Environment Protection Authority

Statutory Review: Radiation Control Act 1990

Final report: November 2021

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This report has been prepared in accordance with section 39B of the *Radiation Control Act 1990*, which requires the Minister to review the Act to ensure that its policy objectives remain valid and its terms are appropriate in securing those objectives.

Overall the provisions of the Act are fit for purpose, but the review identified improvements, which are set out in the recommendations of the report, that will safeguard people and the environment in New South Wales from harmful radiation, while enabling its beneficial use.

Further, some issues identified in the review will be considered in the remake of the Radiation Control Regulation 2013, which is required under the *Subordinate Legislation Act 1989*, and others could be addressed by the EPA in administering the Act.

I thank the Radiation Advisory Council, NSW government agencies and stakeholders whose submissions contributed to this review.

Matt Kean MP

Minister for Energy and Environment

1. Executive summary

The *Radiation Control Act 1990* (the Act) provides a framework for authorising dealings with radioactive substances and radiation apparatus in New South Wales and for managing security enhanced radioactive sources. The Act empowers the NSW Environment Protection Authority (EPA) to manage radiation risks and enforce the Act's requirements.

Section 39B of the Act requires the Minister for Energy and Environment to commence a review of the Act "as soon as practicable" after the 10-year anniversary of reforms made under the *Radiation Control Amendment Act 2010*. This anniversary occurred on 4 November 2020.

The terms of the review are to determine whether the policy objectives of the Act remain valid and whether the terms of the Act remain appropriate in securing those objectives. In conducting the review, the Minister must consult the Radiation Advisory Council (RAC), which is constituted under the Act, and consider the advice of the RAC on the review. The Minister must table a report on the review in both Houses of Parliament.

To assist with the preparation of this report, the EPA consulted a working group comprising members of the RAC and NSW government agencies, prepared an Issues Paper and sought submissions from radiation licensees, key stakeholder groups and the public.

The EPA received 149 submissions in response to the Issues Paper, including 130 survey responses and 19 written submissions. The EPA prepared this report for the Minister, following analysis of the submissions in consultation with the working group and the RAC.

The review found that, overall, the current policy objectives of the Act remain valid and should be retained and that the terms of the Act are largely appropriate for securing the objectives.

The review found the objects of the Act would be enhanced by adding a specific commitment to ecologically sustainable development.

The review also found that securing the objectives of the Act would be improved by adopting a number of changes, which are described in the Recommendations below. These proposed improvements would not significantly alter the regulatory framework.

Recommendation 1: A commitment to ecologically sustainable development is to be added to the Objects of the Act.

Recommendation 2: Transport consignment and disposal of radiation sources are to be added to dealings that require a 'responsible person' to hold a radiation management licence.

Recommendation 3: The requirement for compliance with the national Code for Safe Transport of Radioactive Material is to be migrated from the Radiation Control Regulation 2013 (the Regulation) to the Act, and penalties for non-compliance to increase to align with financial penalties for radiation licence-related offences in section 6 and section 7 of the Act.

Recommendation 4: The requirement for obtaining consent to dispose of regulated material is to be migrated from the Regulation to the Act, and penalties for non-compliance to increase to align with penalties for licence-related offences in sections 6 and 7 of the Act.

Recommendation 5: Provisions relating to source transport security plans are to ensure that security enhanced source movements within NSW are covered by a plan, regardless of the origin of the shipment.

Recommendation 6: Source security plans for security enhanced radioactive sources are to be periodically re-endorsed by an EPA-accredited security assessor.

Recommendation 7: The court is to be empowered to order an offender to pay the cost of disposal for a radioactive source seized by the EPA in accordance with the Act.

Recommendation 8: The jurisdictional limit of the Local Court is to be increased to $110,000, to align with the Protection of the Environment Operations Act 1997 (the POEO Act).

Recommendation 9: The maximum penalties for providing false or misleading information to an authorised officer are to be increased to align with comparable offences in the POEO Act.

Recommendation 10: The maximum penalties for abandoning a radioactive source is to be increased to align with serious waste dumping offences in the POEO Act.

Recommendation 11: The RAC is to be streamlined and modernised in its governance and membership and its advisory functions re-focussed.

Of the following issues raised in the review, some relate to the administration of the Act, rather than its terms, and can be addressed by the EPA, while others are appropriately addressed during the review and remake of the Radiation Control Regulation 2013 (the Regulation) that is to occur in accordance with the *Subordinate Legislation Act 1989*:

- A strong theme emerged in the consultation that the field of non-ionising radiation (for example, cosmetic and medical lasers) requires a regulatory approach. As the Act already provides for the Regulation to prescribe non-ionising radiation sources, this issue could be considered in the review of the Regulation.
- Strengthen the requirements for background checks for individuals who deal with security enhanced radioactive sources, which can be prescribed in the Regulation.
- Regulate the activities of third-party accredited assessors, which are prescribed in the Regulation.

This report sets out the issues canvassed in the issues paper, the questions raised in consultation and feedback received, and findings and recommendations.

2. Introduction

2.1 Radiation Control Act 1990

Radiation is used widely in the community in medical, dental and veterinary treatment, commercial and industrial applications, security screening and research. NSW radiation legislation aims to protect people and the environment by minimising unnecessary radiation exposure, while enabling the beneficial use of radiation.

The Act provides a framework for authorising and managing dealings with radioactive substances and radiation apparatus, ensures the security of radioactive sources, and provides powers to the Minister, the EPA and authorised officers to manage radiation risks and enforce its requirements.

2.2 The review

Section 39B of the Act requires the Minister for Energy and Environment to commence a review of the Act "as soon as practicable" after the 10-year anniversary of changes made by the *Radiation Control Amendment Act 2010*. This anniversary occurred on 4 November 2020.

The terms of the review are:

> To determine whether the policy objectives of the Act remain valid and whether the terms of the Act remain appropriate in securing those objectives.

The Minister is to table a report on the outcome of the review in both Houses of Parliament.

The review has been conducted to ensure that the Act:

- remains robust, modern and fit-for-purpose legislation, giving effect to national standards
- continues to provide a high level of protection for the community and the environment, including the security of high-risk radioactive sources
- is equipped to manage contemporary challenges, in a context of evidence-based policy.

2.3 Consultation

The EPA prepared an Issues Paper in consultation with a working group comprising members of the NSW Radiation Advisory Council (RAC) established under the Act, and representatives of the Ministry of Health and the Department of Regional NSW (Resource Regulator), which regulates radioactive ores. The Issues Paper provided background information on the key issues for the review and included questions to prompt consideration and feedback (Appendix A).

From 23 August 2021 to 26 September 2021, the EPA conducted a targeted consultation with licensees and stakeholder organisations and hosted a public consultation on the Issues Paper via the EPA's Have Your Say page.[1] Respondents could provide feedback by completing a survey or emailing a written submission. The Issues Paper can be accessed on the Have Your Say page.

The EPA directly invited approximately 18,500 radiation licensees and nearly 100 stakeholder organisations to comment on the Issues Paper.

2.4 Submissions and assessment

The EPA received 130 survey submissions and 19 written submissions. Appendix B includes a list of individuals and organisations who provided written submissions and a breakdown of survey

[1] https://yoursay.epa.nsw.gov.au/radiation-control-act-review

respondents. The aggregated results of survey responses are shown in Appendix C. The EPA analysed the feedback and consulted with the working group and the RAC in compiling this report.

3. Findings and recommendations

3.1 The Act remains fit for purpose

The Act is founded on international and nationally adopted radiation protection principles with the overall objective of protecting people and the environment from the harmful effects of radiation, while recognising its beneficial uses. It incorporates the fundamental radiation safety objectives of justification, optimisation and dose limitation and the need to secure radioactive sources from malicious misuse.

The terms of the Act aim to secure those objectives via a system of licensing, accreditation and regulatory requirements that authorise dealings with regulated material (such as its possession, storage and use) and the safety and security of radiation sources. The Act empowers the EPA to enforce these requirements and deal with potentially dangerous situations. The Act also establishes the Radiation Advisory Council to advise the Minister and the EPA on the administration of the Act.

Over 90% of survey respondents said the Act was “satisfactory” or better in securing radiation safety.

However, the review identified several improvements which would enhance the achievement of these objectives.

3.2 Recommendations for improvement

The proposed changes would not significantly alter the regulatory framework. Key recommendations include:

- adopting ecologically sustainable development principles in the Objects of the Act
- measures to improve oversight of transport and disposal of regulated material
- fine-tuning security plan requirements relating to the security of radioactive sources
- broadening orders available to the court, and increased penalties for offences
- amending the composition of the RAC to include representatives of the Secretary of Regional NSW and the NSW emergency services sector.

The recommendations are detailed in the Executive Summary and throughout this report.

3.3 Issues requiring further assessment

Laser regulation

The Issues Paper invited views on the potential for extending the Act to regulate lasers and intense pulsed light (IPL) devices. A majority of respondents (including industry organisations) agreed that some form of proportionate regulation is needed, though views differed on the range of laser and other non-ionising radiation activities that should be regulated and how they should be regulated.

The Act defines non-ionising radiation and provides that the Regulation may prescribe non-ionising radiation sources, like lasers, as regulated material.

Given the significant impact on business and the community of extending the regulatory framework to non-ionising radiation practices, a full regulatory impact assessment is warranted and could

occur as part of the review of the Regulation. See Chapter 7 below for further discussion of this issue.

