Australian Government
Australian Radiation Protection and Nuclear Safety Agency

Regulatory Impact Statement
Final

Code of Practice for Radiation Protection in Veterinary Medicine

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

Chapter 1. Introduction

1.1 Radiation and veterinary medicine

1 X-rays and radioactive nuclides are an essential part of the diagnosis and treatment of animals, and in research in veterinary medicine. The X-ray equipment used ranges from small low-powered portable equipment used for field radiography, to large high-powered fixed radiography equipment and 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 veterinary surgeons, staff and the public.

2 Radioactive materials used in veterinary practice include diagnostic radionuclides such as technetium-99 and therapeutic radionuclides such as iodine-131, used for the treatment of hyperthyroidism in cats.

3 Laser radiation is also used in veterinary medicine overseas and is expected to be used increasingly in Australia in future. Laser radiation is potentially hazardous to the eyes and skin and needs to be used safely to avoid burns, or eye injuries including blindness, both temporary and permanent.

4 The following table lists the current numbers of licensed veterinary surgeons and, where applicable, veterinary nurses, veterinary X-ray units, nuclear medicine practices, veterinary sources in each jurisdiction in Australia.

Jurisdiction	No. of portable Vet X-ray units	No. of fixed Vet X-ray units	No. of Vet Dental X-ray units	No. of licensed Vets	No. of Vet nurses (licensed)	No. Practices licensed for Nuclear Medicine	No./Type of Sealed Therapy Sources
ACT	20 (includes 13 CD mobiles)	4	0	22 (only licence 1 vet/practice)	0 (Not eligible)	1	0
ARPANSA	1						
NSW	390	188	3	824	N/A	12*	12*
NT	10	6	0	12	Not Registered in NT	0	0
QLD	62	271	10	642	17	2	0
SA	59	7	1	235	0		4 × Sr-90
TAS	65	2	1	98	0	0	0
VIC	322	76	10	672	10	8	6 × Sr-90
WA	193	55	5	474	0	1	1 × Sr-90
TOTALS	1087	644	30	2979	27	24	23

5 There are two categories of exposed persons, namely, persons occupationally exposed to radiation and members of the public. Occupationally exposed persons include all members of a department or practice, and temporary or visiting staff whose duties are likely to require their presence during radiographic, radiotherapeutic or nuclear medicine procedures. Veterinary students may also have some exposure to radiation. Members of the public include all other persons, for example, owners of animals, observers, and family of staff members living adjacent to the premises where radiation is used.

1.2 Risk of Radiation Injury in Veterinary medicine

6 All persons involved in the diagnosis and treatment of animals may be exposed to radiation hazards from the sources of radiation used in veterinary medicine.

7 In radiography, the principal hazard arises from the possibility of exposure to the primary X-ray beam. Scattered radiation and radiation leaking from the X-ray tube assembly, which are always present during an exposure, may also contribute further significant doses given the proximity of persons who may be required to hold animals in position for radiography.

8 Positioning animals for radiography is one of the areas of difficulty. Animals may be anaesthetised or sedated, however this is not always the case and there may be a need for an animal to be held in position for radiography. Hence, a member of the veterinary staff or the owner of the animal may need to be close to the X-ray tube and the primary beam during the exposure.

9 Radiography of large animals, eg horses, is often done in the field with the horse standing. There is the consequent need for the film cassette to be held in position for radiography. While handling tools and protective aprons and gloves should be used, again someone is of necessity close to the primary beam during the exposure. It is also true that in outdoor lighting it is much more difficult to see the light beam that indicates the X-ray beam location, hence the beam position is not as well located as would be the case indoors, and there is consequently a greater chance of an assistant having part of their body in the primary beam.

10 In radiotherapy, the radiation dose delivered to the patient is very much greater than in diagnostic procedures and thus the potential hazard may be much greater to the operator. Sealed radioactive sources, eg strontium-90 and cobalt-60, are also used for some veterinary treatments, mainly on large animals, raising further issues of possible damage to or loss of the sources.

11 In nuclear medicine or radiotherapy using liquid solutions, gases or aerosols there is an additional hazard of radioactive contamination from potential inhalation or ingestion risks.

1.3 Current legal position

12 Currently, all jurisdictions regulate the use of ionizing radiation, including both the operation of X-ray equipment and the use of diagnostic and therapeutic sealed and unsealed radioactive sources.

13 Within the regulatory frameworks, the safe use of radiation in veterinary medicine is also controlled by two Codes issued by the National Health and Medical Research Council (NHMRC) within its Radiation Health Series (RHS). These are:

(a) *Code of Practice for the Safe Use of Ionizing Radiation in Veterinary Radiology: Parts 1 and 2* (1982) (RHS No. 3)

(b) *Code of Practice for Safe Use of Ionizing Radiation in Veterinary Radiology: Part 3 – Radiotherapy* (1984) (RHS No. 10).

14 At present all jurisdictions, apart from the Australian Capital Territory, have adopted RHS No.3 as part of their requirements, licensing or registration conditions. Only three jurisdictions however, have adopted the RHS No.10 Code – New South Wales, Victoria and ARPANSA. In jurisdictions where the Codes have not been adopted into the regulatory or licensing system, they are still used as guidance by the regulators and profession.

1.4 Problem

Outdated information

15 The radioactive sources used in veterinary medicine could, if used or transported improperly or if involved in a serious incident, result in radiation exposure that would lead to radiation injury. Further, personnel assisting in work near veterinary radiation sources, both X-ray and radioactive, might not necessarily be fully trained in their use nor would they necessarily be familiar with the properties and potential hazards associated with radiation. The need for appropriate warning signage is also an important consideration, particularly for work away from the surgery situation.

16 The dose rates associated with some of the more 'powerful' X-ray equipment and radioactive sources can be quite significant. A high degree of safety needs to be engineered into the design of X-ray equipment and radioactive source containers and handling equipment to ensure that exposure is kept to a minimum and that, in the event of an incident, the likelihood of exposure is minimal. Consequently, any person who might be required to work with veterinary radiation sources or assist the veterinary surgeon in their use needs to be aware of the potential risks involved to ensure that doses received are kept to a minimum.

17 The 1982 and 1984 NHMRC Codes (RHS 3 and 10 respectively) do not have expiry dates but it is over 20 years since they were both published. The NHMRC does not wish to continue the RHS publications and has handed the responsibility for the review of these publications to ARPANSA. ARPANSA needs to review these two NHMRC Codes to ensure that workers and the public are able to obtain reliable information on the measures to take to avoid radiation exposure that might exceed permissible levels.

