Regulatory Impact Statement

# Proposed Radiation Control Regulation 2003

NSW EPA

ENVIRONMENT PROTECTION AUTHORITY

## Submissions

The Environment Protection Authority invites you to make written submissions on the Regulatory Impact Statement and proposed Radiation Control Regulation 2002.
Submissions should be sent to:

Manager Radiation Policy Unit
Radiation Control Section
NSW Environment Protection Authority
PO Box A290
SYDNEY SOUTH NSW 1232

or emailed to radiation@epa.nsw.gov.au

Submissions will be accepted until close of business on **Monday 30 June 2003**.
This publication is also available on www.epa.nsw.gov.au/radiation/index.htm

Published by:
Environment Protection Authority
59–61 Goulburn Street, Sydney
PO Box A290
Sydney South 1232
Phone: (02) 9995 5000 (switchboard)
Phone: 131 555 (NSW only—information & publications requests)
Fax: (02) 9995 5999
TTY: (02) 9211 4723
Email: info@epa.nsw.gov.au
Website: www.epa.nsw.gov.au



ISBN 0 7347 7572 5
EPA 2003/34
June 2003

Printed on recycled paper

# Contents

# Summary

Many people in New South Wales (NSW) are exposed to ionising radiation while undergoing medical diagnosis and therapy, or through occupational exposure. Intentional radiation exposure has many benefits such as detecting or treating diseases, as well as several industrial benefits. These are commonly weighed against the relatively small risk of damage from exposure.

The regulation of radiation apparatus and substances is warranted because of concerns about the damaging and potentially fatal short- and long-term impacts of radiation on people. In addition, radiation is undetectable by human senses when it is causing harm, so people must rely on protection systems to prevent damage.

The *Radiation Control Act 1990* establishes a broad regulatory scheme for radiation protection. This includes:

- licensing anyone who uses, possesses, sells or gives away any radioactive substances, any ionising radiation apparatus, and non-ionising radiation apparatus as described in the Radiation Control Regulation 1993
- owners registering all sealed radioactive sources, ionising radiation apparatus or prescribed non-ionising radiation apparatus
- accrediting all people engaged as consulting radiation experts.

The Environment Protection Authority (EPA) is proposing a new regulation to replace the current Radiation Control Regulation 1993 (the current Regulation), which is due for automatic repeal on 1 September 2003 under the terms of the *Subordinate Legislation Act 1989*.

The proposed Regulation will retain most of the provisions of the current Regulation, but will expand the range of regulated radiation sources to include mobile and unsealed radiation devices, and radiation therapy equipment. Changes are also proposed to the fees for licensing and registrations and to the levels of penalties. These proposed changes reflect international security concerns that have recently emerged, recommendations of the National Competition Policy (NCP) review of Australian radiation protection legislation, and operational experience gained by the EPA since the current Regulation commenced in 1993.

# 1. Introduction

## 1.1 Purpose and content of the Regulatory Impact Statement

This Regulatory Impact Statement (RIS) concerns the remake of the Radiation Control Regulation 1993. While the *Radiation Control Act 1990* establishes a broad regulatory scheme in NSW for radiation protection, the Regulation sets out licensing, registration and accreditation requirements.

The *Subordinate Legislation Act 1989* provides for the automatic repeal of regulations five years after publication. Due to transitional arrangements and following several extensions, the current Regulation is due for repeal on 1 September 2003.

The current Regulation is being remade. The new Regulation (the proposed Regulation) will enable radiation apparatus and radioactive substances to be consistently regulated.

Under Schedule 2 of the *Subordinate Legislation Act*, a RIS must be prepared to assess the economic, social and environmental costs and benefits of the proposed Regulation and its alternatives.

Radiation is invisible and serious damage, (for example, fatal cancers) may not become apparent until years after exposure. Many people in NSW come into contact with radiation, through medical procedures or their work, or in their daily life. The regulation of people who use or sell radioactive substances or radiation apparatus is therefore necessary to protect the health and safety of people and the environment.

The Commonwealth has signed an international convention that requires regulation of facilities generating radioactive waste. NSW has not yet commenced the parts of the Act that will allow unsealed radioactive sources to be regulated. An unsealed source is a radioactive substance not enclosed in a container which permits controlled emission of radiation.

This legislation will be enforced through requirements incorporated in the proposed Regulation.

The RIS will ensure that the proposed Regulation provides the greatest net benefit at the least net cost to the community, compared with the possible alternatives. It contains the assessment of the economic, social and environmental costs and benefits of the proposed Regulation up to the automatic five-year repeal date of 1 September 2008.

- **Section 1** sets out the purpose and content of this RIS and describes the environmental and health impacts of radiation in NSW.
- **Section 2** sets out the current framework for control of radiation apparatus and radioactive substances in NSW.
- **Section 3** presents the base case or ‘no Regulation’ option, examines alternatives and introduces the proposed Regulation.
- **Section 4** analyses the provisions of the proposed Regulation and assesses their costs and benefits.
- **Section 5** discusses the issues raised by the possible future regulation of lasers.
- **Section 6** summarises and discusses the results of the cost-benefit analysis in section 4.
- A **glossary** of technical terms follows the conclusion in **section 7** and the **references.**

## 1.2 People affected by this Regulation

In NSW, many people either use radiation apparatus or radioactive substances in their work, or are exposed to radiation while receiving medical treatment. The regulatory system:

- licenses users to ensure they have appropriate skills and training
- requires registration of apparatus and premises to ensure that machines and systems are safe.

The main categories of people licensed under the current Regulation include radiologists, radiation oncologists, nuclear medicine specialists, general practitioners, chiropractors, dermatologists, dentists, dental therapists and hygienists, equipment testers and service technicians, veterinary surgeons, medical and industrial radiographers, cardiologists, borehole loggers, moisture/density gauge operators and researchers.

Workers affected by the Regulation include:

- health workers who use x-rays or radioactive pharmaceutical products in nuclear medicine
- workers in the mining industry, mineral exploration, and soil density measurement and moisture control.

Radioactive materials can also be found in some consumer products and used in scientific research (EPA 2003).

A variety of medical and industrial equipment is registered under the current Regulation. This includes x-ray equipment such as medical, diagnostic, chiropractic and dental equipment, as well as fixed industrial gauges.[1]

## 1.3 Planned consultation

Consultation must be undertaken with the public, relevant interest groups and any other groups likely to be affected by the proposed Regulation and its alternatives. The RIS and a copy of the proposed Regulation will be available for public comment for four weeks. The following parties will also be formally invited to comment:

- NSW Radiation Advisory Council
- consulting radiation experts
- relevant professional bodies
- NSW Department of Mineral Resources
- NSW Health Department
- WorkCover NSW
- NSW Emergency Services.

Written submissions from the public and interested parties will be carefully considered before the proposed Regulation is finalised.

A notice calling for submissions from the public and details of where to send these submissions will be published in the NSW Government Gazette, the *Sydney Morning Herald*

[1] Radiation Control Regulation 1993

and the *Daily Telegraph*. Submissions will be accepted until close of business on **Monday 30 June 2003.**

Details of where to send submissions are also included on the reverse side of this document's title page.

## 1.4 Environmental and health effects of radiation

### Population exposure to ionising radiation in NSW

Ionising radiation is so-called because it gives electrical charges to any material it passes through, such as particles and cell matter. It includes:

- electromagnetic radiations—x- and gamma rays
- particle radiations—alpha, beta and neutrons.

Human exposure to ionising radiation comes from natural and man-made sources. Natural sources include:

- cosmic rays
- naturally occurring radioactive material including radon in the air from the decay of uranium and thorium in rocks and potassium in consumable foods.

Man-made sources include:

- diagnostic imaging apparatus (x-ray equipment)
- equipment used for medical therapy such as cancers
- isotopes used in medicine and research
- radioactive waste.

The RIS focuses on:

- the regulation of man-made ionising radiation sources
- occupational exposure to cosmic and natural radiation sources.

Ionising radiation apparatus and radioactive substances are widely used in NSW for medical, scientific research and industrial purposes.

### Medical applications

The major medical applications of ionising radiation apparatus and radioactive substances are in diagnostic imaging, medical and dental applications. Radioactive substances are also used in medical research as tracer chemicals, to allow biological processes to be followed in the test tube or in a living organism.

It is estimated that over 90% of the total radiation exposure of people occurs during diagnostic x-rays, with much less exposure from radiotherapy. Over four million diagnostic x-ray examinations and radiotherapy treatments are given annually in NSW (HIC 2002).

The radiation dose received by diagnostic x-ray patients is generally low, provided the equipment is properly maintained and operated. However, patient exposure to radiation may be increased if x-ray equipment is not properly maintained, for example, through inappropriately low filtration, poorly adjusted beam alignment or poor film processing.

## Industrial applications

The major industrial applications of radiation apparatus and radioactive substances include:

- gamma irradiation sources for sterilisation of medical equipment, food and blood
- industrial radiography of welds to detect any faults in repairs.

Fixed radiation gauges are used in a broad range of industrial applications, including:

- quality control processes for materials and slurries
- element analysis in borehole logging
- road repairs and resurfacing.

In addition, research applications involve the use of liquid unsealed sources as radioactive tracer compounds to allow biological processes to be followed in the test tube or in a living organism. An unsealed source is a radioactive substance not enclosed in a container which permits controlled emission of radiation.

## Occupational exposure

Many people in NSW are employed in occupations that involve the use of ionising radiation apparatus or radioactive substances. These people include radiographers, radiologists, industrial users, medical and scientific researchers and physicians. Exposure can occur by being near radiation devices when they are in use or by inhaling or absorbing radioactive substances.

Several safety provisions minimise occupational exposure to radiation including operator training, the use of equipment shielding, use of safety clothing and monitoring of personal exposure. However, poor maintenance of equipment or poor workplace procedures can result in workers increasing their exposure to radiation.

## Limits to radiation exposure

The International Commission on Radiological Protection (ICRP) has made recommendations on limits to be applied to ionising radiation exposure. Australia has accepted these recommendations, which specify that a member of the public must not receive more than one unit of radiation per year (1 millisievert per year[2]). A radiation worker must not receive more than 20 units per year (20 millisievert per year). These exposures are in addition to the radiation received from natural sources or from any medical procedure. The exposure limits have been set so the calculated risk is not greater than other risks people are exposed to daily.

[2] International Commission of Radiation Protection 1990. These limits are calculated by working out the absorbed radiation dose corrected for type of radiation, and organ and tissue sensitivities. In special circumstances, a higher limit could be allowed in a single year provided the average over five years did not exceed the specified limit. Additional restrictions apply to the occupational exposure of pregnant women.

# 2. Framework of control of radiation apparatus and radioactive substances

This section outlines the State and Commonwealth framework within which the *Radiation Control Act 1990* and the Radiation Control Regulation 1993 must operate. This framework is shaped by State legislation and policies, which regulate specific areas such as radiation safety. Commonwealth involvement includes the National Competition Policy Review, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), and international trends.

## 2.1 The emergence of regulatory controls in NSW

The growth in the use of radioactive substances and radiation apparatus throughout the 1950s prompted the States and Territories to develop and enact legislation to put regulatory controls in place. In NSW, the *Radioactive Substances Act 1957* and the Radioactive Substances Regulation 1959 introduced those controls.

As international guidelines[3] generally formed the basis for legislative provisions, legislation for radiation protection in most countries is broadly similar in structure and technical content. However, the implementation of provisions differs between jurisdictions.

The *Radiation Control Act 1990* replaced the *Radioactive Substances Act 1957* and the proposed Regulation will come under this Act.

## 2.2 The *Radiation Control Act 1990* and the Radiation Control Regulation 1993

The *Radiation Control Act 1990* provides a framework for managing radioactive substances, radiation apparatus, and people working with radiation, to minimise health risks to people and the environment.

The main functions of this Act are:

- controlling the sale, use, possession and disposal of radioactive substances and apparatus by licensing and registering:
  - radioactive substances and the premises where they are kept or used
  - certain types of radiation apparatus
  - users of the above
- ensuring consulting radiation experts (CREs) are accredited
- enforcing safety procedures through:
  - inspections
  - applying penalties for offences
  - giving the NSW Environment Protection Authority (EPA) powers to deal with dangerous situations
  - retaining and disposing of seized property
  - recovering costs involved in enforcement activities

[3] Subcommittees of the International Commission on Radiological Protection (ICRP) published international guidelines for radiation control in 1953 and 1956.

- establishing a Radiation Advisory Council (RAC) to advise the NSW Minister for the Environment and the EPA on:
  - the development and administration of radiation control legislation
  - matters relating to radiation safety
  - matters relating to licensing, registration and accreditation
  - other matters relevant to radiation.

The current Regulation is made under section 40 of the *Radiation Control Act 1990*. The regulation-making powers under section 40 are wide and allow regulations to provide for any matter considered necessary for the implementation of the Act.

The current Regulation sets out fees, certain generic duties, exemptions, exposure limits and standards. Specifically, it makes provision for:

- the definition of a 'radioactive substance'
- regulating activities related to the transport and disposal of radioactive substances or radiation apparatus
- reporting and investigating accidents and incidents
- granting exemptions from licences and registrations
- prescribing activities for consulting radiation experts (CREs)
- radiation safety requirements, including setting radiation dose limits, monitoring workplaces, and placing limits on personal and environmental radiation exposure
- appointing radiation safety officers and committees
- setting fees and charges for services provided by the EPA under the *Radiation Control Act 1990*.

## 2.3 Amendments to the *Radiation Control Act 1990*

There have been several minor amendments to the Act since its commencement in 1993. The most significant amendments have been made through the *Environment Protection Legislation Amendment Act 2002* and the *Radiation Control Amendment Act 2002*.

These amendments included:

- designating authorised officers, rather than inspectors, to align with the *Protection of the Environment Operations Act 1997* (the POEO Act)
- creating a licence to 'possess' radioactive materials as well as use them
- amending the definition of 'environment' so it is the same as in the POEO Act
- providing for review of the *Radiation Control Act* at intervals of no more than 10 years
- amending the powers of the Radiation Advisory Council in matters affecting EPA operations (decisions on issuing licences, registrations and accreditations)
- removing 'temporary' licences
- providing for 'variation' of licences
- referring to the National Directory for Radiation Protection
- providing for adoption of material in the National Directory.

## 2.4 Amendments to the Radiation Control Regulation 1993

The current Regulation, published on 27 August 1993 and commenced on 1 September 1993, was due to be remade under the terms of the *Subordinate Legislation Act 1989* by 1 September 1998. A series of extensions have been granted up to 1 September 2003

because of the need to address amendments to the Act required under the National Competition Review of Radiation Protection Legislation from 1998 to 2002.

The 1998 amending Regulation introduced the requirement that personal monitoring devices be worn in diagnostic radiology. This was introduced at the request of the Health and Research Employees Association.

The 2000 amending Regulation introduced:

- registering diagnostic imaging apparatus and prescribing Radiation Guideline Number 6[4]
- adding ophthalmology, dermatology and rheumatology to the list of professions where people may be exempt from licensing requirements while training
- adding advising on the design of premises and shielding premises to activities of CREs
- requiring employers to give written notice of apparent radiation accidents within 48 hours.

The 2001 amending Regulation introduced:

- registering cyclotrons as radiation apparatus and setting the registration fee
- increasing fees to reflect consumer price index (CPI) increases between 1993 and 2001
- updating the reference to the new version of the *Code of Practice for the Safe Transport of Radioactive Material*.

## 2.5 Other NSW regulatory controls

In NSW radiation safety is primarily controlled under the *Radiation Control Act 1990*. However, several other Acts also control certain activities associated with radiation safety.

- The hazardous substances section of the Occupational Health and Safety Regulation 2001 (under the *Occupational Health and Safety Act 2000*) exempts radiation matters that fall under the *Radiation Control Act 1990*. The 'plant' provisions of the Occupational Health and Safety Regulation 2001 cover safety in design, manufacture and operation of plant equipment as applied to radiation apparatus.
- The *Waste Avoidance and Resource Recovery Act 2001*, administered by the NSW EPA, regulates the generation, storage, transport, processing and disposal of waste, including radioactive waste.
- The *Protection of the Environment Operations Act 1997*, administered by the NSW EPA, regulates the discharge of pollutants into the environment.
- The *Uranium Mining and Nuclear Facilities (Prohibitions) Act 1986*, administered by the Department of Mineral Resources, prohibits the construction of any nuclear facilities and the prospecting for or mining of uranium ore in New South Wales
- The *Mutual Recognition Act (NSW) 1992* entitles a person who has a current authority as an accredited radiation expert in another jurisdiction of Australia to have their accreditation recognised in New South Wales.

Other relevant statutory measures are the *National Environment Protection Measure for the Movement of Controlled Wastes between States and Territories*, and the *National Pollutant Inventory*. These are given effect in NSW either through legislative instruments or other arrangements, in accordance with the *National Environment Protection Council (New South Wales) Act 1995*.

[4] EPA 2000b, *Radiation Guideline Number 6—Registration Requirements and Industry Best Practice for Ionising Radiation Apparatus Used in Diagnostic Imaging*

Additionally, the *Protection of the Environment Administration Act 1991* gives the EPA the objective of reducing risks to human health and preventing the degradation of the environment.

## 2.6 Federal regulatory controls

### 2.6.1 ARPANSA

The Commonwealth's Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) was established by the *Australian Radiation Protection and Nuclear Safety Act 1998.* ARPANSA regulates facilities owned by the Commonwealth, and coordinates and oversees the development of national standards.

### 2.6.2 National Competition Policy Review of Radiation Protection Legislation (NCP review)

The Council of Australian Government's Senior Officials Group agreed in December 1998 that all Australian jurisdictions except Queensland would be the subject of a National Competition Policy Review of Radiation Protection Legislation (NCP review) by 30 June 2002. The review was coordinated by ARPANSA who published a final report containing 19 key recommendations in May 2001. Some recommendations were modified in July 2002. All NCP review recommendations are listed in Appendix A.

Most of the recommendations of the NCP review will be addressed through the development of the *National Directory for Radiation Protection* (the National Directory)[5], the agreed mechanism for achieving national uniformity in radiation protection. ARPANSA drafted and submitted an Implementation Plan for these recommendations, which was submitted to the National Competition Council (NCC).

The NCC accepted the Implementation Plan on the condition that it incorporated clearly defined deadlines for completing each recommendation associated with the development of the National Directory. The recommendations that could be implemented before 30 June 2002 were incorporated into the *Radiation Control Amendment Act 2002*, which commenced on 1 August 2002.

The NCP review showed that there was strong support for prescriptive legislation in the interests of the safety of people and the environment. There was also support for the 'user-pays' principle for full cost recovery by the government, and furthering the process of national uniformity in the interests of the community.

[5] It is expected that when the National Directory (see ARPANSA 2001) is developed in two–three years time it will apply to all mobile radioactive sources in Australia, all premises where unsealed sources are kept or used and all radiation therapy equipment (see glossary for definitions). The various State radiation safety regulators will attach conditions of registration to each type of radiation apparatus or each radioactive substance. As the attachment of these conditions may impose costs, the National Directory would be subject to cost-benefit analysis before being implemented in NSW.

## 2.7 International trends in the regulation of radiation sources

The Commonwealth has signed an international convention[6] that requires the regulation of all radioactive waste management facilities. NSW has not yet commenced the parts of the Act that support this. It is proposed that the requirements to register premises where unsealed sources are kept or used, and register mobile radiation gauges, be commenced in the proposed Regulation (see sections 4.1 and 4.2).

[6] International Atomic Energy Agency (IAEA) *Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management* entered into force on 18 June 2001 and was signed by Australia on 18 November 1989.

# 3. The proposed Regulation and its alternatives

## 3.1 Objectives of the proposed Regulation

The object of the *Radiation Control Act 1990,* amended following the recent NCP Review, is:

'…to secure the protection of persons and the environment from exposure to harmful ionising and non-ionising radiation to the maximum extent that is reasonably practicable, taking into account social and economic factors and recognising the need for the use of radiation for beneficial purposes.'

Section 40 of the *Radiation Control Act 1990* provides for regulations to be made that are not inconsistent with the Act, for any matter required for carrying out or giving effect to the Act. Generally speaking, matters that can be included in the Regulation are the:

- production, manufacture, supply, storage, disposal and transport of radioactive substances and radiation apparatus
- regulation, restriction or prohibition of any activities connected with the production, manufacture, supply, storage and transport of radioactive substances or radiation apparatus
- requirement for specific standards to be observed and procedures to be followed
- recommendation of practices and procedures to be followed to achieve these standards and procedures
- granting or issuing of licences, registrations, accreditations, authorisations, approvals, and the developing of terms and conditions that are applied to these
- keeping of records, furnishing of information, and notification of accidents and incidents
- monitoring of personal exposure for people engaged in activities related to radioactive substances and radiation apparatus, and monitoring of the environment
- protection of people and the environment from harm resulting from activities connected with radioactive substances and radiation apparatus
- application of fees and charges for services provided under the legislation.

