Australian Government

Australian Radiation Protection and Nuclear Safety Agency

Regulatory Impact Statement
Public Consultation Draft

Code of Practice and Safety Guide
For Radiation Protection in Dentistry

Comment on the Regulatory Impact Statement and draft Code of Practice/Safety Guide should be forwarded by 16 September 2005 to:

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

Background

1. Diagnostic X-ray equipment is an essential part of a dentist's facilities and has been widely used in dental practices in Australia and throughout the world for many decades. However, the use of X-rays to aid in diagnosis and treatment must be managed with the knowledge of the impact that ionizing radiation can have on the health and safety of operators, staff and patients. Dental X-ray equipment is generally lower in power than general purpose X-ray equipment used in medical practice, and is designed specifically for use in dental radiology.

2. Dental X-ray equipment does, however, use ionizing radiation to produce radiographs, and hence there are safety and health issues for operators, staff and patients that must be considered.

3. In Australia, it is estimated that there are 10,100 dental X-ray units used for intra-oral radiography, 1,120 orthopantomograph (OPG) X-ray units, used for panoramic radiography of the upper and lower jaws and a lesser number of cephalometric units for lateral skull views used by orthodontists and oral surgeons. Intra-oral equipment is operated by approximately 8,800 dentists, 350 dental hygienists, 1,350 dental therapists and in some jurisdictions where permitted by regulations, 500 dental assistants[1]. Hygienists, therapists and assistants are usually not permitted to operate extra-oral radiographic equipment. Assuming a workload of approximately 20 exposures/week/X-ray unit it can be estimated that approximately 10,000,000[2] intra-oral dental radiographs are taken per year in Australia. The number of OPG radiographs in Australia, estimated at 10/week/X-ray unit or 500,000 per year, is in addition to the above.

4. The total cost of dental health services in Australia was estimated by the Australian Institute of Health and Welfare at $2,566,000,000 in 1998-99 [AIHW, 2002]. The cost of dental radiology can be estimated from the typical fee for an intra-oral radiograph of about $35 and the estimated 10,000,000 exposures per year, added to the typical $90 for each of 500,000 OPG radiographs, ie a total cost of $395,000,000. It is recognised that this figure overestimates the cost as intra-oral radiographs taken as part of endodontic procedures or after restorative dentistry may not have a direct fee. Even allowing for this dental radiology appears to make up more than 10% of the cost of dental health services.

5. Dental radiology plays an essential part in dental health practice, however the use of radiation as an aid to diagnosis must be balanced against the risks to both patients and staff from exposure to ionizing radiation. While the radiation dose from an individual dental radiograph is small, the large number of radiographs taken means that the overall population dose is not insignificant, and the general principles of radiation protection to optimise radiation doses and keep them as low as reasonably achievable (social and economic factors being taken into account) should be applied.

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1 The figures for numbers of X-ray units and dental personnel were derived from advice provided by each of the State, Territory and Commonwealth radiation protection regulatory authorities.

2 Adapted from average figures of 22/week/X-ray unit (intra-oral) and 6/week/X-ray unit (OPG) in 1988 [Monsour 1988], and from information from the AIHW Dental Statistics and Research Unit [0.18 intra-oral radiographs and 0.05 OPG radiographs per visit, 2589 visits/dentist & 7667 dentists – 1994 figures]. For comparison, the number of exposures per year is similar on a population basis to that in of 447 exposures /1000 population in NZ [Williamson 1990].

6. The harmful effects of exposure to ionizing radiation include, at long times after exposure, a small excess of cancers in the irradiated population and, one or more generations later, a small excess of hereditary disorders. More important for setting protection standards is the risk of radiation-induced cancer. After studying the available information, the International Commission on Radiological Protection (ICRP) derived a nominal fatal cancer risk of 5% per Sievert (Sv) and adopted a system of radiation protection based on the principles of Justification, Optimisation and Limitation [ICRP 1991].

7. ***Justification*** involves a demonstration that there is a net benefit from a practice which leads to exposure to radiation. No practice involving radiation exposure should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes.

8. ***Optimisation*** is employed to make the best use of resources in reducing radiation risks, once a practice has been justified. The broad aim is to ensure that the magnitude of individual doses, the number of people exposed, and the likelihood that potential exposures will actually occur should all be kept as low as reasonably achievable, economic and social factors being taken into account (The ALARA principle).

9. ***Limitation*** of dose or risk is to place bounds on risk to individuals so that risks do not exceed a value that would be considered unacceptable for everyday, long-term exposure to radiation. As it is assumed that the probability of stochastic effects occurring increases with dose with no threshold, dose limits do not and cannot define a demarcation between 'safe' and 'unsafe'. Consequently, it is not sufficient merely to ensure that individual doses do not exceed the limits: they should be controlled by optimisation to be as low as reasonably achievable. [Dose limits are not used for medical exposures, where there is a direct benefit to the individual from the exposure].

10. This system of radiological protection has been adopted in Australia in ARPANSA's Recommendations for limiting exposure to ionizing radiation and National Occupational Health and Safety Commission's (NOHSC) National standard for limiting occupational exposure to ionizing radiation (1995) [both republished in Radiation Protection Series publication 1, 2002] [ARPANSA/NOHSC 2002]. RPS 1 is used by State, Territory and Commonwealth Governments to form the basis of the radiation protection requirements, particularly radiation dose limits, adopted in legislation, regulations and/or conditions of licence.

11. The National Health and Medical Research Council published a Code of Practice for Radiation Protection in Dentistry (NHMRC 1987) within its Radiation Health Series, which has been widely used by regulators as part of their licensing framework, and is widely used by the profession. NHMRC has handed responsibility for review of the Radiation Health Series to ARPANSA.

Problems

12. The 1987 NHMRC Code is now over 18 years old. The NHMRC does not intend to continue publication in the Radiation Health Series and has handed responsibility for the review of these publications to ARPANSA. ARPANSA needs to review the 1987 Code to ensure that the dental profession and the public are able to obtain reliable information on what measures to take to reduce radiation levels and therefore radiation risk in dentistry.

13. While the dose to an individual patient from a dental radiograph is not high (approximately 5-10 μSv/film[3] for an intra-oral radiograph), an estimated 10,000,000 such dental radiographs are taken in Australia each year, so that the collective dose from dental radiography is 50-100 person-Sv. The population exposure from OPG radiography is 5-15 person-Sv. 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.

14. In addition, uniformity of radiation controls has been identified as an issue requiring attention. Variations in requirements across borders create impediments to business professionals that move across borders or who operate businesses in more than one jurisdiction. Following Ministerial agreement in 1999, a National Directory for Radiation Protection has been published. The Directory establishes a uniform framework for radiation protection practice, and provides for the national adoption of codes and standards developed jointly by the States, Territories and Commonwealth.

