



Environment Protection Authority

Regulatory Impact Statement

Proposed Protection from Harmful Radiation
Regulation 2025

DRAFT FOR CONSULTATION

May 2025



A vertical decorative strip on the left side of the page featuring intricate Aboriginal artwork. It includes a large circular motif with a central dot and radiating lines, a section with a grid of small dots, and a bottom section with wavy, flame-like patterns. The artwork is rendered in a light blue-grey tone against a white background.

Acknowledgement of Country

The NSW Environment Protection Authority acknowledges the Traditional Custodians of the land on which we live and work, honours the ancestors and the Elders both past and present and extends that respect to all Aboriginal people.

We recognise Aboriginal peoples' spiritual and cultural connection and inherent right to protect the land, waters, skies and natural resources of NSW. This connection goes deep and has since the Dreaming.

We also acknowledge our Aboriginal and Torres Strait Islander employees who are an integral part of our diverse workforce and recognise the knowledge embedded forever in Aboriginal and Torres Strait Islander custodianship of Country and culture.

Aboriginal artwork by Worimi artist Gerard Black

Contents

Acronyms	6
Executive summary	8
The proposed Regulation.....	8
Licensing and radiation management plans	8
Work health and safety.....	9
Clearer ban on commercial UV tanning services.....	9
Financial assurance provisions.....	9
Licence exemptions will cut users' costs.....	9
Licence holders must have radiation management plans.....	9
Proposed Regulation increases penalties.....	10
Costs and fees will change	10
Alternative options considered	10
1 Introduction.....	11
1.1 Purpose of this regulatory impact statement	11
1.2 Consultation	11
1.2.1 How to provide feedback.....	12
2 Radiation protection framework.....	13
2.1 NSW uses a 'graded' (risk-based) approach	13
2.1.1 Act and Regulation aim at safety and security.....	13
2.1.2 Act and Regulation are consistent with standards.....	13
2.1.3 Act and Regulation are based on licensing and obligations.....	13
2.2 Protection from Harmful Radiation Act 1990	14
2.3 Protection from Harmful Radiation Regulation 2013.....	15
2.3.1 Amendments to the Regulation since 2013	16
2.3.2 Authorisation and enforcement.....	16
2.4 Other regulatory frameworks	17
2.4.1 Work health and safety and other NSW legislation.....	17
2.4.2 Commonwealth jurisdiction	17
2.4.3 National uniformity	18
2.4.4 Mutual recognition.....	18
3 The need for government action.....	19
3.1 Managing ionising radiation.....	20

3.1.1	Ionising radiation and its impacts	20
3.1.2	Medical exposure	22
3.1.3	Workplace exposure	22
3.2	Avoiding harm from UV tanning units	23
3.2.1	Prohibition on commercial cosmetic UV tanning services	23
3.2.2	Cancer risks related to UV exposure.....	23
3.2.3	Risks from commercial cosmetic UV tanning services.....	24
3.2.4	Enforcement of the prohibition.....	24
3.3	Mitigating security risks.....	25
3.3.1	Security risks.....	25
3.3.2	National Security Code.....	25
3.4	Natural sources of radiation.....	25
3.4.1	Natural sources of radiation exposure.....	25
3.4.2	Naturally occurring ionising radiation exposure.....	26
3.5	Management of radiation accidents.....	26
3.6	Licensing and accreditation.....	27
4	Options considered	28
4.1	Base case: Remake the Regulation without change (status quo).....	28
4.1.1	Implications of implementing the base case.....	28
4.2	Option 1: No Regulation – allow the Regulation to be automatically repealed	29
4.3	Option 2: Remake the Regulation with changes (the proposed Regulation)	29
5	The proposed Regulation in detail.....	32
5.1	Licensing and exemptions.....	32
5.1.1	Exemptions.....	32
5.1.2	Licence conditions	36
5.1.3	Other	36
5.2	Workplace radiation safety protections and practices.....	36
5.2.1	Preparation of radiation management plans.....	36
5.2.2	Personal monitoring devices.....	37
5.3	Incident reporting	38
5.4	Protection of public health from artificial ultraviolet radiation	39
5.5	Effective operation of the Act	39
5.5.1	Fees.....	40
5.5.2	Classification of laboratories	40
5.5.3	Maximum penalties.....	41

5.5.4	Penalty notice offences.....	41
5.5.5	Delegations.....	41
5.5.6	Other items.....	41
5.6	Security of high-activity radiation sources.....	42
6	Costs and benefits.....	43
6.1	Impacts of remaking the Regulation without change – the base case (status quo)	43
6.2	Impacts of no Regulation (Option 1)	43
6.3	Impacts of the proposed Regulation (Option 2)	46
6.3.1	Part 1: Preliminary.....	46
6.3.2	Part 2: Licensing and accreditation.....	46
6.3.3	Part 3: Security of radioactive sources	50
6.3.4	Part 4: Radiation safety and public health.....	50
6.3.5	Part 5: Miscellaneous	56
6.3.6	Schedule 2: Exemptions from licensing.....	56
6.3.7	Schedule 3 Fees.....	57
6.3.8	Schedule 6 Penalty notice offences.....	59
6.4	Overall analysis: Option 2.....	59
6.5	Comparison of Option 1 and Option 2.....	60
7	Conclusion.....	61
	Appendices.....	63
	Appendix A Better Regulation principles.....	63
	Appendix B Stakeholder engagement	64
	References	65

Acronyms

Acronym or abbreviation	Name
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
CRE	consulting radiation expert
CBA	cost-benefit analysis
Chiropractic Code	<u>Code of Practice for Radiation Protection in the Application of Ionizing Radiation by Chiropractors</u> (ARPANSA 2009)
Dental Code	<u>Code for Radiation Protection in Dental Exposure</u> (ARPANSA 2025)
EPA	Environment Protection Authority (NSW)
Industrial Code	<u>Code of Radiation Protection Requirements for Industrial Radiography</u> (ARPANSA 2018)
Medical Exposure Code	<u>Code for Radiation Protection in Medical Exposure</u> (ARPANSA 2019)
mSv	Millisievert
National Directory	<u>National Directory for Radiation Protection</u> (2 nd edition, 2021)
NORM	Naturally occurring radioactive material
Planned Exposure Code	<u>Code for Radiation Protection in Planned Exposure Situations</u> (ARPANSA 2020)
RAC	Radiation Advisory Council
RIS	regulatory impact statement
RML	radiation management licence
RSA	radiation security assessor
RUL	radiation user licence
Security Code	<u>Code of Practice for the Security of Radioactive Sources</u> (ARPANSA 2019)
UV	ultraviolet radiation
Veterinary Code	<u>Code of Practice & Safety Guide for Radiation Protection in Veterinary Medicine</u> (ARPANSA 2009)
WHS Act	<i>Work Health and Safety Act 2011</i>

Under the *Subordinate Legislation Act 1989*, the Protection from Harmful Radiation Regulation 2013 (the Regulation) will be automatically repealed on 1 September 2025 unless it is remade before that date.

The Regulation supports and puts into effect provisions of the *Protection from Harmful Radiation Act 1990* (the Act). The Act regulates dealings with radioactive substances and radiation apparatus to protect the community and the environment and empowers the Environment Protection Authority (EPA) to administer its functions.

The EPA proposes that the Regulation be replaced by the Protection from Harmful Radiation Regulation 2025 (the proposed Regulation), to continue and improve requirements that protect the community and environment from unnecessary radiation exposure.

The proposed Regulation makes changes to:

- provisions relating to radiation licence exemptions
- requirements for radiation management plans
- workplace health and safety rules
- the security of radioactive sources
- the prohibition on commercial UV tanning services.

The proposed changes reflect an improved, risk-based regulatory approach, emphasising the obligations of persons responsible for regulated material to ensure radiation practices safeguard employees and others.

Proposed fees reflect cost recovery principles, and penalties will be updated to address non-compliance in a proportionate way.

This regulatory impact statement (RIS) analyses the costs and benefits of the proposed Regulation and alternatives. The RIS complies with the requirements of the *Subordinate Legislation Act 1989* and the NSW Government's Better Regulation principles.

Executive summary

Radiation is used widely in healthcare, research and commercial activities for beneficial purposes. However, unnecessary exposure and uncontrolled radiation can have serious health consequences for people and harm the environment.

In NSW, the *Protection from Harmful Radiation Act 1990* (Act) provides the legal framework for managing the sale, possession, use, transport and disposal of radioactive substances and radiation apparatus (regulated material). The Act also empowers the Minister, the Environment Protection Authority (EPA) and authorised officers to manage radiation risks and enforce the Act's requirements.

The Protection from Harmful Radiation Regulation 2013 (Regulation) gives effect to the framework created by the Act. It:

- prescribes requirements relating to licences and accreditations issued under the Act
- sets out exemptions from licensing, workplace radiation safety requirements, and radiation security measures
- prohibits commercial tanning services.

The EPA is responsible for administering the Act and Regulation.

The Regulation will be automatically repealed on 1 September 2025 unless it is remade before that date. Before a regulation is remade, the *Subordinate Legislation Act 1989* requires a draft regulation and a regulatory impact statement (RIS) to be prepared and exhibited. The EPA has prepared this RIS in accordance with the *Subordinate Legislation Act 1989*.

We propose to remake the Regulation with amendments.

The proposed Regulation

The Protection from Harmful Radiation Regulation 2025 (proposed Regulation) applies a risk-based approach to implementing the radiation protection framework created by the Act, ensuring that regulatory measures are proportionate to the radiation risks. It:

- strengthens radiation safety requirements for licensees and accredited persons where appropriate
- better aligns regulatory requirements with international and national best practice
- applies proportionate control measures and conditions to radiation practices.

Specifically, the proposed Regulation improves the management and use of radiation, in a number of ways.

Licensing and radiation management plans

The proposed Regulation:

- amends the scope of licensing exemptions to ensure that licensing is targeted. This will reduce the regulatory burden while strengthening safety requirements

- formalises that the EPA may approve training courses for obtaining a licence or exemption and charge a course assessment fee
- requires radiation users exempt from licensing to comply with safety obligations and applicable national codes of practice and standards
- requires all radiation management licensees to prepare or adopt a radiation management plan within 12 months of the commencement of the proposed Regulation.

Work health and safety

The proposed Regulation:

- improves radiation accident reporting requirements
- clarifies dose limits and requirements for personal radiation dose monitoring
- introduces record-keeping provisions for identity checks conducted for employees who deal with high-activity radioactive sources
- updates references to mining work health and safety legislation and clarifies the current delegations.

Clearer ban on commercial UV tanning services

The proposed Regulation:

- establishes a clearer, more enforceable ban on UV tanning services.

Financial assurance provisions

The proposed Regulation:

- requires the EPA's *Financial Assurance Policy* and *Estimating Financial Assurances: Guideline on Independent Assessment of Costs* to be observed by the EPA and anyone required to provide a financial assurance under the Act.

Licence exemptions will cut users' costs

The proposed Regulation will exempt nearly 4,000 radiation users – about 20% of current radiation user licensees – from needing to hold a licence. This will cut costs significantly for these users. The largest fee savings for industry will come from the exemption of registered dental practitioners from licensing requirements for certain practices: this will save about \$4.5 million over 10 years (net present value). Further savings of about \$852,600 over 10 years (net present value) will flow to dental assistants, and veterinary nurses, technicians and technologists, who will no longer need a user licence for low-risk practices if they meet the requirements for safety, training and supervision.

These exemptions are supported by improved requirements for workplaces to have appropriate supervision and radiation safety plans in place.

Licence holders must have radiation management plans

All radiation management licence holders that are responsible for regulated material will have to prepare or adopt a radiation management plan within 12 months of the proposed Regulation commencing. International and national standards consider that such a plan is essential to reduce

the risk of harm to people exposed to radiation through their occupation, members of the public, and the environment. The plan must meet requirements prescribed in relevant national codes.

Proposed Regulation increases penalties

The proposed Regulation increases maximum penalties and penalty notice amounts for unlawful behaviour. These will provide greater deterrence to committing offences and are proportionate to the potential harm associated with unsafe radiation practices. Most penalty notice amounts have not increased since 2003, when penalty notice offences were introduced for radiation offences.

Costs and fees will change

The proposed Regulation adjusts fees to enable the EPA to recover more of the costs of administering the legislation and protecting the community and the environment from harmful radiation. Some changes in the proposed Regulation are associated with increased costs. For example, the base fee for a radiation management licence will increase by \$99 on average, to cover the administration and compliance costs of regulating radiation practices. Radiation management licensees may incur costs to comply with the new requirement to prepare a radiation management plan. This RIS details the impacts of the proposed changes.

At present fees increase in line with the Australian Bureau of Statistics public sector wage price index. Consistent with other fee regimes, the proposed Regulation seeks to index fees annually according to the consumer price index, from 2026. This will better align the cost of protecting the community and environment from harmful radiation with increases in costs to government.

Alternative options considered

In reviewing the Regulation, the EPA assessed a range of options, including:

- remaking the Regulation without changes (the base case)
- automatic repeal of the Regulation (Option 1)
- remaking the Regulation with changes (the proposed Regulation – Option 2).

The proposed Regulation provides a contemporary, risk-based approach to regulating radiation, by improving oversight of radiation practices, quality assurance and workplace safety. The benefits include avoiding health costs and potential environmental damage, and outweigh the costs associated with the changes. The proposed Regulation also provides fee relief and reduces red tape in many instances.

Option 1 (automatic repeal) is not considered viable, because it does not ensure that radiation can continue to be used safely to improve the quality of life for NSW communities while also protecting human health and the environment. This option would compromise the proportionate and targeted approach to dealing with radiation risks that the Act and Regulation aim to implement – an approach that is consistent with international and national standards.

1 Introduction

1.1 Purpose of this regulatory impact statement

The *Subordinate Legislation Act 1989* requires statutory rules to be reviewed periodically to ensure they remain relevant and effective. If regulations are not remade, they are subject to automatic repeal. Automatic repeal of the Regulation has been postponed until 1 September 2025.

When a principal statutory rule (such as the Regulation) is remade, the *Subordinate Legislation Act* requires the preparation of:

- an analysis of economic and social costs and benefits of the proposed regulation
- a statement of the objectives of the proposed regulation
- an evaluation of options considered to achieve those objectives.

The *Subordinate Legislation Act 1989* also requires:

- consultation with appropriate representatives of consumers, the public, relevant interest groups and any sector of industry or commerce likely to be affected by a proposed regulation
- public exhibition of the requisite analysis
- appropriate consideration of comments and submissions.

The Minister for the Environment authorised the EPA to conduct a comprehensive review of the Regulation in October 2023. Following this review, we developed the proposed Regulation.

This regulatory impact statement (RIS) includes an analysis of the economic and social costs and benefits of the proposed Regulation and its alternatives, taking into consideration stakeholder feedback received during the review process.

The EPA prepared this RIS. We engaged ACIL Allen to conduct the cost-benefit impact analysis component of the RIS.

We are giving stakeholders and the community an opportunity to comment on the RIS and the proposed Regulation.

In accordance with the *Subordinate Legislation Act 1989*, this RIS complies with the requirement to address the NSW Government's Better Regulation principles (Appendix A).

1.2 Consultation

The EPA sought advice from the Radiation Advisory Council in assessing options for the proposed Regulation, as required by section 30 of the Act.

The EPA and ACIL Allen undertook targeted consultation with key stakeholders to inform the development of the proposed Regulation and the cost-benefit analysis for this RIS. This consultation included a series of roundtable discussions. Stakeholders who were invited to provide comments and/or who attended the roundtable discussions are listed in Appendix B. Their feedback is summarised in Chapters 5 and 6.

