There is some distinction made between the use of radiation to persons expected to benefit from the procedure and their management as patients, and use of radiation of persons not expected to benefit from the procedure and their selection as research participants. However, the NHMRC RHS 12 does not provide clear guidance on how to define whether the administration of ionizing radiation to research participants is only for the purposes of research and hence whether the constraints within the Statement are applicable. Consequently, as outlined in paragraph 32, regulators have developed different definitions to decide whether the use of radiation in research projects falls within the scope of the NHMRC RHS 12.
43. The NHRMC 1984 Statement does not specify whether its scope includes clinical trials. As a result, there has been inconsistent application of the existing dose constraints where ionizing radiation is used to monitor the effectiveness of such trials. Although these trials are subject to ethics committee approval, they are not subject to the requirements of RHS 12 as they can be considered to offer direct benefit to the participant as a patient. However, this benefit is not certain and the participant should be afforded the same level of information for informed consent as participants in projects with less certain outcomes. There are no reliable estimates of the number of these trials as they are not required to be reported to regulators.
44. The NHMRC RHS 12 does not contain specific guidance on how to assess the risks of the radiation used against the societal benefits which is needed by researchers to seek the approval of ethics committees and to explain the risk to research participants.

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45. The NHMRC RHS 12 is ambiguous in terms of the role of research participants, researchers, institutions, regulatory authorities and ethics committees.
46. Since 1984, developments in research techniques have resulted in the following impacts:
- a) Use of nuclear medicine by researchers has significantly increased and will continue to do so with studies comparing nuclear medicine with other diagnostic techniques. For example, when the Victorian regulator commenced reporting on the use of radiation in research with humans, a total of 7 operator licences and 6 management licences were approved. This is in comparison to 47 operator and 15 management licences being approved in 2002.
 - b) The potential for higher skin doses than envisaged in 1984 has increased due to current techniques such as multiple CT scans and prolonged fluoroscopic screening.

Uniformity

47. Uniformity of radiation controls has been identified as an issue requiring attention. In July 1998, Health Ministers asked that an uniformity panel, comprising representatives from the States, Territories and Commonwealth, be formed to progress national uniformity. The Australian Health Ministers Council agreed in August 1999 to a proposal arising from discussions of the National Uniformity Implementation Panel (Radiation Control) (NUIP(RC)) that all jurisdictions should jointly develop a National Directory for Radiation Protection, through the endorsement of the Radiation Health Committee. The Directory would take a 'dynamic' form, changing over time as new agreements were reached by jurisdictions, and would be used by all jurisdictions in making changes to existing legislation frameworks. Edition 1 of the National Directory was published in August 2004 and will facilitate the national adoption of codes and standards developed jointly by States, Territories and Commonwealth.
48. The application of the present guidance does not permit this goal of uniformity to be achieved. Variations in requirements across borders create impediments to professionals that move across borders or operate in more than one jurisdiction. Cross-jurisdictional projects such as multi-centre trials, are examples of where the different requirements of jurisdictions would impact on the conduct of trials.

Information Asymmetry

49. Currently most research participants are provided with explanations of risk developed by researchers. In some jurisdictions, these risk statements have been developed in conjunction with regulators. However, many statements do not appropriately categorise risk for fear of deterring research participants from participating. This is due to a lack of understanding by most research participants of the levels of risk from exposure and the corresponding benefit to society. The Victorian regulator has advised that many projects forwarded to the advisory committee for approval are required to make changes to the risk statements for research participants before they are approved.

Objectives

50. To cost-effectively ensure that research participants and ethics committees are accurately informed of the radiation dose and associated risks.
51. To indicate boundaries above which radiation doses from medical research are unlikely to be acceptable
52. To promote uniformity across Australia of radiation protection practices in the exposure of research participants to ionizing radiation for medical research.

Statement of possible options

53. Three options to address the identified problems have been considered:
 - *Option 1: Status quo* — this involves making no regulatory change and hence relying on the current system which involves jurisdiction-based regulation using the guidance and constraints supplied by the *1984 National Health and Medical Research Council (NHMRC) Recommendations* (referred to as RHS 12) and the *ARPANSA Radiation Protection Series 1* (referred to as RPS 1);
 - *Option 2: Self-regulation* — this involves allowing researchers and research institutions to set and enforce their own safety requirements regarding the exposure of research participants to ionizing radiation; and
 - *Option 3: New Code of Practice* — this involves replacing the existing guidelines with a national code of practice which can be adopted into the National Directory as mandatory requirements.

Impact Analysis

Affected Parties

54. The main stakeholder groups affected by the proposed Code are
 - a) Hospitals and universities that conduct medical research and as the responsible person will need to monitor application of the Code.
 - b) Ethics committees that approve research projects
 - c) Researchers using ionizing radiation in their research
 - d) Research participants exposed to ionizing radiation in research
 - e) Regulators in Commonwealth, State and Territory governments that approve and licence the use of ionizing radiation in research.
 - f) Medical physicists that calculate or verify the radiation doses used in research projects

Option 1 – Do nothing - continue with the NHMRC RHS 12

Benefits

Health and safety

55. Radiation protection regulations are often assessed in terms of their impact on average or collective annual effective dose.¹¹ Based on the latest available information — material published by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)¹² — the average annual effective dose for the population from exposure from diagnostic and medical x-ray examinations was 1.2 mSv per year.¹³
56. While there are no legislated exposure limits for medical treatment, it is noted that the average annual effective dose is around 16 times lower than the occupational exposure limits specified in RPS1.
57. One contributing factor in ensuring that medical exposure is kept to the minimum necessary is the promotion by the regulatory regimes of the ALARA principle.¹⁴ Overall, it is generally accepted that the standards in RHS 12 and RPS 1 provide health benefits by offering protection against the over-exposure of research participants of medical research programs.

Costs

58. There are ongoing costs associated with complying with the current regulations. These costs vary in each jurisdiction depending on how regulators apply the guidance and constraints documented in RHS 12 and RPS 1.
59. Differing regulations across jurisdictions create uncertainties and inefficiencies for researchers, particularly those undertaking multi-jurisdictional projects, thus using more resources to be devoted to meeting compliance requirements. While difficult to quantify, these costs have been identified by the Productivity Commission when analysing regulations in various industries, for example, in an assessment of regulations in the mining industry, the Chairman of the Productivity Commission noted:

Interaction between mining and other relevant State/Territory (an even Commonwealth) legislation was characterised by a duplication and lack of co-ordination....The resulting regulatory regime imposed substantial costs, uncertainty and delays while rarely achieving apparent objectives (or doing so only at significant cost).¹⁵

¹¹ N. Morris 1996, *Personal Radiation Monitoring and Assessment of Doses Received by Radiation Workers (1996)*, report prepared for Australian Radiation Laboratory, Department of Health and Family Services, Commonwealth of Australia, Yallambie.

¹² This figure is based on a weighted average of average annual effective annual dose for worker's monitored. The data was taken from United Nations Scientific Committee on the Effects of Atomic Radiation 2000, *Sources and Effects of Ionising Radiation: UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes*, United Nations, New York.

¹³ This is based on a weighted average of the average effective dose and the number of workers monitored over the period 1975 to 1994.