Security background checks

The Act enables the EPA to prescribe, by regulation, security checks for individuals who deal with security enhanced radioactive sources. The Issues Paper invited views on whether the identity checks currently prescribed are adequate or whether a rigorous security check (e.g. including criminal history) should be introduced.

If a more rigorous check is necessary, there are several approaches that could be adopted which are based on existing schemes for other security-sensitive hazards (e.g. security-sensitive biological agents and chemicals of security concern). These options could also be assessed in the review of the Regulation. See Chapter 5.3 below for further discussion of this issue.

4. Policy objectives of the Act

4.1 Current objectives

The objectives stated in section 3 of the Act are:

1. 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
2. to protect security enhanced sources from misuse that may result in harm to people or the environment, and
3. to promote the radiation protection principles of:
    a. ***justification of a practice*** by assessing that the benefits of the practice involving exposure to ionising radiation outweigh any detriment
    b. ***optimisation of protection*** by ensuring that each of the following is kept as low as reasonably achievable taking into account economic and social factors:
        i. the magnitude of individual doses of ionising radiation
        ii. the number of people exposed to ionising radiation
        iii. the likelihood of exposure to ionising radiation.
    c. ***dose and risk limitation*** by setting dose limits or imposing other measures so that the health risks to any person exposed to ionising radiation is kept below levels that are generally considered to be unacceptable.

The Objects require that a person is to take the radiation protection principles into consideration when exercising functions under the Act or under a radiation licence.

These objectives reflect international and national fundamental principles for radiation protection and the general principles adopted by the Commonwealth and other Australian states and territories in their radiation legislation.[2,3]

[2] www.iaea.org/publications/7592/fundamental-safety-principles

[3] www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/fundamentals

4.2 Ecologically sustainable development

The Issues Paper canvassed incorporating a commitment to ecologically sustainable development (ESD) in the objectives of the Act, either:

- by requiring a person exercising functions under the Act or a licence to also take environmental factors into consideration, or
- as a specific objective of the Act, similar to section 5(d) of South Australia's *Radiation Protection and Control Act 2021.*

ESD requires integrating economic, environmental, social and equity considerations in decision-making to provide for the needs of present generations, without compromising the ability of future generations to meet their own needs.

The Protection of the Environment Administration Act 1991 (POEA Act) defines ESD in terms of:

- **the precautionary principle** – if there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation
- **intergenerational equity** – the present generation should ensure that the health, diversity and productivity of the environment are maintained or enhanced for the benefit of future generations
- **conservation of biological diversity and ecological integrity** – this should be a fundamental consideration in environmental planning and decision-making processes
- **Improved valuation, pricing and incentive mechanisms** – environmental factors should be included in the valuation of assets and services, such as the 'polluter pays' principle.

The concept of ESD is incorporated in over 60 pieces of New South Wales legislation.

The *Fundamentals for Protection Against Ionising Radiation* (ARPANSA 2014) identifies environmental exposure as one of the categories of radiation exposure (alongside workers, the public, and patients undergoing medical procedures involving ionising radiation) and incorporates the concept of intergenerational equity in Principle 7: "people and the environment, present and future, must be protected against radiation risks".[4]

ARPANSA also publishes the *Guide for Radiation Protection of the Environment (ARPANSA 2015)*, which states in its foreword:

> "Internationally and nationally, the legal and regulatory framework that governs management of radiation risks encompasses protection of both people and the environment. While the approach to protection of people has continually evolved for about a century, protection of the environment from the harmful effects of radiation is a relatively new addition to the protection framework."[5]

The Guide provides a basis for assessing the environmental impacts associated with exposure to radiation, applicable at a conceptual, operational and regulatory level in a system of radiation protection. This could include planning environmental assessments, environmental monitoring programs and assessing or demonstrating compliance with environment protection objectives.

Consultation and feedback

The Issues Paper invited views on whether the current objectives of the Act remain valid.

[4] www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/fundamentals/rpsf-1

[5] www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/guides-and-recommendations/rpsg-1

Stakeholders were invited to consider whether incorporation of ESD principles in the objectives of the Act would improve the development of radiation regulation in the evolving sphere of radiation protection of the environment.

There was strong support in survey responses for the proposition that the existing objectives of the Act remain valid (87.5%). This is not surprising, as the main objectives of radiation protection are well understood and consistently adopted in radiation frameworks in Australia and elsewhere.

More than 50% of survey respondents supported incorporating ESD principles in the objectives. Several written submissions expressed views on incorporating ESD principles in the Act's objectives.

A submission from ARPANSA supported the current policy objectives and added: "The principles of ecologically sustainable development (ESD) are relevant to radiation protection. The principles align with international recommendations from the International Commission for Radiological Protection (ICRP), and national guidance from ARPANSA and its Radiation Health Committee (RHC). These seek to demonstrate protection of the environment independently to the protection of people and demonstrate protection of biological diversity and have consideration of intergenerational equity."

A submission from the Australian Association of Nuclear Medicine Specialists (AANMS), which represents physicians and radiologists in nuclear medicine, acknowledged that the concepts of intergenerational equity and environmental protection are important to the population and that it is reasonable that this aspect be considered in the light of its environmental impact of radiation activities that produce waste, such as isotope production.

The Australian Institute of Occupational Hygienists (AIOH) submitted that the "radiation protection principles" already embed ESD: "The Act should remain focussed specifically on radiation protection."

Several respondents, including the Medical Radiation Practice Council of NSW, expressed the view that the inclusion of ESD principles must be relevant to provisions within the Act. Others said they would not want unnecessary changes that may restrict the beneficial use of radiation.

Findings and recommendations

ESD comprises more than a general commitment to environment protection: it encompasses the precautionary principle, intergenerational equity, biodiversity conservation and ecological integrity, and includes environmental factors in valuing assets and services.

Radiation protection of the environment is an evolving sphere. Adoption of an ESD object in the Act would provide a mechanism which will allow the EPA to include assessing environmental impacts associated with exposure to ionising radiation in its decision-making now and a mechanism for potential Act or Regulation provisions in line with this objective in the future.

Accordingly, there is justification for an amendment to the Act to incorporate the concept of ESD into the policy objectives of the Act, reflecting the concept of ESD expressed in section 6 of the POEA Act. **(Recommendation 1)**

A proposal of this nature would not introduce specific requirements that would unnecessarily encumber radiation practices unnecessarily, but instead require that – like the principles of justification, optimisation and dose limitation – a person exercising functions under the Act or a licence must take ESD into consideration when exercising functions under the Act or under a radiation licence.

5. Provisions of the Act

5.1 Authorisation of radiation practices – licensing

The EPA authorises radiation practices by licensing organisations and individuals responsible for regulated material and individual occupational users of radiation.

Licensing ensures that anyone who deals with regulated material is a ‘fit and proper’ person and has the knowledge and skills to minimise associated risks.

When consultation on the Issues Paper began in August 2021 there were more than 2,850 organisations and sole traders responsible for regulated material and 17,800 radiation users.

A radiation management licence is issued to a business (e.g. companies and sole traders) or a government organisation – like local health districts – to regulate the sale of, possession, storage and other dealings with radiation equipment and radioactive substances. Details of each unit of regulated material, such as x-ray machines, is attached to the licence as a record, providing for accountability and oversight.

A radiation user licence is issued to an individual who undertakes a radiation practice, such as a radiographer or radiotherapist. User licensing enables the EPA to apply criteria for obtaining a licence (training and qualifications, fitness) and to apply and enforce licence conditions which regulate the scope of radiation practice and how it is undertaken.

Around 49% of radiation users work in medical radiation practices (imaging and therapy) and about 25% use radiation in dentistry. The remaining licensees are mostly veterinary, industrial and security screening.

The Act does not require a licence for some radiation practices. These include the transport and disposal of regulated material. The Regulation requires compliance with the Code for the Safe Transport of Radioactive Material (Safe Transport Code) for the transport and disposal of regulated material. The Regulation also requires a person to obtain consent from the EPA before disposing of regulated material.

In many cases, the person transporting or disposing of regulated material will already be a licensee because they are already required to possess a licence for their other dealings with the regulated material. However, this is not always the case, as transport and disposal may be contracted out to third parties, like logistics companies and radiation services providers.

Licensing of the activities of transport and disposal is typical in other state and territory radiation schemes and there is justification for including these dealings among those that require a radiation management licence. This would improve regulatory oversight, by providing the ability for the EPA to enforce transport and disposal requirements as licence conditions.

Sources of radiation are most vulnerable during their transport and disposal and EPA regulatory experience has shown that the most serious incidents have occurred in the course of these activities being carried out.

It is also notable that the Regulation prescribes relatively minor penalties for transport and disposal offences compared to those available under the Act.

Consultation and feedback

The Issues Paper asked respondents to consider whether the current approach to authorising radiation practices was effective in securing the policy objectives of the Act. Specifically, respondents were asked whether the Act’s objectives would be enhanced by:

- requiring a radiation management licence for the transport and disposal of regulated material, and
- migrating the existing provisions relating to transport and disposal in the Regulation to the Act, where stricter penalties may apply.

80% of survey respondents agreed that the current licensing system is effective. Over 80% of respondents supported the extension of radiation management licence requirements to the dealings of transport and disposal.

A number of respondents emphasised that the key risk in transport occurs at the packaging stage and licence obligations need to concentrate on the consignor, not small ‘common carriers’ and

contractors. Other submissions called for expanding licensing to capture vehicle drivers. It is noted that obligations under the Safe Transport Code apply to all parties involved in transport, regardless of whether they hold a licence.

