

Environment Protection Authority

Radiation Protection and Control Bill

Public consultation report

Radiation Protection and Control Bill – Public consultation report

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Executive summary

In South Australia, the *Radiation Protection and Control Act 1982* (RPC Act) regulates activities involving radiation sources and provides for the protection of people and the environment from the harmful effects of radiation. This includes providing for the licensing of certain activities, and registration of certain items and premises which involve radiation sources. The Act regulates radiation use across a number of industries including industrial processing, mining and petroleum operations, medical and health care, and educational facilities.

The RPC Act has not undergone substantial revision since commencement in 1982. As a result, many of the standard administrative and enforcement provisions are outdated. The new Act will modernise radiation protection regulation in South Australia and implement national commitments.

The major changes within this Bill when compared to the current RPC Act include reforms to significantly reduce the number of licences needing to be held by an individual or a business, the introduction of offences for causing radiation harm when not acting in accordance with the Act, contemporary maximum penalties, and incorporation of modern order-making powers for gaining compliance. These changes will provide a much more risk-based approach to regulation than the RPC Act. A significant amount of reform will also be implemented through regulations. Regulations will be drafted and consulted on separately once the Bill has progressed sufficiently through the Parliament.

There have been two consultation periods to get the draft Bill to its current state. The 2018 Bill was essentially an amended version of the 2013 Bill that has taken into account various issues raised during the 2013 consultation. The current consultation ran for a period of 11 weeks between November 2018 and the end of February 2019. A total of 24 submissions were received.

Most submitters indicated support for the modernisation of radiation protection legislation, many opposed the radiation harm provisions as they were drafted, and others sought clarification of various matters and suggested improvements. Towards the latter part of the consultation period certain key stakeholders were engaged to review possible amendments to the Bill to overcome some of the issues regarding radiation harm raised early on in the consultation. Feedback from those consulted on the proposed amendments has been supportive of those changes. Those changes are reflected in the proposed amendments summarised in section 5 of this report. Some other minor changes to the Bill have been proposed as a result of the consultation.

1 Introduction

In South Australia, the *Radiation Protection and Control Act 1982* (RPC Act) regulates activities involving radiation sources and provides for the protection of people and the environment from the harmful effects of radiation. This includes providing for the licensing of certain activities, and registration of certain items and premises which involve radiation sources. The Act regulates radiation use across a number of industries including industrial processing, mining and petroleum operations, medical and health care, and educational facilities.

The RPC Act has not undergone substantial revision since commencement in 1982. As a result, many of the standard administrative and enforcement provisions are outdated. The new Act will modernise radiation protection regulation in South Australia, implementing a progressive approach rather than a change in direction.

In addition, national commitments have been made via the Australian Health Ministers' Conference (AHMC) and the Council of Australian Governments (COAG) to implement a uniform national framework for radiation protection. The main national initiatives requiring implementation under the RPC Act are the *National Directory for Radiation Protection* and the national *Code of Practice for Security of Radioactive Sources*.

1.1 National Directory for Radiation Protection

Edition 1 of the National Directory for Radiation Protection (National Directory) was developed by the Radiation Health Committee and published in August 2004 by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). It was subsequently endorsed by the AHMC as the uniform national framework for radiation protection in Australia.

The purpose of the National Directory is to provide uniform and agreed requirements for the:

- protection of people and the environment against exposure or potential exposure to ionising and non-ionising radiation
- safety of radiation sources, including provision for the national adoption of codes and standards
- clear regulatory statements for adoption by the Commonwealth, States and Territories into their legislation.

The AHMC agreed the regulatory elements would be adopted in each jurisdiction as soon as possible, using existing regulatory frameworks, following consideration and approval of the provisions of the National Directory.

Some aspects of the National Directory, relating to the regulation of certain activities, have already been adopted into the RPC Act via Part 12 of the *Statutes Amendment (Budget 2010) Act 2010*. This includes the requirement for a Facilities Licence (section 29A of the Act), Licence to Possess a Radiation Source (section 33A), and Accreditation of Third Party Service Providers (Division 3B).

The draft Radiation Protection and Control Bill 2018 (the Bill) includes a number of provisions to reflect the National Directory commitments and recommendations from the National Competition Policy Review of Radiation Protection Legislation. These amendments are summarised as follows:

- Review of legislation not exceeding 10 years.
- Objects of the Act, radiation protection principles and general duty consistent with requirements of the National Directory.
- Offence for registered owner to cause, suffer or permit unlicensed person to operate radiation apparatus.
- Offence for responsible person to cause, suffer or permit unlicensed person to use or handle radioactive substances.
- Adoption of documents forming part of National Directory by regulation.

1.2 Code of Practice for Security of Radioactive Sources

During 2006, the COAG agreed to a National Chemical, Biological, Radiological and Nuclear Security Strategy to provide a framework to strengthen and enhance Australia's existing arrangements. In addressing the security of radiological materials, the COAG also agreed to a number of recommendations. These include the establishment of a national

regulatory scheme for the storage, possession, use and transport of certain radiological materials to minimise the risk of such materials being misused.

A significant component of the response to COAG's decision was the publication by ARPANSA of the *Code of Practice for the Security of Radioactive Sources* (Security Code). The purpose of the Security Code is to 'set out the security requirements to be implemented by persons dealing with a radioactive source in order to decrease the likelihood of the unauthorised access to, or acquisition of, the radioactive source by persons with malicious intent'. The Security Code classifies category 1, 2 and 3 sources as 'security enhanced radioactive sources', which require more stringent security requirements to be put in place.

In order to support this, the Bill refers to security of radioactive sources generally in the objects, and in clause 42 (suspension and cancellation of accreditations and authorisations) to state that an accreditation or authorisation may be cancelled or suspended if the accreditation or authority relates to a security enhanced radioactive source and the holder of the accreditation or authority has failed to pass a security background check.

Most significantly, a new clause (47) has been included for 'power to protect security enhanced radioactive sources and high-risk radioactive sources and materials' to ensure that the Minister can restrict a person's access to security enhanced sources if there is evidence to indicate that they pose a threat to the security of the source. An offence has also been added for obtaining or accessing such a source or material without having undergone a security background check. More detailed requirements of the Security Code will be prescribed in the regulations, should the Bill be passed by Parliament.

2 Overview of the proposed amendments

2.1 Objects, principles and general duty of care

The current section 23 of the RPC Act provides the ‘general objective’. This states that any person must, ‘in carrying on an activity related to radioactive substances or ionising radiation apparatus, endeavour to ensure that exposure of persons to ionising radiation is kept as low as reasonably achievable, social and economic factors being taken into account’. This does not apply to exposure of a person while the person is undergoing radiotherapy.

The general objective was introduced at the inception of the RPC Act and has not been amended since. While it has proved a useful guide in enforcement of the Act, it is in need of revision in order to provide more specific guidance on how the objective is to be applied.

The National Directory also specifies that ‘legislation must include the objective of protecting the health and safety of people and the environment from the harmful effects of ionising and non-ionising radiation’. It goes on to state that regulatory frameworks must follow specified principles and requirements to ensure that the objective of the legislation is met. These principles include, among others, the radiation protection principle, which:

... in regard to ionising radiation, includes justification of practices to ensure that benefits outweigh the detriment, limitation of radiation doses (see Schedule 1) to individuals from all practices, and optimisation of protection and safety so that individual doses, the number of people exposed and the likelihood of exposure are all kept as low as reasonably achievable, economic and social factors being taken into account¹.

The National Directory also specifies management requirements:

... to provide for responsible persons to establish a safety culture, establish quality assurance programs, reduce the probability of human error leading to accidents, make appropriate training and information available to staff, allocate sufficient resources to enable safety and security of radiation sources over their lifetime (including disposal), and provide the qualified expertise necessary to observe the requirements².

The ‘Objects and principles’ (Part 2 of the Bill) ensure that these national requirements are met, including supporting implementation of the Security Code, while the ‘general duty of care’ (clause 53) clarifies the application of the objects and principles to persons and the enforcement mechanisms. A person who breaches the general duty of care will not be, on account of the breach alone, guilty of an offence. However, compliance with the duty may be required through issuing a radiation protection order. A person will be guilty of an offence if he does not comply with the radiation protection order.

These provisions will apply to exposure of a person while undergoing radiotherapy, since the general duty will now be linked to the radiation protection principle, ie exposure must be justified, limited and optimised. Exposure to radiation for therapeutic purposes will not be a breach of the general duty provided it follows the radiation protection principle.

2.2 Responsible persons

The National Directory states that ‘a responsible person is to be primarily responsible for radiation protection and safety’³. The role of the responsible person is broadly outlined in the management requirements (as stated above).