The proposed Regulation and this RIS are available for public comment. The documents are on the EPA Have Your Say website.¹

1.2.1 How to provide feedback

- Use the guided submission on the EPA Have Your Say website and/or
- Email feedback to radiation.reform@epa.nsw.gov.au

¹ <https://yoursay.epa.nsw.gov.au/>

2 Radiation protection framework

The use of radiation benefits the community in many ways in medical, dental and veterinary diagnosis and treatment, scientific research, commercial and industrial applications, and security screening. However, if radiation is not used responsibly, unnecessary exposure can harm people and the environment. Usually, these harms emerge as long-term increased risks of cancer. For this reason, it is necessary to take a protective and precautionary approach to radiation safety.

The risks of radiation exposure are a consideration for workers, patients, members of the public and the environment. It is the role of governments to assess these risks and, if necessary, control them by safety measures.

2.1 NSW uses a ‘graded’ (risk-based) approach

International and Australian standards recommend a risk-based or ‘graded’ approach to radiation protection. This means that control measures and conditions which are applied to a radiation source or a radiation practice are proportionate to the risks associated with that situation.^{2,3} The NSW Government follows this approach.

An example of a graded approach is exempting certain persons from having to hold a licence for particular low-risk radiation practices. This is subject to applicable conditions that manage any risks to achieve the same safety outcome, such as meeting training requirements or complying with codes or standards.

2.1.1 Act and Regulation aim at safety and security

The Act and Regulation provide the NSW radiation protection framework. The framework is aimed at ensuring that:

- organisations that are responsible for or deal with regulated material provide safe and secure oversight
- individuals who use regulated material are competent and use radiation safely.

In this way, the Act and Regulation protect people and the environment from unnecessary radiation exposure as much as possible, while allowing radiation to be used for community benefit.

2.1.2 Act and Regulation are consistent with standards

The Act and Regulation are designed to be consistent with the Principles of Radiation Risk Management outlined in the *Fundamentals for Protection Against Ionising Radiation* (ARPANSA 2014) and relevant international standards.

2.1.3 Act and Regulation are based on licensing and obligations

The Act and Regulation are based on a system of licensing of dealings with radiation, and safety and security obligations placed on persons and organisations that are responsible for regulated

² Fundamental Safety Principles SF-1 (IAEA 2006)

³ Safety Standards Series No. GSR Part 3 General Safety Requirements (IAEA 2014)

material, supported by a range of enforcement approaches. As well as licensing to manage risk, other measures such as training, standards, safety plans, monitoring and guidance also play a role.

2.2 Protection from Harmful Radiation Act 1990

The Act provides the legal framework for regulating dealings with radioactive substances and radiation apparatus (regulated material), and for managing high-activity (or 'security enhanced') radioactive sources.

The objectives set out in section 3 of the Act are to:

- secure the protection of persons and the environment from exposure to ionising and harmful 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;
- protect security enhanced sources from misuse that may result in harm to people or the environment;
- promote the radiation protection principles, being justification of radiation practices, optimisation of protection of radiation exposure and dose and risk limitation;
- promote the ecologically sustainable development principles, being the principles and programs described in section 6(2) of the *Protection of the Environment Administration Act 1991* (NSW).

To minimise health risks to people and the environment posed by radiation, the Act:

- regulates the use, sale, transport, disposal and possession of radioactive substances and radiation apparatus
- ensures the security of high-activity radioactive sources by requiring organisations responsible for these sources to take special protective measures to defend them from unauthorised access and malicious misuse
- accredits third party experts to certify that radiation equipment complies with safety requirements
- provides powers to manage radiation risks and enforce the Act's requirements and deal with dangerous situations, including the power to seize, manage and dispose of items
- provides for a financial assurance to be required from a person to secure or guarantee funding for, or towards the carrying out of, works or programs required by or under a licence
- establishes the Radiation Advisory Council to advise the EPA on the development and administration of radiation control legislation, and matters relating to radiation safety, licensing and accreditation.

Section 5A of the Act delegates the regulation of radioactive ores on mine sites to the Secretary of the Department of Primary Industries and Regional Development, who may exercise such functions of the EPA and the CEO of the EPA that may be prescribed by the Regulation, including any specified conditions or limitations.

2.3 Protection from Harmful Radiation Regulation 2013

The Regulation supports and puts into effect many provisions of the Act. It is made under section 40 of the Act, which sets out the matters that are required to be or may be prescribed in the regulations.

Part 1 of the Regulation contains definitions, prescribes the radiation thresholds at which radioactive ores and substances become regulated by the Act, and specifies that the obligations to ensure health and safety under the Regulation are in addition to obligations under the *Work Health and Safety Act 2011* (NSW).

Part 2 sets out:

- exemptions from licensing requirements for dealing with certain radioactive substances and radiation apparatus
- supervision requirements for exempt persons
- the activities that may be carried out by an accredited consulting radiation expert and a radiation security assessor
- groups of regulated material for the purpose of setting fees.

Part 3 details requirements for the security of security enhanced sources established in the Act and includes provisions for:

- matters that are to be dealt with in security plans
- security measures that a person responsible for a security enhanced source is required to comply with
- the duty to report breaches of security measures
- identity checking requirements.

Part 4 addresses radiation safety and public health protections and includes provisions relating to:

- complying with dose limits
- monitoring devices and records of occupational exposure to radiation
- responsibilities for radiation safety in the workplace
- reporting accidents, faults and defects
- the prohibition of commercial cosmetic ultraviolet tanning services
- exposure to members of the public to radiation
- appointment of radiation safety officers and committees
- loss or theft of regulated material or a security enhanced source.

Part 5 deals with miscellaneous matters, such as providing for the exercise of certain functions by the Secretary of the Department of Primary Industries and Regional Development, the destruction of records, contamination of premises by radioactivity and the forfeiture of property.

Schedule 1 lists the prescribed activity of the radioactive isotopes for the purposes of defining a radioactive substance.

Schedule 2 prescribes how radiation laboratories are to be classified for the purposes of the Regulation.

Schedule 3 specifies licensing exemptions for certain radioactive substances and ionising radiation apparatus.

Schedule 4 specifies the fees payable for licences and accreditations and for services provided by the EPA.

Schedule 5 prescribes dose limits for occupationally exposed persons and members of the public.

Schedule 6 prescribes warning sign (use of the commonly recognised symbol for radiation).

Schedule 7 prescribes penalty notice offences and amounts.

2.3.1 Amendments to the Regulation since 2013

Minor amendments to the Regulation were made by the Radiation Control Amendment (Classification of Laboratories) Regulation 2013 and the Radiation Control Amendment (Exemptions and Fees) Regulation 2016.

The Radiation Control Amendment (Fees) Regulation 2018 aligned changes in fees applied under the Regulation to the public sector wage price index.

The Radiation Control (Amendment) Regulation 2021:

- aligned the Regulation with the *Code for Radiation Protection in Medical Exposure* (ARPANSA 2019) (Medical Exposure Code) by defining ‘medically exposed persons’
- aligned the Regulation with the *Code for Radiation Protection in Planned Exposure Situations* (ARPANSA 2020) (Planned Exposure Code) by introducing lower dose limits for younger occupationally exposed persons
- included the definition of ‘employment’ to clarify that the term includes a person engaged under a contract for service, self-employment and carrying on a business in partnership.

Following a statutory review required by section 39B of the Act, the *Radiation Control Amendment Act 2023* amended the Act and migrated certain provisions relating to the transport of radioactive material and disposal of regulated material from the Regulation to the Act.⁴ These amendments commenced on 23 February 2024.

2.3.2 Authorisation and enforcement

As of late 2024, there were about 21,000 radiation user licensees, about 3,150 management licensees and 100 accredited experts and assessors authorised under the Act.

Compliance and enforcement of the licensing system through inspections and audits is evidence- and risk-based, targeting the largest risks to public health and the environment and those organisations and individuals least likely to be compliant.

From 2013 until early 2025, the EPA has:

- issued 24 penalty infringement notices (ten of which relate to breaches under the Regulation). These penalty offences related to disposal of regulated material without consent, not providing and complying with a radiation management plan, transporting regulated material not in accordance with the Regulation, not providing supervision of an exempt person and providing a UV tanning service.

⁴ Statutory Review: Radiation Control Act (NSW EPA 2021)

- successfully prosecuted five organisations for breaches under the Act and Regulation. These include:
 - a university that failed to ensure regulated material was not dealt with by an unlicensed person and disposed of regulated material without consent
 - a medical research company that transported a security enhanced source without a security plan and contrary to the Regulation
 - a dental practice that permitted unauthorised persons to take x-rays
 - a company that disposed of regulated material without consent
 - a textile company that failed to register a sealed source device and disposed of regulated material without consent.
-

2.4 Other regulatory frameworks

In NSW, radiation safety is primarily administered by the EPA under the Act and the Regulation. However, several other agencies have responsibilities under the Act and other legislation.

2.4.1 Work health and safety and other NSW legislation

The Act and Regulation contain work health and safety elements targeted at employers of people exposed to radiation in the course of their employment, such as minimising their employees' radiation exposure risk and monitoring their exposure.

Section 7 of the current Regulation states that: 'The obligations to ensure health and safety imposed by this Regulation are in addition to and do not derogate from the obligations of a person conducting a business or undertaking under the *Work Health and Safety Act 2011* or the regulations made under that Act.'

Laser equipment used on industrial plant is regulated by SafeWork under the Work Health and Safety Regulation 2017 (section 223), which sets control measures and training requirements, and prohibits the use of some lasers in industry.

NSW Police administer bans on possession and use of prohibited laser pointers under the *Summary Offences Act 1988* (section 11FA).

2.4.2 Commonwealth jurisdiction

Under Australian constitutional arrangements, the Commonwealth and the states and territories have distinct jurisdictions in relation to radiation protection.

The Commonwealth radiation legislation includes the *Australian Radiation Protection and Nuclear Safety Act 1998* (Cth) (ARPANS Act). The ARPANS Act regulates nuclear and radiation activities of Commonwealth entities, their employees and contractors. It is administered by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

ARPANSA has a role in international liaison and national standard setting, including publishing codes, standards and guidance developed by the Radiation Health Committee⁵ in its Radiation

⁵ <https://www.arpansa.gov.au/about-us/advisory-council-and-committees/radiation-health-committee>

Protection Series⁶ and the *National Directory for Radiation Protection (2nd edition, 2021)* (Commonwealth of Australia 2021).⁷

ARPANSA also publishes information on extremely low frequency electrical and magnetic fields.⁸

The Australian Communications and Media Authority sets rules regarding electromagnetic energy and radiofrequency radiation (EME-RF) in communications devices and transmitters.⁹ ARPANSA's national *Standard for Limiting Exposure to Radiofrequency Fields – 100 kHz to 300 GHz (2021)* sets limits of exposure to EME-RF for the public and workers, and includes requirements for protecting the public and managing risk in occupational exposure from EME-RF.

2.4.3 National uniformity

Australian jurisdictions have developed the *National Directory for Radiation Protection* (National Directory) to promote national uniformity in radiation safety. States and territories agree to adopt codes and standards in the National Directory in their regulatory frameworks. The Radiation Health Committee is responsible for developing codes and standards in the Radiation Protection Series (RPS) for inclusion in the National Directory. The EPA represents NSW on the Radiation Health Committee.

Section 37 of the Act provides for the adoption and implementation of RPS codes and standards included in the National Directory. In 2022, the EPA gazetted the new and updated codes and standards included in the second edition of the National Directory published in 2021.

2.4.4 Mutual recognition

Under the Australian and Trans-Tasman mutual recognition schemes, someone holding a registration to carry out activities under an occupation in an Australian state or territory, or New Zealand, may be granted a registration in another state or territory for the equivalent occupation.¹⁰

The automatic mutual recognition (AMR) scheme streamlined mutual recognition by permitting workers in identified categories who are registered to carry on activities in their home Australian state or territory to carry out those activities in another state or territory participating in AMR without the need to apply and pay fees for a licence or registration there.¹¹

Since 1 December 2022, two NSW radiation occupational registrations – radiation user licences and radiation security assessor accreditations – have been included in the AMR scheme. Workers from a state or territory participating in AMR who hold an interstate licence or registration equivalent to one of these NSW occupational registrations may be eligible to work in NSW and therefore comply with requirements under the Act and Regulation.

⁶ <https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series>

⁷ <https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/national-directory-for-radiation-protection>

⁸ <https://www.arpansa.gov.au/understanding-radiation/radiation-sources/more-radiation-sources/electricity>

⁹ <https://www.acma.gov.au/our-rules-eme>

¹⁰ <https://www.dewr.gov.au/skills-support-individuals/mutual-recognition>

¹¹ <https://www.epa.nsw.gov.au/licensing-and-regulation/licensing/automatic-mutual-recognition>

3 The need for government action

The NSW Better Regulation principles in the *NSW Government Guide to Better Regulation* (2019) require that in developing regulations the need for government action should be established, and that action should only occur where it is in the public interest and where the benefits outweigh the costs.¹² This chapter outlines the nature and extent of the problem the proposed Regulation is intended to address.

Exposure to radiation can harm people, increasing cancer risk, and uncontrolled radiation can contaminate the environment, affecting land use, plants, animals and ecosystems.

Radiation can be classified as either ionising or non-ionising. Ionising radiation (for example, x-rays) has a short wavelength and high frequency. It has enough energy to change the structure of a molecule by breaking an electron away from an atom (i.e. ionising it). Exposure to ionising radiation has been shown to increase the risk of cancer. Risk increases as dose increases. In addition, there are unfortunately many instances of uncontrolled radioactive substances contaminating the environment.

Non-ionising radiation has a longer wavelength and lower frequency. It does not have enough energy to change the structure of a molecule but can make molecules vibrate and produce heat. Most UV is considered non-ionising. Exposure to UV radiation has been shown to be linked to a higher incidence of melanoma and other skin cancers. Published studies have identified artificial UV tanning units as particularly harmful to younger users.

It is therefore clear that ionising radiation and non-ionising UV radiation are potential health and environmental hazards that require appropriate safety controls.

Radiation is also beneficial. It is widely used in the community in the medical, dental and veterinary sectors for diagnostic imaging (x-rays) and cancer therapy. Radiation improves the quality of our lives through its use to make donated blood safe and sterilise medical supplies, and in essential medical research. In the commercial sector, radiation is used in manufacturing and mining and for analytical purposes, such as taking radiographs of engineered structures to make sure they are free of dangerous faults.

Professional standards, education and training, and local rules provide a level of protection from radiation harms. However, the risks of radiation exposure to workers, patients, members of the public and the environment are significant. Worldwide, there have been compliance and safety failures associated with the use of radiation. These factors have convinced governments of the need to act: to implement standards via a system of authorisation; to manage radiation risks in a proportionate, evidence-based way; and to provide a mechanism for requiring compliance and enforcing obligations. Such action ensures that radiation can be used safely and in ways that improve the quality of life for NSW communities.

¹² https://www.productivity.nsw.gov.au/sites/default/files/2022-05/TPP19-01_Guide-to-Better-Regulation.pdf

3.1 Managing ionising radiation

3.1.1 Ionising radiation and its impacts

3.1.1.1 Health effects of ionising radiation

When ionising radiation passes through our cells, it produces ionised molecules or free radicals. These free radicals are highly reactive and can interact with, and damage, our DNA. DNA may also be damaged directly by radiation. If the damage is not successfully repaired, the cell may either die or mutate.

The health effects of radiation have been studied in victims of severe radiation accidents, the survivors of the atomic bombings in Japan, workers exposed to radiation in medicine and industry, and patients exposed as part of medical diagnosis and treatment.

Two types of health effects

Health effects are classified as either ‘tissue effects’ or ‘stochastic effects’.

Tissue effects of radiation are definable reactions caused directly or indirectly by radiation. Examples are erythema (skin reddening), skin and tissue burns, cataract formation, sterility, radiation sickness and death. The severity of tissue effects increases with dose.