15. Dentists have for many years now engaged in radiation protection, with guiding regulation and controls developed for the specific needs and appropriateness of the dentistry industry. These radiation protection regulations however, do not consider the impact in a broader context for other professions nor have they been developed as part of a national approach to radiation protection.

Objectives

16. The primary objective is to protect public health by minimising the risk to patients and staff from exposure to radiation in dental practice.

17. A secondary objective is to promote uniformity of radiation protection practices across Australian jurisdictions in regard to how all States/Territories and the Commonwealth regulate the use of ionizing radiation.

18. In relation to dental radiology, adoption of practices based on international radiation protection principles is needed to ensure that dentists and dental auxiliaries can meet radiation protection objectives in their use of X-ray equipment. This includes establishing that equipment meets adequate standards of safety, that safe work procedures are adopted to minimise dose to patients and staff, that fast speed radiographic film is used to reduce dose, and that processing of radiographs is of a high standard to avoid overexposure to radiation being a consequence of underdeveloping of radiographs.

Statement of the Options

Option 1 – Status Quo

19. This entails doing nothing and leaving the National Health and Medical Research Council's Code of Practice for Radiation Protection in Dentistry (NHMRC 1987) in place.

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3 This estimate is derived from publications of the National Radiation Protection Board, UK [NRPB, 1994] and the National Radiation Laboratory, NZ [Williamson, 1990].

Option 2 – Self-Regulation

20. This option would allow industry to set its own radiation safety requirements, subject to other occupational health and safety (OH&S) obligations.

Option 3 – Update the Current Code of Practice

21. This option entails re-writing the 1987 Code and updating it with current radiation protection requirements and philosophies. It would consist of a Code of Practice and Safety Guide with the Code providing a set of requirements to be adopted by State/Territory regulators as part of their regulatory frameworks; and the Safety Guide containing guidance and advisory material for the dental profession to assist in their compliance with the Code.

22. The key changes in the proposed Code, in comparison to the 1987 Code are:
    - The Code will expand the definition of responsibility for ensuring safe practices to include persons in control of institutions, departments or practices using the dental x-ray equipment, rather than relying heavily on the role of dentists. It also specifically includes responsibilities for Dental Hygienists, Dental Therapists and Dental assistants with extended duties.
    - Requires the appointment of a Radiation Safety Officer to supervise radiation protection to minimize personal radiation doses, and other tasks associated with compliance with the Code.
    - The Code will require the preparation of a quality assurance program for film processing, to try and ensure radiographs of appropriate quality are obtained first time rather than having to take repeat radiographs, or make diagnoses from poor standard films. In the 1987 Code, a quality assurance program was recommended but not mandatory.
    - The Code contains only requirements. A Safety Guide giving much explanatory information on issues covered in the Code has been provided. The 1987 Code had no Safety Guide, but had requirements and advice intermingled throughout, making its interpretation less clear.
    - The Code includes reference to digital imaging systems, which were not prevalent in 1987.
    - Requirements for the use of protective aprons and thyroid shields in the 1987 Code have been removed from the Code and become advisory clauses in the new Safety Guide.

Impact Analysis

23. The aim of this assessment is to provide a clear exposition of the nature of the costs and benefits associated with each option, and to quantify these impacts where possible.[4]

Affected Parties

24. The main stakeholder groups affected are:

    (a) Dentists, who would need to implement the Code, and ensure that staff within their practices follow its requirements as well. There are about 8,800 dentists in Australia.

4 While cost-benefit analysis requires all costs and benefits associated with the options to be measured quantitatively in common units (either in monetary units or physical units) to the fullest extent possible, to the extent that quantification is not possible, a comprehensive list of the costs and benefits together with a strong qualitative analysis can often provide a simple but still compelling case. Indeed, this approach is preferable to one where unreasonably broad assumptions are made to generate quantified impacts which provide a false sense of accuracy.

(b) Dental auxiliaries and staff, such as dental hygienists, dental therapists and dental assistants and receptionists, who also operate dental X-ray equipment, or work in the vicinity of dental X-ray equipment. There are approximately 350 dental hygienists, 1,350 dental therapists, and 500 dental assistants authorised to use X-ray equipment in Australia.

(c) The public, as patients of dental practices, and who are subject to X-ray examination. Approximately 10 million dental radiographs are taken in Australia each year.

(d) Commonwealth, State and Territory Governments, as regulators of professions using ionizing radiation, and

(e) Suppliers of dental X-ray equipment, who must provide equipment that complies with the relevant standards mentioned in the Code. It is estimated that there are between 20-30 suppliers in Australia.[5]

Option 1 – Status Quo

25. Under the status quo option, the NHMRC 1987 Code would continue to remain the prime regulatory tool for radiation protection in dentistry. Keeping the status quo would involve no direct costs; however, there are a number of indirect costs potentially incurred by stakeholders, which are discussed below and quantified where possible.

Costs

Compliance

26. There are ongoing compliance costs associated with complying with the 1987 Code, which place a burden on a range of stakeholders. In this regard, it is noted that:

- dentists and dental auxiliaries are already subject to a range of general and specific occupational health and safety duties of care and requirements, many of which would effectively impose similar (but more general) requirements on dentists using x-ray equipment;
- regulatory compliance costs are generally borne by dental practitioners with over half of all practising dentists working in sole practices or in partnerships[6] — as such, many dentists may find it difficult to lower their compliance costs given the lack of scale; and
- variations in requirements across borders create the potential for higher compliance costs for dental professionals who move across borders or who operate dental practices in more than one jurisdiction.

27. As the industry has been subject to the requirements of the 1987 Code for many years now, there is an expectation that compliance is strong (enforced by State and Territory regulators), with ongoing costs reflecting the marginal or day-to-day costs and not the need to implement ongoing costs. In this light, maintaining the status quo is unlikely to raise direct costs, although if there were a better regulatory alternative then keeping the status quo would result in an opportunity cost — this issue is considered later in this impact analysis.

5 The Australian Dental Industry Association has about 20 members, and are may be up to 10 more companies that sell dental X-ray equipment as part of a broader business.

6 D. Teusner and A. Spencer 2003. *Dental Labour Force, Australia 2000.* AIHW cat. no. DEN 116. Canberra: Australian Institute of Health and Welfare (Dental Statistics and Research Series No. 28), p.51.

Administration

28. There are administration costs associated with monitoring and enforcing the 1987 Code, but it is difficult to distinguish these costs within each regulatory agency's general budgets as the administration costs are likely to be incurred in relation to other occupational health and safety and radiation protection related activities, even if there were no code.

29. For jurisdictions which have implemented the 1987 Code in somewhat different fashions the *status quo* option potentially involves some additional administrative costs in dealing with dentists or dental suppliers who operate in more than one jurisdiction. These costs arise from a lack of nationally consistent approach but are too difficult to quantify other than to acknowledge their potential.