¹ ARPANSA 2017, [National Directory for Radiation Protection](#), pg 3.

² As above

³ As above

The National Directory provides that the responsible person:

... in relation to any radioactive source, ionising or non-ionising radiation apparatus, nuclear installation, prescribed radiation facility or premises on which unsealed radioactive sources are stored or used means the person:

- 1 having overall management responsibility including responsibility for the security and maintenance of the source, apparatus, installation or facility;
- 2 having overall control over who may use the source or apparatus, installation or facility; and
- 3 in whose name the source, apparatus, installation or facility, would be registered if this is required⁴.

Responsibilities throughout the Bill will mirror the provisions of the National Directory. However, the term 'responsible person' is not used as, within a legislative context, the responsible person differs depending on the clause and more specific drafting is necessary to ensure culpability rests with the correct 'responsible' person.

Putting the onus on the responsible person, in addition to the owner, to ensure (where required) only licensed persons are operating radiation apparatus or using or handle radioactive materials, will assist in reducing the probability of human error, maintain the safety of radiation sources, and enhance accountability for radiation safety.

2.3 Licensing and registration reforms

The Bill seeks to consolidate existing management licensing and registrations under a single Radiation Management Licence. This provision will replace various licensing obligations under sections 23A, 24, 29, 29A, 30, 32 and 33A of the current Act. The Bill allows for persons engaged in multiple activities that require licences to obtain a single licence authorising all activities. All related registrations will also be able to be recorded on the licence so that all relevant licencing information is available in one document.

The Bill will also consolidate the two existing use licences (sections 28 and 31) under a single Radiation Use Licence in the same manner as above. The Bill will still articulate the various forms of licences separately and administrative consolidation of licences is provided through clause 39.

The Bill removes the requirement for the Minister to refer licence applications to the Radiation Protection Committee (RPC) which will save time in the licensing process in many instances. This has been included as there is already a discretionary power for the Minister to refer matters to the committee. Requiring advice on all licences can be a significant red-tape burden and potential delay for radiation users. It is intended that only major applications are referred to the RPC for advice as needed.

The transport of a radioactive source will require a licence under the Bill. The current Act stipulates various obligations for transporters through the regulations and also potentially requires the licencing of transporters through section 33A – Licence to Possess a Radiation Source – this has not been required of transporters to date. However, the new provision directly related to transport will allow for better targeted licensing requirements, and also for better oversight of adherence with the *Code of Practice for the Safe Transport of Radioactive Material* (ARPANSA 2014).

Financial assurances are also proposed to assist with reducing government liability and assist with the proper disposal and end-of-life management of radiation sources. The Minister may impose a condition on an authorisation requiring the authorisation holder to lodge a financial assurance, the discharge of which is conditional on certain requirements being complied with. It is not intended that financial assurances are used when government liabilities are already addressed through existing arrangements. There is no intention to duplicate assurances for the same liabilities established under other Acts, such as section 62 of the *Mining Act 1971*.

The Bill also introduces provisions where exemptions issued by the Minister will be able to be applied to a person or class of persons, a radiation source or class of radiation source, or a premises or class of premises. In addition, the regulations will be able to prescribe classes of persons or activities that are excluded from various elements of the Act where appropriate. This will allow for flexibility in administering the legislation supporting a graded approach to regulation.

⁴ ARPANSA 2017, [National Directory for Radiation Protection](#), pg 57.

2.4 Offence for causing radiation harm or serious radiation harm

The Act currently contains a series of specific offences set largely within the licensing and registration requirements, and relating to unauthorised use or handling. These offences are necessary; however they are more administrative in nature and are not linked to the harm or risk of harm that a breach of the Act might present. Inclusion of harm in regulatory schemes where there is a risk of harm to human health or the environment is necessary to provide a suitable deterrent. The application of harm provisions to the environment is reflected in the National Directory's objective of radiation protection legislation that 'legislation must include the objective of protecting the health and safety of people and the environment'⁵. Of the Australian States and Territories, only South Australia and Western Australia do not currently have harm elements within their radiation protection legislation (Table 1).

Table 1 Jurisdictional comparison

Legislation		Harm related element
SA	<i>Radiation Protection and Control Act 1982</i>	Nil
NSW	<i>Radiation Control Act 1990</i>	Section 24 – Increased penalty for offence causing serious harm. Maximum penalty: individual \$165,000, body corporate \$1.1 m.
QLD	<i>Radiation Safety Act 1999</i>	Section 43(2) – The licensee must take reasonable steps to ensure any person's health and safety are not adversely affected by exposure to radiation because of the carrying out of the practice with the source. Section 44(2) – A person carrying out the practice with the source must take reasonable steps to ensure any person's health and safety are not adversely affected by exposure to radiation because of the way the person carries out the practice. Maximum penalty: \$65,000 for each offence.
VIC	<i>Radiation Act 2005</i>	Section 23 – Offence to cause serious harm to the environment. Maximum penalty: individual \$290,000, body corporate \$1.45 m. Human health related matters limited to causing exposure over prescribed limits.
WA	<i>Radiation Safety Act 1975</i>	Nil
TAS	<i>Radiation Protection Act 2005</i>	Section 8 – Duty to ensure harm does not result from radiation source. Maximum penalty: \$1.59 m.
NT	<i>Radiation Protection Act</i> <i>Mining Management Act</i>	Section 11 – Duty to ensure harm does not result from radiation source. Maximum penalty: individual \$77,000, body corporate \$387,000. Section 26 – Serious environmental harm. Maximum penalty: individual \$596,000, body corporate \$2.9 m. Section 27 – Material environmental harm. Maximum penalty: individual \$119,000, body corporate \$596,000.
ACT	<i>Radiation Protection Act 2006</i>	Section 12 – General duty to ensure no harm. Sections 53–56 – various offences related to causing harm. Maximum penalty: \$300,000 or 7 years imprisonment

⁵ ARPANSA 2017, [National Directory for Radiation Protection](#), pg 3.

The penalty framework proposed in the Bill draws on the approach undertaken in sections 31–33 of the *Work Health and Safety Act 2013*, and sections 79 and 80 of the *Environment Protection Act 1993* (EP Act) which seek to penalise cases where a person has caused harm (actual or potential) or has been responsible for an unsafe environment.

Part 5 of the Bill provides new offences relating to causing radiation harm, with clause 50 relating to causing serious radiation harm, and clause 51 relating to causing radiation harm. In the 2013 Bill similar provisions were proposed using the term ‘radiation risk’. There was considerable feedback on the use of the term ‘risk’ and it has been amended to better align with ‘harm’ terminology used successfully interstate in radiation protection legislation and in the administration of the EP Act in South Australia.

Radiation harm offences are proposed for inclusion in the Bill to provide a significant penalty in circumstances where an individual, a group of persons or the environment is harmed or likely to be harmed (future outcomes) by exposure to quantities of radiation beyond those lawfully permitted by the remainder of the Bill. The penalty will also act as a deterrent for future unlawful overexposures that cause harm. These provisions do not apply to matters where the harm is considered trivial.

Further to this, harm provisions within the Bill are part of a suite of tools that can be used by the EPA to stop the action from occurring, cause action to prevent an event from occurring again in the future, or penalise for the non-compliance (see ‘Orders’ below). The harm provisions provide a higher order regulatory response, to be applied in situations that are not adequately dealt with through the other provisions.

Radiation harm may occur across all aspects of radiation exposure regulated by the legislation including occupational exposure, diagnostic imaging, radiotherapy, storage and transportation. Radiation harm effects may occur soon after exposure or some time, often many years, after exposure (ie the later development of cancer). Aside from physical harm, a radiation incident can also cause significant harm to the environment through contamination. Radiation harm may be readily quantified in such circumstances through consideration of monetary costs for remediation, disruption to businesses and society (eg if evacuation or abandonment of an affected area is necessary).

The use of harm terminology will provide a risk-based approach to regulation in that circumstances under which the offence is committed and the specific factors of the case will influence the compliance approach. This approach contrasts with the largely administrative nature of the offences provided for in the current RPC Act where compliance with set criteria is required and dismissive of a variable risk profile depending on the circumstances.

Importantly, this approach operates alongside the general defence provided by clause 86, and is available in circumstances where the person has done all that is reasonable and practicable to prevent the offence from occurring. If the defendant has complied with all of their legislative requirements and the conditions of their authorisation then there is a strong argument to be put that they took all reasonable and practicable measures. In addition, as these are criminal offences, proving an allegation of actual or potential radiation harm will require the EPA to convince the court beyond reasonable doubt that the harm is linked directly to the alleged incident.