Respondents observed that in most cases transport consignors and people involved in disposal will have a radiation management licence in any case if they possess regulated material, so the impact of requiring a licence would not be significant. (Note: a single radiation management licence covers the range of dealings.)

Two-thirds of survey respondents agreed that regulatory provisions relating to Safe Transport Code compliance and consent to dispose of regulated material should be migrated from the Regulation to the Act.

Findings and recommendations

Regulating transport consignors and companies involved in disposal activities under management licensing would improve oversight, enabling the EPA to apply all the tools available to it under the Act, including licence conditions and the ability to suspend, vary or cancel a licence.

Requiring compliance with the Safe Transport Code for all persons involved in transport should be retained. Requiring EPA consent to dispose of regulated material should also be retained. There would be a benefit in migrating both provisions to the Act, where penalties more appropriate to the potential for significant harm associated with these activities are available.

There is justification for the following amendments to the Act:

- stipulating in section 6 of the Act that a 'responsible person' in relation to regulated material includes:
    - any person who is responsible for the transport of regulated material as a consignor, and
    - any person responsible for the disposal of regulated material. **(Recommendation 2)**
- migrating the requirement for compliance with the national *Code for Safe Transport of Radioactive Material* from clause 36 of the Regulation to the Act **(Recommendation 3)**
- migrating the requirements for the disposal of regulated material from clause 34 of the Regulation to the Act **(Recommendation 4)** and
- increasing maximum penalties for non-compliance with the migrated provisions to be consistent with the maximum penalties for radiation licence-related offences in section 6 and section 7 of the Act **(Recommendations 3 and 4)**.

5.2 Authorisation of radiation practices – accreditation

The Act provides for the EPA to accredit two classes of individuals as third-party assessors: consulting radiation experts (CREs) and radiation security assessors (RSAs). At the time consultation on the Issues Paper commenced in August 2021, there were more than 111 CREs and 4 RSAs.

CREs perform periodic quality assurance checks on certain equipment, such as diagnostic imaging (x-ray) apparatus and certain industrial gauges, which is required as a condition of a radiation management licence. This ensures that equipment is safe for operators and that patients are not receiving more than the planned dose due to equipment faults.

The EPA also accredits a small group of RSAs who are authorised to endorse security plans for high activity, or 'security enhanced', radioactive sources under requirements in the Act.

Feedback from consultation

The Issues Paper invited comments on whether the accreditation system for CREs is appropriate to achieving the policy objectives of the Act and whether the system could be improved.

Sixty-two per cent of survey respondents agreed that the CRE system is effective, with a further 28% unsure. The 'unsure' percentage is understandable, as only some licensees deal with CREs. Fewer than 10% were unsatisfied with the system.

The Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM), which educates, certifies, registers and supports physicists, scientists and engineers working in medicine, gave detailed comments on the CRE system. ACPSEM programs and accreditation are the main pathway for obtaining accreditation as a CRE for compliance certification of medical equipment.

ACPSEM recommendations included:

- finalising radiation shielding requirements and accrediting CREs to test shielding
- a robust accreditation system for the activities which CREs are authorised to conduct
- linking accreditation in mammography to ACPSEM certification
- periodic review of compliance testing reports
- developing competency-based assessment for CREs
- requiring CREs to undertake continuing professional development (CPD) and/or periodic independent assessment
- consistent accreditation renewal requirements for all CREs
- reconsidering the use of the term 'consulting radiation expert'
- specifying that CREs are not accredited to perform activities outside of the scope of clause 12 of the Regulation or their accreditation conditions.

ACPSEM also commented on the role of the radiation safety officer, being the person who oversees radiation safety within an organisation: "The role for RSOs should be promoted from the Regulations to the Act, including discussion on the relevant types of practice".

The Medical Radiation Practice Council of NSW (MRPC NSW) considered that the accreditation system for CREs is appropriate and noted that the EPA has made improvements over recent years: "However, there is still significant lack of standardisation across CREs and compliance in entities. National alignment with Diagnostic Imaging Accreditation Scheme (DIAS) standards would be one way of improving the accreditation process. Ensuring appropriate on-going education and training should be implemented. In addition, it would be helpful to have additional audit processes in place to ensure that compliance with theoretical expectations is occurring."

AIOH suggested aligning accreditation with existing systems, such as the Australasian Radiation Protection Accreditation Board (ARPAB), and that accreditation should be consistent with national uniformity.

In relation to radiation security assessor accreditation, 55% of survey respondents agreed that the system was effective, while 39% were unsure. The 'unsure' rate is understandable, as few stakeholders have dealings with RSAs. No written submissions were received about radiation security assessors.

Findings and recommendations

The Act provides for the EPA to accredit individuals as CREs and accreditation must not be issued unless the applicant:

- is a fit and proper person to hold an accreditation
- meets any requirements that may be prescribed by the Regulation
- meets any requirements that may be set out in a document forming part of the National Directory for Radiation Protection and adopted by the EPA under section 37 of the Act

- has the qualifications or expertise necessary to properly carry out the activities to be authorised by the accreditation.

The EPA may also apply conditions of accreditation and the Regulation prescribes activities of CREs.

The key submissions from ACPSEM and others can be dealt with in the context of existing EPA powers without the need to change the Act or could be considered in the review of the Regulation.

The submissions on improving the administration of these provisions are important. The EPA should work with key stakeholders, including the ACPSEM and the RAC, to help develop approaches that will improve CRE accreditation and practice, including in the review of the Regulation.

5.3 Security of radioactive sources

The Act requires people responsible for 'security enhanced' radioactive sources to take special protective measures. Security enhanced sources are high activity radioactive sources, which have the potential to cause serious harm to people and the environment if accessed by an unauthorised person or someone with malicious intent.

Australia has recognised the importance of safeguarding high-activity radioactive sources in its Chemical, Biological, Radiological and Nuclear (CBRN) Security Strategy by requiring jurisdictions to adopt and implement the national *Code of Practice for the Security of Radioactive Sources* (ARPANSA 2019) ('Security Code') in their regulatory frameworks.

In NSW, only around 1% of radiation management licence holders are responsible for security enhanced sources. Though security enhanced sources are relatively few, they have vital uses in cancer treatment, irradiation of donated blood to prevent rejection, medical research into cancer and other diseases, and in commercial applications, such as the sterilisation of medical supplies and the radiography of engineered structures to detect faults.

Licensees who are responsible for security enhanced sources must implement risk-based physical security measures, prepare and implement source security plans, manage who has access to the source, and report security incidents.

Source security plans

There are two types of security plan – a site based 'source security plan' and a 'source transport security plan' for source shipments.

These provisions have worked well since they were introduced under the *Radiation Control Amendment Act 2010* based on EPA audits. There has been one serious breach of security requirements. The case involved a source that was moved without a source transport security plan or security plan for the site to which it was moved. The EPA secured a conviction and significant penalty in this case, demonstrating the effectiveness of the provisions.

However, there has been some perceived ambiguity about source transport security plan provisions where a shipment originates in another Australian jurisdiction or is imported but transits or has its final destination in NSW, leading to ambiguity as to the operation of the NSW requirement for a source transport security plan. This has the potential to lead to inconsistent oversight of shipments occurring in NSW.

Regarding site-based source security plans, EPA-accredited RSAs endorse security plans; however, circumstances can change over time. Although the Act requires an annual (internal) review of plans by the responsible licensee, this may not be sufficient to prompt the adjustment of plans to changing circumstances.

Security checks

Individuals who deal with security enhanced sources must comply with security plans and must undergo a prescribed identity check in accordance with the *Requirements for identity checks* published by the EPA.[6] However, these checks are less stringent than those prescribed by the Security Code, which stipulates that a check should include an all-States criminal history check and an ASIO politically-motivated violence (PMV) check.

There are several approaches in Australia to background checking that could provide a model for enhancing checks: for example, the National Health Security check for Security Sensitive Biological Agents (SSBA) and the National Code of Practice for Chemicals of Security Concern.

Consultation and feedback

The Issues Paper asked whether the security provisions are working effectively to achieve the object of the Act to "protect security enhanced sources from misuse".

The Issues Paper specifically asked whether security plans prepared under the provisions should be re-endorsed periodically by an EPA-accredited RSA and whether background checking provisions were sufficient.

Seventy-four per cent of survey respondents said background checks should be broadened to include a criminal history check, while 13% disagreed. Sixty-eight per cent of survey respondents agreed that source-security plans should be periodically re-endorsed by an accredited assessor, while 14% disagreed.

Several respondents commented that a national scheme for background checks would be the preferred approach.

The MRPC NSW suggested that there could be some collaboration with AHPRA to effectively manage background checks for registered health professionals.

Findings and recommendations

There is justification for reform that ensures that any security enhanced source transport that occurs within the NSW jurisdiction is covered by a source transport security plan, regardless of the origin of the shipment. **(Recommendation 5)**

The findings of the review support an amendment to the Act requiring the periodic re-endorsement of source security plans by an accredited assessor. **(Recommendation 6)**

In relation to background checks, in the absence of consensus between the Commonwealth and the states and territories on a national scheme, NSW should take its own risk-based approach to managing this issue. The Act and Regulation provide a mechanism for addressing this issue.

The review of the Regulation could provide the opportunity for the EPA to analyse the costs and benefits of enhancing current provisions to include, at minimum, an 'all States' criminal history check.

