

Review of the Australian Radiation Protection and Nuclear Safety Act 1998



Prepared for the Department of Health and Ageing

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ACRONYMS USED IN THIS REPORT

For the purposes of this report, the acronyms and terms detailed below have the following meanings:

ALRC	Australian Law Reform Commission
ANAO	Australian National Audit Office
ANSTO	Australian Nuclear Science and Technology Organisation
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ARPANS Act	<i>Australian Radiation Protection and Nuclear Safety Act 1998</i>
ARPANS Regulations	<i>Australian Radiation Protection and Nuclear Safety Regulations 1999</i>
CSIRO	Commonwealth Scientific and Industrial Research Organisation
IAEA	International Atomic Energy Agency
IRRS	Integrated Regulatory Review Service. An IRRS follow-up mission (review) of ARPANSA was conducted by the IAEA in 2011
RHSAC	Radiation Health and Safety Advisory Council

CHAPTER 1 – EXECUTIVE SUMMARY

The Review

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), within the Health and Ageing Portfolio, is an Australian Government agency charged under the *Australian Radiation Protection and Nuclear Safety Act 1998* (the ARPANS Act) with responsibility for protecting the health and safety of people, and the environment, from the harmful effects of radiation.

In June 2012, mpconsulting was engaged by the Department of Health and Ageing to consider and report on the scope and operation of the ARPANS Act, and the legal capacity of ARPANSA to carry out the functions outlined in the ARPANS Act.

This review makes recommendations on the most important changes needed for the ARPANS Act, based on consideration of:

- whether the objects of the Act are being achieved, whether they continue to be appropriate and whether the legislative framework provided is appropriate to achieve the objects of the Act
- whether the regulatory powers and reporting responsibilities in the Act facilitate effective and proportionate compliance by licence holders, and enforcement of obligations imposed on them
- whether the monitoring and reporting of the operations of ARPANSA are effective and appropriate in the context of Parliamentary reporting requirements.

Consistent with the terms of reference, the focus of this review has been on the legislative framework that underpins the work of ARPANSA - specifically the ARPANS Act. While regard has been given to other regulatory and quasi-regulatory documents (including the Regulations, and also the policies and procedures of ARPANSA), the focus has been on whether the Act supports the objectives of ARPANSA and specifically whether the monitoring, enforcement and reporting powers are adequate.

To this end, this report explores 6 issues:

- the objects of the Act (Chapter 5)
- the licensing powers of ARPANSA (Chapter 6)
- the monitoring powers of ARPANSA (Chapter 7)
- the enforcement powers of ARPANSA (Chapter 8)
- the reporting obligations of both regulated entities and ARPANSA (Chapter 9).

Assessment criteria

In assessing the appropriateness of the ARPANS Act, mpconsulting has considered:

- the experience of ARPANSA and other stakeholders
- the qualities of best practice regulation, as described by the Office of Best Practice Regulation within the Department of Finance and Deregulation and the Australian National Audit Office (ANAO)
- international precedent, particularly the Codes and Standards of the International Atomic Energy Agency (IAEA)
- whether the legislation continues to be fit for purpose, taking into account both the current Australian radiation and nuclear safety environment, and recent international developments (including learnings from the Fukushima incident).

Analysis

In summary, mpconsulting considers that:

- the broad object of the ARPANS Act continues to be appropriate. The object of the Act is to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation.
- the ARPANS Act provides a reasonable framework for the regulation of Commonwealth entities dealing with radiation sources and nuclear and radiation facilities. The framework:
 - is readily understood by regulated entities
 - is not overly prescriptive
 - is reasonably flexible
 - is transparent
 - does not contain redundancy, inconsistency or overlapping regulation.

However, there are a number of areas where the legislation could be updated and improved to:

- reinforce the focus on proportionate risk-based regulation
- reflect international principles for radiation regulation
- better enable ARPANSA to monitor compliance with the legislation
- provide ARPANSA with a wider range of enforcement responses in the event of non-compliance
- ensure more meaningful reporting of incidents and non-compliance with the legislation

- address some anomalies in the application of the legislation.

Recommendations

This review makes the following conclusions and recommendations.

In relation to the object of the Act

- The existing object of the Act is appropriate and should be maintained. However, the object should be supplemented by key safety principles, based on the IAEA's Fundamental Safety Principles (recommendation A1).
- Recognising that radiation is an evolving technology and that international events and regulatory developments have a strong influence on the regulatory framework, the Act should be reviewed every 5 years. This is also consistent with good regulatory practice (recommendation A2).

In relation to licensing

- The ARPANS Act should be amended to provide greater flexibility to ARPANSA to issue not just source and facility licences, but also licences for processes or sites where these are the most appropriate licensing responses based on risk and promotion of safety (recommendation A3).
- The requirement for the CEO to consider international best practice (when considering licence applications) should be removed from sections 32 and 33 of the Act (recommendation A4). This requirement is unnecessarily subjective and vague. Instead, the Act should describe the fundamental, agreed, international safety principles (refer recommendation A1). These principles should apply across all aspects of ARPANSA's administration of the legislation (issuing of licences, application of conditions, inspections etc).
- ARPANSA licences reference a number of Codes and Standards that are out of date. ARPANSA should, following any Act amendments, review all licence conditions with a view to:
 - identifying a hierarchy of licence conditions that are risk-based and outcomes-focused wherever possible
 - removing unnecessarily prescriptive detail from licence conditions
 - removing references to outdated Codes and Standards.

This review should be staged and coordinated with other initiatives recommended in this report (recommendation A5). This review should also ensure that licence holders are afforded procedural fairness and that there is clear accountability for any decision making by ARPANSA in relation to licence conditions.

- To ensure that licences continue to be up-to-date, a condition should require that, every 5 years (or such lesser time as is prescribed in the licence by the CEO) the

licence holder must review its radiation uses, safety plans and arrangements, and resubmit these to ARPANSA (recommendation A6). If the changes are significant, ARPANSA may request that the organisation apply for a new licence. Alternatively, the licence conditions may stand, or may be amended to reflect the changes.

- There is currently a lack of clarity regarding a number of terms used in the legislation to describe those bound by the legislation (eg occupiers, Commonwealth contractors, persons covered by a licence, and controlled persons). Effective regulation relies on absolute clarity regarding who is captured by the legislation, and the responsibilities of those who are captured. The ARPANS Act should be amended to simplify and clarify the roles and responsibilities of licence holders, persons covered by a licence (those subject to the rules), and authorised representatives of the licence holder (who represent the organisation for the purposes of inspections, receipt of notices etc) (recommendation A7).

In relation to monitoring (inspections)

- The inspection powers described in the Act are from a standard suite of powers used in Commonwealth legislation. While the drafting conventions have evolved over the years such that the description of these powers differs slightly in more contemporary legislation, the overall effect is the same.
- However, other like regulators have some powers to monitor compliance that ARPANSA does not. In particular, this includes the power to: compel the production of documents; compel a person covered by a licence to answer questions, and appoint a person (expert) to assist in inspections where this is reasonable and necessary (recommendation A8).
- ARPANSA should consider opportunities for improving practices, policies and procedures surrounding inspections, with the objective of:
 - clarifying the scope of ARPANSA’s monitoring powers
 - ensuring that inspectors have a clear understanding of their powers and responsibilities, and act in a consistent manner
 - strengthening and clarifying policies and procedures such that licence holders have a clear understanding of what is expected of them in terms of the level of co-operation at inspections
 - improving the timeliness of decision making (recommendation A9).

In relation to enforcement powers

- A comparison of the ARPANS Act with other Commonwealth legislation demonstrates that ARPANSA lacks the range of graduated enforcement powers that would be expected of a regulator charged with regulating radiation sources and nuclear facilities. Specifically ARPANSA has limited capacity to:

- identify non-compliance and require licence holders to address the non-compliance within a certain timeframe (with consequences for failure to do so)
- prohibit activity proceeding if the safety risks are too great.
- The ARPANSA Act should be amended to:
 - enable ARPANSA to issue improvement notices (requiring licence holders who are non-compliant with conditions of licence to rectify the situation within a specified timeframe) and prohibition notices (to prohibit actions that may threaten public health and safety or the environment) (recommendation A10)
 - clarify the application of the Act (including the offence provisions) to the Commonwealth, its employees and others covered by a licence (recommendation A11).

In relation to reporting

- Noting some confusion regarding the distinction between an accident and an incident and the timeframe for reporting accidents, it is recommended that (recommendation A12):
 - ARPANSA review its current guidelines to clearly define an accident including the distinction between an accident and other incidents
 - the CEO of ARPANSA be notified as soon as reasonably practicable of any accident involving a Commonwealth-controlled source or facility
 - a first assessment of causes and consequences should be provided to the CEO within 72 hours.
- ARPANSA should continue to report breaches of licence conditions to the Parliament on a quarterly and annual basis (no Act amendment required). The style of reporting should be improved to include additional detail about the nature of the breach, the significance of the breach and the action taken to rectify the breach (recommendation A13).
- The ARPANSA Act should be amended to also require that ARPANSA, as part of its annual and quarterly reporting, provide information about improvement and prohibition notices that have been issued by ARPANSA (recommendation A14).

Other

- Should Government agree to amend the Act, the opportunity could also be used to make some minor technical amendments to the Act to address anomalies and to better align the legislation with international standards. These technical amendments should be developed in further consultation with ARPANSA and other stakeholders (recommendation A15).

A number of issues were raised by stakeholders that either did not relate to the terms of reference for the review, or are broad policy issues for consideration by governments. For example, some of the issues raised included:

- strengthening Australia's emergency preparedness
- strengthening national uniformity
- expanding the functions of ARPANSA
- clarifying the role of ARPANSA in relation to the transport of radioactive materials.

These issues (and the submissions made in relation to these issues) have been provided to the Department of Health and Ageing for policy consideration.

CHAPTER 2 – PROJECT OVERVIEW

The review

In June 2012, mpconsulting was engaged by the Department of Health and Ageing to consider and report on the scope and operation of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the ARPANS Act), and the legal capacity of ARPANSA to carry out the functions outlined in the ARPANS Act.

Terms of reference

The terms of reference of this review are to make recommendations on the most important changes needed for the ARPANS Act, based on consideration of:

- whether the objects of the Act are being achieved, whether they continue to be appropriate and whether the legislative framework provided is appropriate to achieve the objects of the Act
- whether the regulatory powers and reporting responsibilities in the Act facilitate effective and proportionate compliance by licence holders, and enforcement of obligations imposed on them
- whether the monitoring and reporting of the operations of ARPANSA are effective and appropriate in the context of Parliamentary reporting requirements.