Stochastic effects are defined as effects that occur by chance and their probability or frequency is correlated with increased radiation exposure. Stochastic effects can, in theory, occur at any dose but the probability increases with dose. The main stochastic effect of radiation is cancer.

Effects vary with exposure

In exposures greater than 1 sievert¹³ (such as in cancer treatment), many cells may die and can impair the function of vital organs and systems (ARPANSA, n.d.). Other cells will mutate and increase the risk of cancer.

For radiation exposures between 100 millisieverts (mSv) and 1 sievert, the human body’s immune system is very effective at detecting and destroying mutated cells. However, there is a possibility that a non-lethal transformation of a cell could lead, after a period, to cancer.

The UN Scientific Committee on the Effects of Atomic Radiation (UNSCEAR 2012) has noted that as radiation dose decreases ‘the power of epidemiological studies becomes less and less, although there may be sensitive subgroups within the population for which increased frequency of occurrence of specific disease types may be discernible’.

3.1.1.2 Linear no-threshold model

Although there is little observable evidence of stochastic effects below 100 mSv, the current radiation protection philosophy assumes that there is no safe limit of radiation exposure; zero risk only at zero dose – this is called the ‘linear no-threshold’ (LNT) model, a dose-response model used to estimate risk or delayed effects (like cancer) due to exposure to ionising radiation. It is not possible to accurately determine the effects of low doses because it would require an extremely

¹³ A sievert is a unit of radiation exposure. It is a measure of the risk of ionising radiation on the human body.

large sample of exposed persons and they would need to be monitored an impractical length of time.

In setting regulatory limits, as a precautionary approach, an assumption is made that the long-term risk caused by ionising radiation is directly proportional to the radiation dose.

In 2017, the Australian Radiation Health and Safety Advisory Council (RHSAC)¹⁴ published a *Position Statement on the use of the linear no-threshold model in radiation protection*, which supported the continued appropriate use of the linear no-threshold (LNT) model as a regulatory tool.

RHSAC cautioned that ‘while the LNT model can be used to infer health risks associated with low radiation doses and dose rates, projections of absolute number of cancer cases in a population may not be valid and could be increasingly misleading as doses decrease.’ UNSCEAR 2022 reports conflicting results from relevant studies at such levels.

Due to the unreliability of projections of increased cancer risk at radiation doses of less than 100 mSv, this RIS does not attempt to quantify excess cancer cases caused by radiation exposure at these levels.

3.1.1.3 Dose limits

The International Commission on Radiological Protection (ICRP) makes recommendations on the limits to be applied to ionising radiation exposure.¹⁵ These recommendations have been accepted throughout the world.

Based on a conservative evaluation of low-exposure research, the limits set in Australian and NSW legislation are that a member of the public must not receive more than 1 mSv of ionising radiation per year as a consequence of the use of regulated material in a planned exposure situation and a radiation worker must not receive more than 20 mSv per year on average, over five years. Lower limits apply to occupationally exposed persons aged 16–18 years.

These limits do not include exposure to an individual who is a *medically exposed person*, as defined in the Regulation, or exposure from natural sources of radiation. Schedule 5 of the Regulation adopts these limits and imposes enforceable obligations on employers to ensure that the limits are not exceeded.

It is well-established that radiation exposure *in utero* leads to an increased risk of childhood cancer and leukemia (ICRP 2000). The spontaneous incidence of childhood cancer and leukemia up to the ages of 15 (without radiation exposure above natural background levels) is about 2–3 cases per 1,000 children. It has also been shown that radiation doses of approximately 10 milligray received by a foetus produce an increase in the risk of childhood cancer (Doll & Wakeford 1997). There is also evidence that doses of ionising radiation given through computed tomography examinations of the brain in infancy have effects on cognitive function in adulthood (Hall et al. 2004).

For these reasons, the Regulation makes provision for reducing occupational exposure to radiation during pregnancy, effectively reducing the occupational exposure limit to the member of the public limit.

In addition, radiation practitioners need to make careful judgements about the risk–benefit ratio of exposing pregnant patients to medical procedures involving the use of radiation.

¹⁴ <https://www.arpsa.gov.au/about-us/advisory-council-and-committees/radiation-health-and-safety-advisory-council>

¹⁵ The 2007 Recommendations of the International Commission on Radiological Protection (ICRP 2007)

See Chapter 5 for information on how the proposed Regulation improves protection for pregnant persons.

3.1.2 Medical exposure

Most medical exposure to ionising radiation occurs in diagnostic radiology, nuclear medicine and radiation therapy. Over 90% of the total exposure of people to radiation from medical procedures is estimated to be from diagnostic x-rays.

Diagnostic radiology includes plain radiographs, mammography, fluoroscopy, and computed tomography (CT). Nuclear medicine uses unsealed radioactive substances by injection into the body to obtain images that provide information on the structure or function of various organs. In addition to these uses for diagnosis, radioactive substances are sometimes also used for therapeutic purposes, such as in the treatment of thyroid cancer. Radiation therapy uses ionising radiation to treat cancers. It can be teletherapy, which is the external application of radiation, or brachytherapy, where a radioactive source is placed within the body at the location of the tumour.

Most radiological examinations worldwide are diagnostic, with 26.3% of the total being dental x-rays and about 10% CTs (Mahadevappa et al. 2022). According to Medicare records, over 1.64 million CT procedures and approximately 4.2 million other diagnostic radiology procedures (including mammography and fluoroscopy) were performed in NSW in the 2023–24 financial year. Medical imaging in Australia has been increasing; while CT procedures rates are declining in the youngest age groups, they are increasing markedly in the oldest age groups but with a declining individual dose from relevant procedures (RHSAC 2021).

ARPANSA estimates medical exposure in Australia to be 1.7 mSv per person per year (ARPANSA 2021). The National Council on Radiation Protection and Measurements in the United States estimated that the annual per person effective dose from diagnostic radiology and nuclear medicine in the United States is approximately 2.3 mSv compared with 0.56 mSv worldwide (Mettler et al. 2020).

The Act and Regulation do not regulate limits or other restrictions on the prescription of radiation for patient diagnosis or treatment. However, provisions in the Act and Regulation are intended to:

- ensure, through licensing, that practitioners are competent
- implement radiation safety standards, including the ARPANSA Planned Exposure Code and the Medical Exposure Code
- set requirements for the safety certification of diagnostic imaging equipment, and for reporting obligations for radiation accidents.

The proposed Regulation improves the implementation of these standards: see Chapter 5 for details.

3.1.3 Workplace exposure

Tens of thousands of people in NSW are exposed to ionising radiation in the course of their employment. Occupational exposure can occur from proximity to radiation devices when these are in use, or by exposure to, and inhalation or absorption of, radioactive substances.

Occupationally exposed persons include over 20,000 radiation user licence holders. Approximately 50% of licensees are workers involved in medical imaging and radiation therapy, while 25% carry out dental radiography and 8% perform veterinary radiation practices.

Industrial radiographers and other industrial gauge users make up about 8% of user licensees.

The remainder of occupationally exposed persons use regulated material in security screening, quality assurance, production, laboratory work and education.

Not all occupationally exposed people are radiation user licensees. For example, mine workers and cave guides may be occupationally exposed to naturally occurring radioactive materials, with radon gas being of particular concern.

3.1.3.1 Protections for occupationally exposed people

User licensing under the Act is intended to ensure that the person has the appropriate knowledge of the principles and practices of radiation safety and protection.

The Regulation specifies a number of safety obligations for employers. These apply to all persons who may be occupationally exposed. The employer has a duty to:

- comply with dose limits for occupational exposure
- inform occupationally exposed persons of hazards and safety arrangements
- provide personal radiation monitoring to certain classes of occupationally exposed persons.

In addition, the EPA can require that:

- area radiation monitoring be installed at a premises
- a radiation management plan be prepared
- a workplace radiation safety officer or radiation safety committee be appointed.

The proposed Regulation improves protections for occupationally exposed people: see Chapter 5.

3.2 Avoiding harm from UV tanning units

3.2.1 Prohibition on commercial cosmetic UV tanning services

The Regulation prohibits the provision of commercial cosmetic UV tanning services. This includes prohibiting a person from providing, or offering to provide, another person with a cosmetic tanning service for fee or reward or in connection with another service for fee or reward.

NSW introduced the prohibition on commercial tanning services in 2014 in response to evidence that the use of UV tanning units is associated with an increased risk of melanoma and other skin cancers, particularly among younger users of tanning units (Cust et al. 2011).

All other Australian states and territories have followed NSW's lead in banning commercial tanning services.

3.2.2 Cancer risks related to UV exposure

Skin cancer (melanoma and non-melanoma) is one of the most prevalent cancers in Australia and is closely associated with exposure to UV radiation.

The Australian Institute of Health and Welfare (AIHW) reports that melanoma and non-melanoma skin cancers together account for the largest number of cancers diagnosed in Australia each year (AIHW 2016). Non-melanoma skin cancers are currently not reported to cancer registries; however, melanoma skin cancer alone was the third most diagnosed cancer in Australia in 2023 (AIHW 2023).

In 2019, there were 15,628 new cases of melanoma of the skin diagnosed in Australia (9,134 males and 6,494 females). In 2023, it was estimated that 18,257 new cases of melanoma of the skin were

diagnosed, and an estimated 1,297 number of deaths attributed to melanoma. Overall, from 2019 to 2023, the age-standardised incidence rates of melanoma rose from 63 cases per 100,000 persons (80.6 for males and 51.5 for females) in 2019, to 69.4 cases per 100,000 persons (85.2 for males and 55.6 for females) in 2023 (Cancer Australia, n.d.).

3.2.3 Risks from commercial cosmetic UV tanning services

In 2009, the International Agency for Research on Cancer (IARC) increased its classification for solarium (tanning units) to being 'carcinogenic to humans', the highest classification. This puts them in the same category as tobacco and asbestos (IARC 2009). The use of tanning units is associated with an increased risk of melanoma, particularly among young people. Higher frequency of use and earlier age of first use both increase the risk (Cust et al. 2011; IARC 2012).

Skin cancer, both melanoma and non-melanoma, develop as a result of UV exposure over time. UV exposure can be from both natural and artificial sources, so it is difficult to quantify how banning commercial solarium in 2016 has affected the rate of skin cancer. National health statistics indicate that skin cancer cases are increasing (Cancer Australia, n.d.).

According to a recent study, *Estimated Healthcare Costs of Melanoma and Keratinocyte Skin Cancers in Australia and New Zealand in 2021*, the estimated costs of diagnosis and treatment of new skin cancers in NSW in 2021 is estimated at about \$238.2 million (Gordon et al. 2022). The 2012 RIS for the Regulation indicated that banning solarium would result in health-cost savings to the community of \$46.12 million, based on an estimate of mortality due to cancers and the cost of treating them.

3.2.4 Enforcement of the prohibition

The prohibition on commercial cosmetic UV tanning services has been effective as a public health measure in limiting the promotion and provision UV tanning services in the retail sector; however, reported illegal tanning operations have presented continuing enforcement challenges for the EPA.

Due to the clandestine nature of illegal solarium operations, EPA enforcement of the ban relies on reports from the public (often made to Environment Line¹⁶) and online research (e.g. of social media advertising). It can be difficult to prove that a service was provided, unless there are complaints from people who have sought or received a service from an illegal operator. Cash transactions are understood to be common.

Since solarium were banned in 2016, there have been about 20 reports a year to Environment Line of illegal commercial solarium. The EPA investigates complaints where there is sufficient evidence of illegal activity and where it can identify an address. EPA action has included:

- issuing section 191 notices under the *Protection of the Environment Operations Act 1997* (POEO Act) to provide information and/or records,
- issuing section 203 notices under the POEO Act requiring answers to questions
- formal warning letters
- penalty infringement notices.

The proposed Regulation strengthens the commercial UV tanning services prohibition: see Chapter 5 for details.

¹⁶ <https://www.epa.nsw.gov.au/about-us/contact-us/environmentline>

3.3 Mitigating security risks

3.3.1 Security risks

A security enhanced radioactive source is a radioactive substance in sealed form which, due to its high radioactivity, presents a security risk if an unauthorised person were to gain access to it.

Exposure to an unshielded security enhanced source could cause injury or death, depending on the extent of the exposure.¹⁷

Few security enhanced radioactive sources are used in NSW. And they are becoming even rarer. Certain practices (such as blood irradiation) that used to use high-activity radiation sources (such as Cobalt-60 or Caesium-137) have replaced these sources with x-ray apparatus. However, security enhanced sources are still used in cancer treatment, product sterilisation and medical research, and in commercial applications such as industrial radiography.

The Regulation details:

- requirements for protecting security enhanced radioactive sources
- measures required to protect different categories of security enhanced sources
- matters to be addressed in security plans
- a duty to report security incidents
- requirements for identity checking for people who deal with security enhanced sources.

3.3.2 National Security Code

Australia has recognised the importance of safeguarding security enhanced radioactive sources by adopting and implementing the national *Code of Practice for the Security of Radioactive Sources* (ARPANSA 2019) (Security Code) in its Chemical, Biological, Radiological and Nuclear (CBRN) national response plan.¹⁸ The Act and Regulation specify requirements that reflect those in the Security Code.

3.4 Natural sources of radiation

3.4.1 Natural sources of radiation exposure

The primary source of natural radiation exposure is exposure to non-ionising UV radiation from the sun. Natural UV exposure is not regulated under the radiation framework. ARPANSA's national *Radiation Protection Standard for Occupational Exposure to Ultraviolet Radiation* (2006) provides guidance on minimising workers' exposure to the sun. SafeWork NSW is responsible for administering work health and safety and publishes information on protection from solar UV in occupational situations.¹⁹

¹⁷ Radioactive Sources: Use, Safety and Security (ANSTO 2007)

¹⁸ CBRN Plan (Australian Government Department of Health 2018)

¹⁹ <https://www.safework.nsw.gov.au/hazards-a-z/ultra-violet-radiation>

There are many natural sources of ionising radiation. The most widespread source is the earth's radioactive elements. Some types of elements, called isotopes, are unstable and convert themselves into different elements by emitting radiation. Examples of natural sources of radiation in Australia include potassium, radon gas, thorium, uranium and other minerals. These radioactive isotopes are found in soil, rocks and air, and subsequently in food, drink and our bodies. Other forms of natural ionising radiation come from cosmic particles and radiation from space. These particles and rays are generated by the sun or from outside our solar system. You may be exposed to cosmic radiation when flying in aircraft at altitude.

3.4.2 Naturally occurring ionising radiation exposure

The radiation we receive from natural sources of radiation is referred to as 'background' radiation. Low exposure to ionising radiation at background level is not harmful. The average amount of background radiation people in Australia receive annually is around 1.7 mSv (ARPANSA 2021). This is lower than the world average of around 2.4 mSv (UNSCEAR 2008). To put this in perspective, a typical chest x-ray exposes a person to about 0.2 mSv. The Regulation does not apply to background radiation exposure.

However, naturally occurring radioactive material (NORM) becomes a consideration when it involves occupational exposure. In NSW, occupational exposure to NORM may occur in mining and mineral processing. Show cave guides may be exposed to radon gas.

The Regulation's work health and safety requirements apply to all persons exposed to ionising radiation in the workplace.

3.5 Management of radiation accidents

In the current Regulation, a 'radiation accident' means an occurrence that involves the unplanned or unexpected emission of radiation of such a nature or extent that it is likely to cause unnecessary exposure to radiation or contamination of premises; or an occurrence that involves the misuse of radiation apparatus or maladministration of a radioactive substance used for medical purposes other than as prescribed.

The Regulation requires the timely reporting of radiation accidents and establishes the particulars that must be included in an accident report. Accident reporting:

- encourages situational awareness and fosters a radiation protection culture
- enables the EPA to track overall accident trends to improve regulatory responses
- enables the sharing of lessons learned with others to help prevent future accidents.