5.4 Enforcement

The powers in Chapter 7 (Investigation) of the POEO Act extend to authorised officers exercising powers in connection with this Act and the Regulation. These include the powers:

- to require information and records
- to enter and search premises
- to question persons and require them to identify themselves.

[6] www.epa.nsw.gov.au/your-environment/radiation/sealed-radioactive-sources/security-of-sealed-radioactive-sources/id-checks

In addition to these powers and others specifically provided for in the Act, the Act provides for the EPA to give directions or take action in order to alleviate the danger or potential danger in a situation involving actual or threatened exposure of any person, animal or thing or the environment to an excessive level of radiation or contamination by regulated material.

The Act creates offences and empowers the EPA (or someone authorised by the EPA) to bring proceedings in the Local Court or the Land and Environment Court for offences against the Act. Most offences under the Act are strict liability offences.

Consultation and feedback

The Issues Paper invited views on whether the powers available to the EPA and the Minister are adequate for the enforcement and administration of the Act and whether penalties and orders available to the court are adequate for dealing with breaches of the Act.

The Issues Paper asked whether:

- the penalty for the offence of abandoning a radioactive substance is appropriate to deter unlawful conduct
- the penalty of providing false and misleading information to an authorised officer should be increased
- the court should be able to order costs to pay for the disposal of materials seized by the EPA and forfeited under the Act, and
- the penalties that the Local Court may impose for breaches of the Act should be increased

Most survey respondents believed that the penalties and orders available to the court for dealing with offences are appropriate, but nearly half also agreed that the maximum penalty of $22,000 that may be imposed by the Local Court should increase (25% were unsure and 25% opposed).

Seventy-seven per cent believed the court should be able to order costs of disposal for regulated material seized by the EPA and later forfeited to the Crown.

Forty-six per cent of survey respondents believe the penalties are adequate for the offences of abandoning a radioactive substance and the offence of providing false and misleading information to an authorised officer (28% were unsure and 25% were opposed).

Findings and recommendations

Due to the potential for the EPA to incur high disposal costs when a radioactive source is seized in accordance with the Act for safety reasons and later forfeited to the Crown, it is reasonable that the court be empowered to make an order relating to disposal costs incurred by the EPA against the person from whom the source was seized. **(Recommendation 7)**

The maximum penalty of $22,000 that the Local Court may impose when action is taken by the EPA is insufficient when compared to Local Court penalties available under comparable legislation. The maximum penalties that the Local Court may impose under the POEO Act are up to 1,000 penalty units ($110,000), depending on the offence. The review found there is justification for increasing the penalties available to the Local Court under the Act to those available to it under the POEO Act. **(Recommendation 8)**

The maximum penalties for the offence of providing false or misleading information to an authorised officer are currently $165,000 for a corporation or $27,500 in any other case. Due to the seriousness and potential human health and environmental consequences that can result from providing false or misleading information about regulated material and the need for deterrence, it is appropriate to align penalties to other EPA administered legislation. Under section 211 of the POEO Act, a person who furnishes information knowing that it is false or misleading in a material respect is guilty of an offence with penalties of up to $1m for a corporation or $250,000 for an individual. It is appropriate that the penalties for this offence be brought in line with the penalties for equivalent offences in the POEO Act. **(Recommendation 9)**

The maximum penalties for abandoning a radioactive substance are currently $165,000 for a corporation. In any other case, it's $27,500 or 2 years' imprisonment or both. In other Australian jurisdictions that have an offence of abandoning a radioactive substance, the penalties are generally higher (for corporations and individuals respectively: up to $1.6m for a corporation or $327,000 in Victoria; $0.5m or $100,000 or 10 years' imprisonment in South Australia; $4.5m or $800,000 or 3 years' imprisonment in the ACT; and $860,000 in either case in Tasmania). Abandoning a radioactive substance is a strict liability offence in the NSW Act.

Under section 115 of the POEO Act, an analogous offence of "wilful or negligent disposal of waste causing actual or likely harm to the environment" attracts penalties of up to $5m for a corporation or $1m and/or 7-year imprisonment for wilful offences. For negligent offences, the penalties are $2m or $500,000 and/or 4 years' imprisonment. This approach to tiered penalties for negligent and wilful offences and the penalties are more commensurate with the potential harm and seriousness of abandoning a radioactive substance, and it is appropriate that the offence of abandoning a radioactive substance be aligned to this approach. **(Recommendation 10)**

5.5 Financial assurances

The Act also adopts similar provisions to the POEO Act and the Contaminated Land Management Act 1997 (CLM Act) that enable the EPA to secure or guarantee funding in the form of a 'financial assurance' from a licensee for carrying out works or programs – such as the securing, storage or disposal of regulated material or remediation, clean-up or improvement works with respect to the regulated material.

The Act provides for the Regulation to make guidelines on the conditions which might require financial assurances and how to calculate the amount of financial assurances.

During 2021, the EPA sought public feedback on a draft *Financial Assurance Policy* and a draft *Guideline on Estimating Financial Assurances* for calculating financial assurances.

The draft policy outlines when and how the EPA may require a financial assurance under the relevant Acts. It includes a risk categorisation tool for the EPA to decide whether a financial assurance is justified, based on the level of risk to the environment, the remediation or other work that may be required and the environmental record of the regulated person or company.

Consultation and feedback

No comments were received relating to financial assurances.

Findings and recommendations

The legislative provisions for financial assurances are soundly based and reflect similar provisions in the POEO Act and CLM Act.

When the EPA finalises its *Financial Assurance Policy* and *Guideline on Estimating Financial Assurances*, the Regulation could be amended to adopt these documents, pursuant to section 28F of the Act.

The EPA could then undertake a risk assessment of the need for applying financial assurance provisions to licensees responsible for higher risk radioactive sources.

5.6 Radiation Advisory Council

The Act establishes the Radiation Advisory Council (RAC) which has 17 members who have a range of interests and expertise in radiation protection.

The functions of the RAC include advising the Minister on:

- proposed amendments to the Act and the making, amendment or repeal of regulations under the Act

- the administration of the Act and the Regulation
- measures to prevent or minimise the dangers arising from radiation
- the granting of exemptions for licensing and other requirements under the Act and Regulation
- such other matters relating to radiation safety as the Minister considers appropriate.

The RAC also provides advice to the EPA on the granting of licences and accreditations under Part 2 of the Act and proposed exemptions from licensing in emergency and other situations.

RAC members provide a high level of expertise across the range of radiation sectors. This expertise allows the council to effectively carry out its prescribed functions under the Act.

Consultation and feedback

The Issues Paper invited views on whether the current composition and functions of the RAC are appropriate and whether the RAC remains the best means of providing advice to the Minister and the EPA. Survey respondents' views on the composition and functions of the RAC were positive – over 60% agreed that the composition and functions of the Council are appropriate and that it is the best means of providing advice to the Minister and the EPA on radiation matters.

Some respondents suggested widening the membership of the RAC to include, for example, a wider range of medical radiation practices, medical and cosmetic laser practices, the dental and veterinary sectors, and industry. Fire and Rescue NSW recommended that the RAC includes a member from the emergency management sector.

AIOH's submission noted the RAC is an effective resource supporting the EPA in radiation safety regulation: "The relationship between the RAC providing advice and the EPA making a decision based on that advice seems to provide a good balance between access to expertise and the independence of the EPA."

Findings and recommendations

The RAC is an effective way of obtaining expert advice and the views of key stakeholders in regulated radiation practices and it should be retained.

It is proposed to streamline and modernise the governance and membership of the RAC and refocus its advisory functions. This will include increasing flexibility for future appointments while including members with a range of collective expertise. **(Recommendation 11)**

6. Other provisions and issues

The Issues Paper sought views on other provisions of the Act, including:

- adopting documents forming part of the National Directory for Radiation Protection (NDRP)
- consultation and co-operation between Ministers
- exemption provisions
- periodic review of the Act.

6.1 Adoption of NDRP documents

The importance of better harmonising radiation protection in Australia is supported by section 37 of the Act, which allows the EPA to adopt a document that forms part of the *National Directory for Radiation Protection* (NDRP) (ARPANSA 2017). The NDRP is an agreement document developed by the Radiation Health Committee (RHC), which is established under the ARPANS Act. An EPA officer represents New South Wales on the RHC.

Once documents (such as national codes and standards) are adopted by gazettal, the EPA may use them to determine licence applications and impose licence conditions.

National codes provide a valuable means of applying rigorous licence conditions, supporting national uniformity in radiation protection and more comprehensive and harmonised implementation of international and national standards.

A key observation of the *Integrated Regulatory Review Service (IRRS) Mission to Australia* (IAEA 2018) was that:

> "while jurisdictions have committed to increase the level of national uniformity through instruments like the NDRP, the national codes and guides have not been implemented consistently by all Australian jurisdictions and harmonization and uniformity within the Australian legal and regulatory framework has not been achieved at the necessary level. This could potentially impact the safety of the public, workers and environment".[7]

Australian jurisdictions are working together to implement the recommendations and suggestions of the IAEA Mission via the Standing Committee on Environmental Health (enHealth) – which sits under the Australian Health Protection Principles Committee (AHPPC) – and its Radiation Health Expert Reference Panel (RHERP).

Consultation and feedback

The Issues Paper asked whether harmonising radiation protection is important and how existing provisions could be changed to increase national uniformity.