Methodology for the review

The methodology for this review consisted of:

- reviewing materials provided by the Department of Health and Ageing project team
- comprehensive review and analysis of:
 - the ARPANS Act and ARPANS Regulations
 - ARPANSA's policies and procedures
 - a selection of licences and inspection reports
 - annual and quarterly reports
- review of relevant international materials including the Integrated Regulatory Review Service Follow-up mission (review) of ARPANSA conducted by the IAEA in 2011
- stakeholder consultations. ARPANSA, all licence holders, State regulators and other key stakeholders were invited to make submissions to the review. Thirteen submissions were made. Meetings were also held with key stakeholders.

mpconsulting's approach to the review

In undertaking the review, mpconsulting has been mindful of:

- the principles of best practice regulation as published by both the Office of Best Practice Regulation within the Department of Finance and Deregulation and the ANAO
- Commonwealth policy in relation to offences and enforcement powers as reflected in the September 2011 edition of *'A Guide to framing Commonwealth offences, infringement notices and enforcement powers'*
- international principles, Codes and Standards published by the IAEA
- ensuring consistency between the ARPANS Act and other like Commonwealth legislation
- ensuring, as far as possible, consistency with State radiation legislation
- ensuring that any amendments recommended would not be adversely assessed by the Senate Scrutiny of Bills Committee. Against a set of accountability standards, the Scrutiny of Bills Committee assesses legislative proposals that focus on the effect of proposed legislation on individual rights, liberties and obligations, and on parliamentary propriety. For example, the Committee reports to the Senate about whether a bill:
 - trespasses unduly on personal rights and liberties
 - makes rights, liberties or obligations unduly dependent upon insufficiently defined administrative powers, or non-reviewable decisions
 - inappropriately delegates legislative powers
 - insufficiently subjects the exercise of legislative power to parliamentary scrutiny.

CHAPTER 3 – OVERVIEW OF THE ARPANS REGULATORY FRAMEWORK

The ARPANS Acts

The Australian Radiation Protection and Nuclear Safety Act 1998

The ARPANS Act establishes a scheme to regulate the operation of nuclear installations and the management of radiation sources, including ionizing material and apparatus and non-ionizing apparatus, where these activities are undertaken by Commonwealth entities.

Consistent with the object of the Act (to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation) the Act:

- establishes a statutory officer - the Chief Executive Officer of ARPANSA - for the purposes of performing functions and exercising powers under the Act
- establishes a licensing scheme for the regulation of radiation sources and nuclear (and certain radiation) facilities where these are dealt with by Commonwealth entities
- establishes a Radiation Health and Safety Advisory Council (and supporting Committees) to advise the CEO on matters relating to radiation protection and nuclear safety, to develop uniform standards and codes of practice, and to examine matters of major concern to the community in relation to radiation protection and nuclear safety.

The Australian Radiation Protection and Nuclear Safety (Licence Charges) Act 1998

This Act enables annual charges to be levied in respect of licences issued under the *Australian Radiation Protection and Nuclear Safety Act 1998*.

ARPANS Regulations

Australian Radiation Protection and Nuclear Safety Regulations 1999

The ARPANS Regulations describe much of the detail that underpins the broad framework described in the ARPANS Act. Specifically, the ARPANS Regulations:

- describe types of controlled apparatus, facilities and persons
- describe procedures relating to the Radiation Health and Safety Advisory Council, the Radiation Health Committee and the Nuclear Safety Committee

- set out matters in relation to licences, such as licensing exemptions, detail regarding licence applications, matters to be taken into account by the CEO when issuing a source or facility licence and certain licence conditions
- describe practices to be followed by licence holders – for example, dose limits and codes of practice to be followed
- address other miscellaneous matters such as international agreements, the application of State and Territory laws, and review of decisions made under the regulations.

Australian Radiation Protection and Nuclear Safety (Licence Charges) Regulations 2000

These Regulations describe the annual charges and fees relating to source licences and facility licences.

Other ARPANS regulatory and quasi-regulatory documents

Supporting the regulatory framework are a range of administrative documents published by ARPANSA including:

- The *Statement of Regulatory Policy* – this establishes the high-level framework for ARPANSA's regulatory activities
- various regulatory policies such as:
 - *Regulatory Policy: Compliance and Enforcement v1* (June 2012) – this policy is intended to provide guidance to staff and stakeholders about ARPANSA's graded approach to compliance and enforcement
 - *Regulatory Policy: Inspections v5* (June 2012) – This policy describes ARPANSA's approach to inspections
- Regulatory Guides to assist both applicants and licence holders to achieve compliance with the ARPANS Act and Regulations. There are 23 guides covering topics such as:
 - what to expect during an ARPANSA inspection
 - reporting an accident
 - reporting compliance
 - how to read a source licence
 - plans and arrangements for managing safety
- various template forms to be used for reporting accidents, requesting disposals, instrument authorisation, quarterly report proforma etc

- Codes and Standards - for example:
 - ARPANSA implements the standards, general safety requirements and technical safety requirements of the IAEA through the Codes and Standards published in the Radiation Protection Series (RPS). For example: Radiation Protection Series No. 1 Recommendations for Limiting Exposure to Ionizing Radiation (1995) and National Standard for Limiting Occupational Exposure to Ionizing Radiation (republished 2002); Radiation Protection Series No. 3 Radiation Protection Standards for Maximum Exposure Levels to Radiofrequency Fields - 3 kHz to 300 GHz (2002); Radiation Protection Series No. 5 Code of Practice and Safety Guide for Portable Density/Moisture Gauges Containing Radioactive Sources (2004)
 - ARPANSA also recognises certain Australian Standards and Codes that do not form part of the Radiation Protection Series. For example, the Australian Standard for Safety in Laboratories – Ionizing Radiations (1998).

International

Unlike many other regulatory schemes, the regulation of radiation and nuclear safety is strongly influenced by the international environment.

This is expressly acknowledged in the ARPANS Act, which notes that where the Act confers powers or functions on a person, the exercise of that power or function must not be inconsistent with Australia's obligations under relevant international agreements.

In exercising any powers under the Act, the CEO of ARPANSA, and ARPANSA inspectors, must also have regard to Australia's obligations under international agreements (section 85 of the Act). The agreements include, for example:

- the Agreement between Australia and New Zealand concerning the transfer of uranium (signed on 14 September 1999)
- the agreement for cooperation between Australia and the United States of America concerning technology for the separation of isotopes of uranium by laser excitation, agreed minute and exchange of notes (signed 28 October 1999).

The broader international environment is also highly relevant to the work of ARPANSA.

CHAPTER 4 – OVERVIEW OF THE OPERATION OF THE ARPANS REGULATORY SCHEME

Overview of operation of the scheme

In summary, the ARPANS Act requires that:

- each source or facility must be licensed by ARPANSA, unless exempt from licensing. As at 30 June 2011 there were 59 source licences and 34 facility licences¹
- each licence is subject to conditions, some of which are described in the Act, some in the Regulations and some are determined on a case-by-case basis by ARPANSA
- ARPANSA monitors compliance with the legislation by reviewing documentation submitted by licence holders and other stakeholders and by undertaking inspections of facilities and sources. In 2010-11 ARPANSA undertook 49 inspections. Following an inspection, ARPANSA provides the licence holder with an inspection report which details the nature of the inspection, the findings and the recommendations. In most cases, these inspection reports are published on the ARPANSA website
- if ARPANSA identifies any non-compliance with the legislation, including the conditions of licence, ARPANSA may:
 - raise the matter with the licence holder administratively (i.e. seek to resolve the issue without taking formalised enforcement action under the Act). This is the most common approach
 - vary conditions of licence – ARPANSA has, on occasion, amended licence conditions to minimise the risk of recurrent non-compliance
 - suspend or cancel the licence - ARPANSA has never taken this action in response to non-compliance
 - issue directions - ARPANSA has never taken this action
 - approach the Director of Public Prosecutions (DPP) to initiate proceedings for a criminal offence – ARPANSA has never taken this action.
- ARPANSA report on operations to the Minister, and through him/her to the Parliament. The quarterly and annual reports include details about the licences issued, the inspections undertaken and the compliance action taken. The reports

¹ ARPANSA, *Annual Report of the Chief Executive Officer 2010-2011*, Appendices [Table 16], p77-78.

also include information about breaches of conditions that have been reported to the CEO along with any incidents and accidents. During 2010-11, there were 23 breaches of conditions of licence, 5 incidents involving Commonwealth users of radiation, and no accidents by Commonwealth users of radiation.

Analysis

The following chapters discuss in more detail the five main elements of the regulatory framework

- the objects
- licensing
- monitoring
- enforcement
- reporting.

Before analysing these issues, it is useful to note that:

- ARPANSA only regulates Commonwealth entities (that is, Commonwealth Departments, bodies corporate, companies and employees of such bodies). This distinguishes ARPANSA from many other Commonwealth regulatory bodies that oversee the private sector
- there are only 43 licensed Commonwealth entities. In summary, 43 different Commonwealth entities hold 59 source licenses and 7 Commonwealth entities hold 34 facility licences between them. All of the facility licence holders also hold source licences
- not all of the regulated entities are engaged in high risk activity – there is a range of low risk and higher risk activity undertaken by licensed Commonwealth entities
- ARPANSA is one of a number of regulators in the field of radiation and nuclear safety. Each State and Territory is also responsible for regulating the use of radiation by State bodies and the private sector, within its jurisdiction
- while ARPANSA has a regulatory function (which is the focus of this review), ARPANSA also plays a number of other roles:
 - promoting uniformity across jurisdictions
 - providing advice on radiation protection and nuclear safety
 - undertaking research
 - providing services relating to radiation protection, nuclear safety and medical exposures to radiation.

CHAPTER 5 – ARE THE OBJECTS OF THE ACT APPROPRIATE AND BEING ACHIEVED?

The object of the Act

Section 3 of the ARPANS Act defines the object of the Act as follows:

The object of the Act is to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation.

Stakeholder advice regarding the object of the Act

Overall, stakeholders supported the object of the Act. Stakeholders noted that the object is sufficiently broad to cover people and the environment in relation to the harmful effects of radiation irrespective of source, exposure situation and type of radiation (whether related to accident, security, physical protection or malicious acts).

Analysis

The objectives of the ARPANS Act continue to be sound, and it is recommended that the object of the Act (section 3) remain as is.

However, there may be merit in describing some key principles that underpin the object of the Act.

For example, the IAEA's *Fundamental Safety Principles: Safety Fundamentals* include some principles that are recommended by the IAEA for inclusion in the primary legislation of member states to reflect the significance and fundamental nature of the principles for the regulation of radiation protection and nuclear safety.

These key principles relate to:

- justification - facilities and activities that give rise to radiation risks must yield an overall benefit.
- dose limitation - measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.
- optimisation of protection - protection must be optimized to provide the highest level of safety that can reasonably be achieved.
- safety and security being the primary responsibility of the licence holder - prime responsibility for safety must rest with the person or organization responsible for the facilities and activities that give rise to radiation risks.

