



Australian Government

Australian Radiation Protection and Nuclear Safety Agency

Regulatory Impact Statement

Code of Practice for Radiation Protection in the use of Ionizing Radiation by Chiropractors

Public consultation draft

Comment on the Regulatory Impact Statement and draft Code of Practice should be forwarded by 15 May 2009 to:

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The cost-benefit analysis is for this RIS is based on a separate RIS originally prepared for ARPANSA by The Allen Consulting Group.

Chapter 1. Introduction

1.1 Health effects of ionizing radiation

1. Doses below the thresholds for deterministic effects¹ may cause cellular damage, but this does not necessarily lead to harm to the individual: the effects are probabilistic or ‘stochastic’ in nature. There is good epidemiological evidence – especially from studies of the survivors of the atomic bombings in Japan – that, for several types of cancer, the risk increases roughly linearly with dose. There is statistically significant risk in the range 0-100 millisievert and useful risk estimates for doses as low as 50-100 millisieverts. The risk factor averaged over all ages and cancer types is about 1 in 10,000 per millisievert. The risk of inducing a heritable mutation is estimated to be about 2 in 100,000 per millisievert². Because of the chance nature of cell damage, not everyone who is exposed to the same amount of radiation will get cancer.
2. The embryo or fetus and children are more sensitive to radiation exposure than adults. A dose to the fetus of 100–500 millisievert can cause developmental problems such as malformation or reduced IQ.
3. While studies indicate evidence of radiation-induced effects, epidemiological research has been unable to establish unequivocally that there are effects of statistical significance at doses below a few tens of millisieverts. Nevertheless, given that no threshold for stochastic effects has been demonstrated, and in order to be cautious in establishing health standards, the proportionality between risk and dose observed at higher doses is presumed to continue through all lower levels of dose to zero. This is called the linear, no-threshold (LNT) hypothesis and it is used for developing radiation protection standards. For radiation protection purposes the risk of radiation-induced fatal cancer is taken to be about 1 in 20,000 per millisievert of dose for the population as a whole.

1.2 Chiropractic applications of ionizing radiation

4. This regulatory impact statement applies to the proposed Code of Practice for Radiation Protection in the use of Ionizing Radiation by Chiropractors put forward by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).
5. Chiropractic X-ray examinations involve exposing chiropractic clients (and potentially practitioners and members of the public) to ionizing radiation. There is a natural dichotomy in chiropractic X-ray analyses of a client in that while the radiation is being used to produce an X-ray image, the doses used can be associated with an increased risk of stochastic effects to both the client and other parties.
6. Potential risks are minimised by the proper use of equipment in a fashion that delivers the radiation to the specified area whilst limiting any extraneous radiation production or exposure. The proposed ARPANSA Code of Practice is designed to achieve such an outcome while minimising any unnecessary exposure to the client and occupationally-exposed persons.

Chiropractic X-ray procedures

7. Chiropractic X-ray imaging involves the use of radiation from an X-ray machine that passes through the patient to produce an image, usually of the spine. X-rays penetrate flesh and bone to different degrees and produce images of the internal structures of the body on film.
8. It is difficult to obtain accurate statistics on the annual number of chiropractic X-ray examinations as rebates are not given through Medicare. Further, rebates from private health funds are only given if extra coverage is taken out by the insured to cover chiropractic procedures. A Canadian study by Huda

¹ Biological effects of exposure to ionizing radiation that manifest in the short term due to extreme radiation doses received in a short time. Deterministic effects have a threshold and the severity of the effect depends on the magnitude of the dose beyond that threshold. Deterministic effects range from nausea, vomiting, burns and even death in the short term.

² *Hereditary Effects of Radiation*, UNSCEAR 2001 Report to the General assembly, with Scientific Annex

and Sourkes³ however, cites that 33,000 spinal X-ray studies were performed by chiropractors in Manitoba (population: 1,000,000) in 1987, representing 3.6% of the total number of diagnostic X-ray studies performed in the province in that year. The annual collective dose from chiropractic X-ray examinations was estimated to be 7.3 person-Sv or about 1.2% of the total population exposure from diagnostic procedures that utilise ionizing radiation.

