



**Australian Government**

**Australian Radiation Protection and Nuclear Safety Agency**

## **Regulatory Impact Statement Consultation Draft**

# **Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation**

### **Public Consultation Draft**

Comment on the Regulatory Impact Statement and draft Code of Practice/Safety Guide should be forwarded by 26 October 2007 to:

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The cost-benefit analysis for this RIS was prepared for ARPANSA by The Allen Consulting Group.

## Chapter 1. Introduction

### 1.1 Medical applications of ionizing radiation

1. This regulatory impact statement applies to the proposed Code of Practice for Radiation Protection in Medical Applications of Ionizing Radiation put forward by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). The proposed Code will apply to nuclear medicine, radiology and radiotherapy.
2. Medical practices involving nuclear medicine, radiology and radiotherapy involve exposing patients (and potentially practitioners and members of the public) to ionizing radiation. There is a natural dichotomy in all forms of diagnoses or treatments that involve ionizing radiation in that while the radiation is being used for diagnosis or treatment, the doses used in the medical procedures can be associated with potentially significant side effects and risks (to both the patient and other parties).
3. Potential side-effects and risks are minimised by the proper use of equipment and radioactive sources in a fashion that delivers the radiation to the specified area whilst limiting any extraneous radiation production or exposure — ARPANSA's proposed Code of Practice is designed to achieve such an outcome. The proposed Code is also designed to minimise any unnecessary exposure to patients and occupationally-exposed people.

#### *Nuclear medicine*

4. Nuclear medicine is a branch of medicine that uses radioactive materials as either a diagnostic tool to image a patient's body or a treatment tool to destroy diseased cells. In diagnostic nuclear medicine, the aim is to reliably make the correct diagnosis while keeping the radiation dose to the patient to a minimum. In therapy, the aim is to cure a cancerous, or other, condition or to provide pain palliation and relieve the symptoms of a disease in order to improve the quality of life of a patient.
5. Diagnostic nuclear medicine typically involves the patient being given a radionuclide in a carrying substance which is taken up by the tissue or organ under study. The radionuclide may be administered by injection, ingestion or inhalation. Once inside the body, radionuclides emit gamma rays which can be observed with the use of a gamma camera. The process allows practitioners to observe characteristics about organs and tissues.
6. Nuclear medicine therapy also involves the administration of radionuclides to the patient. The key difference between diagnostic procedures and therapeutic procedures is that in the case of therapy, the patient is given a much higher dose. Doses are set to specifically target diseased tissues and organs.
7. In 2006-07, an estimated 481 000 nuclear medicine procedures were undertaken across Australia.<sup>1</sup>

#### *Radiology*

8. Radiology encompasses a branch of medicine that uses radiation (such as x-rays) or other imaging technologies (such as ultrasound and magnetic resonance imaging) to diagnose or treat disease. Radiology can be either diagnostic or interventional.
9. Diagnostic radiology most commonly involves the use of an x-ray examination whereby radiation from a machine passes through the patient. X-rays penetrate flesh and bone to different degrees and produce images of the internal structures of the body on film.
10. Another common form of diagnostic radiology is the use of computed tomography (CT) scans. CT is a high radiation dose procedure that is used in diagnostic imaging. CT typically accounts for a small proportion of total diagnostic imaging procedures but accounts for a large portion of total doses delivered — in Australia, it has been estimated that in 1996, CT accounted for about 50 per cent of the

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<sup>1</sup> Based on data provided by Medicare Australia 2007, *Group Statistics Reports*, [http://www.medicareaustralia.gov.au/statistics/dyn\\_mbs/forms/mbsgtab4.shtml](http://www.medicareaustralia.gov.au/statistics/dyn_mbs/forms/mbsgtab4.shtml), Accessed 1 August 2007.

total medical radiation dose.<sup>2</sup> The technique involves a fan shaped beam of x-rays being rotated around a patient. An image of a section through the patient can then be reconstructed by a computer to convey detailed diagnostic information.

11. Interventional radiology involves a physician performing a procedure inside the patient's body whilst using a series of x-rays to "see" the patient in real time. Interventional radiology tends to result in patients receiving relatively high doses of radiation and if not properly controlled can also result in high doses of radiation being received by surgeons.
12. In 2006-07, an estimated 13.5 million radiological procedures were undertaken across Australia — about 2.4 million of these procedures were CT scans.<sup>3</sup>

### **Radiotherapy**

13. Radiotherapy treatment is used to kill cancerous cells in the aim of either curing patients completely of cancers or at least relieving the distressing symptoms of cancer. Treatment involves a beam of high energy x-rays, gamma rays or electrons being directed toward the diseased tissue so as to give it a high dose while sparing the surrounding healthy tissue.
14. Radiotherapy treatment encompasses a form of treatment known as brachytherapy. Brachytherapy involves the placement of a radiation source within a patient's body for short periods of time. Brachytherapy is capable of delivering high doses of radiation to the treatment area, which is particularly useful when treating patients for tumours that are deep in the body.
15. It is estimated that about 869 000 radiotherapy procedures were undertaken in Australia in 2006-07.<sup>4</sup>

## **1.2 Current regulations**

16. Regulations governing the practice of nuclear medicine, radiology and radiotherapy are currently the domain of State and Territory regulators. The current regulations are broadly consistent in their objectives but different in some respects in their approach. As a general rule, each of the three forms of medical practice is not governed by specific regulations instead they are regulated by broad requirements that apply to practices involving any form of exposure to radiation. Current State and Territory regulators include health and environmental departments (Table 1.1).

## **1.3 Statement of the Problem**

17. The lack of national uniformity in radiation protection legislation for the medical radiation industry adversely impacts on the effectiveness and efficiency of the administration of radiation protection legislation among jurisdictions. In particular, the lack of national uniformity in licensing, registration or exemption provisions for radioactive sources, radiation equipment and apparatus and occupational groups poses difficulties for users who have to comply with different requirements when operating across jurisdictions or when relocating from one jurisdiction to another. This could be expected to result in higher costs being passed on to those businesses which are the end users, and at the end of the day, to the community.
18. Some parts of the regulatory frameworks in individual jurisdictions in Australia are also out of step with the most up-to-date international guidelines aimed at protecting the health and safety of occupationally exposed personnel, patients, the public and the environment.
19. There are many thousands of Australians who are occupationally potentially exposed to ionizing radiation as a result of the medical use of ionizing radiation. While the fundamental criteria for

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<sup>2</sup> D. McLean, N. Malitz and S. Lewis 2003, 'Survey of Effective Dose Levels from Typical Paediatric CT Protocols', *Australasian Radiology*, 47, pp. 135-142.

<sup>3</sup> Based on data provided by Medicare Australia 2007, *Group Statistics Reports*, [http://www.medicareaustralia.gov.au/statistics/dyn\\_mbs/forms/mbsgtab4.shtml](http://www.medicareaustralia.gov.au/statistics/dyn_mbs/forms/mbsgtab4.shtml), Accessed 1 August 2007.

<sup>4</sup> Medicare Australia, *Health Statistics*, <http://www.medicareaustralia.gov.au>, Accessed 3 September 2007.

limiting occupational exposure is set out in the Radiation Protection Series No. 1, there are specific occupational protection issues relating the medical use of radiation that need to be dealt with.

**Table 1.1 State and Territory Nuclear Medicine Regulations**

Jurisdiction	Regulator	Basis of regulation
NSW	Radiation Control — Dept. of Environment and Conservation	Regulation is based on the <i>Radiation Control Act 1990</i> and <i>Radiation Control Regulation 2003</i> and the <i>Medical Practice Act 1992</i> . Radiation Control Regulation 2003 calls upon ARPANSA Code RPS 2 (2001)
Vic	Radiation Safety Program — Dept. of Human Services	Regulation is based on the <i>Health (Radiation Safety) Regulations 1994</i> and the <i>Health Act 1958</i> . Also incorporated into regulations is RPS 2 (2001)
Qld	Radiation Health — Dept. of Health	Regulation is based on Queensland's <i>Radiation Safety Act 1999</i> and <i>Radiation Safety Regulation 1999</i> and also incorporates ARPANSA Codes RPS 2 (2001) and RPS 8 (2005)
SA	Radiation Protection Division — Environment Protection Authority	Regulation is based on South Australia's <i>Radiation Protection and Control Act 1982</i> and the <i>Radiation Protection and Control (Ionising Radiation) Regulations 2000</i>
WA	Radiological Council	Regulation is based on the <i>Radiation Safety Act 1975</i> and the <i>Radiation Safety (General) Regulations 2003</i> . RPS 2 (2001) and RPS 4 (2002) are also applied in WA
Tas	Dept. of Health and Human Services	Regulation is based on the <i>Radiation Protection Act 2005</i> and <i>Radiation Protection Regulations 2006</i> . A range of NHMRC and ARPANSA Codes are also referred to
NT	Radiation Protection Section — Dept. of Health and Community Services	Regulation is based on the following NHMRC and ARPANSA Codes — RHS 23 (1988), RHS 13 (1985) and RPS 4 (2002)
ACT	Radiation Safety Section — ACT Health	Regulation is based on the ACT's <i>Radiation Act 1983</i> and <i>Radiation Regulation 2002</i>