18 Since the establishment of RHS 3 and 10, there have been significant advances in the use of radiation in the treatment of animals. Radiotherapy using X-ray equipment and radioactive sources, nuclear medicine, veterinary dental, computerised tomography (CT), fluoroscopy and the use of laser treatment have evolved and their use increased in that time. While the two earlier Codes covered the use of some of these modalities to varying degrees, time has necessitated an increase in safety awareness to ensure that operators, assistants and the owners of the animals are not exposed to significant radiation levels. This is particularly important for procedures that were not considered in the earlier Codes such as nuclear medicine, CT and laser work.

19 The two NHMRC veterinary Codes were based on radiation protection limits specified in the International Committee for Radiation Protection (ICRP) Publication No. 26 in 1977. The ICRP publication has been significantly revised since the two NHMRC veterinary Codes were published. As such, the both NHMRC veterinary Codes need to be reviewed to ensure that veterinary procedures are conducted in a manner that the dose limits specified by the ICRP in its 1990 recommendations are not exceeded.

20 Further, the transport requirements in the 1984 NHMRC Code were based on the 1973 edition (revised and amended in 1979) of the International Atomic Energy Agency (IAEA) Regulations for the safe transport of radioactive material. The IAEA has also significantly revised its transport regulations since the 1984 NHMRC veterinary Code was published. An Australian Code of Practice that covered transport of radioactive material has been introduced (originally in 1982) and replaced in 1990, 2001 and 2008 to reflect the changes to the IAEA requirements. As the 1984 NHMRC veterinary Code (RHS 10) covers the use of radioactive materials in veterinary medicine, it also needs to be reviewed to ensure that the current

requirements of the IAEA transport regulations and the *Code of Practice for the Safe Transport of Radioactive Material 2008* are met.

21 This variation in the requirements of the two NHMRC veterinary Codes from the current international recommendations could result in a lack of uniformity across Australia. This could cause confusion for users, manufacturers and suppliers, and a lack of clarity as to which provisions apply to radiation sources used in veterinary medicine if some regulators were to still use the 1982 and 1984 Codes as their provisions are inconsistent with the 2008 Australian Transport Code and Radiation Protection Series No. 1 (RPS1). Increased costs could be experienced as each stakeholder group attempts to find out the requirements that they must comply with in each jurisdiction.

Externalities

22 The uncontrolled use of the radiation sources used in veterinary medicine represents a risk of radiation exposure and injury to users of the devices, workers at the premises, persons assisting in the veterinary procedure, the public, and represents a risk of contamination of the environment. The social costs that can result from uncontrolled exposure to radiation, eg. from a lost radioactive source, could be serious. Relying on market mechanisms for affected parties to directly negotiate with the veterinary practitioner that causes these externalities would involve transaction costs that may not be reasonable for users and members of the public to bear.

23 The Australian Radiation Incidents Register (ARIR) lists 2 incidents involving veterinary radiation sources. One incident involved the loss of a radioactive source and resulted in two regulatory officers attempting to retrieve it over a period of several days. The cost of such a search would be in the order of thousands of dollars in wages alone. The second incident involved the theft of a portable X-ray unit.

24 It is also known, mostly from regulatory inspections of veterinary practices, that other incidents involving veterinary equipment and personnel have occurred in the past that remain unreported to the ARIR. These include the loss of veterinary radioactive sources, inadvertent exposure during the use of radioactive sources, failure to use protective equipment when holding animals in position for radiography and evidence on veterinary radiographs of primary X-ray beam exposure of human limbs. Any improvement to current work practices would be expected to decrease the frequency of such events and increase the reporting of same. Work practices and equipment design requirements for veterinary radiation sources must continue to be stringent to reduce the risk of radiation exposure incidents.

1.5 Desired Objective

25 The objectives of options relating to the veterinary use of ionizing radiation are to:

- have nationally uniform requirements across the jurisdictions; 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

26 This cost-benefit analysis assesses the merits of three models of regulation for radiation protection in the veterinary applications of ionizing radiation, these are:

- *status quo* — this entails doing nothing and leaving two Codes from the National Health and Medical Research Council's — RHS No.3 Code of Practice for the Safe Use of Ionizing Radiation in Veterinary Radiology: Parts 1 and 2 (1982) and RHS No.10, Code of Practice for Safe Use of Ionizing Radiation in Veterinary Radiology: Part 3 – Radiotherapy (1984) — in place;
- *self-regulation* — this option would allow industry to set its own radiation safety requirements, subject to other occupational health and safety (OH&S) obligations; and
- *update the current Codes* — this option entails re-writing both Codes and updating them with the current radiation protection requirements and philosophies. It would consist of combining both Codes as well as expanding to give guidance on veterinary nuclear medicine and the use of lasers in veterinary medicine. The proposed Code would provide a set of requirements to be adopted by State/Territory regulators as part of their regulatory frameworks.

27 This cost-benefit analysis assesses the costs and benefits associated with implementing the new Code relative to the current approach to regulation (referred to in this report as the *status quo*).[1] In the same manner this analysis also assesses the merits of a self regulation approach whereby veterinary practitioners are able to set and enforce their own safety requirements regarding the exposure of staff and the public to radiation.

28 The remainder of the report is structured as follows:

- Chapter 3 highlights areas of concern in relation to the current regulatory approach governing veterinary radiation practices;
- Chapter 4 assesses the viability of a self-regulation approach; and
- Chapter 5 assess the costs of implementing ARPANSA's proposed Code of Practice — these costs are assessed relative to the *status quo*;
- Chapter 6 assess the benefits of implementing ARPANSA's proposed Code of Practice — these benefits are assessed relative to the *status quo*;
- Chapter 7 summarises the cost-benefit analysis; and
- Chapter 8 details the consultation that took place during the process of preparing the proposed Code of Practice;
- Chapter 9 draws conclusions and provides recommendations;

[1] 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 false sense of accuracy.

- Chapter 10 outlines the process of implementation and future review; and
- Chapter 11 lists references used in preparing this RIS.

2.2 Cost benefit analysis for each alternative

29 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.

2.3 Affected Parties

30 The parties who are likely to be affected by the use of veterinary radiation sources include:

(a) Veterinary surgeons who use X-ray equipment, radioactive sources and lasers including those employed in research centres and private practitioners (there are approximately 3000 veterinary surgeons licensed to use radiation sources);

(b) employees of veterinary surgeons such as veterinary nurses and ancillary staff;

(c) assistants to veterinary surgeons, including otherwise untrained animal owners;

(d) suppliers of the equipment and sources;

(e) Government regulators (State, Territory and Commonwealth); and

(f) the community.

Veterinary surgeons using radiation sources need to know correct procedures to ensure the safety of their employees and assistants who may be required to work near radiation sources during the procedure. Companies also need to ensure a duty of care to the wider community. Employees of veterinary surgeons or in veterinary research centres need to be protected from potential harmful effects of exposure to radiation while at the same time not perform any act that might compromise the safety of radiation source or its installation.