Dynamic efficiency

30. 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, there is currently no up-to-date information for dental practitioners or auxiliaries on radiation safety issues other than the general standards put out by ARPANSA, such as RPS1. In the absence of change the status quo will promote standards that are inconsistent and outdated, potentially leading to uncertainty and confusion as to what standards apply.

Benefits

Health and safety outcomes

31. It is generally accepted that the status quo has provided health benefits for those working in the dental profession — including, dentists, dental auxiliaries, staff, and others — and patients — in terms of ensuring that radiation use is optimal for patients' needs.[7]

32. In terms of measuring those benefits, it is usual to consider the impact of radiation exposure in terms of average or collective annual effective dose.[8] For the status quo there are two relevant effective dose measures.

- The average annual effective dose measured for occupational exposure to radiation — that is, the exposure by dentists and others. In fact this is the type of exposure the Code is designed to directly influence. Based on the latest available information — material published by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)[9] — the average annual effective dose for all occupational exposure is 0.24 mSv per year.[10] Although in the area of dentistry measures have been recorded as being significantly lower — for example, closer to 0.02 mSv over the period 1990 to 1994.

7 National Radiological Protection Board, *Guidance Notes for Dental Practitioners on the Safe Use of X-ray Equipment*, June 2001.

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

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

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

- The average annual effective exposure from dental radiography procedures — that is, those that are directly exposed to radiation (such as x-rays) as a result of a trip to the dentist. Based on the latest available information — material published by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) — the average annual effective dose for the population is 0.002 mSv.[11] This is considerably lower than the average annual effective dose exposure from diagnostic medical x-ray examinations, which is 1.2 mSv per year.

33. In terms of occupational exposure, the average annual effective dose is significantly lower than exposure limits specified in the Code. As such factors other than merely specifying a maximum limit must be influencing the caution with which dentist view and act in relation to radiation protection. The most likely explanation is the promotion and adherence to the ALARA principle.[12]

34. Keeping the extremely low levels of occupational exposure in mind, it is reasonable to conclude that the status quo — including the wider occupational health and safety requirements — generates significant benefits (for dentists and workers in the dentistry industry) by avoiding the potential increase in risk of illness associated with unnecessary exposure.

35. While the level of exposure is quite low, it should be recognised that these measures are historical and relate to the application of the ALARA principle in the current regulatory context. It is not unreasonable to expect that this level of exposure might in fact increase for occupational and public exposure if there is no change to the *status quo* as changes in the regulation of radiation protection in other industries and regulatory variations across jurisdictions could result in a less stringent application of ALARA. Different standards and regulatory approaches to radiation protection by jurisdictions or for other industries sends a mixed signal about what constitutes good radiation protection and why ALARA is important.

36. In terms of medical exposure (that is, the second dot point), it is noted that while exposure limits do not apply to medical use of radiation (for patients), the level of average annual effective dose from diagnostic and medical x-ray examinations is also low relative to occupational exposure limits. The extension of the ALARA principle to medical diagnosis or dental diagnosis also appears to be important in ensuring radiation exposure is kept as low as possible.

37. Despite this relatively good performance of the status quo, there have still been some incidents in dentistry involving inappropriate exposure to radiation.

38. The Australian Incidents Register (ARIR) — see table 1.1 — lists five incidents involving dental x-ray units since the Code's introduction in 1987, of which one had a confirmed exposure.[13]

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11 This is estimated using UK data contained from UNSCEAR as a proxy for Australia — see UNSCEAR 2000, op cit, p 387.

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

13 It is likely that the ARIR understates the number of radiation-related incidents due to under-reporting.

Table 1.1

EXTRACT FROM AUSTRALIAN RADIATION INCIDENTS REGISTER — DENTISTRY INCIDENTS

Date	Jurisdiction	Incident description	Exposures/Doses
13-Jul-1982	SA	Faulty timer on dental x-ray equipment which remained 'on' (energised) during routine inspection.	Exposure of inspector of about 11R to hands & about 23mR to head & neck.
11-Apr-1983	ACT	Dental x-ray unit remained "on" due to removal of a faulty isolating switch by a serviceman.	Dose of 118mSv to film badge of Dental nurse.
February 1985	VIC	Faulty relay contact in dental x-ray unit causing x-ray tube be energised when the power was on. 2 patients were exposed for up to 60 seconds.	Skin dose to 2 patients of the order of 30rads to face.
1989	VIC	Patient received a radiation dose from a dental x-ray unit which had a defective timer.	Unknown.
1995	TAS	A dental practice had left two dental x-ray units at its premises after the practice moved interstate.	None.
January 1997	VIC	High radiation dose recorded on the personal TLD monitor of a dentist. Dentist advised that one of his staff had deliberately exposed the TLD.	Dose of 20,130µSv to personal TLD monitor of dentists.
March 2002	COMM	A dental team opened a dental surgery and heard a beeping noise. 2 hours later the noise was identified as a fault in the dental X-ray unit Three personnel were present and possibly exposed during this time.	Unknown
June 2003	NT	A device with a radiation label was reported at a dump site. It turned out to be a dental X-ray machine. The unit was recovered.	None.

Source: Australian Radiation Incidents Register

Option 2 – Industry Self-regulation

Self-Regulation Model

39. 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. But to develop some concept as to what are the costs and benefits of a self-regulatory regime it is necessary to make a judgement as to what the self-regulatory arrangements would look like.

40. One possible approach for dentistry — and perhaps the most likely self-regulatory regime — is what Priest[14] calls 'voluntary codes of conduct' where a peak industry body develops an industry standard on behalf of all dentists. Another possible model is the 'firm-defined regulation'. While these options are contrasted in table 1.2, the cost benefit analysis that follows is relevant for either option.

Table 1.2

MODELS OF SELF-REGULATION

Characteristic	The 'voluntary codes of conduct' model	The 'firm-defined' regulation model
Government involvement	Often little or none, but may be required or encouraged by legislation.	Government requires private industry to establish regulatory structure at firm level.
Source of power	Voluntarily established by contract.	Firm's control their own processes and employees.
Involvement of the public	Usually very little. May have public representative on committee developing code.	Depends. The structure may remove rulemaking from public consultation process.
Accountability	Usually no independent audit of compliance, no accountability to government. Accountability is all internal.	Government monitoring of private rule enforcement. Employee accountability to firm; firm to shareholders.
Rulemaking	Consensual. Approved by those who adopt code.	Rules made at firm or industry level specific to firm or industry requirements. May be approved by government regulator.
Adjudication	May be no provision; otherwise peer review committee, industry ombudsman or other dispute settlement mechanism.	Initial stage of firm discipline labour relations. Secondarily through courts or tribunals.
Sanctions	Often none or involve dismissal from industry organization or right to use logo or other identifier of compliance. Penal sanctions not available.	At first instance at firm level — e.g. fines, employment sanctions, dismissals. Second instance, fines or regulatory sanctions by government.
Offences	Non compliance with code is usually not an offence in law; may have due diligence implications.	Offences in regulatory legislation continue to exist. Adjudication in civil courts continues. First step is private enforcement.
Membership or coverage	Usually adherence to code is voluntary. Free rider issues can be a problem.	The overall legislation covers an industry, the tailored rules cover a firm or smaller industry group.

