IRRS ARM
Summary Report
Australia 2018

Compiled by the Australian Radiation Protection and Nuclear Safety Agency (Commonwealth) in collaboration with:

- Department of Health (Commonwealth)
- Queensland Health (Queensland)
- Environment Protection Authority (New South Wales)
- Department of Health and Human Services (Victoria)
- Environment Protection Authority (South Australia)
- Department of Health and Human Services (Tasmania)
- Radiological Council (Western Australia)
- Department of Health (Northern Territory)
- Health Protection Service (Australian Capital Territory)

Foreword

Australia requested its first Integrated Regulatory Review Service (IRRS) mission in 2007, the fourth IRRS mission organised and coordinated by the International Atomic Energy Agency (IAEA). Australia also requested a follow-up mission in 2011, during which it was acknowledged that most recommendations and suggestions from 2007 could be closed out, whereas work was still ongoing in other areas. The Mission Reports are publicly available.

The reviews in 2007 and 2011 focused entirely on the arrangements for radiation protection and nuclear safety within the Commonwealth of Australia, in particular the activities of the Commonwealth regulator, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). The review covered safety regulation of all nuclear installations (as defined in Commonwealth legislation) in Australia, and all other regulatory activities carried out by ARPANSA. However, the largest number of entities by far using or producing radiation are regulated by the States and Territories that form part of the Australian Federation. All States and Territories were therefore invited, and accepted, to participate in the 2018 IRRS and to carry out a self-assessment in relation to a limited number of the IRRS modules, as further outlined in this report.

In December 2015, Australia requested a second primary IRRS, in accordance with established international practice to request such reviews at about 10-year intervals. As part of the review, a team of 19 international experts including IAEA staff will carry out a review mission to Australia, from 4 to 16 November 2018.

This review and mission is the largest multi-jurisdictional IRRS so far co-ordinated by the IAEA. It will, for the modules completed by all jurisdictions, provide an accurate and complete picture of the national system for radiation protection and nuclear safety, and its implementation in the Commonwealth, the States and the Territories. This also means that matters that concern uniformity of regulation in a multi-jurisdictional context can be identified and discussed during the mission.

This Summary Report has been compiled by ARPANSA staff and is based on the self-assessments and other input provided by regulators in all nine jurisdictions. We would like to express our gratitude to all contributors from regulatory agencies across Australia for their efforts and dedicated work, which has made it possible to put the Advance Reference Material together, of which this Summary Report forms a part.

September 2018

Senator the Hon Bridget McKenzie
Minister for Regional Services, Sport, Local Government and Decentralisation

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Background

About this report

In December 2015 Australia requested the Integrated Regulatory Review Service (IRRS) from the International Atomic Energy Agency (IAEA) to review the arrangements for radiation protection and nuclear safety in Australia against the IAEA safety standards. The review, to be carried out in 2018, will consider the regulatory framework for radiation protection and nuclear safety of the Commonwealth of Australia, and corresponding arrangements in the States and Territories that form part of the Australian Federation.

The Commonwealth, the States and the Territories have contributed to the Advance Reference Material (ARM) that has been provided to the IAEA to help the review team to prepare for the review task and the mission to Australia. The ARM, including this Summary Report, is not intended for publication, whereas the intention is to publish the IRRS review report and the Action Plan, once the review has been completed and the report finalised. An overview of the jurisdictions and the regulatory body that contributed to the preparation of the report, is provided below.

Queensland (QLD)	New South Wales (NSW)	Victoria (VIC)	South Australia (SA)	Tasmania (TAS)	Western Australia (WA)	Northern Territory (NT)	Australian Capital Territory (ACT)
							
Queensland Health	Environmental Protection Authority	Department of Health and Human Services	Environment Protection Authority	Department of Health and Human Services	Radiological Council	Department of Health	Health Protection Service

Figure 1. State and Territory radiation protection regulators

The Commonwealth regulator (the Australian Radiation Protection and Nuclear Safety Agency, ARPANSA) has completed all IRRS modules (full scope), including information that relates to the safety of nuclear installations. State and Territory regulators have completed specific modules: authorisation, inspection, review and assessment, enforcement, regulation of sources, regulation of medical radiation, and transport.

This Summary Report has been compiled by ARPANSA, based on the contributions by all jurisdictions. The Report provides an overview of the legal framework for safety in Australia and is backed up by specific module responses which include attached evidence and references. As such, the report is not intended to provide a complete picture of all practices in Australia; however, it provides information on alignment with the IAEA safety standards with examples of practices where relevant. Where a specific jurisdiction is referenced when providing an example of a practice, it is to highlight useful material in the jurisdiction specific module response and online information. It should not be seen to imply that other jurisdictions do or do not have similar practices.

This Background section of the Summary Report provides general information about Australia and how it is governed; the regulatory framework across all jurisdictions; and the nuclear activities in Australia.

The IRRS modules are dealt with in sections 1–12. Section 13 is devoted to national uniformity. This information has been provided as background to the planned 'policy discussion' on the topic of regulatory uniformity across jurisdictions, and illustrates some of the issues that may be encountered in the development and implementation of a national framework for safety in a multijurisdictional context.

The table below indicates, module by module, which jurisdictions provided information and the corresponding section in this Summary Report. During the time of self-assessment and preparation of the ARM, the IRRS module structure was under review and revision by the IAEA. The table below therefore provides information on how the self-assessment was structured, and where the corresponding information can be found in this Summary Report.

Self-assessment module (with ARPANSA numbering)	Jurisdictions contributing to the ARM	Summary report/ARM section
1 – Responsibilities and functions of government	Commonwealth	1 – Responsibilities and functions of government
2 – Global nuclear safety regime	Commonwealth	2 – Global nuclear safety regime
3 – Responsibilities and functions of the regulatory body	Commonwealth	3 – Responsibilities and functions of the regulatory body
4 – Management system of the regulatory body	Commonwealth	4 – Management system of the regulatory body
5 – Authorisation	All	5.1 – Authorisation – Generic issues
6 – Review and Assessment	All	6.1 – Review and Assessment – Generic issues
7 - Inspection	All	7.1 – Inspection – Generic issues
8 – Enforcement	All	8.1 – Enforcement – Generic issues
9 – Regulations and Guides	Commonwealth	9.1 – Regulations and guides – Generic issues
10 – Emergency Preparedness and Response	Commonwealth	10 – Emergency Preparedness and Response
11a – Regulation of Radiation Sources	All except NT	5.2, 6.2, 7.2, 8.2, 9.2
11b – Regulation of Research Reactors	Commonwealth	5.3, 6.3, 7.3, 8.3, 9.3
11c – Transport of Radioactive Material	All except NT	5.6, 6.6, 7.6, 8.6, 9.6
11d – Safety Requirements for Medical Exposure	All except NT	Additional areas 11.1 – Control of Medical Exposures
11e – Occupational Radiation Protection	Commonwealth	Additional areas 11.2 – Occupational Radiation Protection
5a - Decommissioning	Commonwealth	5.5, 6.5, 7.5, 8.5, 9.5
5b – Disposal of radioactive waste	Commonwealth	5.4, 6.4, 7.4, 8.4, 9.4

Self-assessment module (with ARPANSA numbering)	Jurisdictions contributing to the ARM	Summary report/ARM section
5c – Safety Requirements for existing exposure and remediation	Commonwealth	Additional areas 11.3 Control of Discharges, Materials for Clearance, and Existing Exposure Situations, Environmental Monitoring for Public Radiation Protection
5d – Predisposal management of radioactive waste	Commonwealth	5.4, 6.4, 7.4, 8.4, 9.4
5e – Control of public exposure	Commonwealth	Additional areas 11.3 Control of Discharges, Materials for Clearance, and Existing Exposure Situations, Environmental Monitoring for Public Radiation Protection
12 – Interfaces with nuclear security	Commonwealth	12 – Interface with Nuclear Security

Table 1. List of IRRS modules and ARM sections

General information on Australia and its system of government

Australia is geographically large with a total area of 7.7 million square kilometres, making it the world's sixth-largest country by area. Australia's population is approximately 25 million, which is concentrated in cities on the eastern seaboard. Therefore, the country has a low average population density, with very little habitation in large parts of the country.