According to the *Australian Radiation Incident Register Annual Report* (ARPANSA 2021), 61% of accidents are caused by human error and 14% by equipment failure.

According to the report: "All estimated effective doses [from accidents] were below 100 mSv, the threshold for what is generally referred to as 'low' doses, and 93% were 'very low', i.e. below 10 mSv. Risk for disease later in life at such exposures is generally inferred from models and any health effect later in life would not be possible to unequivocally attribute to the specific exposure event."

See Chapter 5 for information on proposed changes to accident reporting.

3.6 Licensing and accreditation

The Act establishes a broad regulatory scheme for radiation protection in NSW, including a system for licensing individuals and organisations that deal with regulated material. It also establishes accreditation for consulting radiation experts (CREs), who test radiation equipment safety, and radiation security assessors (RSAs), who endorse plans required by the Act for security enhanced sources.

The regulatory regime for radiation protection under the Act includes:

- licensing individuals who use radiation apparatus and radioactive substances ('user licence')
- licensing individuals or organisations who own, sell, possess, consign for transport, dispose of, give away or otherwise deal with regulated material ('management licence')
- accrediting individuals who may engage in the work of a CRE or RSA.

Before issuing (or renewing) a licence or an accreditation, the EPA must be satisfied of two things:

- that the applicant is a 'fit and proper person' to hold the licence or accreditation
- in the case of a radiation user licence or an accreditation – the applicant has appropriate knowledge of the principles and practices of radiation safety and protection applicable to the activities proposed to be carried on by the applicant.

The Regulation supports the implementation of this regime, based on a risk-based approach to protecting the community from harmful radiation. The current Regulation provides licensing exemptions for dealings with certain low-risk regulated material. It also provides user licence exemptions for classes of persons, such as students, who are in supervised training, and dental professionals.

See Chapter 5 for changes to exemption provisions in the proposed Regulation.

4 Options considered

This regulatory impact statement considers the benefit and costs of three options:

- **Base case:** Remake the Regulation without change (status quo)
- **Option 1:** No regulation – allow the Regulation to be automatically repealed
- **Option 2:** Remake the Regulation with amendments (the proposed Regulation).

These options are described below.

4.1 Base case: Remake the Regulation without change (status quo)

This option involves remaking the 2013 Regulation without amendment.

4.1.1 Implications of implementing the base case

This option would continue to protect the community and environment at the current level. However, it would forego the beneficial changes in the proposed Regulation.

- The current exemptions from licensing would be retained but they would not be best targeted to a risk-based approach that reduces red tape and considers appropriate safety, supervision and compliance requirements.
- The EPA would retain the ability to require the preparation of a radiation management plan (RMP). However, the regulatory framework would not align with contemporary best practice in radiation protection, as described in the national codes of practice adopted by the EPA under s 37 of the Act. These codes require all persons responsible for regulated material to develop and implement an RMP.
- Accident reporting requirements would be retained but the definitions of reportable accidents would not be consistently aligned with the national radiation incident reporting framework and reporting requirements more appropriately targeted.
- Personal radiation dose monitoring requirements would remain, but the current language would continue to cause uncertainty within the regulated community as to who requires dosimetry.
- Occupational dose limits would be retained but the determination of these limits would not be as clear and enforceable as they could be.
- Functions delegated to the Secretary of Regional NSW would remain but would not reference all relevant mining work health and safety legislation where the delegations apply and would not empower the Secretary to take certain regulatory actions in relation to offences for which the Secretary has responsibility.
- Identity checking requirements for persons who deal with security enhanced sources would remain but without improved oversight through record keeping.
- The prohibition on commercial tanning services would remain but reported illegal tanning operations may continue to present enforcement challenges for the EPA due to the potential for exploitation of 'loopholes' in the offence and difficulty in evidencing the provision of tanning services in particular instances.

- Penalties for non-compliance would remain but may not be enough to encourage compliance and best practice.
- Fees for licensing and services would remain but would not be optimal to recover more of the administration and compliance costs for regulating radiation practices; also, how fees are increased annually would not be consistent with the now preferred government approach to align fee changes to the consumer price index.

The base case is not preferred as it does not address the need for government action outlined in Chapter 3.

4.2 Option 1: No Regulation – allow the Regulation to be automatically repealed

The Regulation includes many provisions necessary for the efficient and effective operation of the Act.

If the Regulation were repealed, some of these requirements could be prescribed in radiation user and management licences. However, guidelines and codes alone are unlikely to provide a consistent high level of protection against unsafe practices.

Guidance alone would not ensure that suitable safety and security measures would be adopted consistently. Those who do comply could be at a competitive cost disadvantage to those who don't. Without the Regulation, licence conditions would need to be very detailed, making them more challenging to implement and enforce.

Under the Act, many requirements can only be prescribed by Regulation; they cannot be dealt with through licence conditions. Such requirements include:

- matters relating to definitions of essential terms
- exercise of delegated functions under section 5A of the Act
- matters relating to the security of radioactive sources
- activities permitted to be undertaken by CREs and RSAs
- fees and penalty notice offences.

Repealing and not remaking the Regulation is not a preferred option, as it would make some parts of the Act impossible to implement.

4.3 Option 2: Remake the Regulation with changes (the proposed Regulation)

Option 2, the proposed Regulation, carries forward most of the provisions of the current Regulation with changes that strengthen the effectiveness of the Regulation in supporting the Act in a risk-informed and evidence-based regulatory framework.

The EPA has administered the current Regulation, reviewed accident/incident reports and engaged with key stakeholders. This experience has shown need to refine and strengthen regulatory requirements in the proposed Regulation. Below is a summary of the proposed changes. Chapter 5 discusses them in detail.

Table 4.1 Key changes in the proposed Regulation

Topic	Proposed change	Objective	Where discussed in detail in Chapter 5
Licensing and exemptions	Clarifying and, in some cases, extending licensing exemptions for students and certain low-risk users and practices	Improve risk-based licensing and reduce red tape	5.1.1
	Establishing clear exemption criteria, obligations and supervision requirements that emphasise the obligations of individual supervisors, responsible organisations and exempt persons	Improve risk-based licensing and reduce red tape	5.1.1
Workplace radiation safety protections and practices	Requiring that all radiation management licensees prepare or adopt a radiation management plan that describes how licensees are ensuring safety in their workplace	Improves safety oversight	5.2.1
	Migrating the requirements to comply with obligations under ARPANSA Codes of Practice from radiation management licence conditions to the Regulation	Improves safety oversight	5.1.2
Protection against radiation exposure	Strengthening and clarifying provisions relating to occupational exposure monitoring and exposure dose limits	Ensures that employees and the community are protected against radiation exposure	5.2.2
Incident reporting	Ensuring that accident (incident) reporting is appropriately targeted	Improves accident (incident) reporting	5.3
	Ensuring reports provide accurate and timely information, including dose assessment by a medical physicist for more significant incidents.	Improves accident (incident) reporting	5.3
Protection of public health from artificial ultraviolet radiation	Strengthening the offence relating to the prohibition of commercial UV tanning services	Protects public health from exposure to artificial ultraviolet radiation	5.4
Fees	Recovering more of the costs associated with administering licences and accreditations, and other services, through adjustment of fees and tying fee changes to the consumer price index	Recovers the costs of administering the Act and Regulation and applies the user-pays principle	5.5.1
Penalties	Updating maximum penalties and penalty notice amounts to deter offending behaviour	Applies appropriate penalties for non-compliance	5.5.3, 5.5.4
Security of high-activity radiation sources	Requiring records to be kept of identity checks for certain persons who deal with security enhanced radioactive sources for 5 years	Strengthens existing security provisions	5.6

The EPA will ensure that licensees and exempt persons are meeting their obligations through compliance enforcement activity. The emphasis on the obligations of responsible organisations and

employers in the proposed Regulation will enable the EPA to direct its enforcement activities at the organisational level and towards the highest risks, while maintaining proportionate, risk-based controls on lower-risk activities. The proposed changes will also empower and enable the regulated community to actively manage radiation risk.

5 The proposed Regulation in detail

5.1 Licensing and exemptions

5.1.1 Exemptions

Under the current Regulation, radiation users are exempt from having to hold a radiation user licence for certain activities, subject to conditions. These exemptions apply to trained practitioners undertaking practices that expose patients to low levels of radiation (for example, dental radiography) and to certain supervised individuals (for example, students undertaking supervised clinical placement, course work or research).

Removal of current exemption requirement

The proposed Regulation updates radiation user licensing exemptions by removing the requirement for a written approval to be given for a person in an exempt class to operate under an exemption.

Instead, the radiation management licence holder shall document the supervision of exempt persons, consistent with their obligation to ensure radiation safety in the workplace. Removing the requirement for written approvals reduces red tape for licensees.

New offences

The proposed Regulation introduces new obligations related to exempt radiation users.

An offence will be introduced for a **radiation management licence holder** who:

- permits a person who does not meet the criteria for an exemption to use regulated material for which the licensee is responsible, or
- fails to take all reasonable steps to ensure that an exempt person is subject to the appropriate level of supervision.

An offence will also be introduced for a **supervisor** who fails to provide the appropriate level of supervision to an exempt person.

These above changes recognise the importance of proper management and supervision of persons exempt from licensing and were supported by stakeholders consulted during the development of the proposed Regulation.

Additionally, an offence will be introduced for an **exempt person** who fails to observe safety obligations. When using regulated material, exempt persons will be required to:

- comply with the operator requirements in the relevant ARPANSA code of practice or Australian Standard relating to the radiation practice being undertaken
- take all reasonable steps to follow procedures set out in a radiation management plan with respect to the regulated material the person is authorised to use
- not expose any member of the public to ionising radiation that exceed the dose limits
- notify the person responsible of any regulated material that may have faults or defects
- report to the person responsible any occurrences classified as a radiation incident.

Compliance with these obligations will ensure safety for patients, workers and the public. A failure to observe an obligation will make an exempt person liable for regulatory action. The change to require an exempt person to comply with a relevant code or standard was supported by stakeholders consulted during the development of the proposed Regulation.

Medical registrar exemption changes

Medical registrars in training are currently exempt from user licensing. The proposed Regulation would limit this exemption, instead requiring registrars in certain medical specialities to hold a radiation user licence.

To be licensed, registrars will have to complete approved training. The need for licensing is aligned with the radiation exposure risk associated with the use of fluoroscopy in medical specialities and the need for regulatory oversight of practitioners. The change may affect up to 462 medical registrars and will require undertaking a half-day course as a licence prerequisite. The change was supported by stakeholders consulted during the development of the proposed Regulation.

As a transitional arrangement, registrars affected by the change will have 9 months following the commencement of the remade Regulation to complete training. During this period, the affected registrars will remain exempt if they comply with the conditions of exemption.

Student exemption changes

The proposed Regulation updates radiation user licensing exemptions for students and persons doing approved radiation safety courses.

Diagnostic radiography students

An intermediate (indirect) level of supervision will be introduced for **diagnostic radiography students** nearing the end of their studies that recognises their progress towards full competence.

Currently, these students require immediate supervision during clinical experience throughout their studies when using radiation apparatus, where a supervisor observes and directs the use of the regulated material. The change will make indirect supervision available during the final year of a student's training: 'indirect supervision' means the supervisor must be always present at the same workplace where the student is using radiation apparatus and is contactable by the person being supervised. The change was supported by stakeholders consulted during the development of the proposed Regulation.

Postgraduate students

The level of supervision will be improved for **postgraduate chiropractic students** exempt from user licensing. Currently, these students are subject to general supervision. The change will require immediate supervision during clinical experience when using radiation apparatus and general supervision at other times.

The level of supervision will also be improved for other types of **postgraduate students** exempt from user licensing. Currently, these students are subject to general supervision. The change will require immediate supervision for the first 3 months and then general supervision thereafter.

Other students

The level of supervision will be improved for **undergraduate students** and **vocational students** exempt from user licensing. Currently, these students are subject to immediate supervision when

using regulated material in any clinical situation and general supervision at all other times. The change will require immediate supervision when using regulated material in all situations.

The proposed Regulation also specifies that **persons undertaking approved courses** (for radiation licensing or exemption purposes) with organisations that are neither universities nor registered training organisations are exempt from user licensing. These persons will be subject to immediate supervision in all situations when using regulated material.

Registered nurses and medical practitioner exemption changes

The proposed Regulation clarifies that the exemption for registered nurses and medical practitioners to use radiation is limited to the injection of radiopharmaceuticals for diagnostic purposes relating to a seizure or convulsion and only as authorised by the prescribing nuclear medical physician. This exemption is necessary so that patient testing is not delayed in situations where timely intervention is required but a licensee is unavailable. The change was supported by stakeholders consulted during the development of the proposed Regulation.

Veterinary profession exemption changes

The proposed Regulation introduces an exemption from user licensing for a **veterinary nurse, veterinary technician or technologist** undertaking veterinary radiography prescribed by a licensed veterinarian, if they have completed approved training and they are under the general supervision of a licensed veterinarian or under immediate supervision for equine veterinary radiography. Exempt persons are obliged to comply with the operator requirements in the *Code for Practice and Safety Guide for Radiation Protection in Veterinary Medicine* (ARPANSA 2009) (Veterinary Code).

One stakeholder group favoured retaining licensing for these persons, concerned that an exemption would reduce industry standards. However, the proposed change requires an exempt person to complete the same course of training that is currently approved for obtaining a user licence, and strengthens supervision requirements currently specified by licence conditions.

The EPA considers that the proposed exemption is a balanced, risk-based approach, providing an equal or better level of safety, which has the advantage of reducing red tape and providing licence fee relief for a veterinary nurse, veterinary technician or technologist. The requirement for a radiation management plan and enforceable supervisory and radiation management obligations places the emphasis of ensuring radiation safety on the responsible organisation.

Dental profession exemption changes

The proposed Regulation updates radiation user licensing exemptions for the dental profession.

Dental practitioners

The existing exemption from user licensing for **dental practitioners** for the use of x-ray apparatus for taking x-rays with intra-oral image receptors will be extended to also include taking orthopantomogram (OPG) x-rays and lateral cephalometric x-rays. These activities expose patients to comparatively low doses of radiation, and dental practitioners are already trained to carry them out safely.

The exemption would apply as long as a dental practitioner remains registered with the Dental Board of Australia. (Currently, being registered with the Board is the only qualification a dental practitioner needs to get a licence to carry out these activities.) An obligation of the exemption includes complying with applicable requirements of the *Code for Radiation Protection in Dental Exposure* (ARPANSA 2025) (Dental Code).

The change was welcomed by dental industry peak bodies consulted during the development of the proposed Regulation. Some peak body representatives wanted to also extend the exemption for dental practitioners to include the use of cone beam computed tomography (CT) apparatus; however, the proposed Regulation retains licensing for this practice due to the higher radiation exposure risk and the need for additional training.

Dental practitioner students

The existing exemption from user licensing for **dental practitioner students** for the use of x-ray apparatus for taking x-rays with intra-oral image receptors will be extended to also include taking OPG x-rays and lateral cephalometric x-rays during clinical placement.

The existing supervision provisions will be retained, requiring immediate supervision while the person is using regulated material during clinical experience and general supervision at other times. An obligation of the exemption is the person's compliance with operator requirements in the ARPANSA Dental Code.

The exemption will not apply to use of dental cone beam CT.

Dental assistants

An exemption from user licensing will be introduced for **dental assistants** taking dental x-rays (including OPG and lateral cephalometric x-rays) if they have completed approved training and are under the general supervision of a dental practitioner.

Safety obligations apply to the proposed exemption, including the person's compliance with operator requirements in the ARPANSA Dental Code. The training will be the same as the training currently approved for a dental assistant to obtain a licence. Training, supervision and operator safety requirements will maintain safety standards while reducing red tape and providing licence fee relief. The change was welcomed by dental industry peak bodies and other stakeholders consulted during the development of the proposed Regulation.