ARPANSA's submission noted that a national strategy for radiation protection – a recommendation of the IRRS Mission – is currently being developed and will have a bearing on all Australian jurisdictions. "The National Strategy is a key step towards the development of an intergovernmental agreement between the Commonwealth, state and territory governments which will aim to improve harmonisation in the management radiation safety".

AANMS supported the role of national guidelines to produce a consistent approach to radiation safety across Australia.

The MRPC NSW and AIOH said it would be helpful for medical radiation practitioners to have a radiation licence that is recognised by other states and territories. Submissions suggested either a nationally uniform approach to licensing or a national licencing system.

Findings and recommendations

Provisions in the Act for adopting NDRP codes and standards provide a satisfactory means of supporting national uniformity goals and should be retained.

In terms of national licensing, in 2021 NSW passed amendments to the *Mutual Recognition Act 1992* as part of national occupational mobility reforms, which will provide for 'automatic mutual recognition' of radiation licences and facilitate work done by licence holders who operate in multiple jurisdictions. These changes are being introduced in consultation with stakeholders to ensure that they do not compromise safety.

The EPA will continue to participate in national forums that develop and implement nationally uniform approaches.

6.2 Consultation and co-operation between Ministers

Section 38 of the Act provides for the Minister, in administering this Act, to consult and co-operate with the Ministers responsible for the *Work Health and Safety (Mines and Petroleum Sites) Act 2013*, *Mining Act 1992*, *Work Health and Safety Act 2011* and *Offshore Minerals Act 1999* on

[7] www.arpansa.gov.au/regulation-and-licensing/regulation/independence/independent-review-of-regulatory-activities/integrated-regulatory-review-service

matters relating to workplace radiation safety, as well as the Minister administering the *Public Health Act 2010* in relation to protecting public health from radiation.

This provision helps to ensure that radiation safety is a consideration in all workplaces where radiation is used, and that public health is considered in radiation regulation.

Findings and recommendations

These provisions are operating well, with the EPA maintaining, on behalf of the Minister, excellent working relationships with the NSW Ministry of Health and Health portfolio agencies, SafeWork, and – in relation to work health and safety at mines – the Resource Regulator, as well as with those representatives of these portfolios who participated in the working group for this review.

Section 38 of the Act formalises the obligation to consult and cooperate and should be retained.

6.3 Exemptions

Sections 38A and 39 of the Act allow the EPA to grant exemptions from the Act's provisions in certain circumstances including:

- in an emergency or where it is not practicable to comply (such as in an emergency clean-up after a spill) – for up to 60 days or longer if the EPA seeks the advice of the Radiation Advisory Council
- in any circumstances approved by the Minister – for up to 60 days or longer after seeking the advice of the RAC.

During the COVID-19 pandemic in 2020, the EPA used its powers under section 38A of the Act to temporarily relax some licensing, supervision and other requirements relating to the medical sector. The temporary exemptions reduced the need for contact and the risk of spread of infection by supporting an increase in remote working.

During the consultation on this review, the EPA held discussions with emergency services representatives, who also endorsed emergency exemption provisions.

Findings and recommendations

These provisions are necessary and should be retained.

6.4 Review of the Act

Section 39B of the Act required the Act be reviewed by the Minister 10 years after the commencement of certain changes to the Act made in 2010. This report is the outcome of that review.

Finding and recommendations

This review completes the requirements of section 39B. Future reviews of the Act can be incorporated into the EPA legislative program as priorities emerge.

6.5 Other issues and observations

Graded approach

One of the key concepts of radiation safety regulation is using the 'graded approach'. According to the *Code for Radiation Protection in Planned Exposure Situations* (ARPANSA 2020), the graded approach means: "for a system of control, such as a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied is

commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control".[8]

The Act incorporates this concept in, for example, regulating more high-risk radiation practices and sources with more stringency than those of lower risk through, for example, licence qualifications and pre-requisites, different conditions and quality assurance requirements for equipment, and exemptions (for lowest-risk practices).

Feedback from consultation

Seventy-eight per cent of respondents to the Issues Paper said that NSW applies an effective risk-based approach to radiation protection, with 12% unsure and 10% disagreeing.

The AANMS submission supported the current graded approach to radiation protection in the Act: "A strict punitive approach would simply lead to less openness in reporting and undermine attempts to identify the root cause of issues."

AIOH considers that the Act applies an "overly simplified approach to a complex concept. More thought needs to be put into getting this practical and useful for society. The graded approach is a fundamental concept in radiation protection and is rarely adequately implemented. NSW could provide leading legislation in this area by developing a discussion paper on this topic and engaging experts."

Findings and recommendations

Feedback on this issue is noted by the EPA.

Linear no-threshold model

The current radiation protection philosophy assumes zero risk only at zero radiation dose – a model referred to as 'linear no-threshold' (LNT).

A submission questioned the use of the LNT model as the basis for radiation protection.

"The use of the LNT model should be questioned because:

- although the LNT model facilitates the practice of radiation protection, it cannot be supported by valid science
- it is the cause of unnecessary public fears and concerns and is the basis for misleading anti-nuclear propaganda."

The submission also queried the annual dose limits for occupationally exposed persons and members of the public contained in Schedule 5 of the Regulation.

Findings and recommendations

LNT is a dose-response model used to estimate risk or delayed effects (such as cancer) due to exposure to ionising radiation. In the setting of regulatory limits, and as a precautionary approach, assumptions are made that the long-term risk caused by ionising radiation is directly proportional to the radiation dose and there is no dose threshold for the safety of the public.

LNT is a model, not an assumption or science. It is recognised that risk of harm decreases in a linear way with reduced dose towards zero. However, a linear increase has been observed from tens of millisieverts upwards in heritable disease and sensitive population sub-groups must also be

[8] www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/codes-and-standards/rpsc-1

considered in modelling. The ACPSEM's submission noted current literature on effects below 100 millisieverts.[9]

While Radiation effects at low doses and dose rates remain a subject of scientific research and the focus of investigation by major international organisations, Australia's Radiation Health and Safety Advisory Council (RHSAC) supports the continued appropriate use of the LNT model as a regulatory tool.[10]

Regarding dose limits, international recommendations on the limits to be applied to ionising radiation exposure have been accepted as appropriate by Australian jurisdictions as part of the Planned Exposure Code.

Findings and recommendations

The LNT model remains an appropriate basis for the framework of radiation protection.

Dose limits in the Regulation appropriately reflect current national and international standards.

Obligations of referrers

Three survey respondents expressed their view that 'referrers' who request radiological imaging should be regulated, citing the over-ordering of medical imaging procedures. RAC members have also raised this issue with the EPA, citing literature on over-referral and inappropriate imaging and the rise in medical imaging procedures.

Findings and observations

The national *Code for Radiation Protection in Medical Exposure* (ARPANSA 2019) contains several references to the role of referrers and their interaction with licensed medical radiation practitioners. The Code is incorporated in a draft new edition of the NDRP.[11]

ARPANSA also publishes the *Radiation Protection of the Patient* training module, which aims to improve the safety and quality of diagnostic imaging in Australia, highlighting the safety role of all of those involved in patient exposures.

The EPA continues to work with ARPANSA to improve guidance for radiation protection of the patient through codes, standards and guidance.

Other observations

MRPC NSW's submission noted that:

> "Technological improvements to accessing information, updating information and digitisation of records in recent years has been a welcome change providing much needed progress. Additional auditing would assist in ensuring compliance. Audit reports could then be shared with stakeholders to ensure the policy objectives of the Act are being met. Review of other new fields where radiation is being used need to be made to ensure all industries utilising radiation sources are incorporated into the Act."

The MRPC NSW also observed that many medical practitioners that have a radiation user licence – for example, pain medicine physicians or anaesthetists using imaging equipment in operating

[9] National Council on Radiation Protection and Measurements 2018, *Commentary No. 27 – Implications of Recent Epidemiologic Studies for the Linear-Non threshold Model and Radiation Protection*, Bethesda, Maryland.

[10] RHSAC May 2017, *Position statement on the use of the linear no-threshold model in ionising radiation protection*, Miranda.

[11] www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/codes-and-standards/rpsc-5

theatres – may not adhere to accreditation processes (e.g. DIAS accreditation requirements) in addition to radiation safety requirements.

AIOH noted that more emphasis should be placed on naturally-occurring radioactive material (NORM) and radon in workplaces.

Findings and recommendations

These observations are noted. The EPA continues to take an active interest in workplace developments in medical radiation practice and in workplace radon and NORM exposure, guided by the RAC expert members and national codes and standards.

7. Regulation of lasers and other non-ionising radiation

Cosmetic lasers and intense pulsed light (IPL) devices – sometimes also called intense light source (ILS) devices – emit non-ionising radiation (NIR) in the 'visible light' spectrum. While the nature of harm from NIR apparatus is different in character to carcinogenic ionising radiation, lasers and IPL devices can cause burns, blistering, infection leading to permanent scarring and eye damage. Treatment by untrained or inexperienced operators may also delay the diagnosis and treatment of skin cancers.

Several attempts have been made in the past to assess the need for regulating cosmetic lasers and IPL devices, including a Radiation Health Committee (RHC) working group which produced a consultation Regulatory Impact Statement in 2015 that confirmed the harm associated with laser and IPL practices but was inconclusive as to the cost-benefit case for a national regulatory approach. Tasmania, Queensland and Western Australia have gone ahead with regulation using different models.