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

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

Costs

Compliance

41. Many dentists and dental auxiliaries use x-ray equipment — around 8 800 dentists and 2 200 dental auxiliaries and staff. As such, under self-regulation, there is the potential for thousands of alternative radiation protection approaches, which could result in confusion and uncertainty as to appropriate radiation protection practices. For example:

> As very little is known about the ultimate physiological effects of low levels of ionizing radiation, radiologists (and dentists) are at a disadvantage in assessing potential hazards.[15]

42. Furthermore, given that the majority of dental practices are small businesses the compliance burdens associated with self-regulation are likely to be significantly higher than for other industries where small businesses are a much smaller proportion of industry participants.

43. Under self-regulation:

- decision making about exposure to ionising radiation would be delegated and hence decisions on radiation exposure would be made by people who more often than not don't have expertise in radiation use and protection;
- the setting of standards could be influenced by commercial interests and could be subject to change without a rigorous assessment — potentially increasing the risk of over exposure for patients, dentists, dental staff, and others; and
- radiation protection will rely on dentists' ability to organise efficiently and effectively suitable processes, schemes or approaches to manage radiation risks; however, without legal compulsion there may be only limited incentives for such organisation.

44. Despite these issues, overall it is not expected that the 'marginal' compliance costs associated with self-regulation will be particularly high as dentists will still need to satisfy broader occupational health and safety laws — that is, they will still be required to incur compliance costs for those broader safety regulations regardless of whether they actively self-regulate in relation to the Code or not.

Administration

45. Self-regulation could involve some transitionary administrative costs for government if jurisdictions are required to amend legislation or regulatory controls. Presuming a move to self-regulation is acceptable, then legislative amendments are likely to be seen as 'machinery of government' and hence the administrative costs would be small. If however, legislative changes require considerable effort then a move to a self-regulatory approach could involve a one-off cost of up to $400 000 per jurisdiction.[16]

Health and Safety

46. Self-regulation is likely to result in a degree of radiation protection — in terms of both occupational and medical effective dose levels. However, self-regulation may result in increases in average annual effective dose levels, as it is quite likely that some dentists or workers in the dental industry may be inadvertently exposed due to less strict adherence to the ALARA principle or due to less effective alternative compliance approaches. For example:

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15 A. Monsour, B. Kruger, A. Barnes, and A. Sainsbury 1988, 'Measures taken to reduce X-ray exposure of the patient, operator and staff', Australian Dental Journal, vol. 33, no. 3, pp. 181-92.

16 The basis for this cost estimate is set out in section 1.4.

- dentists and/or dental auxiliaries using x-ray equipment in an inappropriate manner; or
- equipment suppliers could provide safety advice but the consistency of the advice might vary considerably with each manufacturer.

47. The following is given by way of example of the potential cost associated with an increase in average annual effective dose. If it is assumed that self-regulation increased the average annual effective dose for dentists to the current average occupational exposure of 0.24 mSv per year — this is consistent with the approach adopted by New South Wales in a recent regulatory impact statement[17] — then this would result in a cost of around $160 000 per year for dentists and those employed in the dental industry.[18] Such an increase in dose would be possible if dentists took less care in a self-regulated environment about where they positioned themselves during radiography.

48. Further, if it was assumed that the move to self regulation lead to a 1 per cent increase in the average annual effective dose for the general public from dental examinations — this could occur if self-regulation resulted in a less rigorous application of ALARA for dental patients — then this could incur costs to the community of around $9 400 per year.[19]

49. Allowing for self-regulation for dentists while maintaining strict radiation protection regulation of other areas could undermine the broader radiation protection message[20] — that is, it could lead to a reduced emphasis on ALARA for all users of radiation — this might result in an increase in exposure from medical x-ray examinations. By way of example, if this resulted in a 1 per cent increase in average annual effective dose from diagnostic medical x-ray examinations (which is currently 1.2 mSv per person per year) then this could cost the community $570 000 per year.

50. An increase in the level of exposure for the general public of 1 per cent for general public may in fact be on the low side. Exposure limits for people who visit a dentist do not form part of the current or proposed regulations — this is done to ensure that dentists and doctors are not limited in their use of diagnostic or therapeutic tools. In this regard therefore, the application of ALARA is all the more important. Yet regulatory variation across professions and across jurisdictions for the same profession about what constitutes appropriate radiation

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

18 This is based on:
— an assumed increase in average annual effective dose of 0.22 mSv per year (i.e. going from dentists current occupational exposure of 0.02 mSv to the average occupational exposure of 0.24 mSv per year) (taken from UNSCEAR 2000, op. cit.);
— a total of 10 000 dentist and dental auxiliaries in Australia; and
— an estimated cost per person sievert of $71 000 — which is an inflation adjusted and exchange rate converted estimate for occupational exposure and is higher than the estimate used in footnote 19 as it includes the cost of occupational exposure. This estimate is taken from United Kingdom National Radiological Protection Board 1986, *Board advice on cost-benefit analysis*, Chilton, UK, p10.

19 This is based on:
— a total population for Australia of 20 million people;
— an estimated cost per person sievert of $23 664 — which is an inflation adjusted and exchange rate converted estimate for public exposure and is lower than the estimate used in footnote 18 as it only includes the cost of public exposure and not the cost of occupational exposure. This estimate is taken from United Kingdom National Radiological Protection Board 1986, *Board advice on cost-benefit analysis*, Chilton, UK, p10; and
— UNSCEAR's estimate that the average annual effective dose from dental x-ray examination is 0.002 mSV per year (UNSCEAR 2000, op. cit., p. 387).

20 It is acknowledged that this is an assertion for which there is no supporting research.

protection for dentists may reduce the degree to which dentists extend radiation protection principles to dental patients. This view is supported by ARPANSA and other Australian regulatory agencies as well as regulatory agencies overseas.

51. Anything that increases the average annual effective dose will lead to a cost to dentists, dental patients, and potentially others in the community. While the size of such a change cannot be predicted in advance, it is reasonable to expect that self-regulation is likely to result in some increased exposure given the nature of ionising radiation — i.e. human senses (sight, taste, smell, etc) cannot detect the level of exposure.

52. Further, self-regulation is likely to make patients less confident that radiation protection has been addressed in a manner that meets community expectations. For example, in a recent survey in the United States, over 80 per cent of respondents thought that imaging personnel should be highly educated and highly regulated.[21] The survey highlighted that most people have limited knowledge about safe exposure limits for radiation.