20. Further, modality specific problems that could require attention have been identified as follows:

***Nuclear medicine***

21. Inadequate quality of the radiopharmaceutical, administration of the incorrect or the incorrect amount of radiopharmaceutical may result in an incorrect diagnosis or the need to repeat a diagnostic procedure, as well as subjecting the patient to an unnecessary radiation dose. In radionuclide therapy, the administration of the incorrect dosage may result in an ineffective therapy if the administered dose is less than the prescribed amount, or in a radiation induced injury to the patient if greater than the prescribed amount is administered. Appropriate precautions need to be observed in regard to pregnant and breast-feeding patients.
22. The storage, preparation, dispensing, administration of radiopharmaceuticals and the imaging of patients are sources of occupational radiation exposure to hospital or practice staff. Radiation exposure may also result from spills or dispersal of radioactive material and from the handling of radioactive waste. The patient undergoing treatment remains a radiation source until the administered radionuclide has decayed, or has been excreted, and is a source of radiation exposure of staff, other patients or visitors, family members and members of the public. Additionally, the patient may be a source of contamination due to the spread of body fluids or excreta. The appropriate regulations, administrative controls, physical facilities, quality assurance procedures and training are required to ensure the radiation protection and safety of staff, the patient and the public.

***Radiology***

23. Irradiation of patients from diagnostic radiology is by far the largest source of man-made exposure to the population from ionizing radiation. Exposures need to be fully justified in terms of benefit to the

patient and there is a need to establish clear responsibility for them and to ensure that they are optimised and minimised to provide maximum benefit with minimum potential risk to the patient.

24. Australia has several publications in the field of medical radiation, published in the NHMRC Radiation Health Series. There was also an Australian Standard (AS2814), now obsolete, which dealt with safe radiological practice. These publications are no longer compatible with the regulatory requirements in Australia, nor are they in line with international trends.
25. Internationally, the European Directive on *Health Protection of Individuals Against the Dangers of Ionising Radiation in Relation to Medical Exposure* and the IAEA Safety Guide on *Radiological Protection for Medical Exposure to Ionizing Radiation* set out comprehensive guidelines for the development of regulations related to radiation protection in medicine. Australia should have regulatory documents that are consistent with these guidelines.

**Radiotherapy**

26. The use of therapeutic ionizing radiation sources has significant benefits to patients suffering from a wide variety of malignant diseases and certain benign conditions. The prescribed dose may be radical with the aim to eradicate the cancerous tissues or palliative to relieve pain and symptoms of the disease. Inadequate standards of treatment, calibration or quality assurance of ionizing radiation emitting devices or radioactive substances used for therapeutic purposes may therefore seriously reduce the positive benefits of cure or cause an unnecessary increase in the incidence of radiation induced injury.

**Radiation Incidents**

27. ARPANSA incident reports show that in the past there have been several cases of incorrect administration of ionizing radiation (Table 1.2) that better regulations may have prevented. ARPANSA notes that the incident register only captures a small proportion of total incidents due to reporting problems.

**Table 1.2 Extracts from ARPANSA Incident Register**

<b>Nuclear medicine incidents</b>	
1990	Nine patients injected with the wrong scanning agent due to similarity of labelling
1995	Wrong radiopharmaceutical injected into patient
2004	A patient was injected with the incorrect type of radionuclide as the administering person had failed to check the patient name on the syringe
<b>Radiology incidents</b>	
2001	A CT scan was given to the wrong patient. It was later found that the wrongly exposed patient had a similar surname to the intended patient
2005	A CT scan was performed on the wrong region of a patient after the radiographer did not reference the patient request form

Source: ARPANSA Radiation Incident Register.

**1.4 Objective of Government Action**

28. The objectives of options relating to the medical use of ionizing radiation are to:
  - have nationally uniform requirements across the jurisdictions;
  - improve the health outcomes of patients; and
  - protect people and the environment against the harmful effects of ionizing radiation in a cost effective manner.

## Chapter 2. Options

### 2.1 This cost-benefit analysis

29. This cost-benefit analysis assesses the merits of three models of regulation for radiation protection in the medical applications of ionizing radiation, these are:
- the *status quo*;
  - the proposed Code of Practice put forward by ARPANSA; and
  - a self regulation model.
30. ARPANSA has identified several shortcomings associated with the current regulatory approaches to nuclear medicine, radiology and radiotherapy. ARPANSA is therefore proposing the adoption of a single and nationally uniform Code of Practice which can be adopted into the National Directory as mandatory requirements.
31. This cost-benefit analysis assesses the costs and benefits associated with implementing the new Code relative to the current approach to regulation (referred to in this report as the *status quo*).<sup>5</sup> In the same manner this analysis also assesses the merits of a self regulation approach whereby practitioners are able to set and enforce their own safety requirements regarding the exposure of staff and patients to radiation.
32. The remainder of the report is structured as follows:
- Chapter 3 highlights areas of concern in respect of the current regulatory approach governing nuclear medicine, radiology and radiotherapy practices;
  - Chapter 4 assess the costs of implementing ARPANSA's proposed Code of Practice — these costs are assessed relative to the *status quo*;
  - Chapter 5 assess the benefits of implementing ARPANSA's proposed Code of Practice — these benefits are assessed relative to the *status quo*;
  - Chapter 6 assesses the viability of a self-regulation approach; and
  - Chapter 7 draws conclusions and provides recommendations.

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<sup>5</sup> While cost-benefit analysis requires all costs and benefits associated with the options to be quantified in common units (either in monetary units or physical units) it may not always be possible to do so. In this event, a comprehensive list of the costs and benefits together with a strong qualitative analysis can often provide for a simple but still compelling analysis from which policy decisions can be based. Indeed, this approach is preferable to one where unreasonably broad assumptions are made to generate quantified impacts that provide a spurious sense of accuracy.

## Chapter 3. The status quo

### 3.1 The status quo

33. As alluded to in Chapter 1, regulation (in some form) is considered necessary to protect patients, practitioners and the general public from the side-effects attributable to medical exposure to radiation. To this end, the current State and Territory radiation protection regulations do result in health and safety outcomes that are deemed to be superior relative to a situation whereby there was an absence of regulations.
34. However, in putting forward possible regulatory alternatives, ARPANSA has identified several shortcomings associated with the *status quo*. These shortcomings may manifest themselves by way of placing what are considered to be unnecessarily high compliance costs on those practicing in the industry or alternatively by way of resulting in sub-optimal health and safety outcomes. Current issues identified by ARPANSA include:
- a lack of uniformity in regulations;
  - an absence of a specialist regulator and a specific set of regulations;
  - the existence of outdated regulations that do not incorporate current best practice;
  - grey areas within regulations; and
  - areas of regulatory omission.
35. These issues are described in more detail below.

#### *Lack of uniformity*

36. A lack of consistent and uniform regulations may cause misunderstandings, inefficiencies, and uncertainties which ultimately lead to compliance and administration costs being higher than they need be. The costs of inconsistent regulations have been identified by the Productivity Commission when analysing 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 (and 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).<sup>6</sup>
37. Irrespective of the field to which they apply, differing regulations across jurisdictions create uncertainties and inefficiencies for affected parties. In this instance the affected parties are medical practitioners and assisting staff, particularly those involved in multi-jurisdictional works. The regulators themselves are also affected as each State and Territory regulator must know and understand the intricacies of their jurisdiction's regulations. The current system offers no avenue for a streamlining of tasks and knowledge as would be apparent in a national framework for regulation.
38. A lack of consistent regulations may also hamper the cross-border activities of medical practitioners. Ideally, medical practitioners should be able to be highly mobile within Australia so that they can practice in areas where they are most needed or so they can practice in multiple jurisdictions at once. While, technically this is possible under the current regulatory approach, practitioners who do choose to move between jurisdictions would be required to have knowledge to be able to work within the different State and Territory regulatory approaches — again this is reflected in the costs of compliance. For example, some jurisdictions allow nuclear medicine physicists to administer radiopharmaceuticals while other jurisdictions allow the administration to be done by nurses or other medical staff.<sup>7</sup>

<sup>6</sup> G. Banks 2003, 'Minimum effective regulation and the mining industry', *Address to the Minerals Council of Australia*, Old Parliament House, Canberra, June.