Suppliers of the veterinary radiation equipment and sources need to ensure that all equipment and sources supplied to users is consistent with international standards and is safe to use.

Governments and the public are stakeholders insofar as any incident involving the use of veterinary radiation sources impacts on public perception of radiation safety generally.

Chapter 3. Status quo

3.1 Impact Analysis

31 The NHMRC does not intend to continue publishing its RHS publications. It has handed the responsibility for the review of RHS publications to ARPANSA. Unless ARPANSA reviews the Code and republishes it, the industry will be left without a code of practice on the safe use of ionising radiation in veterinary radiology and radiotherapy.

32 Under the status quo option, the RHS No. 3 and No. 10 Codes would continue to remain the prime regulatory tool for ensuring radiation protection in veterinary medicine. Keeping the status quo would involve no new costs; however, there are several indirect costs potentially incurred by stakeholders, which are discussed below and quantified where possible.

3.2 Costs

Compliance

33 There are ongoing compliance costs associated with both Codes, which place a burden on a range of stakeholders. In this regard, it is noted that:

- veterinary surgeons and others in the industry 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 veterinary practices using x-ray equipment; and
- regulatory compliance costs tend to be borne disproportionately by small businesses and given a large number of veterinary practices are small businesses — in fact, only 13 per cent of veterinary practices have more than five veterinary surgeons[2] — then the compliance costs of radiation protection legislation may be higher than other areas of radiation protection such as mining.

34 In the main, the veterinary industry has been subject to the requirements of both Codes for many years now; there is therefore an expectation that compliance is strong (enforced by State and Territory regulators), with ongoing costs reflecting the marginal or day-to-day costs. There is no expectation that veterinary practices will need to implement new systems or incur new compliance costs under the *status quo* option. The *status quo* option does however — as with any regulatory option — create opportunity costs — this issue is considered below.

Administration

35 Relative to a perfectly streamlined co-ordinated national regulatory system for radiation protection, the *status quo* involves an opportunity cost for veterinary practices. Currently the regulations differ across jurisdictions thus resulting in different costs depending on location and reducing the scope for nation-wide efficiencies. For veterinary surgeons who operate in multiple jurisdictions then clearly this adds costs.

36 For each jurisdiction the *status quo* results in administration costs associated with monitoring and enforcing both Codes. Individually identifying these costs is somewhat difficult, as they often tend to be absorbed within the entire budget for regulatory agencies rather than reported separately. Further, the administration and enforcement costs may well be incurred regardless of the *status quo* as regulatory agencies are likely to carry out other occupational health and

[2] ABS (Australian Bureau of Statistics) 2001, *Veterinary Services, Australia, 2000*, cat. no. 8564.0, AusInfo, Canberra.

safety and radiation protection related activities — that is, it is extremely hard to separate out the avoidable costs associated with the *status quo*.

Dynamic efficiency

37 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.

38 At the same time, jurisdictions are implementing the National Directory and have adopted (since 1995) the exposure limits set out in RPS1.

39 If the *status quo* option were to be maintained — that is to remake the Codes as they currently stand — then this would result in different radiation protection standards and exposure limits for veterinary surgeons relative to other industries or sectors that use radiation. The health and safety implications of this are discussed later but in essence this could lead to a weakening of the ALARA principle, which states that radiation exposures should be kept as low as reasonably achievable while taking into account economic and social factors.

3.3 Benefits

Health and safety outcomes

40 It is generally accepted that the *status quo* has provided health benefits for those working in the veterinary profession — including, veterinary surgeons, assistants, staff, and others. 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.[3] 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 veterinary surgeons and others working directly in the veterinary sector. 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)[4] — the average annual effective dose for all occupational exposure is 0.24 mSv per year.[5] For veterinary surgeons however, the doses are significantly lower — 0.015 mSv per year.[6] The average effective doses of veterinary surgeons in education departments and research centres are 0.046 mSv and 0.023 mSv respectively. Despite these small variations, exposure levels in the veterinary field are significantly below the exposure limits in the Code and RPS1.

- The average annual effective dose to the public — that is, those that are directly exposed to radiation (such as X-rays) as a result of taking their pets and animals to a veterinary surgery or hospital, and other members of the public in areas close to where radiation is used. Based on the latest available information — material published by the United Nations Scientific Committee on

[3] 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.

[4] 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.

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

[6] The doses for occupationally exposed personnel such as assistants and receptionists are significantly lower, with each group recording an average dose of 0.007 mSv in veterinary practices. *Source: ARPANSA.*

> the Effects of Atomic Radiation (UNSCEAR) — the average annual effective dose for the population is 0.002 mSv.[7]

41 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 veterinary practices view and act in relation to radiation protection. The most likely explanation is the promotion and adherence to the ALARA principle.[8]

42 Keeping the extremely low levels of occupational exposure in mind, it is reasonable to conclude that the *status quo* — including several occupational health and safety obligations — generates significant benefits (for veterinary surgeons and workers in the veterinary industry) by avoiding the potential increase in risk of illness associated with unnecessary exposure.

43 Despite this relatively good performance of the *status quo*, there have still been circumstances where veterinary surgeons have been inappropriately exposed to radiation, particularly for veterinary surgeons who undertake radiographic assessments of horses for yearling sales.[9]

> The Radiation Health Committee is concerned that 'the accumulated dose to those performing the radiography could be significant and possibly above the radiation dose limits in radiation safety regulations and standards…exacerbated by the fact that only a small number of persons are performing the radiography for the yearling sales…'.[10]

44 There are currently at least 20 veterinary surgeons and other personnel undertaking equine radiological assessments or in close proximity to those assessments. Significant benefits could be generated if the *status quo* — or any regulatory approach for that matter — that could avoid any severe adverse consequences from exposure to radiation for this high-risk group. 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 and revenue — are worth in excess of $500 000 per work-place related death.[11]

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

8 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.

9 ARPANSA 2004, *Statement on Veterinary Investigations for Yearling Sales*, Press Release, July.

10 Ibid.

11 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.

Chapter 4. Self-Regulation Model

45 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.

46 One possible approach for veterinary — and perhaps the most likely self-regulatory regime — is what Priest[12] calls 'voluntary codes of conduct' where a peak industry body develops an industry standard on behalf of all veterinary surgeons. Another possible model is the 'firm-defined regulation'. While these options are contrasted in table 4.1, the cost benefit analysis that follows is relevant for either option.

TABLE 4.1. 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.

4.1 Costs

Compliance

47 Nationally, there are around 3 000 licensed veterinary surgeons[13] comprising around 1 800 veterinary practices.[14] Under self-regulation therefore, there is the potential for hundreds of

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

[13] Figures from ARPANSA.