The exemption will not apply to use of dental cone beam CT.

Other changes to exemptions

Authorised officers will be exempt from requiring a user licence when exercising their functions. During compliance enforcement and incident response work, EPA officers may be exposed to radiation. The EPA ensures that officers who deal with regulated material are appropriately trained and supported, in accordance with its work health and safety obligations.

The types of **sealed source devices** and **ionising radiation apparatus** subject to exemption from licensing will be clarified to ensure they capture the appropriate range of low-risk radiation sources as practices and technology change. These changes are minor and do not significantly alter the exemption framework for low-risk regulated materials, currently listed in Schedule 3 of the Regulation.

Summary

The extended exemptions are estimated to apply to nearly 4,000 currently licensed persons who will no longer be obliged to hold a user licence.

Relevant exemption and offence provisions are contained in Part 2, Divisions 3 and 6 and Schedule 2 of the proposed Regulation.

5.1.2 Licence conditions

The proposed Regulation migrates to the Regulation a condition currently specified on radiation management licences. This is the requirement for a licensee to comply with the ‘responsible person’ obligations under the ARPANSA Codes of Practice adopted by the EPA that are relevant to the licensee’s radiation practice. However, the condition as prescribed in the proposed Regulation does not include the obligations relating to safety assessments as outlined in cl 3.1.19 of the *Code for Radiation Protection in Planned Exposure Situations* (PEC). The change makes the requirement more visible to the public. Because the condition is currently specified on radiation management licences, licence holders’ obligations do not change.

The relevant provision is contained in section 10 of the proposed Regulation.

5.1.3 Other

Approval of courses

The proposed Regulation prescribes and formalises the process of applications for, and EPA approval of, courses for licensing, accreditation and exemption purposes. It specifies the power to impose conditions on the approval of a course, and also to charge a fee for the approval, to help recover the costs associated with administering the licensing and accreditation system.

Relevant provisions are contained in Part 2, Division 5 of the proposed Regulation.

CRE accreditations

A small number of CRE (consulting radiation expert) accreditations have been issued without an applicable expiry date. All CRE accreditations that do not have a renewal date will expire 6 months from the commencement of the remade Regulation and will need to be renewed.

Relevant provisions are contained in section 73 of the proposed Regulation.

5.2 Workplace radiation safety protections and practices

The Regulation prescribes limits for the amount of radiation that an occupationally exposed person may be exposed to, and other workplace safety obligations.

The proposed Regulation will strengthen workplace safety obligations by:

- requiring preparation of a radiation management plan
- clarifying occupational dose limits
- clarifying the requirements relating to supplying occupationally exposed persons with personal dose monitoring.

5.2.1 Preparation of radiation management plans

The proposed Regulation requires that all radiation management licence (RML) holders who undertake radiation practices must prepare or adopt a radiation management plan (RMP). The plan must be consistent with the requirements for plans outlined in national codes published by ARPANSA and adopted by the EPA.

Not all radiation practices are encompassed by RMLs (for example, mining and milling activities). Nevertheless, these practices may expose workers to radiation and pollute the environment. The

proposed Regulation will retain an existing option for the EPA and the Department of Primary Industries and Regional Development to direct an employer (who is not a licence holder) to prepare and submit a RMP for approval.

The Planned Exposure Code sets out general requirements for RMPs. The Medical Exposure Code and other practice specific codes published by ARPANSA set out specific requirements for RMPs relevant to these practices.

An RMP should:

- detail the necessary background and operational information for working with radiation in a safe and secure way and how an organisation will manage the equipment and risks associated with radiation
- identify the radiation incidents that could happen and detail the processes and procedures in place to minimise the potential hazards
- be readily available and easily understood by all people working with or around the radiation sources in the radiation practice
- be regularly reviewed and updated whenever any changes have occurred.

The proposed change for RML holders will formalise the requirement by requiring organisations to prepare an RMP within 12 months following the commencement of the remade Regulation.

This is a significant safety reform that forefronts the role of organisations responsible for radiation practices to plan for radiation safety and supports other reforms in the proposed Regulation outlined in this RIS. This change will bring NSW into line with other Australian jurisdictions that already require preparation of RMPs.

Stakeholders consulted were supportive of this change. The EPA will enforce requirements for RMPs.

The EPA plans to publish RMP templates for lower-risk practices (e.g. dental, veterinary and chiropractic) that will help streamline the plan preparation process for an estimated 80% of accountable parties holding RMLs. Many organisations, particularly in the health sphere, already prepare plans voluntarily. Licensees will need to review such plans to ensure they meet the requirements of relevant national codes.

The relevant provisions are contained in section 11 and section 47 of the proposed Regulation.

5.2.2 Personal monitoring devices

The current Regulation has many safety provisions aimed at minimising occupational exposure to radiation. Examples are those that apply to:

- operator training
- equipment safety compliance
- shielding and safety clothing
- occupational exposure limits
- monitoring of personal exposure.

Personal monitoring devices (PMDs) detect and record an accumulated radiation dose over a set period. The PMD is then sent to the dosimetry service provider for analysis and the measured accumulated dose is reported to the employer.

The current Regulation states that an employer must provide approved PMDs to all occupationally exposed persons, in specified occupations with an elevated risk of radiation exposure, who are ‘involved in the use of ionising radiation’.

Some stakeholders have asked for the phrase ‘involved in the use of ionising radiation’ to be clarified. In the proposed Regulation, this phrase is defined as ‘using ionising radiation, or being within two metres of the source of the radiation or the primary beam of the radiation.’

The amendment should provide more certainty for employers about which employees are required to wear a PMD.

Some members of the Radiation Advisory Council suggested that dosimetry should only be required where the person’s exposure is likely to exceed a threshold (for example, 1 mSv – the annual exposure limit for a member of the public). Occupational exposure in radiation practices conducted in NSW is typically low. Nevertheless, the EPA considers that providing dosimetry based on occupational categories, rather than ‘likely’ exposure, gives occupationally exposed workers greater assurance, because it captures unusual or unexpected instances of exposure and provides a cumulative record of radiation exposure throughout a person’s working life. This protective and precautionary approach is appropriate, given the objectives of the NSW radiation protection framework.

The proposed Regulation also prescribes and formalises the process for the approval of PMDs, including the power to impose conditions on the approval. This change will help ensure that occupational dose monitoring from organisations supplying PMDs and personal monitoring services is reliable.

Occupational dose limits were reviewed and updated by the Radiation Control Amendment Regulation 2021, so are not proposed to be changed. However, the notes in Schedule 5 of the current Regulation relating to considerations for calculating dose limits are clarified as being regulatory requirements in the proposed Regulation.

Relevant provisions are contained in Part 4, Division 2 and Schedule 4 of the proposed Regulation.

5.3 Incident reporting

The current Regulation requires certain occurrences defined as ‘radiation accidents’ to be reported to the EPA.

The proposed Regulation makes these changes:

- Adopting the terminology ‘radiation incident’ rather than ‘radiation accident’. An ARPANSA Advisory Note (ARPANSA 2020) suggests ‘incident’ be used when referring to an accident or unauthorised act, as this terminology is most compatible with national codes and reporting and international best practice in radiation protection.
- Aligning radiation accident definitions in the Regulation more closely with the definitions of reportable ‘radiation incidents’ in the *National Directory for Radiation Protection*. This will ensure reporting captures the range of incidents that may occur, and help harmonise reporting nationally.
- Including as a reportable ‘radiation incident’ an unplanned exposure to an embryo or foetus as a result of a planned exposure to a person who is unknowingly pregnant at the time of the exposure. This issue was raised by stakeholders.

- Including as a reportable ‘radiation incident’ the administration of radiation for diagnostic or interventional purposes that results in an unanticipated or unexpected observable acute radiation effect.
- Refining the threshold and criteria for incidents that must be reported to the EPA. This is to reduce the reporting of minor incidents that cause very low exposures and enable the EPA to take a more risk-based approach in responding to reportable incidents.
- Requiring reports relevant to medical incidents to include the
 - name of the person who prescribed the dose of radiation leading to the radiation incident
 - name of the person who administered the dose of radiation leading to the radiation incident.
- Requiring dose calculations for certain incidents to be made by a medical physicist.
- Introducing a power that enables the EPA to request a copy of a record about an incident.
- Specifying a time limit within which the particulars of the steps taken to reduce the risk of a ‘radiation incident’ recurring must be reported to the EPA as part of the duty to report and investigate a radiation incident occurrence.

Relevant provisions are contained Part 4, Division 4 of the proposed Regulation.

5.4 Protection of public health from artificial ultraviolet radiation

In 2014, the NSW Government introduced Australia’s first prohibition on providing commercial cosmetic ultraviolet (UV) tanning services.

The tanning services ban has removed commercial tanning services from the retail business sector (such as in gyms, beauty shops and specialised tanning businesses). However, it is alleged that tanning operations continue to operate illegally, particularly from residential premises promoted by word of mouth and social media. These have presented enforcement challenges.

The proposed Regulation strengthens the ban by making it simpler to administer and more readily enforceable, including by:

- removing potential ambiguities – for example, where a tanning service is provided in connection with goods (not just other services) or in connection with another benefit, including the membership of a club, association or other body, or where services are provided for purported ‘medical purposes’
- capturing all UV-emitting radiation apparatus designed to produce tanning of the human skin, including those combining UV and red light (so-called ‘collariums’).

Stakeholders consulted indicated support for the strengthening of the offence.

Relevant provisions are contained in section 61 of the proposed Regulation.

5.5 Effective operation of the Act

5.5.1 Fees

The Regulation sets fees payable to the EPA for radiation licences, accreditations and other purposes, and how fees are increased annually. The current Regulation calculates fee increases according to changes in the public sector wage price index (PSWPI). The preferred approach in the proposed Regulation is to replace the PSWPI with the consumer price index (CPI). This would be consistent with how government fees are calculated in other legislation.

Other fee changes in the proposed Regulation

- Introducing a fee for the approval of a radiation safety course for the purposes of licences, accreditations and exemptions.
- Removing the fee charged for varying a radiation management licence. (In most cases, the licensee can make this variation themselves through the EPA e-Connect portal.)
- Removing the fee for a radiation management licence that only authorises the selling of regulated material. A radiation management licence authorises the range of dealings, including selling regulated material, so a separate fee and 'sell only' licence class is not needed.
- Increasing the accreditation fee for consulting radiation experts, to help recover the costs of administering an enhanced compliance audit program.
- Increasing the base fee for a radiation management licence, to recover administration and compliance costs of regulating radiation practices.
- Removing the accreditation fee for radiation security assessors. This change that aligns with the radiation regulatory framework in Victoria, which is the only other Australian jurisdiction that accredits assessors. Victoria does not charge a fee for accreditation, which attracts assessors to that market.

Relevant provisions are contained in section 65 and Schedule 3 of the proposed Regulation.

5.5.2 Classification of laboratories

Premises where unsealed radioactive substances are kept or used are licensed under a radiation management licence. These premises (generally laboratories at hospitals and universities) must be classified in the interests of radiation safety into three categories (high, medium and low level). Classification is achieved by referring to Schedule 2 of the current Regulation, which adapts the classification scheme for laboratories in *Australia Standard AS2243.4-2018: Safety in Laboratories – Part 4: Ionising radiations*.²⁰

Instead of adapting the Standard's classification scheme, the proposed Regulation directly references the Standard and requires the classification of a laboratory be determined in accordance with the methodology outlined in the Standard to ensure that all factors for classifying laboratories are accounted for and considered.

The relevant provision is contained in section 66 of the proposed Regulation.

²⁰ https://www.intertekinform.com/en-au/standards/as-nzs-2243-4-2018-98890_saig_as_as_207956/

5.5.3 Maximum penalties

Currently, the maximum penalties against breaches of the current Regulation range up to 400 penalty units for a corporation, and up to 200 penalty units for an individual, depending upon the offence. The proposed Regulation increases the maximum penalties for all offences. The increases are designed to deter offending behaviour and are proportionate to the harm that breaches of the Regulation can cause.

5.5.4 Penalty notice offences

The current Regulation states which offences against the Act and Regulation may be dealt with by a penalty notice and the amounts for penalty notice offences.

In the period from 2013 to early 2025, 24 penalty notices were issued with penalties totalling \$25,750. Ten of these notices related to offences under the Regulation.²¹

Most penalty notice amounts have not increased since 2003 when penalty notice offences were introduced for radiation offences.

Penalty notice amounts have been reviewed to ensure they account for changes in the CPI since 2003 and are sufficient to encourage compliance and deter offences. The largest increases in the proposed Regulation are for offences with a higher level of risk of harm, such as UV tanning units, which are associated with increased skin cancer risk. Additional information about the risks associated with UV tanning units can be found above in section 3.2.

Relevant provisions are contained in Schedule 6 of the proposed Regulation.

5.5.5 Delegations

The EPA has consulted with the Department of Primary Industries and Regional Development (DPIRD) to ensure the current delegations in the Regulation relating to radioactive ores on mine sites remain appropriate. A proposed change includes updating references to mining work health and safety legislation where the delegation applies.

The current delegations are substantially maintained and are enhanced by the addition of section 211 of the POEO Act, which permits DPIRD to take action on offences relating to exercise of Chapter 7 powers – for example, failing to comply with requirements made of the person under that Chapter or obstructing an authorised officer.

Relevant provisions are contained in section 67 of the proposed Regulation.

5.5.6 Other items

The Act specifies that the regulations may make provision for or with respect to guidelines to be observed in relation to financial assurances and in relation to the calculation of the amount of financial assurances. The proposed Regulation will formally adopt the EPA *Financial Assurance Policy* (EPA 2022) and *Estimating financial assurances: Guideline on Independent Assessment of Costs* (EPA 2022).

²¹ Note: two of these penalty notices were issued after the preparation of the cost-benefit analysis for this RIS

Financial assurances can be used as a 'bond' to ensure that organisations responsible for regulated material provide for its end-of-life management, avoiding situations where the management of regulated material becomes a burden on the taxpayer.

Relevant provisions are contained in section 69 of the proposed Regulation.

5.6 Security of high-activity radiation sources

The Act contains requirements for organisations responsible for high-activity ('security enhanced') radioactive sources to take measures and make plans to ensure these sources are protected from unauthorised access or malicious misuse. The Regulation details certain aspects of the measures and plans organisations must take to secure these sources.

The requirements in the Act and Regulation relating to security enhanced sources closely follow the provisions of the national *Code for the Security of Radioactive Sources* (ARPANSA 2019). They are proposed to be retained.

The Regulation contains a requirement for persons responsible for a security enhanced source to undergo an identity check. This requirement is to be retained. There will also be a new requirement for records of identity checks to be kept for up to 5 years. A failure to keep records is an offence and makes the person responsible liable for regulatory action. This minor additional record-keeping requirement will enhance accountability and the regulatory oversight of the identity checking provision.

Relevant provisions are contained in Part 3, Division 4 of the proposed Regulation.

6 Costs and benefits

This chapter describes the impacts of the options outlined in Chapters 4 and 5. It assesses the expected impacts of the two options against the base case (remaking the current Regulation without change).

Option 1 is to let the current Regulation lapse and not replace it. Option 2 is to replace the current Regulation with the proposed Regulation.

The EPA engaged ACIL Allen to conduct a cost-benefit analysis (CBA) for the review of the current Regulation. A modelling period of 10 years (2025 to 2034) was selected for the assessment. A discount rate of 5% per annum has been used for the analysis with sensitivity testing at 3% and 7% (low and high respectively), in line with the *NSW Treasury Guidelines: Cost-Benefit Analysis* (NSW Treasury, n.d.).