Benefits

Flexibility

53. Sometimes a one-size fits all regulatory approach limits innovation and stifles more efficient compliance mechanisms. This is particularly true where there are easily identifiable alternative compliance approaches and that they are cheap and effective to implement.

54. Self-regulation promotes efficiency in providing the opportunity to pursue those alternatives and hence would provide for flexibility for the dentistry profession to manage radiation protection in a manner they determine appropriate rather than the manner imposed by regulators. This has the potential to lower compliance costs; however, as was noted earlier other regulatory obligations and occupational health and safety requirements may limit the extent of this potential benefit (if it exists at all).

Impact Analysis of the Proposed Code

Proposed code of practice

55. The third option involves the revision of the existing NHMRC Code of Practice, the 1987 Code of Practice for radiation protection in dentistry, to bring it into line with current radiation protection regulations.

56. The revised ARPANSA Code of Practice would differ from the 1987 Code of Practice in that it will:

    - include both requirements and advisory material — the proposed code includes only the requirements, with advisory material being published in the accompanying Safety Guide, making it clearer for both users and regulators which provisions are requirements and which are recommendations and advice;
    - expand on the responsibilities of dentists, including specific reference to dental auxiliaries;
    - update references to equipment standards;

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

- provide for digital imaging systems to be included;
- require a quality assurance system for film processing rather than making recommendations non binding;
- incorporate ICRP Publication 60 [1991] and the scheduled dose limit, consistent with RPS1 and the National Directory; and
- update procedures to minimise exposure to radiation, including relaxation of earlier requirements to use protective aprons and thyroid shields.

Costs

Compliance

57. The proposed Code will impact on dentists that use x-ray equipment in a number of ways.

- The Code will expand the definition of responsibility for ensuring safe practices to include persons in control of institutions, departments or practices using the dental x-ray equipment, rather than relying heavily on the role of dentists as per the 1987 Code. This is unlikely to result in additional time for dentists as they should already be familiar with standard practices and safety procedures under the 1987 Code.
- The Code will require the preparation of a quality assurance program for film processing, to try and ensure radiographs of appropriate quality are obtained first time rather than having to take repeat radiographs.[22]
- The initial implementation of quality assurance will involve some costs, both in terms of time from (dental staff) and in terms of upgrading or replacing equipment. There will however, as is discussed later, be savings from the operation of the program to offset these implementation costs. The cost associated with the quality assurance program is as follows.
  - Dental staff: dental staff will be required to perform new duties to run an efficient program. These duties include generating test films for their dental x-ray equipment and some record keeping.
  - The Australian Dental Industry Association advises that around half of all dental practices use digital radiography and hence these practices will not need to undertake film quality assurance. For those practices that will require quality assurance, the use of a step wedge can greatly reduce the time involved. It is expected that all practices that need to undertake film quality assurance will purchase a step wedge. The percentage of practices that will need to buy a step wedge is 48 per cent (an estimated 2 per cent already have a step wedge and 50 per cent of practices use digital radiography). A step wedge will cost $100, hence a total one-off cost of $356 600 (based on a cost of $100 for 3566 practices, which is 48 per cent of all 7430 practices).
  - In terms of dentists and staff time, the initial implementation cost (akin to the time taken to familiarise and train staff on what the Code requires) is assumed to take up to 2 hours and at a rate of $25 per hour per staff member for the 3566 dental practices

22 In fact one of the most common reason cited for repeat radiographs relates to film processing procedures, with at least one-third of dentists identifying this as a problem. For more information see, A. Monsour, B. Kruger, A. Barnes and A. Gordon Macleod 1988 *'A survey of dental radiography'*, Australian Dental Journal, vol. 33, no.1, pp. 9-13.

then this would sum to a one-off cost of $178 300. With the use of the step wedge, ongoing reference test imaging will take 12 hours per year (i.e. 15 minutes per week) and using the same rate of pay per staff member there would be a cost of $1 069 800 per year (i.e. 3566 practices x $25p/h x 12 hours per year).

– In short, film quality assurance will cost $1 604 700 in the first year and then $1 069 800 in subsequent years.

- Under the proposed Code, x-ray equipment will need to comply with the latest Australian Standard AS/NZS 3200.2.201. Satisfying this requirement will involve costs for dentist, particularly for apparatus that are found to be non-compliant. ARPANSA estimate that up to 5 per cent of apparatus may need modification to comply with the Code. The average cost of a dental unit has been estimated to be $7 000 and if all non-complying units need replacing then this implies a one-off cost nationally of $3.5 million. This represents an upper bound estimate though, as a proportion of non-complying apparatus are likely to only require minor modification and not full replacement. For the purposes of this analysis it has been assumed that only half will need to be replaced at a cost of $1.75 million.
- All dentists (who operate radiation equipment) will be required to appoint a radiation safety officer. In the majority of the States and Territories, the appointment of a radiation safety officer is a mandatory requirement as part of the dentistry licensing conditions.[23] As such, most jurisdictions require no further changes with the adoption of the proposed Code.

58. For New South Wales though, radiation safety officers are not currently require to be appointed. Assuming an average number of dentists in each practice is two, then around 1 500 radiation safety officers would need to be appointed in New South Wales.[24] If half a day was needed to familiarise radiation safety officers with the new role (4 hours), and at an average rate of $100 per hour per radiation safety officer, then this provision would involve a cost of $606 000. This is a one-off cost, as ongoing familiarisation costs would be marginal once dentists in the industry became familiar with the role of the radiation safety officer as part of their licensing conditions.

59. Compliance costs would also be incurred by dental auxiliaries who, for the first time, would be obliged to comply with safety aspects of a Code of Practice. It is unlikely however, that the compliance costs would be significant as the safety requirements for this stakeholder group are not appreciably different than those already being carried out as a requirement of current State/Territory training and licensing arrangements.

60. Manufacturers, suppliers and others who deal with dental x-ray equipment will need to update their knowledge of the relevant code of practice and standards. Although, the costs of updating their knowledge are expected to be small as the safety requirements incorporated into the code are based on Australian standards introduced in 2000.

23 The RSO is required to have sufficient professional expertise on all aspects of radiation safety, including advising staff on safe work practices, ensuring that regulatory matters are duly processed, and arranging for records to be provided and kept.

24 There are currently 3 034 dentists in New South Wales. *Source:* Australian Dental Association 2003, *Annual Report 2002-03*, p.5.

Administration

61. 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 Australian for some time now. This is particularly the case for jurisdictions that have adopted the 1987 Code as part of their licensing and registration conditions, ie: New South Wales, Victoria, South Australia, Queensland, Tasmania and ARPANSA.[25]

62. While for Western Australia, the Australian Capital Territory and Northern Territory — who have not directly adopted the 1987 Code — it has been suggested that they are already familiar with the provisions of the Code through other radiation protection measures and therefore face similar administration costs to the other jurisdictions.