The proposed Regulation is substantially the same as the current Regulation, with changes that reflect the EPA's experience in implementing the 1993 Regulation and that respond to the following issues:

- the continued shortfall of fees to cover government costs and the recommendations of the NCP review to implement full cost recovery
- inconsistency between penalties in the current Regulation and those in similar environmental legislation administered by the EPA and in other States
- the need for NSW to introduce registration of premises on which unsealed sources are kept or used, and include all radiation gauges and radiation therapy equipment in the registration requirements, arising from their potential to cause harm — see section 4.1
- the need to correct deficiencies in the safety requirements for users of radiation apparatus and radioactive substances.

The proposed Regulation must be assessed against two broad criteria:

1. whether the proposed Regulation succeeds in implementing and facilitating the aims of the *Radiation Control Act 1990*, which sets the framework for the use, possession and sale of radioactive substances and radiation apparatus in NSW

2. whether the proposed Regulation embodies the best options and strategies for implementing and facilitating these aims.

Specifically, the objectives of the proposed Regulation are:

1. **To protect operators and the public from the misuse of unsealed and portable radioactive sources.**
   The increasing use of unsealed radioactive sources poses significant risks to human and environmental health and safety. The proposed Regulation covers a large range of radioactive sources and radiation apparatus.

2. **To ensure that employees are given the best protection against radiation exposure.**
   The current Regulation contains provisions relating to the protection of employees and members of the community from exposure to radiation. However, these are non-mandatory and carry no financial penalty for breaches of exposure limits. The proposed Regulation further defines these requirements to align them with the provisions of the ARPANSA *Radiation Protection Series No. 1* (ARPANSA 2002) and assist in achieving national uniformity of radiation protection.

3. **To ensure that the provisions of the *Radiation Control Act* can be implemented in an efficient and effective manner.**
   The *Radiation Control Act 1990* leaves certain matters to be prescribed by regulation, such as exemptions for common radiation sources and radioactive materials, fees for licences and registrations, and definitions and exposure standards. The proposed Regulation is therefore necessary for efficient and effective administration of the Act.

4. **To recover the costs of administering the *Radiation Control Act* and Regulation, by applying the user-pays principle.**
   Implementing the Act and Regulation involves issuing and enforcing over 20,000 licences, registrations and accreditations. As recommended by the NCP review and consistent with NSW Government policy, the proposed Regulation seeks to recover these costs from users of the regulated activities.

## 3.2 The base case (no regulation)

The effect of alternatives to the current Regulation must be assessed against a base case. The base case is defined by the absence of any regulation. That is, the current Regulation would be repealed by the *Subordinate Legislation Act* without replacement. Specifically, this means that:

- the definition of what constitutes a radioactive substance, set out in clause 5 and Schedule 1, would be lost; there would be no legislative controls of any kind over the possession, sale, use, storage, and disposal of radioactive substances, with a high probability that there would be serious consequences for the health of people and the environment
- exemptions from licensing given under clause 7 and Schedule 3 for possessing, using and selling minor applications of radiation apparatus would cease, requiring them to be licensed under the *Radiation Control Act 1990*—these include television receivers, video display units, x-ray baggage inspection devices and electron microscopes
- exemptions from the licensing requirements given under clause 8 of the current Regulation for medical registrars, students and assistants to industrial radiographers specified in section 6 of the *Radiation Control Act 1990,* would cease— these groups

would have to be licensed under the *Radiation Control Act 1990*; in addition, the safety requirements that must be fulfilled for granting these exemptions, given under clause 8 of the current Regulation, would cease
- prescribing diagnostic imaging equipment (medical and dental x-ray machines and computerised tomography (CT) scanners) as radiation apparatus would cease— this apparatus could no longer be registered under the *Radiation Control Act 1990* so would not be required to meet appropriate standards or be subject to regular inspection and auditing
- the prescribed activities for accredited radiation experts would lapse, meaning they would no longer be authorised to assess and calibrate radioactive sources and radiation apparatus as required by conditions of registration
- personal and workplace radiation safety requirements would lapse, potentially exposing many people dealing with radiation sources to harm
- requirements and penalties for improper transport and disposal of radioactive substances and radiation apparatus, and for radiation accidents, would lapse.

Licensing requirements to use, possess, sell and register radiation apparatus and radioactive substances are set out in the Act, together with penalties for not being appropriately licensed or registered. These would continue in the absence of the current Regulation. However, as the fees are set by the current Regulation, the EPA could raise no fees to cover the cost of this regulatory oversight.

The RIS for the Radiation Control Regulation 1993 estimated that in the absence of any regulation the annual collective radiation dose would rise by 5% over the long-term (EPA 1993). This was determined by a conservative analysis of the faults found during an audit of 321 x-ray machines conducted in 1991–92 (Colgan, Harrison and Moore 1996), which found 15% of machines tested had major faults. This result is consistent with overseas experience, where a 1999–2000 survey found 15% of 1500 diagnostic x-ray machines with one or more non-compliances (US Food and Drug Administration 2000). In the absence of other relevant studies, this RIS has assumed this fault level is applicable to all diagnostic imaging apparatus.

## Costs

Radiation protection legislation allows society to avoid the potential market failure that could arise if exposure to radiation was not regulated. Market failure occurs when the industry does not consider the costs associated with radiation exposure, or when users or the general community are not provided with accurate information concerning the potential harm caused by radiation exposure.

### *Health/community costs*

Allowing the current Regulation to lapse would result in the community being exposed to higher levels of radiation, leading to increased radiation-induced cancer rates. This would occur because of the absence of any legislative controls over the sale, possession, use, storage or disposal of radioactive substances. Equipment would not be required to meet any safety standards, or be subject to inspection or auditing.

It is estimated that the cost to the community to treat the medical impact of higher radiation exposure due to the discontinuation of registration of diagnostic imaging apparatus would conservatively amount to a net present value (NPV[7]) of $9.56 million over five years[8]. These costs would be associated with higher exposure to radiation leading to increased radiation-induced cancer rates.

Additional costs to the community, such as infrastructure, and the provision of care outside the medical system, have not been included in this estimate. In addition, potential health costs associated with harmful radiation from radiation apparatus other than diagnostic imaging apparatus was not estimated due to the lack of available data. Therefore this $9.56 million is a conservative estimate for health costs under the base case.

There is also strong community concern associated with any exposure to radiation due to the unseen nature and potential for life-threatening consequences of radiation exposure (Chapman and Wutzke 1997). This would make the deregulation of radiation protection unacceptable to the community who expect strict regulation in this area (NCP review—ARPANSA 2001).

***Government costs***

If the Regulation were allowed to lapse, the EPA would continue to administer the radiation protection provisions of the Act without the regulation, which allows the EPA to set fees. This would cost the EPA $1.8 million per year or a NPV of $7.8 million over five years (EPA 2003).

***Industry costs***

Under the base case, industry's current compliance costs would be avoided. However, the exemptions that apply to the licensing of common low-risk radiation apparatus (television display units, video-cassette recorders, x-ray baggage inspection devices, and electron microscopes) would no longer hold. The costs to the community (including industry) to license these currently exempt types of apparatus would be significant. For example, the cost of licensing television sets alone has been estimated at an NPV of over $557 million over five years.[9]

In addition, clause 8 exemptions, associated with requirements for medical registrars, students, assistants and industrial radiographers to meet licence requirements, would no longer hold under the base case. Students and researchers would be required to hold current licences to use radiation apparatus or radioactive substances. This requirement would also be unnecessarily onerous.

[7] Net present value calculations use discounting whereby values in future years are converted to present-day values. This provides for the opportunity cost of money, where people attach a lower value to future costs and benefits (i.e. people discount the future). Consistent with NSW Treasury guidelines, a discount rate of 7% has been used throughout this RIS. Discounting has been applied to both financial and economic values in this RIS. A financial value is the amount of money that a stakeholder actually pays or gains, whereas economic values measure the true resource costs to the community.

[8] Details of this health cost calculation, based on assumed average fault rates for diagnostic imaging apparatus (Colgan, Harrison and Moore 1992) and health costs per person (NRPB 1986; cited in EPA 1993), are outlined in Appendix C.

[9] ABS 2001 *Census of Population and Housing* shows there were 2.34 million households in NSW in 2001. This figure is adjusted by 15% (to 2.7 million) to estimate the number of households in NSW in 2003. Assuming that 95% of households own at least one television, there would be approximately 2.56 million televisions that would require licensing in NSW if the current Regulation lapsed. If these licences cost $50 each per year the total cost to households is estimated at a NPV of $557 million over five years.

### Benefits

***Industry benefits***

As the fees are set under the regulation no fees could be raised from industry, giving a NPV benefit of $4.62 million to industry over five years.[10]

## 3.3 Regulatory alternatives

Continuation of the current Regulation would require no change to current regulatory practice, and would deliver no additional costs or benefits, but would create serious consequences in several areas. Firstly, NSW taxpayer revenue would be required to continue to finance administration of the radiation protection provisions of the Act, effectively subsidising the industry and users of radiation services. Secondly, the following would remain unregulated:

- unsealed sources
- mobile sealed radioactive sources (radioactive substances in a shielded container or gauge that allows the controlled emission of radiation)
- radiation therapy devices (devices using ionising radiation to treat medical conditions).

Finally, making no change is contrary to NCP recommendations concerning the creation of uniform radiation regulation across Australian States and Territories and continued support for a prescriptive approach to regulation.

Therefore, rolling over the existing regulation unchanged is not a suitable option.

[10] It is assumed that annual registration and licence application activity increases by 7% per annum; and registration and licence application and renewal activity expires at a rate of 3% per renewal cycle. Full details of this calculation are set out in Appendix G.

# 4. Provisions of the proposed Regulation

The proposed Regulation is generally the same as the current Regulation except for amendments outlined in this section. The costs and benefits of the provisions under the proposed Regulation are presented below.

## 4.1 Regulation of premises where unsealed radioactive sources are kept or used

### Unsealed radioactive sources in NSW

An unsealed radioactive source is defined in the *Radiation Control Act 1990* as a radioactive substance that is not enclosed in a container which would prevent escape of the substance and permit controlled emission of radiation. This definition includes any encapsulated radioactive source not contained in a gauge, as well as devices such as medical and industrial tracers. For a full definition of an 'unsealed radioactive source', see the glossary.

Unsealed radioactive sources are used in NSW in nuclear medicine, radiation therapy, sterilisation plants and as tracers in research. Medicare rebates for nuclear medicine and radiation therapy in NSW totalled $47 million for approximately 120,000 services in 2002 (HIC 2002). However, these services include the use of some radiation apparatus (for example, linear accelerators), in addition to unsealed radioactive sources.

### The current regulatory situation

NSW is the only State that currently does not require registration of premises on which unsealed radioactive sources are kept or used. Australia is a signatory to the International Atomic Energy Agency Joint Convention. Registering these premises would support the convention articles dealing with management of radioactive waste in the current climate of heightened security.

Section 8 of the *Radiation Control Act 1990* requires that the occupier of any premises on which an unsealed radioactive source is kept or used must register the premises and comply with conditions of the registration. However, this section was not commenced when the current Regulation came into force in 1993. Because registration of radiation apparatus and premises was new to the industry, these provisions were implemented progressively. The requirement for registration of fixed radiation gauges was introduced in 1995 and the registration requirement for diagnostic imaging apparatus implemented in 2000.

### The proposed Regulation

The proposed Regulation brings Section 8 of the *Radiation Control Act 1990* into effect by requiring the registration of premises where unsealed radioactive sources are kept or used. The proposed Regulation will also develop procedures and set fees for such registrations.

### Costs

***Government costs***

The costs imposed by this variation to the Regulation are those of implementing a regulatory system for the estimated 800 premises in which unsealed sources are kept or used.

On average the administration, inspection and auditing costs involved in registering premises where unsealed sources are kept have been estimated to be similar to costs for registering

radiation apparatus, so the same registration fees will be used. The recommended fees are $155 for registration, $105 for registration renewal (every 2 years) and $38 for registration transfer.

Government costs of administrating, auditing and registering these premises will be recovered from the industry through registration application, renewal and transfer fees.

### *Industry costs*

The cost to industry of registration application, renewal and transfer fees is an estimated NPV of $0.35 million over the five years of the proposed Regulation.[11]

There will be additional industry costs associated with compliance with the proposed conditions attached to the registration. Application for registrations will require:

- an inventory of unsealed sources on the premises
- classification of this stock
- maintenance of a stock register
- completion of relevant administration.

Renewal of the registration will require industry to have a consulting radiation expert (CRE) inspect the premises at an estimated NPV cost of $0.38 million over five years.[12] Transfer of registration requires the EPA to be notified and it is assumed that this cost will be minimal.

The total cost of registration and associated compliance is therefore approximately $0.73 million over five years.

For medical users of unsealed sources alone, the Medicare rebates for nuclear therapy and radiation therapy totalled $54.3 million for nearly 140,000 services in 2002 (HIC 2002). The total cost of registration and associated compliance is just over 0.1% of the total rebates. This cost should not have any noticeable effect on the industry or the community.

## Benefits

### *Community benefits*

The immediate economic benefit of registering unsealed sources is that registered owners would be responsible for preventing accidents and misuse. If accidents occurred, 'orphan sources' (radioactive sources that have been illegally disposed of into the environment, the scrap metal stream or waste stream) could be better identified, allowing any necessary clean-up costs to be reclaimed from the owner, instead of general taxpayer revenue. The onus would be on the owner (as well as users already licensed) to ensure that staff are trained and appropriate safety measures are in place.

Registration of premises where unsealed sources are kept would support the international treaty obligations, and assist NSW to comply with recommendations of the NCP review such as full cost recovery.

[11] For the purpose of this calculation, it is assumed to take industry one hour to complete each registration application at $50 per hour, including 50% on-costs. Full details of this calcuation are set out in Appendix D.

[12] For the purpose of this calculation, it is estimated that a CRE inspection costs an average of $200 per inspection. The number of registration applications and renewals has been calculated using data from EPA 1997, *Cost-Benefit Analysis for Radiation Control Guideline 5: Registration Requirements and Industry Best Practice for Premises on which an Unsealed Radioactive Source is Kept or Used*. The number of premises has been projected up 35% from data collected during 1996 for that publication. It is assumed that annual registration applications will increase by 7% per annum; and registration application and renewal activity will expire at a rate of 3% per renewal cycle. Full details of this calculation are set out in Appendix D.

### *Health benefits*

Conditions can be attached to the registration of such premises that will reduce radioactive sources' potential to harm users and the community.

Benefits are anticipated in the following areas:

1. **Reduced occupational exposure benefits**— people working with unsealed sources will potentially reduce their occupational exposure and there will be improved monitoring of impacts through registration. Benefits will increase when the National Directory is implemented two–three years after the introduction of the registration requirements.[13] Clinician and patient overexposure to unsealed medical isotopes formed over 70% of radiation incidents the Radiation Advisory Council investigated in the last five years (EPA 1997, 1998, 1999, 2000, 2001c).

2. **Reduced risk of accidental community exposure**—the major benefit of registration is the potential reduction in radiation exposure from 'orphan sources' (including inappropriately disposed of sealed radioactive sources).[14] If a single orphan source became mixed with recycled metal and contaminated a large integrated steel mill, the estimated costs of a meltdown could be as high as $US100 million (US Nuclear Regulatory Commission 2001). Conservatively assuming a significant incident would cost $50 million, and the introduction of licensing could reduce the chance of an incident occurring from 1% to 0.5% per year, the average benefits per year would be $250,000. In this case, registration would give benefits with a net present value of $1.1 million over the five-year period.

   If all sources in NSW were registered, the incidents of improper disposal should be reduced through conditions of registration requiring appropriate disposal. Registration of premises will also allow for record keeping and better identification of inappropriately disposed of sources, so the number of 'orphan sources' should decrease. The monitoring of incoming scrap metal would be expected to continue, and the reduction in incidents would reduce the radiation exposure of scrap metal transporters and recyclers.

### *Environmental benefits*

It is assumed that measures to reduce human exposure to radiation will also reduce the effects of human-derived radiation on the natural environment. Radiation exposure can cause genetic damage in all species.

Many unsealed radioactive sources and the waste material left from their use are water-soluble. They therefore pose a significant environmental threat if they are not adequately stored. Any leakage could lead to ground and water contamination. The proposed Regulation would ensure that information concerning these materials and the conditions under which they are kept and disposed of, would be recorded and updated as part of the registration requirements.

---

[13] As discussed in section 2.6.2, the development of uniform radiation safety guidelines is being facilitated through the development of a National Directory for Radiation Protection (ARPANSA 2001). It is expected that when the National Directory is developed, it will apply to all unsealed radioactive sources in Australia through conditions of registration attached by the various State radiation safety regulators. As the attachment of these conditions may impose costs, the National Directory would be subject to cost-benefit analysis before being implemented in NSW.

[14] The International Atomic Energy Agency has documented several dramatic incidents that have occurred overseas with orphan sources causing environmental damage, widespread injury and fatalities through direct contact, contamination of recycled metal after it was melted down, and air emissions from a smelting facility (International Atomic Energy Agency 1999).

Regulation would also allow systematic inspections of the premises by EPA authorised officers to monitor the continued safety of storage and disposal of this material.

***Industry benefits***
Metal recycling and related industries would benefit from reduced costs associated with a reduction in the inappropriate or accidental disposal of encapsulated radioactive sources removed from radiation gauges, into their waste streams. The metal recycling industry currently faces considerable costs associated with properly identifying, removing, retaining and disposing of these sources.

When metal recyclers find these 'orphan sources' in their waste stream, they can rarely trace the owners so must be responsible for their storage and ultimate disposal. While the costs to the metal recycling industry of inappropriate disposal of encapsulated radiation sources into waste streams have not been calculated, they are believed to be significant. It is also expected that the number of encapsulated radiation sources will increase considerably in the future.[15]

### Assessment
Allowing full-fee registration of premises where unsealed radioactive sources are kept or used has the potential to reduce exposure of people and the environment to radiation. Although rare, the impacts of these events are major and the $0.73 million needed to reduce the risks is justified.

## 4.2 Regulation of mobile sealed radioactive sources

### Mobile sealed radioactive sources in NSW
Mobile radioactive sources are radioactive substances in a shielded container or gauge, which allows the controlled emission of radiation. They include industrial radiography sources, geological borehole logging sources ('gamma loggers'), and soil moisture and density probes used on construction sites.

### The current regulatory situation
NSW is the only State that does not require registration of mobile sealed radioactive sources. Such registration, together with the registration of premises where unsealed radioactive sources are kept or used (see section 4.1), is required to support national obligations under the International Atomic Energy Agency (IAEA) *Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management* (see section 2.7*).*

Several recommendations of the NCP review of radiation protection legislation also call for the prescriptive regulation and registration of sealed radioactive sources, and recovery of the costs of administration of these provisions.

Under clause 10(1) of the current Regulation all mobile sealed radioactive sources other than fixed radiation gauges, are exempt from registration.

### The proposed Regulation
Under the proposed Regulation, clause 10(1) of the current Regulation will be deleted so all mobile sealed radioactive sources will have to be registered with the EPA. The fee applying

[15] International Atomic Energy Agency 1999, *IAEA Bulletin: Lost & Found Dangers. Orphan Radiation Sources raise global concerns* 41/3/99

to fixed radiation gauges will be applied to all mobile sealed radioactive sources to allow for the full recovery of the costs associated with administration of this provision.

## Costs

### *Government costs*

The EPA will incur administrative and compliance costs associated with the registration of mobile gauges, but there will be no financial impact as the fees recover the full financial cost.

### *Industry costs*

There will be costs associated with complying with the proposed conditions attached to the registration. As with the registration of fixed radiation gauges, industry will need to comply with a minimum set of conditions, such as:

- maintaining a stock register
- notifying the EPA when there is a transfer of ownership or when a source is lost or disposed of
- new applicants having to employ a CRE to inspect gauges on the premises.

Total industry costs of registering mobile sources are an estimated NPV of $0.64 million over the five years of the proposed Regulation. This cost is based on the following estimates:

- registration fee $0.21 million
- registration administration costs $0.11 million[16]
- registration renewal $0.32 million[17].

Several recommendations of the NCP review of radiation protection legislation also call for the prescriptive regulation and registration of mobile sealed radioactive sources, and recovery of the costs of administration of these provisions. Registration renewal will require a CRE inspection every two years. Transfer of registration requires the EPA to be notified and it is assumed this cost will be minimal.

The size of the industries that use mobile sealed radioactive sources has not been determined. However it has been estimated that the proposed Regulation will add $42 to the cost of each device per year.[18] This cost is expected to be transferred to the community by way of increased charges for services. This relatively small cost should not have any noticeable effect on the industry or the community.

## Benefits

### *Community benefits*

Setting appropriate fees for registering mobile sources means the costs of registration will be recovered from the users of the regulated activities.

[16] For the purpose of this calculation, registration applicatin is expected to take one hour of industry time (at $50 per hour, including 50% on-costs) and $100 for a CRE inspection per mobile gauge registered, for 758 guauges over the five years of the proposed Regulation. Full details of this calculation are set out in Appendix E.