Figure 2. Parliament House, Canberra

Australia's economy is ranked among the top 20 countries in the world according to the International Monetary Fund, for both highest per capita income and largest economy.

Australia's system of government is a federal parliamentary constitutional monarchy. The federation consists of six states, two self-governing territories and a federal government. The federal government is often referred to as the Commonwealth Government or the Australian Government (the term Commonwealth will generally be used throughout this report to differentiate the federal jurisdiction from the States and Territories).

Australia's Head of State is the Queen of Australia, currently Her Majesty Elizabeth II. The Queen is represented in Australia through the Office of the Governor-General at the Commonwealth level and the Governor in each State (but not territory). Neither the Governor-General nor the governors have routine decision-making or *de facto* governmental role, but gives effect to the decisions and actions of the Prime Minister and the Federal Executive Council, or the Premier and the State Executive Councils.

The Constitution of Australia is the set of rules by which Australia is governed. The Australian Constitution establishes the composition of the Australian Parliament, and describes how Parliament works, what powers it has, how federal and State Parliaments share power, and the roles of the Executive Government and the High Court. It took effect on 1 January 1901. The Constitution provides for the Commonwealth Government's legislative powers and allocates to it certain powers and responsibilities. All remaining responsibilities are retained by the States, unless specifically delegated to the Commonwealth. Under the Constitution, the Commonwealth has the power to make laws for Australian Territories including allowing Territories to be self-governing. The Northern Territory and Australian Capital Territory were granted self-government in 1978 and 1988 respectively. If the laws of the State or Territory conflict with the laws of the Commonwealth, the law of the Commonwealth will prevail.

The Commonwealth Parliament consists of the Queen (represented by the Governor-General) and two Houses (the Senate and the House of Representatives). Proposed laws have to be agreed to by both the Senate and House of Representatives to become law. The Governor-General's role in passing legislation is limited to providing Royal Assent (approval) to legislation. The Governor-General may recommend changes to legislation but no Governor-General has refused to provide Royal Assent.

There are 150 members elected to the House of Representatives (also referred to as Members of Parliament, MPs). Each member represents one of the 150 electorates in Australia. On average, 100 000 voters live in each electorate. Seventy-six senators represent Australian States and Territories. There are 12 senators from each State and two senators from each Territory.

The Parliament is located in Canberra, in the Australian Capital Territory. The Australian Parliament has four main roles: making and changing federal laws; representing the people of Australia; providing a place where government is formed, and keeping a check on the work of the government.

Nuclear activities – An overview

Australia was an early adopter of nuclear technology. The *Atomic Energy Act 1953* ushered Australia into the atomic age, and the country's first reactor reached criticality in 1958. Australia's nuclear program is, and has been in the past, centred on one major research reactor and associated facilities for the production of nuclear medicine and research. All nuclear installations (as defined in the Commonwealth legislation) are located at the Lucas Heights Science and Technology Centre (LHSTC) in southern Sydney, and are operated by the Australian Nuclear Science and Technology Organisation (ANSTO).

The Open Pool Australian Lightwater (OPAL) research reactor was licensed to operate in 2006. OPAL is a modern 20 megawatt multi-purpose research reactor that uses low enriched uranium fuel for a range of medical, research, scientific, industrial and production applications. This includes the production of nuclear medicine and irradiated silicon, as well as the use of neutron beamlines for research and material analysis.

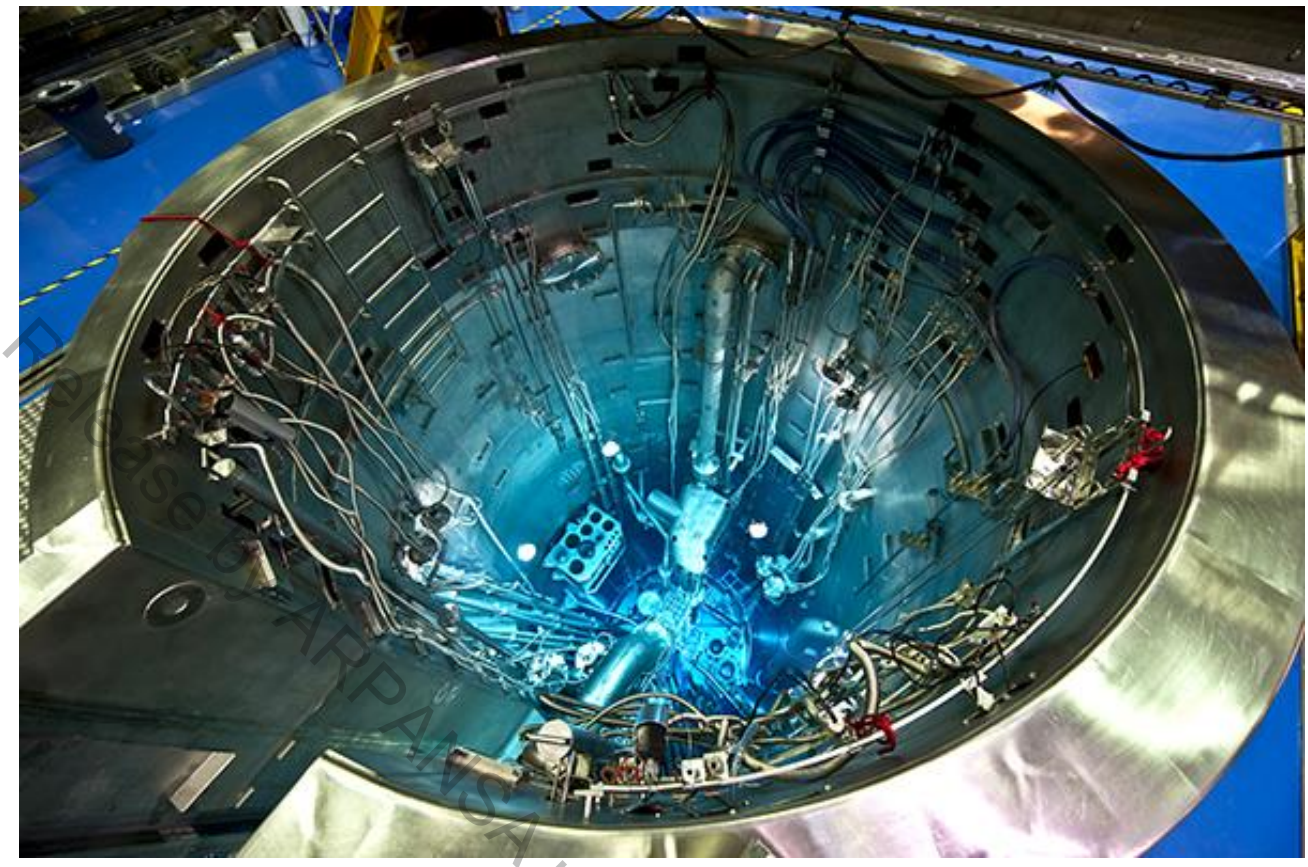

Figure 3. OPAL Reactor at ANSTO's Lucas Heights Facility

The High Flux Australian Reactor (HIFAR) was a 10 megawatt research reactor used for nuclear medicine production and research. In 2007, following the commissioning of OPAL, the reactor was permanently shut down and defueled. HIFAR is covered by a 'possess and control' licence from ARPANSA, prior to decommissioning, during which time only non-radioactive equipment may be removed.

ANSTO also operated a small 100 kW reactor, MOATA, between 1961 and 1995. It was a research reactor used for research and training, which later included activation analysis and neutron radiography. MOATA was dismantled in 2009 following its decommissioning.

Australia is the world's third largest exporter of uranium. Australia produced 5882 tons of uranium in 2017 from mining in South Australia and processing of stockpiled uranium ore in the Northern Territory. Production has fluctuated around this value since 2010. Further information on Australia's uranium mining activities is available from the Department of Industry, Innovation and Science website. Uranium mining and associated activities and facilities, including waste management, are not within scope of this IRRS.