¹⁴ The ALARA principle encourages users of radiation to ensure that radiation exposure is kept as low as reasonably achievable (ALARA) after taking into account economic and social factors.

¹⁵ G Banks 2003, 'Minimum effective regulation and the mining industry', *Address to the Minerals Council of Australia*, Old Parliament House, Canberra, June.

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60. Anecdotal evidence suggests that there is often confusion by the sponsors of multi-jurisdictional projects as to whether project approval needs to be obtained from State and Territory regulators (and if so, how to go about getting approval) due to the varying requirements in each jurisdiction. For example, researchers involved in a multi-jurisdictional project operating in NSW, Victoria and Queensland were surprised to learn that the project only required approval to be sought from the Victorian regulator. Project approval was not needed in NSW and Queensland due to those States having different regulatory requirements. Also each year, the Victorian regulator regularly identifies that a number of projects are submitted that do not require their approval¹⁶.
61. In recent years, researchers have also expressed concern over the unnecessary difficulties associated with having to submit statements to regulators that differ in design across jurisdictions.
62. Differing regulations across jurisdictions influence the type of research participants that ‘select’ themselves to participate in research projects. The community reacts differently to the regulations that are stipulated in each jurisdiction and as such different types of people have been found to participate in research across jurisdictions. This has implications for research in that findings may be biased due to the type of research participants used. At the very least, it has implications for the comparison of results from research undertaken in different jurisdictions as the participant base from which results are drawn may be quite different across jurisdictions as a result of the regulatory approach adopted. This represents a form of resource misallocation and is identified as a compliance cost of the status quo.
63. Disparities between RHS 12 and RPS 1 (described in Paragraphs 39 and 40) are noted as a potential cause for confusion among researchers.
64. Ambiguities in RHS 12 itself also create additional compliance costs, for example, RHS 12 is unclear on:
- Defining whether the use of ionizing radiation is for medical research (research participants are not expected to benefit) or medical treatment (research participants are expected to benefit);
 - Defining whether the scope of the RHS 12 is for therapeutic trials; and
 - Outlining the role of research participants, researchers, institutions and ethics committees.
65. Under the status quo, there is no avenue for researchers involved in multi-centre projects within one jurisdiction to only make a single submission to the regulator. As a result, regulators often receive multiple submissions at different times for what is effectively the same project being undertaken at different locations. This situation creates additional and unnecessary costs for researchers and regulators. This in turn may decrease the amount of research undertaken and hence reduce the benefits associated with medical research in this field.
66. Quantifying the compliance costs associated with the status quo is difficult, especially as costs are likely to vary across jurisdictions depending on the regulations adopted. However,

¹⁶ Refer footnote 8.

estimations of these costs can be made. Information supplied by state regulators and the Radiation Health Committee Working Group indicates that researchers generally spend between one and five hours per project in complying with regulations. This time encapsulates tasks such as preparing documentation, preparing patient consent forms and information sheets, and calculating dose estimates. In 2002, approximately 60 projects involving the use of ionizing radiation on humans were approved by regulators around Australia.¹⁷ As such, it is estimated that researchers spent between 60 and 300 hours complying with regulations in 2002.¹⁸ Using average weekly earnings data, the value of this time is estimated to equate to between \$1 480 and \$7 390.¹⁹

67. Costs associated with the development of RHS 12 and RPS 1 are sunk, and therefore are not an ongoing cost associated with the status quo. That is, jurisdictions, researchers, and institutions don't have to create new systems to manage radiation protection.
68. There are administration costs associated with monitoring and enforcing compliance with RHS 12 or RPS 1, but these administrative costs tend to be bundled/subsumed within each regulatory agency's general budgets. That is, it is difficult to disaggregate administrative costs associated specifically with the RHS 12 or RPS 1 in comparison to other radiation-related enforcement costs. However, rough estimations of the costs involved can be made.
69. Information supplied by the Victorian regulator suggests that around 10 to 15 hours per week of one employee's time is devoted to reviewing and approving projects. The regulator also estimates that the average salary of employees responsible for the review and approval of projects is \$60 000. On this basis, the annual cost borne by the Victorian regulator in administering the current regulations is estimated to be between \$15 790 and \$23 680.²⁰
70. In addition to these costs, the Victorian regulator bears the costs associated with meetings held by the Radiation Advisory Committee to review and approve projects. The 10-member Committee meets 11 times a year and is estimated to dedicate around 44 to 53 hours per year in assessing projects involving the exposure of humans to radiation; as such total person hours per year dedicated to reviewing projects are estimated to be around 440 to 530 hours. Based on average weekly earnings data, the cost of this time is approximated to be between \$10 850 and \$13 060.
71. Combining both forms of regulatory costs borne by the Victorian regulator (the one employee and the Radiation Advisory Committee) results in total costs of between \$26 640 and \$36 740 per year.

¹⁷ Note, this is a conservative estimate based on available data.

¹⁸ This approach does not consider time taken by researchers in complying with regulations in cases where projects are not approved.

¹⁹ Assuming a 38 hour week, 60 to 300 hours is estimated to represent 0.03 to 0.15 per cent of working hours in a year. As a percentage of annual average earnings (estimated by the ABS to be \$49,296), this equates to an approximate range of \$1 480 and \$7 390.

²⁰ These figures are calculated using the assumption of a 38 hour working week. According to the Victorian regulator, this is a valid assumption.

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72. Available data indicate that Victoria accounts for approximately 60 per cent of the Australia-wide total for the number of medical research projects undertaken.²¹ Therefore a rough estimation of the costs for regulators on a national basis, assuming each jurisdiction has similar regulatory costs to that of Victoria, is around \$44 400 to \$61 230 per year.
73. The status quo also places administrative costs on ethics committees as researchers are required to seek approval for projects from the ethics committee within the institution with which the researcher operates.²² The costs borne by ethics committees in undertaking this role are also difficult to pin point but estimates can be made.
74. In South Australia, it is common practice for ethics committees, generally containing between 16 and 18 people, to meet twice for each project reviewed. According to the South Australian regulator, there are approximately 20 projects reviewed per year. This equates to 40 meetings per year for 16 to 18 people. Assuming each meeting lasts one hour, this equates to around 640 to 720 person hours per year dedicated by South Australian ethics committees to reviewing projects. Based on the number of projects approved in 2002, South Australia is estimated to account for around 22 per cent of national research involving ionizing radiation.²³ Grossing the South Australian time data up to calculate a national estimate results in an estimation of between 2 910 and 3 270 person hours being dedicated by ethics committees to reviewing research proposals per year. In monetary terms, it is estimated that this time is roughly equal to between \$71 730 and \$80 600 per year.²⁴
75. The total costs of administration under the status quo (combining the costs borne by regulators and ethics committees) are estimated as being within the range of \$116 130 and \$141 830 per year.
76. On assessment, the administrative costs under the status quo are likely to be higher than they need be. Because each jurisdiction has taken their own approach to RHS 12 or RPS 1 and radiation protection in the area of medical research, it is likely that there are ongoing administrative costs associated with dealing with research institutions operating in more than one jurisdiction and in addressing any issues that arise as a result of a lack of a nationally consistent approach.²⁵
77. These costs may be somewhat analogous to the costs associated with occupational and professional licensing before the introduction of mutual recognition legislation. A recent

²¹ This estimate is an approximation based on the proportion of nationally approved projects that were undertaken in Victoria in 2002. It is acknowledged that the true proportion may differ due to different regulatory requirements across jurisdictions and other data limitations.