The maximum penalty is the highest that can be imposed by a sentencing court and must reflect the worst possible offence that could occur. In practise it is extremely rare that the court imposes the maximum penalty and higher penalties are reserved for the most serious, repeated and aggravated contraventions.

The following maximum penalties are proposed for each offence:

- Clause 50(1) – Intentionally and recklessly causing serious radiation harm:
 - body corporate – \$5,000,000
 - natural person – \$1,000,000 or 15 years imprisonment or both.
- Clause 50(2) - Causing serious radiation harm:
 - body corporate – \$2,500,000
 - natural person – \$500,000 or 10 years imprisonment or both.
- Clause 51(1) - Intentionally and recklessly causing radiation harm:
 - body corporate – \$1,000,000

- natural person – \$200,000 or 5 years imprisonment or both.
- Clause 51(2) – Causing radiation harm:
 - body corporate – \$500,000
 - natural person – \$100,000 or 2 years imprisonment or both.

The maximum penalties have been set by Parliamentary Counsel with consideration of the nature of the legislation, the particular offences they relate to and the precedent set by other comparable legislation. Of particular relevance, sections 8 and 9 of the *Nuclear Waste Storage Facility (Prohibition) Act 2000* have similar maximum penalties of \$5 m for a body corporate for the offences of construction or operation of nuclear waste storage facility, and importation or transportation of nuclear waste for delivery to nuclear waste storage facility where the potential consequences, in the worst case scenario, are comparable.

These provisions of the Bill were raised throughout the consultation period as being of concern to industry and industry professionals in that, as drafted, there were perceptions that the offence could be applied to all and any radiation exposures. This view is based on the theoretical ‘Linear No Threshold model’ where it is considered that all radiation exposures have the potential to cause harm. Amendments have been proposed to limit the application of these provisions to incidents where the act causing the potential offence has not been in good faith, is not in accordance with the RPC Act or is negligent. A further proposed amendment will increase the burden of proof for the ‘radiation harm’ provisions requiring the EPA to prove that harm was ‘likely’ rather than the lesser burden of ‘potential’ for radiation harm. Industry engagement on the amendments during the consultation period indicate that these amendments will address the concerns raised. These changes are detailed in sections 4 and 5 of this consultation report.

2.5 Orders

The Bill seeks to introduce a number of new provisions to allow orders to be issued by the Minister. The Bill provides for three types of orders – radiation protection orders, reparation orders, and radiation protection cessation orders.

A radiation protection order would be issued in the event that a person is undertaking an action or activity in contravention with the Act (including the general duty of care) or a condition of an accreditation or authority (licence or registration), in particular an action or activity which is causing harm to people or the environment through exposure to radiation.

A radiation protection order may include any condition necessary to eliminate or mitigate the risk of harm or actual harm being caused, such as requiring the person to take, discontinue or not commence specified actions.

A reparation order would be issued in the event that an action or activity has already taken place in contravention with the Act or a condition of an accreditation or authority, which has caused harm to people or the environment through exposure to radiation. This order may include conditions requiring a person to undertake certain actions or make payment in order to make good any resulting damage to people or the environment. The Bill also provides for a reparation authorisation which may be issued to a third party in order to allow to undertake the action necessary to make good on the resulting damage caused by the person.

A radiation protection cessation order may be issued to prevent or minimise harm, or for dealing with stockpiled or abandoned material after the activities or operations have ceased.

These orders provide an alternative enforcement mechanism to strict liability prosecutions through the court. The sole purpose of an order is to mitigate and remediate harm rather than penalise the person. An order can achieve a more desirable outcome for all parties and ensure that actions are taken as soon as possible to stop further harm being caused.

2.6 Amended maximum penalties

The relatively consistent maximum penalty that most offences under the Act attract (\$10,000) is currently less than penalties in equivalent legislation that also seek to protect public health and safety.

In many instances the maximum penalty does not accurately reflect the severity of the offence. For example, if a person fails to follow a direction of the Minister in relation to the disposal of a radiation source after a licence or registration is

suspended or cancelled, the maximum penalty is \$10,000. This is grossly inadequate for these types of offences given the risk that improper disposal creates and the financial gain of not following the direction may exceed the maximum penalty.

Similarly, the maximum penalty for issuing false or misleading information in relation to the Act is \$10,000. Again this is grossly inadequate considering the radiation harm that may result and the fact that the financial gain associated with issuing false or misleading information may also exceed the maximum penalty.

The RPC Act also does not make allowance for higher maximum penalties for body corporates than for a natural person. Given that the Act regulates many individuals as well as businesses which include multinational companies, it is inappropriate in many instances to apply one maximum penalty to all situations.

All maximum penalties in the Act have been revised.

2.7 Miscellaneous amendments to the RPC Act

Radiation Protection Committee

The composition and operation of the Radiation Protection Committee (RPC) will be amended and the RPC must consist of up to nine members, rather than the current 10, and members may have collective attributes of knowledge and practical experience.

One of the committee members nominated by the Minister must be a person selected by the Minister for Health to represent the interests of the Minister for Health on the Committee. This acknowledges the significant expertise that the public health system has in the use of radiation and effective regulatory approaches.

Aligned with licensing reforms, discussed above, the function of advising the Minister on all licences has been removed as there is ability for the RPC to advise the Minister on complex licences within the broader function of advising the Minister on various matters. The current Act prescribes four subcommittees that are not well utilised. The Bill will remove these standing subcommittees and prescribe that the Minister may establish subcommittees on matters as needed.

Enforcement of the Act

The Bill introduces civil penalties where a penalty may be negotiated in certain circumstances in lieu of court proceedings. Civil penalty provisions have been used successfully in the EP Act and were recently included in the *Local Nuisance and Litter Control Act 2016*. The ability to negotiate a penalty in lieu of court proceedings provides a reduced cost outcome to both the regulator and the alleged offender. The use of civil penalties under the EP Act is guided by an EPA policy that ensures they are only used in appropriate circumstances and not in circumstances where there is considerable public interest. It is intended that any use of civil penalties under the RPC Act would be guided by an updated or similar EPA policy.

An offence to abandon a radiation source has been introduced. It will be an offence, in the absence of a reasonable excuse, to abandon an ionising radiation source or non-ionising radiation source of a prescribed class.

Review of administrative decisions

The Bill proposes that persons may apply to the South Australian Civil and Administrative Tribunal (SACAT), rather than the Supreme Court, for a review of an administrative decision. The SACAT is a low-cost jurisdiction specifically set up for hearing administrative matters.

3 Consultation on the draft Bill

3.1 2013 consultation

In 2013 a Bill to replace the RPC Act was consulted on. The 2018 Bill is essentially an amended version of the 2013 Bill that has taken into account various issues raised during the 2013 consultation. It is therefore relevant to the current Bill to document the consultation in 2013.

Consultation on this draft Bill 2013 was held from 1 October to 30 November 2013. This included two public consultation forums and meetings with individual stakeholders.

A total of 21 submissions were received, and were generally supportive of the purpose of the Bill and acknowledged the need for nationally consistent and more flexible legislation. The majority of submissions were received from industry associations, the mineral resources sector and law associations.

A number of elements of the 2018 Bill are a result of the 2013 consultation. New provisions have been inserted in the Bill regarding 'financial assurances' (clause 37), 'death, bankruptcy, etc of holder of authority' (clause 45) and 'offence to abandon radiation source' (clause 29).

3.2 2018–19 consultation

The RPC Bill 2018 and an explanatory report were released for consultation on 29 November 2018 for an 11-week period. The consultation was advertised in *The Advertiser* and on the EPA website. Consultation documents were available on the EPA website from that date. Letters were also sent to relevant industry and professional associations and emails were sent to all licensees.

A total of 24 submissions were received during the consultation period. These came from industry and professional associations (7), businesses (7), universities (4), government agencies (2) and private citizens (4).

Most submitters indicated support for the modernisation of radiation protection legislation. Many submitters raised opposition to the radiation harm provisions and others sought clarification of various matters and suggested improvements. A full list of submitters is included as [Appendix A](#).

4 Comments – clause by clause

The following section documents all relevant comments made in consultation submissions. Care has been taken to transcribe comments faithfully to their intent as in some cases rewording has been necessary to assist with their understanding. Where comments are similar across multiple submissions a single comment may be used in some cases.