9. Further, a UK study by Hart and Wall⁴ cites an estimated contribution to the 1997/1998 collective dose from chiropractic X-ray procedures in the UK to be 34 person-Sv. The study notes that a major change in the frequency of chiropractic X-ray examinations would have little effect on the total UK population dose over time and therefore, chiropractic X-ray procedures were assumed to maintain the same absolute contribution to population dose for the purposes of their 2004 study as the earlier figures. The UK value represents 0.15% of the estimated annual per caput effective dose of 0.38 mSv from health care in the UK. It also represents between 41-44% of the contribution to the collective dose from dental examinations as cited in the report.
10. In the absence of substantiated figures for the number of chiropractic X-ray examinations performed in Australia each year, it would not be unreasonable to assume that the contribution to the collective dose from chiropractic X-ray procedures would be about 1% based on the Canadian and UK figures.
11. The Chiropractors' Association of Australia (CAA) has advised⁵ that there are approximately 3000 chiropractic centres in Australia. Each centre sees approximately 10 "new" clients per week resulting in a figure of about 1.44 million chiropractic clients in Australia, or nearly 7% of the total population⁶. The CAA estimates that 10% of the Australian population have been to a chiropractor at some time although many do not return or continue with their treatment. Consequently, the CAA assumes that the figure of 7% would be an upper value.
12. The CAA also advise that 12-16% of new clients are X-rayed on dedicated chiropractic equipment resulting in a total number of chiropractic X-rays taken each year of between 172,800 and 230,400. It should be noted that these figures do not include chiropractic clients referred to radiology clinics for radiography.
13. The Queensland regulator has advised that approximately 447 chiropractic X-rays are taken each week on 47 dedicated chiropractic X-ray machines in that jurisdiction, or 23,224 per annum.
14. Using these values, if we assume that the ratios are similar for Australia, a country with a similar health care regime as the UK, the collective dose from chiropractic X-ray to those Australians who visit chiropractors would be between 306-642 person-Sv⁷. To minimize the risk of health effects arising from radiation exposure, all exposures should be kept as low as reasonably achievable, social and economic factors being taken into account.

1.3 Current regulations

15. Regulations governing chiropractic X-ray procedures 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, chiropractic X-ray procedures are governed by specific regulations and also include regulation by broad requirements that apply to practices involving any

³ W. Huda, A.M. Sourkes 1989, 'Individual and population doses in Manitoba from chiropractic x-ray procedures', *Journal of Radiological Protection* Vol. 9 No. 4 (1989) pp 241-245.

⁴ D. Hart, B.F Wall 2004, 'UK population dose from medical X-ray examinations', *European Journal of Radiology* 50 (2004) pp 285-291.

⁵ From a personal discussion with the Executive Director of the Chiropractors' Association of Australia – Victoria.

⁶ Based on 3000 centres by 10 "new" patients for 48 working weeks. The Australian population was taken as 21,000,000.

⁷ Based on minimum and maximum collective dose ratios of chiropractic X-ray to dental radiography of 41% and 44% given in the UK study and the collective dose from dental radiography data of 50-100 person-Sv given in the Regulatory Impact Statement for the Code of Practice and Safety Guide for Radiation Protection in Dentistry, ARPANSA, 2005.

form of exposure to radiation. Current State and Territory regulators include health and environmental departments (Table 1.1).

1.4 Statement of the Problem

16. The lack of national uniformity in radiation protection legislation for the chiropractic X-ray 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 X-ray equipment 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. Chiropractors, for example, require licensing in some jurisdictions but not others and the range of procedures that they can perform also vary across the jurisdictions. 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.
17. 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, chiropractic clients, the public and the environment. For example, the dose limits prescribed in the Northern Territory legislation are still in the non-SI unit of rem rather than the now used quantity, sievert.
18. There are many hundreds of Australians who are occupationally potentially exposed to ionizing radiation as a result of the chiropractic use of ionizing radiation. For example, Victoria alone issues over two hundred operator licences to chiropractors to carry out X-ray procedures⁸. While the fundamental criteria for limiting occupational exposure are set out in the Radiation Protection Series No. 1, there are specific occupational protection issues relating the chiropractic use of radiation that need to be dealt with. However, without adequate shielding, operational procedures including the optimisation of radiation doses and consideration of justification of procedures, and the training of staff who might assist in the procedures, doses to the chiropractor, staff and chiropractic clients might be higher than they need be.

Table 1.1 State and Territory Regulations Covering Chiropractic X-ray Examinations

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> .
Vic	Radiation Safety Section — Dept. of Human Services	Regulation is based on the <i>Radiation Regulations 2007</i> and the <i>Radiation Act 2005</i> .
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> .
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> .
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> .
NT	Radiation Protection Section — Dept. of Health and Community Services	Regulation is based on NHMRC and ARPANSA Codes
ACT	Radiation Safety Section — ACT Health	Regulation is based on the ACT's <i>Radiation Act 1983</i> and <i>Radiation Regulation 2002</i>

19. Irradiation of persons from diagnostic radiology, of which chiropractic X-ray procedures are considered to be a subset, 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 person being exposed. There is

⁸ *The Annual Report of the Radiation Advisory Committee for the Year Ending September 2006*, Department of Human Services, Victoria.

a need to establish clear responsibility for the exposures and to ensure that they are optimised and minimised to provide maximum benefit with minimum potential risk to the person being exposed.