While these principles would require refinement for inclusion in legislation, the advantage of including the principles in the legislation are that:

- it expands on the object of the Act by clearly describing ARPANSA's approach to radiation safety
- it better aligns Australia's approach with the recommendations of the IAEA
- it is consistent with the approach starting to be adopted in Australian States and Territories. For example, the Queensland *Radiation Safety Act 1999* includes a description of the principles that are intended to guide the achievement of the Act's main object. The Queensland Act includes reference to the concepts of justification, limitation, optimisation, specifying emission or absorption standards, and avoidance. The Queensland Act also includes a section which expressly provides that:

In interpreting a provision of this Act, a construction that would promote radiation safety, protection and security principles is to be preferred to a construction that would not promote radiation safety, protection and security principles.

A similar provision could be considered for inclusion in the ARPANS Act.

While the inclusion of principles would not fundamentally change the way the Act is administered, it would clearly signpost ARPANSA's approach to fundamental safety principles, and Australia's commitment to internationally agreed principles.

The main disadvantage of including principles in the legislation, rather than in supporting documentation, is that if they are changed internationally, the Act would probably require amendment.

In addition to describing the safety principles that underpin the Act, there may also be value in better articulating ARPANSA's approach to regulation. For example, that ARPANSA will adopt an approach that is:

- risk-based (that is, regulation should be commensurate with the risks associated with the facility or activity, in accordance with a graded approach)
- proportionate. As noted in the submission made by the Radiation Health and Safety Advisory Council '*overregulation of all industries including the nuclear/radiation protection sector can be detrimental if it takes ownership of safety away from the operator. There is recognition that encouragement of a 'strong safety culture' within operations is the most effective way of regulating potentially high risk industries, along with a 'fair culture' to encourage transparency, openness and continuous learning/improvement*'
- transparent

- outcomes-focused (ideally the regulation should describe the outcome to be achieved by regulated entities rather than the means by which they should achieve the outcome).

On balance, it is not recommended that this approach to regulation be specifically included in the legislation. This is because this approach:

- relates to implementation of the legislation
- should underpin the implementation of all legislation (it is not specific to ARPANSA)
- should be reflected throughout ARPANSA policies and procedures. If these principles of good regulatory practice are not included in the legislation they must underpin all of ARPANSA's work, be reflected throughout its policies and procedures and be operationalised by ARPANSA.

By contrast, the fundamental safety principles:

- are specific to the regulation of radiation safety
- directly support the achievement of the objects of the Act
- are relevant for both ARPANSA and regulated entities.

In addition to including principles in the legislation, it is recommended that the Act be reviewed every 5 years. This ensures that:

- the regulatory framework retains currency, particularly noting that radiation safety is an evolving area of science, and that public confidence in regulation can quickly change (including in response to significant international events)
- the regulation continues to be consistent with good regulatory practice
- key recommendations from the IAEA missions can be incorporated into the regulatory framework if required.

It is not proposed that the Act be amended to require a review every 5 years but simply that this occur as a matter of good administrative practice².

² The Productivity Commission recently produced a report entitled *Identifying and evaluating regulation reforms* (December 2011). The report notes that review requirements should be embedded in legislation when there is significant uncertainty in regard to the effectiveness of the regulation, the efficiency of the chosen approach, or the impacts of the regulation. As this is not the case with respect to ARPANSA, it is not considered necessary to embed the review requirements in legislation.

Recommendations

- A1. That key safety principles, based on the IAEA's Fundamental Safety Principles, be described in the Act.
- A2. That the regulatory framework be reviewed every 5 years.

CHAPTER 6 – ASSESSMENT OF REGULATORY POWERS – LICENSING

Context

While the terms of reference for the review do not explicitly require assessment of ARPANSA's licensing powers, it is not possible to effectively review ARPANSA's monitoring, enforcement and reporting powers without understanding the system of licences against which ARPANSA assesses compliance and takes action in the event of non-compliance.

This Chapter therefore explores some of the strengths and weaknesses of the existing licensing regime, including areas for possible improvement.

Existing licensing arrangements

As noted in Chapter 4:

- each Commonwealth-controlled source or facility must be licensed by ARPANSA (unless exempt from the licensing requirements) (sections 30 and 31 of the Act)
- each licence is subject to conditions, some of which are described in the Act, some in the Regulations, and some are determined on a case-by-case basis by ARPANSA. The conditions relate to:
 - procedural matters (for example, it is a condition of licence that licence holders: consent to entry of premises by ARPANSA inspectors; lodge reports; and notify ARPANSA of incidents)
 - operational requirements
 - compliance with relevant Codes and Standards.

Stakeholder advice regarding licensing

On the whole, stakeholders supported the existing approach to licensing.

There was general consensus that any licensing scheme should be:

- risk-based, with regulatory effort commensurate to risk
- outcomes-focused, with the regulator setting the outcome to be achieved and the licence holder determining the most effective and efficient way to achieve that outcome.

There were, however, a number of suggestions about how the licensing system should

be improved.

These suggestions included:

- 'big picture' policy suggestions such as:
 - enabling ARPANSA to licence exposure situations that are unrelated to licensed facilities or sources (such as licensing of remediation and clearance)
 - extending the power of ARPANSA to regulate all sources and facilities (not just Commonwealth entities)
- suggestions relating to specific Act provisions, or the implementation of such provisions. For example:
 - clarifying the meaning of international best practice which is one of the matters that must be taken into account by ARPANSA before issuing a licence
 - enabling a licence to be issued for a limited period of time rather than being indefinite.

Those suggestions that relate to 'big picture' policy issues are not discussed in detail in this report but have been provided to the Department of Health and Ageing for policy consideration.

Those suggestions relating specifically to the Act and its implementation are analysed below.

Analysis

Based on discussions with stakeholders, and the review of the legislation, there appear to be five sets of issues regarding licences:

- the type of licence that can be issued by ARPANSA
- the matters to be considered by ARPANSA in assessing licence applications
- the licence conditions
- the duration of licences
- the holder of the licence, and those covered by the licence.

Each of these is discussed below.

Type of licence

Under the ARPANS Act, ARPANSA only has the capacity to issue source licences or facility licences. ARPANSA does not have the capacity to license a process from end-to-end, or to license a site with multiple facilities where this promotes the most effective safety culture.

For example, the production of nuclear medicine at ANSTO involves a single process but the process occurs across a number of buildings and utilises a number of discrete sources. Under the current regime, ARPANSA separately licenses each of the separate buildings (facilities), and also each of the separate sources, even though these are all part of a single process.

By licensing discrete parts of the process, rather than looking at the process in its entirety, there is a risk that regulatory gaps will emerge. Further, a segmented approach undermines the focus on end-to-end control which is critical to radiation and nuclear safety.

It is therefore recommended that the ARPANS Act be amended to provide greater flexibility to ARPANSA to issue not just source and facility licences, but also licences for processes or sites where this is the most appropriate response based on risk and promotion of safety.

The detail of this proposal would require further consideration (and discussion with stakeholders) including to:

- ensure that while ARPANSA has flexibility, there is also regulatory certainty and clarity for licence holders regarding the most appropriate licence type
- consider the impact on fees and charges.

Matters to be considered by ARPANSA in assessing licence applications

The ARPANS Act provides that when the CEO is deciding whether to issue a source or facility licence, the CEO must take into account:

- international best practice in relation to radiation protection and nuclear safety
- the matters (if any) specified in the regulations. The Regulations specify six matters for source licences and seven matters for facility licences. These matters include, for example: whether the application includes the required information; whether there is a net benefit from carrying out the proposed conduct; whether the magnitude of doses are as low as reasonably achievable; and whether the applicant has the capacity to comply.

Overall, this is a graded approach to the description of matters to be considered by ARPANSA. That is:

- the broad framework is described in the Act

- a more detailed (but still broad) description of the relevant matters is included in the Regulations, which is more easily amended over time
- the very detailed requirements are included in application forms published by ARPANSA. These application forms can be adjusted on an as-needed basis.

mpconsulting's only observation in relation to the matters to be taken into account is that it is unusual to require, through the Act, that the CEO take into account international best practice. 'International best practice' is:

- a vague concept
- something that changes over time
- something that is quite subjective.

While mpconsulting acknowledges the value of ARPANSA having regard to the international environment, it is equally important that there is regulatory certainty.

If the Act sets out the fundamental safety principles (as suggested in recommendation A1) then this will guide consideration of best practice rather than requiring the CEO to consider the vague notion of 'international best practice' in relation to each individual licence application.

It is recommended, therefore, that the requirement for the CEO to consider international best practice be removed from sections 32 and 33 of the Act. Instead, the Act should describe the fundamental international safety principles and these principles should apply across all aspects of ARPANSA's administration of the legislation (issuing of licences, application of conditions, inspections etc).

If there are other specific considerations that ARPANSA considers are international best practice, these could be set out in the Regulations or application forms as matters that must be addressed by the applicants for a licence.

Licence conditions

As noted previously, some conditions of licence are described in the Act, some in the Regulations and some are imposed by ARPANSA on a case-by-case basis.

Based on advice from ARPANSA and other stakeholders, mpconsulting understands that:

- ARPANSA maintains a core set of licence conditions for all facilities and for all sources
- this core set of conditions references relevant Codes and Standards that apply to various uses of radiation. For example, medical uses, or uses for particular lasers

- if there is no relevant Code or Standard ARPANSA develops, on a case-by-case basis, a specific relevant condition.

This general approach is broadly consistent with good regulatory practice. That is, there is a hierarchy of conditions – with some described in the Act, some described in Regulations (or other delegated legislation) and some set by the regulator by reference to Codes and Standards, or through the development of licence-specific conditions.

mpconsulting’s concerns relate to how this framework is actually applied.

Some specific concerns include:

- there is no clear articulation of the outcome sought to be achieved from licence conditions
- some conditions are unnecessarily prescriptive rather than outcomes-focused (noting that it is appropriate for some kinds of conditions to be prescriptive, where it is not practical for them to be outcomes-focused)
- the conditions reference Codes and Standards of which many are outdated. For example, some Codes date back to 1984. While conditions require licence holders to observe ‘relevant’ parts of the Codes and Standards, there is a degree of uncertainty. This leads to ARPANSA negotiating with the licence holder about how they expect the Code to be interpreted (i.e. which provisions should not be followed because they are outdated or no longer best practice) and which provisions the licence holder is expected to observe
- there are differing interpretations of licence conditions including when there has been non-compliance with a licence condition. While this is, to some extent, inevitable, it is imperative that ARPANSA has a consistent and transparent approach to the interpretation of conditions.

The concerns described above are undesirable from the perspective of both ARPANSA and the regulated entities. Further, if there is an incident, there is likely to be a lack of clarity regarding the expected compliance with the Codes and Standards.