[17] For the purpose of this calculation, registration renewal has been costed at $200 per CRE inspection for 1,185 gauges over the five years of the proposed Regulation. The number of registration applications and renewals has been calculated using the number of registrations in 2002, and assuming that annual registration application activity increases by 7% per annum; and registration application and renewal activity expires at a rate of 3% per renewal cycle. Full details of this calculation are set out in Appendix E.

[18] For the purpose of this calculation, it is assumed that there will be 1943 mobile gauges registered or re-registered (renewed) over the 5 years of the proposed Regulation (see Appendix E). A total of $0.41m spread over 1943 gauges over a 5-year period equals approximately $42 per device per year.

Conditions can be attached to the registrations that will reduce the potential of the sources to harm users and the community. As with unsealed sources, benefits are anticipated in the following areas:

1. **Reduced occupational exposure benefits** will potentially occur, as the users of these sources will have improved monitoring of impacts through registration. These benefits will increase when the National Directory is implemented two–three years after the introduction of the registration requirements.[19]

2. **Reduced risk of accidental community exposure**— a regulatory analysis for registering radiation sources in the USA (US Nuclear Regulatory Commission 2001) identified the major benefit of registration to be the potential reduction in radiation exposure from incidents caused by 'orphan sources' (see glossary for definition). The impacts of such events are estimated to cost up to US$100 million. Many of the most dangerous 'orphan sources' come from mobile sources such as abandoned encapsulated gamma-ray sources from borehole logging gauges.

Finally, registered owners would be responsible in the event of accidents and misuse of mobile radiation sources registered under their name. In such circumstances 'orphan sources' could be better identified, allowing any necessary clean-up costs to be reclaimed from the owner, instead of from general taxpayer revenue. The onus would be on the owner (as well as users already licensed) to ensure that staff are trained and appropriate safety measures are in place.

***Environmental benefits***

As noted in section 4.1, it is assumed that measures to reduce human exposure to radiation will also reduce the effects of human-derived radiation on the natural environment. Radiation exposure can cause genetic damage in all species.

For example, in 1989 an iridium-192 encapsulated source was removed from a gauge for temporary storage in a shielded container. Due to improper documentation and monitoring, the container and iridium-192 was returned to the manufacturer. When the container and iridium-192 finally reached the manufacturer after three weeks' transportation, it was discovered that an unknown number of people could have been exposed to up to 5 millisieverts of radiation, and several truck drivers may have received up to 310 millisieverts.[20] The latter is over 15 times the permitted annual occupational dose and more than 300 times the annual permitted dose for a member of the public.

## Assessment

The recovery of regulatory costs will not have any significant impact, and the number of mobile radioactive sources will not decrease as a result of the fee.

Registration of mobile sealed radioactive sources will reduce the risk of harmful exposure of people and the environment to radiation. Although very rare, the impacts of events such as the example noted above are major and the $0.64 million needed to reduce the risks is justified.

[19] As discussed in section 2.6.2, the development of uniform radiation safety guidelines is currently being facilitated through the development of a National Directory for Radiation Protection (ARPANSA 2001). It is expected that when the National Directory is developed, it will apply to all mobile radioactive sources in Australia through conditions of registration attached by the various State radiation safety regulators. As the attachment of these conditions may impose costs, the National Directory would be subject to cost-benefit analysis before being implemented in NSW.

[20] International Atomic Energy Agency (IAEA) 1998, *IAEA Satety Reports Series No. 7 1998—Lessons Learned from Accidents in Industrial Radiography*, International Atomic Energy Agency, Vienna

## 4.3 Regulation of radiation therapy equipment

### Radiation therapy equipment in NSW

Radiation therapy is the use of ionising radiation to treat medical conditions, primarily cancer. The type of radiation used may be x-rays, gamma rays, or high-energy electron beams and these are directed to selectively destroy the affected tissue. Other medical conditions also benefit from radiation treatment, such as pterygia (a growth on the eye) and keloid (prominent scar tissue).

Radiation therapy may involve the use of:

- radiation apparatus—linear accelerators, x-ray apparatus, and x-ray simulators—see section 1.4
- sealed radioactive sources—brachytherapy devices and radioisotope teletherapy apparatus—see section 4.2
- unsealed radioactive sources—ophthalmic applicators—see section 4.1.

Diagnostic imaging x-ray machines used for chest x-rays or CT scans produce relatively small, low energy x-rays for brief periods of time. A typical diagnostic x-ray imaging device produces x-rays at approximately 100 thousand electron volts, whilst a linear accelerator used in radiotherapy typically produces x-ray beams in the range of 6 to 20 million electron volts. The amount of radiation delivered to the patient in diagnostic imaging is in the order of a few microsieverts, while a typical dose delivered in radiotherapy is significantly higher (usually hundreds or thousands of millisieverts).

### Size of the industry

Approximately 15,000 patients receive treatment from radiation therapy equipment in NSW each year, which consists of over 700,000 treatments. Over 700 staff administer treatments from therapy equipment.[21]

There are 12 radiation oncology centres in NSW, most located in the public sector. Most dermatological and ophthalmological treatment is performed in private clinics. It is estimated that approximately 140 radiation therapy devices will be registered under the Regulation.[22]

### The current regulatory situation

Medical practitioners currently require licences to use radiation therapy equipment under the *Radiation Control Act 1990* but the radiation therapy equipment is not registered.

In most other States and Territories, the owner must register therapy equipment, and radiation users must be licensed.

Because of the very high doses of radiation given during radiation therapy treatments, the current Regulation is deemed to provide inadequate safety and protection for recipients of radiation therapy, relevant occupational groups and the general community. Radiation therapy has a high accident rate, coupled with significant and potentially fatal consequences. Overseas evidence indicates that systematic errors can remain undetected for long periods

[21] Radiation therapy patient numbers are based on EPA 2003, *Radiation Protection in Radiotherapy: draft Guideline 7*. The guideline estimates patient numbers in 1997 to be 11,500 and this number is estimated to have increased by 30% since 1997. It is estimated that staff numbers would have increased by 8%.

[22] The number of radiation therapy devices has been estimated based on a 30% ncrease in the number of units calculated in the EPA 1997 *Draft Therapy Guideline 7—Cost-Benefit Analysis*. For a breakdown of numbers of each type of equipment, see Appendix F.

and can affect many people, and that many accidents can be foreseen and prevented through effective regulation.

## The proposed Regulation

The proposed Regulation will introduce a requirement for radiation therapy equipment to be registered, with appropriate registration fees set by the EPA to allow for full cost recovery. In introducing this legislation, NSW will follow the practices of most other States.

## Costs

### *Government costs*

The government will incur costs from introducing registration of radiation therapy equipment. However, these costs will be fully recovered by the registration application, renewal and transfer fees.

The administration, inspection and auditing involved in registering radiation therapy apparatus has been estimated to be similar to registering other radiation apparatus, so the same registration fees will be used. The recommended fees are $155 for registration, $105 for registration renewal (every 2 years) and $38 for registration transfer.

### *Industry costs*

There will be a minimum set of requirements imposed on registrations, including:

- inventory of equipment
- record keeping
- ensuring only licensed people have access to the equipment.

Further conditions of registration will be introduced following the completion of the National Directory for Radiation Protection and the adoption nationally of a therapy guideline.[23] Costs of the registration fee and complying with registration requirements have been estimated at a NPV of $70,000 over five years.[24] Transfer of registration will require the EPA to be notified and this cost will be minimal.

For medical users of unsealed sources alone, the Medicare rebates for radiation therapy totalled over $0.75 million for nearly 17,000 services in 2002 (HIC 2002). The total cost of registration and associated compliance costs represents just fewer than 2% of the total rebates. This cost should not have any noticeable impact on the industry or the community.

## Benefits

### *Community benefits*

Registered owners would be responsible for equipment registered in their name in the event of accidents and misuse. ‘Orphan sources’ (see glossary) could be better identified, allowing any necessary clean-up costs to be reclaimed from the owner, instead of from general

[23] The EPA completed *Guideline 7— Cost-Benefit Analysis for Registration Requirements and Industry Best Practice for Ionising Radiation Equipment Used in Radiation Therapy* in 1997. Since this time, responsibility for developing these codes of practice has shifted to the Commonwealth, following the NCP review. The development of the National Directory for Radiation Protection, being coordinated by ARPANSA, was discussed in section 2.6.2. Following the introduction of this National Directory over the next two– three years, CRE inspection requirements and equipment monitoring requirements will be introduced and be subject to a separate cost-benefit analysis.

[24] For the purpose of this calculation, it is assumed to take industry one hour to complete each registration application at $50 per hour (including 50% on-costs), and one hour of industry work (also at $50 per hour) for each registration renewal thereafter. Total industry registration costs are estimated at a NPV of $50,000 over five years, while industry administration costs are estimated at a NPV of $20,000 over five years. Full details of this calculation are set out in Appendix F.

taxpayer revenue. The onus would be on the registered owner (as well as users already licensed) to ensure that staff are trained and appropriate safety measures are in place.

By setting fees for registering radiation therapy equipment, registration costs are appropriately allocated to industry.

***Health benefits***

The benefits of the proposed Regulation include the avoidance of accidents and incidents which could lead to medical, occupational or public exposure.

These benefits have not been quantified due to lack of information on the number of radiation incidents and exact costs associated with them in NSW. In addition, the concept of 'collective dose' (see glossary for definition) is not appropriate for therapy doses. That is, the value of the collective dose would not provide a measure of the objective health detriment because the severity of the effects will be dependent on the dose.[25] For example, incidents of harmful medical exposure include both overexposure and underexposure relative to the prescribed radiation dose. Collective dose calculations assume the lower the dose, the fewer the adverse heath impacts.[26]

Health benefits will be in the following areas:

1. **Reduced risk of harmful radiation exposure during medical treatment**—harmful radiation exposure during radiation therapy treatments can have serious, if not fatal, consequences. For example, in early 1997 a four-year-old child received a full course of radiation therapy to the left side of the brain instead of the right. The maladministration of the treatment has significantly reduced the patient's chances of survival and at the least has impeded future development. In another incident, a patient died from pulmonary complications after receiving twice the prescribed dose for radiation therapy treatment to the brain.

   Regulation of the equipment used in these accidents would have reduced the possibility of such misuse by ensuring medical practitioners followed a strict system of checks and balances.

2. **Reduced occupational exposure benefits**—people working with these sources will potentially reduce their occupational exposure and there will be improved monitoring of impacts through registration. As the use of radiation therapy increases, the number of staff in the industry will also increase. Benefits will also increase when the National Directory is implemented by ARPANSA two–three years after the registration requirements are introduced—see section 2.6.2. and footnote 14

3. **Reduced risk of accidental exposure**—accidental harmful radiation exposure could arise when radiation therapy equipment is disposed of improperly or used by unqualified people. The regulation of radiation therapy equipment would reduce the potential for accidents such as these to occur, by helping to ensure that the equipment is disposed of carefully and is only used by appropriate practitioners.

***Environmental benefits***

As discussed in sections 4.1 and 4.2, measures to reduce human exposure to radiation will also reduce the effects of human-derived radiation on the natural environment. Radiation exposure can cause genetic damage in all species.

[25] The International Commission for Radiological Protection (ICRP 1982) notes there are difficulties in applying optimisation techniques to radiation protection of patients undergoing radiotherapy.

[26] Radiotherapy delivery errors may be classified as systematic (either patient-based or institutional) or ramdon. Systematic errors can affect many people over long periods

In the town of Goiania in Brazil in September 1987, a shielded caesium-137 source was removed from a radiation therapy machine in an abandoned hospital. The machine was then dismantled in a residential garden to be sold as scrap metal. Over the following 16 days, the caesium-137 was scattered over a wide area and affected the total population of approximately 120,000 people.

In addition to the significant health impacts of this incident, which included the death of four people,[27] several residences and public places became seriously contaminated. Decontamination of 42 houses was required and 3,500 cubic metres (275 truckloads) of contaminated soil and other material had to be removed and permanently stored.

### Assessment

The use of radiotherapy is likely to increase in the future (NHMRC 1996), as cancer continues to increase. While radiation therapy is often the only appropriate treatment for many patients and is widely recognised as saving many lives, it can also kill people.

Allowing full-fee registration of radiation therapy equipment can reduce the exposure of people and the environment to radiation. Although rare, the impacts of events such as the accident in Brazil described above, are major and the estimated $70,000 over the five years of the proposed Regulation needed to reduce the risks is justified.

## 4.4 Protecting users of radiation under the Radiation Control Regulation

### The current regulatory situation

As discussed in section 1, many people in NSW come into direct contact with radiation from sources and apparatus through their work.

The *Radiation Control Act 1990* contains provisions to protect the health and safety of workers exposed to radiation as part of their work, including provisions that require the monitoring of levels of radiation exposure.

Section 40 allows regulations to be made that cover other radiation safety issues. These include, but are not limited to:

- protecting the health and safety of people engaged in producing, manufacturing, supplying, keeping, conveying, using or otherwise dealing with radioactive substances or radiation apparatus (section 40(3)(f))
- monitoring levels of radiation exposure of people engaged in producing, manufacturing, supplying, keeping, conveying, using or otherwise dealing with radioactive substances or radiation apparatus (section 40(3)(i)).

Part 3— Radiation Safety of the current Regulation contains several clauses relating to radiation monitoring and radiation accidents. These include:

- personal monitoring devices approved by the EPA must be provided by employers and worn by any occupationally exposed person when issued (clause 15)

[27] Approximately 30 people received large doses of radiation, 249 were contaminated internally and externally and 112,000 people were monitored.

- the Director General of the EPA can issue a notice directing premises to be equipped with approved area monitoring devices (clause 17)
- employers are required, upon becoming aware of any fault in any radiation apparatus, to investigate and remedy the fault, and inform any people that have been exposed to radiation in excess of that received from the apparatus in a faultless condition (clause 27)
- dose limits must be set for occupationally exposed people and the public, with occupationally exposed people permitted to receive higher doses of radiation as their exposure is subject to monitoring and supervision. However, exposure limits specified in the current Regulation are not mandatory and no penalty is applied to breaches.

## The proposed Regulation

The proposed Regulation improves the radiation safety of users.

**1. Power to attach conditions to approval of personal and area monitoring devices**
Although the EPA must approve the personal and area monitoring devices that can be used, it does not have the power to attach conditions to the approval. This lack of power can lead to inappropriate or ineffective use of the monitoring devices. The power to apply conditions is already contained in the EPA's licensing and registration activities. This proposal is a refinement of these provisions, allowing the EPA to, for example:

- require the devices to be calibrated to accepted international benchmarks, giving users and the EPA confidence that the system is operating accurately
- ensure that the processing and interpretation of results of exposure will be carried out to consistent and reliable standards
- make it compulsory for service providers to notify employers and the EPA where a monitoring device shows that an employee has been exposed to an amount of radiation which would, if left unchecked, exceed or have exceeded the levels specified in Schedule 2 of the Regulation (clause 15).

The proposed Regulation will attach an appropriate fee for EPA approval of personal and area monitoring safety devices.

**2. Requirements to wear personal monitoring devices for all users of radiation gauges that emit neutrons**
Neutron radiation gauges are used in industrial applications, such as soil moisture monitoring, pavement surfacing and oil/ water well logging. The Radiation Advisory Council has recommended that all users of such devices be incorporated into the list of users who must wear personal monitoring devices (clause 18).

**3. Requirement for dosimeter service providers to supply dose information to employers using the dosimeters**
Employers must keep dosimeter records of personal and area exposure. These dosimeters are supplied and subsequently read by a service provider. If a service provider withholds the exposure records, the employer is in technical breach of the current Regulation. The proposed Regulation makes it mandatory for service providers to supply this information to employers.

**4. Bringing occupational and public exposure limits in line with Australian standards**
The occupational exposure limits in the current Regulation exclude application of dose limits to certain occupational groups that are exposed to naturally occurring radiation, such as radon and cosmic radiation.

Guidelines adopted elsewhere in Australia support the need to incorporate flight crew personnel and tour guides in caves into these exposure limits. These workers can be

exposed to high levels of radiation as a direct result of their occupation.[28] For example, flight crew personnel travelling regularly across the North magnetic pole will be exposed to high doses of radiation.[29] This exposure can be effectively limited through a rostering system.

Placing such occupational groups in the proposed Regulation will allow them an annual limit of 20 millisieverts only.

**5. Mandatory requirements to meet occupational dose limits**
The proposed introduction of a new offence for failure to comply with occupational dose limits is discussed further in section 4.5. Under the current Regulation the occupational dose limit is a recommendation that cannot be enforced. Requiring adherence with the dose limit brings NSW in line with the recommendations contained in ARPANSA 2002, 'Recommendations for limiting exposure to ionising radiation (1995)' and 'National standard for limiting occupational exposure to ionising radiation (1995)', *Radiation Protection Series No. 1,* that are used across Australia and that NSW will need to adopt as part of the National Directory for Radiation Protection (see section 2.6.2 and footnote 14).

## Costs

### *Government costs*

The costs of attaching conditions to approvals of radiation monitoring devices is minimal, as the EPA currently requires the full range of information from the applicant, and conditions are already developed and attached to any approvals issued. Government auditing and enforcement activities, such as the inspection of the calibration of these devices, and record keeping, are expected to be minimal.

Government costs under the proposed Regulation will be fully recovered through the fees and conditions attached to the personal and area monitoring devices.

### *Industry costs*

The introduction of a power to attach conditions to the approval of personal and area monitoring devices would impose costs on industry associated with obtaining approval for the model and design of personal and area monitoring safety devices used by their workers. The costs for each approval are estimated to be $525 based on five hours of administration work at $50 per hour and five hours of inspection/auditing at $55 per hour. Currently less than one approval is granted each year, but if in future one approval were granted each year of the proposed Regulation, the total NPV cost over the five years would be $2,300.

The introduction of a requirement for users of neutron radiation gauges to wear personal monitoring devices is estimated to cost industry $20,000[30] over the five years of the proposed Regulation.

[28] The proposed Regulation would only affect commercial airlines beause the controls would apply only in an occupational context.
[29] Trips across both the poles increase the amount of exposure to cosmic rays because of effects associated with sheltering by the Earth's magnetic field. Exposure to cosmic rays nearer the equator is not zero but is significantly lower than exposure near the poles. The altitude of a flight also contributes to cosmic radiation exposure. Generally, the level of exposure rises with altitude. Long-haul flights give a greater radiation dosage than short flights because the latter tend to use lower altitudes.
[30] Industry costs have been calculated on the assumption that there are an estimated 50 people using neutron radiation gauges each year over the five years of the proposed Regulation. Personal monitoring devices cost $15 each (this cost includes the calibration of exposure doses by the service provider) and must be replaced every two months.

The costs to industry of requiring service providers to keep and supply their records to the employer and the EPA would be minimal because there are few providers and these conditions require no more than current best practice.

Industries employing flight crews and cave guides would incur costs from the requirement to establish basic working conditions that minimise the risks to these employees of excessive exposure to cosmic and natural background radiation. This would involve the establishment of average doses for particular work schedules and applying rostering conditions that reflect the estimated exposures. The exact costs of these changes could not be determined, but these requirements operate in other jurisdictions in Australia without significant impact.

### Benefits

***Community/health benefits***
This provision would also be expected to lead to improvements in health outcomes due to the enforcement of occupational exposure limits and the use of personal and area radiation monitoring devices according to proper and rigorous industry standards. Furthermore, the conditions attached to approval of these devices can be amended in response to technological improvements or the introduction of new exposure limits across the industry.

The benefits of setting occupational radiation exposure limits for pilots and cave guides are that their radiation exposure would be monitored, allowing them to reduce their health risks if they were exposed to high radiation levels.

***Benefits for the goverment***
The proposed Regulation provides the government with more flexibility in how it administers the legislation. Necessary changes to the approval and use of personal monitoring devices can be made efficiently without requiring additional regulatory amendments.

The proposed Regulation also ensures that the government has better access to information on the occupational exposure of workers, facilitating the development and maintenance of appropriate regulatory practices.

***Benefits for employers***
The application of a requirement for service providers to supply records would remove the anomaly in the current Regulation whereby employers bear the legal responsibility for the potential negligence of service providers.

## Assessment

The net economic benefits of introducing provisions relating to personal and area monitoring devices are:

- improved standards
- improved confidence in the reliability of exposure results
- alignment with internationally recognised standards of safety in radiation exposure.

Substantial improvements would also occur in:

- record keeping and scrutiny which in turn would improve risk management of incidents that excessively expose employees to radiation
- the reduced inappropriate legal liability of employers when service providers withhold exposure records
- health outcomes, from proposed improvements in standards of exposure monitoring (although these cannot be quantified).

Setting radiation dose limits for flight crew personnel and cave guides would allow for improvements in health outcomes for these groups in terms of control of their exposure to natural radiation.

The introduction of a requirement for users of neutron radiation gauges to wear personal monitoring devices is estimated to cost industry $20,000 over the five years of the proposed Regulation. The introduction of a power to attach conditions to the approval of personal and area monitoring devices would impose costs to industry of an estimated NPV of $2,300 over the five years of the proposed Regulation. The impacts of these changes on industry are considered minor, and are not expected to have any noticeable effect on consumers.