20. In 2008, ARPANSA published its *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation*. As chiropractors are however not permitted to be called “medical practitioners”, the chiropractic profession was unable to be included in the Medical Applications Code. Therefore, there are still no uniform, formal requirements to cover chiropractic X-ray procedures.
21. Further, a now obsolete Australian Standard (AS2814) dealt with safe X-ray practice but this publication is no longer compatible with the regulatory requirements in Australia, nor is it in line with international trends.

1.5 Objective of Government Action

22. The objectives of options relating to the chiropractic use of ionizing radiation are to:
 - have nationally uniform requirements across the jurisdictions;
 - improve the health outcomes of chiropractic clients; 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

23. This cost-benefit analysis assesses the merits of three models of regulation for radiation protection in the chiropractic use of ionizing radiation, these are:
- the *status quo*;
 - a proposed Code of Practice put forward by ARPANSA; and
 - a self regulation model.
24. This cost-benefit analysis assesses the costs and benefits associated with implementing a new Code relative to the current approach to regulation (referred to in this report as the *status quo*).⁹ In the same manner this analysis also assesses the merits of a self regulation approach whereby chiropractors would set and enforce their own safety requirements regarding the exposure of staff and clients to radiation.
25. The remainder of the report is structured as follows:
- Chapter 3 highlights areas of concern in respect of the current regulatory approach governing chiropractic X-ray procedures;
 - Chapter 4 assesses the costs of implementing ARPANSA's proposed Code of Practice — these costs are assessed relative to the *status quo*;
 - Chapter 5 assesses 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;
 - Chapter 7 summarises the outcomes of the cost-benefit analysis;
 - Chapter 8 evaluates the options and makes a conclusion as to the preferred option; and
 - Chapter 9 outlines the consultation carried out;
 - Chapter 10 describes what implementation and review criteria will be performed should a Code of Practice approach be accepted.

⁹ 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

26. As alluded to in Chapter 1, regulation (in some form) is considered necessary to protect chiropractic clients, practitioners and the general public from the side-effects attributable to chiropractic 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.
27. 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. Licensing (authorisation) requirements and the range of procedures that are permitted to be performed by Chiropractors vary across the jurisdictions;
 - an absence of a specialist regulator and a specific set of regulations. Each State and Territory regulator administers their own radiation legislation;
 - the existence of outdated regulations that do not incorporate current best practice. For example, the Northern Territory legislation still uses outdated radiation units;
 - grey areas within regulations. Although implicit within legislation, many jurisdictions do not formally require a chiropractor to justify the need for a particular procedure; and
 - areas of regulatory omission such as there being no formal requirement for training of staff beyond the general requirements to enable licensing.
28. These issues are described in more detail below.

Lack of uniformity

29. 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).¹⁰
30. 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 chiropractors 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.
31. A lack of consistent regulations may also hamper the cross-border activities of chiropractors. Ideally, chiropractors should be able to be highly mobile within Australia so that they can practice in multiple jurisdictions at once. While, technically this is possible under the current regulatory approach, chiropractors 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.

¹⁰ G. Banks 2003, 'Minimum effective regulation and the mining industry', *Address to the Minerals Council of Australia*, Old Parliament House, Canberra, June.

32. It may be the case that the unnecessary compliance costs are preventing some chiropractors from being highly mobile or practicing in multiple jurisdictions.¹¹

Different skill-sets

33. In observing the different training requirements for chiropractors, 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 chiropractors across Australia. For example, some jurisdictions issue a licence based simply on registration with the respective Chiropractic Board whereas other jurisdictions require a pass in a separate radiation safety examination before issuing a licence.
34. Anecdotal information from regulatory staff in Queensland provides support for a consistent and mandatory approach to training across Australia so as to ensure optimal protection of chiropractic clients, practitioners and chiropractic staff.

Outdated regulations

35. There are instances within the current regulatory framework whereby State and Territory regulations are based on outdated material such as the obsolete Australian Standard AS2814-1985. *Diagnostic X-ray Facilities—Safe Practices*.
36. 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. Even though none of the NHMRC radiation related Codes specifically applied to chiropractors, any that are used by Australian radiation regulators to cover chiropractic X-ray procedures do not provide up to date information for practitioners and their 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

37. 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 chiropractic X-ray, such areas identified in different jurisdictions include:
- the principle of obtaining adequate justification for undertaking a chiropractic X-ray examination;
 - giving adequate consideration to the necessity of X-raying children and pregnant women;
 - the placement of signs informing clients of the need to notify the chiropractor that they may be pregnant; and
 - the implementation of a comprehensive quality assurance program.
38. 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