It is therefore recommended that, following any amendments to the legislation, ARPANSA review all licence conditions with a view to:

- identifying a hierarchy of licence conditions that are outcomes-focused wherever possible
- removing unnecessarily prescriptive detail from licence conditions
- removing references to outdated Codes and Standards.

This review should:

- be staged and coordinated with other initiatives recommended in this report
- ensure that licence holders are afforded procedural fairness
- ensure that there is clear accountability for any decision making by ARPANSA in relation to licence conditions.

Duration of licence

ARPANSA licences continue in force until they are cancelled or surrendered. The licences are not time-limited and there is no period for review of the licences. While ARPANSA could administratively undertake reviews of licences (and amend licence conditions to reflect the outcomes of the review), there is no express legislative power to review or reconsider licences after a period of time.

This means that:

- licence conditions can become dated
- the uses of the radiation source may have changed quite considerably since the time the licence was issued.

On the other hand, radiation sources and facilities are often quite significant enterprises, and there is a need for certainty on the part of the organisation investing in the source or facility. For this reason it is undesirable for licences to automatically lapse or expire after a certain period of time.

It is, however, recommended that a condition of licence³ require that, every 5 years (or such lesser time as is prescribed in the licence by the CEO) the licence holder must review its radiation uses, safety plans and arrangements, and resubmit these to ARPANSA. If the changes are significant, ARPANSA may request that the organisation apply for a new licence. Alternatively, the licence conditions may stand or may be amended to reflect the changes.

Persons covered by a licence

A fundamental principle of good regulation is that there must be clarity with regard to whom the regulation applies. It is also a fundamental tenet of safety-based regulation that there must at all times be a person in charge. That is, one or more persons who are 'key personnel' with authority to act on behalf of the organisation, and who are responsible for ensuring that the regulatory requirements are met.

³ The inclusion of such a condition of licence could be achieved in a number of different ways: through amendment to the Act (not recommended); through changes to the Regulations (to describe the condition either as an adjustment to regulation 50 or a new regulation); or by the CEO adding the condition to licences.

Under the ARPANS Act, a range of terms are used to describe those organisations and individuals that are subject to regulation.

For example, various provisions of the ARPANS Act apply to:

- a Commonwealth entity (being the Commonwealth, a body corporate or company of the Commonwealth, or an employee of one of those bodies)
- a controlled person (being a Commonwealth entity, a Commonwealth contractor, an employee of a Commonwealth contractor, or a person in a prescribed Commonwealth place)
- an occupier (being, in relation to premises, a person present at the premises who is in apparent control of the premises)
- a person covered by a licence (being a controlled person who is authorised under the licence to deal with a controlled apparatus or controlled material, or to undertake an activity in relation to a controlled facility)
- persons authorised by the licence. This term is not defined but is used throughout the Act
- a licence holder. This term is used in the Act and Regulations but is only defined in the Regulations. The Regulations define a holder of a licence as a controlled person to whom the licence is issued.

This has led to confusion, both within ARPANSA and within regulated entities, about:

- when one of these terms applies to a legal entity (i.e. a Commonwealth Department) compared to an individual (i.e. an employee of a Commonwealth Department)
- the application of the legislation to Commonwealth contractors particularly where those contractors may be undertaking work for a Commonwealth entity but using their own radiation equipment (i.e. a private contractor who x-rays military ammunition)
- who must give consent to entry by an inspector – the occupier of the premises (who may be a junior government employee) or the authorized representative of the controlled person (for example, the CEO of the organisation, or other person who has effective control of the radiation source)
- whether ‘persons covered by the licence’ includes subcontractors of a Commonwealth contractor.

It is therefore recommended that the Act be amended to simplify and clarify:

- the legal entity that applies for, and holds, the licence. For example, the Department of Defence, ANSTO or CSIRO

- the individuals who are covered by the licence and must comply with any applicable requirements. It should be clear that this includes employees, contractors, subcontractors or anyone else acting on behalf of the legal entity that holds the licence
- the authorised representative(s) of the licence holder (by reference to a position or positions). These are the people responsible for the safe operation of the facility or source. These are the primary contacts for ARPANSA in terms of gaining consent to enter premises, to discuss non-compliance, or to serve notices. These people are variously referred to in Commonwealth legislation as: 'key personnel', 'authorised representatives' or 'responsible individuals'. Regardless of the terminology adopted, it should be clear who is/are the authorised representative(s) of the licence holder.

Recommendations

- A3. That the ARPANS Act be amended to provide greater flexibility to ARPANSA to issue licences for processes or sites where this is the most appropriate way to manage risk.
- A4. That the requirement for the CEO to consider international best practice be removed from sections 32 and 33 of the Act. Instead, the Act should describe the fundamental international safety principles and these principles should apply across all aspects of ARPANSA's administration of the legislation (issuing of licences, application of conditions, inspections etc).

If there are other specific considerations that ARPANSA considers are international best practice, these could be set out in the Regulations or application forms as matters that must be addressed by the applicants for a licence.

- A5. That following any amendments to the legislation, ARPANSA review all licence conditions with a view to:
- identifying a hierarchy of licence conditions that are risk-based and outcomes-focused wherever possible
 - removing unnecessarily prescriptive detail from licence conditions
 - removing references to outdated Codes and Standards.

This review should be staged and coordinated with other initiatives recommended in this report. This review should also ensure that licence holders are afforded procedural fairness and that there is clear accountability for any decision making by ARPANSA in relation to licence conditions.

- A6. That a condition of licence require that, every 5 years (or such lesser time as is prescribed in the licence by the CEO) the licence holder must review its radiation uses, safety plans and arrangements, and resubmit these to ARPANSA. If the changes are significant, ARPANSA may request that the organisation apply for a new licence. Alternatively, the licence conditions may stand or may be amended to reflect the changes.
- A7. That the Act be amended to simplify and clarify the roles and responsibilities of licence holders (Commonwealth entities), persons covered by a licence and authorised representatives of the licence holder.

CHAPTER 7 – ASSESSMENT OF REGULATORY POWERS – MONITORING

Context

For the purpose of this report, ‘monitoring’ refers to the activities undertaken by ARPANSA to monitor compliance with the legislation by licence holders.

Under the Act, the only monitoring power that is described is the power to undertake inspections of premises. However, ARPANSA can (and does) supplement inspections with administrative (non-legislative) monitoring such as desk audits or other education activities aimed at encouraging compliance.

This chapter describes:

- the legislative provisions relating to monitoring (i.e. inspections)
- ARPANSA's approach to monitoring compliance and to the conduct of inspections
- stakeholder advice regarding monitoring powers
- an analysis of the monitoring powers, including any gaps or deficiencies
- recommendations for reform.

Existing monitoring powers

Under the ARPANS Act, ARPANSA may appoint inspectors to undertake inspections. There are three types of inspections envisaged in the legislation:

- inspections for the purposes of monitoring compliance with the legislation – The Act provides that an inspector may enter premises for the purposes of finding out whether the legislation has been complied with (i.e. for monitoring compliance). Entry must be with consent of the occupier, or under a warrant issued by a Magistrate. In monitoring compliance, the inspector may, for example:
 - search the premises
 - take photographs
 - ask questions
 - produce documents
 - make copies of documents
- inspections in response to concerns regarding hazardous situations – The Act provides that an inspector may enter premises (and exercise certain powers)

because the inspector has reasonable grounds for suspecting that there may be a hazardous item at the premises. It may be necessary, in the interest of public health, to exercise the powers to avoid an imminent risk of death, serious illness, serious injury or serious damage to the environment. In this case, the inspector's powers are more curtailed, with a focus on searching the premises for the hazardous item, seizing it if necessary, and avoiding the imminent risk of death, injury or illness

- inspections in relation to suspected offences – The Act provides that an inspector may enter premises and exercise certain powers if he/she has reasonable grounds for suspecting that there may be evidential material on the premises. The inspector may only enter the premises with the consent of the occupier, or under a warrant.

On the basis of advice from ARPANSA:

- ARPANSA's inspection program commenced in 2002
- ARPANSA schedules inspections on the basis of risk. While there is a formalised process for risk-rating source licences, this is yet to be developed for facilities. ARPANSA does not publish its inspection schedule, nor the criteria used to determine the scheduling of inspections
- ARPANSA undertakes both announced and unannounced inspections. ARPANSA aims to undertake 10% unannounced inspections per year. ARPANSA considers an inspection to be unannounced if no notice is given or if a small amount of notice is given e.g. 2 to 24 hours
- to date, all inspections have been with the consent of the occupier, and all have been for the purposes of monitoring compliance with the legislation. ARPANSA has never sought a warrant in order to exercise inspection powers
- following an inspection, ARPANSA prepares an inspection report. The inspection report describes: the basic details about the inspection; the scope; the key findings; the conclusion (including whether or not there was non-compliance); and recommendations. In terms of process, ARPANSA:
 - aims to complete the inspection report within 30 days of the inspection (where non-compliance has been identified), or within 10 days (where there is no non-compliance)
 - sends the inspection report to the licence holder for comment and to check the factual accuracy. Licence holders are expected to respond within 10 days if no non-compliance has been identified, or 28 days if non-compliance has been identified
 - considers the information provided by the licence holder and aims to settle the inspection report within a reasonable period

- publishes the inspection report on the ARPANSA website in most cases.

ARPANSA's approach to inspections is described in:

- *Regulatory Policy: Inspections v5* (June 2012)
- *Regulatory Procedure: Inspection v6* (June 2012)

Stakeholder advice regarding the monitoring powers

Some stakeholders noted that, in the past, there have been some tensions regarding the exercise of inspection powers. For example, there has been a lack of clarity regarding the role of inspectors, the power of inspectors to require documents, and the appropriateness of inspectors conducting private interviews with staff. However, stakeholders also acknowledged that there have been a number of improvements over the past year and that, generally speaking, the process surrounding inspections is now much clearer.

Potential areas for improvement that were identified by stakeholders include:

- the need to ensure that inspectors have sufficient skills and expertise
- the importance of clarity regarding the scope of the inspection powers
- the need to minimise disruption caused by inspections, particularly where safety critical functions are being performed
- the desirability for inspections to be focused on the existence of quality systems (i.e. a safety culture) rather than on technical compliance with prescriptive administrative requirements.

ARPANSA also raised the following issue:

- a concern that consultant experts cannot be appointed as inspectors (limiting capacity for effective monitoring).