63. It is estimated that the number of hours associated with familiarisation with a new code may be of the order of 40 person-hours. Using an average figure of approximately $25 to $30 per hour per staff member and an on-cost multiplication factor of 2.23, the cost to a regulatory body for retraining/familiarisation would be between $2 200 and $2 700. Nationally, this equates to between $17 800 and $21 400.

64. The introduction of the proposed Code would likely mean that each jurisdiction may need to amend regulations. As discussed earlier, changing regulations requires resources and costs on behalf of government, including seeking policy approvals, draft changes, and making regulations.

65. 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, consumers of products that use radioactive substances, nor 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 of what this might costs:

    - in Western Australia, the average cost of legislative amendments that was directly attributable to a department was estimated to be around $45 000 — although it was acknowledged that this was an underestimate of the costs;[26] and
    - in the United Kingdom it was estimated that to implement regulatory changes relating to European Works Councils would involve an administrative cost of amending legislation of approximately $400 000.[27]

66. While these examples are for legislative amendments, they highlight that changing regulations will also involve costs, albeit probably significantly lower than the above range of $400 000 and $3.6 million.

Benefits

Health and safety

67. There are a number of health benefits associated with the adoption of the proposed code. There should be increased health outcomes because of several factors:

25 National Directory for Radiation Protection, Annex 3, p.46

26 Department of Local Government and Regional Development 2003, *Annual Report 2002-2003*, Perth, p. 21.

27 Department of Trade and Industry (UK) 1998, ‘Implementation of the Regulations on European Works Councils — Regulatory Impact Assessment, London, p. 10.

- equipment will meet the current standards for radiation safety;
- procedures will be adopted to appropriately manage radiation protection (including radiation safety officers);
- the tightening of the occupational dose limits;
- better quality assurance of film processing techniques;
  - For patients this should lead to better diagnosis or at least a reduction in misdiagnosis. It is estimated that poorer quality films results in misdiagnosis in 0.1 per cent of cases. As such, fillings are undertaken when not required and for those that will need to adhere to the quality assurance requirements then this will mean that there is a potential saving in avoiding misdiagnosis in 10 000 cases (or 0.1 per cent of 5 million intra-oral films per year) at a cost of $1.25 million (assuming a cost of $250 per filling). Or if a filling is required but misdiagnosed and not undertaken it could end up requiring a root canal filling at a cost of up to $1000 per filling, therefore the cost of misdiagnosis that would be avoided by having a quality assurance scheme could be as high as $5 million per year.
- not taking as many unnecessary radiographs.
  - This will have three identifiable benefits: benefits for patients who will not be exposed unnecessarily, benefits for dentists who will not have to repeat unnecessary x-rays, and benefits in terms of resources savings for dentists who don’t waste x-ray film and other resources.
  - Paragraph 6 set out that ICRP has derived a nominal fatal cancer risk of 5 per cent per Sievert. ARPANSA and the Australian Dental Industry Association advise that up to 5 per cent of x-rays are repeated and that at least half of these could be avoided if the proposed quality assurance regime were introduced. There are over 10 million x-rays per year and as already stated half of these would be subject to quality assurance. Given each x-ray delivers a dose of 10 microsieverts and each OPG delivers a does of 30 microsieverts, then avoiding these repeat x-rays could save between 0.07 and 0.14 lives per year. Based on value of life estimates this represents a benefit to the community in the range of $35 000 up to $140 000 (if the value of life ranges between $500 000 and $1 million — see paragraph 67).
  - In terms of resources saved, dentists will save on the time now not needed to repeat unnecessary x-rays and on the cost of film and other resources. On the basis that it would take10 minutes to repeat and x-ray (which includes the time needed to develop an x-ray only to realise that it requires repeating) then the saving to dental practices who take up the new quality assurance requirements will be $525 000 per year.[28]
  - Dental practices will also save on the cost of films and other resources by not having to repeat x-rays. On the assumption that these costs (film and other resource costs) are equivalent to $1 per x-ray, then the amount saved will be $126 000 per year.

68. While the potential for improvement on current levels of occupational exposure may be low, the proposed Code may in fact produce benefits relative to the status quo and self regulation if it avoids increases in exposure levels that might otherwise occur under those alternatives.

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28 This estimate is based on an estimate of 126 000 x-rays avoided — which is 2.5 per cent of 10.5 million x-rays per year times the percentage of dental practices affected by the proposed regulations on quality assurance, that is 48 per cent. The time saving is estimated to range between 5 minutes and 10 minutes at a cost of $25p/h.

69. The proposed Code may however, result in improved health and safety outcomes for the community if the Code leads to a reduction in radiation exposure from diagnostic medical x-ray examinations more generally.[29] In part this could occur as a result of adopting and ensuring a uniform approach to radiation protection and consistent promotion of radiation protection across Australia, which encourages a more rigorous application of the ALARA principle and optimisation of radiation protection.

70. The introduction of the proposed Code could therefore result in reduced average annual effective dose for patients (i.e. dental patients as well as patients for other medical treatment). If it is assumed that the proposed Code will reduce the effective dose for patients by 0.1 per cent — this is broadly consistent with the approach taken by NSW 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 as high as $570 000 per year.[30]

71. In terms of incidents, it will not take many avoided radiation incidents to generate significant savings. 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) can range between $500 000 and $1 000 000 per work-place related death.[31] It is noted that there have not been any reported deaths, and only a relatively few radiation incidents, in dentistry.

72. Overall, while the direct health benefits for dentists and dental auxiliaries may not be all that large since radiation exposure is already extremely low, there is reason to believe that there will be considerable benefits to the broader community resulting from reduced exposure to radiation as part of medical treatment and diagnosis.

Uniformity

73. In addition to health benefits — and in fact a contributing factor to those health benefits — the proposed Code is likely to result in benefits associated with better coordination and uniformity of radiation protection regulation, for example:

- the advisory material being published in the accompanying Safety Guide — will give clear up-to-date national guidance on safety obligations for all who deal with dental x-ray equipment; and
- regulatory obligations can be better promoted through a consistent message from all jurisdictions regardless of location.

74. The proposed Code includes safety requirements for dental auxiliaries, thereby formally recognising (in a regulatory sense) their role in radiation protection, thereby promoting a uniform approach to safe working practices by dental auxiliaries across Australia.

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29 As noted earlier, this is an assertion that does not have supporting research.

30 This is based on the same assumptions set out in footnote 21 although the analysis examines a reduction in the average annual effective dose of 0.15 per cent rather than an increase of 1 per cent.