The benefits to the community and to industry outweigh the comparatively small costs to industry of the introduction of these provisions.

## 4.5 Increasing penalties and penalty notices (PINs)

### The current regulatory situation

The provisions of the Regulation are designed to protect the environment and people from a person acting improperly when dealing with radiation apparatus or radioactive substances. The primary role of penalties is to deter dangerous conduct.[31] As in similar environmental and occupational health legislation, penalties can be imposed on people or corporations breaching the provisions.

The maximum penalties against breaches of the Radiation Control Regulation 1993 are considerably lower than those provided for in the *Pesticides Act 1999.*[32] The result of the low penalties can be seen in the few prosecutions under the *Radiation Control Act* and Regulation in local courts.[33]

At present the maximum penalties for breaches of the Regulation are typically 15 penalty units ($1650) to 25 penalty units ($2750). Section 40(4) of the *Radiation Control Act 1990* limits penalties for breaches of the Regulation to 100 penalty units. The value of a penalty unit under the *Crimes (Sentencing Procedure) Act 1999* is $110, making the maximum penalty $11,000.

Unlike most other environment protection legislation administered by the EPA and similar occupational health and safety legislation, the current Regulation has no provision to issue PINs[34] or on-the-spot fines. The lack of PIN powers for minor breaches of the Regulation

[31] According to the Law Reform Commission, penalties are imposed for offences against the Regulation as 'a salutary reminder that the conduct in question will not be tolerated and therefore deter potential offenders' (Law Reform Commission 1996). They are efficient to administer and incidentally raise revenue for the State, but their primary role is as a deterrent. Determining appropriate penalty amounts is not readily subject to economic analysis. The approach taken in the proposed Regulation has therefore been to introduce penalties consistent with other environmental offences.

[32] For example, the disposal of a radioactive substance without the approval of the Director General of the EPA (current Regulation, clause 21(1)) carries the maximum penalty of 100 penalty units ($11,000), while using a pesticide contrary to the label (*Pesticides Act*, Section 15(1)) carries a maximum fine of $120,000 for a corporation or $60,000 for an individual.

[33] In the seven years from October 1995, the EPA conducted seven prosecutions under the *Radiation Control Act* and Regulation in local courts and the total value in fines imposed was only $3,600.

[34] According to the *EPA Prosecution Guidelines* (EPA 2001b) PINs are appropriate where:

- the breach is minor
- the facts are apparently incontrovertible
- the breach is a one-off situation that can be remedied easily
- the issue of a PIN is likely to be a practical and viable deterrent.

mean these breaches are not pursued by the EPA, or pursued at considerable expense with no or low fines imposed by the Court.

## The proposed Regulation

The EPA proposes to increase the maximum penalties for various offences to bring them into line with similar legislation the EPA administers. The proposed Regulation increases penalties for all offences and applies the maximum penalty of 100 penalty units where appropriate, enabling courts to impose larger penalties for breaches of the Regulation.

The proposed Regulation will also introduce penalty notices (on-the-spot fines—PINS) for minor offences against the Act and Regulation, consistent with the approach under other Acts.

Common situations where PINS would be suitable include:

- using a radiation apparatus without a licence
- a person or establishment failing to comply with instructions from an EPA officer in an appropriate timeframe
- an owner using equipment when it has a fault that could give rise to harmful exposure of operators or patients.

The proposed Regulation will give the EPA the ability to issue PINs with fines of $250, $500 or $1000 against most breaches.[35]

The ability to issue PINs adds the flexibility to impose small fines on the spot against minor breaches that can be easily remedied. It is not possible to provide an accurate assessment of the potential number of PINs that could be issued given the scheduled increase in compliance audits, but this mechanism provides a valuable alternative to prosecuting minor breaches.

A complete list of penalties and PINs can be found in Appendix B.

## Additional offences under the proposed Regulation

The proposed Regulation will create three new offences:

- **failure to comply with occupational dose limits (clause 15—arises from a revision of the occupational exposure provisions of the Act and Regulations discussed in section 4.4)**— comparable pieces of legislation such as the *Occupational Health and Safety Act 2002* have similar fines for breaches of their health and safety codes, therefore the proposed fine of up to $11,000 is not unreasonable
- **failure to investigate faults or defects in sealed sources (clause 30(2)(a))**, and **failure to inform people of excess radiation exposure from a faulty or defective sealed radioactive source** (clause 30(2)(b))— these offences attach a PIN and maximum fine to offences that contravene registration requirements for all sealed radioactive sources, not just fixed radiation gauges.

## Costs

### *Government costs*

The economic costs, or true resource cost to the community associated with the increased penalties, are largely limited to the resources spent defending legal proceedings. The

[35] PINs were introduced under the *Environment Protection Legislation Amendment Act 2002*.

increased fines themselves do not impose any additional financial or economic costs on the government.[36]

The level of evidence the EPA requires to pursue a prosecution remains unchanged, and as the EPA usually seeks to recover the costs of investigating and prosecuting breaches and orders for any remedial work required, the increased penalties will not affect EPA resources used in any individual prosecution.

For the EPA the costs of issuing PINs are negligible, as they are typically issued on-the-spot or immediately after conducting an inspection or audit.

### *Industry costs*

The impact of the changed penalties on industry should be minimal. Even the maximum penalty of $11,000 is relatively low. Industry is being encouraged to be a good corporate citizen and not find itself facing prosecutions.

The economic costs of PINs are also mainly related to the resources that industry could expend on legal defence by electing to take the matter to court. However as PINs can only be issued where the facts are 'apparently incontrovertible' and the penalties are in the range of $250 to $1000 the number of court elections is expected to be low.

## Benefits

### *Health benefits*

The main benefit of increased penalties and the addition of PINs would arise from the deterrence of behaviour associated with exposure of people to unsafe levels of radiation. The proposed Regulation would increase penalties to ensure that the cost of compliance remains lower than the maximum penalty.

As discussed previously, the total benefits of reduced radiation exposure under the current Regulation are conservatively estimated at $9.56 million over five years. If the increased fines and PINs lead to a 1% reduction in exposure there will be economic benefits of nearly $100,000 over the five-year period.

Increased penalties and the introduction of PINs would conform to community expectations that sanctions are commensurate with the seriousness of the offence. They would also comply with NCP review recommendations that States and Territories maintain uniform radiation protection legislation across Australia. Currently other States have much higher penalties for similar offences.

### *Benefits for the government*

PINs represent a more efficient use of resources since they can often achieve the same outcome using fewer government resources than a prosecution. Issuing of PINs allows EPA officers an additional regulatory option, with prosecution used as a strategy of last resort or for more serious breaches of the law. The introduction of PINs has an additional benefit in that EPA officers issuing PINs can give face-to-face advice to licensees and owners on how to comply with the legislative provisions. It is reasonable to expect licensees and owners to be more receptive to learning how to comply with relevant legislative requirements than when a PIN could not be issued.

[36] Reference is made in the RIS to the difference between economic and financial costs and benefits. A financial value is the amount of money that a stakeholder actually pays or gains, e.g. a fee. However, financial values are not always the same as economic values, which measure the true resource costs to the community.

### Assessment

The overall impact to industry and the community of the increased penalties would be minimal. Given the degree of public concern over matters involving radiation there is an expectation of higher penalties. However, even if the prosecutions trebled and the average fine increased to $5000, the net impact on industry would only amount to an NPV of $65,000 over the five-year period.[37]

Fines attached to PINs issued by the EPA raise a similar amount of revenue to fines imposed by court prosecutions (EPA 2001a), so the total fines are similarly expected to be in the order of $65,000 over the five-year period. This is negligible compared to the size of the regulated industry in NSW, where, for example, medical diagnostic imaging practitioners received approximately $286.3 million in Medicare rebates in 2002 (HIC 2002). Furthermore, industry can choose to avoid these costs by obeying the law.

.

## 4.6 Adjusting fees to reflect full cost recovery

### Current fee levels

It is consistent with NSW Treasury Guidelines that a government agency recovers their costs through fees for licences, registrations and other regulatory instruments.[38] It is therefore proposed that these fees be increased to reflect full cost recovery. This is consistent with Section 40(3)(l) of the *Radiation Control Act 1990* that provides for regulations under the Act to require 'the payment of fees and charges for services provided by the Authority under this Act'. It is also in line with recommendations of the NCP review of radiation protection legislation.

The fees were last changed in November 2001 to reflect CPI increases from when the current Regulation commenced in September 1993 to June 2001, and to attach a fee for registration of cyclotrons. Even with this increase, the NSW Government is not recovering its full costs from current fee levels.

### Adjustment of fee levels to achieve full cost recovery

Four regulatory authorisations are established under the *Radiation Control Act 1990.*

1. **Licences**—licences are required under section 6 for anyone who uses, possesses, sells or gives away any radioactive substance or radiation apparatus. The application fee for a licence is currently $82, and the annual renewal fee is $46. There are currently over 11,000 licences issued in NSW.

2. **Registrations**—the owners of fixed sealed radioactive sources and certain types of radiation apparatus must register them under section 7 of the Act. Registration fees are currently $121 for new applications, $97 for renewals, and $24 for transfers. It was determined that radioactive sources and radiation apparatus would be renewed at two- or five-year periods according to the level recommended by the Radiation Advisory Council. There are currently over 6,600 registered sources and pieces of apparatus in NSW. The Regulation was amended in December 2001 to allow for the registration of cyclotrons with an application fee of $1000 and renewal fee of $800. As these registration fees were only recently set, no adjustment is proposed at this time.

[37] If the total amount of fines and penalties raised (including those raised by prosecution) was $15,000 per year, this would have a NPV of $65,000 over the five years of the Regulation, using a 7% discount rate.
[38] NSW Treasury 2001, *Guidelines for Pricing of User Charges.*

3. **Accreditation**—accreditation of consulting radiation experts (CREs) is established under section 9 of the *Radiation Control Act 1990*. The activities that CREs can undertake are prescribed in clause 11 of the current Regulation and include: advising on radiation safety requirements, assessing radiation safety plans, and assessing and calibrating radioactive sources and radiation apparatus to ensure compliance with registration requirements. The current fee for accreditation is $82. There are currently over 70 CREs in NSW.

4. **Area and personal radiation monitoring devices**—the EPA must issue approvals of area and personal radiation monitoring devices under clauses 15 and 17 of the Regulation (see section 4.4). A fee is proposed to cover the costs incurred in issuing these approvals.

In 2002 the EPA issued 1,753 licences, 643 registrations and 17 accreditations, many of which required significant input from EPA radiation experts and the Radiation Advisory Council. The EPA also processed renewals for 12,565 licences and 1,421 registrations during that period[39] as well as inspecting, auditing and responding to requests for variation of regulated activities. The EPA also maintains a 24-hour hotline and responds to radiation incidents at regulated and unregulated premises across NSW.

Table 1 on the next page compares the fees under the current and proposed Regulations. To determine appropriate fees, the EPA estimated the average time involved in issuing, renewing and amending licences, registrations and accreditations, based on administration and audit/inspection time. Administration covers:

- receiving the application
- entering the details
- checking for and following up requirements for approval
- issuing the registration, licence or accreditation to the applicant.

The weighted average cost of this time is $50 per hour (which includes costs of staff, IT, accommodation, etc). Auditing and inspection involves the requirement to visit, inspect and audit premises, and has a weighted average cost of $55 per hour.

[39] As renewals are currently required either every two or five years depending on the type of apparatus, 1421 renewals for 2002 have been calculated by averaging the number of two- and five- year renewals for 2002.

**Table 1—Current and proposed fees**

| Activity | | Current fees ($) | Proposed fees ($) | Change ($) | Estimated number of activities over five years (rounded) |
|---|---|---|---|---|---|
| 1. | Section 6 licence applications | $82 | $117 | +$35 | 10,000 |
| | Renewal of licence under section 11 | $46 | $67 | +$21 | 70,000 |
| | Variation of licence | nil | $83 | +$83 | 11,000 |
| 2. | Registration applications (under sections 7 and 8 of the Act) | $121 | $155 | +$34 | 4,000 |
| | Renewal of registration under section 11 (other than for cyclotrons) | $97 | $105 | +$8 | 9,000 |
| | Section 7 registration (for cyclotrons) | $1000 | $1000 | nil | 1 |
| | Transfer of registration under section 12 | $24 | $38 | +$14 | 150 |
| 3. | Accreditation under section 9 | $82 | $128 | +$46 | 100 |
| | Renewal of accreditation | nil | $103 | +$103 | 200 |
| | Variation of accreditation | nil | $91 | +$91 | 12 |
| 4. | Approval of area and personal monitoring devices | nil | $525 | +$525 | 5 |

**Proposed NSW and current Interstate radiation fees**

In most cases proposed fees are comparable on an annual basis with fees charged by neighbouring States, as shown in Table 2 overleaf. The exception is that NSW will be setting fees for licence variations. Each licence allows the licensee to use specific radiation equipment or radioactive substances for a particular purpose. Licence variations occur when the licensee wants to:

- use a different type of equipment to that already specified
- use the same piece of equipment for a different purpose
- use different radioactive isotopes.

These variations constitute substantial changes in the professional terms of their licence, since an assessment of the licensee's qualifications needs to be undertaken. Minor changes, such as changes in name or address, are not considered licence variations.

**Table 2—Comparison of proposed NSW and current interstate radiation fees**

| Regulatory instrument | Activity | Cost per year | | |
|---|---|---|---|---|
| | | NSW (proposed) | Victoria | Queensland |
| **Licence** (users) | Issue | $117 | $99–$320 | $85 |
| | Renewal | $67 | $99–$321 | $35 |
| | Variations | $83 | | |
| **Registration** (owners) | Issue | $155 | $24–$260 | $157–$240 |
| | Renewal | $105 | $24–$260 | $130–$140 |
| | Transfer | $38 | | |
| **Accreditation** (consultants) | Issue | $128 | | $83–$150 |
| | Renewal | $103 | | $50 |
| | Variation | $91 | | |
| **Area & personal monitoring devices** (service providers) | Approval | $525* | | |

* The approval fee for area and personal monitoring devices is only applicable to organisations/service providers that provide a personal radiation dose monitoring service. For a provider of such a service to market a particular type of device, the EPA (Director General) must approve it.

## Costs

### *Government costs*

The proposed fees have been set to recover the administrative costs to the government of providing the licensing services. Since licensing is required under the *Radiation Control Act 1990*, costs would be incurred regardless of whether fees were charged. It is assumed that the change in proposed fees will have no impact on the number of licences and registrations.

### *Industry costs*

The fees represent a financial cost to licence, registration and accreditation holders and applicants. It is expected that the proposed fees will impose financial costs of a NPV of $7.36 million over five years, spread across all licences, registrations and accredited people. This represents a NPV increase of $2.74 million on fees that would be payable under the current Regulation.[40]

The increased fees in no way alter the regulatory compliance requirements imposed by affected licences, registrations or accreditations, so industry will not incur any additional compliance costs. This is because the compliance obligations are created in the Act.[41]

The largest affected industry sector is diagnostic imaging, which includes medical, chiropractic, dental and veterinary sectors. Medicare paid rebates for 4.13 million services in NSW in 2002, and by conservatively adjusting that number by 50% to account for dental and veterinary imaging[42] the total number of services in NSW would be 6.2 million per year. This

[40] Full details of this calculation are set out in *Appendix G.*

[41] The level of administration for issue, renewal and amendment of licences, registrations and accreditations is similar, as these are mainly set processes of checking supporting information, entering details on the licence database, banking the fees and generating and issuing the authorisation. The level of inspection and audit of the authorisations varies, with registered premises, radiation apparatus, and accredited radiation experts requiring more time and expertise than the largely paper-based auditing of licensees.

[42] Dental and veterinary imaging do not receive rebates under Medicare although they are diagnostic imaging services for the purpose of the proposed Regulation.

would mean that the costs of regulation would be approximately $0.10 per service,[43] compared, for example, to an average Medicare rebate of over $69 per service in 2002.[44]

**Benefits**

The proposed Regulation would ensure the safest possible protection against dangerous levels of radiation exposure in the community. In addition, it would ensure the enforceability of licences and registrations under the *Radiation Control Act 1990.*

The proposed fees are consistent with the user-pays principle. That is, if these costs were not recovered from industry, the subsidy would be spread across NSW taxpayers. The change represents a more equitable outcome for the general community, consistent with government policy and the NCP review.[45]

## Assessment

In the context of Section 40(3)(l) of the *Radiation Control Act 1990* and the NCP review, the option of the proposed fee structure for full cost recovery is considered the most appropriate. The increase will at most only have a minor impact on the cost of services provided by the industry, and proposed fee increases are comparable with similar fees charged in other States. Table 3 demonstrates that under the current Regulation, industry is being subsidised by approximately $3.18 million and this subsidy would be largely eliminated under the proposed Regulation.

**Table 3—Comparison of EPA cost recovery under the current and proposed Regulation**

| Type of Regulation | Cost recovery under the current Regulation over five years (rounded) | Cost recovery under the proposed Regulation over five years (rounded) | No. of activities over five years under the proposed Regulation |
|---|---|---|---|
| Licences | $3,500,000 | $6,000,000 | 114,025 |
| Registrations | $1,120,000 | $1,320,000 | 13,020 |
| Accreditations | $7,000 | $35,000 | 361 |
| **Total** | **$4.62 million*** | **$7.36 million** | **127,406** |

*The estimated Treasury funding to administer EPA activities under the current Regulation is estimated at a NPV of $7.8 million over five years, indicating a recovery deficit of approximately $3.18 million.

[43] The NPV increase over the current Regulation equals $3 million not discounted. This total o $3 million divided by 5 years divided by 6.2 million rebates per year equals approximately 10 cents per rebate.

[44] Medicare paid $286.3 million in rebates divided across 4.13 million services. This equals approximately $69 per service.

[45] Fees were increased by 21% in December 2001 to reflect CPI increases from the commencement of the Regulation in September 1993 to June 2002. However, even with these fee increases the EPA does not recover its full costs, as implementation has proved more costly than anticipated in 1993. The fees would have raised approximately $4.62 million over the five years, while the cost to the EPA is **$**7.8 million over the same period. This $2.74 million shortfall represents an inappropriate 59% subsidy to the industry that is inconsistent with government policy and the NCP review.

# 5. Possible future regulation of high-power lasers and their operators

The proposed Regulation does not include introducing the registration of lasers. The EPA invites comments from stakeholders about the possible need to regulate lasers in the future.

This section explains:

- the potential health impacts of lasers
- the current regulatory situation
- the use of lasers in NSW
- the possible reasons for licensing users of lasers and registering high-power lasers in the future.

## 5.1 High-power lasers in NSW

Lasers are classified under the Standards Australia Association Standard AS/NZS2211.1: 1997 *(Laser Safety—Part 1, Equipment classification requirements and user's guide)* according to their potential to inflict harm on people. The classification scheme is outlined in Table 4 below.

**Table 4—Laser classes and typical uses**

| Class of laser | Biological effects | Typical uses |
|---|---|---|
| 1 | Intrinsically safe due to low power or interlocked protection | Laser pointers, laser printers, CD players, speed cameras |
| 2 | Potential to cause temporary eye injury but mitigated by blink reflex | Laser pointers, laser levelling equipment |
| 3A | Can cause temporary eye injury with direct viewing, or permanent effects if viewed with optical instruments | Laser levelling equipment, laser 'acupuncture' devices, entertainment lasers |
| 3B* | Direct laser beam can cause permanent eye and skin injury | Medical lasers, entertainment lasers, research lasers, industrial marking lasers, military laser rangefinders |
| 4* | Direct or scattered laser beam can cause permanent eye and skin injury | Industrial cutting lasers, research lasers, medical lasers |

Source: Standards Australia 1997

*Available data suggest that class 3B and class 4 lasers are the only classes that can permanently injure eyes or skin through normal use.

Medical lasers are used in several areas of clinical practice including cosmetic surgery (mainly skin resurfacing and hair removal), corrective corneal surgery ('Lasik'), and in removing occlusions in arteries. Medical laser use poses the highest potential for injury, as the lasers are applied directly to the human body.

A NSW Health Care Complaints Commission report (HCCC 1999) into cosmetic surgery in NSW estimated that there are 200 to 250 providers using lasers in Australia, including cosmetic physicians, general practitioners, nurses, dermatologists, plastic surgeons, cosmetic surgeons and beauty therapists. However, this medical industry sector is rapidly growing and the numbers estimated for NSW appear low when compared with data from Western Australia, where class 3B and 4 lasers have been registered since 1983.

Industrial lasers of class 3B and 4 are used for cutting and marking metals and plastics. This industry largely consists of specialised companies operating several computer-numerically-controlled (CNC) laser cutting or marking machines doing work under contract. The 2002 Sydney Yellow Pages lists over 80 such companies operating in Sydney.