39. There are several areas of oversight in the current regulations relating to chiropractic X-ray procedures. Given the increased risks from radiation exposure involved with X-ray procedures in general, these oversights may be potentially damaging to chiropractic clients and the health of the chiropractor (as

¹¹ Liaison with the regulators on the Radiation Health Committee has indicated support for a national Code such that there could be consistency in regulations across Australia.

well as the health of the public and other chiropractic staff). Examples where current regulations may be lacking include:

- Few jurisdictions require training of occupationally exposed individuals at a practice other than the licence holder. This proposed requirement of the Code is intended to increase the safety culture and hazard awareness within the organisation.
- Similarly, access to expert advice on optimisation, dosimetry and quality assurance is not formally required by Australian regulators. As this would only require, essentially, a name and phone number of a qualified expert, the benefits of improved radiation protection knowledge appears to outweigh the costs.

3.2 Conclusions

40. Current State and Territory regulations that relate to chiropractic X-ray procedures are designed to minimise exposures to ionizing radiation for chiropractic clients, chiropractic staff and the 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.
41. The lack of cross-border uniformity by maintaining the status quo can also be seen as increasing costs, particularly for those chiropractors who work in multiple jurisdictions or move from one jurisdiction to another as they familiarise themselves with the different requirements.
42. Further, it is considered untenable that a professional group who deliver radiation doses to humans are not covered by a specific uniform national Code of Practice, particularly as the Medical Code has now been published.

Chapter 4. Costs of the proposed Code of Practice

4.1 Introduction

43. In light of the issues identified with regard to the current system of regulation, ARPANSA has developed a Code of Practice to regulate chiropractic X-ray practices. 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

44. The proposed Code establishes a range of obligations on chiropractors working with X-rays. 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

45. Under the proposed Code, all procedures involving X-ray exposure must be justified in accordance with the justification principle.

No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes.^{12 13}

46. 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.¹⁴ 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.¹⁵

47. *The once-off compliance costs associated with coming to terms with the justification requirements are estimated to be around \$78,400.*

48. This cost estimate is based on the following:

- An estimated 196 chiropractic X-ray units, other than Queensland, for which the Responsible Person will be required to come to terms with the new justification principles.¹⁶
- 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.¹⁷

¹² ICRP 60 (1991), paragraph 112.

¹³ ARPANSA 2008, *Code of Practice for Radiation Protection in the use of Ionizing Radiation by Chiropractors*, initial draft, p. 4.

¹⁴ Information provided from the Tasmanian regulator, the Department of Health and Human Services.

¹⁵ 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.

¹⁶ The estimated total number of chiropractic X-ray units in Australia is 243 based on Queensland, Tasmanian and Victorian registration data indicating that there are approximately 47, 5 and 70 chiropractic X-ray units in those jurisdictions respectively or an average 0.016 units per 1000 people. The total number of units in Australia was estimated using this ratio of units to population and ABS data on population, see ABS 2006, *Population by Age and Sex, Australian States and Territories*, cat. no. 3201.0.

Radiation management plans

49. Under the proposed Code there are requirements for the defined 'Responsible Person' to develop, document, resource, implement and regularly review a radiation management plan. The radiation management plan addresses a raft of topics around the safety of chiropractic X-ray practices and is designed to formalise, in writing, the working rules, emergency procedures and other specific requirements required by the Code of Practice. It is considered that preparation of a radiation management plan would engender an improved safety culture within the organisation by raising the awareness of radiation hazards thus reducing the likelihood of radiation incidents. An improved safety culture would also contribute to lowering occupational and client doses through improved work practices and better awareness of radiation risk. It should be noted that most Australian jurisdictions are currently moving toward this outcome based form of regulation. 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 chiropractic practices and their roles and responsibilities; and
 - actions necessary to manage a radiation incident including emergency procedures, reporting and investigation.
50. Regulations in Queensland and Tasmania already require that chiropractors 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.¹⁸ 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

51. The preparation of a radiation management plan will bring about an initial once-off cost of about \$78 400 based on the following:
- An estimated 191 centres in Australian jurisdictions other than Queensland and Tasmania being required to prepare an initial radiation management plan.¹⁵
 - Indications from State regulators that it may take about four hours to prepare a radiation management plan for a chiropractic centre that has chiropractic X-ray equipment.¹⁹
 - 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.¹⁶

Review of radiation management plans

52. Requirements to review radiation management plans will bring about recurrent annual costs estimated to be between \$9 600 and \$19 100 based on the following:
- An estimated 191 centres across all jurisdictions other than Queensland and Tasmania being required to review a radiation management plan²⁰.
 - Indications from State regulators that it may take between one half to one hour per year to review a radiation management plan.²¹

¹⁷ The rate of \$100 per hour for Radiation Safety Officers has been used in previous ARPANSA cost-benefit analyses.