Analysis

On the basis of discussion with stakeholders, review of the ARPANS Act and a comparison of the ARPANS Act with other like Commonwealth legislation, it is apparent that:

- the inspection powers described in the Act are from a standard suite of powers used in Commonwealth legislation. While the drafting conventions have evolved over the years such that the description of these powers differs slightly in more contemporary legislation, the overall effect is similar
- other like regulators have some powers to monitor compliance that ARPANSA

does not. In particular, this includes the power to issue a notice to produce or attend. This is described in more detail below

- there is some confusion around the interpretation and application of some of the inspection powers. This includes the capacity of ARPANSA to utilise experts for inspections and confusion regarding who should be present at an inspection
- there is potential room for administrative improvements in terms of how the inspections are conducted and followed up.

Each of these issues is addressed below.

Notice to produce or attend

Under the ARPANS Act, an inspector may enter premises and request documents, or require the occupier to answer questions. However, there is no general power under the Act to enable the CEO of ARPANSA to call upon a person to answer questions or provide documents where the CEO has reasonable grounds to believe there is non-compliance with the Act.

A 'notice to produce or attend' provision enables a regulatory agency to require a person to produce information or documents, or to appear before an officer of an agency to answer questions. This is a common enforcement mechanism used to assist in the administration of Commonwealth legislation.⁴

For example, this power exists in the:

- *Aged Care Act 1997* – sections 9-2, 9-3, 9-3A, 9-3B empower the Secretary of the Department of Health and Ageing to request certain information from approved providers of aged care, with a criminal penalty for non-compliance
- *Migration Act 1958* – subsection 306D(2) gives the Migration Agents Registration Authority the power to obtain documents from an inactive migration agent
- *Australian Meat and Livestock Industry Act 1997* – section 51 enables the Secretary to require a person to produce any documents that relate to the industry or, for example, the meat or livestock business of the person

Often these provisions are accompanied by criminal consequences for non-compliance. If non-compliance with a notice to produce or attend is to be an offence, the maximum penalty for non-compliance is generally six months imprisonment and/or a fine of 30 penalty units.

While such coercive powers should not be routinely exercised (noting that licence holders and others would generally voluntarily comply with requests for information

⁴ Attorney-General's Department, *A Guide to framing Commonwealth Offences, Infringement Notices and Enforcement Powers, Commonwealth of Australia*, September 2011 edition, p.88

from the CEO of ARPANSA) it is considered important that the CEO of ARPANSA has the capacity to compel the production of information if this is not forthcoming.

It is therefore recommended that the Act be amended to include the power for the CEO of ARPANSA to compel the production of documents, and for a person covered by a licence to answer questions. Further consideration should be given to the limits on this power (i.e. when it would apply), and also the persons to whom it should apply (consistent with the proposed changes to the legislation relating to licence holders, persons covered by a licence, and authorised representatives).

Use of experts

As noted above, queries have been raised regarding the capacity of ARPANSA to utilise experts for inspections.

This could be readily addressed through an amendment to the Act enabling an assistant to accompany and assist an inspector.

This would be consistent with section 166 of the *Work Health and Safety Act 2011*, which provides that:

- an assistant, including an interpreter, may accompany the inspector entering a workplace to assist the inspector if the inspector considers the assistance is necessary.
- the assistant may do those things reasonably required to assist the inspector to exercise compliance powers but must not do anything that the inspector does not have power to do, except as permitted under a search warrant.
- anything done lawfully by the assistant is taken for all purposes to have been done by the inspector.

Similarly section 234 of the *Clean Energy Act 2011* provides that:

- an inspector may be assisted by other persons if that assistance is necessary and reasonable
- a person assisting the inspector may enter the premises and exercise monitoring powers but only in accordance with a direction given to the person by the inspector
- a power exercised by a person assisting the inspector is taken for all purposes to have been exercised by the inspector.

Like provisions could be included in the ARPANS Act to ensure that inspectors have access to specialist expertise, where required.

Administrative improvements

If ARPANSA is to exercise its powers effectively, it is critical that ARPANSA's inspectors and all licence holders have a common understanding of how ARPANSA will exercise its monitoring powers and what is expected of licence holders. This:

- minimises the risk of disagreement at an inspection
- improves co-operation by licence holders (as they know what is expected of them)
- ensures that processes are transparent.

While mpconsulting did not undertake a detailed analysis of ARPANSA's internal processes, it is apparent (based on discussions with stakeholders and a review of the policies and procedures) that there is room for improvement particularly in terms of:

- clarifying the scope of ARPANSA's monitoring powers
- ensuring that inspectors have a clear understanding of their powers and responsibilities and act in a consistent manner
- strengthening and clarifying policies and procedures such that licence holders have a clear understanding of what is expected of them in terms of the level of co-operation at inspections
- improving the timeliness of decision making.

For example:

- based on discussions with stakeholders, there are differing views regarding the scope of powers able to be exercised by ARPANSA, the way that these powers will be exercised and the consequence of non-compliance with requests made by inspectors. For example, there were differing views surrounding whether ARPANSA could conduct interviews with staff in private and when matters identified during inspections needed to be referred to the CEO of ARPANSA. This could be clarified in written advice to licence holders from ARPANSA and would not require a legislative amendment
- based on discussions with ARPANSA, it seems that most unannounced inspections are subject to some notice (for example between 2 hours and 48 hours). If an inspection is categorised as unannounced, it should be without any notice at all. However, upon arrival at the service the authorised representative of the licence holder should be provided with clear information about the nature of the inspection, the scope of the inspection, the capacity (if any) for the authorized representative of the licence holder to refuse entry and the level of co-operation expected
- there may be potential to strengthen inspector training around the exercise of monitoring powers, specifically: the limits on the exercise of their powers; principles of administrative and criminal law; the legal rights and responsibilities of licence holders and their representatives; and the distinction between the role

of the CEO and the role of inspectors during an inspection

- the timeliness of decision making following an inspection could be improved. Currently, if non-compliance is identified as part of an inspection, it can take 2 months or more to finalise the inspection report. This is because ARPANSA takes up to 30 days to prepare the inspection report and then provides the licence holder a further 28 days to comment on the draft inspection report, before ARPANSA considers the comments and finalises the report.

While ARPANSA needs to be thorough and licence holders also need to be afforded procedural fairness, it is considered that this timeframe is excessive particularly where there is identified non-compliance. As noted by the Australian National Audit Office (ANAO) as part of their *Better Practice Guide for Administering Regulation*, a regulator's decision-making process must be timely, proportionate, lawful and fully documented. There should also be a clear distinction between the process and timeframe related to:

- ARPANSA identifying the non-compliance, communicating it to the licence holder, and confirming the existence of the non-compliance. This should occur in a timely manner, for example, within 14 days
- the licence holder addressing the non-compliance. A reasonable period of time should be provided to the licence holder to address the identified non-compliance and put systems in place to minimise the risk of recurrence. The appropriate time will depend on the nature of the non-compliance and could be specified in an improvement notice (discussed in Chapter 8).

Recommendations

- A8. That the Act be amended to: include the power for the CEO of ARPANSA to compel the production of documents and for a person covered by a licence to answer questions; and appoint a person (expert) to assist in inspections where this is reasonable and necessary.
- A9. That ARPANSA consider opportunities for improving practices, policies and procedures surrounding inspections with the objective of:
- clarifying the scope of ARPANSA's monitoring powers
 - ensuring that inspectors have a clear understanding of their powers and responsibilities and act in a consistent manner
 - strengthening and clarifying policies and procedures such that licence holders have a clear understanding of what is expected of them in terms of the level of co-operation at inspections
 - improving the timeliness of decision making.

CHAPTER 8 – ASSESSMENT OF REGULATORY POWERS – ENFORCEMENT POWERS

Context

For the purposes of this Report, the term ‘enforcement powers’ is interpreted broadly to mean the powers available to ARPANSA to enforce compliance with the legislation, or to take action in the event of non-compliance.

The objective of any enforcement power is to:

- stop the unlawful conduct
- deter future offending conduct
- undo the harm caused by the contravening conduct (if possible)
- encourage the effective use of compliance systems
- where warranted, punish the wrongdoer by the imposition of penalties or fines.⁵

This chapter explores:

- ARPANSA’s current enforcement powers
- the outcomes sought by stakeholders in relation to ARPANSA’s enforcement powers
- the strengths and limitations of the existing ARPANSA enforcement powers
- options for expanding the suite of enforcement powers available to ARPANSA to ensure ARPANSA can apply a graduated, proportionate approach to any instances of non-compliance.

Enforcement powers available to ARPANSA

Under the ARPANS Act, ARPANSA has five main enforcement powers:

- ***the power to issue a direction*** - Under section 41 of the Act, the CEO has the power to issue a direction where there is a reasonable belief that a controlled person is not complying with the Act or Regulations, and such action is considered necessary to protect the health and safety of people, or to avoid damage to the

⁵ Australian Competition and Consumer Commission, *Compliance and Enforcement Policy*, Commonwealth of Australia, 2012, pg.1

environment. A direction issued under section 41 is required to be tabled in Parliament, and a copy provided to the Minister.

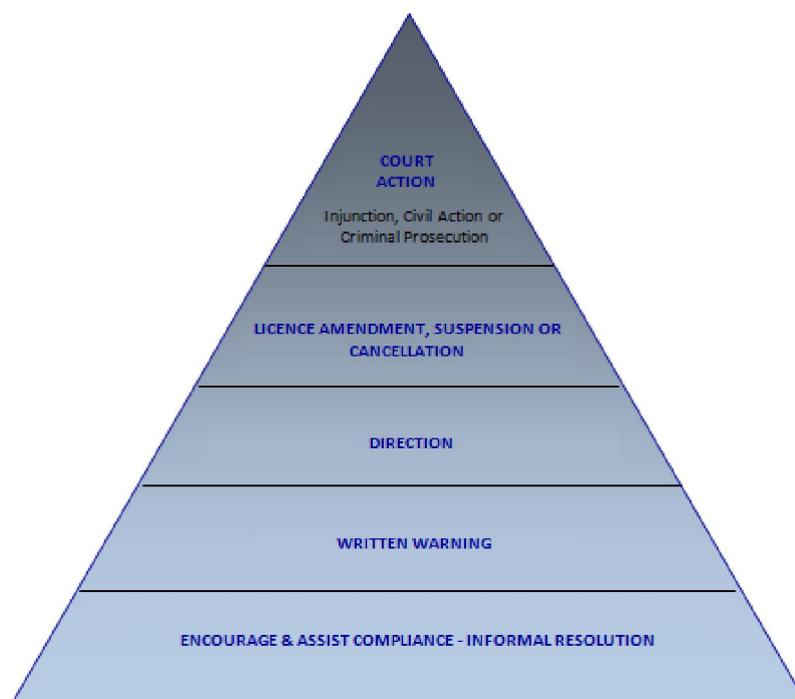
- ***the imposition of additional licence conditions*** – Section 36 of the Act provides that the CEO may impose additional licence conditions, remove or vary licence conditions that were imposed by the CEO, or extend or reduce the authority granted by the licence. Depending on the nature of the non-compliance, it may be considered appropriate to amend the licence to facilitate compliance or address any new risks that have been identified.
- ***suspension or cancellation of licence*** - Under section 38 of the Act, the CEO may decide to suspend or cancel a licence in circumstances where:
 - a condition of the licence has been breached by the licence holder or by a person covered by the licence
 - there are reasonable grounds to believe that an offence has been committed by the licence holder or by a person covered by the licence
 - the licence was obtained improperly.
- ***referral to the Director of Public Prosecutions*** - The laws administered by ARPANSA create a number of offences. The office of the Commonwealth Director of Public Prosecutions (DPP) prosecutes these offences. The decision to refer a matter to the DPP for prosecution of an offence is made by ARPANSA.
- ***injunction*** - Under section 43 of the Act, the CEO can make an application to the Federal Court of Australia for an injunction in circumstances where a person has engaged, is engaging, or is proposing to engage in any conduct that would be an offence against the Act, or where there has been, or is proposed to be, a refusal or failure to do a thing, of which refusal or failure would be an offence against the Act. Injunctions are likely to be sought in exceptional circumstances, for example, where there is an immediate threat to the health and safety of people, or to the environment.