The use of entertainment lasers by light show operators has received widespread publicity through their use during events such as the 2000 Olympic Games and new year's celebrations. Although this industry in Australia operates under National Health and Medical Research Council guidelines (NHMRC 1995) and has a good safety record to date, there have been entertainment laser injuries recorded overseas (Rockwell 1994). Approximately ten operators are based in NSW but some additional operators are also contracted in NSW from other States.

Research lasers are used in scientific and research establishments such as universities and high-technology companies that use the unique optical properties of lasers in basic research or in developing medical and industrial laser applications. The Australian armed forces use laser-based rangefinders in certain weapons, but this use is restricted to military bases that fall under the jurisdiction of the Commonwealth.

## 5.2 The injury record of high-power lasers

The best record of laser injuries is a voluntary database maintained by Rockwell Laser Industries in the USA (Rockwell 1994). A review of 272 events from 1964 to 1994 indicated that over 73% of the injuries were eye injuries, 90% of these indicating some function loss of which 77% were permanent. Other injuries were skin burns and indirect injuries caused by fire and electrical shock. The most common activity causing injury was beam alignment (37%) and failure to use protective eyewear was a contributing factor in 36% of incidents. The occupations of people involved in incidents (Table 5 overleaf) shows the most commonly injured groups to be technicians and scientists, who are the most likely to be involved in beam alignment.

The only record of laser injuries in Australia is the Australian Radiation Incidents Register maintained by ARPANSA. This register is not well publicised and only contains three incidents: one fatal medical laser incident in Victoria in 1992 and two unconfirmed eye injuries in Western Australia. However, it is recognised that laser injuries are under-reported and there are some claims that only 10% of incidents are reported on injury registers. The rest are apparently resolved through workers' compensation or medical malpractice systems.

**Table 5 —Occupation of people involved in laser incidents in the USA (1964–1994)**

| Occupation | Number of injuries | Percentage |
|---|---|---|
| Technicians | 58 | 21.3 |
| Scientists | 48 | 17.6 |
| Patients | 35 | 12.9 |
| Plant workers | 29 | 10.7 |
| Doctors/nurses | 25 | 8.4 |
| Students | 23 | 8.4 |
| Spectators | 13 | 4.8 |
| Laser show operators | 11 | 4.0 |
| Pilots/military personnel | 9 | 3.3 |
| Equipment users | 9 | 3.3 |
| Field service staff | 7 | 2.6 |
| Officer staff | 5 | 1.8 |

Source: Rockwell1994

## 5.3 Current regulatory situation

While there is currently provision in the *Radiation Control Act 1990* for registering lasers as non-ionising radiation apparatus and licensing users of such equipment, these provisions have not yet been prescribed in the Regulation.

Western Australia has regulated high-power lasers (class 3B and 4) since 1983. Tasmania has regulated class 3B and 4 medical and industrial lasers since 1994, and Queensland has regulated class 4 medical lasers since 2000.

There is no accurate data for the number of class 3B and 4 lasers in NSW. The most reliable information on potential numbers of laser licences and registrations was obtained from the Radiation Health Section of the Western Australian Department of Health. The number of potential laser licences and registrations in NSW was estimated to be 1210 and 960 respectively based on data from the Australian Bureau of Statistics (ABS 2001) employment numbers for the applicable industry sector.

## 5.4 Regulation of lasers under the *Radiation Control Act 1990* — main drivers

The need to possibly regulate high power lasers and their operators has been highlighted in several forums:

- recommendation to the Minister by the Radiation Advisory Council in October 1997 that class 3B and 4 lasers be registered and their use restricted to licensed people
- the New South Wales Health Care Complaints Commission 1999 report (HCCC 1999) into cosmetic surgery recommending that class 3B and 4 medical lasers be registered, and their users be licensed under the *Radiation Control Act 1990*

- comments provided to the HCCC by the Australasian College of Dermatologists that lasers are a ‘disaster waiting to happen’ because the equipment is widely available without proper training
- the National Competition Policy review of radiation protection legislation (ARPANSA 2001) recommending that high power lasers be subject to uniform national legislation.

## 5.5 Consultation on the regulation of lasers

The EPA invites comments from stakeholders and the community on whether all high-power lasers (class 3B and 4) should be regulated in NSW. Other options include regulating only high-power lasers used in medical procedures including cosmetic surgery, or regulating only lasers used in industrial and entertainment activities.

The EPA prefers to give priority to implementing the other changes to the Regulation, and to continue to monitor the value of regulating lasers.

# 6. Summary of costs and benefits

The *Subordinate Legislation Act 1989* requires that a RIS include an assessment of the costs and benefits of the proposed Regulation, its alternatives, and an assessment of which option provides the greatest net benefit at the least net cost to the community.

The base case, or no Regulation, would lead to the government having to administer the provisions of the *Radiation Control Act 1990* at a NPV cost of $7.8 million over 5 years, while being unable to recover this cost from industry. Furthermore, community radiation exposure would be expected to rise, with potential NPV health costs of $9.56 million over five years.

Continuation of the current Regulation would require no change to current regulatory practice, and would deliver potential health benefits from expected improvements in collective dose levels compared with the base case. However, NSW taxpayers would continue to subsidise industry and users of radiation services, inconsistent with full cost recovery and the user-pays principle. In addition, unsealed sources, sealed mobile radioactive gauges and radiation therapy devices would remain unregulated, posing a considerable health risk to the community. There would be heightened concerns about the deliberate misuse of radioactive materials. In addition, making no change is contrary to NCP recommendations concerning creating uniformity of radiation regulation across Australian States and Territories. While all the costs of this option cannot be quantified, this option clearly is not favoured.

The proposed Regulation succeeds in implementing and facilitating the aims of the *Radiation Control Act 1990*, which sets the framework for managing radioactive substances and radiation apparatus in NSW, and embodies the best options and strategies for implementing and facilitating these aims.

Most provisions of the proposed Regulation prescribe equipment and information requirements necessary for the efficient functioning of the *Radiation Control Act 1990*. Therefore, the economic costs of those activities are attributable to the Act and the proposed fees do not represent the economic cost of the proposed Regulation—see Table 6.

**Table 6—Summary of economic costs and benefits of the proposed Regulation**

| BENEFITS | COSTS |
|---|---|
| **Registration of unsealed sources** | |
| • Will allow protection of users and the community from accidental and deliberate exposure to unsealed radioactive sources—costs of meltdown in a steel mill estimated at $100 million.<br>• Will help NSW and Australia to support international obligations for control of radioactive substances. | • Total industry costs estimated at a NPV of $0.73 million over the five years of the proposed Regulation. |
| **Registration of mobile sources** | |
| • Will allow protection of users and the community from accidental or deliberate exposure to mobile radioactive sources.<br>• Will assist NSW and Australia in complying with national and international obligations for control of radioactive substances. | • Total industry costs estimated at a NPV of $0.64 million over the five years of the proposed Regulation. |
| **Registration of radiation therapy devices** | |
| • Will allow protection of users and the community from harmful exposure to radiation therapy devices.<br>• Health benefits are believed to be considerable but cannot be quantified due to the often severe nature of the illnesses being treated and the relatively large radiation doses being delivered | • Imposes costs of registration to industry estimated at NPV of $0.05 million, in addition to compliance costs estimated at a NPV of $0.02 million over the five years of the proposed Regulation. |

| BENEFITS | COSTS |
|---|---|
| **Protection of users** | |
| • Will allow for recovery of costs for approving radiation monitoring devices.<br>• Will impose a penalty for failure to comply with occupational dose limits, leading to potential health benefits for users.<br>• Will ensure new groups, such as users of neutron gauges, flight crews and cave workers, have their occupational exposure monitored and recorded.<br>• Will align NSW radiation protection standards with national standards. | • Imposes industry costs estimated at a NPV of $22,300 over the five years of the proposed Regulation, with most of these costs falling on industry using neutron radiation gauges. |
| **Increased penalties and PINs** | |
| • Penalties imposed against breaches of the Regulation more commensurate with community expectations and other comparable breaches.<br>• Immediate fines able to be imposed for minor breaches of the Act and Regulations through PINs.<br>• Potentially reduced exposure through better enforcement: a 1% reduction in exposure reduces community radiation exposure costs by nearly $100,000 over the five years of the proposed Regulation.<br>• Imposing immediate penalties helps to encourage lawful behaviour among corporations and citizens and provides a more graduated approach to radiation control regulation. | • Industry costs may rise from legal costs associated with breaching regulatory provisions, but these costs can be avoided through lawful behaviour. |
| **Cost recovery** | |
| • Largely eliminates subsidy of $3.18 million to industry through fees not reflecting the costs of adequate regulatory oversight. | • Industry costs to rise by an estimated NPV of $2.74 million over the five years of the proposed Regulation, leading to increases to consumers of $0.10 per medical service. |

# 7. Conclusion

The RIS has presented the alternative options for the remake of the Radiation Control Regulation 1993, and analysed which regulatory options will provide the maximum net benefits for NSW.

The industrial and medical benefits of the use of radioactive substances and radiation apparatus outweigh the potential detrimental health effects of their use. However, the regulation of radiation, through licensing and registration provisions in the *Radiation Control Act 1990* and the Radiation Control Regulation 1993, remains an important mechanism to ensure that the many people in NSW who come into direct contact with radiation are not exposed to harmful doses.

The RIS demonstrates that the proposed Regulation provides the maximum net benefits to society, through:

- minimising the risk of harmful radiation exposure
- complying with recommendations of the NCP Review
- supporting Australia's international convention obligations
- supporting the user-pays principle.

The proposed Regulation will ensure that the objectives of the Act are achieved and that costs are recovered in a fair way. It is therefore recommended that the proposed Regulation be made.

# References


ABS 2001. *6291.0.40.001— Labour Force (EJ) Employed—Industry—Australia—Quarterly*, Australian Bureau of Statistics, Canberra.

ABS 2001, *2015.1 Census of Population and Housing,* Australian Bureau of Statistics, Canberra.

ARPANSA 2001, *Final Report, National Competition Policy Review of Radiation Protection Legislation—May 2001*, ARPANSA, Sydney.

ARPANSA 2002, 'Recommendations for limiting exposure to ionising radiation (1995)' and 'National standard for limiting occupational exposure to ionising radiation (1995)'*, Radiation Protection Series No.1*, Australian Government Publishing Service, Canberra.

Australian Standard AS/NZs2211.1:1997 *Laser Safety —Part 1, Equipment classification requirements and user's guide*, Standards Australia, 1997.

Chaplin, Vince, 2002, *Personal communication,* Corporate Manager—Environment, Metalcorp.

Chapman, S and Wutzke, S1997, 'Not in my backyard— media coverage of community opposition to mobile phone towers: an application of Sandman's outrage model of risk perception', in *Australian and New Zealand Journal of Public Health*, 1997, 21, pp.614– 620.

Colgan, P, Harrison, D and Moore, W1992, 'Guideline Development and Impact Assessment for Registration of Medical, Dental and Veterinary X-ray Apparatus', Radiation Protection in Australia, Vol. 14, No. 4.

Environment Protection Authority (EPA) 1993, *Regulatory Impact Statement—Proposed Radiation Control Regulation 1993*, NSW Environment Protection Authority, Sydney.

EPA 1994. *Regulatory Impact Statement: Environmentally Hazardous Chemicals Regulation 1985*, NSW Environment Protection Authority, Sydney.

EPA 1997, *Radiation Advisory Council Annual Report 1996–97*, NSW Environment Protection Authority, Sydney.

EPA 1997, *Cost-Benefit Analysis for Radiation Control Guideline 5: Registration Requirements and Industry Best Practice for Premises on which an Unsealed Radioactive Source is Kept or Used,* NSW Environment Protection Authority, Sydney

EPA 1998, *Radiation Advisory Council Annual Report 1997–98*, NSW Environment Protection Authority, Sydney.

EPA1999, *Radiation Advisory Council Annual Report 1998–99*, NSW Environment Protection Authority, Sydney.

EPA 2000a, *Radiation Advisory Council Annual Report 1999–2000*, NSW Environment Protection Authority, Sydney.

EPA 2000b, *Radiation Guideline Number 6 —Registration Requirements and Industry Best Practice for Ionising Radiation Apparatus used in Diagnostic Imaging.*

EPA 2001a, *Annual Report 2000–2001*, NSW Environment Protection Authority, Sydney.

EPA 2001b, *EPA Prosecution Guidelines*, NSW Environment Protection Authority, Sydney.

EPA 2001c, *Radiation Advisory Council Annual Report 2000–2001*, NSW Environment Protection Authority, Sydney.

EPA 2003, *Radiation Protection in Radiotherapy: draft guideline 7.*

HCCC 1999, *The Cosmetic Surgery Report*, NSW Health Care Complaints Commission, Sydney.

Health Insurance Commission (HIC) 2002,. *Medicare Benefits Schedule Group Statistics Reports*, from www.hic.gov.au/statistics/dyn_mbs/forms/mbsgtab4.shtml

International Atomic Energy Agency 1999, *IAEA Bulletin: Lost & Found Dangers. Orphan Radiation Sources raise global concerns* 41/3/1999.

International Atomic Energy Agency (IAEA), *Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management*, entered into force on 18 June 2001and signed by Australia on 18 November 1989.

International Atomic Energy Agency (IAEA) 1998, 'Lessons Learned from Accidents in Industrial Radiography', *IAEA Safety Reports Series No. 7 1998,* International Atomic Energy Agency, Vienna 1998.

International Commission on Radiological Protection 1982, 'Cost-Benefit Analysis in the Optimisation of Radiation Protection', *ICNRP Publication 37*, Pergamon Press, Sydney.

International Commission on Radiological Protection 1990. 'Radiation Protection: Recommendations of the ICRP Publication 60', *ICRP Publication 37*, Pergamon Press, Sydney.

Law Reform Commission 1996, *Report 79—Sentencing*, NSW Attorney General's Department, Sydney.

National Health and Medical Research Council (NHMRC) 1995, *Code of practice for the safe use of lasers in the entertainment industry*, Australian Government Publishing Service, Canberra.

National Radiological Protection Board 1986, *Cost-Benefit Analysis in the Optimisation of Radiological Protection*, ASP 9, HMSO, London.

NSW Treasury 2001, *Guidelines for Pricing of User Charges.*

Rockwell, R.J 1994, 'Laser Accidents: reviewing thirty years of incidents: what are the concerns—old and new?' *Journal of Laser Applications*, No. 6, pp. 203–211.

US Nuclear Regulatory Commission 2001, *Regulatory Analysis: Requirements for the Possession of Industrial Devices containing Byproduct Material*, Rockville, MD, USA.

# Glossary

| | |
|---|---|
| **ARPANSA** | The Australian Radiation Protection and Nuclear Safety Agency is a Federal Government agency charged with responsibility for protecting the health and safety of people and the environment from the harmful effects of ionising and non-ionising radiation. |
| **Collective dose** | A measure of the population dose from ionising radiation. |
| **CRE** | A certified radiation expert is a person accredited by the EPA under the Radiation Control Act to carry out certain prescribed activities relating to assessing radiation apparatus, radioactive substances, and premises. |
| **Discounting** | Discounting is a procedure through which values in future years are converted to present-day values. This provides for the opportunity cost of money, where people attach a lower value to future costs and benefits (i.e. people discount the future). Consistent with NSW Treasury guidelines, a discount rate of 7% has been used throughout this RIS. |
| **Dose** | Level of exposure to ionising radiation, commonly measured in sieverts (1 sievert = 1,000 millisieverts (mSv)). |
| **Ionising radiation** | Radiation of sufficient intensity to cause electrification (ionisation) of particles and cell matter. |
| **Sealed radioactive source** | A radioactive substance enclosed in a container which prevents escape of the substance and permits controlled emission of radiation from the container, for example, a radiation gauge—either fixed or mobile. |
| **NCC** | The National Competition Council was established by Australian Commonwealth, State and Territory governments in November 1995 to act as a policy advisory body to oversee their implementation of the NCP. |
| **NCP** | National Competition Policy refers to the package of reforms recommended by the Independent Committee of Inquiry into ways of enabling and encouraging competition in Australia. |
| **NPV** | Net present value is the value of a cost or benefit after discounting. |
| **Orphan source** | A radioactive source that has been illegally disposed of into the environment or into the scrap metal stream or waste stream. |
| **PIN** | Penalty notices are an enforcement mechanism usually issued by the EPA where there has been a minor breach of licence conditions; where the facts appear incontrovertible; the breach is a one-off and can be remedied easily; or a penalty notice is likely to be a viable deterrent. |
| **RAC** | Radiation Advisory Council: a NSW Council that advises the Minister for the Environment on the development and administration of radiation control legislation; matters relating to radiation safety; matters relating to licensing, registration and accreditation; and other matters. |
| **Radiation therapy device** | A radiation therapy device uses ionising radiation to treat a medical condition. These devices include: |

| | |
|---|---|
| | • apparatus, such as linear accelerators, x-ray apparatus, superficial therapy units, and x-ray simulators;<br>• sealed radioactive sources such as brachytherapy devices, and radioisotope teletherapy apparatus;<br>• unsealed radioactive sources such as ophthalmic applicators. |
| **Sievert** | Units of the energy deposited into tissues by radiation, weighted for the type of radiation and the type of body tissue. |
| **Unsealed radioactive source** | A radioactive substance that is not a sealed radioactive source, for example, the radioisotopes in solutions used in nuclear medicine; and encapsulated sources removed from radiation gauges. |

# Appendices

## Appendix A—Recommendations of the National Competition Policy Review of radiation protection legislation

### Recommendation 1:

Jurisdictions are to ensure that the objectives of their radiation protection legislation include the goal of protecting the health and safety of people and the environment from the harmful effects of ionising and non-ionising radiation

### Recommendation 2:

Jurisdictions are to identify duplication and discrepancies between radiation protection legislation and other related legislation, standards or codes of practice and take action to minimise the duplication and discrepancies consistent with national uniformity policies.

### Recommendation 3:

Jurisdictions are to include nationally consistent provisions in radiation protection legislation to protect people from the harmful effects of non-ionising radiation.

### Recommendation 4:

Jurisdictions are to retain the regulatory approach to achieve radiation protection objectives.

### Recommendation 5:

Jurisdictions are to consider using performance-based approaches where appropriate (that is, description of outcomes rather than the prescription of required action) based on risk management principles and all applicable quality and process standards. This is to be done in a nationally uniform manner within the framework of the *National Directory for Radiation Protection.*

### Recommendation 6:

Jurisdictions are to incorporate risk management principles in the *National Directory for Radiation Protection.*

### Recommendation 7:

Jurisdictions are to develop a uniform set of protocols on functions that can be outsourced to third party service providers and establish national accreditation processes and guidelines for such providers. This could be done as part of the *National Directory for Radiation Protection.*

### Recommendation 8:

Jurisdictions are to legislate to review their radiation protection legislation at intervals of no more than 10 years.

### Recommendation 9:

Jurisdictions are to participate fully and unconditionally in the formulation and implementation of the *National Directory for Radiation Protection* and conduct a review of its effectiveness and efficiency within three years of its commencement.

### Recommendation 10:

The *National Directory for Radiation Protection* should take account of all existing standards, including those produced by ARPANSA, the National Health and Medical Research Council, the National Occupational Health and Safety Commission and Standards Australia.

### Recommendation 11:

Standards and codes of practice that will be adopted in the *National Directory for Radiation Protection* are to be, as far as practicable, consistent with relevant recommendations of international organisations and international standards.

### Recommendation 12:

The current systems of licensing and registration of operators, radiation equipment and radioactive substances are to be retained.

### Recommendation 13:

Jurisdictions are to review the need to license dentists as part of the development of the *National Directory for Radiation Protection.*

### Recommendation 14:

Jurisdictions are to retain the current prescriptive approach to their legislation, while making efforts to move towards a performance-based approach as required under Recommendation 5.

### Recommendation 15:

Jurisdictions are to take into account the needs of rural, remote and Aboriginal and Torres Strait Islander communities when formulating radiation protection policies.

### Recommendation 16:

Jurisdictions are to remove any provision that restricts any licensee, holder of an exemption or registration from referring to that fact in any advertising or promotional material.

### Recommendation 17:

Jurisdictions are to incorporate an administrative protocol in the *National Directory for Radiation Protection* for the application of mutual recognition principles to the grant of licences and registrations to inter-State/Territory applicants.

### Recommendation 18:

Jurisdictions should recover the cost of their regulatory oversight from licensing and registration fees except for activities of the regulatory authorities that are of a public good nature.

### Recommendation 19:

Jurisdictions should agree on a nationally uniform system of classification for radiation incidents, accidents or emergencies and develop a cost-effective national system to collect and collate information and publish a national register for radiation incidents.