Australia has considered developing a nuclear power program or an expanded nuclear fuel cycle industry at various points in the last 70 years. Although Australia has contributed to successful advances in research, a nuclear power program has not been developed.

Australia does not have a national facility for the storage or disposal of radioactive waste. Australia has accumulated almost 5,000 cubic metres of radioactive waste, not including waste from uranium mining and milling. This waste is low-level (including contaminated soil, laboratory items such as paper, plastic, gloves and filters), and intermediate level (including material from the production of nuclear medicines and the operation of the reactors).

In the 1990s, the Australian Government entered into agreements with the UK and France to reprocess HIFAR's spent nuclear fuel. Radioactive waste emanating from reprocessing was returned to Australia from France at the end of 2015, with some remaining waste expected to be returned in the next few years. ANSTO is now temporarily storing the waste at Lucas Heights pending decisions for its final management including disposal. A first shipment of OPAL fuel has recently been dispatched to France for reprocessing, with the resulting waste planned to be returned to Australia. There is no high-level radioactive waste in Australia, and no generation of such waste is currently foreseen.

The current process for selecting and establishing the Commonwealth's national radioactive waste management facility began in May 2015. The Commonwealth proposes that this site act as a disposal facility only for low-level waste, with potential co-located storage of intermediate level waste until a site for disposal of intermediate level waste has been identified and a disposal facility established at that site.

Australia's obligations under a range of treaties and agreements aimed at control and accounting of nuclear material are administered by the Australian Safeguards and Non-Proliferation Office (ASNO) under the Department of Foreign Affairs and Trade. These arrangements are generally out of scope for this IRRS.

Regulatory bodies – An overview

Each Australian State and Territory, and the Commonwealth, has one or more regulatory authorities with responsibilities for regulatory management of radiation risks. The IAEA uses the term 'regulatory body' in its safety standards. The 'regulatory body' may be a system of authorities that collectively carry out regulatory functions relevant to the IAEA safety standards. The federal system of government in Australia means that authorities of the Commonwealth, States and Territories carry out such functions. The term 'regulatory body (bodies)' will be used throughout this report; it will be clear from the context when it refers to specific entities such as regulatory agencies, to specific jurisdictions, or to the national regulatory framework.

'Safety' as used in this report refers to all actions aimed at managing radiation risks and covered in the IAEA safety standards. It includes radiation safety (here synonymous with radiation protection and radiological protection), nuclear safety, waste safety, transport safety and emergency preparedness and response. It also includes security to the extent security is incidental to the legal framework for safety (excluding accounting for nuclear material and safeguards). It does not include other aspects of safety such as covered in work health and safety legislation unless it interfaces or overlaps with safety as it relates to management of radiation risks.

Across Australia (the Commonwealth, State and Territory jurisdictions), there are more than 7000 radiation management licences and more than 50 000 individual radiation use licences. These cover a range of medical, industrial and commercial applications.

The bodies with main responsibility for managing these licences are detailed in Figure 1 on page 4. Each jurisdiction's regulatory body operates under its own relevant jurisdiction legislation. These Acts either directly establish the regulatory bodies or establish them under administrative arrangements with powers assigned to an individual, such as the Chief Health Officer within a state or territory or the CEO of ARPANSA. In two jurisdictions (ACT and WA), some functions of the radiation safety regulator are granted to a separate authority. In the ACT the approval and inspection powers are held by separate authorities. However, as these authorities work together closely, they can be treated as a single regulatory body for the purposes of this report.

Some jurisdictions also have separate regulatory bodies for resource and mining activities, environmental protection, workplace health and safety, and public health. These regulatory bodies may have specific roles in relation to safety (as defined in the IAEA safety standards). For example in WA, the Department of Mines, Industry Regulation and Safety co-regulate safety of industries such as the mining of naturally occurring radioactive material with the Radiological Council (noting that such activities are out of scope for this IRRS).

Each of the jurisdictions' primary regulatory bodies with responsibility for radiation protection is represented on the Radiation Health Committee (RHC). The RHC is the primary body for developing policies and draft publications on uniform regulation of radiation, for consideration by the jurisdictions. One of the functions of the CEO of ARPANSA is to promote uniformity (the CEO is a statutory member of the RHC). The RHC maintains the National Directory for Radiation Protection (NDRP), which is a summary of agreements aimed at achieving nationally consistent outcomes in terms of the protection of health and safety of people, and of the environment, from the harmful effects of radiation.

Each regulatory body reports to the relevant State, Territory or Commonwealth government. The primary intergovernmental body for national decisions is the Council of Australian Governments (COAG), where each Government is represented by the Prime Minister (Commonwealth), Premier (States) or Chief Minister (Territories). Similarly, each Government's Health Minister is a member of the COAG Health Council, which discusses health specific issues, such as the use of radiation in medicine and also approves new or amended regulatory elements captured in the NDRP. Most regulatory bodies are within their jurisdictions' health portfolio and report to their health minister directly or through their department. Two regulatory bodies (in SA and NSW) sit in the environment portfolios and brief their health portfolio counterparts on relevant issues. APRANSA is an agency under the health portfolio, with direct reporting lines to the Minister and Parliament.