4.1 Clause 3 – Interpretation

Comments

- Definition of ‘radiation source’ is indirectly referring to an apparatus. If so it is suggested that the word ‘apparatus’ is included in the definition.
- ‘Apparatus’ is not defined.
- Definition of ‘non-ionising radiation’ is broad and may include electrical equipment that is not intended for regulation.
- The interpretation of ‘vehicle’ does not include trains.
- The interpretation of ‘vehicle’ includes aircraft whereas *Radiation Protection Series C-2* states that transport of radioactive substances by aircraft is covered by the Civil Aviation Act (ie outside state jurisdiction). Need to check jurisdiction but application is of broader relevance than licensing such as authorised officer powers.

Response

‘Radiation source’ is defined broadly so as to capture all sources. ‘Apparatus’ is captured within the definition.

Apparatus takes as its common meaning throughout the Bill: ‘an assemblage of instruments, machinery, appliances, materials etc, for a particular use’. It is not necessary to define terms that take their common meaning.

There is a need to provide a broad definition of ‘vehicle’ within the Act to allow for the full operation of clause 69 – Powers of authorised officers regarding inspection, etc. For this reason it is appropriate to retain ‘aircraft’ and to add ‘trains’ to the definition. Additionally, trains will be necessary for the correct operation of clause 21. Consideration will be given to the need for amendments to licensing elements of the legislation in the context of lack of jurisdiction for aircraft noting that the carriage of dangerous goods by aircraft is covered by the Civil Aviation Act 1988 (Cwth). This will likely be reflected in clause 21 as an exclusion rather than an amendment to the definition of ‘vehicle’ as it is necessary to keep various other powers of inspection, etc related to aircraft when they are not flying but may contain items relevant to an investigation (not transporting).

Amendments

- Amendment to the definition of ‘vehicle’ to include trains.
- Liaise with Parliamentary Counsel regarding transport licensing to ensure appropriate limits of jurisdiction in the context of transport of radioactive material by aircraft being a Commonwealth responsibility under the *Civil Aviation Act 1988* (Cwth).

4.2 Clause 5 – Objects of Act

Comments

There is potential for the RPC Bill to become out of step with amendments to the Environment Protection Act regarding the term ‘ecologically sustainable development’ (ESD). Is duplication required?

Response

The principle of ecologically sustainable development is relevant in certain settings particularly where contamination from radiation may arise. The reference to the principle is linked to the EP Act so that any amendments to this Act are reflected in the new legislation. No amendments are proposed.

4.3 Clause 6 – Radiation protection principle

Comments

- Alignment with International Commission on Radiation Protection (ICRP) publication and the National Directory for Radiation Protection regarding wording.
- That existing procedures (including radiation management plans) are recognised as sufficient information in justification for X-ray procedures.
- Have considerations been made regarding other principles of radiation risk management and their application as per the ARPANSA document *Radiation Protection Series F–1 Fundamentals for Protection Against Ionising Radiation*?
- Inclusion of a modified version of the radiation protection principles from National Directory for Radiation Protection (RPS 6) provides an appropriate foundation for the 2018 draft Bill.

Response

While the clause 6 principle is not drafted verbatim to the ICRP and the *Radiation Protection Series F–1 Fundamentals for Protection Against Ionising Radiation* it carries the same meaning. The drafting ensures that the terms are legally binding.

Radiation Management Plans can provide general guidance however procedures need to be justified on a case-by-case basis.

The other principles within the ARPANSA document are implemented through the legislation as a whole, including the regulations. No amendments are proposed.

4.4 Clause 7 – Principles of ecologically sustainable development

Comments

This is a principle of the EP Act. Is it necessary to include section 4 given this in the Bill? Please consider as there is potential for the RPC Bill to become out of step with the amendments to the EP Act.

Response

As above, the principle of ecologically sustainable development is relevant in certain settings particularly where contamination from radiation may arise. The reference to the principle is linked to the EP Act so that any amendments to this Act are reflected in the new legislation. No amendments are proposed.

4.5 Clause 8 – Radiation Protection Committee

Comments

- That membership requirements consider skills related to veterinary use of radiation.
- Subclause 8(3) where 'Commission' is not otherwise defined or mentioned. Suggest this is changed to Committee.

Response

The expertise listed for the committee includes radiology, nuclear medicine, radiation oncology and health or medical physics which are relevant to the radiation aspects within a veterinary context. To allow for suitably qualified veterinarians to be members of the Committee it is proposed to remove 'human' from subclause (a) 'radiology or human diagnostic radiography such that this portion of the membership may be selected on merit from both human and veterinary fields. The Bill also allows for the establishment of subcommittees (clause 13) where the Minister may appoint additional members. If there is a significant issue relevant to veterinary practice, a subcommittee with additional veterinarian representation may be formed.

'Commission' is a typographic error.

Amendments

- Remove 'human' from subclause 4(a)
- 'Commission' to be changed to 'Committee' where necessary in the Bill

4.6 Clause 10 – Functions

Comments

Clarification sought as to why the function of the Radiation Protection Committee to advise the Minister on all licences and conditions has been removed.

Response

The function of advising the Minister on all licences has been removed as there is ability for the Radiation Protection Committee to advise the Minister on complex licences within the broader function of advising the Minister on various matters. It is an unnecessary and inefficient requirement that the Radiation Protection Committee advise the Minister on every license that is sought. The majority are for low-risk matters that can be readily processed in a timely manner by staff under delegation from the Minister. No amendments are proposed.

4.7 Clause 12 – Proceedings

Comments

Subclause 12(6) 'Commission' is not otherwise defined or mentioned. Suggest this is changed to 'Committee'.

Response

These are typographical errors.

Amendments

'Commission' to be changed to 'Committee' where necessary in the Bill

4.8 Clause 15 – Provision of services

Comments

Given the importance of the Committee it is suggested that 'may' be replaced with 'will' or 'must'.

Response

The provision of departmental services to the Committee is a resourcing matter for the Minister and the Chief Executive. It is not appropriate for Parliament to dictate this. The clause is modelled on similar provisions in other legislation and is consistent across the statute book. No amendments are proposed.

4.9 Part 4 – Division 1 – Radiation management licence

Comments

- As written, it is unclear if the Bill will require one or multiple radiation management licences for parties undertaking more than one activity. Multiple Radiation Management Licence types create inefficiencies, increases costs and leads to duplication of regulation of these activities. It is suggested that a single radiation management licence is adopted.
- Legislation should require a radiation management licence for all of the activities within a single section.
- Need for separate licences for construction, establishment and control of a radiation facility. Can a licence be granted before works are completed?
- That the licence to possess radiation sources and the registration of individual sources be merged into a single process.

- Opposition to the notion that owners and the responsible person may be found guilty of an offence for allowing an unlicensed person to operate an apparatus when they have no knowledge that an unlicensed operator is using radiation or is handling radioactive substances.
- Will there still be provision for staff without a licence but under the supervision of a licensed user, in accordance with procedures and training, to carry out work using unsealed radioactive sources?
- If legislation can focus on serious risks and establish *de minimis* levels of risk that are not subject to regulatory control, this would be beneficial to society generally in harnessing the benefits of radiation use.
- Regarding transport licensing it is suggested that *Radiation Protection Series C-2* be adopted in full.
- Concerns around the transport licensing requirements and the concentration levels at which transport licences are required, as these levels remain unclear in the Bill at this stage.
- Transport by foot should be able to be undertaken without a licence.
- Creates an additional regulatory authorisation for transport of radioactive material
- Has an assessment of the regulatory impact of this additional (transport licensing) requirement been undertaken?
- License to possess and registration should be merged into one process.
- That regulations surrounding the registration and use of Computerised Axial Tomography be updated to allow veterinarians to both own and operate these diagnostic machines.
- Clarity is sought as to whether a core storage facility at a mine site authorised under clause 19 – Mining or mineral processing will also require authorisation under either clause 20 – Construction, establishment, control, etc of a radiation facility or clause 25 – Premises in which unsealed radioactive materials are handled or kept?
- The consolidation of licences provides many advantages to holders of multiple authorisations. This is a significant streamlining efficiency initiative.

Response

Attempts were made to condense licensing provisions into fewer clauses (one for each type of licence). This has not been successful because of the breadth and diversity of the activities regulated and the complexity of the licensing scheme. It would have required extremely long provisions and resulted in a considerable number of cross references being required in the Bill which would not be very user friendly. There are only two licence categories and per clause 39 the application process will allow for multiple activities under a single licence. The Bill also allows for registrations to be listed on a licence however there may be a need for further registrations to be added to a licence over time.

The activity 'construction, establishment, control etc of radiation facility' will be part of an overall Radiation Management Licence where relevant and may include other activities on the licence. Staged approvals are through condition of licence.

The responsibilities within a Radiation Management Licence includes limiting access to apparatus to those persons suitably licenced or otherwise allowed to access the equipment in the regulations (such as the regulations allowing staff to operate under supervision in certain circumstances). It is appropriate to apply controls regarding access to radiation equipment.