<sup>7</sup> Based on personal communication with staff of the Victorian Regulator.

39. It may be the case that the unnecessary compliance costs are preventing some practitioners from being highly mobile or practicing in multiple jurisdictions and ultimately this may lead to sub-optimal health and safety outcomes as situations may arise whereby there is a shortage of practitioners in particular areas.<sup>8</sup>

### ***Different skill-sets***

40. A recent editorial in *ANZ Nuclear Medicine* highlighted concerns about the differences in regulatory requirements across Australia.<sup>9</sup> The editorial focused on State requirements for granting CT licences to nuclear medicine technologists, particularly in the context of the growing use of SPECT. According to the editorial, the increasing use of SPECT<sup>10</sup> (rather than PET<sup>11</sup>) means that nuclear medicine technologists are required to learn new skills in the areas of radiation safety. A number of disparities were noted in jurisdictional requirements for the granting of CT licenses to nuclear medicine technologists:
- at the time of writing, the editorial noted that there were no nuclear medicine technologist registration or licence requirements operating in Western Australia;
  - in Victoria, there are no additional education or training requirements above undergraduate and accreditation requirements;
  - in New South Wales, technologists are required to complete a 6 month Sydney University postgraduate program;
  - in Queensland, technologists are required to complete a 6 month Sydney University postgraduate program plus 4 to 5 days of manufacturers' application training plus 5 days in-house training at another practice; and
  - requirements in South Australia are as per those in Queensland with additional requirements to observe (over a 2 week period) CT setup and diagnostic practice for treatment to several different body parts.
41. In observing the different training requirements on nuclear medicine technologists, the editorial notes that there appears to be a variable understanding of the needs of the profession and that current training requirements are arbitrary rather than based on a sound assessment of what the industry needs. A consistent approach across all jurisdictions is needed so as to maintain confidence in skills and abilities of nuclear medicine technologists across Australia.
42. Anecdotal information from regulatory staff in Victoria provides support for a consistent and mandatory approach to training across Australia so as to ensure optimal protection of patients, practitioners and carers especially given the increasing complexity of technology in the field of radiation-related treatments.

### ***Absence of a specialist regulator and regulations***

43. The current jurisdictional approach to regulation relies upon a mixture of health and environmental agencies to administer the relevant pieces of legislation. While this is not considered to be failing of the current regulatory system in itself, such a situation can be considered to be sub-optimal relative to a situation whereby a single *national* specialist organisation oversees the implementation of one set of radiation safety regulations.

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<sup>8</sup> Liaison with the regulators in New South Wales, Queensland and the Northern Territory has indicated support for a national Code such that there could be consistency in regulations across Australia.

<sup>9</sup> M. Bellon 2006, 'Educating the Regulators', Guest Editorial in *ANZ Nuclear Medicine*, March.

<sup>10</sup> Single Photon Emission Computed Tomography — an imaging technique using gamma rays that is able to provide three dimensional information.

<sup>11</sup> Positron Emission Tomography — imaging technique that produces a three-dimensional image or map of functional processes in the body.

44. A national specialist organisation could draw on its expertise in the general field of radiation protection and apply it to the different medical practices that involve exposure to ionizing radiation. The ability to draw on such a depth of knowledge and expertise may be limited under the current regulatory framework that is done on an individual jurisdiction basis.

#### ***Outdated regulations***

45. There are instances within the current regulatory framework whereby State and Territory regulations are based on outdated material. For example, regulations in the Northern Territory incorporate NHMRC Codes of Practice RHS 13 (1985) and RHS 23 (1988).
46. 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 Codes that are used by Tasmania and the Northern Territory do not provide up to date information for practitioners and medical staff on radiation safety issues. Lack of currency in the Codes may lead to sub-optimal health and safety outcomes and the absence of enforceable standards that have the ability to be updated suggest that dynamic efficiency is, and will continue to be, compromised.

#### ***Grey areas in current regulations***

47. Some of the regulations that are applicable in the jurisdictions are not as specific as they could be and this may lead to uncertainties and may ultimately compromise health and safety outcomes. For example, there are many standards of practice that are not specifically stated in licence conditions or regulations but are implemented through other mechanisms such as professional registration and accreditation. In the case of nuclear medicine alone, such areas identified in different jurisdictions include:
- the principle of obtaining adequate justification for undertaking a nuclear medicine procedure;
  - giving adequate consideration to the necessity of administrations made to children and pregnant women;
  - the placement of signs informing patients of the need to notify the practitioner if they may be pregnant; and
  - the implementation by hospitals of a comprehensive quality assurance program.
48. Health and safety outcomes may not be being optimised under regulatory regimes whereby standards that are aimed at minimising risks are not specifically spelled out in regulations but rather dealt with through other mechanisms. An approach whereby a single set of uniform regulations contains all relevant health and safety information could be considered more optimal than the current approach.

#### ***Areas of regulatory omission***

49. There are several areas of oversight in the current regulations. Given the risks involved in the administration of medical procedures that involve radiation, these oversights may be potentially damaging to patient and practitioner health (as well as the health of the general public and other medical staff). Examples where current regulations may be lacking include:

##### ***In respect of nuclear medicine***

- In New South Wales and Victoria there are no regulations that stipulate requirements for the regular testing of nuclear medicine equipment. Information from regulators in Victoria indicates that the quality control of nuclear medicine equipment is paramount and that most Victorian practices have some form of a quality assurance program in place, although this may not always be the case.
- In South Australia there are no regulations that require medical procedures involving exposure to ionizing radiation to be undertaken in purpose designed facilities nor are there any regulatory requirements to give consideration to any administrations to children and pregnant women. The

latter point may lead to increased levels of radiation exposure being received by embryos or foetuses.

- In Western Australia, regulations regarding dose limits do not specify limits applying to the lens of the eye, the skin or the hands and feet. Current international thinking on exposures considers such limits to be necessary to protect the health of occupational workers.

#### *In respect of radiotherapy*

- In New South Wales, Victoria and South Australia there are no regulations that require computer treatment planning systems to be tested before implementation. The testing of computer treatment planning systems allows practitioners to check whether computed dose distributions are within acceptable tolerances.
- In Victoria there are no regulatory provisions that require organisations undertaking radiotherapy procedures to have available a radiation survey meter to monitor the radiation that is emitted by equipment.
- In Western Australia there are currently no specific licence or registration procedures pertaining to the undertaking of x-ray radiotherapy or brachytherapy and there are no regulated requirements on standard conditions in these fields.

### **3.2 Conclusions**

50. Current State and Territory regulations that pertain to nuclear medicine, radiology and radiotherapy are designed to minimise exposures to ionizing radiation for patients, medical staff and the general public and in the vast majority of cases, there is no doubt that the current regulations do achieve their objectives. However, disparities between regulations in different jurisdictions result in compliance and administration costs being higher than they need be. In some cases regulations are outdated and in important instances they can be considered to be lacking in their degree of rigour.

## Chapter 4. Costs of the proposed Code of Practice

### 4.1 Introduction

51. In light of the issues identified with regard to the current system of regulation, ARPANSA has developed a Code of Practice to regulate practices in nuclear medicine, radiotherapy and radiology. It is intended that the Code could be brought in by the National Directory and would therefore provide one single set of regulations for the country as a whole. This chapter outlines the costs of the proposed Code relative to the *status quo*.

### 4.2 Compliance costs

52. The proposed Code establishes a range of obligations on medical practitioners working with ionizing radiation. In most cases, the requirements of the proposed Code are already being implemented by practitioners in the field despite current regulations perhaps not being as specific as those set out in the proposed Code. This section details and where possible, quantifies the compliance costs that are in addition to those incurred under the *status quo*.

#### *Justification*

53. Under the proposed Code, all procedures involving ionizing radiation must be justified in accordance with the justification principle.

*No practice involving exposure of individuals to radiation should be adopted unless it produces sufficient benefit to that individual or to society to offset the detriment caused by the radiation.*<sup>12</sup>

54. Queensland is the only jurisdiction that currently utilises justification regulations of a very similar nature to that of the proposed Code. Information from other State regulators indicates that justification requirements are not explicit in their regulations yet similar requirements are already being undertaken to some extent, for example licensing and accreditation requirements in Tasmania deal with the concept of justification.<sup>13 14</sup> For this reason, the additional costs brought about in adhering to the justification principle in the proposed Code will be the result of time spent coming to terms with the new requirements.<sup>15</sup>

55. *The once-off compliance costs associated with coming to terms with the justification requirements are estimated to be around \$1.4 million.*

56. This cost estimate is based on the following:

- An estimated 3605 centres at which the Responsible Person is required to come to terms with the new justification principles.<sup>16</sup>

<sup>12</sup> ARPANSA 2007, *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation*, version for industry consultation, p. 4.