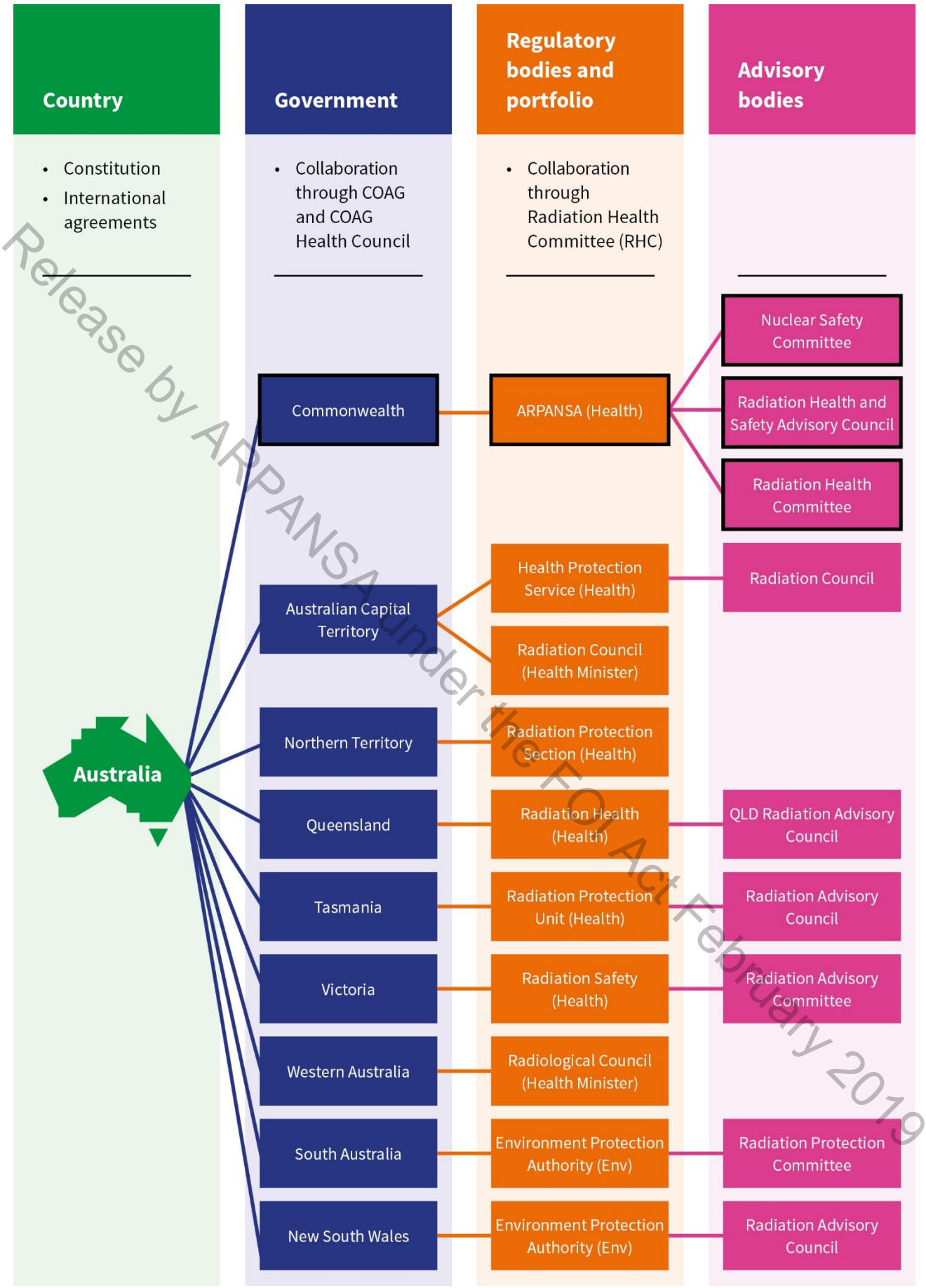

Figure 4. Overview of primary radiation safety regulatory bodies in Australia

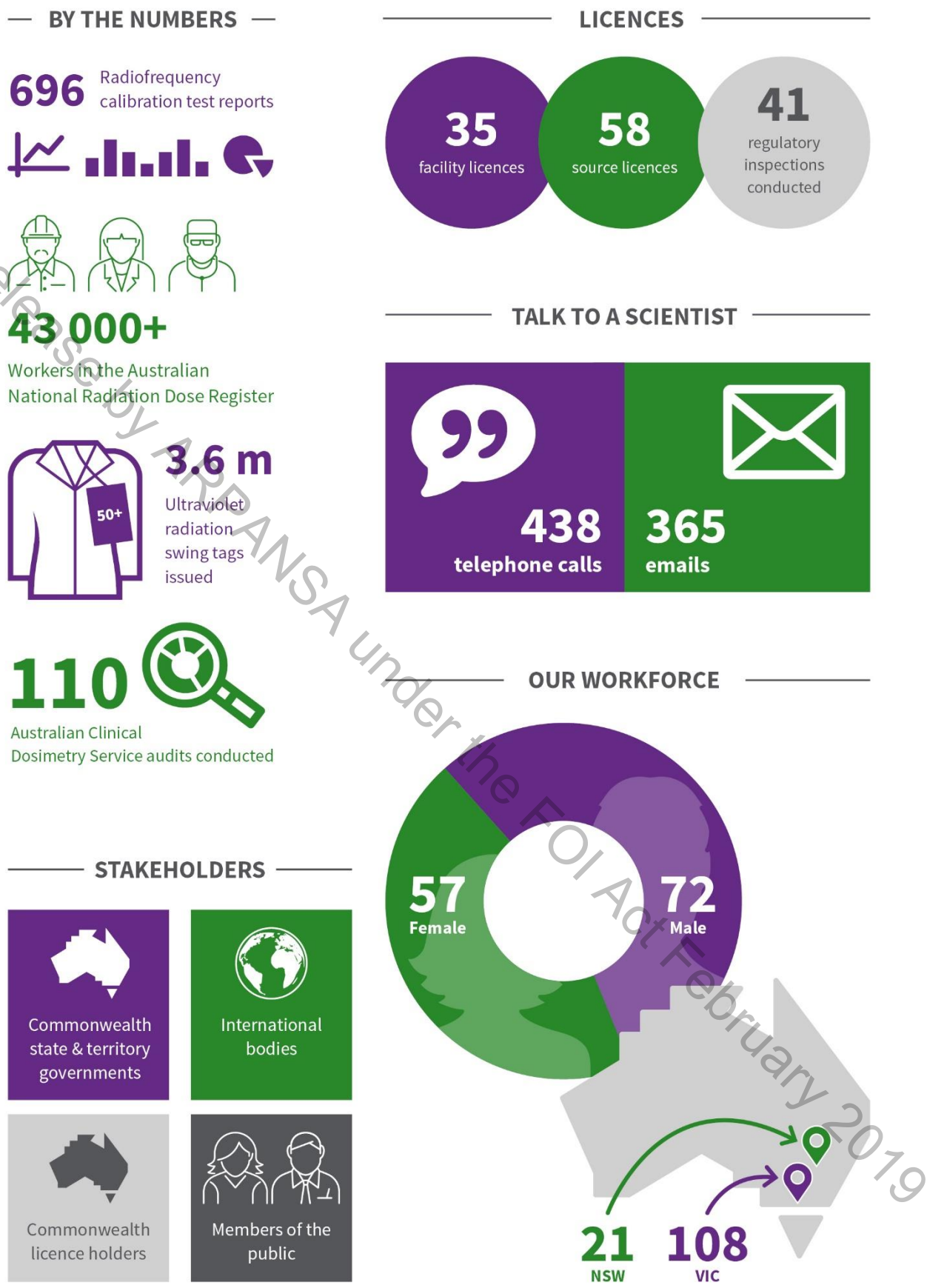

Figure 5. Statistics for the Commonwealth regulator, ARPANSA, for the 2017-18 financial year.

1. Responsibilities and functions of the government

This section outlines the Commonwealth arrangements for safety. Information is also provided on State and Territory arrangements where they interface or interact with those of the Commonwealth, or to provide context.

1.1 National policy and strategy for safety

Related to GSR Part 1 (Rev. 1): Requirement 1

Australia is a federation comprising of nine jurisdictions; the Commonwealth of Australia, the six States (Queensland (QLD), New South Wales (NSW), Victoria (VIC), Tasmania (TAS), South Australia (SA) and Western Australia (WA)) and two Territories (Australian Capital Territory (ACT) and Northern Territory (NT)). Each jurisdiction has its own radiation safety act, regulations and regulatory bodies.

This section focuses on the responsibility and functions of the Commonwealth. The roles and responsibilities of the Commonwealth's regulatory body for safety[1], the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), are discussed in section 3 of this Summary Report. Additional Commonwealth bodies with responsibilities related to management of radiation risks are considered in section 1.5 on coordination of authorities with responsibilities for safety within the regulatory framework.

National policy and strategy documents

Australia has not published a national policy and strategy for safety contained in a single document. However, the Commonwealth has made provisions and commitments in legislation, agreements and other documents that address Requirement 1 of GSR Part 1.

The *Australian Radiation Protection and Nuclear Safety Act 1998* (ARPANS Act) and the Australian Radiation Protection and Nuclear Safety Regulations 1999 (ARPANS Regulations) reflect the Commonwealth's intent with regards to safety. The Office of the CEO of ARPANSA, as well as ARPANSA, was established in 1998 through the ARPANS Act to regulate the safety of Commonwealth entities that use or produce radiation. These entities are predominantly Commonwealth departments, agencies and Commonwealth-owned businesses. The ARPANS Act also provides the CEO of ARPANSA with other functions, such as promoting national uniformity, undertaking research and providing services. With the establishment of ARPANSA, the pre-existing Nuclear Safety Bureau (NSB) in Sydney and the Australian Radiation Laboratory (ARL) in Melbourne, and their respective functions, were expanded and consolidated into one agency, and the predecessors ARL and NSB were abolished.

[1] 'Safety' in this report refers to all actions aimed at managing radiation risks covered in the IAEA safety standards unless otherwise indicated.

The relevant jurisdictions legislation establishes the regulatory body for safety in each State and Territory. Health Ministers of all nine jurisdictions agreed in 1999 to publish the *National Directory for Radiation Protection* (NDRP) with a view to ensuring the regulatory controls in each jurisdiction were able to be nationally consistent. The NDRP was published in 2004 with regulatory principles, uniform regulatory elements and guidance, including adoption of national codes and standards for radiation protection. The NDRP sets out the agreed overall framework for radiation protection in Australia. It is expected that jurisdictions will adopt these principles as reviews of legislation come forward. The mechanisms for amending the NDRP are described in sections 9 and 13 of this Summary Report.

The current edition of the NDRP is due to be replaced by a revised, 2nd edition (this has been made available to the IRRS team) of the NDRP, which has been endorsed by the regulators from all Australian jurisdictions in July 2018, through the Radiation Health Committee (RHC). It is expected to be approved by the Health Ministers by mid-2019. This Summary Report will draw on the content of the 2nd edition of the NDRP, unless otherwise stated.