The Transport Code has been adopted in full through the regulations with minor alterations as needed. These will be reflected in regulations under the new Act. Transport licensing details will be incorporated in the regulations. Transport licensing does not apply to transport within an authorised premises.

Qualifications and other requirements for licensing are established in the regulations. Regulations will be made under the new legislation and will be consulted on prior to the new legislation commencing. No amendments are proposed.

4.10 Part 4 – Division 2 – Radiation use licence

Comments

- The Bill should allow for a single radiation use licence. No benefit is gained in having separate use licence types, as individual licence conditions are added to licences based on the proposed radiation use. The separate use licence types require duplication of administration. This creates confusion in oversight of employee radiation licences, additional checks and administrative processes are required. Propose a single licence is adopted, a single anniversary date is adopted for all individuals, and an easily searchable public register is made available.
- Two separate use licence types is inefficient and creates an unnecessary burden to the regulated community.
- Does clause 24(1)(b) relate to lasers?
- Staff under supervision should not require licensing.
- Enclosed X-ray cabinets should be able to be operated without a licence.
- Veterinary nurses with the Certificate IV in Veterinary Nursing should be eligible to be licenced to operate X-ray equipment
- That a suitable course be recognised as an appropriate condition for registered veterinarians to become licensed to operate CT equipment and fluoroscopy.
- That regulations surrounding the registration and use of Computerised Axial Tomography and C-Arm be updated to allow veterinarians to both own and operate these diagnostic machines.
- Veterinary theatre staff be allowed to receive C-Arm licenses or use under supervision.

Response

Attempts were made to condense licensing provisions into fewer clauses (one for each type of licence) but this was not successful because of the breadth and diversity of the activities regulated and the complexity of the licensing scheme. It would have required extremely long provisions and would have resulted in a considerable number of cross references being required in the Bill which would be very un-user friendly. There are only two licence categories and per clause 39 the application process will allow for multiple activities under a single licence.

Non-ionising radiation of a prescribed class will be determined by the regulations. Prescribed classes of persons or apparatus excluded from licence requirements, such as certain staff when supervised by a licensed person, will be determined in the regulations. Regulations will be made under the new legislation and consulted on prior to the new legislation commencing.

Qualifications and other requirements for licensing are established in the regulations. Regulations will be made under the new legislation and consulted on prior to the new legislation commencing. Veterinary qualifications will be considered as part of this process. No amendments are proposed.

4.11 Clause 25 – Premises in which unsealed radioactive materials are handled or kept

Comments

It is unclear if a licence separate to a Radiation Management Licence is required here. It is assumed that a registration will appear on the Radiation Management Licence where the conditions of the licence will be based on what is registered. Is this true?

Response

That is correct. No amendments are proposed.

4.12 Clause 26 – Sealed radioactive sources

Comments

- Under the current Act an exemption is required regarding sources used for medical applications that have half-lives not exceeding two years and are routinely swapped back to the manufacturer. It is suggested that this is taken into account in the Bill.
- Supervision of unlicensed staff should still be possible.

Response

Clause 26(3) allows for sources of a prescribed class to be excluded from the provision if this is deemed suitable. This will be addressed in the Regulations made under the new legislation and consulted on prior to the new legislation commencing. No amendments are proposed.

4.13 Clause 27 – Radiation apparatus

Comments

Non-ionising radiation apparatus of a prescribed class should be removed. Non-ionising radiation apparatus includes everything from a mobile phone, optical imaging equipment, microwave, etc.

Response

The Bill states that only non-ionising apparatus of a prescribed class requires registration. This allows the more significant apparatus to be included through the regulations whereas low-risk equipment such as that listed above will not be prescribed. No amendments are proposed.

4.14 Clause 29 – Abandonment of radiation sources

Comments

- Without reasonable excuse seems too vague and is not defined as to what would be reasonable.
- Bill does not include the procedure in performing source handover or surrendering a source in the event of the circumstances described in clause 29.

Response

Reasonability will be determined on a case-by-case basis and by considering the facts of the case. Source handover or surrender is not abandonment but procedures will be addressed in the Regulations made under the new legislation and will be consulted on prior to the new legislation commencing. No amendments are proposed.

4.15 Clause 30 – Accreditation process

Comments

How is an accreditation determined and by whom?

Response

The process will be addressed in the Regulations made under the new legislation and will be consulted on prior to the new legislation commencing. The determination will be made under delegation from the Minister. No amendments are proposed.

4.16 Clause 31 – Authority conferred by accreditation

Comments

The process to be accredited is unclear.

Response

This will be addressed in the Regulations made under the new legislation and will be consulted on prior to the new legislation commencing. There will also be non-legislative guidance provided by the EPA in the lead up to commencement of the new legislation. No amendments are proposed.

4.17 Clause 37 – Minister may require financial assurance to secure compliance with conditions of authorisation

Comments

It is unclear, if this is in addition to the Department of Energy and Mining mandated closure provisions. Greater clarity regarding what this bond is designed to cover is sought.

Response

The financial assurance provisions in the Bill will only be applied to liabilities related to specifically to radiation protection that are not already subject to a financial assurance or bond. There is no intent to duplicate obligations across different acts and indeed duplicate bonds held on behalf of the state government may not be lawful. No amendments are proposed.

4.18 Clause 38 – Duration of accreditation or authorisation and renewal

Comments

- Period of accreditation or authorisation proposed is too short.
- Annual fees should be replaced by fees that represent the term of the approval.
- Renewal date should be the same for all licences.

Response

Any activities within a single licence will be due at the same time however establishing a single date for all renewals is not practical in managing staff workload. Annual fees are standard across most government licensing. The Bill extends licensing to 5-year maximum term. No amendments are proposed.

4.19 Clause 39 – Issue of single authorisation

Comments

Adding a provision to allow multiple authorisations to be combined into a single authorisation leads to another layer of complexity to the legislation.

Response

This is a drafting approach that will allow for the issue of a single radiation management licence that includes multiple activities and registrations or a single radiation use licence that includes multiple activities. The application process for licences with multiple activities will be straightforward. No amendments are proposed.

4.20 Clause 43 – Review of decisions

Comments

- Concerns that the role of SACAT is limited and does not encompass challenging the EPA on their interpretations of any part of the Act.
- Clause states that all reviewable decisions are made by the Minister. Subclause 43(4) refers to a 'person' who makes a reviewable decision.

Response

The role of SACAT is to review administrative decisions made under the legislation. The ERD Court considers the validity of EPA argument on criminal matters. Reviewable decisions are generally made by EPA staff under delegation from the

Minister and it is those persons that may need to give a written statement of the reasons for the decision as required by the legislation, in addition to the Minister when the Minister makes a decision themselves. No amendments are proposed.

4.21 Clause 46 – Power to deal with dangerous situations

Comments

- The Minister or persons acting on behalf of the Minister should be radiation safety experts to ‘take action, or cause action to be taken’ in case of dangerous situations, to avoid further dangerous situations caused by their actions taken.
- A police officer is not a radiation safety expert and could incur more damage to the environment or themselves if they do not know how to handle radioactive sources or apparatus. They cannot judge what a safe action because they do not have the proper training in radiation safety.
- The definitions of ‘dangerous situation’ and ‘potentially dangerous situation’ are vague, particularly when referring to ‘imminent risk or environmental harm’. Further clarity to this section may be beneficial to all parties.

Response

Police officers are authorised to act in emergencies in most scenarios under the *Fire and Emergency Services Act 2005*. This simply gives them additional powers of direction. Directions would be in accordance with the State Emergency Management Plan and the EPA (radiation experts within the agency) is the technical adviser for radiation matters under that plan. No amendments are proposed.

4.22 Clause 49 – Limits of exposure to ionising radiation not to be more stringent than limits fixed under certain codes etc

Comments

- It is unclear as to why mining is specified. Does this imply that regulation or an accreditation can impose different exposure requirements for other industries? The setting of dose limits should follow national uniformity.
- Reference to obsolete documents from National Health and Medical Research Council (NHMRC) should be removed.
- NHMRC is no longer involved in setting limits of radiation exposure.
- The wording should be revised.

Response

This is an existing provision of the RPC Act (section 26) and is limited to mining and mineral processing. The purpose of the provisions is as it reads. This provision is regarding setting limits in regulations and through conditions of licence, not adoption of standards. Limits must fall between the least stringent and most stringent. Five documents from NHMRC have yet to be revised and one of these are still relevant in the mining context (RHS No.28) for which this clause is limited to. No amendments are proposed.