²² In reviewing applications, ethics committees also pass applications on to internal radiation sub committees (RSCs). RSCs spend relatively little time reviewing applications and as such the costs of these reviews are excluded from this analysis as they are assessed as being of minimal consequence to the overall assessment.

²³ This estimate is an approximation based on the proportion of nationally approved projects that were undertaken in South Australia in 2002. It is acknowledged that the true proportion may differ due to different regulatory requirements across jurisdictions and other data limitations.

²⁴ This estimate is based on ABS average weekly earnings data and assumes a 40 hour working week.

²⁵ It is estimated that there have been five multi-jurisdictional projects undertaken in the last two to three years. It is difficult to determine whether unnecessarily high administration costs for multi-jurisdictional projects acts as a deterrent to them being undertaken.

study undertaken by the Productivity Commission found that mutual recognition legislation has been effective in achieving objectives such as decreasing costs to industry and increasing workforce mobility across jurisdictions. ‘By allowing producers and registered occupations to meet only one set of standards, rather than two or more, mutual recognition reduces the barriers and costs to movements across jurisdictions.’²⁶

78. Other aspects of the status quo are also assessed as creating unnecessarily high administration costs, for example, the fact that regulators receive multiple submissions from multi-centre projects operating within one jurisdiction (as mentioned above as a compliance cost) is also noted as an unnecessary administrative cost. Further, general confusions and inconsistencies as also mentioned previously in this document are considered to create unnecessary costs as time and resources are allocated toward clarifying common uncertainties.

Inconsistent regulations

79. Under the status quo there is a risk that compliance with health and safety standards may be compromised (or achieved at greater cost) if inconsistencies associated with implementing the RHS 12 and/or the RPS 1 create confusion as to which standard is relevant in any particular situation. For example, the RHS 12 effectively allows a cumulative exposure to radiation of 8.3 mSv for subjects up to 18 years of age whereas, the RPS 1 only allows a cumulative dose of 5 mSv. This lack of adoption of a single “best practice” set of standards means that the risks of potential over-exposure are not managed as adequately as they could be.
80. Confusion surrounding the interpretation of the current regulations has also resulted in cases where researchers have failed to obtain project approval from the regulator. Anecdotal evidence from Victoria suggests that up to 20 to 30 per cent of projects are not reported due to ambiguities in the current regulations. To date, the radiation exposure doses in these instances have been minimal. However, the failure to obtain project approval is viewed poorly when considering health and safety issues regarding the status quo. This is especially the case since it is common for researchers undertaking these projects to be experts in fields other than radiation — hence the risks of over-exposure are considered significant.
81. Failing to obtain regulatory approval also has implications in that research participants are potentially not informed that their participation in the project will involve them being exposed to radiation. Failure to inform participants of such information potentially exposes researchers to litigation as participants may be exposed to radiation without granting consent. Further, such a failure is viewed as generally not reflecting well on the industry as a whole and community perceptions of the industry may be tarnished as a result.
82. Other health and safety costs associated with the status quo stem from the fact that it is unclear as to whether the RHS 12 and RPS 1 regulations apply to therapeutic trials. Anecdotal evidence indicates that this confusion has created a situation whereby many clinical trials of new drugs do not adequately consider the appropriate levels of radiation that patients are exposed to. Again, this situation creates a risk that patients of trials will be subject to excessive levels of radiation, particularly given the fact that medical trials may often be conducted by experts in fields other than radiation.

²⁶ Productivity Commission 2003, *Evaluation of the mutual recognition schemes*, Research Report, Canberra, p. xv.

Inability to update

83. Regulatory regimes should seek to provide a framework that:

- allows industry to respond in a flexible manner to achieve the regulatory obligations; and yet
- can adjust to best practice developments.

84. The NHMRC has rescinded all of its health based codes that are over 10-years old and has no mechanism for renewing or updating them. As such, the RHS 12 does not provide up to date information for researchers on radiation safety issues. Lack of currency and the absence of enforceable standards suggest that dynamic efficiency is compromised under the status quo.

Option 2 – Self regulation by the industry

85. Industry self-regulation describes a regulatory system whereby it is industry participants who primarily determine the type of actions or procedures that constitute appropriate conduct.

86. To develop some concept as to what are the costs and benefits of a self-regulatory regime it is necessary to make a judgement as to what a self-regulatory arrangement will look like. The most likely self-regulatory regime for medical research is what Priest²⁷ calls ‘firm-defined regulation’. This is largely because there is no single peak industry body that could organise itself to participate in the development of an industry standard. Researchers using ionizing radiation in research with humans belong to various professional bodies, for example, the Royal Australian and New Zealand College of Radiologists, the Australian Institute of Radiography, the Australian and New Zealand Association of Physicians in Nuclear Medicine and the Australian and New Zealand Society of Nuclear Medicine. The professions these bodies represent may have inconsistent priorities with regard to acceptable dose constraints, which could in turn result in non-uniform standards.

Benefits*Flexibility*

87. A self-regulatory approach would allow individual researchers and research organisations to adopt their own approach to safety standards. A key benefit therefore is the flexibility offered to choose the resources dedicated and the manner in which radiation protection is addressed in medical research.

88. Under self-regulation, researchers would be able to adopt procedures that were suitable to their own situation rather than being forced to comply with broad-based regulations. In principle, this promotes the potential for efficient radiation protection procedures more suited to the specific environment in which each medical researcher operates. This could lead to savings in compliance costs and hence allow for resources to be reinvested back into medical research.

²⁷ See M. Priest (1997-98), ‘The privatization of regulation: Five models of self-regulation’, *Ottawa Law Review*, Vol. 29, p. 233.

89. Self-regulation has the potential to not only benefit the industry but also benefit the community as a whole. For every \$1 spent on medical research, the wider community gains \$5 from health and safety improvements²⁸, thus even a small increase in resources going back into research would be beneficial.

Costs

Compliance

90. While in principle self-regulation could result in a more efficient response to radiation protection, it is recognised that self-regulation could also lead to less resources being dedicated to radiation protection. Abrogating wider responsibilities and not spending money on radiation protection measures may well lower costs to medical researchers — and hence would be seen as a direct benefit to researchers — but as was discussed earlier it would result in lower health and safety outcomes for patients, researchers, and the public more generally.

91. Under most self-regulatory regimes compliance costs are reduced compared with having to operate under a specific regulatory regime. This reduction is generally a function of two factors:

- the flexibility associated with a self-regulatory regime means that researchers can develop least-cost compliance approaches; and
- some researchers may reduce their compliance costs by seeking to minimise their self-defined control of the problem (i.e. by lowering the regulatory standard).

92. However, in some cases, a self-regulatory regime in place of the RHS 12 or RPS 1 will not reduce compliance costs significantly (if at all). For example, a self-regulation approach may result in individual researchers determining appropriate exposure levels for research. As such every individual researcher would either have to maintain current standards or have to undergo analysis to satisfy themselves of acceptable exposure constraints. The process of each individual researcher having to make informed decisions themselves creates additional costs for researchers.