31 Derived from Industry Commission 1995, *Work, Health and Safety*, AGPS, Canberra. Collins and Lapsley note that 'The human capital approach is necessarily always adopted in benefit-cost analysis (BCA) where the nature of the task is to compare, on a common basis, time streams of costs and benefits.' — D. Collins and H. Lapsley 2002, *Counting the Cost: Estimates of the Social Costs of Drug Abuse in Australia in 1998-99*, Monograph Series No. 49, Commonwealth Department of Health and Ageing, Canberra, p. 14.

75. The proposed Code also introduces provisions for digital imaging systems. Suppliers, users and those who service this type of equipment will have clear direction on safety obligations, thus reducing regulatory variation across jurisdictions.

Efficient operations

76. There are efficiency savings for dental practices associated with the quality assurance program. These savings are:

- film and processing chemicals — better management of radiographic examination prescriptions will help avoid waste of both films and film processing chemicals;
- equipment — dental x-ray equipment and film processors will be put under less stress as the reduction in the number of radiographic examinations will increase the longevity of critical components such as x-ray tubes; and
- operation of practice — dental teams may see staff work more efficiently and effectively from reducing the number of repeated films and better diagnostic quality of the radiographs at lower radiation doses.
- the proposed code also sets out responsibilities for dentists including the determination of the clinical need for the examination. This requirement has the effect of minimising unnecessary examinations and thereby containing the cost to patients, and reducing medical insurance claims. While there are no specific figures on the number of examinations in dentistry that might be unnecessary, it has been an issue in the past when dental practice was to conduct a full mouth series of radiographs on a routine basis.

<u>Summary of cost benefit analysis</u>

77. The costs and benefits for each of the options are not necessarily spread evenly among the community. Relative to the status quo, the major distributional impacts associated with:

- self-regulation include:
  - there will be a greater onus on patients, dental auxiliaries and dentists to protect themselves by being knowledgeable of risks, and enforcing their rights under other regulatory obligations. Given that employees and the general public are not usually in the best position to protect themselves, largely because of information asymmetries, they will likely bear the burdens associated with reduced health and safety outcomes;
  - government regulators may in principle ‘save’ administration costs associated with the 1987 Code, but administration and enforcement costs will not change significantly as those resources are likely to be transferred and needed to enforce general occupational health and safety regulatory requirements;
- the introduction of the new code includes:
  - preparation of quality assurance program will incur additional costs, although this will be offset by reduced amount of inputs needed for film processing;
  - one-off costs associated with complying with the new x-ray equipment standards and that of appointing radiation safety officers;
  - direct health benefits to the broader community;

  - increased costs for regulators as they come up to speed on the Code, however, such costs are not considered to be significant; and
  - there is likely to be greater clarity in the Code and Safety Guide procedures.

78. In summary:

- the *status quo* has the benefit of familiarity (and hence attendant low compliance and administrative costs), but will promote an inconsistent approach to radiation protection more broadly;
- self-regulation is constrained by the fact that to be successful:
  - there must be common understanding of the risks associated with radiation safety and procedures amongst all practitioners;
  - there must be sufficient power and commonality of interest within an industry to deter non-compliance; and
  - the cost of non-compliance must be small.

  These issues are not satisfied with respect to the use of dental x-ray equipment.
- The proposed code entails higher administration and compliance costs than the *status quo*, but there are likely to be offsetting health and safety benefits.

79. The costs and benefits of the self-regulation model and proposed code have been assessed according to whether the impacts are minimal, higher or significantly higher compared with the status quo and these impacts (with the status quo being used as the base comparator). This assessment is summarised in table 2.3.

80. The change to the cost of visiting the dentist can be estimated by dividing the ongoing costs of $1.1 million per year by the total number of X-rays per year (10,500,000). That is, it is unlikely that introducing the Code will make any difference to the cost of a visit to the dentist.

Table 2.3

NATURE OF IMPACTS COMPARED TO THE *STATUS QUO*

Impact	Self-Regulation		New Code	
Cost	**Impact**	**Description**	**Impact**	**Description**
Compliance	*Minimal additional compliance costs*	Potentially some additional costs may need to be incurred in order to keep up to date on radiation protection requirements and to implement new systems for compliance.	*Significantly higher costs*	The initial generation of quality assurance programs is estimated to cost dental x-ray users up to $534 900 as a one-off cost and there will be ongoing costs of around $1.1 million per year. Upgrading to new equipment standards will account for up to $3.5 million in replacement costs. Appointing radiation safety officers will cost an additional $600 000, offset by health benefits from better radiation safety practices.
Administration	*Minimal changes to administration costs*	Increased costs associated with legislative amendments.	*Significantly higher costs*	Up to $21 000 in one-off staff training costs for regulators. Ongoing additional costs are not considered significant. May need to amend regulations to accommodate a new code may incur one-off administrative costs.
Health and safety	*Significantly higher costs*	Reduced regulatory control is likely to lead to higher effective dose levels which could result in a cost of up to $739 400 per year.		
Cost sub-total	*Significantly higher costs*	The likely increase in health and safety costs probably outweighs the costs associated with compliance and international standardisation	*Significantly higher costs*	Costs are likely to be higher in the first year, but reducing to after one-off establishment costs have been incurred.
Benefit				
Flexibility	*Higher benefits*	This option allows greater flexibility for industry to determine the appropriate exposure levels and whether conditions are mandatory or not.		

Impact	Self-Regulation	New Code	
Uniformity		*Higher benefits*	There is likely to be greater clarity in the Code and Safety Guide procedures, for dental auxiliaries and digital imaging systems.
Health and safety		*Significant benefits*	By not having to repeat x-rays following the implementation of QA, there should be savings of: between $1.25 million and $5 million per year for avoided misdiagnosis; between $35 000 and $140 000 in lives saved; $525 000 in dental staff time savings; and $126 000 in resource savings. Reduced exposure to radiation for the general community is estimated have a benefit of up to $570 000 per year.
Efficient operations		*Significant benefits*	There are efficiency savings for dentists from better operation of practices through the quality assurance program
Benefit sub-total	*There is likely to be only limited benefits, if they exist, in terns of additional flexibility.*	*There are significant benefits associated with the proposed code*	
TOTAL	***Moving to this option would more than likely result in a net cost***	***Introducing the proposed Code is likely to result in an overall net benefit to the community. In Net Present Value terms this benefit could range between $11 million and $50 million.***[32]	

32 This net present value assessment is calculated over a 20 year period using a discount rate 8 per cent. In other RISs the Office of Regulation Review has advised undertaking sensitivity analysis on the discount rate. In this case though, it is not been considered necessary to use a range such as 5 per cent or 10 per cent as this will not in anyway impact on the final result that the net benefits clearly outweigh the costs regardless of the discount rate.