The fundamental safety objectives and safety principles

The object of the ARPANS Act is well aligned with the fundamental safety objective of IAEA Safety Fundamentals No. SF-1 *Fundamental Safety Principles*. Section 3 of the ARPANS Act states: The object of this Act is to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation'. At the national level, the NDRP states at the outset in part A (General Principles) that jurisdictions have agreed to adopt in their legislation the objective of protecting the health and safety of people and the environment from the harmful effects of ionising and non-ionising radiation.

All jurisdictions have recognised the Fundamentals for Protection Against Ionising Radiation (2014) (RPS-F1) as the primary basis for managing safety. In addition to setting out and explaining the 10 fundamental safety principles of the IAEA Safety Fundamentals (SF-1), RPS-F1 incorporates the elements *of The 2007 Recommendations of the International Commission on Radiological Protection (ICRP 103)* that relate to different exposure situations, explicitly identifies 'environment' as an exposure category, and includes basic information on the effects of ionising radiation on human health and the environment. RPS-F1 also discusses the interdependencies of the radiation protection, safety and security objectives.

The Commonwealth has also provided for protection of the environment through the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act). Under the EPBC Act, actions that have, or are likely to have, a significant impact on a matter of national environmental significance require approval from the Commonwealth Minister for the Environment. This includes the following 'nuclear actions':

- establishing or significantly modifying a nuclear installation
- transporting spent nuclear fuel or radioactive waste products arising from reprocessing
- establishing or significantly modifying a facility for storing radioactive waste products arising from reprocessing
- mining or milling uranium ores, excluding operations for recovering mineral sands or rare earths
- establishing or significantly modifying a large-scale disposal facility for radioactive waste
- decommissioning or rehabilitating any facility or area in which an activity described above has been undertaken.

The Commonwealth has provided for safeguards and non-proliferation arrangements under the *Nuclear Non-Proliferation (Safeguards) Act 1987* and the *Comprehensive Nuclear-Test-Ban Treaty Act 1998*. These Acts are administered by the Australian Safeguards and Non-Proliferation Office (ASNO), whose functions include:

- the application of safeguards in Australia, consistent with the Treaty on the Non-Proliferation of Nuclear Weapons
- the physical protection and security of nuclear items in Australia, consistent with the Convention on the Physical Protection of Nuclear Material
- the operation of Australia's bilateral safeguards agreements
- contribution to the operation and development of IAEA safeguards and the strengthening of the international nuclear non-proliferation regime.

International agreements

The ARPANS Act (part 8, section 84) requires the CEO's powers in the Act to be exercised in accordance with international agreements listed in the ARPANS Regulations. See also section 2 of this Summary Report, Global Nuclear Safety Regime.

The scope of the governmental, legal and regulatory framework for safety

Through the ARPANS Act, the Commonwealth has specified the scope of the governmental, legal and regulatory framework for safety for Commonwealth entities dealing with radiation. For example:

- The safety requirements in the Act apply to Commonwealth entities wherever they operate (including overseas)
- The Act prohibits the issuing of a licence to operate a nuclear fuel fabrication facility, a nuclear power plant, an enrichment plant, or a reprocessing facility
- Limiting the application of the Act to Commonwealth entities, and their contractors, and certain 'permitted persons' (defined in the Act).

The scope of the CEO's regulatory and other functions in relation to safety are specified in section 15 of the ARPANS Act. They include issuing licences; monitoring compliance with the licensing requirements of the Act; promotion of national uniformity; provision of advice and services, including research, technical and commercial services; and accreditation of persons.

The scope of the governmental, legal and regulatory framework for safety in the States and Territories are specified by the governments of each State and Territory. Jurisdictions have agreed to ensure that the scope of the governmental, legal and regulatory framework for safety comprises certain elements, as outlined in the NDRP.

Human and financial resources

The ARPANS Act does not contain a policy or strategy for human and financial resources. However, the Act (section 58 - *staff and consultants)* provides the CEO of ARPANSA the power to engage staff and consultants to assist in the performance of the CEO's statutory functions. Similarly, the Act provides for application fees (sections 34) and service charges (section 54) that allow for the recovery of costs for regulatory activities. The *Australian Radiation Protection and Nuclear Safety (Licence Charges) Act 1998* outlines the annual licence charges applicable to licence holders. Additionally, the Department of Health and ARPANSA engage in the preparation of the Portfolio Budget Statement, which sets out financial provisions for each year.

At the national level there is no agreement in the NDRP for a national approach to provide for human and financial resources for safety. However, similar provisions for charging, budget proposal and administrative arrangements apply in each jurisdiction.

Provision and framework for research and development

The ARPANS Act (section 15) states that a function of the CEO of ARPANSA is to undertake research in relation to radiation protection, nuclear safety and medical exposures to radiation. ARPANSA carries out such research, mainly at its facilities and laboratories in Melbourne, and is also a strong contributor to international scientific forums such as the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).

Other Commonwealth organisations such as the Australian Nuclear and Science and Technology Organisation (ANSTO) and the Commonwealth Scientific and Industrial Research Organisation (CSIRO) have a role in research and development involving radiation. ANSTO is established under the *Australian Nuclear Science and Technology Organisation Act 1987 (*ANSTO Act) and conducts research and development in relation to nuclear science and technology, provides advice to Government and undertakes international liaison in nuclear-related matters. In addition to operating the OPAL research reactor, ANSTO research facilities include a suite of neutron beam instruments, accelerator facilities, as well as the Australian Synchrotron located in Melbourne.

Additionally, the Commonwealth has addressed research and development requirements for waste management in section 6.4 of the recently published *Australian Radioactive Waste Management Framework (April 2018).* This framework is further described in section 1.7 of this Summary Report.

Jurisdictions have made a commitment in the NDRP to undertake research and development in order to contribute to and enhance safety and have agreed that the legal framework will provide powers or functions to the regulator to "*promote or conduct studies, investigations and research associated with radiation protection and nuclear safety, including public health and safety and environmental considerations"* (NDRP, section 2.3)

Mechanisms for taking account of social and economic developments

The ARPANS Act and Regulations ensure that the CEO of ARPANSA takes into account social and economic factors in licensing decisions by including the justification and optimisation principles (as well as dose limitation) as mandatory requirements in the Regulations. Under regulations 41 and 42, the CEO must take into account matters that are specified in those regulations before issuing a facility or source licence. Among the matters that the CEO must take into account are:

- whether the applicant has shown that there is a net benefit from carrying out the conduct relating to the controlled facility/dealing with the controlled apparatus or material
- whether the applicant has shown that the magnitude of individual doses, the number of people exposed, and the likelihood that exposure will happen, are as low as reasonably achievable, having regard to economic and social factors.

The advisory bodies to ARPANSA, being the Radiation Health and Safety Advisory Council (RHSAC), the Radiation Health Committee (RHC) and the Nuclear Safety Committee (NSC), advise the CEO on a variety of matters, including on social and economic developments when relevant. The functions and operations of the advisory bodies are summarised in Roles and Expectations of the Advisory Bodies (see section 1.3). All advisory bodies have a member to represent the interests of the general public.

The Radiation Health and Safety Advisory Council's functions under the Act include:

- To identify emerging issues in relation to radiation protection and nuclear safety and to advise the CEO on them
- To examine matters of major concern in the community in relation to radiation protection and nuclear safety and to advise the CEO on them.

At the national level, the jurisdictions have agreed in the NDRP to give effect to the justification, optimisation and limitation principles in each jurisdiction's regulatory framework. These are underpinned by the guidance in RPS F-1, and by requirements outlined in the *Code for Radiation Protection in Planned Exposure Situations (2016)* (the Planned Exposure Code; RPS C-1).

The promotion of leadership and management for safety, including safety culture

ARPANSA promotes safety as part of its Work Health and Safety policy and strategies as further explained in section 4 of this Summary Report. ARPANSA also actively promotes leadership for safety and safety culture among its staff and licence holders through the *Holistic Safety Guidelines*, which outline principles and provides guidance on key technological, human, and organisational aspects of safety that are necessary to consider in a holistic approach to safety. Safety is promoted by ARPANSA's leadership team, and the Work Health and Safety Committee is led by the CEO. A 'safety moment' is included in the agenda of every meeting of the ARPANSA Executive Group (EG) and Strategic Management Committee (SMC). The Work Health and Safety Coordinator provides a safety update at each EG meeting. See also section 9.7 of this Summary Report.