In 2018, the NSW Parliament's Joint Committee on the Health Care Complaints Commission (HCCC) inquired into cosmetic health services in NSW. The committee's report noted the 'regulatory gap' around cosmetic lasers and IPL services and, in the absence of a national approach, recommended that the NSW Government consider whether to introduce legislation to provide minimum standards for cosmetic health service providers offering laser and IPL services. [12]

While the frequency and seriousness of adverse events in the cosmetic laser and IPL sector is not clear, there is no doubt that adverse outcomes occur which have a significant physical and psychological impact on individual victims. This is evidenced by complaints received by NSW Fair Trading and public reporting.

NIR-emitting devices are also used in medical settings and these practices and devices are also not currently regulated under the radiation legislation.

Consultation and feedback

The Issues Paper invited comments on whether cosmetic laser and IPL practices should be regulated under the Act and, if so, what model of regulation would be appropriate.

Seventy per cent of survey respondents supported licensing cosmetic lasers and light devices and their users with minimum proficiency requirements. Although medical laser regulation was not

[12] www.parliament.nsw.gov.au/committees/inquiries/Pages/inquiry-details.aspx?pk=2476#tab-otherdocuments

specifically canvassed in the issues paper, during the consultation several respondents also raised the question of regulating lasers and light devices in all settings.

Industry bodies, medical associations, government agencies and experts made submissions on this issue.

The Aesthetic Practitioners Advisory Network (APAN) – a national industry standards body/association representing skin therapists, aestheticians, laser practitioners, cosmetic tattooists and cosmetic nurses – recommends the need for regulating IPL and laser devices used for cosmetic purposes. It cited ongoing reported evidence of burns, scarring and hyperpigmentation suffered by consumers. APAN recommended regulation based on existing accredited training available for qualifications for cosmetic laser practitioners (for example, NSW TAFE courses). This would potentially be subsidised by government industry-skills funding.

Another industry member-based organisation (name withheld), representing clinics in the spa and salon sector, recommended that laser hair removal devices and medical aesthetic equipment (such as lasers and IPL) should not be subject to the same regulations as x-rays and medical equipment that emit high levels of radiation. It suggested that regulations be limited to rules regarding issues such as correct eyewear to prevent eye damage from light and heat-based devices, appropriate signage, correct room set up, and the removal of reflective surfaces to ensure eye safety. The organisation cautioned that over-regulation of these devices would negatively impact practitioners, clients and businesses.

The Australian Society of Dermal Clinicians (ASDC), a member-based organisation representing skin health practitioners, strongly recommended the regulation of therapies that use non-ionising light and laser apparatus for 'cosmetic' and 'therapeutic' purposes: "In both of these settings, treatments can alter cellular processes and lead to changes within skin structure and/or function and have the potential to cause injury and harm. In many cases, the apparatus used in both settings includes risks and complications associated with the treatment, whether it be cosmetic or therapeutic."

ASDC recommended basing regulation on a framework or standards of competency, educational requirements, and limitations to the scope of practice through licencing. The ASDC provided detailed recommendations on its preferred approach to regulatory standards, including enforcement and accident reporting.

Associate Professor Lee Collins, the RAC's expert in non-ionising radiation and Chair of the Standards Australia committee on medical lasers and intense light, recommended:

- regulating Class 3B and Class 4 lasers used in **any** therapeutic, diagnostic, surgical, cosmetic, aesthetic, dental and veterinary practice
- requiring compliance with AS IEC 60601.2.22: **"Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment"**
- regulating intense light source (ILS) devices in the higher risk (RG3) group used in **any** therapeutic, diagnostic, surgical, cosmetic, aesthetic, dental and veterinary setting
- requiring compliance with AS IEC 60601.2.57: **"Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use"**
- ideally, regulating Class 4 lasers in any setting
- requiring mandatory reporting of accidents involving regulated lasers and ILS devices
- a licensing approach to mandate training and operational requirements.

ARPANSA provided a detailed submission, noting that the use of lasers and IPL sources is a rapidly changing field of technology and it is important that "any approach to radiological protection is future-proofed accordingly. For example, using the terminology of 'cosmetic non-ionising

radiation sources' enables broader coverage to include other modalities such as LED and radiofrequency."

ARPANSA notes that the World Health Organization (WHO) is expected to publish a coherent and overarching framework for health protection from NIR soon, aimed at promoting a globally consistent approach for the protection of people from NIR. "Designed and based on decades of practical experience, the framework will provide guidance on establishing clear national health and safety objectives and how they should be achieved. It supports multisectoral action and engagement by providing a common language and systematic risk-based approach for managing non-ionizing radiation."

ARPANSA also notes that the WHO framework aligns with IAEA General Safety Requirements Part 3 and applies modified principles of justification, optimisation and limitation to achieve safety and protection objectives.

The Australian Medical Association (NSW) (AMA) noted that "variability in the requirements for training and licensing to operate cosmetic lasers and IPL sources has the potential to cause misunderstanding and misuse of therapies and could result in adverse outcomes and medico-legal claims from both therapeutic and cosmetic services."

The NSW AMA supports the regulation of cosmetic laser and IPL sources with a view to:

- providing regulatory consistency
- protecting clients and patients during cosmetic procedures
- reducing liability for potential medico-legal claims arising from cosmetic incidents, and
- establishing a comprehensive framework for practices involved in the cosmetic application of lasers.

The MRPC NSW, AIOH, AANMS and survey respondents also made comments supporting the regulation of lasers. Submissions also mentioned the use of Class 3B and 4 lasers/laser systems in industry and research.

Findings and recommendations

There is clear support for developing a regulatory approach to managing risks associated with laser and IPL devices and potentially other NIR sources. Any regulatory approach needs to be proportionate, evidence-informed and risk-based.

Though it is not possible to fully canvass the detailed submissions provided during the consultation in this report, the input is appreciated and will inform analysis of these issues going forward.

The Act provides for the Regulation to prescribe non-ionising radiation sources as regulated material, thereby bringing them under the Act's regulatory framework.

The review of the Regulation required by the *Subordinate Legislation Act 1989* provides an opportunity to consult with stakeholders, explore options and assess the costs and benefits of regulation.

Appendix A: Consultation process

An Issues Paper published on the EPA's Have Your Say web page outlined the main areas for review and questions for consideration in each area, as listed below.[13] Stakeholders were invited to undertake a survey based on these questions and encouraged to comment on these and any other issues they believed were relevant to the review. Alternatively, stakeholders could comment on the Issues Paper and questions in a written submission.

Policy objectives

1. Do the current policy objectives of the Act remain valid?
2. Would the Act be enhanced by any additional objectives, including ESD principles?

Authorisation of radiation practices

3. Is the radiation management/user licence system appropriate to securing the policy objectives of the Act?
4. Are there activities that are not currently regulated that should require a licence?
5. What changes would you like to see to the way the EPA uses the Act to collect and use data?

Transport of radioactive materials

6. Is the current approach to regulating the transport of radioactive material appropriate to securing the policy objectives of the Act?
7. Do you support NSW requiring a radiation management licence for those who are responsible for the transport of regulated material?
8. Do you support shifting transport of radioactive materials provisions from the Regulation to the RC Act as a way of enhancing oversight and allowing increased penalties for non-compliance?

Disposal of radioactive material

9. Is the current NSW approach to regulating disposal of radioactive sources appropriate to securing the policy objectives of the Act?
10. Do you support requiring a radiation management licence for those who are responsible for disposing of radioactive sources?
11. Do you support shifting disposal of radioactive materials consent provisions from the Regulation to the RC Act as a way of enhancing oversight and allowing increased penalties for non-compliance available in the RC Act?

Accreditation

12. Is the accreditation system for consulting radiation experts appropriate to achieving the policy objectives of the Act?
13. How could the consulting radiation expert system be improved?

Security of radioactive sources

14. Are the security provisions appropriate for achieving the policy objectives of the Act?
15. What approach should be taken to background checks? For example, should these be broadened from the current requirement for identity checks and, if so, what should they entail?

[13] https://yoursay.epa.nsw.gov.au/radiation-control-act-review

16. Would periodic re-endorsement of a security plan by a radiation security assessor every three years improve security planning?
17. Do you have any other suggestions about how the security provisions in the Act could be improved?

Enforcement

18. Are the powers available to the EPA and the Minister adequate for the enforcement and administration of the Act?
19. Are the penalties and orders available to the court adequate for dealing with breaches of the Act?
20. Should the Act require an offender to pay disposal costs for any forfeited material?
21. Should the maximum penalty that may be imposed by a Local Court for a breach of the Act be raised from the current $22,000 per offence?
22. Should *mens rea* (criminal intent) be required for any offence under the Act?

Financial assurances

23. Are the considerations under the Act whether a financial assurance should be required adequate?
24. Should any other considerations be included?

Radiation Advisory Council

25. Are the current composition and functions of the RAC appropriate?
26. Does the RAC remain the best means of providing advice to the Minister and the EPA?

Other offences and enabling provisions

27. Is the offence of abandoning a radioactive substance sufficient to deter unlawful activity? If not, how could it be improved?
28. Is the offence of providing false or misleading information about regulated material broad enough and supported by an appropriate penalty?
29. Is harmonisation of the Act with radiation protection legislation in other Australian jurisdictions important? How could specific provisions of the Act be changed or included to support national uniformity?
30. Should consultation by the Minister with Ministers responsible for other legislation be extended to any other Acts or industries?
31. Are the exemptions under sections 38A and 39 of the Act appropriate? Should they be expanded to take into account any other specific circumstances?
32. Should the Act be subject to ongoing review every 10 years?