Consultation

81. The Australian Dental Association (ADA), which has over 90% of Australian dentists as members, was represented on the working party that drafted the Code and has had significant input to its development. The ADA and was also responsible for requesting that the 1987 Code of Practice be reviewed and updated and is a strong supporter of the need for a Code. Its representatives support the content of the Code.

82. All State, Territory and Commonwealth regulators participated in the development of the proposed Code via their membership of the Radiation Health Committee.

83. The draft Code of Practice has been made available from the ARPANSA web site at www.arpansa.gov.au for a period of public comment until 16 September 2005. The following organisations have been advised of the availability of the proposed ARPANSA Code and this Regulatory Impact Statement and submissions have been requested:

    - Australian Dental Association (National and State Branches)
    - Victorian Dental Therapists Association
    - Dental Health Services Victoria
    - Rudolf Gunz & Co
    - Victorian Dental Service
    - University of Melbourne, School of Dental Science
    - Dental Board of Victoria
    - NSW Dept of Commerce, Electromedical Section
    - Sydney University Dental School, Oral Diagnosis and Radiology
    - NSW Radiation Advisory Council
    - NSW Hospital and University Radiation Safety Officer Group
    - NSW Dental Board
    - Radiation Control Section NSW Dept of Environment & Conservation
    - School of Medical Radiation Sciences, University of Sydney
    - Australian Institute of Radiography, NSW Branch
    - Health Services Union
    - Mr Bruce Waters (NSW)
    - Launceston General Hospital
    - State Dental Co-ordinator, Dept of Community & Health Services (TAS)
    - Tasmanian Dental Service
    - Dental Board of Tasmania
    - Australian Institute of Radiography, Tasmanian Branch
    - Tasmanian Dental Therapists Association
    - Medical Imaging Dept, Royal Hobart Hospital
    - ACT Radiation Council
    - Dental Board of the ACT
    - Queensland Diagnostic Imaging
    - Dr Paul Monsour (QLD)
    - University of Queensland Dental School
    - Statewide Medical Physics Services, Royal Brisbane Hospital
    - Radiation Health, Queensland Health
    - Oral Health Unit, Queensland Health
    - Australasian College of Physical Scientists in Medicine

- Dental Board of Queensland
- Mr R Bower (WA)
- Ms L Hartley (WA)
- Perth Dental Hospital & Community Services
- University of Western Australia Dental School
- Health Technology & Consultancy Services (WA)
- Director, Dental Radiography Course for Dental Assistants
- Chief Radiographer, SA Dental Service
- SA School of Dental Therapy
- University of South Australia, School of Medical Radiations
- Jones & Partners, Oral & Maxillo-facial Imaging Centre
- University of Adelaide, Dept of Dentistry
- Aduchem Pty Ltd
- Australian Dental Industry Association
- Australasian Central Association of Dentists Inc.
- Health Professions Licensing Authority, NT
- Department of Defence
- CSIRO, OHS&E
- Dental Health Services, Victoria
- Oral Health Branch, NSW Health Department
- Dental Health Program, ACT Department of Health
- Oral Health Branch, Queensland Health
- SA Dental Service
- Dental Services, Territory Health Services, NT
- Australian Dental Council
- Australasian Academy of Paediatric Dentistry
- Australasian Assoc of Orofacial Orthopaedics
- Aust & NZ Society of Paediatric Dentistry
- Australian Prosthodontic Society Inc
- Australian Society of Orthodontists
- Australasian Osseointegration Society Ltd
- Australian & NZ Academy of Periodontists
- Australian & NZ Academy of Endodontists
- International College of Dentists
- Academy of Dentistry International, Australasian Section
- Chief Radiographer, Sydney Dental Hospital
- General Secretary, Australian Institute of Radiography
- ANZSNM Accreditation Board
- Australian Radiation Services Pty Ltd (Vic)
- Radiation Safety Services (WA)
- Radiation-Wise (WA)
- Royal Australian and New Zealand College of Radiologists
- Australasian Association of Educators in Medical Radiation Sciences
- Radiation Safety Committee, School of Clinical Sciences, Charles Sturt University
- Discipline of Medical Radiation Science, University of Newcastle
- Radiation Protection Solutions (Qld)
- Australian Radiation Protection Society

Evaluation and Preferred Option

84. Allowing the Code to lapse without replacement (option 1) would lead to a lack of consistent, up to date radiation protection advice to the profession and possibly higher doses to patients and staff. It could potentially lead to uncertainty and confusion as to what standards apply.

85. By way of example, in dentistry the current licensing, personal radiation monitoring, equipment standards, equipment testing and quality assurance requirements vary from jurisdiction to jurisdiction.

86. As discussed above, ARPANSA and other regulatory agencies are undertaking a significant review and reform of all radiation protection regulations, users and uses of radiation — not limited to dentistry, which is covered in this RIS. Coming out of that process, regulators plan to promote and enforce the regulatory changes and educate users of the new radiation protection requirements; this will draw, at least in part, on a message of national consistency.

87. While any regulatory changes need to be considered in the context of this RIS, it is worth noting that regulation of radiation in dentistry forms part of the broader regulation of radiation in all sectors and industries. National consistency therefore relates to the issue of consistency across jurisdictions as well as consistency across other professions and other radiation protection regulations.

88. The success of the ALARA principle in keeping dentists occupational exposure well below the occupational exposure limits — as is discussed later — may be jeopardised if radiation protection regulations promote different standards of protection for the same level of radiation depending on the profession or industry. A message that says dentist and dental patients should be more (or less) careful about radiation exposure than say, vets, doctors, miners, researchers, and so on, is likely to undermine the message and adherence to ALARA for all users. For dentists specifically, a message that says that a dentist in one jurisdiction should be more (or less) careful about radiation protection than a dentist undertaking similar work in another jurisdiction significantly undermines the emphasis for dentists of the ALARA principle.

89. A self-regulation model (option 2) has increased compliance, administrative and health and safety costs, which would outweigh any limited benefit from increased flexibility. Therefore the self-regulation option was not preferred.

90. For the option of a new code, there will be cost increases in the first year, but ongoing costs are expected to be minimal. The savings to the community in the form of consistency of regulatory approach across Australia and across industries that use or are potentially exposed to radiation, the further promotion of the ALARA principle, and clarity of the regulatory requirements, regulatory structures, and ongoing regulatory certainty. Option 3 is therefore the preferred option.

Implementation and Review

91. The proposed Code will be promulgated by ARPANSA and made available to the dentistry profession and to regulators for adoption. It is proposed that the Code will be referenced in the National Directory of Radiation Protection, which is being 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 the 1987 Code.

92. The Code will be reviewed through the ARPANSA Radiation Health Committee in 10 years time to ensure that it is still relevant to the radiation protection needs of the dental profession and the community. Earlier review would be undertaken if there are identified problems in the implementation of the Code or should international or national radiation protection objectives change.

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