93. Simple calculations can be used to provide rough estimates of the potential costs to the industry resulting from researchers having to undertake their own assessments of appropriate exposure standards. Assume that under a self-regulation approach, a researcher will spend between one and five days per year in undertaking activities to ensure that over-exposure risks are minimised. This may involve, for example, researching material on acceptable exposure limits. This time that is dedicated to ‘self-compliance activities’ approximately represents between 0.4 and 2.0 per cent of available working days in a year. Based on average weekly earnings data, this time represents a cost of between \$197 and \$986 per researcher per year.

94. The researcher also bears additional compliance costs under a self-regulation approach associated with ensuring adherence to existing laws. The current guidelines and constraints documented in RHS 12 and RPS 1 may capture constraints set out in existing laws. While a self-regulation approach would mean that RHS 12 and RPS 1 no longer need to be considered

²⁸ Access Economics 2003, *The value of investing in health R&D in Australia*, Report prepared for the Australian Society for Medical Research.

by researchers, the constraints of the existing laws would remain. Self-regulation would thus require individual researchers and research institutions to ensure that they understand which laws apply to their activities.

95. Under a self-regulatory approach, compliance costs are also pushed on to actual and potential research participants. Research participants may need to undertake more effort to satisfy themselves that they are not unduly exposed by participating in medical research, particularly given that researchers have an incentive to minimise compliance costs by lowering regulatory control.
96. It is difficult to quantify how compliance cost changes would flow through the industry because they will be highly dependent upon the individual strategies of each participant. However in principle, it is reasonable to expect that self regulation could in some instances:
 - increase the cost, time, and resources involved in undertaking medical research;
 - decrease the resources available to medical research (as more were taken up with self management of radiation protection); and
 - lead to a reallocation of resources to research where the risks were easier to manage or avoid but not necessarily research that had the highest expected return in terms of potential lives saved, health improved, or commercial prospect.
97. On the other hand, for many researchers, self-regulation would mean that they would have, and would possibly exercise, the opportunity to reduce their expenditure on complying with health and safety standards.
98. Overall, compliance costs under self-regulation are expected to be slightly lower than those under the status quo, however, they will not be reduced to zero.

Administration

99. With no Code to administer, regulators across Australia would have the opportunity to reduce their expenditure on research-related monitoring and enforcement. However, administrative costs would still exist. The enforcement of safety standards would arise from private actions taken for damages associated with over-exposure.
100. In cases where private actions are taken against researchers suspected of being negligent, it is likely that a common means of seeking redress will be through the courts. Under a self-regulatory approach, the costs associated with taking cases through the courts (both resource costs in terms of time and financial costs in terms of money) are borne by the researchers and the research participants. It is possible that the risk of having to pay these resource and financial costs would deter both research participants and medical researchers from undertaking research projects involving exposure to radiation. Hence, medical research is likely to be lower and health and medical outcomes for the community would be lower than otherwise would be the case.
101. Further, due to the lack of specific industry-based regulations, more resources may need to be devoted by government to ensure that researchers are abiding by wider radiation protection legislation. This represents a further administrative cost.

Health and safety

102. The use of ionizing radiation in medical research is often an incidental, rather than a core, element of the research. While some research involving ionizing radiation is focussed on the effects of ionizing radiation on humans, the majority of medical research uses ionizing radiation to assess the effects of the drugs or treatment methods that are being tested. For example, a research project may involve research participants being subject to a particular type of treatment and then having numerous x-rays to assess the effects of the treatment. As such, researchers that use ionizing radiation are often experts in fields other than ionizing radiation.
103. Self-regulation has the potential to compromise health and safety outcomes as researchers who are not experts in the field of radiation may be called upon to make decisions regarding exposure levels for research participants. Further, governments have no direct control over exposure and dose limits and safety procedures. Instead, the determination of exposure levels and safety procedures rest with the researchers themselves. This could be detrimental to the health and safety of research participants in medical research as the potential for research participants being over-exposed to ionizing radiation is increased.
104. According to the President of Australasian College of Physical Scientists and Engineers in Medicine ‘allowing researchers to produce their own ground rules under which they would operate would lead to a fragmented, inconsistent, potentially hazardous and generally unacceptable outcome.’²⁹
105. On the basis that it would be reasonable to expect that a move to self-regulation would result in higher exposure by research participants relative to the status quo, then it is possible to estimate the potential impact.
106. Assuming that self-regulation resulted in an increase in the average annual effective dose for research participants of 1 per cent — this is consistent with the approach adopted by New South Wales in a recent regulatory impact statement³⁰ — then this would result in a cost of around \$10 000 per year for research participants.

Community perceptions

107. Self-regulation may not satisfy expectations of potential research participants that their safety is not being unnecessarily jeopardised. Research has identified strong community concern regarding exposure to radiation.³¹ There is reason to believe that potential research participants would prefer exposure limits to be well defined and enforced by regulators. For example, in a recent survey of community perceptions of radiation risks associated with medical imaging it was found that 90 per cent of respondents wanted providers of medical

²⁹ L. D. Oliver, Submission to ARPANSA on the Code of Practice for the Exposure of Human Subjects to Ionizing Radiation for Medical Research Purposes, Australasian College of Physical Scientists and Engineers in Medicine.

³⁰ New South Wales 2003, Radiation Control Regulations 2003: Regulatory Impact Statement, Appendix C, Sydney p. 53.

³¹ S. Chapman and S Wutzke 1997, ‘Not in our backyard: Media coverage of community opposition to mobile phone towers—an application of Sandman’s outrage model of risk perception’, *Australian and New Zealand Journal of Public Health*, vol. 21, no. 6, pp. 614-620.

imaging to be licensed and regulated.³² Self-regulation may discourage research participants, particularly given, that in many cases, research participants do not stand to benefit directly from being involved in the project.³³

108. The costs of reduced numbers of research participants are difficult to estimate but potentially large. Given the above mentioned survey, the lack of regulation could result in a decline in participant numbers and a consequent reduction in the viability of research projects due to insufficient numbers of participants. The total cost to the community as a whole would be even larger when you consider that potential health benefits from medical research might be lost.

109. Even if there is no real health risk associated with a move to self-regulation, the community may nevertheless be concerned that governments do not view radiation protection in research as important.

Option 3 - implement a revised national code of practice

110. ARPANSA has developed a Code of Practice which outlines procedures to be adopted by the research industry to ensure levels of exposure to ionizing radiation comply with standards of best practice. The Code provides a set of requirements that would be adopted by State and Territory regulators as part of their frameworks for controlling the use of ionizing radiation in research with humans.

111. A code of practice would:

- Clarify which exposures are relevant to regulatory requirements;
- have a set of constraints for specific organs and tissues in accordance with international developments in radiation protection;
- be consistent with Part 2 and the dose constraints for children of ARPANSA RPS 1;
- contain guidance material for the categorisation of risk and the corresponding benefit of the research to society;
- require researchers to take into account research participants exposure history;
- clarify responsibilities and streamline current processes for researchers, regulators and ethics committees, and
- provide a consistent reference for evaluation of risk and development of risk statements.