[14] Australian Veterinary Association, *2003 Annual Report*, Accessed 10 November 2004 at http://www.ava.com.au/, p.7.

alternative radiation protection approaches. This could result in confusion and uncertainty as to appropriate radiation protection practices, it will certainly add compliance costs to the industry, and it will make it difficult for regulatory agencies to assure themselves that radiation protection was being appropriately undertaken.

48 Furthermore, given that the majority of veterinary 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.

49 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 may not 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 veterinary surgeons, veterinary staff, the public and animals (pets); and
- radiation protection will rely on a veterinary practices' 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 to do so.

50 These factors lead to a conclusion that veterinary practices will need to incur most costs and dedicate more time to radiation protection under self regulation that under the *status quo.* This could cost up to $450 000 per year in compliance costs, assuming that it requires each veterinary practice to devote 1 full day to radiation protection per year.[15]

Administration

51 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.[16]

Health and Safety

52 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 some veterinary surgeons or assistants in the veterinary industry may be inadvertently exposed due to less strict adherence to the ALARA principle[17] or due to less effective alternate compliance approaches. For example:

- veterinary surgeons and/or assistants using x-ray equipment while positioning an animal for a diagnostic treatment; or

[15] This estimate is based ABS data which states that per practitioner income was $70 000 per year in 2001—ABS 2001 Cat 8564.0 — and an estimated number of working days of 280 in a year. The cost to veterinary practices is the value of the lost day due to self-regulation (as measured in terms of lost income), which is $250 per veterinary practice per year (based on $70,000/280) and multiplied by the number of veterinary practices (ie 1800).

[16] The basis for this cost estimate is set out in the section on the "Proposed Code of Practice".

[17] It is acknowledged that this is an assertion for which there is no supporting research.

- veterinary surgeons during radiotherapy treatments, where the radiation dose delivered to the patient is very much greater than in diagnostic procedures.

53 If self-regulation increased the average annual effective dose for veterinary surgeons to the current average occupational exposure of 0.24 mSv per year — then this would result in a cost of around $46 860 per year for veterinary surgeons and those employed in veterinary medicine.[18]

54 Like the exposure level of veterinary surgeons, the average occupational dose for all industries is still significantly below the proposed exposure limits. In this light, if self-regulation resulted in exposure levels of around 1 mSv per year then the cost would increase to just under $200 000 per year and if the exposure level increased to the proposed exposure limit of 20 mSv per year then the cost would be just under $4 million per year.

55 Anything that increases the average annual effective dose will lead to a cost to veterinary practices, assistants, researchers 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.

4.2 Benefits

Flexibility

56 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 which are cheap and effective to implement.

57 Self-regulation promotes efficiency in providing the opportunity to pursue those alternatives and hence would provide for flexibility for the veterinary 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).

[18] This is based on:

— an assumed increase in average annual effective dose of 0.22 mSv per year (i.e. going from the current occupational exposure of 0.015 mSv to the average occupational exposure of 0.24 mSv per year) (taken from UNSCEAR 2000, op. cit.);

— a total of 3 000 vets in Australia; and

— an estimated cost per person sievert of $71 000 — which is an inflation adjusted and exchange rate converted estimate taken from United Kingdom National Radiological Protection Board 1986, *Board advice on cost-benefit analysis*, Chilton, UK, p10.

Chapter 5. Costs of proposed code of practice

5.1 Introduction

58 The third option involves the revision of the two Codes issued by the National Health and Medical Research Council within its Radiation Health Series, to bring it into line with current radiation protection regulations.

59 ARPANSA has prepared a draft Code of Practice to provide guidance on uses of radiation in veterinary medicine. If implemented, the ARPANSA Code will replace 1982 and 1984 NHMRC Codes and will be published as part of the new ARPANSA Radiation Protection Series. In addition to updating the guidance provided in the NHMRC Codes, the proposed ARPANSA Code has been expanded to include guidance on veterinary nuclear medicine and the use of lasers in veterinary medicine.

60 It will supplement the radiation control legislation of the Commonwealth, States and Territories and will be implemented by the appropriate regulatory authorities in each of these jurisdictions. It is intended that the Code would be brought in through the National Directory process 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*.

61 The proposed ARPANSA Code applies to the use of radiation in the practice of veterinary medicine, teaching and research and embraces diagnostic radiology, radiotherapy and nuclear medicine. It lays down detailed requirements for the following protective measures:

(a) allocation of responsibility for all safety procedures and radiation surveillance,

(b) provision of appropriate premises and installations,

(c) provision of appropriate radiation and ancillary equipment, and

(d) provision of appropriate maintenance and safety checking of equipment.

62 The revised ARPANSA Code of Practice would differ from the RHS No. 3 and 10 Codes of Practice in that it will:

- require explicit compliance with the justification, optimisation and limitation principles of radiation protection. While these principles are already entrenched within RPS1 and the legislation of each jurisdiction, the proposed Code highlights the need for following those principles;
- update the guidance provided in these two Codes into a single Code;
- expand on the guidance on veterinary nuclear medicine;
- expand on the guidance on the use of lasers in veterinary medicine;
- incorporate ICRP Publication 60 [1991] and the scheduled dose limit, consistent with RPS1 and the National Directory;
- require the preparation and implementation of a Radiation Management Plan for all veterinary practices, thereby engendering a safety culture at the practice;
- introduce the *Code of Practice for the Safe Transport of Radioactive Material (2008);* and
- require better practices for holding X-ray units or film cassettes during diagnostic, therapeutic or radiography cases.

5.2 Compliance Costs

63 The proposed Code establishes a range of obligations on veterinary practices that use ionizing radiation. In most cases, the requirements of the proposed Code are already being implemented by practitioners in the field. This section details and where possible, quantifies the compliance costs that are in addition to those incurred under the *status quo*.

Justification

64 Under the proposed Code, all procedures involving ionizing radiation 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.*[19] [20]

65 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 requirements in Tasmania deal with the concept of justification.[21] [22] 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.[23]

66 *The once-off compliance costs associated with coming to terms with the justification requirements are estimated to be around $720 000.*

67 This cost estimate is based on the following:

- An estimated 1800 centres at which the Responsible Person is required to come to terms with the new justification principles.
- 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.[24]

Radiation management plans

68 Under the proposed Code there are requirements for the defined 'Responsible Person' to develop, document, resource, implement and regularly review a radiation management plan.

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[19] ICRP 60 (1991), paragraph 112.

[20] ARPANSA 2009, *Code of Practice for Radiation Protection in Veterinary Medicine* (draft).

[21] Information provided from the Tasmanian regulator, the Department of Health and Human Services.

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

[23] 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.