In addition to the enforcement powers described in the legislation, ARPANSA can also take a range of administrative actions to bring an organisation back into compliance.

The ARPANSA *Regulatory Policy: Compliance and Enforcement v1 (June 2012)* provides guidance for staff and stakeholders about ARPANSA's approach to compliance and enforcement.

As detailed in this document, ARPANSA strives to take a graded approach to non-compliance that is proportionate to risk. The level of regulatory response is based on the severity of the non-compliance, taking into account a number of criteria. ARPANSA depicts its graded approach as follows:

Figure 1: Graded response to non-compliance



ARPANSA advises that:

- the regulatory response will commence at the most appropriate level depending on the circumstances of the non-compliance, and will be proportionate to any risks posed by the non-compliance
- the initial regulatory response will most often be at a lower level, but will be escalated if the licence holder fails to respond.

Stakeholder advice regarding ARPANSA enforcement powers

Most stakeholders acknowledged that:

- where possible ARPANSA should be able to work with licence holders to achieve compliance without the need to rely on legislated enforcement actions. It was noted that all licence holders are Commonwealth entities, and that there should theoretically be a high degree of cooperation to ensure compliance
- some non-compliance with the legislation (particularly some of the conditions of licence) is unintended or based on differing interpretations of Codes. In these circumstances, an educative approach by ARPANSA is the most effective and efficient way to achieve compliance
- in the event that a licence holder does not cooperate or ARPANSA identifies clear non-compliance, ARPANSA should have a range of options available to enforce

compliance. These options should enable a graded response to be taken, and should be appropriate for application to Commonwealth agencies.

Analysis

ARPANSA has, in the past, relied heavily on negotiation to achieve regulatory compliance, rather than the exercise of statutory powers. In fact, ARPANSA has never issued directions, suspended or cancelled a licence because of non-compliance, nor made a referral to the DPP.

The reasons for this could be:

- cultural; or
- because there is strong compliance by licence holders; or
- because ARPANSA has lacked the appropriate tools to take action.

While the reasons are likely to be a combination of the above factors, a comparison of the ARPANSA Act with other Commonwealth legislation demonstrates that ARPANSA lacks the range of graduated enforcement powers which would be expected of a regulator charged with regulating radiation sources and nuclear facilities.

For example, while ARPANSA may issue directions requiring action to be taken, the CEO of ARPANSA must first be satisfied that not only is the controlled person not complying with the Act, but also that the issue of directions is necessary in order to protect the health and safety of people, or to avoid damage to the environment.

This sets the bar very high, and does not enable ARPANSA to:

- identify non-compliance (regardless of its impact on safety and the environment) and require compliance. In other regulatory schemes this would commonly be achieved through the issue of an improvement notice
- put an immediate stop to an activity that threatens health, safety or the environment. In other regulatory schemes this is achieved through the issue of a prohibition notice.

In the absence of comprehensive powers to address non-compliance (and encourage a culture of continuous improvement), ARPANSA has included 'recommendations' in its inspection reports.

These recommendations appear to be a blend of:

- 'for information' comments relating to largely administrative matters
- suggestions that would assist the conduct of further inspections but are not critical to the operation of the facility

- best practice suggestions
- quasi-conditions with which ARPANSA would expect future compliance.

Examples of some of the recommendations that have been included in inspection reports include:

- *‘Finalise Local Arrangements Forms for PET/CT scanners’*
- *‘The following improvements to enhance best practice were discussed with licence holder representatives during the inspection: A letter should be sent to ARPANSA explaining the disposal of the UV source; the old laser warning labels should be replaced by the new standard labels; if used frequently the X-ray units should be surveyed quarterly. It is recommended that wipe testing of the source in use is done at annual intervals.’*

While ARPANSA has an expectation of compliance with these recommendations (and advises that the recommendations are followed up at subsequent inspections) there are no legal means by which to enforce these recommendations.

Further, it would not be immediately apparent to licence holders whether these recommendations are:

- intended to describe how a licence holder should address a contravention of the legislation; or
- simply suggestions for continuous improvement.

For these reasons, it is undesirable for ARPANSA to continue making recommendations in inspection reports in circumstances where neither the purpose nor effect of the recommendations is clear.

Instead it is recommended that the Act be amended to include:

- the power for inspectors to issue improvement notices
- the power for inspectors to issue a prohibition notice.

Improvement notices

An improvement notice is a notice requiring a person to remedy a contravention or likely contravention, or the matters or activities occasioning the contravention or likely contravention, within a period specified in the notice. Generally speaking, improvement notices:

- state that the inspector is of the opinion that a contravention or likely contravention has occurred, or that there are certain matters or activities occasioning a contravention or likely contravention
- state the reasons for that opinion
- require that the person rectify the problem (the notice may also state the method by which the contravention is to be remedied)
- describe the date by which the problem must be rectified
- describe the person's review rights
- describe the consequences of non-compliance with the improvement notice. For example, the legislation could provide that it is a criminal offence to not comply with an improvement notice.

In the ARPANSA context, improvement notices would enable inspectors to identify areas of non-compliance and require licence holders to address these non-compliances within a certain period of time. This would formalise existing recommendations and ensure that the inspector clearly states the contravention and their reasons for believing the condition of licence has been contravened. This provides:

- discipline for inspectors
- transparency of decision making
- a clear timeframe for rectification of the problem
- review rights to the licence holder if they wish to contest the matter (rather than relying on protracted and uncertain negotiation as has occurred in the past).

Improvement notices are utilised in other Commonwealth legislation such as the *Work Health and Safety Act 2011*.

Improvement notices would also need to be underpinned with consequences for non-compliance. For consistency with the rest of the ARPANS Act, it is suggested that the requirement to comply with an improvement notice be underpinned with:

- a criminal penalty
- capacity for ARPANSA to:
 - amend licence conditions or suspend or cancel the licence on the basis of non-compliance with an improvement notice
 - report non-compliance with an improvement notice to the Parliament

- seek an injunction to compel compliance.

Recognising the limited capacity for ARPANSA to initiate criminal action against Commonwealth entities, the real disincentive for non-compliance with an improvement notice derives from ARPANSA's power to report such non-compliance to the Parliament and also to suspend or cancel a licence on this basis.

Prohibition notices

A prohibition notice prohibits a certain activity and requires an immediate action. A prohibition notice may mean an immediate stop is put to: an activity; the use of equipment or plant; or the use of a substance.

A prohibition notice will generally:

- state the basis for the belief on which the service of the notice is based, and specify the activity which the officer believes involves, or will involve, the risk, and the matters which give, or will give, rise to the risk
- if the officer believes that the activity involves a contravention or likely contravention, of a law, specify that provision and the basis for that belief
- include information about review rights
- describe the consequences of non-compliance with the notice.

For example, section 195 of the *Work Health and Safety Act 2011* provides that:

- if an inspector reasonably believes that: (a) an activity is occurring at a workplace that involves or will involve a serious risk to the health or safety of a person emanating from an immediate or imminent exposure to a hazard; or (b) an activity may occur at a workplace that, if it occurs, will involve a serious risk to the health or safety of a person emanating from an immediate or imminent exposure to a hazard, then the inspector may give a person who has control over the activity a direction prohibiting the carrying on of the activity, or the carrying on of the activity in a specified way, until an inspector is satisfied that the matters that give or will give rise to the risk have been remedied
- the direction may be given orally, but must be confirmed by written notice (a prohibition notice) issued to the person as soon as practicable.
- a prohibition notice must state:
 - that the inspector believes that grounds for the issue of the prohibition notice exist and the basis for that belief
 - briefly, the activity that the inspector believes involves or will involve the risk and the matters that give or will give rise to the risk
 - the provision of the Act that the inspector believes is being, or is likely to be, contravened by that activity.

- the penalty for non-compliance with a prohibition notice is, in the case of an individual, \$100 000 and, in the case of a body corporate, \$500 000.

Similar provisions could be introduced into the ARPANS Act. The advantage of this approach is that it compliments existing ARPANSA powers by ensuring that ARPANSA has a range of responses available for different situations from minor (where an improvement notice might be issued) through to very significant responses where an activity threatens health and safety or the environment and must be stopped.

As for improvement notices, prohibition notices would also need to be underpinned with consequences for non-compliance such as:

- a criminal penalty
- capacity for ARPANSA to:
 - amend licence conditions or suspend or cancel the licence on the basis of non-compliance with the prohibition notice
 - report non-compliance with a prohibition notice to Parliament
 - seek an injunction to restrain the licence holder from engaging in the conduct that is prohibited.

Clarifying the application of the legislation to the Commonwealth

Section 4 of the Act provides that the Act binds the Crown in each of its capacities but that nothing in the Act renders the Crown liable to be prosecuted for an offence.

While this is a standard provision in Commonwealth legislation, it can create confusion in the context of the ARPANS Act where the only entities being regulated are Commonwealth entities, and where prosecution for a criminal offence forms part of the suite of enforcement options available.

It may therefore be valuable to include provisions in the ARPANS Act which clarify the application of the Act (and the various enforcement actions) to the Commonwealth and its agents (i.e. employees, contractors and others covered by a licence).

Recommendations

- A10. That the Act be amended to enable ARPANSA to issue improvement notices and prohibition notices, with consequences for non-compliance.
- A11. That the ARPANS Act be amended to clarify the application of the Act in relation to the Commonwealth and its agents (i.e. employees, contractors and others covered by a licence).