112. The Code provides a set of requirements that would be adopted by State and Territory regulators as part of their regulatory frameworks in controlling uses of ionizing radiation in research with human participants.

³² R. Ludwig and L. Turner 2002, 'Effective patient education in medical imaging: Public perceptions of radiation exposure risk', *Journal of Allied Health*, Fall, 2002, 31-3, p.159.

³³ People are far more likely to accept risks that have obvious benefits attached than those that do not, see for example, *Radiation in perspective*, The US Department of Energy Assistant Secretary, <http://tis.eh.doe.gov/radiation/Radiation-final-6-20.pdf>, accessed 28 June 2004.

Benefits

Health and safety

113. One of the key benefits associated with the implementation of the proposed Code is the potential to improve health outcomes. Improved health outcomes are expected to arise from the provision of:

- constraints applying to cumulative effective doses over a number of years (not present in RHS 12);
- constraints applying to doses relating to a specific organ or tissue or portion of organ or tissue (not present in RHS 12 or RPS 1);
- constraints applying to doses given to research participants over the age of 60 and 70 (not present in RHS 12 or RPS 1);
- constraints applying to doses given to children and foetuses (more detailed than is provided in RHS 12 and RPS 1); and
- constraints applying to doses given to specific organs or tissues of children (not present in RHS 12 or RPS 1).

114. The specifications set out in the proposed Code are based on Australia's most recent radiation protection standards and incorporate current international guidelines of dose limits. Using the most up-to-date information ensures that cases of over-exposure are minimised. According to research published in 1993:

new data and new interpretations of earlier information indicate with reasonable certainty that the risks per unit dose associated with ionizing radiation are higher than they were estimated to be a decade ago.³⁴

115. The proposed Code also offers a more stringent system of checks and balances to ensure risks of accidental over-exposure are minimised. For example, the proposed Code requires researchers to ensure dose calculations and associated risk information provided to ethics committees have been checked by a medical physicist. Other precautionary measures adopted by the proposed Code include requirements on researchers to provide ethics committees with:

- the reasons as to why it is necessary to expose research participants to ionizing radiation for the purposes of research;
- details of steps taken to ensure radiation exposure is kept to a minimum;
- details of information to be given to the subjects and the consent form to be used; and
- arrangements for the review of radiation doses delivered and dose records for the project where 'novel' uses of radiation are used.³⁵

³⁴ D. Beninson 1993, 'The ICRP radiation protection philosophy bases and trends', *Radiation Protection in Australia*, vol. 11, no. 2, pp. 67-70.

³⁵ 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

116. In this regard the proposed Code establishes a clear and consistent framework to be used by ethics committees in reviewing applications for research projects. The framework provided by the proposed Code provides ethics committees with verified information regarding the doses and risks of the radiation in proposed research projects. This creates an environment whereby the risks of over-exposure are better controlled as it is unlikely that projects would ‘fall through the cracks’ as they do under the status quo due to ambiguities in regulation. The proposed Code also ensures that research participants are able to express informed consent regarding the exposure to radiation.
117. The proposed Code of Practice requires that researchers confirm with the relevant ethics committee that the site(s) at which the research is to take place and the apparatus used comply with relevant standards. An audit of Australia x-ray machines undertaken in the early 1990s identified that 15 per cent of machines audited had major faults.³⁶ A similar outcome was found more recently in the United States.³⁷ By ensuring sites and apparatus used are of suitable quality, the proposed Code of Practice reduces risks of accidental exposure due to poor or faulty equipment. This aspect of conduct is not present under the status quo and cannot be ensured under a self-regulation approach.
118. The scope of the proposed Code covers therapeutic trials and as such is an all-inclusive system that offers simplicity and efficiency. Covering therapeutic trials also means that research participants participating in these trials will be protected by the standards offered. Anecdotal evidence suggests that many clinical trials of new drugs do not consider the radiation exposure that the research participants may receive, thus leaving potential for the uninformed exposure of research participants.
119. The combination of improved specification of exposure levels, tighter controls to minimise risks of accidental over-exposure and increased scope of coverage are viewed as large positives for the Code in relation to likely health and safety outcomes. The proposed Code is also likely to result in:
- greater confidence for volunteers participating in research activities that radiation protection is being well managed;
 - improved outcomes in medical research as resources are better allocated to those research activities that appropriately match and manage radiation protection; and
 - enhanced community understanding, confidence, and support for medical research that uses radiation.
120. Quantifying these benefits requires consideration of the impact on average annual effective dose. If the introduction of the proposed Code results in lower average annual effective dose then research participants and the public more generally will benefit. For example, if it is assumed that the proposed Code will result in the effective dose reducing by 0.15 of a per cent

derived using anthropomorphic phantoms. In these circumstances, it is essential that the actual doses received are calculated or measured.

³⁶ P. Colgan, D. Harrison and W. Moore 1992, ‘Guideline development and impact assessment for registration of medical, dental and veterinary x-ray apparatus’ *Radiation Protection in Australia*, vol. 14, no. 4, pp. 80-86.

³⁷ United States Food and Drug Administration 2000, <http://www.fda.gov/cdrh/annual/fy2000/annualreport-2000-7.html>, accessed 14 July 2004.

— this is consistent with the approach adopted in a recent NSW regulatory impact statement and consistent with the approach adopted in the cost benefit analysis for the National Directory — then the benefit to research participants will be around \$2 000 per year.

Uniformity

121. While there are costs associated with complying with the proposed new code, there are also some compliance benefits. In particular:

- the new code would give clear up-to-date guidance and provide advice on appropriate exposure levels for research participants of medical research;
- a single Code would also enable a uniform approach to radiation protection for researchers across Australia. This would ensure that all stakeholders would be aware of their obligations even when operating in another jurisdiction; and
- the public would be able to refer to a single uniform Code to provide guidance on acceptable dose constraints to help inform decisions about volunteering for medical research.

122. Overall, compliance costs are likely to be reduced for researchers or research institutions that have cross-jurisdictional operations, that is, they will be able to have a single standardised operational approach across jurisdictions.

123. The proposed Code of Practice will bring administrative benefits to regulators and ethics committees as it offers the simplicity of an all-inclusive framework that is clear in its requirements and consistent across jurisdictions.

Dynamic efficiency

124. Another advantage of implementing the proposed Code of Practice is that it will ensure consistency is maintained over time and that radiation protection standards are current through regular updates by the Radiation Health Committee to reflect changes in international dose limits or domestic policy initiatives.

International standardisation

125. A new code would refer to Australia's most recent radiation protection standards that, in turn, incorporate current international radiation protection guidelines using dose limits in ICRP Publication 60 (1991). It would also incorporate current international best practice for minimising the risks of over-exposure in medical research. In effect, a new Code will make the Australian regulatory regime compliant with international best practice.