# Appendix B—Proposed changes to penalties under the proposed Regulation

## Current and proposed Radiation Control Regulation penalties

| Clause (current/ *proposed*) | Offence | Penalty notice | Maximum penalty amount | | |
|---|---|---|---|---|---|
| | | | Current | Proposed | Change |
| **8(5)** ***9(5)*** | Fail to ensure that approval given to each person to whom it relates or is conspicuously displayed | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **8(6)** ***9(6)*** | Fail to ensure that each approved person is supervised by qualified person | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| ***15*** | Fail to ensure that each occupationally exposed person not exposed to excessive health limits | $1000 | None | 100 pu $11,000 | +$1100 |
| **13** ***16*** | Fail to ensure that each occupationally exposed employee is made aware of, and kept informed of any changes in, prescribed particulars | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **14(2)** ***17(2)*** | Fail to comply with direction | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **14(3)(a)** ***17(3)(a)*** | Fail to ensure that copy of radiation safety manual available to all occupationally exposed employees | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **14(3)(b)** ***17(3)(b)*** | Fail to ensure all reasonable steps in manual followed by all peoples | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **15(1)** ***18(1)*** | Fail to ensure that all relevant occupationally exposed employees are issued with approved monitoring devices | $500 | 15 pu $1650 | 50 pu $5500 | +$3850 |
| **15(2)** ***18(2)*** | Fail to wear approved monitoring device in course of person's employment | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **16(1)** ***19(1)*** | Fail to keep record | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **16(3)(a)** ***19(3)(a)*** | Fail to cause a copy of radiation exposure records to be given to employee upon leaving employment | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **16(3)(b)** ***19(3)(b)*** | Fail to cause a copy of radiation exposure records to be given to future employer if employee consents | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **16(4)** ***19(4)*** | Fail to ensure warning given to an employee | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **16(5)** ***19(5)*** | Fail to ensure records available for inspection | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **17(3)** ***20(4)*** | Contravene direction | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **18** ***21*** | Fail to ensure monitoring devices checked, maintained or calibrated | $500 | 15 pu $1650 | 50 pu $5500 | +$3850 |
| **19** ***22*** | Fail to keep records | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **20** ***23*** | Expose other person to ionising radiation | $500 | 15 pu $1650 | 50 pu $5,500 | +$3850 |
| **21(1)** ***24(1)*** | Dispose of radioactive substance without consent of DirectorGeneral | $1000 | 100 pu $11,000 | Same | n/a |
| **21(2)** ***24(2)*** | Dispose of radiation apparatus without consent of DirectorGeneral or apparatus still operable | $1000 | 100 pu $11,000 | Same | n/a |
| **22(1)** ***25(1)*** | Fail to maintain records | $1000 | 100 pu $11,000 | Same | n/a |
| **23** ***26*** | Cause radioactive substance to be transported otherwise than in accordance with Code of Practice | $1000 | 100 pu $11,000 | Same | n/a |
| **25(1)** ***28(1)*** | Fail in duty to investigate and report apparent pollution accident | $250 | None | 25 pu $2750 | n/a |

| | | | | | |
|---|---|---|---|---|---|
| **26(1)** ***29(1)*** | Fail to maintain records | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **27(a)** ***30(1)(a)*** | Fail to investigate fault in radiation apparatus and cause it to be removed, replaced or repaired if necessary | $500 | 50 pu $5,500 | Same | n/a |
| **27(b)** ***30(1)(b)*** | Fail to inform all people of excess radiation exposure from faulty radiation apparatus | $500 | 50 pu $5,500 | Same | n/a |
| **None** ***30(2)(a)*** | Fail to investigate fault or defect in sealed radioactive source and cause it to be removed, replaced or repaired if necessary | $500 | None | 50 pu $5,500 | +$5,500 |
| **None** ***30(2)(b)*** | Fail to inform all people of excess radiation exposure from faulty or defective sealed radioactive source | $500 | None | 50 pu $5,500 | +$5,500 |
| **28(2)(a)** ***31(2)(a)*** | Fail to appoint radiation safety officer or committee | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **28(2)(b)** ***31(2)(b)*** | Allow functions of radiation safety officer or committee to be exercised otherwise than by the officer or committee | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **29(1)** ***32(1)*** | Destroy or otherwise dispose of records | $250 | 15 pu $1650 | 25 pu $2750 | +$1100 |
| **31(1)** ***34(1)*** | Fail to cause notice of loss or theft of radioactive substance or radiation apparatus to the DirectorGeneral | $1000 | 15 pu $1650 | 100pu $11,000 | +$9350 |
| **33** ***36*** | Fail to ensure warning sign conspicuously displayed | $250 | 10 pu $1,100 | 25 pu $2750 | +$1100 |

## Proposed *Radiation Control Act* penalties

| Clause | Offence | Penalty notice (Corporation/individual if applicable) |
|---|---|---|
| 6(2) | Possess, use, sell or give away prescribed substance or apparatus without holding a licence | $1500/$750 |
| 6(3) | Possess, use, sell or give away prescribed substance or apparatus to someone that does not hold a licence | $1500/$750 |
| 7(2) | Fail to register a prescribed thing or fail to comply with registration conditions | $1500/$750 |
| 7(3) | Allow person who does not have authorisation to use registered thing | $1500/$750 |
| 8(1) | Keep or use unsealed radioactive source at a premises that is unregistered or conditions of registration not complied with | $1500/ $750 |
| 8(2) | Allow person who does not have authorisation to use unsealed radioactive source | $1500/ $750 |
| 9(1) | Carry on prescribed activities of a consulting radiation expert without accreditation | $500 |
| 13(6) | Fail to surrender a suspended or cancelled licence, registration or accreditation to the appropriate authority | $100 |
| 18(4) | Fail to comply with notice | $1000 |
| 19(4) | Contravene or obstruct directions given under powers to deal with dangerous situations | $1500/$750 |

## Appendix C —Estimated health costs under the base case scenario (1993 Regulatory Impact Statement)

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | 3,696 | person sieverts[1] | Cost/person sievert[2] | | $ 19,200 | | |
| Year | Current (1993 Regulations) | | | No Regulation from 2003 | | | | |
| Ending | % Change | Coll. Dose | Cost ($M) | % Change[3] | Coll. Dose | Cost ($M) | Net B'fit | |
| 1994 | -0.15% | 3690 | $ 70.86 | -0.15% | 3690 | | | |
| 1995 | -0.15% | 3685 | $ 70.75 | -0.15% | 3685 | | | |
| 1996 | -0.15% | 3679 | $ 70.64 | -0.15% | 3679 | | | |
| 1997 | -0.15% | 3674 | $ 70.54 | -0.15% | 3674 | | | |
| 1998 | -0.15% | 3668 | $ 70.43 | -0.15% | 3668 | | | |
| 1999 | -0.15% | 3663 | $ 70.33 | -0.15% | 3663 | | | |
| 2000 | -0.15% | 3657 | $ 70.22 | -0.15% | 3657 | | | |
| 2001 | -0.15% | 3652 | $ 70.12 | -0.15% | 3652 | | | |
| 2002 | -0.15% | 3646 | $ 70.01 | -0.15% | 3646 | | | |
| 2003 | -0.15% | 3641 | $ 69.91 | 1.00% | 3683 | $ 70.71 | $ 0.81 | |
| 2004 | -0.15% | 3635 | $ 69.80 | 1.00% | 3720 | $ 71.42 | $ 1.62 | |
| 2005 | -0.15% | 3630 | $ 69.70 | 1.00% | 3757 | $ 72.13 | $ 2.44 | |
| 2006 | -0.15% | 3625 | $ 69.59 | 1.00% | 3794 | $ 72.85 | $ 3.26 | |
| 2007 | -0.15% | 3619 | $ 69.49 | 1.00% | 3832 | $ 73.58 | $ 4.09 | |

| Year | Increase in Sv under Current Reg over 5 years | Costs ($m) |
|---|---|---|
| 2003/04 | 42 | $ 0.81 |
| 2004/05 | 84 | $ 1.62 |
| 2005/06 | 127 | $ 2.44 |
| 2006/07 | 170 | $ 3.26 |
| 2007/08 | 213 | $ 4.09 |
| | | **$9.56** |

1- EPA (1993) Radiation Control Regulation 1993 RIS: Collective Dose given as 3,696 person Sieverts

The shaded area represents that portion of the 20-year forecast from the 1993 RIS relevant to the proposed Regulation.

2- National Radiological Protection Board (1986) Cost-Benefit Analysis in the Optimisation of Radiological Protection. ASP 9.HMSO:London.

3- It is assumed that in the absence of Regulation (the Base case) the annual collective dose would rise by 1%. Under the proposed Regulation it is assumed that there would be a 15% decrease in the average collective dose. These fault rates are based on the Colgan, Harrison and Moore (1992) study. featured in the EPA 1993 RIS. $19,800 is equal to the upper range cost per sievert given in this study, and has been adjusted for inflation and to Australian dollars.

## Appendix D—Cost of registering premises where unsealed sources are kept or used

N.B. Numbers A–K are column headings only and have no other meaning

### 1. Projected number of premises

| Laser Type | 1996 Guideline 5 CBA data | | | | Projected Numbers for 2002[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | Low | Medium | High | Total | Low | Medium | High | Total |
| | A | B | C | D | E | F | G | H |
| | Guideline 5 | Guideline 5 | Guideline 5 | Guideline 5 | | | | |
| Education & Research | 270 | 30 | 0 | 300 | 364.5 | 40.5 | 0 | 405 |
| Nuclear Medicine (diagnostic & therapy) | 120 | 60 | 0 | 180 | 162 | 81 | 0 | 243 |
| Pathology | 100 | 0 | 0 | 100 | 135 | 0 | 0 | 135 |
| Sales & Service | 10 | 0 | 0 | 10 | 13.5 | 0 | 0 | 13.5 |
| **TOTAL** | **500** | **90** | **0** | **590** | **675** | **121.5** | **0** | **797** |

1 - Numbers projected up 35% from data collected for 1996 Cost-Benefit Analysis of Radiation Guideline 5 - Registration of Sealed Sources.

### 2. Projected costs to industry of registration of premises

Annual activity application increase: 7%

Activity expiry rate per cycle: 3%

Discount Rate: 7%

| Activity | Fees per activity | | 2002 Activities | Projected Activities | | | | | Activities | NPV |
|---|---|---|---|---|---|---|---|---|---|---|
| | Current | Proposed | | 2003/04 | 2004/05 | 2005/06 | 2006/07 | 2007/08 | 2003/04-07/08 | |
| | A | B | C | D | E | F | G | H | I | J |
| | 1993 Reg | 2003 Reg | As per Table 1 | | | | | | | |
| **Registrations** | | | | | | | | | | |
| Registration application[2] | $ - | $ 155 | 797 | 825 | 83 | 91 | 100 | 110 | 1209 | $ 177,261 |
| Registration renewal - 2 year[3] | $ - | $ 105 | 0 | 0 | 0 | 800 | 81 | 865 | 1745 | $ 170,398 |
| Registration transfer[4] | $ - | $ 103 | 0 | 0 | 0 | 4 | 0 | 4 | 9 | $ 836 |
| **TOTAL (with amendments separate)** | | | | | | | | | 2963 | $ 348,495 |

2 - The number of registrations in the first year of the proposed Regulation is based on Guideline 5 data (table 1 above).

3- Annual numbers calculated based on 2 year licences initially issued in 2002 being renewed plus additional licences.

4 - Transfer of registration estimated to be 1% of applications and renewals.

## 3. Projected costs to industry of compliance with registration

Annual activity application increase: 7%

Activity expiry rate per cycle: 3%

Discount Rate: 7%

| | Compliance costs | | | | | | | Total | |
|---|---|---|---|---|---|---|---|---|---|
| **Activity** | **Proposed** | **Activities** | **2003/04** | **2004/05** | **2005/06** | **2006/07** | **2007/08** | **Activities** | **NPV** |
| | B | C | D | E | F | G | H | I | K |
| | 2003 Reg | As per Table 1 | | | | | | | I |
| **Registrations** | | | | | | | | | |
| Registration application | $ 50 | 797 | 825 | 83 | 91 | 100 | 110 | 1209 | $ 57,181 |
| Registration renewal - 2 year | $ 200[5] | 0 | 104 | 0 | 800 | 81 | 865 | 1849 | $324,568 |
| **TOTAL (with amendments separate)** | | | | | | | | | $ 381,749 |

5 It is estimated to cost industry $200 for a CRE inspection

# Appendix E—Cost of registering mobile radiation gauges

N.B. Numbers A–K are column headings only and have no other meaning

Table 1 shows uses the ratio of registrations and licenses active in Victoria in 2001 to estimate the number of registrations based on current licenses in NSW.

## 1. Projected number of mobile sources

| Mobile Radiation Apparatus Source Type | Licenses | Licenses[1] | Registrations | Ratio License: Registration | Projected No. Registration NSW |
|---|---|---|---|---|---|
| | NSW data | Vic Data | Vic Data | | |
| Industrial Radiography | 125 | 265 | 130 | 0.49 | 61 |
| Bore Hole Probes | 35 | 32 | 44 | 1.38 | 48 |
| Moisture and/or Density Probes | 671 | 250 | 160 | 0.64 | 429 |
| **TOTAL** | **831** | **547** | **334** | | **540** |

1 - The current NSW Regulation licenses, but doesn't register, mobile sources.

## 2. Projected costs to industry of registration of mobile radiation gauges

Annual activity application increase: 7%

Activity expiry rate per cycle: 3%

| Activity | Fees per activity | | | | | Projected Activities | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Current | Proposed | Estimated No. Activities 2003 | 2003/04 | 2004/05 | 2005/06 | 2006/07 | 2007/08 | Activities 2003/04-07/08 | Estimated NPV cost |
| | A | B | C | D | E | F | G | H | I | K |
| | 1993 Reg | 2003 Reg | As per Table 1 | | | | | | | |
| **Registrations** | | | | | | | | | | |
| Registration application | $ - | $ 155 | 540 | 578 | 40 | 43 | 46 | 50 | 758 | $ 112,762 |
| Registration renewal - 2 year[2] | $ - | $ 105 | 0 | 0 | 0 | 560 | 39 | 586 | 1185 | $ 100,211 |
| Registration transfer[3] | $ - | $ 38 | 0 | 6 | 0 | 6 | 1 | 6 | 19 | $ 626 |
| **TOTAL (with amendments separate)** | | | | | | | | | 1962 | $ 213,599 |

2 - Annual numbers calculated based on 2 year licences initially issued in 2002 being renewed plus additional licences.

3 - Transfer of registration estimated to be 1% of applications and renewals.

## 3. Projected compliance costs to industry of registration of mobile sources

Annual activity application increase: 7%

Activity expiry rate per cycle: 3%

| Fees per activity | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Activity** | **Proposed** | **Estimated No. Activities 2002** | **2003/04** | **2004/05** | **2005/06** | **2006/07** | **2007/08** | **Activities** | **Estimated NPV cost** |
| | B | C | D | E | F | G | H | I | K |
| | 2003 Reg | As per Table 1 | | | | | | | |
| **Registrations** | | | | | | | | | |
| Registration application | $ 150 | 540 | 578 | 40 | 43 | 46 | 50 | 758 | $ 109,124 |
| Registration renewal - 2 year | $ 200[4] | 0 | 0 | 0 | 560 | 39 | 586 | 1185 | $324,568 |
| **TOTAL (with amendments separate)** | | | | | | | | | $ 381,749 |

4 - It is estimated to cost industry $200 for a CRE inspection

# Appendix F—Cost of registering radiation therapy equipment

N.B. Numbers A–K are column headings only and have no other meaning

## 1. Projected numbers of radiation therapy equipment

| Type of Equipment | 1996 Guideline 7 CBA data | Projected Numbers for 2002[1] |
|---|---|---|
| ***Part 1: Radiation Oncology*** | | 0 |
| Brachytherapy units | 9 | 10 |
| Linear accelerators | 28 | 40 |
| x-ray stimulators | 12 | 20 |
| Radioisotope teletherapy apparatus | 1 | 1 |
| ***Part 2: Dermatology*** | | |
| Superficial therapy units | 25 | 30 |
| x-ray apparatus up to 400kVp | 9 | 10 |
| **Part 3: Ophthalmology** | 20 | |
| Sr-90 opthalmic applicators | | 30 |
| **TOTAL** | **104** | **141** |

1 - Numbers projected up 30% from data collected for EPA 1997 *Cost-Benefit Analysis of Radiation Guideline 7—Registration requirements for radiation therapy*

## 2. Projected cost of registering premises

Annual activity application increase: 7% Activity expiry rate per cycle: 3% Discount Rate: 7%

| Activity | Fees per activity | | 2002 | Projected Activities | | | | | Activities | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Current | Proposed | Activities | 2003/04 | 2004/05 | 2005/06 | 2006/07 | 2007/08 | 2003/04-07/08 | NPV |
| | A | B | C | D | E | F | G | H | I | J |
| | 1993 Reg | 2003 Reg | As per Table 1 | | | | | | | I |
| **Registrations** | | | | | | | | | | |
| Registration application | $ - | $ 155 | 141 | 145 | 10 | 11 | 12 | 13 | 191 | $ 26,027 |
| Registration renewal - 2 year[2] | $ - | $ 105 | 0 | 0 | 0 | 141 | 10 | 147 | 297 | $ 23,845 |
| Registration transfer[3] | $ - | $ 38 | 0 | 0 | 0 | 1 | 0 | 1 | 2 | $ 58 |
| **TOTAL (with amendments separate)** | | | | | | | | | 490 | $ 49,930 |

2 - Annual numbers calculated based on two-year licences initially issued in 2002 being renewed plus additional licences.

3 - Transfer of registration estimated to be 1% of applications and renewals.

## 3. Projected cost of compliance with registration

Annual activity application increase: 7% Activity expiry rate per cycle: 3% Discount Rate: 7%

| Activity | Compliance costs | | 2003/04 | 2004/05 | 2005/06 | 2006/07 | 2007/08 | Total activities | NPV |
|---|---|---|---|---|---|---|---|---|---|
| | Proposed | Activities | | | | | | | |
| | B | C | D | E | F | G | H | I | K |
| | 2003 Reg | As per Table 1 | | | | | | | B*I |
| **Registrations** | | | | | | | | | |
| Registration application | $50 | 141 | 141 | 145 | 10 | 11 | 12 | 13 | $ 14,177 |
| Registration renewal—2 year[2] | $50 | 0 | 0 | 0 | 0 | 141 | 10 | 147 | $ 5,711 |
| **TOTAL (with amendments separate)** | | | | | | | | 160 | $ 19,888 |

# Appendix G—Cost of fees under the proposed Regulation

N.B. Numbers A–K are column headings only and have no other meaning

Annual activity application increase: 7%

Activity expiry rate per cycle: 3%

Discount Rate: 7%

| EPA Activity | Fees per activity | | 2002 | Projected Activities | | | | | Activities | Net Present Value | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Current | Proposed | Activities | 2003/04 | 2004/05 | 2005/06 | 2006/07 | 2007/08 | 2003/04-07/08 | Current | Proposed |
| | A | B | C | D | E | F | G | H | I | J | K |
| | 1993 reg | 2003 reg | EPA data | | | | | | | | |
| **Licenses** | | | | | | | | | | | |
| Licence application[1] | $ 82 | $ 117 | 1753 | 1823 | 1896 | 1972 | 2051 | 2133 | 9875 | $ 700,050 | $ 998,852 |
| Licence renewal | $ 46 | $ 67 | 12565 | 14318 | 16141 | 18037 | 20009 | 22060 | 90565 | $ 2,798,118 | $ 4,075,519 |
| Licence variation[2] | $ - | $ 83 | 0 | 2148 | 2421 | 2706 | 3001 | 3309 | 13585 | $ - | $ 965,195 |
| **Registrations** | | | | | | | | | | | |
| Registration application | $ 121 | $ 155 | 643 | 667 | 693 | 719 | 746 | 774 | 3600 | $ 376,653 | $ 482,490 |
| Registration renewal - 2 year[3] | $ 97 | $ 105 | 951 | 987 | 94 | 1152 | 292 | 1326 | 3851 | $ 319,844 | $ 346,223 |
| Registration renewal - 5 year[3] | $ 97 | $ 105 | 4729 | 0 | 0 | 0 | 4918 | 486 | 5404 | $ 418,957 | $ 453,510 |
| Registration transfer[4] | $ 24 | $ 38 | 63 | 17 | 8 | 19 | 60 | 62 | 165 | $ 3,389 | $ 5,365 |
| **Accreditations** | | | | | | | | | | | |
| Accreditation application[5] | $ 82 | $ 128 | 17 | 18 | 18 | 19 | 20 | 20 | 78 | $6,749 | $ 10,534 |
| Accreditation renewal | | $ 103 | 0 | 17 | 35 | 53 | 72 | 92 | 269 | $0 | $ 22,879 |
| Accreditation amendment[2] | $ - | $ 91 | 3 | 2.6 | 2.7 | 2.9 | 3.0 | 3.1 | 14.3 | $ - | $ 1,123 |
| **TOTAL (with amendments separate)** | | | 20721 | 19977 | 21271 | 24623 | 31097 | 30171 | 127404 | $ 4,623,759 | $ 7,361,691 |

1 - As temporary licences were abolished in June 2002, assumes all temporary licences will become permanent licences.

2 - Amendments estimated to be 15% of total activities per licence or accreditation cycle.