¹⁸ Information provided by the Queensland and Tasmanian regulators.

¹⁹ Based on information from State regulators.

²⁰ 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.

²¹ 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

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- Time costs of \$100 per hour using data for the Radiation Safety Officer as used in existing ARPANSA regulatory impact analyses.¹⁷

Total costs of radiation management plans

53. *In total, it is estimated that the initial preparation of radiation management plans will bring about once-off compliance costs of approximately \$78 400 and ongoing review costs of between \$9 600 and \$19 100 per year.*

Optimisation

54. 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).
55. 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 chiropractic X-ray procedures; and
 - reviewed to determine whether radiation protection has been optimised in cases where chiropractic X-ray procedure levels have been exceeded.
56. 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.
57. *It is estimated that the ongoing compliance costs relating to the optimisation requirements of the proposed Code would be between \$97 200 and \$194 400 per year.*
58. This cost estimate is based on the following:
- An estimated 243 centres incurring additional costs relative to the status quo.
 - 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.¹⁷

Inadvertent irradiation of the embryo or foetus

59. 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 client be sought regarding any other 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 client is informed about the magnitude of the radiation dose to the embryo or foetus and counselled about any potential risks.

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.

60. 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.
61. *It is estimated that the compliance costs relating to the optimisation requirements of the proposed Code would be between \$274 and \$549 per year.*
62. 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. These figures however cover the entire medical field. Using the Canadian value that chiropractic X-ray procedures represent 3.6% of the total number of diagnostic X-ray studies (para 8), approximately 1.9 cases would be expected per year in New South Wales due to chiropractic procedures. This estimate equates to about 4.0 cases per 1,000,000 people²² or approximately 5.8 cases in the population of Australians who visit chiropractors. For all jurisdictions less New South Wales and Queensland (neither of which will incur additional compliance costs) it is estimated that there are about 2.74 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).¹⁷

Formalisation of training

63. 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;
 - the X-ray equipment that the individual may be required to use; and
 - potential radiation hazards associated with the practice.
64. Jurisdictions currently have training requirements in place similar to those of the proposed Code for licensed staff, for example, chiropractors and radiographers. The proposed Code will not create any new or additional compliance costs relating to training for these staff.
65. It should be noted that the *National Standard for Limiting Occupational Exposure to Ionizing Radiation* (RPS-1) requires induction and on-going training for all employees who may be exposed to ionizing radiation in their work. The training requirement clause has been included in the Code to formalise the training needed in the chiropractic field. As induction and on-going training is mandatory under the National Standard, the cost of this particular requirement should therefore be minimal. The following costs are included as an indication for those centres who might not already be providing training. Additional compliance costs will therefore be incurred in training or instructing ancillary staff who do not currently receive training or instruction in ionizing radiation. There will be an initial once-off cost to train all current ancillary staff working in areas where they may be exposed to ionizing radiation and there will also be ongoing costs in training all new ancillary staff. It is assumed that 10% of staff would require training through the introduction of the Code.
66. *The initial cost is estimated to be approximately \$3 300-\$6 600 and the ongoing training costs are estimated to be approximately \$3 800 per year.*
67. Details of estimates are provided below.

²² Based on the number of NSW persons who visit chiropractors using NSW to Australian population data.

Initial training costs

68. Based on information provided by the State regulators, it is estimated that the training requirements of the proposed Code may take between half to one hour to fulfil.
69. Using ABS average weekly earnings and hourly rate data for health and community services workers,

Stakeholders are invited to identify if there are any other costs of complying with the proposed Code that have not been identified in the draft RIS and provide an estimate of what these costs are likely to be.

(i.e. chiropractic ancillary staff) is estimated at about \$27 per hour (based on weekly earnings of \$1075 and a 40-hour work week).²³ Total initial costs associated with additional training for 243 existing ancillary staff will be \$3 300-\$6 600.

Ongoing training costs

70. Using earnings and hours data as immediately above and assuming that on-going refresher training requirements would take about half an hour to complete then it can be expected that ongoing training costs associated with the proposed Code may be about \$3 300 per year.

4.3 Administration costs – Regulatory

71. 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

72. 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 requirements of the proposed Code have been used in other areas of radiation protection in Australia for some time now.
73. 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 member²⁴, 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

74. 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.
75. 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 \$40 800.²⁵ Assuming legislative amendment costs are the same in each jurisdiction then national costs may be in the order of \$326 400.
76. *The total administrative burden associated with the introduction of the proposed Code will result in a once-off cost of about \$334 400-\$336,000.*

²³ ABS 2007, *Average Weekly Earnings*, cat. no. 6302.0, May.

²⁴ 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*.

²⁵ Department of Local Government and Regional Development 2006, *Annual Report 2005-06*, p. 26.