A CBA is an analytical tool used to quantitatively assess the costs and benefits of regulatory proposals to identify the option with the highest net benefit. However, sometimes it is difficult to quantify all outcomes and net benefit is not always the most accurate representation of the best outcome for the community; for example, it is difficult to determine the quantitative health benefits of changes to personal dose monitoring, radiation management plans and other changes that address radiation exposure below 100 mSv (see discussion of the 'linear no-threshold hypothesis' above in section 3.1.1) and the quantitative incremental benefit of changes to the existing ban on UV tanning services.

For the purposes of the impact analysis, changes that could be quantified are included in *Part 2: licensing and accreditation* and *Part 4: radiation safety and public health*.

6.1 Impacts of remaking the Regulation without change – the base case (status quo)

This option involves remaking the 2013 Regulation without any changes.

The costs and benefits for the base case do not need to be calculated for this analysis. The base case does not have a net present value (NPV) or benefit–cost ratio (BCR) because it is the baseline.

6.2 Impacts of no Regulation (Option 1)

The 2012 RIS assessed the impacts of making the Radiation Control Regulation 2013 (the 2012 RIS) and examined the costs and benefits of the then proposed Regulation (now the Protection from Harmful Radiation Regulation 2013), compared to no Regulation.

The 2012 RIS estimated:

- the one-off and ongoing benefits associated with the 2013 Regulation – \$1,922,000 and \$17,824,000 in NPV (over a 5-year period using a 7% discount rate) in \$2012, respectively
- the costs of the 2013 Regulation (compared to no Regulation) to be \$110,963 in NPV (over a 5-year period using a 7% discount rate) in \$2012.

The estimates provided in the 2012 RIS have been incorporated into this analysis by converting to \$2024, adjusting time frames to 10 years, adjusting discount rates and adjusting for population growth.

Table 6.1 shows the one-off costs, annual costs and annual benefits (and the parties to which they accrue) associated with the Regulation included in the 2012 RIS. The last 3 columns show the annual costs and benefits and NPV of the proposed Regulation adjusted in line with the above.

Table 6.1 Costs and benefits of Option 1 (no Regulation) compared to the base case (current Regulation)

Category	Item	Party accruing to	One-off costs (\$2012)	Annual costs (\$2012)	Annual benefits (\$2012)	Annual costs (\$2024)	Annual benefits (\$2024)	NPV (\$2024)
Security enhanced sources	Security and background costs	Industry		\$74,000	-	\$119,360	-	-\$1,045,991
	Develop transport security plans	Industry	\$285,000	-	-	-	-	-
	Vehicle upgrades	Industry	\$116,000	-	-	-	-	-
	Implementing security code	Industry	\$1,495,000	-	-	-	-	-
Training costs	Training costs	EPA	\$26,000	\$3,400	-	\$5,484	-	-\$48,059
Licensing cost	Licence application costs	Industry	-	\$292,000	-	\$470,990	-	-\$4,127,411
Regulatory cost to the EPA	Assumed cost (2012)	EPA		\$557,471	-	\$899,189	-	-\$7,879,356
Avoided administration costs to industry and regulatory costs to EPA	Avoided EPA costs	EPA	-	-	\$402,000	-	\$648,417	\$5,682,273
	Avoided Industry costs	Industry	-	-	\$100,000	-	\$161,298	\$1,413,501
Solaria provisions	Morbidity*	Society	-	-	\$640,000	-	\$1.32,306	\$9,046,404
	Mortality*	Society	-	-	\$36,600,000	-	\$59,035,014	\$517,341,247

* Based on the results from the end of the 2012 RIS time frame, as the 2012 RIS expected savings to ramp up at the end of the time period.

Note: Negative figures in NPV column represent a cost of the base case (benefit of Option 1) and positive figures represent a benefit of the base case (cost of Option 1).

Source: ACIL Allen analysis of *Regulatory Impact Statement: Proposed Radiation Control Regulation 2012*

The 2012 RIS allocated grouped costs and cost savings into 2 categories: industry and the EPA. Additional benefits, such as reduced misuse and the solaria provisions, can be said to accrue to the community. The probabilities of misuse used in the 2012 RIS were illustrative only but reflect the potential ongoing benefits of avoiding misuse.

The costs and benefits to industry, the EPA and society of Option 1 are shown in **Table 6.2**. Option 1 would have lower costs for industry and the EPA, but at a larger cost to the community.

Table 6.2 Costs and benefits of Option 1 relative to the base case distributional analysis (\$2024)

	Industry	EPA	Society	Total
Costs	\$1,413,501	\$5,682,273	\$526,387,652	\$533,483,425
Benefits	\$5,173,412	\$7,927,915	\$0	\$13,101,328
Net benefit	\$3,759,912	\$2,245,643	-\$526,387,652	-\$520,382,097
BCR	3.66	1.40	N/A	0.02

Source: ACIL Allen analysis of *Regulatory Impact Statement: Proposed Radiation Control Regulation 2012*. Figures to nearest dollar.

Costs and benefits

The costs of Option 1 would be an increase in the risk to human health and safety and the environment from exposure to ionising and harmful non-ionising radiation (or the loss of the ongoing benefits associated with the 2013 Regulation).

Based on the estimated 2024 figures in **Table 6.2**, the present value costs (or foregone benefits) of Option 1 would be approximately \$533.5 million (over a 10-year period using a 5% discount rate) in \$2024. These are offset by present value benefits of \$13.1 million making for a quantifiable net present value of -\$520.4 million.

The non-quantifiable costs (foregone non-quantifiable benefits) from Option 1 would be reduced regulatory oversight and an increased risk of misuse or incorrect disposal of radioactive material. Misuse and incorrect disposal can have high associated costs (including damage to human health) as the examples in **Figure 6.1** show.

EPA v Universal Dye Works Pty Ltd

In 2016, a scrap metal yard detected a radiation source at its weigh station. An investigation found that a textile company had negligently disposed of the source during a site demolition. The EPA learned that this source had been imported without permit, was never registered with the EPA, and did not have safety compliance certification. The company disposed of it without consent. The EPA prosecuted the company, which was ordered to pay for the source's disposal in an overseas facility.

Scrap metal export to Thailand

Thai authorities found that an export shipment of scrap metal from Australia contained a radioactive source. The EPA determined that the source was likely from an industrial gauge that had been accidentally disposed of but could not identify the original owner. The exporter had to pay a \$350,000 recovery bill and the EPA incurred steep investigation costs.

WA orphan source incident (Bourke 2023)

In January 2023, Rio Tinto lost a small 6 mm by 8 mm radioactive capsule containing caesium-137 on a road between a mine in the Pilbara and Perth. A search was conducted from 27 January until it was found on 1 February. The precise cost of the search has not been publicly released but Rio Tinto made a \$4 million donation to the WA Government.

University of Washington sealed source incident (Kamen et al. 2023)

In 2019, a contractor at the University of Washington mishandled a large store of caesium-137, causing the contamination of 7 floors of the research building and 13 people. The clean-up cost was estimated to be \$150 million in USD.

Figure 6.1 Misuse and incorrect disposal of radioactive material – case studies

The benefits of Option 1 (no Regulation) would be:

- elimination/reduction of compliance and administrative costs for stakeholders who currently must comply with the Regulation
- reduced regulatory costs for the NSW Government in administering the regulatory regime, including administrative, monitoring and enforcement costs.

Based on the estimated 2024 figures in **Table 6.2**, the quantifiable benefits (or avoided costs) of Option 1 (shown as negative figures in last column) would be around \$13.1 million in NPV (over a 10-year period using a 5% discount rate) in \$2024.

6.3 Impacts of the proposed Regulation (Option 2)

This section assesses the impacts of the proposed Regulation (Option 2) compared to continuing with the current Regulation (base case) for each of the main categories of proposed changes described in Chapter 5.

6.3.1 Part 1: Preliminary

The proposed changes to *Part 1: Preliminary* are to terminology only so there are no expected costs or benefits.

6.3.2 Part 2: Licensing and accreditation

The main changes to licensing and accreditation are:

- changes to who is exempt from holding a radiation user licence
- giving force to codes of practice published by ARPANSA and to Australian Standards
- new offences
- new supervision requirements
- shifting obligations from licence conditions to Regulation provisions.

These proposed changes and their estimated impacts are discussed below.

6.3.2.1 Exemption from holding a radiation user licence

Under the proposed Regulation, veterinary nurses, technicians and technologists, and most dental practitioners and dental assistants will be exempt from holding a radiation user licence (RUL). Certain medical registrars performing medical fluoroscopy who are currently exempt will require a RUL.

Allowing for increases in the demand for RULs each year based on population growth, and allowing for a reduction in licences for exempt users, the proposed Regulation will decrease the annual number of new applications and renewals for RULs. These transactions are expected to reduce by about 2,400 in 2026 compared to the base case, and then by about a further 35 in each subsequent year.

Costs and benefits

Table 6.3 shows the estimated net benefit from changes to radiation user licences and **Table 6.4** shows the net present value from the reduction in fees from changes in radiation user licences (where negative values represent a decrease in total fees).

Table 6.3 Net benefit – changes to radiation user licences \$2024

	Nature of change	Type	Distribution category	NPV
Benefits	Change in applications (compliance)	Vet nurses, technicians and technologists' inclusion	Dental, veterinary and chiropractic	\$25,586
		Authorised officers' inclusion	Other government (EPA)	\$120,286
		Dental practitioners' inclusion	Dental, veterinary and chiropractic	\$1,039,029
		Dental assistants' inclusion	Dental, veterinary and chiropractic	\$33,815
	Change in approvals (administration)	Reduction in RUL approvals (EPA)	Other government (EPA)	\$218,750
Subtotal				\$1,437,467
Costs	Change in training (compliance)	Medical fluoroscopy training costs	Hospital and Medical imaging	\$1,332,383
	Change in applications (compliance)	Medical fluoroscopy exemption exclusion	Hospital and Medical imaging	\$103,544
Subtotal				\$1,435,927
NPV				\$1,540
BCR				1.00

Source: ACIL Allen. Figures to nearest dollar.

Table 6.4 Changes in fees (present value terms) \$2024

Type	Distribution category	NPV5**
Medical fluoroscopy exemption exclusion	Hospital and Medical imaging	\$635,343
Veterinary nurses, technicians and technologists inclusion	Dental, veterinary and chiropractic	-\$398,449
Authorised officer inclusion*	Other government (EPA)	\$0
Dental practitioners	Dental, veterinary and chiropractic	-\$4,525,321
Dental assistants	Dental, veterinary and chiropractic	-\$454,103
EPA change in revenue	Other government (EPA)	\$4,742,530

* Fees were not collected for authorised officer licences.

** Net present value at 5% discount rate

Source: ACIL Allen. Figures to nearest dollar.

Costs include:

- the costs of applying for and processing a licence (and hence the cost savings from a licence exemption)
- the cost of completing an application
- the cost to approve an application
- licence fees (a transfer of cost from industry to the EPA)
- additional training costs for medical fluoroscopy (the cost of the training course and the registrar's time spent training).

The reductions in fees are neither economic costs nor benefits, as they represent a transfer from industry to the EPA; however, they are impacts that will be felt by stakeholders. The largest fee savings come from the exclusion of dental practitioners, with that industry sector saving about \$4.5 million over the period in present value terms. Overall industry savings are approximately \$4.7 million.

Benefits include a reduction in the number of licence applications and approvals and a reduction in compliance costs. The easing of licensing requirements recognises the low-risk and low exposure levels of the procedures being performed while the new licensing requirement for medical fluoroscopy recognises the potentially higher-risk and higher exposure nature of such procedures. While the overall number of licensees will go down, it is expected there will be an overall improvement in safety with the inclusion of licensing and training for medical fluoroscopy, which will lower the regulatory burden.

Conclusion

The proposed Regulation will result in a small net benefit of \$1,540 NPV, with net benefits slightly higher than net costs. The largest saving will be from increased licensing exemptions (particularly those of dental practitioners and dental assistants). This will be largely offset by the cost of increased licensing and training obligations for medical fluoroscopy.

While the quantified costs of this change only narrowly outweigh the benefits, when considered alongside the strengthened safety procedures for medical fluoroscopy, it is expected the changes will have a net benefit.

6.3.2.2 Giving force to codes of practice published by ARPANSA and Australian Standards

This change will make it an obligation of exemptions for:

- medical registrars in training to comply with the operator requirements in the *Code for Radiation Protection in Medical Exposure* (ARPANSA 2019)
- students in medical radiation practice training in diagnostic radiography, nuclear medicine or radiation therapy to comply with the operator requirements in the *Code for Radiation Protection in Medical Exposure* (ARPANSA 2019)
- students in chiropractic practice to comply with the operator requirements in the *Code of Practice for Radiation Protection in the Application of Ionizing Radiation by Chiropractors* (ARPANSA 2009)
- veterinary students and persons assisting veterinarians (veterinary nurses, technologists and technicians) to comply with the operator requirements in the *Code of Practice & Safety Guide for Radiation Protection in Veterinary Medicine* (ARPANSA 2009)
- assistants to industrial radiographers to comply with the operator requirements in the *Code of Radiation Protection Requirements for Industrial Radiography* (ARPANSA 2018)
- registered nurses and medical practitioners at a hospital who are exempt if injecting diagnostic radiopharmaceuticals in particular circumstances to comply with the requirements applicable to the operator in the *Code for Radiation Protection in Medical Exposure* (ARPANSA 2019)
- undergraduate students, vocational students, postgraduate students and other persons undertaking courses for licensing or exemption purposes whose course work or research involve the use of portable density/moisture gauges containing radioactive sources to comply with the

operator requirements in the *Code of Practice and Safety Guide for Portable Density/Moisture Gauges containing Radioactive Sources* (ARPANSA 2004)

- undergraduate students, vocational students and postgraduate students whose course work or research involve the use of regulated material in laboratory situations to comply with the Standards Australia publication *AS/NZS 2243.4:2018 Safety in laboratories Part 4: Ionizing radiations*
- dental practitioners and dental students to comply with the relevant requirements in the *Code for Radiation Protection in Dental Exposure* (ARPANSA 2025).

Costs and benefits

While the costs and benefits of these changes cannot be quantified, stakeholders thought they were appropriate.

Stakeholders suggested that the compliance cost of these changes would be very low, and that any such cost was merely the cost of best practice, as practitioners already understand and follow the codes.

Conclusion

By incorporating ARPANSA's codes of practice and the relevant Australian Standards into the Regulation, the EPA will be able to enforce best practice. In preliminary consultations, stakeholders suggested that this was an appropriate way to ensure that practitioners were able to meet best practice. Any additional compliance and enforcement cost for achieving best practice should be exceeded by the benefits of protecting human health and the environment.

6.3.2.3 Machinery regulation changes

There are no expected costs or benefits of this change.

6.3.2.4 New offences

The new offences proposed under the proposed Regulation aim to strengthen the enforceability of the existing requirements.

For example, where someone claims an exemption from user licensing, there is a new legal obligation for the RML holder to ensure that this exempt person (the user) is appropriately qualified or enrolled in a course and supervised. There is also a new offence for supervisors who fail to provide appropriate supervision. Additionally, there is a new offence for an exempt person who fails to observe safety obligations.

With regards to the security of high-activity radiation sources, there is a new legal obligation for the person responsible to keep records of identity checks.

Costs and benefits

The new proposed offences are not considered a cost of Option 2 because non-compliance costs (including fines for failing to comply with a regulation and legal fees, including costs incurred in court and tribunal processes) are avoidable, and so are not considered a regulatory burden (OIA 2022).

It is expected that this change will increase compliance among RML holders, supervisors and users exempt from licensing, which in turn will lower the risk of radiation incidents occurring.

Conclusion

As there is expected to be increased compliance, and the cost of compliance is not considered a cost for the purpose of this analysis, it is expected that this change will result in a net benefit.

6.3.2.5 New supervision requirements

Supervision changes in Part 2 include the introduction of a new ‘indirect’ supervision requirement for diagnostic radiography students in the final year of their studies. Indirect supervision is characterised as falling between general supervision (which only requires the supervisor to ensure that proper processes are followed) and immediate supervision (which requires the supervisor to be present at all times when an exempt person is using regulated material).