[24] The rate of $100 per hour for Radiation Safety Officers has been used in previous ARPANSA cost-benefit analyses, for example, see ARPANSA, *Code of Practice and Safety Guide for Radiation Protection in Dentistry, Regulatory Impact Statement*.

The radiation management plan addresses a raft of topics around the safety of veterinary practices involving radiation 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 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 and non-ionizing (laser) radiation;
- the training, qualifications and supervision of the staff of the medical practices and their roles and responsibilities;
- actions necessary to manage a radiation incident including emergency procedures, reporting and investigation; and
- arrangements for the storage of radioactive material.

69 Regulations in Queensland and Tasmania already require that practitioners prepare and implement radiation management plans similar to the requirements put forward in the proposed Code so additional compliance costs will not be incurred in these two States.[25] 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

70 The preparation of radiation management plans will bring about an initial once-off cost of about $588 000 based on the following:

- An estimated 1400 veterinary centres in Australian jurisdictions (other than Queensland and Tasmania) being required to prepare an initial radiation management plan.[26]
- Indications from State regulators that it may take about four hours to prepare a radiation management plan for small centres and up to 8 hours to prepare a radiation management plan in larger centres.[27]
- The assumption that 95 per cent of affected centres (equivalent to 1330 centres) are small and will therefore require 4 hours preparation time and that the remaining 5 per cent of centres (70) are large and therefore will require 8 hours preparation time.
- Assuming an hourly time cost of $100 per hour for Radiation Safety Officers (or the Responsible Person) who will likely be responsible for preparing the radiation management plans.[17]

If, however, 10% of the centres are considered to be "large" centres, this initial one-off cost for preparation of a radiation management plan could be as high $616 000.

[25] Information provided by the Queensland and Tasmanian regulators.

[26] The number of centres in jurisdictions other than Queensland and Tasmania were estimated using the combined Queensland and Tasmania populations as a ratio of centres to total population and ABS data on population, see ABS 2006, Population by Age and Sex, Australian States and Territories, cat. no. 3201.0.

[27] Based on information from State regulators.

Review of radiation management plans

71 Requirements to review radiation management plans will bring about recurrent annual costs estimated to be between $94 500 and $119 000 based on the following:

- An estimated 1400 centres across all jurisdictions other than Queensland and Tasmania being required to prepare a radiation management plan[28].
- Indications from State regulators that it would take about half an hour per year for smaller centres (90-95% of the total) to review a radiation management plan and up to half a day (4 hours) per year for the larger centres with multiple sources of radiation.[29]
- Time costs of $100 per hour using data for the Radiation Safety Officers as used in existing ARPANSA regulatory impact analyses.

Total costs of radiation management plans

72 *In total, it is estimated that the initial preparation of radiation management plans will bring about once-off compliance costs of between $588 000 and $616 000 and ongoing review costs of between $94 500 and $119 000 per year*.

Formalisation of training

73 The proposed Code requires the Responsible Person to ensure that all individuals who may be occupationally exposed to ionizing radiation have training that relates to:

- the type of work being undertaken;
- radiation producing equipment or source of radiation that the individual may be required to use; and
- potential radiation hazards associated with the practice.

74 Jurisdictions currently have training requirements in place similar to those of the proposed Code for licensed staff such as veterinary surgeons. The proposed Code will not create any new or additional compliance costs relating to training for these staff.

75 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 veterinary Code to formalise the training needed in the veterinary 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 that might not already be providing training. Additional compliance costs will therefore be incurred in training or instructing veterinary assistants who do not currently receive training or instruction in ionizing and non-ionizing radiation. There will be an initial once-off cost to train all current veterinary assistants working in areas where they may be exposed to ionizing or non-ionizing radiation and there will also be ongoing costs

[28] 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.

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

in training all new nursing staff or assistants. However, many larger practices already include training as part of induction and specific training for staff who are required to work in radiation areas. It is assumed that 50% of veterinary nurse and ancillary staff would require training through the introduction of the Code. This figure however, could be an upper limit as modern veterinary nurse training course have a component on the risks of exposure to radiation on radiation protection.

Initial training costs

76 At present there are about 3 600 veterinary nurses and ancillary staff working in Australia.[30] In the absence of more specific information, it is assumed that all of these nurses work in areas where they may be occupationally exposed to ionizing radiation. If we assume that 50% of these nurses are already receiving training or instruction, then 1 800 veterinary nurses and ancillary staff would require training or instruction as a result of the Code being introduced.

77 Based on information provided by the State regulators, it is estimated that the training requirements of the proposed Code may take anywhere between half to one hour to fulfil.[31]

78 Using ABS average weekly earnings and hourly rate data for health and community services workers, the cost of a veterinary nurse time is estimated at about $25 per hour (based on weekly earnings of $1000 and a 40-hour work week).[32] Total initial costs associated with additional training for 1 800 existing nurses will be between $22 500 and $45 000.

Ongoing training costs

79 If we assume that about 275 new nurses come into the profession each year[33], using earnings and hours data as immediately above and assuming that training requirements would take between half and one hour to complete then it can be expected that ongoing training costs associated with the proposed Code may be about $3 430 and $6 875 per year.

Total costs of radiation protection training

80 *The initial cost is estimated to be between $20 400 and $40 700 and the ongoing training costs are estimated to be between $15 500 and $31 050 per year.*

Other associated costs of the proposed Code

81 The proposed Code will impact on veterinary practices that use X-ray equipment in several other ways as follows:

- The proposed Code introduces several requirements for ensuring safe practices for staff and visitors, such as requiring:
  - warning signs;
  - irradiation indicators; and
  - X-ray tube shielding.

[30] Based on discussion with the Victorian regulator, the number was estimated as two veterinary nurses/ancillary staff per practice.

[31] Information received from State regulators indicated that training requirements may take between half and one hour.

[32] ABS 2007, *Average Weekly Earnings*, cat. no. 6302.0, May.

[33] This assumption is based on the ratio of new to existing nursing staff in the medical nursing profession. In 2005-06, there were 23 000 new medical nurses coming into a population of 302 000 existing medical nurses giving a ratio of 0.076.

These requirements are unlikely to result in additional costs for veterinary practices as they should already be familiar with and have implemented systems consistent with standard practices and safety procedures under the Australian Standards.