4.4 Summary of costs

77. A summary of costs incurred under the proposed Code is provided in Table 4.1.

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 of about \$78 400 as the Responsible Person in each relevant chiropractic centre comes to terms with the new regulations.</p> <p>In total, it is estimated that the initial preparation of radiation management plans will bring about once-off compliance costs of approximately \$78 400 and ongoing review costs of between \$9 600 and \$19 100 per year.</p> <p>It is estimated that the ongoing compliance costs relating to the optimisation requirements of the proposed Code would be between \$97 200 and \$194 400 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 \$274 and \$549 per year.</p> <p>The initial cost is estimated to be approximately \$3 300-\$6 600 and the ongoing training costs are estimated to be approximately \$3 300 per year.</p>
Administration costs – Regulatory	The administrative burden associated with the introduction of the proposed Code will bring about a once off cost of about \$335 000.
Total costs	<p>Initial once-off costs estimated to be between \$495 100 and \$498 400.</p> <p>Ongoing costs are estimate to be between \$110 374 and \$220 649 per year.</p>

Chapter 5. Benefits of the proposed Code of Practice

5.1 Introduction

78. 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

79. 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.

80. These health and safety benefits are discussed below.

Improving radiation protection awareness

81. 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 chiropractic X-ray. 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.

82. Among other things, radiation management plans are required to stipulate practices to optimise the protection of the client receiving the exposure.

83. These requirements are expected to 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.²⁶

84. Discussion with the Tasmanian regulator has indicated that the Radiation Management Plans already required in that jurisdiction have been received favourably, with some licensees advising that regulator that the Plan has increased the safety culture and radiation safety awareness within their respective organisations. This benefit is largely unquantifiable although as already noted, it is generally accepted that improved safety culture should lead to a reduced risk of incidents occurring. Further, the use of “template” radiation management plans that would be made available from the websites of ARPANSA or the State and Territory regulatory bodies would reduce the preparation costs.

²⁶ 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

85. The proposed Code, through the explicit justification criterion, is intended to reduce instances whereby chiropractic clients are unnecessarily exposed to ionizing radiation. Under the proposed Code of Practice, the chiropractor has the role of providing justification for medical exposures and the criterion requires that a chiropractic X-ray 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.
86. 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.
87. A UK study estimated the potential annual dose savings that could be achieved if unnecessary and unhelpful X-ray examinations were eliminated.²⁷ 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.
88. 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 person.Sv.y⁻¹, or about 14% of the total collective dose, in the medical area. Translated into the chiropractic X-ray area, this would represent a decrease of between 43-90 person.Sv.y⁻¹.

Stakeholders are invited to comment specifically on how realistic they feel the assumption of a 14% reduction is and what they consider a more realistic figure would be.

89. It has however been suggested that 14% may be an overestimate for chiropractic X-ray procedures and that 5% could be more realistic. That being the case, a 5% reduction in total collective dose translated to the chiropractic profession would represent a decrease of between 15-32 person.Sv.y⁻¹.
90. Given a cost per person sievert of \$46 675²⁸, the benefits that would arise would be in the order of \$700 000-\$4 201 000 per year.

Formalisation of training

91. 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 chiropractic ancillary staff for whom regulations requiring training do not currently apply.
92. If it is assumed that the proposed Code will reduce effective doses received by occupationally-exposed ancillary staff 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 \$104 per year.²⁹

²⁷ 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.

²⁸ 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 and was taken to be “about £12,500” in 1990. This estimate was then adjusted for inflation and exchange rate movements taking 2.5% as the average inflation rate over 18 years and a conversion rate of UK£0.48444 per AUD\$1 as of July 2008. 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.

²⁹ 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 243 chiropractic ancillary staff (one per X-ray unit) who are occupationally-exposed to ionizing radiation.

93. There are however areas in chiropractic X-ray where the benefits of training would significantly exceed the 1% saving outlined above. Appropriate training:

- reduces the likelihood of incidents; and
- allays fears of radiation exposure that could, in a worst case scenario, result in a client not receiving appropriate assistance during an X-ray procedure.

These benefits are unquantifiable but as already noted in paragraph 83, it would not take too many avoided incidents to realise a significant benefit above the ongoing 1% saving outlined here.

94. 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 occupational dose limits

95. 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).

96. 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 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 members of the public. The specification of such dose limits is more clear-cut than current Victorian regulations that stipulate that the effective dose [*sic*] limit for the woman's uterus is 1 millisievert after she has notified the licence holder that she is pregnant.³⁰ The specification of dose limits to the embryo or fetus in the proposed Code provides an added degree of clarity 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 chiropractic X-ray.³¹

5.3 Other benefits

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

Uniformity

98. 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 chiropractic workers across Australia. This would ensure that all stakeholders would be aware of their obligations even when operating in another jurisdiction; and

— 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

³⁰ *Radiation Regulations 2007*, Regulation 7, p.6 and Table B of Schedule 2, p.29.