<sup>13</sup> Information provided from the Tasmanian regulator, the Department of Health and Human Services.

<sup>14</sup> A form of justification process is also applied to all medical applications under the Medicare system. For example, the Medicare Benefits Schedule Book notes that Medicare will pay benefits to services that are 'clinically relevant' or considered necessary, see section 1.1.4. These justification principles are not as stringent or enforceable as those in ARPANSA's proposed Code and do not require that detailed justification takes place before a procedure is actually undertaken. Further, the Medicare justification system does not prevent a non justified procedure from taking place but rather only prevents a Medicare rebate being granted for such a procedure.

<sup>15</sup> Information provided by State regulators indicates that the time required to adhere to the justification principle in the proposed Code would likely amount only a few minutes per procedure and that by and large, similar action is already being undertaken.

<sup>16</sup> The estimated number of centres is based on information provided by the New South Wales regulator indicating that there are 1200 centres in New South Wales or 0.2 centres per 1000 people. The number of centres in other jurisdictions were estimated using the New South Wales ratio of practices to population and ABS data on population, see ABS 2006, *Population by Age and Sex, Australian States and Territories*, cat. no. 3201.0.

- A once-off time cost of half a day (four hours) for familiarisation of the requirements of the proposed Code.
- An hourly time cost of \$100 per hour for the Responsible Person who will be required to ensure the justification principles are adhered to.<sup>17</sup>

### ***Radiation management plans***

57. Under the proposed Code there are requirements for the defined 'Responsible Person' to develop, document, resource, implement and regularly review a radiation management plan. These radiation management plans must address a raft of topics around the safety of medical practices involving radiation. Selected examples of the requirements for the radiation management plans include:
- work practices and protocols for all procedures involving exposure to ionizing radiation to ensure the proper planning and delivery of doses;
  - the training, qualifications and supervision of the staff of the medical practices and their roles and responsibilities;
  - actions necessary to manage a radiation incident including emergency procedures, reporting and investigation; and
  - arrangements for the storage of radioactive material.
58. Regulations in Queensland and Tasmania already require that practitioners prepare and implement radiation management plans similar to the requirements put forward in the proposed Code so additional compliance costs will not be incurred in these two States.<sup>18</sup> For the remaining jurisdictions, the proposed Code will bring about compliance costs in relation to preparing initial radiation management plans and reviewing and ensuring compliance.

### ***Preparation of radiation management plans***

59. The preparation of radiation management plans will bring about an initial once-off cost of about \$3.26 million based on the following:
- An estimated 2814 centres in Australian jurisdictions other than Queensland and Tasmania being required to prepare an initial radiation management plan.<sup>19</sup>
  - Indications from State regulators that it may take about four hours to prepare a radiation management plan for small centres and up to 80 hours<sup>20</sup> to prepare a radiation management plan in larger centres.
  - The assumption that 90 per cent of affected centres (equivalent to 2533 centres) are small and will therefore require 4 hours preparation time and that the remaining 10 per cent of centres (281) are large and therefore will require 80 hours preparation time.
  - Assuming an hourly time cost of \$100 per hour for Radiation Safety Officers (or the Responsible Person) who will likely be responsible for preparing the radiation management plans.<sup>17</sup>

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<sup>17</sup> The rate of \$100 per hour for Radiation Safety Officers has been used in previous ARPANSA cost-benefit analyses, for example, see ARPANSA, *Code of Practice and Safety Guide for Radiation Protection in Dentistry, Regulatory Impact Statement*.

<sup>18</sup> Information provided by the Queensland and Tasmanian regulators.

<sup>19</sup> The estimated number of centres is based on information provided by the New South Wales regulator indicating that there are 1200 centres in New South Wales or 0.2 practices per 1000 people. The number of centres in other jurisdictions were estimated using the New South Wales ratio of centres to population and ABS data on population, see ABS 2006, Population by Age and Sex, Australian States and Territories, cat. no. 3201.0.

<sup>20</sup> Based on information from State regulators.

If, however, 20% of the centres are considered to be “large” centres, this initial one-off cost for preparation of a radiation management plan could be as high \$5.4 million.

### ***Review of radiation management plans***

60. Requirements to review radiation management plans will bring about recurrent annual costs estimated to be between \$141 000 and \$1.1 million based on the following:
- An estimated 2814 centres across all jurisdictions other than Queensland and Tasmania being required to prepare a radiation management plan<sup>21</sup>.
  - Indications from State regulators that it may take between half an hour and half a day (4 hours) per year to review a radiation management plan.<sup>22</sup>
  - Time costs of \$100 per hour using data for the Radiation Safety Officers as used in existing ARPANSA regulatory impact analyses.<sup>17</sup>

### ***Total costs of radiation management plans***

61. *In total, it is estimated that the initial preparation of radiation management plans will bring about once-off compliance costs of between \$3.26 and \$5.4 million and ongoing review costs of between \$141 000 and \$1.1 million per year.*

### ***Optimisation***

62. The proposed Code requires the Responsible Person to ensure that radiation doses to occupationally exposed persons and members of the public:
- do not exceed the dose limits specified in RPS1; and
  - are kept ‘as low as reasonably achievable’ (ALARA).
63. In addition the Responsible Person must establish a program to ensure that radiation doses administered to a patient for diagnostic purposes are:
- recorded and periodically compared with ‘diagnostic reference levels’ for all commonly performed diagnostic procedures; and
  - reviewed to determine whether radiation protection has been optimised in cases where diagnostic procedure levels have been exceeded.
64. Adherence to the optimisation of the proposed Code will bring about compliance costs primarily relating to comparing exposure data to diagnostic reference levels. Information provided by State regulators indicates that exposure data are generally recorded however additional time would be needed under the proposed Code to generate comparisons with diagnostic reference levels. It is estimated that the comparison process may require several hours work per year per practice.
65. *It is estimated that the ongoing compliance costs relating to the optimisation requirements of the proposed Code would be between \$1.4 million and \$2.8 million per year.*
66. This cost estimate is based on the following:
- An estimated 3535 centres incurring additional costs relative to the status quo. Large centres in Queensland already undertake such comparison procedures.<sup>23</sup>

<sup>21</sup> Both Queensland and Tasmania require each centre to regularly review their Radiation Management Plan. This is usually done annually although some centres review their Plans more frequently.

<sup>22</sup> Some State regulators indicated that it might take far less time than half a day to review a radiation management plan. Again, the cost estimates are based on time requirements at the upper end of available estimates so as to err on the side of overestimating rather than underestimating costs. This will also ensure that the costs of doing a comprehensive review as required by the proposed Code are captured. It is also assumed that time costs involved in ensuring that Radiation Management Plans are properly being enforced are captured in the review costs.

- The assumption, based on information provided by regulators, that it may take between four and eight hours per year per practice to analyse data against reference levels.
- Time costs of \$100 per hour for the Responsible Person.<sup>17</sup>

### ***Inadvertent irradiation of the embryo or foetus***

67. In cases where an embryo or foetus inadvertently receives a radiation dose of more than 1 mSv, the Responsible Person must ensure that:
- advice from the patient be sought regarding any other medical radiation procedures that may have taken place during gestation;
  - the referrer be provided with information about the radiation dose to the embryo or foetus and the likely risks involved; and
  - the patient is informed about the magnitude of the radiation dose to the embryo or foetus and counselled about any potential risks.
68. Information supplied by jurisdictional regulators indicates that similar procedures are already in place in New South Wales and Queensland. It is assumed that additional compliance costs associated with the requirements of the proposed Code will be incurred in the remaining States and Territories.
69. *It is estimated that the compliance costs relating to the optimisation requirements of the proposed Code would be between \$7400 and \$14 700 per year.*
70. The compliance costs are relatively low because it is estimated that there are relatively few cases in which an embryo or foetus is inadvertently irradiated receiving more than 1 mSv. The cost estimate is based on the following:
- An estimate provided by the New South Wales regulator that there are about 52 cases per year (in New South Wales) in which an embryo or foetus is inadvertently exposed to a radiation dose above 1 mSv. The New South Wales estimate equates to about 0.008 exposures per 1000 people. This ratio was applied to other jurisdictions to determine estimates of the number of inadvertent exposures. For all jurisdictions less New South Wales and Queensland (neither of which will incur additional compliance costs) it is estimated that there are about 74 cases per year where an embryo or foetus inadvertently receives a dose of over 1 mSv.
  - Estimates that it would take between one and two hours per inadvertent exposure to adhere to the requirements of the proposed Code.
  - A time cost of \$100 per hour for the Responsible Person who will be required to undertake the tasks (rather than administrative staff).<sup>17</sup>

### ***Formalisation of training***

71. The proposed Code requires the Responsible Person to ensure that all individuals who may be occupationally exposed to ionizing radiation have training that relates to:
- the type of work being undertaken;
  - radiation producing equipment or source of radiation that the individual may be required to use; and
  - potential radiation hazards associated with the practice.
72. Jurisdictions currently have training requirements in place similar to those of the proposed Code for licensed staff, for example, radiographers, radiation therapists, nuclear medicine technologists and

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<sup>23</sup> Our population based estimate of the number of relevant practices in Australia is 3605 and it is estimated that 70 of these practices are large Queensland practices and therefore already undertake comparison procedures thus leaving 3535 affected practices.

medical practitioners. The proposed Code will not create any new or additional compliance costs relating to training for these staff.