Costs

Compliance

126. Implementing and enforcing the Code of Practice involves a range of compliance costs on researchers. The following requirements of the Code would all involve compliance costs:

- the preparation of a submission to human research ethics committees with detailed information about the proposed project;

- ensuring that the selection of research participants is conducted according to the requirements of ethics committees and other requirements stipulated in the Code;
- providing research participants with information about the project such that they can give informed consent to participate;
- ensuring the radiation dose to subjects is kept at the minimum level practicable;
- ensuring that ethics committees are provided with verified advice from an independent medical physicist about the proposed doses if the proposed doses exceed constraints outlined by the Code;
- maintaining records of signed consent forms, radiation doses and other details of the research;
- seeking advice from a medical physicist that key information provided to the ethics committees in the research proposal is correct; and
- providing the subject with a record of the radiation dose received during the project with instructions to retain the record.

127. In addition, adhering to the Code of Practice also involves a range of compliance costs on medical physicists arising from the following requirements:

- verifying and assessing the effective doses and risk assessments which have been provided by the researcher;
- obtaining a verification of a dose assessment by a second medical physicist in cases where dose constraints are exceeded; and
- preparing a written report including details of effective doses, risks as well as a statement as to whether dose constraints are likely to be exceeded.

128. It is expected that the costs associated with these tasks would be passed back on to the researcher such that all compliance costs listed above would, in the end, be borne by researchers.

129. Compliance requirements under the proposed Code of Practice are similar, yet more stringent, than those under the status quo. While difficult to estimate compliance costs in exact terms, comparisons can be made to the status quo. As outlined earlier in the document, compliance costs in 2002 under the status quo are estimated to be approximately between \$1 480 and \$7 390, this equated to researchers spending between one and five hours per project in preparing a submission for approval. Based on the more rigorous compliance requirements of the proposed Code, it is thought that researchers would, on average, have to spend at least one full day (around 8 hours) in preparing submissions — this equates to an annual cost of around \$11 800.

130. Similarly if we assume that, on average, a medical physicist would spend around one full day in meeting the requirements of the Code for each research project that took place, then the compliance costs arising from requirements placed on medical physicists can also be approximated at \$11 800.³⁸ In addition to these costs, projects that involve the administration

³⁸ This approach uses average weekly earnings data to estimate total costs of the physicist's time. It is likely that the value of a medical physicist's time would be greater than average earnings, however, the extent to which a physician would charge full rates to a medical researcher is also unknown. The above approach is used in the

of doses above 5 millisieverts require a second medical physicist to verify and assess dosage levels — we assume that such a process may take around 2 hours to complete. In 2002, it is estimated that there were 19 medical research projects undertaken that involved doses of greater than 5 millisieverts. As such, total annual costs for the review by a second medical physicist would be around \$1 000.

131. Assuming that physicists pass all costs back on to the researcher then the total compliance costs borne by the researcher associated with the proposed Code can be estimated at around \$24 600 per year (based on the number of projects that took place in 2002).

132. Such compliance costs are likely to impact on smaller research operations that lack the ability to lower average compliance costs through economies of scale. The costs of compliance will be greatest in the first year or so following the introduction of the proposed Code. Efficiencies gained from the existence of a clear and consistent framework will help reduce compliance costs over time.

Administration

133. The proposed Code requires ethics committees to assess research proposals involving ionizing radiation in terms of the likely benefits and risks of undertaking the project. In doing so, ethics committees are required to consider:

- the estimates of expected radiation doses and associated risks;
- the manner in which the radiation doses and risks are provided to the research participant;
- the justification of the exposure level should it exceed the guidelines of the Code; and
- the measures to be taken during the project to assess radiation doses actually received from novel uses of radiation.

134. The responsibilities placed on ethics committees are similar to those which exist under the status quo. Offsetting this however is the fact that the requirements of regulators are much diminished under the proposed Code when compared to the status quo.³⁹

135. For the status quo, we estimated the administration costs incurred by ethics committees to be around \$71 730 to \$80 600 per year. It is likely that the costs incurred by ethics committees under the proposed Code are of a similar magnitude.

136. With the introduction of a new code, the ethics committees would require some retraining and familiarisation which would represent an initial administrative cost associated with the implementation. It should be noted, however, that the proposed Code is not an entirely new code and essentially revises the RHS 12 and RPS 1. Retraining and familiarisation of the ethics committees with the new Code should therefore not be as extensive as would be the case with a completely new code. Assuming that retraining and familiarisation would require

absence of more specific data and should be considered as an indicative estimate of costs which can be compared in magnitude to that of the status quo.

³⁹ The proposed Code is designed such that the assistance of regulators is only necessary in cases where it is requested by the ethics committee. For simplicity, this analysis assumes that the costs borne by regulators under the proposed Code are zero.

up to 10 per cent more time per project in the first year relative to status quo, then the administrative costs could be in the range of \$78 900 and \$88 660 for the first year of the Code's operation.

137. However, beyond the first year for which the Code is implemented, it is likely that the simplicity (the proposed Code provides ethics committees with information to assist them in undertaking the required tasks) and consistency of the proposed Code would lead to lower administrative costs over time.

Consultation

138. The Code was developed by a working group of the Radiation Health Committee (RHC). The RHC includes representation of all Commonwealth, State and Territory radiation protection regulators, a person representing the interests of the public and members of medical and academic institutions. All RHC members participated in the development of the proposed Code via their membership of the Committee.

139. The draft Code was prepared by a working group with representation from the South Australian Environment Protection Agency, the Royal Australian and New Zealand College of Radiologists (RANZCR) and the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM), with a secretariat provided by ARPANSA. The draft therefore contains the views of those that would be regulated by such a code and those would use the code to regulate the relevant use of ionizing radiation in research.

140. The draft Code of Practice was released for a period of public comment from 11 February until 26 March 2004. Copies of the proposed Code were also available on the ARPANSA web site at www.arpansa.gov.au. Two hundred and sixty-six organisations were advised of the availability of the proposed ARPANSA Code and the draft Regulatory Impact Statement for their comment. These organisations consisted of:

- a) Radiation Protection Regulators
- b) Radiation Advisory Committees/Councils
- c) NHMRC Australian Health Ethics Committee, State Govt Ethics Committees
- d) University/Hospital: RSO's, HRECs registered with NHMRC
- e) Professional bodies: RANZCR, ACPSEM, AIR, ANZAPNM, ANZSNM, RACP, the Australian Society for Medical Research

141. Twenty-three public submissions were received following the release of draft in early 2004. The draft Code was revised taking into account the comments made in public submissions and a second round of consultation with a revised draft of the Code was undertaken in December 2004 with those people and organisations that had provided comments. Thirteen public submissions were received as a result of the second round of consultation. A third revision of the Code has been produced following consideration of comments arising from the second round of consultations.

142. The first round of consultations raised the following comments:

- Overlap with the requirements of the NHMRC National Statement on Ethical Conduct in Research Involving Humans
- The need for additional advisory material
- The need to include standard model risk statements
- The impost of requiring the review of all projects by the regulator
- The application of the Code to clinical trials
- The need for age and gender specific risk estimates
- Application of the dose limits to children aged 0 to 2 years
- Clarification of the definition of medical benefit and societal impact
- Appropriateness of the quantitative analysis used in the RIS

All of the above issues were accepted and the Code was modified accordingly

143. Following circulation of the revised draft for a second round of public consultation, most of the comments submitted were in relation to the new annexes developed following consideration of the first round of public comments. These comments were mostly accepted and the draft was modified accordingly. A number of second round submissions supported the revised Code. One submission from the Royal Australian and New Zealand College of Radiologists suggested a change to the dose constraints used in Table 1, however the Radiation Health Committee discussed the proposal at their March 2005 meeting and agreed that the current dose constraints are appropriate for the Code and consistent with the public dose limit.