Non-ionising radiation regulation

33. Should cosmetic laser and IPL sources be regulated under the radiation legislation?
34. What model of regulation would be appropriate for these sources – e.g. licensing or training requirements?
35. Are there other non-ionising radiation issues the Act should address?

Other review questions

36. Does the NSW Government implement an effective graded – or risk-based – approach to radiation protection?
37. Are there any other issues relevant to the objectives of this review that should be considered?

Appendix B: Respondents

Written submissions

Below is a list of 15 of the 19 respondents who provided a written submission to the review. The names of 4 respondents are to remain confidential at the request of the respondents and have not been listed.

- Aesthetics Practitioners Advisory Network (APAN)
- Associate Professor Prof Lee Collins
- Australasian Association of Nuclear Medicine Specialists (AANMS)
- Australian Dental Association – NSW Branch (ADA NSW)
- Australian Institute of Occupational Hygienists (AIOH)
- Australasian College of Physical Scientists & Engineers in Medicine (ACPSEM)
- Australian Medical Association NSW (AMA NSW)
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)
- Australian Society of Dermal Clinicians (ASDC)
- Bartolo Safety Management Service (Bartolo)
- Department of Regional NSW
- Fire and Rescue NSW
- Medical Radiation Practice Council of NSW (MRPC NSW)
- Radiation Protection Unit, Public Health Services, Tasmanian Dept of Health (RPU Tas)
- Royal Australian and New Zealand College of Radiologists (RANZCR)

Survey submissions

The EPA received 130 survey submissions. A breakdown of survey respondents is presented in Table 1.

Table 1. Breakdown of survey respondents (n=130)

Individual (n=113)	Organisation (n=17)
Radiation user licence holder (n=105) • 50 Medical • 30 Dental • 10 Industrial • 7 Veterinary • 8 Other	**Radiation management licence holder** (n=15) • 6 Medical • 1 Dental • 4 Industrial • 1 Veterinary • 3 Other
Consulting Radiation Expert (n=7) • 5 Diagnostic imaging apparatus • 2 Fixed industrial gauge	**Other** (n=2) • 1 Industry/business • 1 Industry body (name withheld)
Private citizen (n=1)	

Appendix C: Survey results

Figure 1: What is your general view of the effectiveness of NSW's radiation control legislation in securing radiation safety? (n=129)

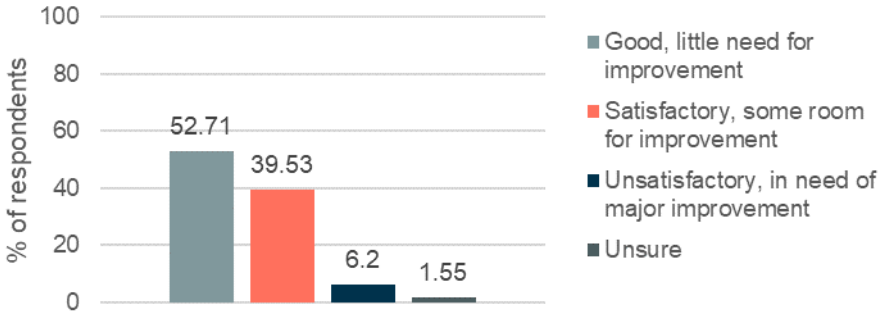

Figure 2: Do the policy objectives of the Radiation Control Act remain valid?

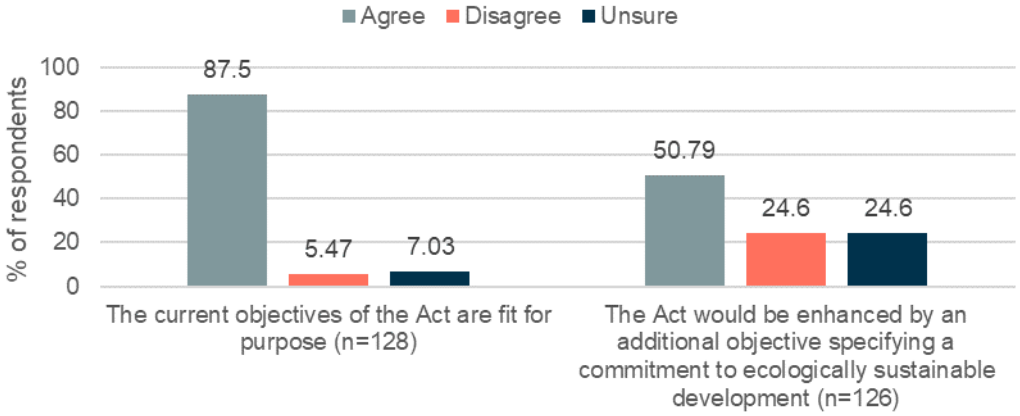

Figure 3: Are the Radiation Control Act's systems of licensing and accreditation appropriate for achieving the objectives of the Act?

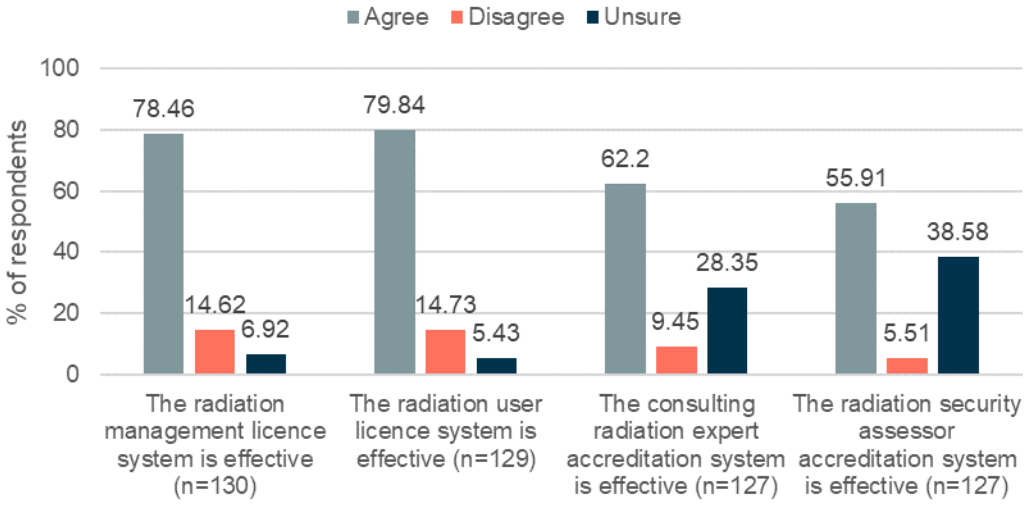

Figure 4: Do you support regulating the transport of radioactive materials under the Radiation Control Act as a way of enhancing oversight and allowing increased penalties for non-compliance?

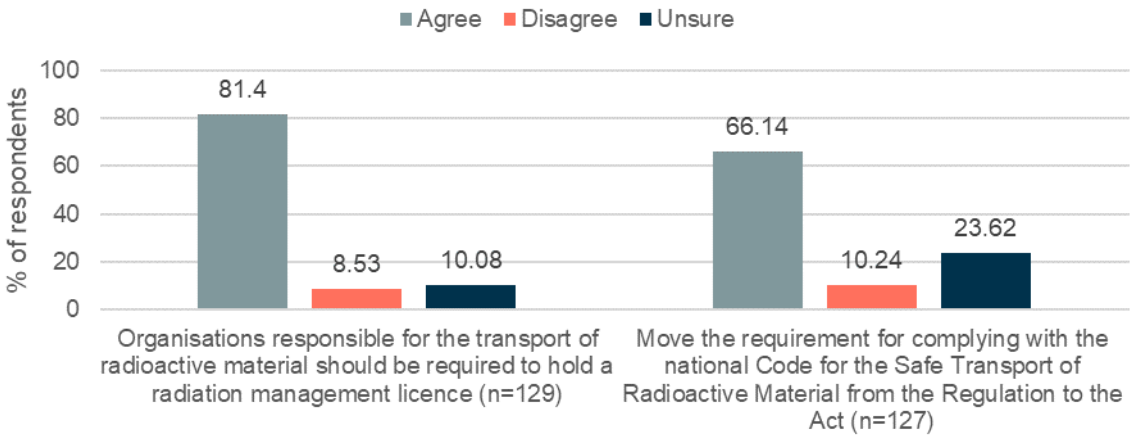

Figure 5: Do you support regulating the disposal of radioactive material under the Radiation Control Act as a way of enhancing oversight and allowing increased penalties for non-compliance?

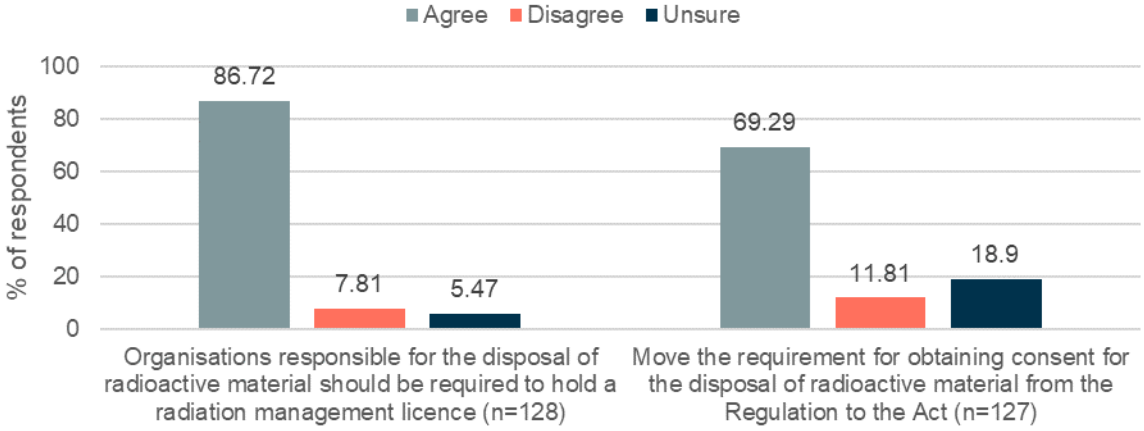

Figure 6: Do you support measures proposed in the Issues Paper to enhance the security of radioactive sources?