CHAPTER 9 – ASSESSMENT OF REGULATORY POWERS - REPORTING

Existing reporting powers

In summary, the key reporting obligations of both licence holders and ARPANSA are:

- licence holders must:
 - inform the CEO of ARPANSA about any accident within 24 hours and give the CEO a written report about the accident within 14 days of the occurrence (as required by regulation 46)
 - provide quarterly reports to ARPANSA
- ARPANSA must:
 - give quarterly and annual reports to the Minister for tabling in Parliament (sections 59 and 60 of the Act)
 - make a report to Parliament if a serious accident or malfunction occurs at a nuclear installation (section 61 of the Act).

ARPANSA's quarterly and annual reports must include:

- details of directions given by the Minister under section 16
- details of any breaches of licence conditions by a licensee, of which the CEO is aware
- details of all reports received by the CEO in relation to the Radiation Health and Safety Advisory Council and the Nuclear Safety Committee.

In addition, the quarterly report must include a list of all facilities licensed during the quarter.

Stakeholder advice regarding ARPANSA reporting

Stakeholders suggested that:

- because the Act requires that all breaches of licence conditions be reported, administrative or technical breaches are reported in the same way as breaches which impact safety or have the potential to impact safety
- the way that ARPANSA currently reports does not enable the technical breaches to be distinguished from the more critical breaches that are of interest to stakeholders.

ARPANSA also expressed concern that:

- significant incidents could go unreported for up to 24 hours
- there is no clear definition of accident, in the Act, to guide either licence holders or ARPANSA
- there is no provision in the Act that requires a controlled person to report any radiation-related accident that the controlled person is aware of (regardless of whether the accident occurred in relation to an ARPANSA licensed activity).

Analysis

Reporting of accidents

As noted above, licence holders must tell the ARPANSA CEO about any accident involving controlled materials, apparatus or facilities within 24 hours of the accident and give the CEO a written report about the accident within 14 days (as required by regulation 46 of the ARPANS Regulations).

Accident is not defined in the ARPANS legislation. However, in its regulatory guide on reporting accidents, ARPANSA provides the following guidance:

An accident is any occurrence, associated with controlled apparatus, controlled materials or a controlled facility, which results in, or has the potential to result in, exposure to radiation, such as to cause injury, damage or harm to any person or the environment. This includes occurrences involving, or resulting from, acts or omissions that were deliberate, reckless or negligent.

ARPANSA also provides examples of types of accidents that must be reported under regulation 46.

In 2010-11 some reports of accidents were made to ARPANSA but ARPANSA did not consider that these met the definition of an accident and they were not therefore reported to Parliament.

Despite the guidance issued by ARPANSA there would appear to be some confusion regarding the distinction between an accident and other incidents. Given the importance of clarity regarding accidents (not just in terms of reporting but also response) it is recommended that ARPANSA review their existing guidance on this matter.

It is also considered that for something as important as the notification of an accident involving facilities, apparatus and materials utilising radioactive or nuclear material it is inappropriate to allow 24 hours for reporting an accident and a further 14 days for a written report.

By contrast to ARPANSA, other regulators such as the Australian Maritime Safety

Authority, the Work Health and Safety Regulator and the Australian Transport Safety Bureau, require initial reporting within a very short period of time with fuller written reports to the relevant regulator within 48 to 72 hours.

For example

- the *Work Health and Safety Act 2011* requires that notifiable incidents (being death, serious injury or a dangerous incident which exposes a worker or any other person to a serious risk to health or safety) must be reported immediately after the person who conducts the business became aware that such an incident has occurred and the regulator may request a written report within 48 hours.
- the Australian Maritime Safety Authority requires that, in the case of general incidents at sea, the master of a ship must submit a report within 4 hours of an incident occurring where these incidents relate to: accidents, damage to ships, injuries to crew, births, deaths and marriages on board, as well as any marine pollution, or potential marine pollution, from ship. This incident alert is designed to inform the authorities that an incident has occurred without requiring detailed information about the incident. The full details of the incident are included in a “detailed report” that is provided to the Australian Maritime Safety Authority within 72 hours of submission of the incident alert.
- The Australian Transport Safety Bureau distinguishes between ‘immediately reportable matters’ and ‘routine reportable matters’. An immediately reportable matter is a serious transport safety matter that covers occurrences such as accidents involving death, serious injury, destruction of, or serious damage to vehicles or property or when an accident nearly occurred. Under the *Transport Safety Investigation Act 2003* immediately reportable matters must be reported as soon as is reasonably practical. A routine reportable matter is a transport safety matter that has not had a serious outcome and does not require an immediate report but transport safety was affected or could have been affected. Such matters must be reported within 72 hours with a written report.

Consistent with these schemes, it is recommended that:

- ARPANSA review its current guidelines to clearly define an accident including the distinction between an accident and other incidents
- the CEO of ARPANSA be notified as soon as reasonably practicable of any accident involving a Commonwealth-controlled source or facility
- a first assessment of causes and consequences should be provided to the CEO within 72 hours.

This would not require amendment to the Act but would require amendment to the Regulations and ARPANSA guidance.

Reporting of accidents by non-licence holders or persons covered by a licence

On the question of whether it should be mandatory for ARPANSA licence holders (or persons covered by a licence) to report all accidents (regardless of whether they relate to Commonwealth controlled sources or facilities), this expands the scope of ARPANSA's powers. While such an obligation would assist the CEO to ensure that the Australian Radiation Incident Register is kept up to date, this is an issue for broader policy consideration because it relates to the reach of ARPANSA functions and powers.

Reporting of breaches

In 2010-11, ARPANSA reported 22 breaches of licence conditions by licensees.⁶

These breaches were described by reference to:

- the licencees and licence number
- the nature of the breach.

The nature of the breach was described in a short statement such as:

- *Breach of s.31(2) of the ARPANS Act for failure to comply with licence condition 6, compliance with relevant Codes and Standards*
- *Breach of s.31(1) of the ARPANS Act for dealing with a laser without an appropriate licence*
- *Breach of s.31(2) of the ARPANS Act for failure to comply with licence condition 6 by not calibrating its radiation monitors annually*
- *Breach of s.31(2) of the ARPANS Act for failure to comply with licence condition 3. Staff members had not undergone radiation safety training.*
- *Breach of s.31(2) of the ARPANS Act for failure to comply with Regulation 52 of the APRANS Regulations which requires the licence holder to tell the CEO about changes unlikely to have implications for safety.*
- *Breach of s.31(1) of the ARPANS Act for dealing with a small animal PET-CT scanner without an appropriate licence.*

For each of the above breaches the ARPANSA annual report notes that 'No enforcement action was initiated as Licence Holder undertook appropriate corrective measures'. The ARPANSA CEO notes on page 7 of the annual report that in all cases of breaches in 2010-2011, no enforcement was required.

It has been suggested that the requirement for licence holders to report all breaches

⁶ ARPANSA, *Annual Report of the Chief Executive Officer 2010-2011*, Commonwealth of Australia, Appendix 6: ARPANSA Licensing Activities, pg.74

to the CEO and for the CEO also to report these to Parliament leads to over-reporting including of very minor technical breaches such as failure to submit a quarterly report on time.

mpconsulting considers that while it may be possible to distinguish between technical breaches and breaches with safety implications (with only this latter type of breach being reported by ARPANSA) this risks debate regarding which breaches have safety implications (when the focus should be on establishing a quality system and an overall safety culture). It also risks a loss of public confidence if there is an acknowledgement that some breaches are less important (i.e. with less demand for public transparency and scrutiny) than others.

It is therefore suggested that, rather than amending the legislation to distinguish between non-reportable breaches and reportable breaches, ARPANSA should:

- structure its conditions of licence such that they are risk-based and outcomes-focused (as suggested in recommendation A5)
- improve its reporting of breaches so that there is more information about the breach and its potential impact (or otherwise) on safety. ARPANSA's reporting should also indicate what action has been taken to address the non-compliance.

Additional reporting - Improvement notices and directions

As noted in relation to recommendation A9, it is also recommended that ARPANSA report when it has issued improvement notices and prohibition notices.

Recommendations

A12. That:

- ARPANSA review its current guidelines to clearly define an accident including the distinction between an accident and other incidents
- the CEO of ARPANSA be notified as soon as reasonably practicable of any accident involving a Commonwealth-controlled source or facility
- a first assessment of causes and consequences should be provided to the CEO within 72 hours.

A13. That ARPANSA should continue to report breaches of licence conditions to the Parliament on a quarterly and annual basis (no Act amendment required). The style of reporting should be improved to include more detail about the nature of the breach, the significance of the breach and the action taken to rectify the breach.

A14. That the Act be amended to require that, as part of its annual and quarterly reporting, ARPANSA provide information about improvement and prohibition

notices that have been issued by ARPANSA.

CHAPTER 10 – SUMMARY OF RECOMMENDATIONS

Overall assessment of regulatory framework

As noted previously, mpconsulting considers that:

- overall the legislative framework continues to be appropriate
- against the five features of regulation that contribute to compliance burdens that are not justified⁷ the legislation performs positively. For example, the legislation does not include redundant regulation, excessive regulation, excessive reporting requirements or inconsistent or overlapping regulatory requirements.

However, there are areas for improvement which, if adopted, could strengthen the regulatory scheme. These have been identified in the body of this report.

The key objectives of any reform are:

- to continue to protect (and enhance) the independence of ARPANSA – this is critical for public confidence
- to ensure that ownership for safety continues to rest with the operator
- to ensure that the level of regulation applied is commensurate with risk – not all activity subject to regulation by ARPANSA is high risk
- to improve certainty for licence holders and ARPANSA. The licence holders must be clear what is expected of them (i.e. the outcome that they are expected to achieve) and the regulator needs to be clear what they are auditing/inspecting against
- to provide a high level of transparency and predictability with respect to licensing decisions (including monitoring and enforcement action)
- to ensure that regulation is risk-based and outcomes-focused (where appropriate) not overly prescriptive
- to enable ARPANSA to adopt a graduated, proportionate response to non-compliance.

⁷ In 2006 the *Taskforce on Reducing the Regulatory Burden on Business* identified five features of regulations that contribute to compliance burdens on business that are not justified: excessive coverage including regulatory creep; regulation that is redundant; excessive reporting or recording requirements; variation in definitions and reporting requirements; and inconsistent and overlapping regulatory requirements.

Summary of all recommendations

The recommendations can be grouped into those which require amendment to the ARPANS Act and those which can be implemented administratively.

Administrative changes

Subject to Government's agreement to the recommendations contained in this report, it is proposed that the following administrative change be made:

- A5. That, following any amendments to the legislation, ARPANSA review all licence conditions with a view to:
- identifying a hierarchy of licence conditions that are risk-based and outcomes-focused wherever possible
 - removing unnecessarily prescriptive detail from licence conditions
 - removing references to outdated Codes and Standards.

This review should also ensure that licence holders are afforded procedural fairness and that there is clear accountability for any decision making by ARPANSA in relation to licence conditions.