- The proposed Code requires the Responsible Person to ensure that radiation safety assessments be carried out when the X-ray high voltage generator is replaced or otherwise modified. This could cost the industry around $225 000, if up to half a day is needed per premise to carry out the assessment.[34]

82 The proposed Code includes guidance on the use of lasers in veterinary medicine. At present only the Commonwealth, Western Australia and Tasmania regulate the use of dealing with (particular classes of) non-ionising radiation apparatus or equipment. These jurisdictions, however, currently do not regulate particular classes of lasers likely to be used in veterinary practices and therefore the guidance material will not impact on veterinary practices in those jurisdictions. For the other States and the Northern Territory, veterinary practices will not be impacted unless these jurisdictions regulate non-ionising radiation.[35]

83 Under the proposed Code, guidance has been expanded to include advice on the use of nuclear medicine in veterinary practices. This involves both the procedures and facilities relevant for using unsealed radioactive sources for either diagnostic or therapeutic purposes. Nationally, there are 23 veterinary practices licensed for nuclear medicine.[36] The proposed Code requires:

- special dedicated facilities for storing, safe handling, manipulating and dispensing of unsealed radioactive sources;
- approval of the design and the facilities by the relevant authority;
- protective aprons and gloves;
- dedicated facilities used for nuclear medicine procedures for housing of animals;
- completing records.

84 The proposed Code will require familiarisation with the *Code of Practice for the Safe Transport of Radioactive Material (2008)* which sets out the internationally accepted standards for packaging, loading and transporting of radioactive substances. At the time of writing, the *Code of Practice for the Safe Transport of Radioactive Material (2008)* was in the process of being adopted by all jurisdictions and should not therefore result in additional time or resources for veterinary industry members or regulators.

85 Manufacturers, suppliers and others who deal with veterinary X-ray equipment will need to update their knowledge of the proposed Code of Practice. The costs of this are expected to be small however as the safety requirements incorporated into the proposed Code are already familiar to them as equipment aspects are incorporated in particular Australian Standards. Many of these suppliers also provide similar equipment to the medical profession where the standards are higher due to consideration of the dose received by human patients. As their equipment would already meet the more stringent standards required for medical X-ray equipment, the requirements of the proposed Code would have minimal costs for these suppliers.

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[34] The inputs used here were discussed earlier in footnote 15, namely the value per day for a veterinary surgeon's time is $250.

[35] The Australian Capital Territory cannot regulate non-ionising radiation, as non-ionising radiation is not defined in its Act.

[36] These practices are in New South Wales, Victoria, Queensland and Western Australia.

Administration

86 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 for certain jurisdictions — New South Wales, Victoria, and ARPANSA — as they have adopted both existing Codes as part of their licensing and registration conditions.[37]

87 For the remaining jurisdictions – Queensland, Western Australia, South Australia, Tasmania, the Australian Capital Territory and Northern Territory who have not directly adopted the RHS 10 Code (nor the RHS 3 Code in the case of the Australian Capital Territory) – it has been suggested that there would be a small cost associated with familiarisation with the Code.

88 For these jurisdictions, 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 2.2, the cost to a regulatory body for retraining/familiarisation would be between $2 200 and $2 700. Nationally, this equates to between $13 200 and $16 200.

89 The introduction of the proposed Code would also 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.

90 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.

91 By way of example of what this might entail, 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.[38]

92 Using these estimates as a guide to the administrative cost of implementing the proposed Code, then the total administrative cost of amending legislation nationally could be around $405 000. This assumes that all jurisdictions need to pass some legislative amendments. The actual cost could be much lower as these amendments are relatively non-controversial, would have been subject to considerable debate, and some of the jurisdictions have already adopted both Codes in their legislative frameworks — hence it should not consume significant parliamentary or departmental resources.

5.3 Summary of costs

93 A summary of costs incurred under the proposed Code is provided in Table 5.1.

[37] National Directory for Radiation Protection, Annex 3, p.48.

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

5.1 Summary of Costs of Proposed Code

Cost category	Discussion of costs relative to the *status quo*
Compliance costs:	
—justification	A once-off compliance cost as the Responsible Person in each relevant veterinary practice comes to terms with the new regulations of about $720 000.
—radiation management plans	In total, it is estimated that the initial preparation of radiation management plans will bring about once-off compliance costs of between $588 000 and $616 000 and ongoing review costs of between $94 500 and $119 000 per year.
—formalisation of training	The initial cost is estimated to be between $22 500 and $45 000 and the ongoing training costs are estimated to be between $3 430 and $6 875 per year.
—radiation safety assessment following modification of a high voltage generator or radioactive source device	An as required cost to the industry of approximately $225 000. Taken as an ongoing (annual) cost.
Administration costs – Regulatory	The administrative burden associated with the introduction of the proposed Code in retraining and familiarisation of regulatory staff will bring about a once off cost of about $13 200-$16 200. The national costs of amending legislation in each jurisdiction will bring about a once off cost of about $405 000.
Total costs	***Initial once-off costs estimated to be between $1.16 and $1.8 million.*** ***Ongoing costs are estimated to be between $322 900 and $350 875 per year.***

Chapter 6. Benefits of the proposed Code of Practice

6.1 Introduction

94 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.

6.2 Health and safety benefits

Improving radiation protection awareness

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

96 The requirement to prepare and implement a radiation management plan is expected to maintain, and even 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.[39]

97 Discussion with the Tasmanian regulator has indicated that the Radiation Management Plans already required for other occupational categories that use radiation 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 could be made available from the websites of ARPANSA or the State and Territory regulatory bodies would help to reduce the preparation costs.

Reducing unnecessary exposure

98 The proposed Code, through the explicit justification criterion, is intended to reduce unnecessary radiation exposures. Under the proposed Code of Practice, a veterinary surgeon has the role of providing justification for medical exposures and the criterion requires that a veterinary 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.

[39] 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.

99 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 may reduce instances of unnecessary exposure. This will result in health and safety benefits primarily for the general population but also for occupationally-exposed individuals.

100 Reductions in occupational doses from veterinary radiology, nuclear medicine and radiotherapy procedures would also result in benefits being derived. It would however, be difficult to estimate the potential benefits due to data limitations.

Formalisation of training

101 The formalisation of training for all workers who may be occupationally exposed to ionizing radiation will improve occupational safety and particularly occupational exposures. In particular, the Code will improve safety for occupationally-exposed veterinary nurses and ancillary staff for whom regulations requiring training do not currently apply.

102 If it is assumed that the proposed Code will reduce effective doses received by veterinary nurses and 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 is still very small due to the already low doses received by veterinary staff.

103 There are however areas in veterinary radiation where the benefits of training would significantly exceed the 1% saving outlined above. Appropriate training:

- reduces the likelihood of incidents;
- provides the background information needed to ensure that spills of radioactive materials are cleaned up with minimum risk to the employee, other staff and the public; and
- allays fears of radiation exposure.

These benefits are unquantifiable but as already noted in paragraph 96, it would not take too many avoided incidents to realise a significant benefit above the ongoing 1% saving outlined here.

Tightening of occupational dose limits

104 The proposed Code sets dose limits for occupationally exposed individuals and members of the public by referring to the dose limits established in RPS 1 (Recommendations for Limiting Exposure to Ionizing Radiation).