4.23 Clauses 50 and 51 – Causing radiation harm and causing serious radiation harm

Comments

- The system of radiation protection is based on the concept that any exposure to radiation has a corresponding effect. This is a model that is perhaps not accurate, but which is upheld at an international level due for reasons of convenience and practicality. The implication is that any exposure to radiation causes harm, and is therefore an offence.
- If the regulatory assumption is that the risk of secondary cancer is linear with no threshold then all medical uses of radiation has the potential to cause harm.
- The Linear No Threshold model dictates that all exposures increase potential for harm.
- ‘Potential radiation harm’ is actually risk.
- Lawful procedures that are known from the onset to cause harm would be captured.

- Imaging of wrong limb could trigger this provision.
- If the word 'harm' is to be maintained, then it be quantified to provide certainty for users, the public and radiation protection professionals.
- While the terminology is unfamiliar it is not dissimilar to concepts already introduced in the WHS legislation and for this reason I don't think it will pose problems in practice.
- Terminology has the potential to cause the deleterious effect of creating fear and misunderstanding amongst members of the public.
- The provision is out of step with other state legislation.
- These sections should only capture cases of deliberate negligence and not the everyday application of radiation in medicine.
- Overly harsh penalties in the medical imaging environment.
- Clauses should include a reference to the general defence (clause 86)
- Serious harm could be caused by an accident, including if all the known practicable measures to prevent the accident are followed. But according to this clause, even in those cases, the person is guilty of an offence.

Response

It is recognised internationally that all radiation exposure has the potential to cause harm (Linear No-Threshold model) and radiotherapy specifically is the process of causing harm (often considerable) to treat a patient in that the benefit outweighs the detriment. This is not the type of harm that the Bill seeks to address. Instead it provides a penalty for harm that results from a situation where harm is caused as a result of significant breaches of the legislation.

Furthermore there is a view among professionals in the field that under the wording of the Bill, if the theoretical Linear No-Threshold model is accepted as a determinant of the 'potential' for harm they would potentially be in breach every time they expose someone to radiation even when they comply with all other parts of the legislation (dose limits, protection, etc). The reliance on the general duty (clause 86) to defend such actions provides no certainty or comfort regarding compliance in their everyday work.

It is proposed to amend clauses 50 and 51 such that they do not apply to acts done in good faith, in accordance with the Act and without negligence. It is further proposed to replace the term 'potential' with 'likely' increasing the burden of proof that harm has occurred or is likely to occur as a result of the Act and removing any link to the theoretical Linear No-Threshold model.

The Act needs to be read as a whole regarding the need to reference to clause 86 on general defence.

Amendments

- Amend clauses 50 and 51 such that they do not apply to acts done in good faith, in accordance with the Act and without negligence.
- Replace the term 'potential' with 'likely' in all references with clauses 50 and 51.

4.24 Clause 53 – General duty of care

Comments

- To be consistent with clause 6 it is suggested that (a) should refer to optimisation rather than just ALARA (as low as reasonably achievable) or general duty is that a person must adhere to the radiation protection principle.
- Subclause (b) should be re-written with the following in mind: when radiation become dangerous, what effects constitute danger, is danger present for stochastic risk, or only for deterministic radiation effects.
- It is suggested that in subclause (b) 'minimised' should not be used and is replaced with 'optimised' to be consistent with the radiation protection principle.
- The principles of ecologically sustainable development are duplicated from other Acts and may therefore be redundant in the RPC Bill. There is potential for the Bill to become out of step with the EP Act.

Response

The provisions of the general duty of care articulate the requirements of the duty rather than principles. Regard to the radiation protection principle (clause 6) in determining compliance with the duty is applied through the application of subclause (2).

The principle of ecologically sustainable development is relevant in certain settings particularly where contamination from radiation may arise. The reference to the principle is linked to the EP Act so that any amendments to that Act are reflected in the new legislation. No amendments are proposed.

4.25 Clause 54 – Radiation protection orders**Comments**

- It is not clear why some of the radiation protection orders are given by the Minister and in subclause (5) by an authorised officer.
- Request that contravention of the general duty of care will not be sufficient by itself to issue a radiation protection order. There should be a requirement to make reference to one or more breaches or a specific section, regulation or paragraph of an adopted standard.

Response

Authorised officers may only issue an order in urgent circumstances. A radiation protection order may be used to prevent a future breach from occurring and is a preventative measure rather than a punitive measure. No amendments are proposed.

4.26 Clause 55 – Radiation protection cessation orders**Comments**

It is unclear if the Minister can issue a radiation protection cessation order to protect the public, is this intentional?

Response

It is agreed that the addition of protection of the public would improve the operation of the clause.

Amendments

- Amend clause 55(1)(a) by adding reference to preventing or minimising harm to people.

4.27 Clause 56 – Action on non-compliance with radiation protection order**Comments**

- Subclause (2) is acceptable providing that the authorised officer is a radiation safety expert.
- Subclause (3) mentions a 'person taking action'. It is not clear whether that person is an authorised officer or not.

Response

Authorised officers are employed with qualifications relevant to their role, in this case radiation protection. Actions that may be required here are not necessarily all undertaken by a radiation expert. For example if earthworks were a requirement or other building works while probably under supervision from an expert in radiation safety, the work may be carried out by someone who is authorised by the Minister to do so. No amendments are proposed.

4.28 Clause 58 – Action on non-compliance with reparation order**Comments**

- Subclause (2) is acceptable providing that the authorised officer is a radiation safety expert.
- Subclause (3) mentions a 'person taking action'. It is not clear whether that person is an authorised officer or not.

Response

Authorised officers are employed with qualifications relevant to their role, in this case radiation protection. Actions that may be required here are not necessarily all undertaken by a radiation expert. For example, if earthworks were a requirement or other building works while probably under supervision from an expert in radiation safety, the work may be carried out by someone who is authorised by the Minister to do so. No amendments are proposed.

4.29 Clause 65 – Orders made by ERD Court

Comments

Additional resources are required for the ERD Court in the form of a specialist commissioner who has expertise in the medical use of radiation.

Response

Clause 81 of the Bill details the constitution of the court when exercising jurisdiction under the legislation. Subclause (c) requires that, where commissioners are used, at least one of them must have been specifically designated by the Governor as a person who has expertise in fields that are relevant to the jurisdiction conferred on the court by the legislation. No amendments are proposed.

4.30 Clause 66 – Civil penalties

Comments

- Are civil penalties a fine? That definition is not clear, or not given here.
- Subclause (2) is very confusing and very hard to understand. It is a sentence that is too long with vague statements.
- Subclause (10) – according to subclause (1) if the person agreed to pay a civil penalty, should the person not be prosecuted, as it is stated in (10)(b) when the criminal proceedings are mentioned?

Response

Civil penalties are a negotiated penalty that usually includes a monetary penalty. It is not a 'fine' within the context of the legislation. More information on civil penalties and how they are applied by the EPA can be found at https://www.epa.sa.gov.au/our_work/civil-penalty-calculation-policy.

Subclause (10)(b) links to subclause (9) in that where a civil penalty negotiation has commenced it is only with authorisation from the Attorney-General that criminal proceedings can be commenced. In these circumstances the negotiations for a civil penalty are stayed and may only be resumed if there is a verdict of not guilty. No amendments are proposed.

4.31 Clause 67 – Appointment of authorised officers

Comments

The appointment of authorised officers should be less generic than what is stated here. Authorised Officers have big responsibilities, since in many cases they act on behalf of the Minister. There is nothing stating that authorised officers need to be suitably qualified.

Response

Authorised officers are employed with qualifications relevant to their role, in this case radiation protection. It is at the Minister's discretion to appoint authorised officers as they see fit. This approach is common throughout South Australian statutes. No amendments are proposed.

4.32 Clause 69 – Powers of authorised officers

Comments

- The powers given to authorised officers, who are not radiation safety experts, can be very dangerous.
- Subclause (6) should only require that a person is not fluent in English.

- It should be noted that if an identity card has not been issued then the identity of the authorised officer cannot be established by a member of the public. It is suggested to remove ‘unless the identity card is yet to be issued’.

Response

An authorised officer is appointed by the Minister and legally has the powers upon appointment by the Minister rather than upon issue of a card (from a public servant). In practice an authorised officer would unlikely operate alone prior to a card being issued. It is an offence to purport to be an authorised officer [Clause 72(1)(h)]. These provisions are modelled on similar provisions in other legislation and is consistent across the statute book. No amendments are proposed.