144. The public consultation draft of the Regulatory Impact Statement (RIS) included requests for information from stakeholders on compliance costs, however no such information was received. Consultants⁴⁰ were engaged to undertake an analysis of the proposal focussing on the costs and benefits, and the resulting analysis has been included in this RIS.

Recommended Option

A list of the costs and benefits provided by each of the three identified options (with the status quo being used as the base comparator) is shown in table 3.

⁴⁰ The Allen Consulting Group

Table 3**NATURE OF COSTS COMPARED TO THE STATUS QUO**

Costs	Self-Regulation		New Code	
	Impact	Discussion	Impact	Discussion
Compliance	<i>Slightly Lower</i>	As regulatory obligations are reduced (but not eliminated, due to the fact that researchers will have to make their own decisions on acceptable exposure levels) compliance costs will fall for researchers. An estimation of compliance costs is given at between \$197 and \$986 per researcher per year. The magnitude of the decrease in compliance costs will depend on decisions taken by individual researchers regarding the resources that should be devoted to ensuring safety standards are maintained.	<i>Higher</i>	More stringent requirements on researchers will result in increased compliance costs, particularly in the first year or so of implementation. An estimation of compliance costs is given at around \$24 600 per year. Efficiencies gained from the existence of uniform standards will help to reduce compliance costs over time.
Administration	<i>Slightly Lower</i>	Administration costs borne by regulators are effectively reduced to zero under a self-regulation approach. However, there are some risks of increased administrative costs arising from a potential rise in litigation disputes over negligence.	<i>Lower</i>	Administrative costs will be lower as there are fewer requirements on regulators. An estimation of administrative costs is given at around \$78 900 to \$88 660 in the first year. Efficiencies gained from the existence of uniform standards will help to reduce administrative costs over time.
Health and safety	<i>Higher</i>	Self-regulation is likely to result in cases whereby standards are lowered thus potentially resulting in adverse health outcomes. A small increase in exposure levels has the potential to result in significant costs to research participants.		
Community perceptions	<i>Higher</i>	There is a risk that self-regulation will deter research participants from participating in medical research involving ionizing radiation. Such an occurrence has the potential to cost the industry of several million per year and the wider community suffer from a decrease in research outcomes.		

Cost sub-total	Higher	The increase in costs associated with adverse health and safety outcomes and community perceptions is viewed as a major factor acting against the adoption of a self-regulatory approach. The increase in these costs outweighs moderate decreases in compliance and administration costs.	Lower	Increases in compliance costs are more than offset by reductions in administrative costs.
Benefits				
Flexibility	Higher	Allowing researchers the flexibility to implement their own safety procedures would result in efficiency gains as procedures could be tailored to different work environments.		
Health and Safety			Higher	Improved health and safety outcomes associated with the new Code are expected to be highly favourable due to the adoption of more up to date and comprehensive standards. A small decrease in annual average effective doses has the ability to generate benefits to research participants.
Uniformity			Higher	The existence of a single uniform regulatory approach should benefit researchers, regulators and ethics committees by alleviating current confusions and ambiguities associated with the status quo.
Dynamic efficiency			Higher	Dynamic efficiency will be improved relative to the status quo as the Code can be updated over time.
International standardisation			Higher	Australia will move more into line with international standards.
Benefits sub-total	Higher	Giving researchers increased flexibility is identified as the only benefit of self-regulation.	Significantly Higher	Several improved health and safety outcomes are viewed as a major benefit of the proposed Code. Improved uniformity, dynamic efficiency and better international standardisation are also viewed as positives.
TOTAL	Net Cost	The significant increase in costs is not outweighed by the moderate increase in benefits.	Net Benefit	The significant increase in benefits combined with a small reduction in costs creates a net benefit in favour of the proposed Code, particularly over the medium to long term as costs are expected to fall further.

Distributional impacts

145. The costs and benefits identified are not necessarily spread evenly among the community. Relative to the status quo, the major distributional impacts associated with:

a) self-regulation include:

- government regulators will save administration costs associated with RHS 12 and RPS 1;
- there will be a greater onus on research participants of medical research to protect themselves by being knowledgeable of risks. Given that the general public is not usually in the best position to protect themselves, largely because of information asymmetries, they will likely bear the burdens associated with reduced health and safety outcomes;

b) the introduction of the new Code include:

- researchers will bear the costs associated with adhering to the regulations. Such costs are likely to be disproportionately borne by smaller operations that lack the ability to lower average compliance costs through economies of scale;
- reduced administrative costs overall yet increased costs for ethics committees as they come up to speed on the Code. Such costs are not considered to be significant; and
- standardisation of the regulation of research projects across Australia should provide relatively greater benefits for researchers that operate in more than one jurisdiction.

Option 1: Status quo

Health and safety

146. Option 1 status quo has the benefit of familiarity (and hence attendant low compliance costs) but may be perceived as not generating health and safety outcomes consistent with best practice in Australian and overseas standards. The sub-optimal health and safety outcomes are assessed as arising from two key observations:

- first, the status quo is not in line with the most up to date radiation exposure standards, for example it does not specify exposure limits for a specific organ or tissue; and
- second, ambiguities associated with status quo have given rise to cases where projects that should have sought regulatory approval have not.

Inconsistent regulations

147. The failure of the status quo to provide a clear framework for the review and approval process is assessed as a large cost on the industry. Ambiguities and inconsistencies across jurisdictions are assessed as creating unnecessarily high administrative and compliance costs that are borne by researchers, regulators and ethics committees. Further, the lack of clear and consistent approach is observed as leading to situations where research participants are potentially exposed to radiation without being fully informed of the doses and risks that are involved.

148. Overall, relative to other scenarios, the status quo is not assessed as being an optimal outcome due to the existence of ambiguities, inconsistencies and sub-optimal health and safety outcomes.

Option 2: Self-regulation

149. Self-regulation is constrained by the fact that to be successful:

- there must be common understanding of the risks associated with the use of radiation safety and procedures amongst all researchers; or
- there must be sufficient power and commonality of interest within an industry to deter non-compliance; or
- the cost of non-compliance must be small.

150. These issues are not satisfied with respect to research projects involving the use of ionizing radiation.

Health and safety

151. Adverse health and safety outcomes associated with over-exposure may also arise due to an absence of regulation. This risk is especially apparent as in many cases researchers undertaking projects involving the use of ionizing radiation are experts in fields other than radiation. It is estimated that the costs of the sub-optimal health and safety outcomes for research participants. The potential for a self-regulatory approach to give rise to community concerns about the safety of research involving exposure to ionizing radiation, thus leading to difficulties in attracting research participants, is also assessed as a cost.

152. Overall, the risks of adverse health and safety outcomes arising from a self-regulatory approach are assessed as being far higher than those found under either of the other two scenarios.

Compliance and administrative costs

153. Given that a self-regulatory approach may only result in a relatively small reduction in compliance and administrative costs, it is assessed that there are insufficient benefits to outweigh the costs of the approach.