73. However, the proposed Code requires *all* staff that may be occupationally-exposed to ionizing radiation to undertake appropriate training. Additional compliance costs will therefore be incurred in training nursing staff who, according to State regulators, do not currently receive formal training. There will be an initial once-off cost to train all current nurses working in areas where they may be exposed to ionizing radiation and there will also be ongoing costs in training all new nursing staff.
74. *The initial cost is estimated to be between \$204 000 and \$407 000 and the ongoing training costs are estimated to be between \$15 500 and \$31 050 per year.*
75. Details of estimates are provided below.

#### ***Initial training costs***

76. At present there are about 302 000 nurses working in Australia.<sup>24</sup> In the absence of more specific information, it is assumed that 5 per cent of nurses work in areas where they may be occupationally exposed to ionizing radiation — this equates to about 15 100 nurses.
77. Based on information provided by the State regulators, it is estimated that the training requirements of the proposed Code may take anywhere between half to one hour to fulfil.<sup>25</sup>
78. Using ABS average weekly earnings and hourly rate data for health and community services workers, the cost of nurse time is estimated at about \$27 per hour (based on weekly earnings of \$1075 and a 40-hour work week).<sup>26</sup> Total initial costs associated with training 15 100 existing nurses will be between \$204 000 and \$407 000.

#### ***Ongoing training costs***

79. About 23 000 nurses registered for the first time in 2005-06.<sup>27</sup> It is assumed that 5 per cent (equivalent to about 1150 nurses) of newly registered nurses move into areas where they may be occupationally-exposed to ionizing radiation.
80. Using earnings and hours data as immediately above and assuming that training requirements would take between half and one hour to complete then it can be expected that ongoing training costs associated with the proposed Code may be about \$15 500 and \$31 050 per year.

### **4.3 Administration costs**

81. The introduction of the proposed Code will bring about administration costs for regulators. Regulators will incur retraining and familiarisation costs and there will also be costs associated with undertaking the actual legislative process of introducing the proposed Code. This section quantifies these administrative costs.

#### ***Retraining and familiarisation***

82. With the introduction of any new code, the regulators themselves require some retraining and familiarisation with the code. It is expected that this will involve only a small cost as most of the

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<sup>24</sup> Estimates of nurses working in each Australian State are taken from nurse registration data from the State nursing boards. Data for the Northern Territory and the Australian Capital Territory are estimated based on the number of nurses per 1000 people in the States and assuming that the nurse to population ratio in the Territories is similar to that of the States.

<sup>25</sup> Information received from State regulators indicated that training requirements may take between half and one hour.

<sup>26</sup> ABS 2007, *Average Weekly Earnings*, cat. no. 6302.0, May.

<sup>27</sup> Estimate derived from nurse registration data from the State nursing boards. Data on newly registered nurses in the Northern Territory and the Australian Capital Territory are estimated based on the number of nurses per 1000 people in the States and assuming that the nurse to population ratio in the Territories is similar to that of the States.

requirements of the proposed Code have been used in other areas of radiation protection in Australia for some time now.

83. It is estimated that the number of hours associated with the familiarisation with any new code may be in the order of 40 person-hours. Using an average figure of approximately \$25 to \$30 per hour per staff member<sup>28</sup>, the cost to the regulatory body for retraining/familiarisation would be between \$1000 and \$1200. Nationally, this equates to between \$8000 and \$9600.

#### ***Legislative changes***

84. The introduction of the proposed Code would likely mean that each jurisdiction may need to amend regulations. Changing regulations requires resources and costs on behalf of government, including seeking policy approvals, draft changes and making regulations.
85. These costs will be one-off and will have no further impact on the way in which jurisdictions regulate radiation protection issues nor will they have any impact on industry, or the public more generally. While such administrative costs are rarely costed in regulatory impact analysis, it should be acknowledged that even machinery of government legislative changes impose costs. By way of example in Western Australia, the average cost of legislative amendments that was directly attributable to a department was estimated to be around \$40 800.<sup>29</sup> Assuming legislative amendment costs are the same in each jurisdiction then national costs may be in the order of \$326 400.
86. *The total administrative burden associated with the introduction of the proposed Code will result in a once-off cost of about \$326 000.*

#### **4.4 Summary of costs**

87. A summary of costs incurred under the proposed Code is provided in Table 3.1.

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<sup>28</sup> As used in existing ARPANSA regulatory impact analyses, see for example, ARPANSA 2005, *Regulatory Impact Statement, Code of Practice and Safety Guide for Radiation Protection in Dentistry*.

<sup>29</sup> Department of Local Government and Regional Development 2006, *Annual Report 2005-06*, p. 26.

**Table 4.1 Summary of Costs of Proposed Code**

Cost category	Discussion of costs relative to the <i>status quo</i>
Compliance costs: —justification  —radiation management plans  —optimisation  —inadvertent irradiation of embryo or foetus  —formalisation of training	<p>A once-off compliance cost as the Responsible Person in each relevant medical centre comes to terms with the new regulations of about \$1.4 million.</p> <p>In total, it is estimated that the initial preparation of radiation management plans will bring about once-off compliance costs of between \$3.26 and \$5.4 million and ongoing review costs of between \$141 000 and \$1.1 million per year.</p> <p>It is estimated that the ongoing compliance costs relating to the optimisation requirements of the proposed Code would be between \$1.4 and \$2.8 million per year.</p> <p>It is estimated that the ongoing compliance costs relating to the procedures required in cases of inadvertent irradiation of the embryo or foetus would be between \$7 400 and \$14 700 per year.</p> <p>The initial cost is estimated to be between \$204 000 and \$407 000 and the ongoing training costs are estimated to be between \$15 500 and \$31 050 per year.</p>
Administration costs	The administrative burden associated with the introduction of the proposed Code will bring about a once off cost of about \$326 000.
<b>Total costs</b>	<p><b><i>Initial once-off costs estimated to be between \$5.2 and \$7.5 million.</i></b></p> <p><b><i>Ongoing costs are estimate to be between \$1.6 and \$3.9 million per year.</i></b></p>

## Chapter 5. Benefits of the proposed Code of Practice

### 5.1 Introduction

88. This chapter outlines the costs and benefits of the proposed Code relative to the *status quo*. The main areas where the proposed Code is expected to provide for beneficial outcomes are in health and safety, uniformity, dynamic efficiency and consistency with international standards.

### 5.2 Health and safety benefits

89. 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 primarily arise from the following areas:

- improving radiation protection awareness and safety culture throughout the industry by formal requirements for radiation management plans;
- reducing unnecessary exposure;
- the formalisation of training for all occupational staff who may be exposed to ionizing radiation; and
- the formalisation of occupational dose limits through referring to Radiation Protection Series No. 1.

90. These health and safety benefits are discussed below.

#### *Improving radiation protection awareness*

91. The proposed requirement for a formal written radiation management plan combined with the formalisation of training for all occupational staff will increase safety awareness in the medical industry. Better safety awareness and improved safety culture should lead to a reduction in the potential for incidents or abnormal radiation exposures. These benefits would flow to the community as a whole from reduced incident investigation or compliance activity costs, and a greater confidence in the level of safety in the industry and a lower likelihood of incidents leading to less potential for harm to the environment.

92. Among other things, radiation management plans are required to stipulate practices to:

- ensure that the prescribed radiation procedure is performed on the correct patient;
- ensure the proper planning and delivery of radiotherapy doses;
- govern the preparation and dispensing of radiopharmaceuticals; and
- optimise the protection of the patient.