Costs and benefits

The introduction of new supervision requirements may put additional obligations on the supervisors in some situations. In the case of indirect supervision, this will require intermittent attendance and a consistent availability throughout regulated procedures. Some stakeholders raised concerns that in-person supervision can be difficult in regional areas where doctors may not be readily available.

Conclusion

While there is limited evidence to suggest there have been any incidents caused by a lack of supervision, stakeholders consulted suggested that the new requirements are sensible, balancing safety with additional regulatory burden.

6.3.2.6 Shifting obligations from licence conditions to the Regulation

This change gives the EPA more power to enforce compliance with existing licence conditions. However, it does not change the obligations of industry and practitioners. To the extent that this change may improve compliance with the Regulation, it is beneficial overall.

6.3.3 Part 3: Security of radioactive sources

The only proposed change to Part 3 of the Regulation relevant to the impact assessment is the introduction of a new section requiring that persons responsible for a security enhanced source maintain records of identity checks for 5 years. This is not expected to result in additional compliance cost but will provide a ‘paper trail’ that can be followed in the event of non-compliance and is expected to create a stronger incentive for responsible persons to ensure compliance.

6.3.4 Part 4: Radiation safety and public health

The main changes proposed to Part 4 of the Regulation, Radiation safety and public health include:

- an increase in penalties
- stronger workplace radiation safety protections and practices, including the requirement for all radiation management licensees to prepare a radiation management plan (RMP)
- updated protections for occupationally exposed persons and members of the public
- changes to incident reporting
- changes to definitions
- a clearer, more enforceable ban on commercial UV tanning services.

These are discussed below.

6.3.4.1 Requirement to prepare a radiation management plan (RMP)

Under the proposed regulation, **all** RML holders would have to prepare a RMP. This is a new requirement.

Some organisations (such as medical imaging facilities, large industrial users and hospitals) already have such plans in place. An estimate of the number of existing RMPs for each industry suggests that most are in the medical imaging sector and large industry. In the base case, with no additional requirement to prepare an RMP, it's estimated there would be about 400 RMPs in 2026. As the population grows, so too will the number of medical imaging facilities, hospitals and large industrial users. As a result, even under the base case, the number of RMPs is projected to rise to 445 in 2035.

Under the proposed Regulation, every organisation with an RML is expected to prepare an RMP. Organisations that have not prepared an RMP before will be required to prepare one in 2026. After that, only new RML holders will need to prepare one. The estimated numbers of **additional** RMPs per year are shown in **Table 6.5**. These numbers include new RMPs prepared by new RML holders in the medical imaging, large industrial and hospital sectors – that is, these numbers take into account how these sectors will grow as the population grows.

Table 6.5 Proposed Regulation, new radiation management plans prepared every year

Licences	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Dental	1,978	27	26	25	23	22	21	21	20	20
Veterinary	261	4	3	3	3	3	3	3	3	3
Chiropractic	98	1	1	1	1	1	1	1	1	1
Security screening	98	1	1	1	1	1	1	1	1	1
Medical imaging	2	2	2	2	2	2	2	2	2	2
Industrial small (<= 5 RM*)	326	4	4	4	4	4	4	3	3	3
Industrial large (> 5 RM)	2	2	2	2	2	2	1	1	1	1
Hospital	1	1	1	1	1	1	1	1	1	1
Sell only	98	1	1	1	1	1	1	1	1	1

* RM refers to number of items of regulated material linked to each licence

Source: ACIL Allen analysis of NSW EPA data and NSW population projections (ABS)

Costs and benefits

It is expected that the costs of a new RMP will be limited to the costs of creating a new plan (i.e. the cost of compliance). It is not expected that the EPA will review plans (except plans it has directed be prepared). As a result, there will be no additional material administration cost associated with this regulatory change.

The cost of compliance is expected to depend on how complex the plan is, which in turn will depend on how large and complex the organisation is. The EPA will develop templates to help lower-risk practices develop RMPs, to speed up the process for them. Further, businesses that already have a plan will only need to spend a small amount of time checking that it is compliant.

The cost-benefit results of this change under Option 2 (relative to the base case) are shown in **Table 6.6**. This table shows that the greatest cost is to the dental, veterinary and chiropractic group, which contains over 70% of RMLs. This group will benefit from the EPA templates.

Introducing a requirement for a RMP is expected to reduce exposure to harmful radiation, but this impact can't be quantified. This is because, for doses below 100 mSv, ARPANSA reports there is insufficient evidence to describe the impact on human health (ARPANSA 2015). However, clarifying policies and procedures will help organisations better prevent and respond to incidents.

Table 6.6 Net impact: requirement to prepare a radiation management plan 2026–35 (\$2024)

	NPV3	NPV5	NPV7
Community	\$0	\$0	\$0
Dental, veterinary and chiropractic	-\$606,751	-\$591,113	-\$576,553
Security, industrial	-\$139,550	-\$135,696	-\$132,131
Hospital and Medical imaging	-\$5,683	-\$5,176	-\$4,737
University and research	-\$284	-\$258	-\$236
Other government (EPA)	\$0	\$0	\$0
Total	-\$752,268	-\$732,244	-\$713,656

Source: ACIL Allen analysis of EPA data. Figures to nearest dollar.

NPV3, NPV5 and NPV7 represent discount values of 3%, 5% and 7% over 10 years used for sensitivity testing, with 5% being the accepted discount rate

Conclusion

The Commonwealth Office of Impact Assessment publishes the value of a statistical life (VSL) and value of a statistical life year (VLY) (OIA 2023). The VSL is based on the value society places on reducing the risk of dying. In this case, the life is assumed to be of a young adult with 40 years of life ahead. At the time of preparing this economic analysis it was estimated to be \$5.6 million (in \$2024). This is substantially larger than the cost of radiation management plans over the period.

The VLY is a related concept and refers to the value of one year of life. This is estimated to be \$245,172 (in \$2024). While an estimate is not formally included in this model, RMPs will only need to save approximately 3 life years over the period to fully offset the costs of this proposed reform.

Given these VYL values are low relative to the net cost of the changes, it is expected that the changes will produce a net benefit.

6.3.4.2 Changes to incident reporting

There were 588 incidents reported to the EPA in 2023 and 2024 (an average 294 per year):

- 309 in radiology
- 164 in radiation oncology
- 113 in nuclear medicine
- 5 classified as 'other'.

Assuming that 75% of these accidents were reported by a medical physicist, and assuming that 25% of all incidents were major, those that were not major would be considered minor. Major incidents include exposures involving a therapeutic dose of radiation, a dose of radiation for interventional purposes, or unplanned exposure of an embryo or foetus.

Table 6.7 shows these values projected into the future.

Table 6.7 Status quo (base case) – total number of radiation incidents reported by medical physicists

Licences	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Reportable incidents (Medical physics specialist, minor)	170	172	174	176	178	180	182	184	186	187
Reportable incidents (Medical physics specialist, major)	57	57	58	59	59	60	61	61	62	62
Reportable incidents (RSO, minor)	57	57	58	59	59	60	61	61	62	62
Reportable incidents (RSO, major)	19	19	19	20	20	20	20	20	21	21

NOTE: Numbers may not align exactly with the table above due to rounding.

Source: ACIL Allen analysis of NSW EPA data and NSW population projections (ABS)

Under the proposed Regulation, radiation exposure for all major incidents will have to be calculated by a medical physicist. Table 6.8 shows the number of incidents reportable by a medical physics specialist under the base case but highlights in blue the cases where a medical physics specialist would be required. It shows that an additional 6.25% of incidents would be reported by a medical physicist, bringing the total to 81.25%.

Table 6.8 Major and minor incidents reported by a medical physics specialist or otherwise (2024)

	Major (25%)	Minor (75%)
Currently reported by medical physics specialist (75%)	18.75%	56.25%
Not currently reported by medical physics specialist (25%)	6.25%	18.75%

Source: ACIL Allen based on EPA advice

While there are some changes to the way incidents are reported (in particular, the reportable thresholds), there is no change to the total volume expected.

Table 6.9 shows the total number of incidents reported by medical physicists for Option 2, projected into the future.

Table 6.9 Option 2 – total number of incidents reported by medical physicists

Incidents	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Reportable incidents (medical physics specialist, minor)	170	172	174	176	178	180	182	184	186	187
Reportable incidents (medical physics specialist, major)	75	76	77	78	79	80	81	82	82	83
Reportable incidents (RSO, minor)	57	57	58	59	59	60	61	61	62	62
Reportable incidents (RSO, major)	0	0	0	0	0	0	0	0	0	0

NOTE: Numbers may not align exactly with the table above due to rounding.

Source: ACIL Allen analysis of NSW EPA data and NSW population projections (ABS)

Costs and benefits

Radiation exposure from an incident is calculated by either medical physics specialists or radiation safety officers. The proposed Regulation will see more calculations done by medical physics specialists. The only change in costs will be the difference in cost of a medical physics specialist's time and the cost of a radiation safety officer. It is estimated that a radiation safety officer earns \$92,183 per year while the average medical physics specialist earns \$201,324 per year.^{22,23} Including the standard NSW Government on-costs of 22.6%, the rate per hour is \$61 and \$134, respectively.

The results of the cost-benefit analysis for this change are shown in **Table 6.10**, with an estimated net cost to the NSW economy of \$123,210 over the 10-year period.

Table 6.10 Net impact of changes to incident reporting 2026–35 (\$2024)

Net benefit	NPV3	NPV5	NPV7
Community	\$0	\$0	\$0
Dental, veterinary and chiropractic	-\$97,764	-\$88,281	-\$80,106
Security, Industrial	-\$24,560	-\$22,178	-\$20,124
Hospital and Medical imaging	-\$9,551	-\$8,625	-\$7,826
University and research	-\$4,570	-\$4,127	-\$3,744
Other government (EPA)	\$0	\$0	\$0
Total	-\$136,444	-\$123,210	-\$111,800

Source: ACIL Allen analysis of EPA data. Figures to nearest dollar.

Conclusion

The costs of the changes to incident reporting are modest compared to the expected benefits. It is expected that medical physics specialists will calculate exposure more accurately, which will help other practitioners treat affected individuals more appropriately, improving health outcomes. More accurate exposure data can also strengthen the EPA's awareness and response to emerging issues.

6.3.4.3 Changes to the requirements for personal monitoring devices

Section 29 of the current Regulation requires that an occupationally exposed person to whom an approved monitoring device has been provided in accordance with this section must wear the device while involved in the use of ionising radiation in the course of the person's employment.

It is estimated that approximately 11,067 staff are provided with a personal monitoring device (PMD) across NSW, and the devices are replaced about 4 times a year.

Under the proposed Regulation there is a new definition to clarify this requirement, which is likely to result in personnel having to wear fewer PMDs – nominally, 2% fewer than in the base case.

The estimated number of PMDs that will be issued over a 10-year period will be about 43,998 in 2026, rising to about 48,567 in 2035.

²² Radiation safety officer earnings based off the value identified at indeed.com, accessed 6 March 2024.
<https://au.indeed.com/career/radiation-safety-officer/salaries>

²³ Based on the mid-range of Table 1 of the Public Hospital Medical Physicists (State) Award 2023.
<https://www.health.nsw.gov.au/careers/conditions/Awards/hsu-ph-medical-physicists.pdf>

The cost of a PMD is about \$15 per unit, and units are replaced either monthly or quarterly.

Costs and benefits

The expectation is that there will be fewer PMDs issued; however, those who will no longer receive a PMD are expected to be those who did not need one – i.e. staff who were not in regularly in such close proximity to an ionising radiation source that they would expect that they might receive an unsafe dose of radiation. As a result, there is expected to be no adverse safety impact.

The results of the cost-benefit analysis are shown in **Table 6.11**. The benefit is large relative to the size of the assumed decrease in PMDs and accrues entirely to the hospital and medical imaging sectors. This means that larger reductions in PMDs will lead to a strong net benefit.

Table 6.11 Net impact: changes to requirements for personal monitoring devices 2026–35 (\$2024)

Net benefit	NPV3	NPV5	NPV7
Community	\$0	\$0	\$0
Dental, veterinary and chiropractic	\$0	\$0	\$0
Security screening, industrial	\$0	\$0	\$0
Hospital and Medical imaging	\$147,145	\$132,325	\$119,590
University and research	\$0	\$0	\$0
Other government (EPA)	\$0	\$0	\$0
Total	\$153,362	\$132,325	\$119,590

Source: ACIL Allen based on analysis of EPA data. Figures to nearest dollar.

The analysis assumed that there will be a 2% reduction in personal monitoring devices. The net benefit of a 1% reduction in personal monitoring devices is approximately \$63,210. This means that the overall package of reforms will break even, all else being equal, if the reduction in PMDs was about 14.7%.

Conclusion

By better targeting PMD requirements, fewer PMDs will be required without compromising safety. As there is a saving but no material cost, this change will be a net benefit.

6.3.4.4 Changes to definitions

There are no expected costs or benefits from changes to definitions.

6.3.4.5 Stricter rules around commercial UV tanning services

Under the Regulation, cosmetic tanning services are banned, except for medical purposes and when used privately in the home. There have been reports of illegal solariums operating in NSW, despite the ban.²⁴

Under the proposed Regulation, the offence has been strengthened and penalties increased. However, it is unknown how much this will decrease the number of consumers who use UV tanning units for commercial purposes despite the ban. Prior to the ban, it was estimated that 13.8% of adults

²⁴ See, for instance, Cook (2023)

aged 25–44 years used cosmetic tanning services in 2006–07, suggesting that there may be many consumers who would use cosmetic tanning services if they were available (Gordon et al. 2020).

A 2020 study from the QIMR Berghofer Medical Research Institute estimated the impact of banning commercial UV tanning units (solaria) across Australia in 2016 (Gordon et al. 2020). It reported that for UV tanning unit users under 35 years, the relative risk of developing melanoma was 1.59% and 1.56% for keratinocyte cancers. Importantly, it estimated that over a cohort of 6.95 million young Australians, the ban averted 468,249 keratinocyte cancers and 31,009 melanomas – saving Australia \$580 million (\$2018). As discussed above, it was assumed that about 13.8% of adults used commercial UV tanning services.

It is estimated that the ban reduced demand for cosmetic tanning services demand by about 951,000 users (13.8% of a cohort of 6.95 million) across Australia, resulting in a total saving of \$64 million in healthcare costs and \$516 million in productivity costs. Dividing the total benefit by the decrease in consumers using cosmetic tanning services, the ban on solaria led to an average saving of \$605 per user.

The stricter rules around commercial UV tanning services are not expected to drive large changes in the number of people using these tanning units, as they are already banned. However, the regulatory changes will reduce the ability of businesses to operate within loopholes (such as offering the use of a UV tanning unit as a ‘reward’ for buying an unrelated product).

In the analysis, no assumption was made about how many people will stop using commercial UV tanning services in NSW if the regulatory controls were changed. The net benefit of one fewer person using UV tanning services is assumed to be \$605. This means that the overall package of reforms will break even, all else being equal, if there were 1,387 fewer people who used UV tanning services.

Conclusion

Commercial UV tanning services come with a high cost, as melanoma and other cancers cost individuals and the community a significant amount in both health costs and lost productivity. As a result, tightening the prohibition is expected to drive a net benefit to NSW.

6.3.5 Part 5: Miscellaneous

The changes to Part 5 include:

- updates to the machinery of the Regulation
- guidelines about financial assurances to be adopted.

Neither are expected to lead to a material cost or benefit.