At the national level, jurisdictions have agreed in the NDRP that each jurisdiction's regulatory framework will, in accordance with a graded approach, impose requirements on the responsible person in a practice to establish a management system that promotes, among other things, a culture for safety.

1.2 Establishment of a framework for safety

Related to GSR Part 1 (Rev. 1): Requirement 2 and GSR Part 3: Requirement 2

The Commonwealth has promulgated a legal framework for safety through the ARPANS Act and Regulations. On a national level, all jurisdictional safety regulators agree on the implementation and interpretation of requirements through the Radiation Health Committee; these agreed requirements are captured in the NDRP. As discussed further in this Summary Report (e.g. in sections 9.1 and 13), the establishment of a nationally consistent framework for safety is a complex and often time-consuming

process, and its implementation across the nation may differ. Initiatives have been taken by both jurisdictional regulators represented on the RHC and by the Commonwealth Government to explore options for achieving a more unified and efficient approach (see section 13).

Principles and framework

The ARPANS Act establishes ARPANSA and aims to 'protect the health and safety of people, and to protect the environment, from the harmful effects of radiation.'

The principle of dose limitation is given effect in the ARPANS Regulations and via licence condition from RPS C-1 Schedule A and B. These limits are in line with the dose limits in GSR Part 3. However the provision in Schedule III.2 of GSR Part 3 was not adopted in Australia. Trainees and students between the ages of 16–18 are subject to the same limits as adult workers. In practice, occupational exposures are well below the dose limit prescribed in Schedule III.2 of GSR Part 3 for trainees and students aged 16–18.

The optimisation principle is provided for in the ARPANS Regulations in regulations 4, 4A and 5 (see also the aforementioned provisions in regulations 41 and 42 concerning both optimisation and justification). Together these regulations provide that a licence holder must ensure that actions that introduce or alter a source, or alter the exposure, are justified; and that radiation protection and safety are optimised so that the magnitude of individual doses, the number of people who are exposed, and the likelihood of incurring exposures to radiation are as low as reasonably achievable after taking into account economic and societal factors. Both the *Fundamentals* (RPS F-1) and the *Planned Exposure Code* (RPS C-1) – the latter a standard condition of licence for all ARPANSA licence holders under regulation 48 – also explain the principles of justification, optimisation and limitation in the regulatory context (see sections 4.4 and 4.5 of RPS F-1 and sections 2.1 and 2.2 of RPS C-1).

Scope of framework and authorisations

The ARPANS Act, part 5, requires authorisation for each stage of the life cycle of controlled facilities, and dealing with (possession, control, use or operation, and disposal) controlled material or controlled apparatus.

'Controlled facilities' are defined in the ARPANS Act (section 13) as a nuclear installation, a prescribed radiation facility or a prescribed legacy site. These facilities are prescribed under the ARPANS Regulations (Regulation 6) and include large particle accelerators, irradiators, and facilities used for production or disposal of material above certain levels. These authorisations are for specific stages of a facility life cycle, namely preparation of a site, construction, possession or control, operation, decommission, disposal or abandonment, and remediation of a legacy site.

'Controlled material' and 'controlled apparatus' are defined in section 13 of the ARPANS Act and includes all radioactive material and apparatus which may emit ionising radiation, and prescribed non-ionising apparatus. However sources may be exempted by regulation or by a specific exemption granted.

Occupational and medical exposure is managed through the granting of licences to authorised parties. This is discussed in section 11.1 and 11.2.

The rationale for decision making process

The matters that must be taken into account by the CEO during the authorisation process are listed in subsections 32 and 33 of the ARPANS Act. These subsections state that the CEO must take into account the

matters specified in the regulations and international best practice (guidance on which is provided on the ARPANSA website) in relation to radiation protection and nuclear safety. For a nuclear installation, the CEO must also take into account the content of all public submissions made by members of the public.

The Regulations, specifically regulations 41 and 42, specify a number of criteria including completeness of application, net benefit (justification), optimisation, public comments received, the capacity to comply with the requirements and ensuring that the proposed conduct can be carried out without undue risk to the health and safety of people and the environment. Guidance on the required information to be submitted, including the plans and arrangements for managing safety, is provided in regulatory guides.

The rationale for issuing a licence is documented in the Regulatory Assessment Report (example of a recent assessment report) and, where applicable, the Statement of Reasons (example of a recent statement). These documents are made available online for key decisions and key facilities.

Consultation and involvement of interested parties

The ARPANS Act makes provisions for interested parties' input into decision making for the licensing of nuclear installations and radiation facilities. Under the ARPANS Regulations (regulation 40), the CEO of ARPANSA must, as soon as practicable after receiving an application for a facility licence, publish a notice in a daily newspaper circulating nationally, and in the Australian Government *Gazette*, stating that the CEO intends to make a decision on the application. If the application relates to a nuclear installation, the CEO must also include an invitation to make submissions about the application and information on the time period and procedures for making submissions. Regulation 41 further states that the CEO, when deciding on whether to issue a licence for the nuclear installation, must take into account the content of submissions made in relation to the application.

The ARPANS Act also makes provisions for the involvement of interested parties and stakeholders through the establishment of three advisory bodies, the RHSAC, the RHC and the NSC. The roles and responsibilities for advisory bodies are publicly available on the website to provide information and transparency on the roles of the advisory bodies.

These advisory bodies have legislated roles in relation to stakeholder engagement and community concerns, e.g. for RHSAC – "to examine matters of major concern to the community in relation to radiation protection and nuclear safety and to advise the CEO on them" and for RHC – "to consult publicly in the development and review of policies, codes and standards in relation to radiation protection"'. The ARPANS Act (sections 21, 24 and 26) requires the RHSAC, RHC and NSC to have members that represent a cross section of interests in radiation protection and nuclear safety. Each advisory body has a member representing the interests of the general public and submissions to these members may be made through the website. The appointment of each member (other than the CEO) is made only after consultation with appropriate consumer groups and environmental groups.

Legal responsibility for safety of facilities and activities

The principle that legal responsibility for safety rests with the persons or organisations responsible for the facilities and activities is captured in the NDRP, in the Fundamentals (RPS F-1) and in the *Planned Exposure Code* (RPS C-1). This Code, which is a general condition of licence under the ARPANS Regulations (regulation 48), states the role of the Responsible Person. Additionally, the regulations set clear responsibility on the licence holder, such as regulation 49, which is a general condition of licence that requires licence holders to take all reasonably practicable steps to manage the safety of their facilities and sources.

The ‘plans and arrangements’ mentioned in regulation 49 are fundamental to the way in which responsibility for safety is placed on the licence holder under the legal framework administered by ARPANSA. This includes requirements on an applicant for a licence to detail how the applicant will exercise effective control, and to provide a safety management plan/radiation protection plan.

The legal obligation on a licence holder to implement the plans and arrangements for managing safety that were approved by ARPANSA when issuing a licence is created by regulations 49 and 50 of the ARPANS Regulations. These are general conditions of licence that require a licence holder to take all reasonably practicable steps to manage the safety of the facility including having in place plans and arrangements, and ensuring that they are implemented and periodically reviewed. See further section 1.4 on the responsibilities of the licence holder.

Provision for the review and assessment of facilities and activities

Review and assessment takes place before an authorisation is issued and over the lifetime of an authorisation (see section 6 for further details on review and assessment). The ARPANS Act (e.g. sections 32 and 33) and Regulations (39, 41 and 42: Schedule 3 Parts 1 and 2) contain provisions that enable the CEO of ARPANSA and regulatory staff to undertake review and assessment associated with an authorisation. These reviews are conducted using a graded approach.