105 Current regulations in most jurisdictions already incorporate standards that are equivalent to those set out in RPS 1 however there are some cases whereby the proposed Code, through its linking with RPS 1, is expected to bring about health and safety benefits. These benefits, though difficult to quantify, are discussed below.

- The proposed Code sets annual dose limits for exposure to the lens of the eye, the skin (for occupationally-exposed individuals and members of the public) and the hands and feet (for occupationally-exposed individuals only). These dose limits, which have been incorporated due to current international thinking on safe levels of radiation exposure, are absent in the Western Australian regulations.[40] The introduction of the proposed Code will deliver health and safety benefits to occupationally-exposed individuals and members of the public in Western Australia via the incorporation of more prescriptive dose limits.

[40] *Radiation Safety (General) Regulations 1983*, Schedule 1, p. 85.

- 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.[41] The specification of dose limits to the embryo or foetus 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 veterinary radiation.[42]

6.3 Other benefits

106 Since occupational radiation exposure in veterinary medicine and public exposure is already extremely low as discussed earlier, then the move to the proposed Code is unlikely to produce significant additional health and safety benefits for veterinary practices, for those who work in the veterinary industry and the public.

107 The proposed Code may however, result in improved health and safety outcomes for the community if, as was discussed earlier in terms of dynamic inefficiencies in the *status quo* option or increased exposure under self-regulation, the proposed regulations facilitates the avoidance of increased exposure. That is, while not contributing to a reduction in exposure in the veterinary industry, the proposed Code is expected to help maintain the importance and commitment to ALARA. The proposed Code will result in cost savings due to costs avoided.

108 Overall, while the direct health benefits for veterinary surgeons, assistants, and staff 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 industry and the broader community resulting from reduced exposure to radiation as part of veterinary treatment and diagnosis.

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

Uniformity

110 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 material being published in the single proposed Code — will give clear up-to-date national guidance on safety obligations for all who deal with veterinary X-ray equipment;
- regulatory obligations can be better promoted through a consistent message from all jurisdictions regardless of location;
- a single Code would also enable a uniform approach to radiation protection for veterinary workers across Australia. This would ensure that all stakeholders would be aware of their obligations even when operating in another jurisdiction; and

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

[42] *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 veterinary procedures involving ionizing radiation.

111 Overall, compliance costs are likely to be reduced for veterinary practices and staff that have cross-jurisdictional operations, that is, they will be able to have a single standardised operational approach across jurisdictions.

112 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

113 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.

114 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

115 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 veterinary procedures involving ionizing and non-ionizing radiation.

6.4 Summary of benefits

116 A summary of benefits incurred under the proposed Code is provided in Table 6.1.

6.1 Summary of Benefits

Benefit category	Discussion of benefits relative to the *status quo*
Health and safety benefits from:	
— improving radiation protection awareness	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).
— reducing unnecessary exposure	This is difficult to estimate due to data limitations (see paras 98 to 100 for discussion)
— formalisation of training	Formalisation of training for all staff but particularly nurses should bring about lower levels of occupational exposure. The direct fiscal benefits of training are small due to the already low doses experienced in veterinary practice but the low term benefits of training are difficult to calculate and well established.
— tightening of occupational-dose limits	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 *status quo*.
Dynamic efficiency	The proposed Code of Practice will ensure consistency is maintained over time and that radiation protection standards are current through regular updates by the Radiation Health Committee.
International standing and consistency	The proposed Code would incorporate current international best practice with respect to veterinary radiation procedures involving ionizing radiation.
Total benefits	***Health and safety initiatives will potentially bring large benefits to the community. Uniformity will reduce longer term compliance and administration costs and dynamic efficiency will ensure radiation protection in Australia remains up to date with developments in best practice.***

Chapter 7. Summary of cost benefit analysis

7.1 Summary

117 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 veterinary practices, staff and the public to protect themselves by being knowledgeable of risks, and enforcing their rights under other regulatory obligations. Given that employees and the 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 both Codes, 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:
  - direct health benefits to the veterinary industry and the broader community;
  - increased costs for regulators as they come up to speed on the Code; and
  - greater clarity in the Code.

118 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.

119 These issues are not satisfied in relation to the use of radiation in veterinary medicine.

120 The proposed code entails higher administration and compliance costs than the *status quo*, but there are likely to be offsetting health and safety benefits.

121 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 7.1.

TABLE 7.1. NATURE OF THE IMPACTS COMPARED TO THE *STATUS QUO*

Impact	Self-regulation	Proposed Code
Costs		
Compliance	*Minimal additional compliance costs* Up to $450 000 incurred in order to keep up to date on radiation protection requirements and to implement new systems for compliance.	*Higher costs* The responsible person must ensure that radiation safety assessments be carried out when the X-ray high voltage generator is replaced or otherwise modified. This could cost the industry around $225 000 per year, if up to half a day is needed per premise to carry out the assessment. Costs for veterinary practices to establish nuclear medicine services as a result of upgrading procedures and facilities. These costs are not expected to be high as there are few veterinary practices providing these services and the Code is similar to existing regulatory requirements.
Administration	*Minimal changes to administration costs* A one-off cost of up to $400 000 associated with legislative amendments.	*Higher costs* Up to around $16 000 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 of up to $405 000.
Health and Safety	*Minimal costs* Reduced regulatory control is likely to lead to higher effective dose levels which could result in a cost of between $46 860 to $4 million per year.	
Cost sub-total	*Minimal costs* The likely increase in health and safety costs probably outweighs the costs associated with compliance	
Benefit		
Flexibility	*Minimal benefits* This option allows greater flexibility for industry to determine the appropriate levels and whether conditions are mandatory or not.	
Uniformity		*Higher benefits* There is likely to be greater clarity in the Code and Safety Guide procedures, for veterinary practices and veterinary staff.
Health and safety		*Higher benefits* Reduced exposure to radiation for the general community is estimated to have a nett benefit due to costs avoided.
Benefit sub-total	*There is likely to be only limited benefits, if they exist, in terns of additional flexibility.*	*There are greater benefits associated with the proposed Code.*
TOTAL	***Moving to this option would result in minimal benefits and minimal costs.***	***Moving to this option would more than likely result in net benefits***

Chapter 8. Consultation

122 The proposed Code was developed by a working group of the Radiation Health Committee. The Radiation Health Committee includes representation of all Commonwealth, State and Territory radiation protection regulators.

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

124 The draft Code of Practice was initially made available on the ARPANSA web site from 8 September 2005 until 29 October 2005. Following the public comment period, the Radiation Health Committee reviewed the method of preparing Radiation Protection Series publications and recommended that changes be made to the draft veterinary Code of Practice to incorporate the newer style. Changes included requiring the preparation of a Radiation Management Plan and dropping the requirement for the appointment of a Radiation Safety Officer among several other issues. Public comment for the veterinary Code of Practice was therefore accepted beyond the closing date while the changes were effected.