6.3.6 Schedule 2: Exemptions from licensing

These changes are not expected to have significant costs and benefits, as they pertain to activities that are deemed safe. However, modest net cost savings are likely from reducing the compliance burden on these users. Updating of the exemption covering PET scanners and apparatus used for quality control inspections may also provide a minor but unquantifiable cost saving, both by clarifying user obligations and by allowing minor reductions to regulated material or apparatus listed on relevant management licences.

As there are only minor savings associated with these changes, they are a net benefit.

6.3.7 Schedule 3 Fees

Changes in Schedule 3 relevant to the impact assessment include:

- changes to the consulting radiation expert fee
- removal of the fee for varying an RML
- a new fee for assessing a radiation safety course
- increasing the base fee for an RML by \$99 on average
- changing the indexation of fees from the public sector wage price index to the consumer price index.

6.3.7.1 Changes to the consulting radiation expert fee

The proposed Regulation will increase the fee for a consulting radiation expert, to cover the costs of administering an enhanced compliance audit program.

Costs and benefits

The proposed amendments to fees for consulting radiation experts will reflect the level of cost recovery associated with the administration of the Regulation, hence increasing allocative efficiency.²⁵

It is expected that the enhanced compliance audit program will improve the quality of consulting radiation experts and the safety of the machines they test.

There are currently about 107 licensed consulting radiation experts. Based on the increase in fee units, the distribution of fees is shown in **Table 6.12**. It shows that under Option 2, consulting radiation experts – allocated to the hospital and medical imaging sectors – will pay an increased fee of \$359,220 over the 10-year period in net present value terms.

Table 6.12 Fee distribution 2026–35 (\$2024)

	NPV3	NPV5	NPV7
Hospital and Medical imaging	-\$393,190	-\$355,311	-\$322,641

Source: ACIL Allen. Figures to nearest dollar.

Conclusion

While fees are generally considered to be transfers between industry and the government, the revenues generated by this change are used directly to fund government programs; as a result, they are costs to industry. However, it is expected that the benefit of increased compliance will outweigh the costs to industry.

6.3.7.2 Removal of fee for varying radiation management licences

It is expected that removing the fee for varying licences will save businesses \$18,256 in fees per year. Importantly, it will also save the EPA \$30,427 in administration costs (representing a true

²⁵ Allocative efficiency is achieved when the value consumers place on a good or service equals the cost of resources used up in production of that good or service. By requiring payment for goods/services provided by government, cost recovery charges can give important signals to users about the costs of the resources involved in their provision (Victorian Department of Treasury and Finance 2013, *Cost Recovery Guidelines*).

economic benefit). The net benefit is \$249,403 in the central case relative to the status quo, with further details shown in **Table 6.13**.

Table 6.13 Net benefit of removing fee for varying radiation management licences 2025–34 (\$2023)

Net benefit	NPV3	NPV5	NPV7
Lost revenue (EPA)	-\$163,794	-\$148,014	-\$134,405
Reduced costs (EPA)	\$272,989	\$246,690	\$224,008
Reduced fees (sum of below)	\$163,794	\$148,014	\$134,405
Dental, veterinary and chiropractic	\$110,015	\$99,588	\$90,584
Security, industrial	\$27,638	\$25,018	\$22,756
Hospital and Medical imaging	\$10,748	\$9,729	\$8,850
University and research	\$5,142	\$4,655	\$4,234
Total	\$272,989	\$246,690	\$224,008

Source: ACIL Allen analysis of EPA data. Figures to nearest dollar.

6.3.7.3 New fee for assessing radiation safety courses

It is expected that between 3 and 7 courses will be accredited per year, taking one hour of an EPA officer's time. This accreditation is currently taking place, but there is no fee associated with it.

The proposed Regulation includes a new fee for assessing new and existing radiation courses with respect to licensing, accreditations and exemptions under the Act or Regulation. However, as fees are payments from one party to the other, this is treated as a transfer payment rather than an economic cost. That is, fees do not represent a net cost or benefit to society, even though they represent costs and benefits to each party.

6.3.7.4 Price increase for radiation management licences

The EPA expects to raise an additional \$99 per RML because of changes to the fee schedule. As fees are payments from one party to the other, this is treated as a transfer payment rather than an economic cost. That is, fees do not represent a net cost or benefit to society, even though they represent costs and benefits to each party.

The results by stakeholder group are shown in **Table 6.14**, noting that it is assumed the average cost of a licence in each group will increase by the same \$99.

Table 6.14 Net benefit of price increases for RML licensing 2026–35 (\$2024)

Net benefit	NPV3	NPV5	NPV7
Dental, veterinary and chiropractic	-\$2,075,246	-\$1,875,321	-\$1,702,896
Security screening, Industrial	-\$521,340	-\$471,115	-\$427,799
Hospital and Medical imaging	-\$202,743	-\$183,212	-\$166,366
University and research	-\$97,004	-\$87,659	-\$79,599
Other government (EPA)	\$2,896,333	\$2,617,307	\$2,376,660
Total	\$0	\$0	\$0

Source: ACIL Allen based on analysis of EPA data. Figures to nearest dollar.

6.3.8 Schedule 6 Penalty notice offences

The proposed Regulation will increase the penalties for penalty notice offences under the Act and the Regulation, to:

- reflect inflation adjustments
- reduce the rate of offending for certain offences
- ensure parity with amounts for common penalty notice offences that increased under the *Environment Protection Legislation Amendment (Stronger Regulation and Penalties) Act 2024*.

The amounts for penalty notice offences in the current Regulation have not been updated since 2013, and some date back to 2003.

Costs and benefits

Non-compliance costs are the avoidable consequence of non-compliant behaviour, so they are not considered a cost under a CBA. As a result, the proposed increases in penalties are not considered a cost of Option 2.

The proposed increases in penalty notice offences beyond inflation adjustments are intended to change behaviour (i.e. reduce the rate of offending in relation to certain offences).

The main benefit of the increases above inflation proposed for certain penalty offences will be a reduction in risks of unplanned radiation exposure. However, the extent of this benefit is unclear because it's uncertain how much increasing penalties will deter unwanted behaviour.

Nevertheless, even if increased penalties did not comprehensively change the behaviour of non-compliant persons, the benefits to the public of avoiding unplanned radiation exposure are high relative to the costs of compliance.

Conclusion

While the benefits of increasing penalties cannot be accurately quantified, any additional cost of compliance is not considered a cost for the purposes of a cost-benefit analysis. Changes to penalties should encourage compliance with the Regulation and are therefore beneficial overall.

6.4 Overall analysis: Option 2

Table 6.15 shows the net quantifiable benefit of this package of reforms relative to the base case. It shows that, when only considering the quantifiable costs and benefits, this package of reforms has an observed net present value cost of \$839,233 over 10 years in the central case (NPV 5%).

These figures assume only nominal changes as a result of personal monitoring device requirements (2% decrease in demand).

These figures also do not account for non-quantifiable health impacts from enhanced safety requirements. These include:

- improvements to radiation safety practice, as ARPANSA's code of practice and relevant Australian Standards are included in the Regulation
- enhanced compliance by RML holders, supervisors and radiation users exempt from licensing through the introduction of new offences for breaches of exemption conditions
- improved supervision of exempt practitioners

- enhanced accountability through new record-keeping requirements regarding identity checks
- increased incentive to comply with the Regulation through higher penalties
- safer procedures and practices through the implementation of RMPs
- greater accuracy in reports of radiation incidents
- a small reduction in compliance costs as a result of updating the exemption of PET scanners and apparatus used for quality control inspections
- improved compliance of consulting radiation experts as a result of the enhanced compliance auditing program.

Table 6.15 Net benefit of Option 2 compared with base case (\$2024)

	Item	NPV3	NPV5	NPV7
Benefits	Personal monitoring devices	\$147,145	\$132,325	\$119,590
	Changes in licences	\$3,627	\$1,540	-\$187
Subtotal		\$150,773	\$133,865	\$119,403
Costs	Radiation management plans	\$752,268	\$732,244	\$713,656
	Fees and penalties	\$130,451	\$117,644	\$106,614
	Reportable incidents	\$136,444	\$123,210	\$111,800
Subtotal		\$1,019,164	\$973,098	\$932,071
Total NPV		-\$868,391	-\$839,233	-\$812,668
Total BCR		0.15	0.14	0.13

Source: ACIL Allen. Figures to nearest dollar.

6.5 Comparison of Option 1 and Option 2

The costs and benefits of Option 1 (no Regulation) and Option 2 (proposed Regulation) relative to the base case (current Regulation) are shown in **Table 6.16**.

Both Option 1 and Option 2 have negative NPVs relative to the base case. However, this does not account for the impact of changes to PMDs and commercial UV tanning services, which cannot be quantified.

Table 6.16 Costs and benefits of each option

	Option 1 relative to base case	Option 2 relative to base case*
Costs	\$533,483,425	\$973,098
Benefits	\$13,101,328	\$133,865
NPV	-\$520,382,097	-\$839,233
BCR	0.02	0.14

* This does not include the impact of safety, personal monitoring devices and cosmetic tanning services

Source: ACIL Allen. Figures to nearest \$.

7 Conclusion

The following options have been considered in this RIS:

- **Base case (current Regulation)** – the base case for this impact analysis is remaking the 2013 Regulation without any changes (the status quo option).
- **Option 1 (no Regulation)** – this option entails letting the 2013 Regulation lapse and not replacing it
- **Option 2 (proposed Regulation)** – this option entails making the proposed Regulation.

Option 1 (letting the Regulation lapse/be repealed and not replacing it) is not considered appropriate because there would be a large increase in risk to the community, the Act would be less effective and, after accounting for the present values of quantifiable benefits and costs, would result in a **net present value cost to NSW of around \$520.4 million**. An impact analysis has been conducted comparing Option 1 and Option 2 to the base case of remaking the current Regulation.

The cost-benefit analysis quantified the costs and benefits for which reasonable estimates could be made. Of the changes that could be quantified, it is estimated that after accounting for present values of quantifiable benefits and costs, there will be a **net present value cost of about \$0.84 million (Table 6.16)** for Option 2. There are, however, significant benefits that could not be quantified. These include:

- improvements to radiation safety practice with the inclusion of ARPANSA's codes of practice and relevant Australian Standards in the Regulation
- enhanced compliance through the introduction of new obligations relating to exemptions
- improved supervision of exempt practitioners
- enhanced accountability through new record-keeping requirements for identity checks
- increased incentive to comply through higher penalties
- safer procedures and practices through the implementation of RMPs
- greater accuracy in reports of radiation incidents
- a small reduction in compliance costs as a result of updating the exemption of PET scanners and apparatus used for quality control inspections
- improved compliance of consulting radiation experts as a result of the enhanced compliance auditing program.

Sensitivity analyses in the cost-benefit analysis showed that there will only need to be a reduction in PMDs of 14.7% or a decrease of 1,387 cosmetic tanning services users for there to be a quantifiable net benefit. These quantities, particularly for PMDs, were considered reasonable by stakeholders consulted.

Additionally, one benefit that was discussed qualitatively, is the reduced level of unplanned radiation that the public will be exposed to. This benefit was not included because it is unknown to what extent the level of radiation would be reduced and the extent to which radiation itself causes harm. However, minimising exposure to harmful unplanned radiation is one of the key objectives of the Act and strengthening safety requirements to reduce accidents and incidents is one of the main ways of delivering this outcome. At the time this economic analysis was undertaken, the estimate of

value of a statistical life was about \$5.6 million. If the net impact of the proposed Regulation has a 1 in 6 chance of saving only one additional life, it will be close to breaking even.

While Option 2 of remaking the Regulation with the improvements (as outlined in Chapter 5) results in a quantifiable net cost, it is the preferred option because it best addresses the need for government action in supporting a risk-based approach to protecting the community and environment. This option is also the most consistent with the Act and Regulation objectives and is expected to provide an overall net benefit to the community, with some of that benefit unquantifiable. Specifically:

- Changes to licence exemption provisions will ensure they are better targeted with no increase in exposure risks due to other mitigations.
- Preparation of radiation management plans will ensure that risk management is aligned to the scale and characteristics of organisations' use of regulated material and apparatus.
- Incident reporting requirements will better align to the potential level of concern of different types of incidents and reporting will be more reliable.
- Requirements for personal monitoring devices will be clearer and more reliable.
- The public will be better protected from artificial UV radiation by strengthening commercial use offence provisions.
- Increases in offence and penalty infringement amounts will provide greater deterrence to committing offences.
- Fees indexed to inflation will enable the EPA to recover more of the costs of protecting the community from harmful radiation.

It is expected that these additional unquantifiable benefits, will contribute to a positive NPV for the proposed Regulation (Option 2) as a whole. On this basis, it is expected that the implementation of the proposed Regulation will lead to the highest net benefit to NSW.

Appendices

Appendix A Better Regulation principles

Under the *NSW Government Guide to Better Regulation* (NSW Treasury 2019), for new and amending regulations, a regulatory impact statement (RIS) is required to address the Better Regulation principles set out in the guide. (This is in addition to meeting the requirements of the *Subordinate Legislation Act 1989*.) These principles have been applied throughout this RIS, as detailed in **Table A.1**.

Table A.1 Compliance with Better Regulation principles

Better Regulation principle	Compliance under the RIS
Principle 1: The need for government action should be established. Government action should only occur where it is in the public interest, that is, where the benefits outweigh the costs.	Chapter 3
Principle 2: The objective of government action should be clear.	Chapter 5
Principle 3: The impact of government action should be properly understood, by considering the costs and benefits (using all available data) of a range of options, including non-regulatory options.	Chapter 6
Principle 4: Government action should be effective and proportional.	Chapter 5
Principle 5: Consultation with business, and the community, should inform regulatory development.	Chapter 1
Principle 6: The simplification, repeal, reform, modernisation or consolidation of current regulation should be considered.	Chapter 4, Chapter 5
Principle 7: Regulation should be periodically reviewed, and if necessary reformed, to ensure its continued efficiency and effectiveness.	Chapter 1

Appendix B Stakeholder engagement

Table B.1 Key stakeholders consulted during the development of the proposed Regulation

Medical
Medical Radiation Practice Council of NSW https://www.medicalradiationpracticecouncil.nsw.gov.au
Australian Medical Association New South Wales https://www.amansw.com.au/
Royal Australasian College of Physicians https://www.racp.edu.au
Royal Australian and New Zealand College of Radiologists https://www.ranzcr.edu.au
Royal Australasian College of Surgeons https://www.surgeons.org
Australian and New Zealand College of Anaesthetists https://www.anzca.edu.au
Australian and New Zealand Society of Nuclear Medicine https://www.anzsnm.org.au/
Australasian Association of Nuclear Medicine Specialists https://aanms.org.au/
Australian Society of Medical Imaging & Radiation Therapy https://www.asmirt.org/
Australasian College of Physical Scientists & Engineers in Medicine https://www.acpsem.org.au/Home
Hospital and University Radiation Safety Officers Group
Dental
Australian Dental Association (NSW Branch) https://www.adansw.com.au/
Australian Dental and Oral Health Therapists' Association https://www.adohta.net.au/
Dental Hygienists Association of Australia https://www.dhaa.info/
Dental Assistants Professional Association https://secure.dapa.asn.au/home/
Veterinary
Australian Veterinary Association https://www.ava.com.au/
Veterinary Nurses Council of Australia https://www.vnca.asn.au/
Industrial radiography
Australian Institute of Non-Destructive Testing https://aindt.com.au/
Bartolo Safety Management Service
Tanning units
Australasian College of Dermatologists https://www.dermcoll.edu.au/
Subject matter expert – Professor Anne Cust, cancer epidemiologist, Deputy Director of the Daffodil Centre (joint venture between Cancer Council NSW and the University of Sydney) https://www.sydney.edu.au/medicine-health/about/our-people/academic-staff/anne-cust.html
Subject matter expert – Adjunct Associate Professor Craig Sinclair – Head of Prevention, Cancer Council Victoria https://www.cancer.org.au/people/craig-sinclair

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