3 - Annual numbers estimated due to effects of initial 5 and 2 year licences issued in 2002 being renewed plus additional licences.

4 - Transfer of registration estimated to be 1% of applications and renewals.

5 - Any Accreditations that are issued before the remake of the Radiation Control Regulation will be given 'lifetime" accreditations.
The expiry year of these accreditations will be 3000, therefore these Accreditations will never expire.

New South Wales

# Radiation Control Regulation 2003

under the

Radiation Control Act 1990

## Explanatory note

This Regulation replaces, without any changes in substance, the *Radiation Control Regulation 1993*.

This Regulation deals with matters relating to the following:

(a) the licensing of persons to use certain radioactive substances and radiation apparatus,

(b) prescribing activities that may only be carried out by an accredited radiation expert,

(c) regulating the use of radiation apparatus and radioactive substances in the workplace and requiring employers to supply certain information to persons who are, or are likely to be, exposed to radiation in the course of their employment,

(d) requiring the radiation doses received by persons in the course of their employment to be monitored,

(e) regulating the disposal and transport of radiation apparatus and radioactive substances and the discharge of radioactive substances,

(f) requiring employers to take certain action in the event of a radiation accident,

(g) enabling the Director-General to direct an employer to appoint a radiation safety officer or radiation safety committee or both for a workplace,

(h) exemptions from certain provisions of the Act and this Regulation.

This Regulation is made under the *Radiation Control Act 1990*, including section 40 (the general regulation–making power) and various other sections mentioned in this Regulation.

The Regulation is made in connection with the staged repeal of subordinate legislation under the *Subordinate Legislation Act 1989*.

Radiation Control Regulation 2003

# Contents

Radiation Control Regulation 2003

Contents

# Radiation Control Regulation 2003

under the

Radiation Control Act 1990

## Part 1 Preliminary

### 1 Name of Regulation

This Regulation is the *Radiation Control Regulation 2003*.

### 2 Commencement

(1) Subject to subclause (2), this Regulation commences on 1 September 2003.

(2) Clause 10 (b) commences on 1 February 2004.

**Note.** This Regulation replaces the *Radiation Control Regulation 1993* which is repealed on 1 September 2003 under section 10 (2) of the *Subordinate Legislation Act 1989*.

### 3 Definitions

(1) In this Regulation:

***approved*** means approved for the time being by the Director-General.

***calibrating*** means measuring and assessing radiation doses.

***Dentistry Radiation Guideline*** means the document published by the Authority entitled *Radiation Guideline 6: Registration requirements & industry best practice for ionising radiation apparatus used in diagnostic imaging—Part 3—Dentistry (Including maxillofacial)*.

***Director-General*** means the Director-General of the Authority.

***effective dose*** has the same meaning as it has in the 1990 ICRP recommendations.

***equivalent dose*** has the same meaning as it has in the 1990 ICRP recommendations.

***Fluoroscopy and Radiography Radiation Guideline*** means the document published by the Authority entitled *Radiation Guideline 6: Registration requirements & industry best practice for ionising radiation apparatus used in diagnostic imaging—Part 2—Fluoroscopy & Radiography*.

***Mammography Radiation Guideline*** means the document published by the Authority entitled *Radiation Guideline 6: Registration requirements & industry best practice for ionising radiation apparatus used in diagnostic imaging—Part 1—Mammography*.

***occupationally exposed person*** means a person who is exposed to radiation directly arising out of, or in the course of, the person's employment.

***radiation accident*** is defined in clause 26.

***the Act*** means the *Radiation Control Act 1990*.

***the 1990 ICRP recommendations*** means the document entitled *1990 Recommendations of the International Commission on Radiological Protection* and numbered ICRP Publication 60, as adopted by the International Commission on Radiological Protection in November 1990, a copy of which is deposited in the offices of the Authority.

***Tomography and Bone Mineral Densitometry Radiation Guideline*** means the document published by the Authority entitled *Radiation Guideline 6: Registration requirements & industry best practice for ionising radiation apparatus used in diagnostic imaging—Part 5—Computed Tomography and Bone Mineral Densitometry*.

***Veterinary Radiation Guideline*** means the document published by the Authority entitled *Radiation Guideline 6: Registration requirements & industry best practice for ionising radiation apparatus used in diagnostic imaging—Part 4—Veterinary Science*.

(2) In this Regulation, a reference to a radioactive substance of a particular Group is a reference to a radioactive substance referred to in the corresponding Group in Schedule 1.

(3) Notes in the text of this Regulation, other than in Schedules 2 and 4, do not form part of this Regulation.

### 4 Definition of "radioactive ore" (s 4)

(1) For the purposes of the definition of ***radioactive ore*** in section 4 (1) of the Act, the prescribed concentrations of uranium and thorium are:

(a) in the case of an ore that contains uranium but not thorium, 0.02 per cent by weight of uranium, or

(b) in the case of an ore that contains thorium but not uranium, 0.05 per cent by weight of thorium, or

(c) in the case of an ore that contains both uranium and thorium, a percentage by weight of uranium and thorium such that the expression:

$$\frac{U}{0.02} + \frac{Th}{0.05}$$

is greater than or equal to one.

(2) In the expression referred to in subclause (1) (c):

***U*** represents the percentage by weight of uranium.

***Th*** represents the percentage by weight of thorium.

### 5 Definition of "radioactive substance" (s 4)

(1) For the purposes of the definition of ***radioactive substance*** in section 4 (1) of the Act, the prescribed amount is 100 becquerels per gram.

(2) For the purposes of the definition of ***radioactive substance*** in section 4 (1) of the Act, a substance has the prescribed activity if the expression:

$$\frac{A1}{40} + \frac{A2}{400} + \frac{A3}{4000} + \frac{A4}{40000}$$

is greater than or equal to one.

(3) In the expression referred to in subclause (2):

***A1*** represents the total activity, in kilobecquerels, of the Group 1 radionuclides contained in the substance.

***A2*** represents the total activity, in kilobecquerels, of the Group 2 radionuclides contained in the substance.

***A3*** represents the total activity, in kilobecquerels, of the Group 3 radionuclides contained in the substance.

***A4*** represents the total activity, in kilobecquerels, of the Group 4 radionuclides contained in the substance.

### 6 Safe dose limits to be taken into account by the Authority

When making a decision under the Act, the Authority is to take into account, where relevant, the dose limits for exposure to ionising radiation, and the notes for assessing those limits, set out in Schedule 2.

# Part 2 Licensing, registration and accreditation

### 7 Exemptions from s 6 licensing requirements for certain radioactive substances and radiation apparatus

(1) A person is exempt from the requirement to be licensed under section 6 of the Act in relation to the use of the kinds of radioactive substances specified in Part 1 of Schedule 3.

(2) A person is exempt from the requirement to be licensed under section 6 of the Act in relation to the possession, use or sale of the kinds of radioactive substances specified in Part 2 of Schedule 3.

(3) A person is exempt from the requirement to be licensed under section 6 of the Act in relation to the use of the kinds of ionising radiation apparatus specified in Part 3 of Schedule 3.

(4) A person is exempt from the requirement to be licensed under section 6 of the Act in relation to the possession, use or sale of the kinds of ionising radiation apparatus specified in Part 4 of Schedule 3.

### 8 Exemptions from s 6 licensing requirements for certain persons

(1) The following persons are exempt from the licensing requirements of section 6 of the Act in relation to the use of radioactive substances and ionising radiation apparatus:

(a) a person who is a medical registrar at a hospital and is training in nuclear medicine, diagnostic radiology, radiation oncology, ophthalmology, dermatology, rheumatology or in a medical discipline which uses fluoroscopy,

(b) a person who is a student in medical radiation technology and is a trainee technologist in nuclear medicine, diagnostic radiology or radiation oncology,

(c) a person who is an assistant to an industrial radiographer,

(d) an undergraduate student in a university or other educational institution who is undertaking course work or research,

(e) a postgraduate student in a university or other educational institution who is undertaking research or higher studies,

(f) a person who is a registered nurse at a hospital or a medical officer at a hospital and is required to inject radiopharmaceuticals by that hospital (but only if a person

who is the holder of a licence and who is able to inject the radiopharmaceuticals is not readily available at the hospital).

(2) This exemption does not have effect with respect to a person unless the person:

(a) is the subject of an approval under this clause, and

(b) is complying with the conditions to which the approval is subject.

(3) A person who holds a licence may give approvals for the purposes of this clause, but only if the conditions of the licence so allow.

(4) An approval must:

(a) be in writing, and

(b) specify the radioactive substances or radiation apparatus to which it relates, and

(c) set out any conditions to which it is subject, and

(d) identify each person, or class of persons, to whom it relates, and

(e) identify the person or persons who are to supervise each person, or class of persons, to whom it relates.

(5) A person who gives an approval for the purposes of this clause must ensure that a copy of the approval:

(a) is given to each person to whom it relates, or

(b) is conspicuously displayed at each place in which the radioactive substances or ionising radiation apparatus to which the approval relates are proposed to be used.

Maximum penalty: 25 penalty units.

(6) A person who grants an approval must ensure that each person so approved is supervised by a qualified person as follows:

(a) a person referred to in subclause (1) (a) must be subject to:

(i) immediate supervision at all times during the first 6 months of the person's training, and

(ii) general supervision after that period,

(b) a person referred to in subclause (1) (b) must be subject to:

(i) immediate supervision at all times while the person is using the radioactive substances or radiation apparatus to which the approval relates during clinical experience in the course of training, and

(ii) general supervision at all other times,

(c) a person referred to in subclause (1) (c) must be subject to immediate supervision at all times,

(d) a person referred to in subclause (1) (d) must be subject to:

(i) immediate supervision at all times while the person is using the radioactive substances or radiation apparatus to which the approval relates in any clinical situation, and

(ii) general supervision at all other times,

(e) a person referred in subclause (1) (e) or (f) must be subject to general supervision at all times.

Maximum penalty: 25 penalty units.

(7) In this clause:

***general supervision*** means supervision by a qualified supervisor who oversees the person being supervised and ensures that the person follows safe radiation work practices in relation to the use of radioactive substances or radiation apparatus.

***immediate supervision*** means supervision by a qualified supervisor who is present at all times during, and is observing and directing, the use by the person being supervised of radioactive substances or radiation apparatus.

***qualified person***, in relation to supervision for a particular radioactive substance or item of radiation apparatus, means a person who is the holder of a licence which allows the person to provide supervision with respect to that substance or item.

### 9 Registration of certain sealed radioactive sources

(1) All sealed radioactive sources, other than fixed radiation gauges, are exempt from the application of section 7 of the Act.

(2) This clause ceases to have effect on 1 March 2004.

### 10 Registration of certain radiation apparatus

For the purposes of section 7 (1) (b) of the Act, the following kinds of radiation apparatus are prescribed as apparatus to which section 7 applies:

(a) any ionising radiation apparatus used or intended to be used for any medical diagnostic, veterinary diagnostic or dental diagnostic purpose,

(b) any ionising radiation apparatus used or intended to be used for radiotherapy or radiotherapy planning purposes,

(c) any cyclotron.

### 11 Requirements for registration of radiation apparatus

For the purposes of section 7 (5) of the Act, the applicable requirements for registration of ionising radiation apparatus of a type specified in Column 1 of the table to this clause are the requirements specified opposite that type in Column 2 of the table.

| Column 1 | Column 2 |
|---|---|
| **Type of ionising radiation apparatus** | **Requirements for registration** |
| Apparatus for dental diagnostic purposes | The requirements specified in Schedule 1 to the *Dentistry Radiation Guideline* |
| Apparatus for fluoroscopy or radiography | The requirements specified in Schedule 1 to the *Fluoroscopy and Radiography Radiation Guideline* |
| Apparatus for mammography | The requirements specified in Schedule 1 to the *Mammography Radiation Guideline* |
| Apparatus for tomography or bone mineral densitometry | The requirements specified in Schedule 1 to the *Tomography and Bone Mineral Densitometry Radiation Guideline* |
| Apparatus for veterinary diagnostic purposes | The requirements specified in Schedule 1 to the *Veterinary Radiation Guideline* |

**Note.** The Guidelines referred to in this clause, and defined in clause 3 (1), are available from the Environment Protection Authority.

### 12 Consulting radiation experts

(1) For the purposes of section 9 (1) of the Act, the following activities are prescribed as the activities of a consulting radiation expert:

(a) advising on the design of premises to be registered under section 8 of the Act in relation to radiation safety requirements,

(b) assessing plans for premises to be registered under section 8 of the Act in relation to radiation safety requirements for the purpose of certifying compliance with the requirements necessary for registration,

(c) calibrating ionising radiation apparatus used for medical therapy,

(d) calibrating ionising radiation apparatus used for diagnostic purposes,

(e) advising on the design of premises, in relation to radiation safety requirements, in which sealed radioactive sources or radiation apparatus prescribed under section 7 (1) of the Act are kept or used,

(f) assessing plans for premises in which sealed radioactive sources or radiation apparatus prescribed under section 7 (1) of the Act are kept or used, for the purpose of certifying compliance with any requirements for registration under section 7 (5) of the Act,

(g) assessing radiation apparatus, sealed radioactive sources and premises that are required to be registered under section 7 or 8 of the Act for the purpose of certifying compliance with the requirements for registration,

(h) assessing the integrity of any shielding of premises in which sealed radioactive sources or radiation apparatus prescribed under section 7 (1) of the Act are kept or used for purposes of certifying compliance with the requirements for registration.

(2) Authorised officers are exempt from the provisions of section 9 (1) of the Act.

### 13 Fees

The following fees are prescribed for the purposes of the Act and this Regulation:

**Table of fees**

| | |
|---|---|
| Licence under section 6 of the Act | $117 |

**Table of fees**

| | |
|---|---|
| Registration under section 7 of the Act (other than for cyclotrons) | $155 |
| Registration of cyclotron under section 7 of the Act | $1,000 |
| Registration under section 8 of the Act | $155 |
| Variation of licence under section 10A of the Act | $83 |
| Renewal of licence under section 11 of the Act | $67 |
| Renewal of registration under section 11 of the Act (other than for cyclotrons) | $105 |
| Renewal of registration of cyclotron under section 11 of the Act | $800 |
| Accreditation under section 9 of the Act | $128 |
| Variation of accreditation under section 10A of the Act | $91 |
| Renewal of accreditation under section 11 of the Act | $103 |
| Transfer of registration under section 12 of the Act | $38 |
| Approval of personal monitoring devices required by clause 17 | $525 |
| Approval of area monitoring devices required by clause 19 | $525 |

# Part 3 Radiation safety

## Division 1 Radiation safety in the workplace

### 14 Duty to comply with occupationally exposed persons

An employer must ensure that each occupationally exposed person in his or her employ is not exposed to ionising radiation that exceeds the dose limits set out in Schedule 2.

Maximum penalty: 100 penalty units.

### 15 Duty to inform occupationally exposed persons

An employer must ensure that each occupationally exposed person in his or her employ is made aware of, and kept informed of any changes in, the following particulars:

(a) the hazards that can arise in connection with the use of radioactive substances and radiation apparatus,

(b) the safety arrangements that exist to protect persons from such hazards and of the steps that the person must take in order to minimise the likelihood that such a hazard will arise,

(c) the name of the radiation safety officer or other person to whom the person should refer in connection with any matters relating to the use of radioactive substances and radiation apparatus.

Maximum penalty: 25 penalty units.

### 16 Radiation safety manual

(1) The Director-General may, by notice in writing served on an employer, direct the employer:

(a) to prepare or adopt a radiation safety manual, and

(b) to submit a copy of the manual to the Council for approval,

within such period of time as is specified in the direction.

(2) An employer must not fail to comply with such a direction.

Maximum penalty: 25 penalty units.

(3) An employer whose radiation safety manual has been approved by the Council:

(a) must ensure that a copy of the manual is available to all occupationally exposed persons employed by the employer, and

(b) must take all reasonable steps to ensure that the procedures set out in the manual with respect to the use of radioactive substances and radiation apparatus are followed by all persons in his or her employ.

Maximum penalty: 25 penalty units.

(4) A radiation safety manual may not be approved by the Council unless it conforms to the document adopted by the Council and entitled *Guideline: Preparation of Radiation Safety Manuals*, a copy of which is deposited in the offices of the Authority.

## Division 2 Radiation monitoring

### 17 Personal monitoring devices

(1) An employer must ensure that all occupationally exposed persons in his or her employ who are involved in the use of ionising radiation for any one or more of the following purposes are issued with approved personal monitoring devices for detecting and measuring cumulative exposure to ionising radiation:

(a) radiotherapy,

(b) industrial radiography,

(c) nuclear medicine,

(d) scientific research in laboratories classified as medium or high level laboratories (within the meaning of Part 4 of AS 2243.4—1998, *Safety in laboratories–Ionizing radiations*, published from time to time by Standards Australia) where unsealed radioactive sources are used,

(e) diagnostic radiology (other than dentistry, veterinary and chiropractic applications).

(f) neutron based detection, analysis and gauging.

Maximum penalty: 50 penalty units.

(2) An occupationally exposed person to whom an approved monitoring device has been issued in accordance with this clause must wear the device while involved in the use of ionising radiation in the course of the person's employment.

Maximum penalty: 25 penalty units.

(3) The Director-General may impose conditions on the approval of a personal monitoring device referred to in this clause.

### 18 Personal radiation exposure record

(1) An employer must ensure that, for each occupationally exposed person to whom a personal monitoring device is issued, a record is kept, on an appropriate periodic basis:

(a) of the amount of radiation to which the person has been exposed, as measured by the device, and

(b) of the results of any tests carried out or caused to be carried out by the employer in relation to the person for the purpose of determining the amount of radiation to which the person has been exposed.

Maximum penalty: 25 penalty units.

(2) Such a record must contain the following particulars:

(a) the full name, sex and date of birth of the occupationally exposed person,

(b) the current home address of the occupationally exposed person or, if the person is no longer employed by the employer, the person's last known home address,

(c) the date of commencement of employment (and, if applicable, the date of cessation of employment) as an occupationally exposed person,

(d) the kind of work performed by the occupationally exposed person,

(e) details of the types of ionising radiation to which the occupationally exposed person may have been exposed in the course of employment with the employer, including information about radioactive substances in unsealed form (if any) to which the occupationally exposed person may have been exposed,

(f) details of any radiation accidents in which the person has been involved or by which the person may have been affected,

(g) details of the personal monitoring device worn by the occupationally exposed person,

(h) the results of monitoring the levels of radiation exposure of the occupationally exposed person.

(3) When an employee leaves an employer's employment, the employer:

(a) must cause a copy of the radiation exposure records relating to the employee to be given to the employee, and

(b) if the employee is taking up employment as an occupationally exposed person with another employer and if the employee requests, must cause a further copy of those records to be given to the other employer.

Maximum penalty: 25 penalty units.

(4) An employer must ensure that a warning in the following terms accompanies a copy of the radiation exposure records given to an employee by the employer in accordance with subclause (3):

THESE RECORDS SHOULD BE KEPT SAFELY AND PERMANENTLY AND BE GIVEN TO ANY FUTURE EMPLOYER EMPLOYING YOU AS A RADIATION WORKER.

Maximum penalty: 25 penalty units.

(5) An employer by whom records are required to be kept must ensure that the records are available for inspection by the person to whom they relate at reasonable times during normal working hours.

Maximum penalty: 25 penalty units.

### 19 Area monitoring devices

(1) On the recommendation of the Council, the Director-General may, by notice in writing served on an employer, direct the employer to take specified action with respect to the monitoring of radiation on specified premises.

(2) In particular, such a direction may require the employer to ensure that specified premises are equipped with approved monitoring devices for the purpose of monitoring the presence and level of radiation on the premises.

(3) The Director-General may impose conditions on the approval of a monitoring device referred to in this clause.

(4) An employer must not contravene a direction in force under this clause.

Maximum penalty: 25 penalty units.

### 20 Maintenance of monitoring devices

An employer must ensure that all monitoring devices that are issued or installed by the employer in accordance with the requirements of this Division are checked, maintained and calibrated in accordance with the document adopted by the Council and entitled *Guideline: Monitoring Devices*, a copy of which is deposited in the offices of the Authority.

Maximum penalty: 50 penalty units.

### 21 Records to be kept of monitoring equipment

An employer must ensure that, for each monitoring device issued or installed by the employer in accordance with this Division, a record is kept of the following particulars:

(a) the date on which the device was acquired,

(b) the date of each occasion on which the device was repaired and the details of the repairs,

(c) the date on which the device was last calibrated.

Maximum penalty: 25 penalty units.

## Division 3 Voluntary exposure to radiation for scientific or research purposes

### 22 Voluntary exposure to radiation for scientific or research purposes

A person must not expose any other person to ionising radiation for scientific or research purposes except in accordance with the document entitled *Administration of Ionizing Radiation to Human Subjects in Medical Research* as published from time to time by the Australian Radiation Protection and Nuclear Safety Agency.

Maximum penalty: 50 penalty units.