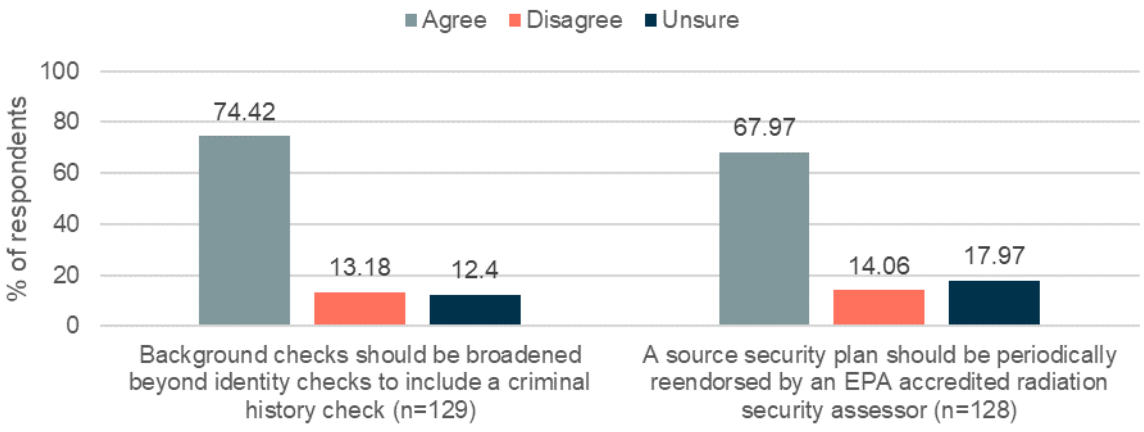

Figure 7: The use of cosmetic laser and intense pulsed light (IPL) radiation sources is not currently regulated under the Radiation Control Act. Do you support their regulation?

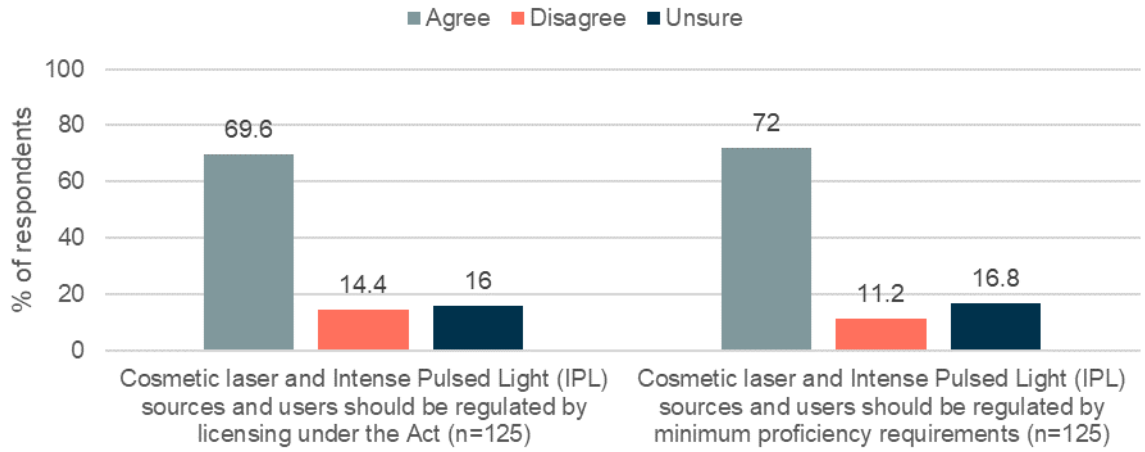

Figure 8: Are the powers available to the EPA and the courts to enforce and administer the Radiation Control Act adequate?

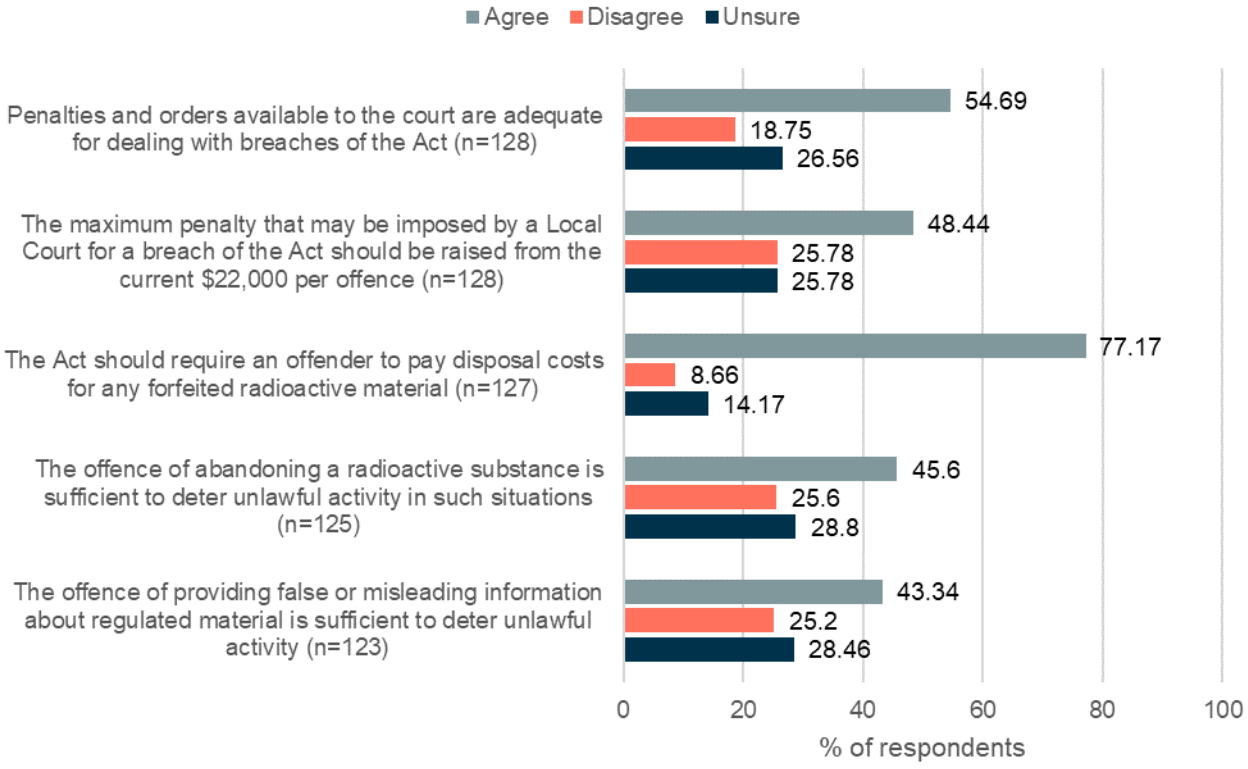

Figure 9: Do you support the current role of the Radiation Advisory Council?

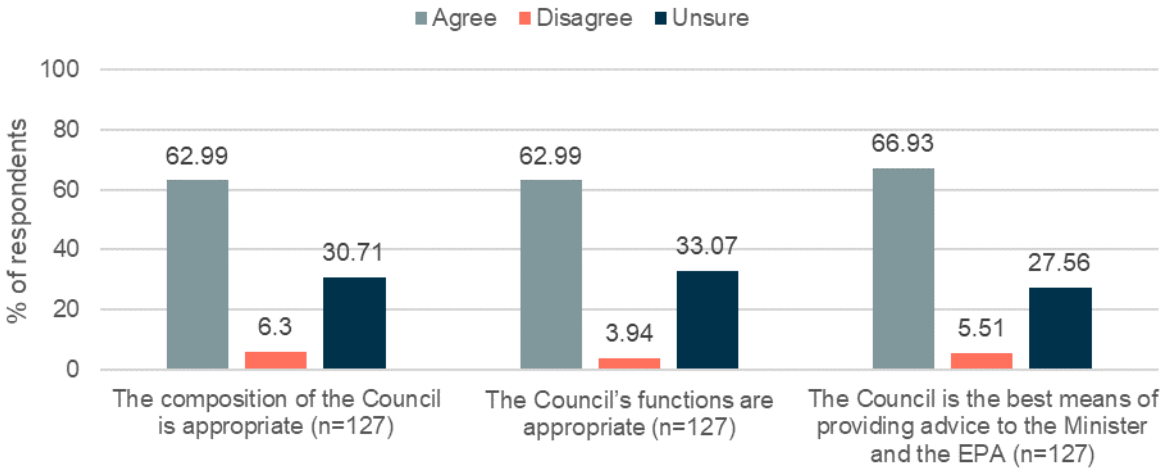

Figure 10: Overall, does the Radiation Control Act implement an effective risk-based approach to radiation protection? (n=125)