Option 3: Proposed Code

Compliance costs

154. The rigorous nature of the compliance requirements (on both researchers and medical physicists) of the proposed Code will result in relatively higher compliance costs which would ultimately be borne by researchers. However, offsetting this will be efficiencies gained through having a standardised approach that is clear in its demands and consistent across jurisdictions. Compliance costs are estimated to be higher than those that are currently observed under the status quo, particularly in the initial stages of introduction. Over time as systems and processes are bedded down and efficiencies are gained through the existence of a consistent regulatory framework, compliance costs are expected to fall somewhat but are still expected to remain above those incurred under the status quo.

Administrative costs

155. In comparison to the status quo, the proposed Code places fewer requirements on regulators, it is therefore expected that administrative costs would be lower than those currently incurred. Ethics committees will still be required to administer many aspects of the approval processes for research projects and from their perspective administrative costs are likely to remain broadly similar to those of the status quo. As is the case for compliance costs, administrative costs are expected to fall over time as systems and processes are established and general efficiencies are gained as a result of the implementation of a clear and consistent framework.

Health and safety

156. The rigorous nature of the proposed Code lends itself towards relatively high compliance and administrative costs (at least in the initial years of introduction), however, these costs arise from the desire to achieve better health and safety outcomes. In contrast, much of the administrative and compliance costs apparent under the status quo exist because of ambiguities and inconsistencies in the current regulations and therefore the costs do not contribute toward the achievement of a meaningful objective.

157. The proposed Code offers health benefits associated with the adoption of international best-practice standards as well as the use of more stringent measures to guard against accidental over-exposure. Estimates of the value of the health and safety benefits of the proposed Code are in the order of \$2 000 per year for research participants. Given that the health benefits are ongoing, while the costs of implementation of a new code are largely incurred in the first year, the introductions of a new code should be beneficial over a medium to longer term.

Uniformity

158. The fact that the Code provides for a clear and consistent framework by which researchers, regulators, ethics committees and research participants can exercise informed judgement also works strongly in its favour.

Conclusion

159. The above analysis demonstrates that the proposed Code can cost-effectively ensure that research participants and ethics committees are accurately informed of the radiation dose and associated risks. The Code clarifies the boundaries for acceptable use of radiation in research with humans. By incorporation of the Code in the next edition of the National Directory for Radiation Protection, national uniformity in the exposure of humans to ionizing radiation for research purposes will be promoted.

160. The proposed Radiation Protection Code of Practice for safe exposure of humans to ionizing radiation for research purposes is the recommended option to meet the objectives stated in paragraphs 50 - 52.

Implementation and Review

161. The proposed Code will be published by ARPANSA as a Radiation Protection Series publication. After publication the Code will be proposed for incorporation into the next

edition of the National Directory for Radiation Protection. All regulators in the Commonwealth, State and Territory, who manage activities pertaining to ionizing radiation will be expected to adopt the Code by express reference in their regulations.

162. The Code will be reviewed through the ARPANSA Radiation Health Committee within 10 years of its commencement to ensure it is still relevant to the radiation protection needs of the community. Earlier review would be undertaken if there are problems in the implementation of the Code, if international or national radiation protection objectives change or if there is new information from international research.

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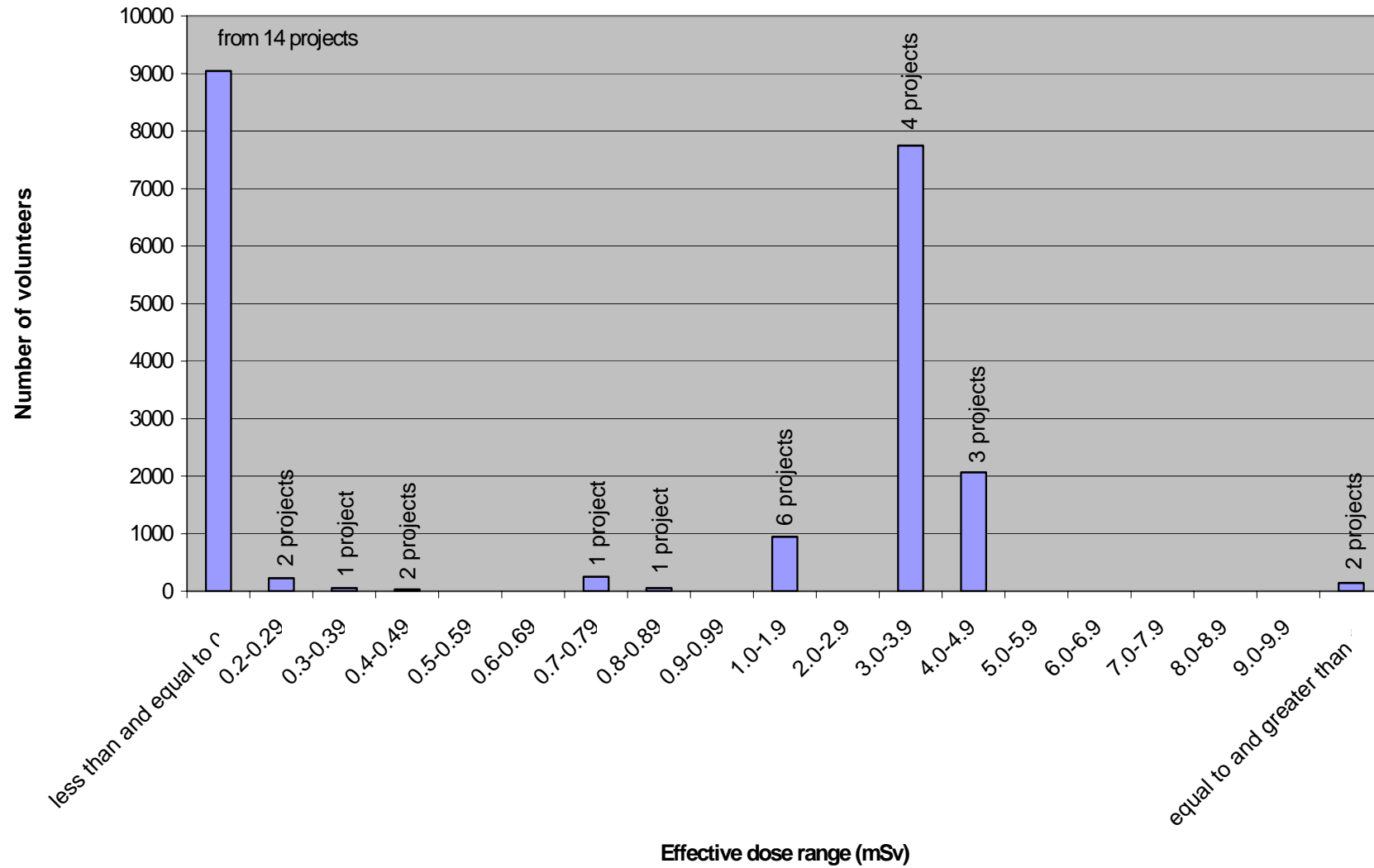
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Effective dose received by volunteers in research projects in Victoria during 2002



Effective doses per number of volunteers and number of projects, at a Sydney Teaching Hospital
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