## Division 4 Disposal and transport of radioactive substances and radiation apparatus

### 23 Disposal of radioactive substances and radiation apparatus

(1) A person must not dispose of any radioactive substance or any radiation apparatus except with the consent of the Director-General.

Maximum penalty: 100 penalty units.

(2) A person must not dispose of any radiation apparatus unless the apparatus has been rendered permanently inoperable.

Maximum penalty: 100 penalty units.

(3) The consent of the Director-General may be given generally or in a particular case and may be subject to such conditions as the Director-General thinks fit to impose.

### 24 Records to be kept of discharge of radioactive substances

(1) The occupier of any premises on which radioactive substances are kept must maintain a record of all radioactive substances discharged from the premises.

Maximum penalty: 100 penalty units.

(2) The record must include the following information:

(a) the type of radioactive substances discharged,

(b) an estimate of the total activity of the radioactive substances discharged,

(c) the manner in which the radioactive substances were discharged,

(d) the date on which the radioactive substances were discharged.

### 25 Transport of radioactive substances

A person must not cause any radioactive substance to be transported otherwise than in accordance with the requirements of the *Code of Practice for the Safe Transport of Radioactive Material* published in September 2001 by the Chief Executive Officer of the Australian Radiation Protection and Nuclear Safety Agency.

Maximum penalty: 100 penalty units.

## Division 5 Radiation accidents

### 26 Certain occurrences are taken to be radiation accidents

(1) For the purposes of this Regulation, a radiation accident is to be treated as having occurred if there is an occurrence that involves the unplanned or unexpected emission of radiation (such as spillage or leakage of a radioactive substance or damage to radiation apparatus) and that is of such a nature or extent that it is likely:

(a) that one or more persons have, or could have, received a dose of radiation equal to or in excess of:

(i) 5 millisieverts, in the case of an occupationally exposed person, or

(ii) 1 millisievert, in any other case, or

(b) that premises or the environment may have become contaminated within the meaning of section 21 of the Act.

(2) For the purposes of this Regulation, a radiation accident is to be treated as having occurred if there is an occurrence that involves the misuse of radiation apparatus or maladministration of a radioactive substance used for medical purposes, including:

(a) the administration of a radioactive substance for diagnostic purposes in a quantity of more than 50 per cent more than that prescribed,

(b) the administration of a radioactive substance for therapeutic purposes at an activity differing by more than 15 per cent from that prescribed,

(c) administration of a therapeutic dose of radiation from radiation apparatus or a sealed radioactive source which differs from the total prescribed treatment dose by more than 10 per cent,

(d) the unintended administration of radiation as a result of a malfunction of radiation apparatus,

(e) administration of a radiopharmaceutical otherwise than as prescribed.

### 27 Duty to report and investigate apparent radiation accidents

(1) An employer must give written notice to the Director-General of the particulars:

(a) specified in subclause (2) (a)–(d) within 48 hours of becoming aware of an apparent radiation accident, and

(b) specified in subclause (2) (e) within 10 days of becoming aware of an apparent radiation accident.

Maximum penalty: 25 penalty units.

(2) The notice must contain the following particulars:

(a) particulars of the accident indicating, as far as is possible, the place where it occurred and the period during which emission of radiation was uncontrolled,

(b) particulars of the area over which any radioactive substances may have been dispersed,

(c) particulars of any steps taken to rectify the accident,

(d) particulars of any personal injury or exposure that may have resulted,

(e) particulars of any assessment of the radiation dose to which any person may have been exposed as a result of the accident.

### 28 Register of accidents

(1) An employer must maintain a record of all radiation accidents.

Maximum penalty: 25 penalty units.

(2) Such a record must, for each radiation accident that is reported to the employer, contain the following particulars:

(a) particulars of the accident indicating, as far as is possible, the place where it occurred and the period during which emission of radiation was uncontrolled,

(b) the name of any occupationally exposed person or other person who was there during that period,

(c) an estimate of the radiation dose to which any person may have been exposed,

(d) details and results of any medical examinations undertaken as a result of the accident,

(e) particulars of the area over which any radioactive substances may have been dispersed,

(f) particulars of any steps taken to rectify the accident,

(g) the time at which the accident was reported to the employer,

(h) the probable cause of the accident,

(i) particulars of any investigations conducted into the accident, together with the results of the investigations,

(j) details of any steps taken to reduce the risk of a similar accident occurring in the future.

### 29 Faults or defects

(1) An employer, on becoming aware that a fault may exist in any radiation apparatus:

(a) must investigate the apparent fault and, if necessary, cause the apparatus to be removed, replaced or repaired, and

(b) must inform all persons who may have been exposed to radiation in quantities in excess of those that would normally

be received from the apparatus in faultless condition that they may have been so exposed.

Maximum penalty: 50 penalty units.

(2) An employer, on becoming aware that a fault or defect may exist in any sealed radioactive source:

(a) must investigate the apparent fault or defect and, if necessary, cause the sealed radioactive source to be removed, replaced or repaired, and

(b) must inform all persons who may have been exposed to radiation in quantities in excess of those that would normally be received from the sealed radioactive source in faultless condition that they may have been so exposed.

Maximum penalty: 50 penalty units.

# Part 4 Radiation safety officers and committees

### 30 Appointment of radiation safety officers and committees

(1) On the recommendation of the Council, the Director-General may, by notice in writing served on an employer:

(a) direct the employer to appoint a radiation safety officer or a radiation safety committee, or both, for a workplace, and

(b) in the case of a direction to appoint a radiation safety officer, determine the qualifications to be held by a person so appointed, and

(c) direct what functions are to be exercised by a radiation safety officer or radiation safety committee so appointed.

(2) An employer:

(a) must not fail to appoint a radiation safety officer or a radiation safety committee, or both, in accordance with a direction under this clause, and

(b) must not allow the functions of the radiation safety officer or radiation safety committee to be exercised otherwise than by the officer or the committee, as the case requires.

Maximum penalty: 25 penalty units.

# Part 5 Miscellaneous

### 31 Destruction or disposal of records

(1) An employer must not destroy or otherwise dispose of any records required to be kept under this Regulation otherwise than in accordance with this clause.

Maximum penalty: 25 penalty units.

(2) An employer may, with the consent of the Director-General, destroy or otherwise dispose of any records that the employer is required by this Regulation to keep.

(3) The Director-General is not to give consent to the destruction of any records kept under clause 18 by an employer until at least 5 years after the cessation of employment with the employer of the employee concerned.

(4) An employer may forward to the Director-General the records kept under this Regulation by the employer if the employer ceases to carry on business in New South Wales.

(5) The Director-General may dispose of any records forwarded to or kept by the Director-General in accordance with this Regulation.

### 32 Contamination of premises by radioactivity (s 21)

(1) For the purposes of section 21 (4) of the Act, the prescribed level of activity for premises inside a building is:

(a) 0.04 becquerels per square centimetre for any Group 1 or Group 2 radioactive substance that emits alpha radiation, or

(b) 0.4 becquerels per square centimetre for any Group 3 or Group 4 radioactive substance that emits alpha radiation, or

(c) 0.4 becquerels per square centimetre for any radioactive substance that emits beta or gamma radiation.

(2) For the purposes of section 21 (4) of the Act, the prescribed level of activity for premises outside a building is:

(a) 0.01 becquerels per square centimetre for any Group 1 radioactive substance, or

(b) 0.1 becquerels per square centimetre for any Group 2 radioactive substance, or

(c) 1.0 becquerels per square centimetre for any Group 3 radioactive substance, or

(d) 10.0 becquerels per square centimetre for any Group 4 radioactive substance.

### 33 Loss or theft of radioactive substance or radiation apparatus

(1) If any radioactive substance, or any radiation apparatus registered under section 7 of the Act, is lost or stolen:

(a) the person who is the owner of the substance or apparatus, and

(b) any other person who is the holder of a licence and is employed to use, or to supervise the use of, the substance or apparatus,

must cause notice of the loss or theft to be given to the Director-General within 3 days after the person becomes aware of the loss or theft.

Maximum penalty: 100 penalty units.

(2) Notice does not have to be given by any one of those persons if notice has already been given by any other of those persons.

### 34 Forfeiture of property (ss 26 and 27)

(1) An application made by or on behalf of the Authority for the purposes of section 26 (2) of the Act is to be in writing.

(2) A notice referred to in section 27 (1) (b) of the Act is to be in writing addressed to the owner of the substance or thing concerned at that person's address last known to the Authority.

### 35 Warning signs

The occupier of any premises in or on which any radiation apparatus or radioactive substance, not specified in Schedule 3, is kept must ensure that a warning sign in or to the effect of the form set out in Schedule 4 (with colouring as indicated in the note to that Schedule) is conspicuously displayed in the immediate vicinity of the apparatus or substance.

Maximum penalty: 25 penalty units.

### 36 Penalty notice offences

For the purposes of section 25A of the Act:

(a) each offence created by a provision specified in Column 1 of Schedule 5 is declared to be a penalty notice offence, and

(b) the prescribed penalty for such an offence is the amount specified in Column 2 of Schedule 5.

### 37 Repeal

The *Radiation Control Regulation 1993* is repealed.

### 38 Savings provision

Any act, matter or thing that, immediately before the repeal of the *Radiation Control Regulation 1993*, had effect under that Regulation continues to have effect under this Regulation.

# Schedule 1 Prescribed activity of a radioactive substance

(Clause 3 (2))

| Column 1 | | | | | | | | Column 2 |
|---|---|---|---|---|---|---|---|---|
| **Group 1** | | | | | | | | |
| Ac227 | Am241 | Am243 | Cf249 | Cf250 | Cf252 | Cm242 | Cm243 | 40 kilo-becquerels |
| Cm244 | Cm245 | Cm246 | Np237 | Pa231 | Pb210 | Po210 | Pu238 | |
| Pu239 | Pu240 | Pu241 | Pu242 | Ra223 | Ra226 | Ra228 | Th227 | |
| Th228 | Th230 | U230 | U232 | U233 | U234 | | | |
| Any alpha emitting radionuclide that is not included in any other Group in this Schedule | | | | | | | | |
| **Group 2** | | | | | | | | |
| Ac228 | Ag110m | At211 | Ba140 | Bi207 | Bi210 | Bk249 | Ca45 | 400 kilo-becquerels |
| Cd115m | Ce144 | C136 | Co56 | Co60 | Cs134 | Cs137 | Eu152 | |
| Eu154 | Ge68 | Hf181 | I124 | I125 | I126 | I131 | I133 | |
| In114m | Ir192 | Mn54 | Na22 | Pa230 | Pb212 | Ra224 | Ru106 | |
| Sb124 | Sb125 | Sc46 | Sr89 | Sr90 | Ta182 | Tb160 | Te127m | |
| Te129m | Th234 | T1204 | Tm170 | U236 | Y91 | Zr95 | | |
| Any radionuclide that is not alpha emitting and is not included in any other Group in this Schedule | | | | | | | | |

| Column 1 | | | | | | | | Column 2 |
|---|---|---|---|---|---|---|---|---|
| **Group 3** | | | | | | | | |
| Ag105 | Ag111 | Ar41 | As73 | As74 | As76 | As77 | Au196 | 4 mega-becquerels |
| Au198 | Au199 | Ba131 | Ba133 | Be7 | Bi206 | Bi212 | Br75 | |
| Br76 | Br82 | C14 | Ca47 | Cd109 | Cd115 | Ce141 | Ce143 | |
| Cl38 | Co57 | Co58 | Cr51 | Cs129 | Cs131 | Cs136 | Cu64 | |
| Cu67 | Dy165 | Dy166 | Er161 | Er169 | Er171 | Eu152m | Eu155 | |
| F18 | Fe52 | Fe55 | Fe59 | Ga67 | Ga68 | Ga72 | Gd153 | |
| Gd159 | Hf175 | Hg195m | Hg197 | Hg197m | Hg203 | Ho166 | I123 | |
| I130 | I132 | I134 | I135 | In111 | In115 | In115m | Ir190 | |
| Ir194 | K42 | K43 | Kr85m | Kr87 | La140 | Lu177 | Mg28 | |
| Mn52 | Mn56 | Mo99 | Na24 | Nb93m | Nb95 | Nd147 | Nd149 | |
| Ni63 | Ni65 | Np239 | Os185 | Os191 | Os193 | P32 | Pa233 | |
| Pb203 | Pd103 | Pd109 | Pm147 | Pm149 | Pr142 | Pr143 | Pt191 | |
| Pt193 | Pt197 | Rb81 | Rb86 | Re183 | Re186 | Re188 | Rh105 | |
| Rn220 | Rn222 | Ru103 | Ru105 | Ru97 | S35 | Sb122 | Sc47 | |
| Sc48 | Se75 | Si31 | Sm151 | Sm153 | Sn113 | Sn121 | Sn125 | |
| Sr85 | Sr91 | Sr91 | Sr92 | Tc96 | Tc97 | Tc97m | Tc99 | |
| Te125m | Te127 | Te129 | Te131m | Te132 | Th231 | TI200 | TI201 | |
| TI202 | Tm171 | U239 | V48 | W181 | W185 | W187 | Xe135 | |
| Y87 | Y90 | Y92 | Y93 | Yb175 | Zn62 | Zn65 | Zn69m | |
| Zr97 | | | | | | | | |

| Column 1 | | | | | | | | Column 2 |
|---|---|---|---|---|---|---|---|---|
| **Group 4** | | | | | | | | |
| Ar37 | C11 | Co58m | Cs134m | Cs135 | Cu62 | Ga68 | Ge71 | 40 mega-becquerels |
| H3 | I129 | In113m | Kr81m | Kr85 | N13 | Nb97 | Ni59 | |
| O15 | Os191m | Pt193m | Pt197m | Rb87 | Re187 | Rh103m | Se73 | |
| Sm147 | Sr85m | Sr87m | Tc96m | Tc99m | Th nat | Th232 | U nat | |
| U235 | U238 | Xe131m | Xe133 | Y91m | Zn69 | Zr93 | | |

# Schedule 2 Dose limits for exposure to ionising radiation

(Clauses 6 and 14)

| Application | Dose limit Occupationally exposed person | Dose limit Member of public (other than patient) |
|---|---|---|
| Effective dose..... | 20 mSv per year averaged over a period of 5 consecutive calendar years[4][5][6] | 1 mSv in a year[7] |
| Equivalent dose to: | | |
| (a) lens of the eye | 150 mSv in a year | 15 mSv in a year |
| (b) skin[8] | 500 mSv in a year | 50 mSv in a year |
| (c) the hands and feet | 500 mSv in a year | No limit specified |

**Note 1.** The limits apply to the sum of the relevant doses from external exposure in the specified period and the 50-year committed dose (to age 70 years for children) from intakes in the same period.

**Note 2.** Any dose resulting from medical diagnosis or treatment should not be taken into account.

**Note 3.** Any dose attributable to normal naturally occurring background levels of radiation should not be taken into account.

**Note 4.** With the further provision that the effective dose must not exceed 50mSv in any single year.

**Note 5.** When a female employee declares a pregnancy, the embryo or foetus should be afforded the same level of protection as required for members of the public.

**Note 6.** When, in exceptional circumstances, a temporary change in the dose limitation requirements is approved by the Authority, one only of the following conditions applies:

(a) the effective dose limit must not exceed 50mSv per year for the period, that must not exceed 5 years, for which the temporary change is approved,

(b) the period for which the 20mSv per year average applies must not exceed 10 consecutive years and the effective dose must not exceed 50mSv in any single year.

**Note 7.** In special circumstances, a higher value of effective dose could be allowed in a single year, provided that the average over 5 years does not exceed 1mSv per year.

**Note 8.** The equivalent dose limit for the skin applies to the dose averaged over any 1 square centimetre of skin, regardless of the total area exposed.

# Schedule 3 Exemptions from licensing

(Clause 7)

## Part 1 Exemptions from licensing for use of radioactive substances

1 radioactive substances used for gas chromatography detectors

2 sealed radioactive sources used for radiation gauging installed in fixed positions

3 industrial smoke detectors that contain Am–241, if they do not contain any other radioactive substance.

## Part 2 Exemptions from licensing for possession, use and sale of radioactive substances

1 clocks, watches and other devices that have luminous dials

2 gaseous tritium luminous devices (including self luminous “EXIT” signs)

3 radioactive substances used in nuclear medicine for checking gamma cameras and dose calibrators and having a level of activity of less than 40 megabecquerels

4 radioactive substances used as laboratory reference sources and having a level of activity of less than 40 megabecquerels

5 radioactive substances for demonstration, teaching and training having a level of activity of less than 40 megabecquerels

6 uranium metal of natural isotopic composition, or depleted in uranium 235, which is used as radiation shielding in transport packages for radioactive substances or in any other manner.

## Part 3 Exemptions from licensing for use of radiation apparatus

1 x-ray baggage inspection apparatus

2 cabinet x-ray inspection apparatus installed in a fixed position.

## Part 4 Exemptions from licensing for possession, use and sale of radiation apparatus

1 television receivers

2 visual display units

3 cold cathode gas discharge tubes

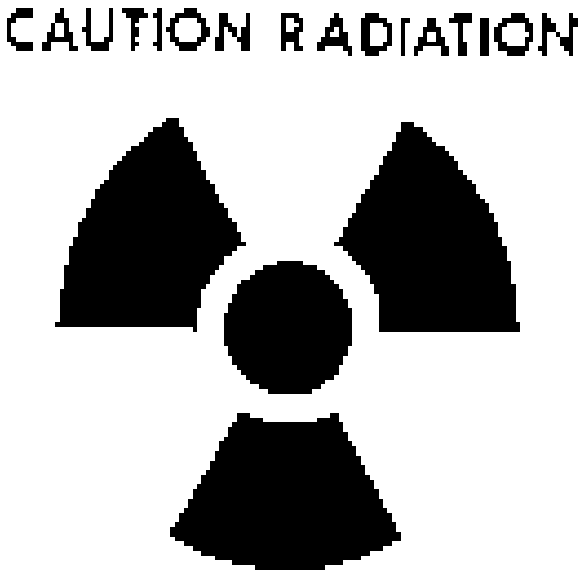
4 electron microscopes.

# Schedule 4 Prescribed warning sign

(Clause 35)

**Note.**

The sign is to have a yellow background with the distinctive symbol in black and the lettering “CAUTION RADIATION” in black.



# Schedule 5 Penalty notice offences

(Clause 36)

| Column 1 | Column 2 |
|---|---|
| **Provision** | **Penalty** |
| Section 6 (2) of the Act | $1500 for a corporation<br>$750 for an individual |
| Section 6 (3) of the Act | $1500 for a corporation<br>$750 for an individual |
| Section 7 (2) of the Act | $1500 for a corporation<br>$750 for an individual |
| Section 7 (3) of the Act | $1500 for a corporation<br>$750 for an individual |
| Section 8 (1) of the Act | $1500 for a corporation<br>$750 for an individual |
| Section 8 (2) of the Act | $1500 for a corporation<br>$750 for an individual |
| Section 9 (1) of the Act | $500 |
| Section 13 (6) of the Act | $100 |
| Section 18 (4) of the Act | $1000 |
| Clause 8 (5) of this Regulation | $250 |
| Clause 8 (6) of this Regulation | $250 |
| Clause 14 of this Regulation | $1000 |
| Clause 15 of this Regulation | $250 |
| Clause 16 (2) of this Regulation | $250 |
| Clause 16 (3) (a) of this Regulation | $250 |

| Column 1 | Column 2 |
|---|---|
| **Provision** | **Penalty** |
| Clause 16 (3) (b) of this Regulation | $250 |
| Clause 17 (1) of this Regulation | $500 |
| Clause 17 (2) of this Regulation | $250 |
| Clause 18 (1) of this Regulation | $250 |
| Clause 18 (3) (a) of this Regulation | $250 |
| Clause 18 (3) (b) of this Regulation | $250 |
| Clause 18 (4) of this Regulation | $250 |
| Clause 18 (5) of this Regulation | $250 |
| Clause 19 (4) of this Regulation | $250 |
| Clause 20 of this Regulation | $500 |
| Clause 21 of this Regulation | $250 |
| Clause 22 of this Regulation | $500 |
| Clause 23 (1) of this Regulation | $1000 |
| Clause 23 (2) of this Regulation | $1000 |
| Clause 24 (1) of this Regulation | $1000 |
| Clause 25 of this Regulation | $1000 |
| Clause 27 (1) of this Regulation | $250 |
| Clause 28 (1) of this Regulation | $250 |
| Clause 29 (1) (a) of this Regulation | $500 |
| Clause 29 (1) (b) of this Regulation | $500 |

| Column 1 | Column 2 |
|---|---|
| **Provision** | **Penalty** |
| Clause 29 (2) (a) of this Regulation | $500 |
| Clause 29 (2) (b) of this Regulation | $500 |
| Clause 30 (2) (a) of this Regulation | $250 |
| Clause 30 (2) (b) of this Regulation | $250 |
| Clause 31 (1) of this Regulation | $250 |
| Clause 33 (1) of this Regulation | $1000 |
| Clause 35 of this Regulation | $250 |