It is proposed that this recommendation not proceed until after any Act amendments have been made. This will reduce the need to undertake a further review of licences once Act amendments have been made. However, in the interim, ARPANSA could continue work reviewing the relevant parts of Codes and Standards to identify:

- those Codes and Standards which most urgently require review
 - those conditions which form part of Codes and Standards but which should be directly referenced in conditions of licence. For example, if large parts of a Code or Standard are no longer relevant but a few important elements remain, these should form conditions of licence rather than the entire Code or Standard being referenced in the licence conditions.
- A6. That a condition of licence require that, every 5 years (or such lesser time as is prescribed in the licence by the CEO) the licence holder must review its radiation uses, safety plans and arrangements, and resubmit these to ARPANSA. If the changes are significant, ARPANSA may request that the organisation apply for a new licence. Alternatively, the licence conditions may stand or may be amended to reflect the changes. This condition of licence could be reflected in Regulations or included in licence conditions as the licences are reviewed.

- A9. That ARPANSA consider opportunities for improving practices, policies and procedures surrounding inspections with the objective of:
- clarifying the scope of ARPANSA’s monitoring powers
 - ensuring that inspectors have a clear understanding of their powers and responsibilities and act in a consistent manner
 - strengthening and clarifying policies and procedures such that licence holders have a clear understanding of what is expected of them in terms of the level of co-operation at inspections
 - improving the timeliness of decision making.

A12: That:

- ARPANSA review its current guidelines to clearly define an accident including the distinction between an accident and other incidents
- the CEO of ARPANSA be notified as soon as reasonably practicable of any accident involving a Commonwealth-controlled source or facility
- a first assessment of causes and consequences should be provided to the CEO within 72 hours.

These changes could be achieved through changes to ARPANSA guidance materials and to Regulations. It is suggested that these changes be implemented following any Act amendments (noting that there may need to be consequential changes to Regulations as a result of the Act amendments).

- A13. That ARPANSA should continue to report breaches of licence conditions to the Parliament on a quarterly and annual basis (no Act amendment required). The style of reporting should be improved to include more detail about the nature of the breach, the significance of the breach and the action taken to rectify the breach.

As noted in the body of this Report it is proposed that the Act be reviewed every 5 years (recommendation A2). It is recommended that the next review occur 5 years after the Act amendments (described below) have been made.

Legislative changes

The following changes require amendments to the ARPANS Act:

- the addition of key safety principles, based on the IAEA’s Fundamental Safety Principles (recommendation A1)

- the creation of two new classes of licence – for processes or sites where this is the most appropriate way to manage risk (recommendation A3)
- the removal of the requirement for the CEO to consider international best practice be removed in section 32 and 33 (recommendation A4)
- simplification and clarification of the roles and responsibilities of licence holders (Commonwealth entities), persons covered by a licence and authorized representatives of the licence holder (recommendation A7)
- the inclusion of a power for: the CEO of ARPANSA to compel the production of documents and for a person covered by a licence to answer questions; inspectors to be assisted by experts where necessary and reasonable (recommendation A8)
- the inclusion of new powers for ARPANSA to issue improvement and prohibition notices with consequences for non-compliance (recommendation A10) and for information about these notices to be included in quarterly and annual reports (recommendation 14)
- clarification of the application of the Act in relation to the Commonwealth entities, employees, contractors and persons covered by a licence (recommendation A11)
- the technical changes suggested in Attachment B.

Should Government agree these recommendations, it is suggested that:

- further consultation be undertaken with stakeholders regarding any amendments to the ARPANS Act (including any additional amendments that may arise from the broader policy issues that are being considered separately to this review)
- an amending Bill could be developed for introduction into Parliament in the 2013 Autumn sitting (February to April 2013) or Winter sitting (May – July 2013)
- ideally the legislative changes would take effect from 1 July 2013 to align with the financial year and existing ARPANSA reporting obligations. This would require passage of the legislation by end April 2013 to enable consequential changes to be made to delegated legislation and for ARPANSA to make necessary changes to policies, procedures and systems to take effect from 1 July 2013. If the amendments are not made by end April 2013, consideration could be given to the amendments taking effect at a later date (noting any implications for financial year reporting).

ATTACHMENT A – TABLE SUMMARY OF RECOMMENDATIONS

A1.	That key safety principles, based on the IAEA’s Fundamental Safety Principles, be described in the Act.
A2.	That the regulatory framework be reviewed every 5 years.
A3.	That the ARPANS Act be amended to provide greater flexibility to ARPANSA to issue licences for processes or sites where this is the most appropriate way to manage risk.
A4.	<p>That the requirement for the CEO to consider international best practice be removed from sections 32 and 33 of the Act. Instead, the Act should describe the fundamental international safety principles and these principles should apply across all aspects of ARPANSA’s administration of the legislation (issuing of licences, application of conditions, inspections etc).</p> <p>If there are other specific considerations that ARPANSA considers are international best practice, these could be set out in the Regulations or application forms as matters that must be addressed by the applicants for a licence.</p>
A5.	<p>That, following any Act amendments, ARPANSA review all licence conditions with a view to:</p> <ul style="list-style-type: none"> • identifying a hierarchy of licence conditions that are risk-based and outcomes-focused wherever possible • removing unnecessarily prescriptive detail from licence conditions • removing references to outdated Codes and Standards. <p>This review should be staged and coordinated with other initiatives recommended in this report. This review should also ensure that licence holders are afforded procedural fairness and that there is clear accountability for any decision making by ARPANSA in relation to licence conditions.</p>
A6.	That a condition of licence require that, every 5 years (or such lesser time as is prescribed in the licence by the CEO) the licence holder must review its radiation uses, safety plans and arrangements, and resubmit these to ARPANSA. If the changes are significant, ARPANSA may request that the organisation apply for a new licence. Alternatively, the licence conditions may stand or may be amended to reflect the changes.
A7.	That the Act be amended to simplify and clarify the roles and responsibilities of licence holders (Commonwealth entities), persons covered by a licence and authorised representatives of the licence holder.

A8.	That the Act be amended to: include the power for the CEO of ARPANSA to compel the production of documents and for a person covered by a licence to answer questions; and appoint a person (expert) to assist in inspections where this is reasonable and necessary.
A9.	That ARPANSA consider opportunities for improving practices, policies and procedures surrounding inspections with the objective of: <ul style="list-style-type: none"> • clarifying the scope of ARPANSA’s monitoring powers • ensuring that inspectors have a clear understanding of their powers and responsibilities and act in a consistent manner • strengthening and clarifying policies and procedures such that licence holders have a clear understanding of what is expected of them in terms of the level of co-operation at inspections • improving the timeliness of decision making.
A10.	That the Act be amended to enable ARPANSA to issue improvement notices and prohibition notices, with consequences for non-compliance.
A11.	That the ARPANS Act be amended to clarify the application of the Act in relation to the Commonwealth, consistent with like provisions in the <i>Work Health and Safety Act 2011</i> .
A12.	That: <ul style="list-style-type: none"> • ARPANSA review its current guidelines to clearly define an accident including the distinction between an accident and other incidents • the CEO of ARPANSA be notified as soon as reasonably practicable of any accident involving a Commonwealth-controlled source or facility • a first assessment of causes and consequences should be provided to the CEO within 72 hours.
A13.	That ARPANSA should continue to report breaches of licence conditions to the Parliament on a quarterly and annual basis (no Act amendment required). The style of reporting should be improved to include more detail about the nature of the breach, the significance of the breach and the action taken to rectify the breach.
A14.	That the Act be amended to require that, as part of its annual and quarterly reporting, ARPANSA provide information about improvement and prohibition notices that have been issued by ARPANSA.

A15.	Should Government agree to amend the Act, the opportunity could also be used to make some minor technical amendments to the Act to address anomalies and to better align the legislation with international standards. These technical amendments should be developed in further consultation with ARPANSA and other stakeholders.

ATTACHMENT B – TECHNICAL AMENDMENTS

ARPANSA has suggested that a number of minor changes be made to definitions in order to better align the definitions with internationally recognised terminology and expressions in common usage in the industry.

Should amendments be made to the Act (as recommended in this Report) the opportunity could be used to make these changes. Further consultation should be undertaken to ensure that the changes are agreed by stakeholders to be appropriate.

Definitions (section 13)

controlled apparatus

The definition of ‘controlled apparatus’ includes ‘an apparatus that produces ionizing radiation because it contains radioactive material’.

ARPANSA has advised that the use of the word ‘apparatus’ for equipment containing radioactive material is not in accord with general usage in the industry. The word ‘device’ is more often used to describe equipment containing radioactive material to distinguish it from an ‘apparatus’ which produces radiation by artificial means, that is, when energised.

ARPANSA has suggested that this part of the definition of controlled apparatus be deleted and devices containing radioactive material be included in the definition of ‘controlled material’.

nuclear installations

ARPANSA has advised that the use of the word, ‘nuclear material’ in paragraph (a) of the definition of ‘nuclear installations’ is incorrect where it is used in relation to medical use. Where reference is made to the production of material for medical use, the reference should be to ‘radioactive material’. ARPANSA has therefore suggested that paragraph (a) of the definition of ‘nuclear installations’ be amended to substitute ‘radioactive material’ for ‘nuclear material’.

radioactive waste

ARPANSA has advised that the term ‘nuclear waste’ is incorrectly used in the Act. It has been suggested that the reference should be to radioactive waste, which is defined in the IAEA Safety Glossary. ARPANSA has therefore proposed that all references to ‘nuclear waste’ in the Act be amended to ‘radioactive waste’ and the latter be defined in the Act.

Delegation by the CEO (section 18)

Section 18 enables the CEO to delegate to Departmental officers. However the description of offices has become outdated (for example, the Act refers to Senior Officers Grade A, B or C). Amendments should be made to the Act to update these provisions.

Prohibitions (sections 30 to 31)

Sub-sections 30(3) and 31(3) require a 'person covered by a licence' to comply with a licence condition, but do not provide for any penalties for not complying with a licence condition. The preceding provisions, sub-sections 30(2) and 31(2) respectively, make it an offence for a licence holder to not comply with a licence condition punishable by a penalty of up 2,000 penalty units (\$220,000). This highlights the issue identified in relation to recommendation A11 whereby it is unclear what the consequences of non-compliance are for individuals covered by a licence (who are Commonwealth Government employees, contractors or others)

Review of licence decisions (section 40) and review of decisions to give directions (section 42)

Under these sections a controlled person who receives a licence decision or directions from the CEO may apply to the Minister to review the decision. The Minister's decision can be further appealed to the Administrative Appeals Tribunal.

The timeframe for seeking review by the Minister is 90 days. This is out of line with current regulatory practice and extends the period of uncertainty. It is recommended that the timeframe within which the controlled person may seek review by the Minister of a decision made in relation to a licence should be 28 days.

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