125 The following organisations were advised of the availability of the proposed ARPANSA Code and this Regulatory Impact Statement and their comments have been requested:

- Australian Veterinary Association
- Australian Veterinary Association (Vic Division)
- Australian Veterinary Association (SA Division)
- Australian Veterinary Association (ACT Division)
- Australian Veterinary Association (Qld Division)
- Australian Veterinary Association (NT Division)
- Australian Veterinary Association (WA Division)
- Australian Veterinary Association (NSW Division)
- Australian Veterinary Association (Tas Division)
- Australian Equine Veterinary Association
- Animal Health Australia
- Australian Pesticides and Veterinary Medicines
- Commonwealth Veterinary Association, Dept of Primary Industries
- School of Veterinary Sciences, University of Queensland
- National Farmers' Federation
- Faculty of Veterinary Science, Camperdown Campus, University of Sydney
- School of Veterinary and Biomedical Sciences, Murdoch University
- Faculty of Veterinary Science, Camden Campus, University of Sydney
- Veterinary Nurses Council of Australia
- Australian College of Veterinary Scientists
- Director of International Programs (Health Sciences), Curtin University
- Faculty of Veterinary Science, The University of Melbourne
- Institute of Medical and Veterinary Science
- Post-graduate Foundation in Veterinary Science, University of Sydney
- Dr Max Zuber
- Veterinary Practitioners' Registration Board of Victoria
- Institute of Veterinary, Animal and Biomedical Sciences, Massey University, NZ
- Veterinary Health Research
- Ballarat Veterinary Practice
- Dr John Hamilton
- Veterinary Surgeons Board of WA
- Dept of Agriculture, Fisheries and Forestry (ACT)
- Veterinary Surgeons Board of Queensland
- Australasian Veterinary Boards Council
- The Veterinary Board of Tasmania

- Vet Surgeons Board of the ACT
- Veterinary Board of the NT
- ANZSNM Accreditation Board
- Veterinary Surgeons Board of NSW
- Veterinary Surgeons Board of SA
- Veterinary Surgeons Board of WA
- Mr Peter Collins, Royal Adelaide Hospital
- Dr Barry Chatterton, Dept of Nuc Med & Bone Densitometry, Royal Adelaide Hospital
- Australian Radiation Services P/L
- Radiation Safety Services
- Radiation-Wise P/L
- Australian Diagnostic Imaging Association
- Australian Institute of Radiography
- Royal Australian and New Zealand College of Radiologists
- Australasian Association of Educators in Medical Radiation Sciences
- Radiation Safety Committee, Charles Sturt University
- Agriculture and Animal Science, NMIT
- Medical Radiation Science, University of Newcastle
- Australian Training Products
- Science and Technology Faculty, Canberra Institute of Technology
- Centre for Biotechnology and Animal Sciences, Box Hill Institute
- Rural Skills Australia
- RSPCA Australia Inc
- Australian Veterinary Practice Management Association
- Faculty of Science, Engineering and Technology, Victoria University
- Agricultural Colleges of Queensland
- Australasian Radiation Protection Society
- Radiation Advisory Council (Qld)
- Director-General, Queensland Health
- Rural Training Council of Australia
- Animal Industries Resource Centre
- Oakey Veterinary Hospital
- Animal Science Dept, Brisbane North Institute of TAFE0
- Radiation Protection Solutions
- Dr Christopher Reardon
- Magic Millions Sales P/L
- Montrose Veterinary Centre (Tas)
- CSIRO Occupational Health & Safety
- CSIRO Livestock Industries

126 Stakeholders who disagreed with the conclusions contained in the consultation draft of the Regulatory Impact Statement were urged to substantiate their view with a description and quantification of costs to apply, implement, administer or enforce the proposed ARPANSA Code of Practice or Safety Guide. Stakeholders were also invited to provide input with relevant information that could add value to the Regulatory Impact Statement.

127 The consultation process resulted in 35 submissions that included comments on the draft Code of Practice, the draft Safety Guide and the Regulatory Impact Statement. The public comment was separated into each of the relevant topics and forwarded to the Working Group for consideration.

Chapter 9. Evaluation and Preferred Option

9.1 Conclusions and recommendations

128 Over time, continuing with the *status quo* could actually lead to a deterioration in the health of veterinary staff and the public. 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 veterinary applications.

129 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.

130 ARPANSA has identified several shortcomings associated with the current regulatory approaches to veterinary nuclear medicine, radiology and radiotherapy. ARPANSA is therefore proposing the adoption of a single and nationally uniform Code of Practice which can be adopted into the National Directory as mandatory requirements and this is the preferred option for the future regulation of radiation protection in veterinary applications involving ionizing radiation. The proposed Code will incorporate current radiation protection and practices.

131 The proposed Code will bring about costs to veterinary practices in initially implementing the regulations and adhering to the sometimes more stringent requirements. In total, these costs are expected to amount to between $1.16 and $1.8 million for once-off costs and between $298 400 and $385 000 in ongoing costs.

132 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.

133 In addition, the proposed Code is expected to lower exposures to occupationally exposed individuals and, consequently, also bring ongoing benefits to the community. For example, better training may lead to reductions in exposure amongst the veterinary nursing profession. The uniformity of the proposed Code would reduce costs for organisations operating in several jurisdictions, as it would standardise requirements. The health and safety benefits of the proposed Code are significant especially considering that in the longer term, the implementation of the proposed Code will allow regulations to keep pace with international best practice, unlike the *status quo*.

134 Of all the options, the proposed Code is the most effective way of ensuring the continued low effective doses of radiation associated with veterinary applications. The proposed Code aligns health and safety requirements with international best practice and Radiation Protection Series No. 1, and would remain current through regular updates to reflect changes in international dose limits. The proposed Code best supports the application of the ALARA principle, which is at the heart of the system of radiation protection across Australia.

Chapter 10. Implementation and Review

135 The proposed Code would be published by ARPANSA under its Radiation Protection Series and made available to the veterinary profession and to regulators for adoption. ARPANSA's Radiation Health Committee would review the Code within 10 years of its commencement to ensure it is still relevant to radiation protection needs. Earlier review would be undertaken if there are problems in the implementation of the Code, if international or national radiation protection objectives change or if there is new information from international research.

136 Once published, the Code 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.

137 Once the Code is published, all organisations listed in paragraph 125, and other stakeholders made known to ARPANSA during the consultation period, will be advised of its publication. Regulatory authorities in each jurisdiction will, in turn, inform licensed veterinary practices within their jurisdiction of the promulgation of the Code.

Chapter 11. References

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