93. These requirements are expected to markedly reduce the number of radiation incidents in Australia. It would not take many avoided radiation incidents to generate significant benefits. For example, as a rough guide, a human capital model of workplace costs suggests that the major categories of indirect costs associated with workplace-related disease-induced death — i.e. consequential overtime, loss of productivity, staff turnover costs, retraining costs, lost future earnings, legal costs, pain and suffering, loss of income, health and medical costs, loss of gross domestic product (i.e. human capital), and loss of tax revenue — are worth between \$1.6 million and \$2.5 million per workplace-related death.<sup>30</sup>

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<sup>30</sup> Bureau of Transport and regional Economics 2000, *Road Crash Costs in Australia*, Report 102, No. 79, AGPS, Canberra. P. Ableson 2003, 'The Value of Life and Health for Public Policy', *The Economic Record*, 79: S2S13. Bureau of Transport and Regional Economics 2006, *Cost of Aviation Accidents and Incidents*, Report 113.

***Reducing unnecessary exposure***

94. The proposed Code, through the explicit justification criterion, is intended to reduce instances whereby patients are unnecessarily exposed to ionizing radiation. The criterion requires that a medical procedure involving exposure to ionizing radiation should not go ahead unless it is established that there is a sufficient benefit that can be derived from the procedure.
95. While there are already some implicit or explicit justification requirements in place in jurisdiction based regulations, the explicit nature of the justification procedure as included in the proposed Code is expected to reduce instances of unnecessary exposure. This will result in health and safety benefits primarily for the general population but also for occupationally-exposed individuals.
96. A UK study estimated the potential annual dose savings that could be achieved if unnecessary clinical unhelpful examinations were eliminated.<sup>31</sup> The results are presented here by way of example of the scope of dose reductions that may be achievable under the proposed Code and the formalisation of the justification principle — it is not intended that the results from the UK study be applied directly to the situation in Australia.
97. Rough quantitative estimates derived in the study by the Royal College of Radiologists and the National Radiological Protection Board indicate that the elimination of clinically unhelpful examinations alone could reduce the collective dose by about 3200 man Sv per year. Considering other measures such as reducing fluoroscopy time and reducing repeat rates of certain medical procedures could take the total collective dose reduction to 7500 man Sv per year. To put this in perspective, this reduction is equivalent to a reduction of nearly one-half in collective population dose from x-rays at the time that the research was undertaken.
98. Using a quantitative approach to provide indicative dose savings through the tightening of the justification principle indicates that the potential for benefits arising in the area of CT scans alone is significant. It is worthy of note that numerous research articles have pointed to the growing use of CT scans in Australia and the relatively high per capita doses that the Australian population receives from CT scans relative to other developed nations.<sup>32</sup>
99. Available data indicate that the mean dose to patients receiving a CT scan is 11.7 mSv<sup>33</sup> and that in 2006-07, about 2.4 million CT scans were undertaken in Australia.<sup>34</sup> The result is a collective effective dose of about 27 800 Sv. Reducing the number of CT scans undertaken in Australia by as little as 1 per cent would reduce the collective dose by about 278 Sv. Given a cost per person sievert of \$46 675<sup>35</sup>, the benefits that would arise would be in the order of \$13 million per year. Reducing the number of CT scans undertaken each year by 5 per cent would result in benefits in the order of \$65 million per year and a 10 per cent reduction would result in benefits in the order of \$130 million per year.
100. The above estimates of potential benefits are derived having after considered the impact that the proposed Code and its justification principle may have on the number of CT scans undertaken. Reductions in doses from nuclear medicine, radiotherapy and other forms of radiology would also result in benefits being derived. These potential benefits could not be estimated due to data limitations.

<sup>31</sup> Royal College of Radiologists and the National Radiological Protection Board 1990, *Patient Dose Reduction in Diagnostic Radiology*, Documents of the National Radiation Protection Board, vol. 1, no. 3.

<sup>32</sup> See for example, D.V Webb, S.B Solomon and J.E.M Thomson 1999, 'Background Radiation Levels and Medical Exposure Levels in Australia', *Radiation Protection in Australasia*, vol. 16, no.2; or K.N Wise and J.E.M Thomson 2004, 'Changes in CT Radiation Doses in Australia from 1994 to 2002', *The Radiographer*, vol. 51, August, pp. 81-85.

<sup>33</sup> K.N Wise and J.E.M Thomson 2004, 'Changes in CT Radiation Doses in Australia from 1994 to 2002', *The Radiographer*, vol. 51, August, pp. 81-85.

<sup>34</sup> Based on data provided by Medicare Australia 2007, *Group Statistics Reports*, [http://www.medicareaustralia.gov.au/statistics/dyn\\_mbs/forms/mbsgtab4.shtml](http://www.medicareaustralia.gov.au/statistics/dyn_mbs/forms/mbsgtab4.shtml), Accessed 1 August 2007.

<sup>35</sup> Derived from estimates made by the Royal College of Radiologists and the National Radiological Protection Board in the UK. Value derived based on harm associated with exposure to ionizing radiation. The estimate used in this analysis has been adjusted for inflation and exchange rate movements. For more information see, Royal College of Radiologists and the National Radiological Protection Board 1990, *Patient Dose Reduction in Diagnostic Radiology*, Documents of the National Radiation Protection Board, vol. 1, no. 3.

### ***Formalisation of training***

101. The formalisation of training for all workers who may be occupationally exposed to ionizing radiation will improve occupational safety and particularly occupational exposures. In particular, the Code will improve safety for occupationally-exposed nurses for whom regulations requiring training do not currently apply.
102. If it is assumed that the proposed Code will reduce effective doses received by occupationally-exposed nurses by as little as 1 per cent — this is broadly consistent with the approach taken by New South Wales and is consistent with the approach adopted in the recent cost-benefit analysis for the National Directory — then the benefit to the community could be about \$5600 per year.<sup>36</sup>
103. The introduction of one single set of training requirements for all occupationally-exposed individuals will also result in national consistency in training requirements and will work to decrease any uncertainties caused by differences across jurisdictions.

### ***Tightening of occupation dose limits***

104. The proposed Code sets dose limits for occupationally exposed individuals and members of the public by referring to the dose limits established in RPS 1 (Recommendations for Limiting Exposure to Ionizing Radiation).
105. Current regulations in most jurisdictions already incorporate standards that are equivalent to those set out in RPS 1 however there are some cases whereby the proposed Code, through its linking with RPS 1, is expected to bring about health and safety benefits. These benefits, though difficult to quantify, are discussed below.
  - The proposed Code sets annual dose limits for exposure to the lens of the eye, the skin (for occupationally-exposed individuals and members of the public) and the hands and feet (for occupationally-exposed individuals only). These dose limits, which have been incorporated due to current international thinking on safe levels of radiation exposure, are absent in the Western Australian regulations.<sup>37</sup> The introduction of the proposed Code will deliver health and safety benefits to occupationally-exposed individuals and members of the public in Western Australia via the incorporation of more prescriptive dose limits.
  - The proposed Code sets occupational dose limits for female employees who are pregnant such that the embryo or foetus is to receive no more than the specified dose limits for general members of the public. The specification of such dose limits is more specific than current Victorian regulations that stipulate that ‘the embryo or foetus must be afforded the level of radiation protection specified by the Chief General Manager having regard to internationally accepted standards of practice’.<sup>38</sup> The specification of exact dose limits in the proposed Code provides an added degree of clarity and hence safety relative to the current Victorian regulations.
  - Dose limits in the Northern Territory are not measured in terms of millisieverts but instead are measured in units of rems. The use of rems is not consistent with current international standards of measurement. The adoption of the proposed Code would bring the Northern Territory into line with current developments in the field of medical radiation.<sup>39</sup>

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<sup>36</sup> These calculations are based on:  
—an assumed actual exposure for occupationally-exposed nurses of 0.8 mSv per year based on data available in UNSCEAR 2000, *Sources and Effects of Ionizing Radiation*, Annex E;  
—an assumed 15 100 nurses who are occupationally-exposed to ionizing radiation.  
—an estimated cost per person sievert of \$46 675 — which is an inflation adjusted and exchange rate converted estimate for occupational exposure. This estimate is taken from: Royal College of Radiologists and the National Radiological Protection Board 1990, *Patient Dose Reduction in Diagnostic Radiology*, Documents of the National Radiation Protection Board, vol. 1, no. 3

<sup>37</sup> *Radiation Safety (General) Regulations 1983*, Schedule 1, p. 85.

<sup>38</sup> *Health (Radiation Safety) Regulations 1994*, Schedule 1, p.50.

<sup>39</sup> *Radiation (Safety Control) Act*, Schedule 3, p. 25.