³¹ *Radiation (Safety Control) Act*, Schedule 3, p. 25.

- 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 chiropractic X-ray procedures.
99. Overall, compliance costs are likely to be reduced for chiropractic staff and practices that have cross-jurisdictional operations, that is, they will be able to have a single standardised operational approach across jurisdictions.
100. 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

101. 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.
102. 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

103. 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 60 (1991). The proposed Code would incorporate current international best practice with respect to administering chiropractic X-ray procedures.

5.4 Summary of benefits

104. 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 elimination of clinical unhelpful examinations is estimated to generate benefits of between \$700 000 and \$4 201 000 per year. Formalisation of training for all staff but particularly chiropractic ancillary staff should bring about lower levels of occupational exposure. Benefits of small reductions in exposure for chiropractic ancillary staff alone may be in the order of \$104 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> .

Benefit category	Discussion of benefits 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 in relation to chiropractic X-ray procedures
Total benefits	<i>Health and safety initiatives will potentially bring benefits to the industry. 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>

Chapter 6. The self regulation model

6.1 Introduction

105. 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.
106. An Office of Best Practice Regulation Regulatory checklist³² lists three criteria that should apply for self regulation to be successful, 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 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 — chiropractic X-ray is seen as an important aid to assessing the treatment of a given chiropractic client;
 - the market is characterised by a small number of businesses who communicate with each other and are members of industry associations — the chiropractic industry is not characterised by a small number of businesses. In Victoria alone, there are about 70 practices that are able to perform their own X-ray procedures and many others refer their clients to radiology clinics; and
 - the industry has a strong desire for self regulation to work — the chiropractic 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 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.
107. Existing State and Territory regulation does not completely cover all areas of chiropractic X-ray and therefore self-regulation is not really an option.
108. 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 field of chiropractic X-ray.

³² Best Practice Regulation Handbook, page 65 (Box 6.3), August 2007.

Chapter 7. Summary of cost benefit analysis

7.1 Summary

109. 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 regarding exposure to ionizing radiation and chiropractic X-ray are all factors that do not work in favour of self regulation.
110. 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 chiropractic centres that use X-ray equipment brought about by the compliance requirements (justification, radiation management plans and training) of approximately \$206 600;
- initial administrative costs on governments as they become accustomed to the new regulations of about \$335 000. However, ongoing administrative costs should be reduced over time;

Ongoing costs

- ongoing compliance costs borne by chiropractic centres of between \$127 074 and \$243 349 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 chiropractic X-ray exposures as the justification principle in the proposed Code results in fewer unnecessary procedures being undertaken will bring substantial benefits to the community — an equivalent to that cited in the UK for the elimination of clinically unhelpful chiropractic X-procedures could result in benefits in the order of \$700 000-\$4 201 000 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 chiropractors 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.
111. 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>
COSTS	
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 chiropractic centre comes to terms with the new regulations of about \$78 400.</p> <p>In total, it is estimated that the initial preparation of radiation management plans will bring about once-off compliance costs of approximately \$78 400 and ongoing review costs of between \$9 600 and \$19 100 per year.</p> <p>It is estimated that the ongoing compliance costs relating to the optimisation requirements of the proposed Code would be between \$97 200 and \$194 400 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 \$274 and \$549 per year</p> <p>The initial cost is estimated to be approximately \$7 600 and the ongoing training costs are estimated to be approximately \$3 800 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>
Total costs	<p>Initial once-off costs estimated to be about \$498 400. Ongoing costs are estimate to be between \$110 374 and \$220 649 per year.</p>
BENEFITS	
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 elimination of clinical unhelpful examinations is estimated to generate benefits of between \$700 000 and \$4 201 000 per year.</p> <p>Formalisation of training for all staff but particularly chiropractic ancillary staff should bring about lower levels of occupational exposure. Benefits of small reductions in exposure for chiropractic ancillary staff alone may be about \$104 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>
Total benefits	<p>Health and safety initiatives will potentially bring benefits to the industry. 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.</p>

Chapter 8. Evaluation and Preferred Option

8.1 Conclusions and recommendations

112. 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 chiropractic practice.
113. Other shortcomings of the status quo (such as those discussed in chapter 3) can be overcome by the introduction of the Code of Practice. The grey areas in the existing 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.
114. ARPANSA has identified several shortcomings associated with the current regulatory approaches to chiropractic X-ray. ARPANSA is therefore proposing the adoption of a single and nationally uniform Code of Practice that can be adopted into the National Directory as mandatory requirements and this is the preferred option for the future regulation of radiation protection in chiropractic X-ray applications. The proposed Code will incorporate current radiation protection and practices.
115. 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 approximately \$498 400 for once-off costs and between \$110 374 and \$220 649 per year in ongoing costs.
116. 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 resulted in the elimination of clinical unhelpful examinations alone, it is estimated to generate benefits of between \$700 000 and \$4 201 000 per year (irrespective of potential reductions in other forms of chiropractic X-ray applications) based on a reduction of unhelpful X-ray examinations of between 5-14%.