While not specifically provided for in the legislation, periodic reviews are performed. ARPANSA undertakes review and assessment of licences through a structured periodic source and facility licence review to ensure that licences issued by ARPANSA continue to be appropriate and promote the safety objective. Licence holder reviews of safety may be required as a condition of licence, such as a (normally) 10-year periodic safety and security review for research reactors, and five years after commencement of operation for the recently licenced ANSTO Nuclear Medicine Mo-99 Facility.

Figure 6. ANSTO Nuclear Medicine Facility

Preparation of regulation and guidance

The provision to make regulations is provided in the ARPANS Act (section 85). The regulation making process may involve ARPANSA proposing the making or amendment of regulations. The proposal is approved by the relevant Minister responsible for ARPANSA, and the drafting is prepared by the Office of Parliamentary Counsel in consultation with ARPANSA. However, the legal power to make regulations rests with the Governor-General on the advice of the Federal Executive Council (and Parliament by virtue of its power to disallow the regulations).

Consistent with the functions of the CEO under the Act, ARPANSA prepares extensive national guidance including national Codes jointly with State and Territory regulators, as well as guidance to Commonwealth licence holders and applicants. Further detail is provided in section 9 of this Summary Report, on regulations and guides.

Inspection of facilities and activities, enforcement of regulations

Under the ARPANS Act (section 15(1)(h)) a function of the CEO is to monitor compliance with division 1 of part 5 of the Act. This part prohibits certain conduct in relation to facilities and dealing with sources unless authorised by a facility or source licence (unless the conduct or dealing is exempt from the need to be licensed) and requires the licence holder to comply with the conditions of the licence. To facilitate the compliance monitoring, the Act has provisions with powers for the CEO and their inspectors. The provisions in the Act that provide these powers are sections 35(3) and (4) – power to enter and inspect at reasonable times:

- section 44A – power to require provision of information, produce documents, or appear before the CEO to answer questions
- section 65 – powers for dealing with hazardous situations
- section 66 – powers for searches and seizures
- section 67 – general powers of inspection
- section 80A – power to issue improvement notices.

The CEO's enforcement powers are provided in part 5, division 2 and 3 of the ARPANS Act, including:

- amendment of licence (section 36)
- cancellation and suspension of licence (section 38)
- give directions to controlled persons (section 41)
- seek a Federal Court injunction to restrain a person from doing something that would be an offence against the Act (section 43).

Provision for appeals

A licence holder may appeal a licence decision of the CEO to the Minister, under section 40 of the ARPANS Act. A licence decision includes a refusal to grant a licence, imposing conditions on a licence, and not approving the surrender of a licence. Appeal provisions also exist for many other regulatory decisions made by the CEO, such as the refusal to grant an exemption.

Applications may be made to the Administrative Appeals Tribunal (AAT) for a review of the Minister's decision (section 40(5)). The Commonwealth AAT provides an independent review of a wide range of decisions made by the Commonwealth. In other jurisdictions, similar bodies serve this function, such as the ACT Civil and Administrative Tribunal (ACAT).

Provision for preparedness for, and response to, a nuclear or radiological emergency

The CEO can request information relevant to a licence application (regulation 39 and Schedule 3 Parts 1 and 2 of the Regulations) and must under regulations 41 and 42 take into account several matters before issuing a facility or source licence. This includes emergency plans for the facility or radioactive material or apparatus. The CEO has published detailed guidance on what the licence holder must demonstrate in the emergency plans and procedures and how the licence holder is to demonstrate preparedness for an emergency. The guidance is available in Chapter 7 of the Regulatory Guide *Plans and Arrangements for managing safety*. Additional guidance is captured under the published *Recommendations for Intervention in Emergency Situations Involving Radiation Exposure (2004)*, to be replaced by the Emergency Exposure Guide, RPS G-3 (draft).

Emergency management arrangements require significant coordination with other Commonwealth agencies as well as with jurisdictional agencies with responsibilities for emergency management. The arrangements are explained in further detail in section 9 of this Summary Report.

Under the ARPANS Act (section 84) and the ARPANS Regulations (regulation 65), the CEO or a licence holder must, in exercising a power or function, take into account all relevant international agreements listed in Schedule 5 of the ARPANS Regulations in relation to preparedness for and response to a nuclear or radiological emergency. The relevant international agreements listed in the schedule are the *Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency* and the *Convention on Early Notification of a Nuclear Accident*.

Interfaces with nuclear security and with the system for control and accounting in relation to nuclear material

The ARPANS Act (see section 82) is to operate in conjunction with the *Nuclear Non Proliferation (Safeguards) Act 1987*, which is the legislation that provides the legal framework for the Australian Safeguards and Non-proliferation Office for the control of nuclear material safeguards and nuclear security. ARPANSA and ASNO have a memorandum of understanding in place and have established procedures for cooperation in relation to licencing, in particular those regarding nuclear installations (see section 1.5 on coordination with other authorities, and section 12 on interface with nuclear security).

Provision for the financing of management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities

There is no specific provision in any Commonwealth legislation that establishes arrangements in respect of financial provision for decommissioning of facilities and termination of activities. However, a framework for management of radioactive waste has recently been released (the Australian Radioactive Waste Management Framework) and is discussed in section 1.7. The CEO of ARPANSA may, under regulation 39 of the ARPANS Regulations, ask for some or all of the information in Schedule 3 or any other relevant or appropriate information about the application. In addition to requesting all relevant information in Parts 1 and 2 of Schedule 3 (which includes a radioactive waste management plan), the CEO may, under regulation

39, request information on financial provisions for the management of radioactive waste and of spent fuel, and for the decommissioning of facilities and termination of activities.

Budget allocations have been made for specific decommissioning activities. For example in the 2018-2019 budget, $7.7 million was allocated for funding Radioactive Waste Management and Decommissioning Projects, which includes activities associated with the permanently shut down HIFAR reactor located at Lucas Heights outside Sydney.

National competence

The ARPANS Act (section 58) empowers the CEO to engage staff and consultants to assist in performing the CEO's functions. Apart from the CEO and three Senior Executive Service staff (the three Branch Heads), ARPANSA staff are engaged under the *Public Service Act 1999* (PS Act). The PS Act provides the CEO of ARPANSA the power to create positions and engage sufficient staff to ensure that necessary competence is available within ARPANSA. The PS Act also provides that, wherever possible, public servants must be employed as ongoing employees.

Most of ARPANSA's licence holders, being Commonwealth entities, also employ their safety-related staff under the PS Act. In some cases, staff are employed under legislation that creates the Commonwealth entity (e.g. the *Australian Nuclear Science and Technology Act 1987*). In each case, the legislation provides agency heads the power to employ staff to ensure competence and safety.

The provision for acquiring and maintaining the necessary national competence for ensuring safety, including national training programs, are discussed in section 1.8.

Decommissioning and the criteria for release from regulatory control and exemption

The ARPANS Act requires that decommissioning of Commonwealth facilities is not performed without authorisation; aspects of authorisation, review and assessment, and inspection in relation to decommissioning is discussed in sections 5.5, 6.5 and 7.5 of this Summary Report.

The ARPANS Regulations lists exempt dealings and exemption levels under which material does not require authorisation, and makes provision for exemption on application.

The ARPANS Act and Regulations do not contain explicit criteria for release from regulatory control such as clearance levels. There are, however, provisions in the Act and Regulations to deal with disposal, abandonment of sites following decommissioning of a facility and to deal with particular situations involving radioactive material.

The 2nd edition of the NDRP, which has been agreed by jurisdictional regulators represented on the RHC, is proposing to incorporate by reference Schedule I of GSR Part 3, which, when implemented, will require all jurisdictions to incorporate the provisions in GSR Part 3 for exemptions and clearance into their legal and regulatory frameworks. Information for disposal by the user are found in Schedule 14 of NDRP edition 1; the RHC has decided to republish the values as a stand-alone Code, RPS C-6.

Existing exposure situations are discussed in section 11.3.