### 5.3 Other benefits

106. Other benefits from the proposed Code include uniformity, dynamic efficiency and international standing and consistency benefits. Each of these benefits is discussed below.

#### *Uniformity*

107. While there are costs associated with complying with the proposed new code, there are also some compliance benefits. In particular:
- the proposed Code will give clear up-to-date guidance and provide advice on appropriate exposure levels for occupationally-exposed individuals;
  - a single Code would also enable a uniform approach to radiation protection for medical workers 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 the requirements to be adhered to in respect of medical procedures involving ionizing radiation.
108. Overall, compliance costs are likely to be reduced for medical staff and medical institutions that have cross-jurisdictional operations, that is, they will be able to have a single standardised operational approach across jurisdictions.
109. The proposed Code will bring administrative benefits to regulators as it offers the simplicity of an all-inclusive framework that is clear in its requirements and consistent across jurisdictions. It is expected that long-term administrative costs will be lower under the proposed Code than under the *status quo*.

#### *Dynamic efficiency*

110. 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.
111. Such dynamic efficiency cannot, to such a great extent, be achieved under the *status quo* because some jurisdictions are still using NHMRC codes which are no longer being updated to reflect new information.

#### *International standing and consistency*

112. The proposed 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 10 (1991). The proposed Code would incorporate current international best practice with respect to administering medical procedures involving ionizing radiation.

### 5.4 Summary of benefits

113. A summary of benefits incurred under the proposed Code is provided in Table 5.1.

**Table 5.1 Summary of Benefits**

Benefit category	Discussion of benefits relative to the <i>status quo</i>
Health and safety benefits from: —improving radiation protection awareness  —reducing unnecessary exposure  —formalisation of training  —tightening of occupational-dose limits	Improved radiation protection awareness as a result of requirements to implement radiation management plans. It would not take many avoided incidents to generate significant benefits (workplace related disease induced deaths are estimated to cost between \$1.6 million and \$2.5 million per death).  The justification principle is expected to reduce unnecessary exposures. Considering CT scans alone: a one per cent reduction in the number of CT scans undertaken would deliver benefits in the order of \$13 million per year.  Formalisation of training for all staff but particularly nurses should bring about lower levels of occupational exposure. Benefits of small reductions in exposure for nurses alone may be in the order of \$5600 per year.  There are cases whereby the proposed Code, through its linking with RPS 1, is expected to bring about health and safety benefits to occupationally-exposed workers by tightening and updating dose requirements.
Uniformity	National uniformity will provide certainty and hence efficiencies and encourage inter-jurisdictional migration of workers. Longer term administrative costs will also be lower under the proposed Code relative to the <i>status quo</i> .
Dynamic efficiency	The proposed Code of Practice will ensure consistency is maintained over time and that radiation protection standards are current through regular updates by the Radiation Health Committee.
International standing and consistency	The proposed Code would incorporate current international best practice with respect to administering medical procedures involving ionizing radiation.
<b>Total benefits</b>	<p><b><i>Large benefits may be derived from reductions in unnecessary exposures — a one per cent reduction in the number of CT scans undertaken would generate benefits in the order of \$13 million per year.</i></b></p> <p><b><i>In addition, other health and safety initiatives will potentially bring large benefits to the community. Uniformity will reduce longer term compliance and administration costs and dynamic efficiency will ensure radiation protection in Australia remains up to date with developments in best practice.</i></b></p>

## Chapter 6. The self regulation model

### 6.1 Introduction

114. 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. Self regulation can be preferable to government intervention because it can allow industry to meet regulatory objectives in a more efficient way than if it were constrained to direction from government.
115. An Office of Best Practice Regulation Regulatory checklist lists three criteria that should apply for self regulation to be successful,<sup>40</sup> none of which strongly apply to the radiation protection:
- *There is no major public interest concern, in particular no major public health and safety concern* — the exposure of individuals to ionizing radiation may bring about health benefits but it also poses a variety of risks in that over-exposure or accidental exposure can be very damaging to human health. In short, there can be serious health and safety concerns associated with overexposure to radiation.
  - *The problem is a low risk event of low impact or significance, that is, the consequences of self regulation failing to resolve a specific problem are small* — over-exposure to ionizing radiation brings about direct health implications. The problem is not low risk and the adverse health impacts can be severe. The consequences of over-exposure are not of low significance and therefore this criterion does not apply to radiation protection.
  - *There is an incentive for industry to develop and comply with self-regulatory arrangements* — self regulation is most effective when:
    - the product being regulated is non-essential — diagnosis or treatment using radiation therapy is far from a non-essential product as it is critical to the maintenance of human health for a great variety of patients;
    - the market is characterised by a small number of businesses who communicate with each other and are members of industry associations — the medical radiation industry is not characterised by a small number of businesses. In New South Wales alone, there are about 1200 practices that are able to undertake medical procedures involving ionizing radiation. Further there is no single peak industry body that could organise itself to participate in the development of an industry standard — radiation specialists belong to various professional bodies, for example, the Royal Australian and New Zealand College of Radiologists, the Australian Institute of Radiographers and the Australian and New Zealand Society of Nuclear Medicine. The professions these bodies represent may have inconsistent priorities with regard to radiation safety, which could in turn result in non-uniform standards; and
    - the industry has a strong desire for self regulation to work — the medical practice industry has a long history of being regulated and while there more than likely is a desire for self regulation to work, there are impediments (such as the diverse and multi-faceted nature of the industry or the highly complex procedures that are performed) which may see self regulation as being difficult to effectively implement. The industry itself is used to being regulated and may struggle to devote the necessary resources to self regulation to see it work successfully.
116. Given the nature of the risks to human health and the nature of the industry, self regulation does not provide a workable alternative to regulation in the fields of nuclear medicine, radiotherapy and radiology.

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<sup>40</sup> Taskforce on Industry Self-Regulation 2000, *Industry Self Regulation in Consumer Markets*, August.

## Chapter 7. Summary of cost benefit analysis

### 7.1 Summary

117. This cost-benefit analysis assesses the merits of three models of regulation for radiation protection in the medical applications of ionizing radiation, these are:
- the *status quo*;
  - the proposed Code of Practice put forward by ARPANSA; and
  - a self regulation model.
118. After giving consideration to the factors required for a self regulation model to be successful, it is concluded that self regulation is not deemed to be suitable for a field whereby the health and safety of the public is at risk from exposure to ionizing radiation. The significance of the risks involved combined with the general level of public interest concern regarding exposure to ionizing radiation and the multi-faceted and diverse nature of the medical industry are all factors that do not work in favour of self regulation.
119. The remaining options of the maintenance of the *status quo* and the introduction of ARPANSA's proposed Code each have their costs and benefits that are not necessarily spread evenly among the community. Relative to the status quo, the major distributional impacts associated with the proposed Code include:

#### *Once-off costs*

- once-off establishment costs for medical practices brought about by the compliance requirements (justification, radiation management plans and training) of between \$5.2 million and \$5.4 million;
- initial administrative costs on governments as they become accustomed to the new regulations of about \$330 000. However, ongoing administrative costs should be reduced over time;

#### *Ongoing costs*

- ongoing compliance costs borne by medical practices of between \$1.6 million and \$3.9 million per year as a result of the detailed health and safety requirements of the proposed Code;

#### *Ongoing benefits*

- improved health outcomes could result from an increased awareness of safety and tightened dose limits that are aligned with Radiation Protection Series No.1 and international standards — it would not take many avoided incidents to generate significant benefits (workplace related disease induced deaths are estimated to cost between \$1.6 million and \$2.5 million per death);
  - potential reductions in medical exposures as the justification principle in the proposed Code results in fewer unnecessary procedures being undertaken will bring substantial benefits to the community — a one per cent reduction in the number of CT scans alone could result in benefits in the order of \$13 million per year;
  - improved health outcomes for occupationally-exposed workers through standardised training and a tightening of occupational dose limits;
  - the establishment of uniform regulations that would reduce costs for organisations operating in several jurisdictions and would minimise potentially dangerous confusion and encourage businesses and workers to move between jurisdictions; and
  - the establishment of regulations that are able to be updated such that they can be kept consistent with international best practice.
120. The costs and benefits of the proposed Code are summarised in table 6.1.