It is acknowledged that 5-14% might be an overestimate for chiropractic X-ray examinations. As such, stakeholders are invited to advise what they consider a more realistic figure of the reduction of unhelpful X-ray examinations would be.

117. In addition, the proposed Code of Practice is expected to lower exposures to occupationally exposed individuals and, consequently, also bring ongoing benefits to the community. The uniformity of the proposed Code of Practice would reduce costs for chiropractic organisations operating in several jurisdictions, as it would standardise requirements. The health and safety benefits of the proposed Code of Practice 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*.
118. Of all the options, the proposed Code of Practice is the most effective way of ensuring the continued low effective doses of radiation associated with medical applications. The proposed Code of Practice 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. The proposed Code of Practice best supports the application of the ALARA principle, which is at the heart of the system of radiation protection across Australia.

Chapter 9. Consultation

119. All State, Territory and Commonwealth regulators participated in the development of the proposed Code of Practice via their membership of the Radiation Health Committee.
120. A draft Code of Practice was made available for a period of public comment from 23 March to 15 May 2009. Many stakeholders were contacted directly and invited to comment. The following organisations were advised of the availability of the revised ARPANSA Code and the Regulatory Impact Statement:
- Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM)
 - Australasian Radiation Protection Society (ARPS)
 - Australian Institute of Radiography (AIR)
 - Chairman, Tasmanian Radiation Advisory Council
 - Chiropractors' Association of Australia
 - Radiation Health and Safety Advisory Council (RHSAC)
 - Radiation Health Committee (RHC)
 - Royal Australian and New Zealand College of Radiologists (RANZCR)
 - RACGP
 - The State, Territory and Commonwealth Radiation Regulators
 - The State and Territory chiropractors' registration boards
 - A range of individuals who had responded to the consultation draft of the Medical Code in relation to chiropractors.

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

Stakeholders are invited to comment on any aspect of the proposed Code of Practice.

Stakeholders are also invited to consider the estimates of costs and benefits provided in this draft Regulation Impact Statement. Have the main costs and benefits been identified? (For example, could there be additional staffing costs associated with tightening the occupational dose limits?) Do you agree with the estimates? If you disagree, can you provide alternative estimates of the likely costs or benefits, noting the basis on which your estimates are derived.

Chapter 10. Implementation and Review

10.1 Implementation and review

121. The proposed Code of Practice would be published by ARPANSA under its Radiation Protection Series and made available to the chiropractic 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.
122. Once published, the Code of Practice would be referenced in the *National Directory of Radiation Protection*, which has been established to enhance uniformity of radiation controls among jurisdictions in Australia. The National Directory was agreed by Health Ministers at the AHMC meeting in August 1999 as the mechanism to achieve uniformity. The ministerial agreement requires that all jurisdictions then adopt the Code within their regulatory frameworks, in a similar way to other Radiation Protection Series Codes and Standards. Typically, this is done by making compliance with the Code of Practice a condition of authorisation.

References

- ARPANSA 2005, *Regulatory Impact Statement, Code of Practice and Safety Guide for Radiation Protection in Dentistry*, August.
- Bureau of Transport and regional Economics 2000, *Road Crash Costs in Australia*, Report 102, No. 79, AGPS, Canberra.
- Bureau of Transport and Regional Economics 2006, *Cost of Aviation Accidents and Incidents*, Report 113, AGPS, Canberra.
- 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.
- G. Banks 2003, 'Minimum effective regulation and the mining industry', *Address to the Minerals Council of Australia*, Old Parliament House, Canberra, June.
- M. Bellon 2006, 'Educating the Regulators', Guest Editorial in *ANZ Nuclear Medicine*, March.
- Medicare Australia 2007, *Group Statistics Reports*, http://www.medicareaustralia.gov.au/statistics/dyn_mbs/forms/mbsgtab4.shtml, Accessed 1 August 2007.
- P. Ableson 2003, 'The Value of Life and Health for Public Policy', *The Economic Record*, 79: S2S13.
- 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.
- Taskforce on Industry Self-Regulation 2000, *Industry Self Regulation in Consumer Markets*, August.
- United Nations Scientific Committee on the Effects of Atomic Radiation 2000, *Sources and Effects of Ionizing Radiation*.