4.33 Clause 76 – Exemptions

Comments

- As a general comment, using conditions of licence as a means of regulation would minimise the use of exemptions. Due to the current publishing method access, tracking, and review are cumbersome, imperfect and time consuming, making it easy to miss important legislative changes.
- The current approach to exemptions is not transparent, creates uncertainty and increases the regulatory burden.
- This section should be revised to explicitly allow inclusion of exemptions in clause 98 of the Bill.

Response

Each relevant section allows for ‘prescribed’ exclusions for classes of persons or apparatus. When something is ‘prescribed’ in legislation it is enacted through Regulations. Examples can be found at clauses 18(3), 19(3), 20(2), 21(2), 22(2), 23(2), 24(2), 25(2), 26(3), 27(2), and 29(2). Providing for individual person or apparatus exemptions through regulations is inefficient and ineffective as regulation changes must go to Cabinet and the Regulations would need to be re-published each time an exemption was granted. A condition can only apply a control, it cannot remove a control. This must be done by an exemption. No amendments are proposed.

4.34 Clause 77 – register of accreditations, authorisations, exemptions and permits

Comments

- An electronic public register is encouraged.
- It is unclear whether a fee is to be applied to a physical copy, an electronic copy or both.

Response

Fees will be addressed in the Regulations made under the new legislation and will be consulted on prior to the new legislation commencing. Encouragement for an electronic register is noted. No amendments are proposed.

4.35 Clause 78 – Adoption of documents forming part of National Directory

Comments

- Support for the idea of standardising practices by adopting national documents from the National Directory for Radiation Protection published by ARPANSA. This could avoid the use of international documents from different practices that could lead to discrepancies between them.
- It is suggested that these documents are specified as a condition of licence minimising the need to formally gazette any changes.
- National Directory should be added to the interpretation.

Response

It is likely that regulatory obligations contained within such documents will also be contained as a condition of licence.

With regard to the definition of ‘National Directory’ appearing in the clause rather than the interpretation section, it is drafting practice that where a term is only used in one clause of a Bill it is defined within that clause. No amendments are proposed.

4.36 Clause 84 – Vicarious liability

Comments

- Is the purpose of vicarious liability to impose legal responsibilities to both employees and employers for an omission or act against provisions of the Act?

Response

Yes. No amendments are proposed.

4.37 Clause 86 – General defence

Comments

- If a person who committed a contravention against the Act provides all evidence for general defence, is that person not guilty? If not, what is the purpose of defining options for general defence?
- Where a diagnostic medical radiation procedure is performed, the general defence does not appear to apply.
- It is noted that the ERD Court may impose orders despite a person using the general defence. We see a potential that medical radiation practitioners are still prevented from practicing their profession following routine medical procedures even if the general defence applies.

Response

The general defence is available to anyone that is prosecuted under the legislation. If they successfully demonstrate this defence to the Court then they are found not guilty. The ability to issue orders under clause 65 is separate from a conviction. This is to allow for circumstances such as remedy, remediation, compensation, etc. Being found not guilty under the general defence does not relieve responsibility for these other matters. No amendments are proposed.

4.38 Clause 88 – Imputation of state of mind of officer, employee, etc

Comments

It is not clear as to the definition of 'state of mind' (it seems a vague legal term). Does this clause remove the responsibility of an employee for proceedings of an offence, and impute it to the employer?

Response

This clause imputes the state of mind elements for certain offences committed by employees to the employer (whether a body corporate or natural person). These types of offences have a mens rea element in that there is a requirement to prove a mental element, such as intent. An example is clause 50(1). No amendments are proposed.

4.39 Clause 98 – Regulations

Comments

- It is noted that without subordinate legislation the full regulatory impact of the Bill is unknown.
- Need to explicitly allow for exemptions to be made in regulations.

Response

This is already provided for in the Bill through clause 98(1) and the various provisions throughout the Act allowing classes of persons or things to be prescribed as excluded from application of the Act. No amendments are proposed.

4.40 General comments

Penalties

- That the EPA prioritise an educative approach in the implementation of the legislation and punitive measures be reserved to address deliberate and repetitive non-compliance.
- Examples of maximum penalties of other relevant comparable new legislation could be provided in the Response to Submissions Document, to support the current position.

Guidance documents

- Support for guidance documents to assist industry understanding of obligations.

National consistency

- Similar to work health and safety legislation, a model national act and regulations adopted by all jurisdictions should be pursued.

4.41 Additional matters relevant to future regulations**Comments**

- An additional fee category for mines in 'care and maintenance' should be considered. This may also be a relevant consideration for other parts of the legislation.
- The outcomes of the Uranium Oxide Concentrate (UOC) Transport Review Project may require consideration in the regulations. For example, all SA uranium producers have a UOC transport plan to move uranium within the state. Currently transporters adopt the producers transport plan. Regulations may wish to formalise this arrangement.
- Interstate stakeholders regularly visit South Australia's core library and undertake XRF assessments using their own apparatus. It is understood, these individuals and XRFs require state licences and registrations with exemptions sought from the EPA. Streamlining this approach would be welcomed.
- Exemption for a natural person to possess a Radiation Use Licence to operate an ionising apparatus if the apparatus is a cabinet X-ray apparatus that complies with regulatory obligations. It is currently limited to only certain activities (regulation 56).

Response

These issues will be addressed in the Regulations made under the new legislation and will be consulted on prior to the new legislation commencing.

5 Summary of recommended changes to the draft Bill

Clause	Recommendation
Clause 3 – Interpretation	<ul style="list-style-type: none"> ➤ Amendment to the definition of ‘vehicle’ to include trains. ➤ Liaise with Parliamentary Counsel regarding transport licensing (clause 21) to ensure appropriate limits of jurisdiction in the context of transport of radioactive material by aircraft being a Commonwealth responsibility under the <i>Civil Aviation Act 1988</i> (Cwth). Suggest not applying the clause to transport of radioactive materials regulated under the <i>Civil Aviation Act 1988</i> (Cwth).
Clause 8 – Radiation Protection Committee	<ul style="list-style-type: none"> ➤ Remove ‘human’ from subclause 4(a). ➤ ‘Commission’ to be changed to ‘Committee’ where necessary in the Bill.
Clause 12 – Proceedings	<ul style="list-style-type: none"> ➤ ‘Commission’ to be changed to ‘Committee’ where necessary in the Bill.
Clause 50 – Causing serious radiation harm	<ul style="list-style-type: none"> ➤ Amend clause 50 such that it does not apply to acts done in good faith, in accordance with the RPC Act and without negligence. ➤ Replace the term ‘potential’ with ‘likely’.
Clause 51 – Causing radiation harm	<ul style="list-style-type: none"> ➤ Amend clause 51 such that it does not apply to acts done in good faith, in accordance with the RPC Act and without negligence. ➤ Replace the term ‘potential’ with ‘likely’.
Clause 55 – Radiation protection cessation orders	<ul style="list-style-type: none"> ➤ Amend clause 55(1)(a) by adding reference to preventing or minimising harm to ‘people’.

6 Conclusion and next steps

There have been two consultation periods to get the draft Bill to its current state. The 2018 Bill is essentially an amended version of the 2013 Bill and has taken into account various issues raised during the 2013 consultation. The current consultation ran for a period of 11 weeks between November 2018 and end February 2019.

A total of 23 submissions were received. Most submitters indicated support for the modernisation of radiation protection legislation. Many submitters raised opposition to the radiation harm provisions as they were drafted and others sought clarification of various matters and suggested improvements. Towards the latter part of the consultation period certain key stakeholders were engaged to review possible amendments to the Bill to overcome some of the issues regarding radiation harm raised early on in the consultation. Feedback from those consulted on the proposed amendments has been supportive of those changes. Those changes are reflected in the proposed amendments summarised in section 5 of this report. Some other minor changes to the Bill have been proposed as a result of the consultation.

The amended Bill will now be considered by the Minister for Environment and Water, Hon David Spiers MP and by Cabinet, and approval sought for the Bill to be introduced into Parliament. A detailed explanation of the parliamentary process can be found at:

www.parliament.sa.gov.au/AboutParliament/HowParliamentWorks/TheParliamentaryProcess/Pages/HowaBillbecomesanActofParliament.aspx

Appendix A List of submitters

Private citizens

PJ Collins

Kent Gregory

Alice Jagger

Marianne Keller

Government agencies

Department for Energy and Mining

SA Medical Imaging

Industry associations/professional societies

Australasian College of Physical Scientists and Engineers in Medicine

Australasian Radiation Protection Society (SA Branch)

Australian and New Zealand Society of Nuclear Medicine

Australian Society of Medical Imaging and Radiation Therapy

Australian Veterinary Association

South Australian Chamber of Mines and Energy

Veterinary Nurses Council of Australia

Universities

University of Adelaide – Animal and Veterinary Sciences

University of Adelaide – Microscopy

University of Adelaide – SAHMRI

University of South Australia

Businesses

Benson Radiology

Clinpath

Genesis Care

Heathgate Resources

Scantech

Smiths Detection

Vet Partners

Appendix B Radiation harm hypothetical examples

Terrorism

Example 1 – A person accesses radioactive material to create a ‘dirty’ bomb and detonates it, exposing a large area and many people to radiation.