**Table 7.1 Summary of Costs and Benefits**

Cost and benefit category	Discussion of benefits relative to the <i>status quo</i>
<b>COSTS</b>	
Compliance costs: —justification —radiation management plans —optimisation —inadvertent irradiation of embryo or foetus —formalisation of training Administration costs	<p>A once off compliance cost as the Responsible Person in each relevant medical centre comes to terms with the new regulations of about \$1.4 million.</p> <p>In total, it is estimated that the initial preparation of radiation management plans will bring about once-off compliance costs of between \$3.26 and \$5.4 million and ongoing review costs of between \$141 000 and \$1.1 million per year.</p> <p>It is estimated that the ongoing compliance costs relating to the optimisation requirements of the proposed Code would be between \$1.4 and \$2.8 million per year.</p> <p>It is estimated that the ongoing compliance costs relating to the procedures required in cases of inadvertent irradiation of the embryo or foetus would be between \$7 400 and \$14 700 per year</p> <p>The initial cost is estimated to be between \$204 000 and \$407 000 and the ongoing training costs are estimated to be between \$15 500 and \$31 050 per year.</p> <p>The administrative burden associated with the introduction of the proposed Code will bring about a once off cost of between \$334 000 and \$336 000.</p>
<b>Total costs</b>	<p><b>Initial once-off costs estimated to be between \$5.2 and \$7.5 million.</b>  <b>Ongoing costs are estimate to be between \$1.6 and \$3.9 million per year.</b></p>
<b>BENEFITS</b>	
Health and safety benefits from: —improving radiation protection awareness —reducing unnecessary exposure —formalisation of training —tightening of occupational-dose limits Uniformity Dynamic efficiency International standing and consistency	<p>Improved radiation protection awareness as a result of requirements to implement radiation management plans. It would not take many avoided incidents to generate significant benefits (workplace related disease induced deaths are estimated to cost between \$1.6 million and \$2.5 million per death).</p> <p>The justification principle is expected to reduce unnecessary exposures. Considering CT scans alone: a one per cent reduction in the number of CT scans undertaken would deliver benefits in the order of \$13 million per year.</p> <p>Formalisation of training for all staff but particularly nurses should bring about lower levels of occupational exposure. Benefits of small reductions in exposure for nurses alone may be about \$5600 per year.</p> <p>There are cases whereby the proposed Code, through its linking with RPS 1, is expected to bring about health and safety benefits to occupationally-exposed workers by tightening and updating dose requirements.</p> <p>National uniformity will provide certainty and hence efficiencies and encourage inter-jurisdictional migration of workers. Longer term administrative costs will also be lower under the proposed Code relative to the <i>status quo</i>.</p> <p>The proposed Code of Practice will ensure consistency is maintained over time and that radiation protection standards are current through regular updates by the Radiation Health Committee.</p> <p>The proposed Code would incorporate current international best practice with respect to administering medical procedures involving ionizing radiation.</p>
<b>Total benefits</b>	<p><b>Large benefits may be derived from reductions in unnecessary exposures — a one per cent reduction in the number of CT scans undertaken would generate benefits in the order of \$13 million per year.</b>  <b>In addition, other health and safety initiatives will potentially bring large benefits to the community. Uniformity will reduce longer term compliance and administration costs and dynamic efficiency will ensure radiation protection in Australia remains up to date with developments in best practice.</b></p>

## Chapter 8. Consultation

121. Three Working Groups were initially involved in the preparation of three separate draft Codes and Safety Guides to cover radiology nuclear medicine and radiotherapy. The Radiation Health Committee decided that it would be prudent to combine the three Codes into a single combined Code while keeping the three separate Safety Guides to outline best practice for those three modalities. The three Working Groups comprised health professionals from all three medical fields including radiologists, nuclear medicine specialists, radiation oncologists, medical physicists, nuclear medicine technologist, radiotherapists, radiographers and regulators.
122. All State, Territory and Commonwealth regulators participated in the development of the proposed Code via their membership of the Radiation Health Committee.
123. A draft combined Code of Practice was made available for a six week period of industry consultation from 28 May to 2 July 2007. Following that consultation period, a sub group of the Radiation Health Committee revised the draft Code based on the comment received with a view to placing the latter on the ARPANSA web site at [www.arpansa.gov.au](http://www.arpansa.gov.au) for a period of public comment until 26 October 2007. The public comment period commenced on 24 August 2007. The following organisations were advised of the availability of this revised ARPANSA Code and this Regulatory Impact Statement and submissions were requested:
- ACPSEM
  - ANZAPNM
  - ANZSNM
  - Australasian Radiation Protection Society
  - Australian Institute of Radiography
  - Chairman, Tasmanian Radiation Advisory Council
  - Chief Physicist, Radiation Oncology Victoria
  - Radiation Safety Adviser, Launceston General Hospital
  - Radiation Oncology Department, Royal Prince Alfred Hospital
  - The Royal Australasian College of Physicians
  - The Royal Australian and New Zealand College of Radiologists
  - Senior Physicist, Radiation Oncology Victoria
  - Chief Physicist, Department of Medical Physics, Royal Adelaide Hospital
  - Radiation Health Committee
  - Radiation Health and Safety Advisory Council
  - Nuclear Medicine Code and Safety Guide Working Group
  - Radiology Code and Safety Guide Working Group
  - Radiotherapy Code and Safety Guide Working Group
  - Radiation Safety Advisor, St Vincent's Hospital
  - The Royal Australian and New Zealand College of Radiologists
  - Royal Hobart Hospital

**Note:** This space will be expanded in the final RIS to list other organisations that have been invited to comment.

## Chapter 9. Evaluation and Preferred Option

### 9.1 Conclusions and recommendations

124. Over time, continuing with the *status quo* could actually lead to a deterioration in health outcomes. This is because the *status quo* is out of step with changes to international standards and Radiation Protection Series No.1. As a result, there is a risk of confusion for users as to which standard is applicable in any given situation, and the inconsistency is likely to undermine adherence to the ALARA principle more broadly. In a practical sense, this could potentially lead to an increase in the exposure to radiation of people exposed to ionizing radiation through medical applications.
125. Other shortcomings of the status quo (such as those discussed in chapter 3) can be overcome by the introduction of the proposed Code. The grey areas in the current regulations and areas of regulatory omission will be rectified by the proposed Code and again this will lead to improved health and safety relative to the *status quo* for occupationally-exposed workers and the community more generally.
126. The preferred option for the future regulation of radiation protection in medical applications involving ionizing radiation is the proposed Code of Practice. The proposed Code will incorporate current radiation protection and practices.
127. The proposed Code will bring about costs to organisations in initially implementing the regulations and adhering to the sometimes more stringent requirements. In total, these costs are expected to amount to between \$5.2 and \$7.5 million for once-off costs and between \$1.6 and \$3.9 million in ongoing costs.
128. The potential benefits of the proposed Code are very significant when potential lower exposures to ionizing radiation are considered. The proposed Code would not have to have much of an effect to bring substantial net benefits to the community. If the proposed Code reduced the number of CT scans by 1% alone (irrespective of potential reductions in other forms of medical applications of ionizing radiation), it would generate benefits of about \$13 million per year.
129. In addition, the proposed Code is expected to lower exposures to occupationally exposed individuals and, consequently, also bring ongoing benefits to the community. For example, better training may lead to reductions in exposure amongst the nursing profession. The uniformity of the proposed Code would reduce costs for organisations operating in several jurisdictions, as it would standardise requirements. The health and safety benefits of the proposed Code are significant especially considering that in the longer term, the implementation of the proposed Code will allow regulations to keep pace with international best practice, unlike the *status quo*.
130. Of all the options, the proposed Code is the most effective way of ensuring the continued low effective doses of radiation associated with medical applications. The proposed Code aligns health and safety requirements with international best practice and Radiation Protection Series No.1, and would remain current through regular updates to reflect changes in international dose limits. Of all the options, the proposed Code best supports the application of the ALARA principle, which is at the heart of the system of radiation protection across Australia.

**Stakeholders who disagree with the conclusions above are urged to substantiate their view with a description and quantification of costs to apply, implement, administer or enforce the proposed ARPANSA Code of Practice or Safety Guides.**

**Stakeholders are also invited to provide input with relevant information that could add value to the Regulatory Impact Statement.**

## **Chapter 10. Implementation and Review**

### **10.1 Implementation and review**

131. The proposed Code would be published by ARPANSA under its Radiation Protection Series and made available to the medical profession and to regulators for adoption. ARPANSA's Radiation Health Committee would review the Code within 10 years of its commencement to ensure that it is still relevant to radiation protection needs. Earlier review would be undertaken if there were problems in the implementation of the Code, if international or national radiation protection objectives change or if there was new information from international research.
132. Once published, the Code would be referenced in the National Directory of Radiation Protection, which has been established to enhance uniformity of radiation controls between jurisdictions in Australia. The National Directory was agreed by Health Ministers at the AHMC meeting in August 1999 as the mechanism to achieve greater uniformity. All jurisdictions will then adopt the Code within their regulatory frameworks, in a similar way to other Radiation Protection Series Codes and Standards.

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