Serious radiation harm that is intentional or reckless [clause 50(1)] could be argued to have occurred in such a scenario as the radiation exposure is on a wide scale and intention is easily proven. It would also need to be proven beyond reasonable doubt that the radiation exposure caused harm to, or has the potential to cause harm to, presently or in the future, the health or safety of a person or the environment [clause 50(4)].

Determination of harm to health and safety of persons would rely on an assessment of exposure and any immediate harms or potential for future harm. Harm to the environment could be demonstrated to the court using the cost to remediate the area. A number of other contraventions of the legislation could also likely be proven. Anti-terrorism laws would also be applied in such circumstances and a decision would need to be made as to whether to pursue the offence of serious radiation harm in addition to such charges.

Transport

Example 2 – Poorly secured and packaged radioactive material is being transported in a vehicle not displaying transport placards. The vehicle gets into an accident resulting in a radioactive material being spilt on a public road. Some of the material makes its way into the stormwater system.

Both the consigner and the carrier of the radioactive material will continue to have requirements in the regulations in relation to securing and packaging the material. The driver of the vehicle will continue to have requirements under the regulations in relation to reporting any damage to the package. Depending on the specific circumstances leading up to and surrounding the incident the consigner, carrier, driver or all could be prosecuted for a breach of the regulations. The carrier may also be in breach of their licence (clause 21).

Given that some of the material made its way into the stormwater system, which could result in significant harm to the environment as well as people’s health, the EPA could investigate the radiation harm offence in clause 51 if deemed that the penalties for the offences above were insufficient. Who would be prosecuted (carrier, consignor, driver) under this provision would depend on the facts surrounding the incident. In the immediate term the EPA would issue a reparation order (clause 57) requiring remediation of the area. To whom this is issued to will depend on the facts of the case.

Medical

Example 3 – A hospital treating a patient with radiotherapy (through the use of a linear accelerator) gives the patient an excessive dose of radiation, resulting in serious side effects. The patient’s family make a complaint to the EPA. The hospital is found to have not carried out essential calibration checks on equipment and had not exercised due diligence. The patient suffered non-life threatening burns as a result that were unlikely to have occurred if the procedure were done as clinically determined.

This offence could be prosecuted as a breach of a condition of a Radiation Management Licence (possession of radiation source) under clause 22 of the Bill. Through a condition of licence, the licensee would be required to ensure calibration of the equipment. Not complying with this requirement would constitute a breach of licence condition [clause 36(5)]. A condition of licence requiring calibration of radiotherapy instruments would likely be considered a major condition for the purposes of clause 36(5) in that the potential harm from overexposure would be significant when compared with other low-dose forms of equipment. The maximum penalty for this offence is \$500,000 for a body corporate and \$100,000 or 10 years imprisonment or both for a natural person.

However, if the action was considered reckless or intentional, or the harm or potential harm was considered more significant than the non-life threatening burns (ie high potential for cancers), that the above penalty was considered an insufficient deterrent, the EPA could pursue an investigation and possible prosecution of the hospital (if considered responsible) under clauses 50 or 51 for causing radiation harm or serious radiation harm. This would be a decision for the EPA as regulator and, as with all offences in the Bill, would need to be proven beyond all reasonable doubt.

Example 4 – A hospital treating a patient with radiotherapy (through the use of a linear accelerator) gives the patient a clinically determined dose resulting in serious side effects in the patient. The patient suffered non-life threatening burns as a result. The patient’s family make a complaint to the EPA. An investigation determined that no conditions of licence were breached and that the hospital had demonstrated its general duty of care (clause 53).

The EPA, having determined that the harm was caused by a lawful exposure, would not pursue an investigation any further. In coming to this determination the EPA would have considered whether any licence conditions were breached and whether the general duty of care had been demonstrated. These considerations are intrinsically linked to the general defence (clause 86) in that the EPA will not proceed with a prosecution of any form where the alleged contravention did not result from any failure to take all reasonable and practicable measures to prevent the contravention. The radiation protection principle would inform such an assessment.

In the context of medical exposures more generally, where a procedure is delivered in a way that is not contrary to licence conditions and an expected outcome of such a procedure is that harm or potential harm will be caused it could not be a reasonable or practicable expectation of the practitioner to prevent such harm.

Mining and industrial

Example 5 – A mining worker removes a radiation source from the site and keeps it at their home. The radiation source is low level and there is no evidence to suggest that injuries were caused as a result.

Clause 22 prescribes that a person must not be in possession of a radiation source unless authorised by a radiation management licence to do so. The person may be prosecuted under this provision. A maximum penalty of \$100,000 may apply to a natural person for this offence.

An investigation may also consider whether the owner of the source had complied with their Radiation Management Licence requirements under clause 22 regarding securing the source.

As the material is low level and there is no evidence to suggest harm or potential future harm could be linked directly (and beyond reasonable doubt) to the exposure, the radiation harm provisions of the Bill could not be applied.

Example 6 – A borehole logging service provider directed an unlicensed (and potentially unqualified) employee to use a sealed radiation source. At completion of work the employee failed to check the area and did not realise the source had been dropped. The source was left in a work area and resulted in other workers receiving doses above prescribed exposure limits and acute exposure effects (burns and hair loss).

The offence of the employee being unlicensed and handling the source is dealt with by clause 23. The employee would be in breach of clause 23(1) for handling radioactive material without a radiation use licence. The offence carries a maximum penalty of \$50,000. The owner (including a hirer if source has been leased or hired) would be in breach of clause 23(3) for causing the material to be handled by an unlicensed person (where a licence was required). This offence has a maximum penalty of \$50,000 for a natural person and \$250,000 for a body corporate.

The harm alleged to be caused is directly attributable to the over-exposure and can be proven beyond reasonable doubt. A determination would need to be made by the EPA depending on the facts of the case as to whether there would be merit in proceeding with both the initial offence and the offence of causing radiation harm. The EPA could pursue both offences.

Example 7 – A mine worker inhales uranium dust while performing maintenance in the uranium plant. An investigation found that the worker had not been adequately trained to work in the uranium plant. There was no observable harm from the exposure and the investigation, specific to this incident, found there to be a very low increase to the risk of future cancer (<2% chance).

An investigation into this incident would focus on whether the owner of the facility had breached a condition of their Radiation Management Licence [clause 36(5)(b)] by failing to adequately train staff with access to radioactive material. Whether or not the condition of licence was considered minor or major would depend on the facility. Penalties differ depending on the significance of the condition to radiation protection outcomes.

Harm offences would not be pursued as, specific to this incident, there were no observed effects from the exposure and the investigation found there was a very low risk of future cancer (<2% chance) as a result of the exposure.

Example 8 – A mine worker inhales uranium dust while performing maintenance in the uranium plant. An investigation showed that the worker was well trained to work in the area. The investigation also found that safety procedures for the area were very thorough and that the worker had deliberately disregarded those procedures. It was determined that the disregard for those procedures was the main cause of the exposure.

An investigation into this incident would focus on whether the mine worker was accessing the radioactive material without due authority or whether they had breached obligations as a radiation worker under the regulations.

The investigation has determined that the owner of the facility had done all that is reasonable and practicable to prevent the exposure through appropriate workplace practices and training and was not at fault. No action would be taken against the owner of the facility however a review of systems in place to prevent future incidents would take place.

Example 9 – A former mine employee who was regularly exposed to radiation through their employment over several years makes a complaint to the EPA accusing their previous employer of causing their incurable cancer. The complaint does not contain any allegations of individual over-exposures, poor workplace procedures or any other shortcomings.

An investigation has determined that the type of cancer does have a known link to radiation exposure, among other causes. The investigation has also found that the exposure records for the individual held by the company indicate there were no exposures above the radiation worker limit of 20 mSv/year. An interview with the complainant has not identified any extraordinary exposures. The company has no relevant historical compliance breaches.

The EPA investigation has concluded that the company was operating at all times within its legislative obligations during the complainant's tenure and that, in the circumstances, had done all that was reasonable and practicable to prevent harm from occurring to its workers. The EPA would not take action against the company.

Important note: The above examples are fictitious and the EPA considers the full facts of any incident in determining the appropriate regulatory action which may differ from those outlined above.