The specification of offences and the corresponding penalties

Offences and penalties are specified in the ARPANS Act. These include:

- Subsection 30(1) - A controlled person must not prepare a site for a controlled facility, construct a controlled facility, have possession or control of a controlled facility, operate a controlled facility, de-commission, dispose of or abandon a controlled facility, or remediate a prescribed legacy site unless the person is authorised to do so by a facility licence; or the person is exempted in relation to the conduct concerned by regulations made for the purposes of this section. Penalty: 2,000 units
- Subsection 30(2) – The holder of a facility licence must comply with the conditions of the licence. Penalty: 2,000 units or such lower amount prescribed in the ARPANS Regulations
- Subsection 31(1) – A controlled person must not deal with a controlled material or controlled apparatus unless the dealing is authorised by a source licence, or facility licence or the dealing is prescribed by the regulations as exempt. Penalty: 2,000 units
- Subsection 31(2) – The holder of a source licence must comply with the conditions of the licence. Penalty: 2,000 units or such lower amount prescribed in the ARPANS Regulations.

A penalty unit is currently equivalent to A$210.

It should be noted that, while a number of enforcement options are available to ARPANSA (such as directions and suspension or cancellation of a licence) that support the safety objective of the Act, nothing in the Act renders the Crown liable to be prosecuted for an offence (section 4 of the ARPANS Act).

Import and export

The provisions for controls on the import of radioactive material and export of high activity radioactive material are in the following regulations:

- Import – regulation 4R of the Customs (Prohibited Imports) Regulations 1956.
- Export – regulation 9AD of the Customs (Prohibited Exports) Regulations 1958.

The authorised officer for the issue of import and export permits under these regulations is the CEO of ARPANSA or delegate. As exemption limits do not currently apply to the import of radioactive material, any quantity of material will require some level of regulatory control. More regulatory effort is applied to higher activity material and complex material such as waste. While all radioactive material is subject to import restrictions, a more graded approach is applied to export controls which are only required for high activity sources consistent with the IAEA Code of Conduct on the Safety and Security of Radioactive Material, Imports and Exports Guidance.

Permits for the import of nuclear material are issued by ASNO under the *Nuclear Non-proliferation and Safeguards Act 1987*.

Permits for the export of nuclear material are granted by the Department of Industry under regulation 9 of the Customs (Prohibited Exports) Regulations 1958.

1.3 Establishment of a regulatory body and its independence

Related to GSR Part 1 (Rev. 1): Requirements 3 and 4, and GSR Part 3: Requirement 2

As briefly reviewed in section 1.1, the Commonwealth has established a legal framework for safety through the ARPANS Act and ARPANS Regulations. However, this legal framework is only for the Commonwealth.

Other jurisdiction regulatory bodies have been established under their legal framework in accordance with the relevant jurisdiction legislation.

ARPANSA sits within the Health portfolio but is independent in its regulatory decision making. This was enabled by the Government by establishing the office of the CEO of ARPANSA as an independent statutory office holder to be appointed by the Governor-General of Australia and who will be the head of a statutory agency called ARPANSA (see sections 14, 14A, 45 and 58 of the ARPANS Act). The CEO reports to the relevant Minister responsible for ARPANSA, and prescribed reports, such as Quarterly Reports, must be tabled in Parliament by the Minister within 15 sitting days. The CEO may also at any time table a report in Parliament about any matter that relates to the CEO's functions under the ARPANS Act (section 61 of the ARPANS Act).

The establishment of the CEO as a statutory office holder and the formation of the CEO and ARPANSA as a statutory agency accountable to Parliament protects the agency from external pressures. Additionally, being administered under the Health portfolio, ARPANSA is structurally separate from and independent of the parent departments of its largest licence holders.

Notwithstanding the above, the Minister can direct the CEO and the CEO must comply with such directions. The Minister can, however, only direct the CEO if it is in the public interest to do so. Furthermore, the Minister must table a direction in Parliament within 15 sitting days. The CEO has so far never received a direction under the ARPANS Act.

Recognising that the CEO of ARPANSA has both regulatory and non-regulatory functions under subsection 15(1) of the Act, the Government took steps to ensure the integrity of the CEO's regulatory function by enacting subsection 15(2) as follows: '*The CEO must take all reasonable steps to avoid any conflict of interest between the CEO's regulatory functions and the CEO's other functions*'.

ARPANSA's Radiation Health Services Branch (RHSB) and Medical Radiation Services Branch (MRSB) hold facility and source licences issued by the CEO of ARPANSA. The assessment for the issuing of these licences and the inspection of the authorised facilities and sources operated or dealt with by RHSB and MRSB, are undertaken by inspectors from the Regulatory Services Branch, which is functionally separate from RHSB and MRSB. In addition, the authorisation, inspection and enforcement activities in respect of the licences held by the RHSB and MRSB are overseen by a regulator from one of the States and Territories, who certifies that the regulatory activities have been undertaken independently and at arm's length. The management of conflicts of interest is further explained in the document on intersection between regulatory and other functions, available on ARPANSA's website.

The CEO and all ARPANSA staff are required to make an annual declaration of any interest concerning themselves and their family members that might conflict, or be perceived as conflicting with the performance of their duties. Where a regulatory officer or inspector has a conflict of interest, it is managed through the allocation of another regulatory officer to be the lead or alternate inspector for the facilities or sources that that licence holder is authorised for.

The Commonwealth allocates financial resources to the CEO of ARPANSA to fulfil their statutory functions from its Consolidated Revenue Fund. The CEO bids for funding from this fund annually. In addition, under section 54 of the Act, the CEO may charge for services. The CEO is also able to collect application fees (ARPANS Act, section 34) and annual licence charges (Licence Charges Act, sections 4 and 5).

The ARPANS Act establishes three independent advisory committees to support the CEO with advice. ARPANSA publishes the Roles and expectations for advisory bodies, which provide an overview of the

purpose and function of the advisory bodies and outlines procedural arrangements. This covers conduct, conflicts of interest, meeting procedures and support.

Each advisory body includes a member representing the interests of the general public, who facilitates the interaction between the advisory bodies and the public. The member reports on any specific contacts made by members of the public relevant to the functions of the advisory body.

The NSC deals with matters relating to nuclear safety and the safety of controlled facilities. The NSC advise the CEO and the Council; review and assess the effectiveness of standards, codes, practices and procedures; develop detailed policies and prepare draft publications to promote uniform national standards; and report to the CEO on matters relating to nuclear safety and the safety of controlled facilities (see part 4, section 26 of the Act).

The NSC membership includes the CEO of ARPANSA, a local government representative from an area affected by a controlled facility; and up to eight persons with expertise related to nuclear safety or other industrial or safety related regulation, or other relevant expertise. Members are appointed after public nominations including expressions of interest and an internal selection process, which includes review by the RHSAC.

The RHC deals with matters relating to radiation protection across Australia, including formulating draft national policies, codes and standards. In relation to radiation protection the RHC: advises the CEO and the Council; develops policies and prepares draft publications for the promotion of uniform national standards; formulates draft national policies, codes and standards for consideration by the Commonwealth, the States and the Territories; from time to time review national policies, codes and standards to ensure that they continue to substantially reflect world best practice; and consults publicly in the development and review of such policies, codes and standards (see part 4, section 23 of the Act).

The RHC includes the CEO of ARPANSA and a radiation control officer to represent each State and Territory. Radiation control officers are senior officers from the regulatory body who are expected to have their jurisdictions' authority to engage in discussions and provide advice for promoting national uniformity. Members are appointed after nominations from State and Territory Government and the public and an internal selection process, which includes review by the RHSAC.

The RHSAC identify emerging issues and provide advice on radiation protection and nuclear safety. In relation to radiation protection and nuclear safety RHSAC identify emerging issues, examine matters of major concern to the community, consider the adoption of recommendations, policies, codes and standards, and advise and report to the CEO at the CEO's request or as Council considers appropriate (see part 4, section 20 of the Act).

For RHSAC, a broad representation from a wide range of professional backgrounds, skill sets and qualifications is sought in order to enable RHSAC to generate independent, informed and objective advice of high quality on a broad range of issues. Members are appointed by the minister after seeking public and government nominations, including nomination of one member by the Chief Minister of the Northern Territory.

Members of any of the above advisory bodies can only be appointed after consultation with appropriate consumer groups and environmental groups.

1.4 Responsibility for safety and compliance with regulations

Related to GSR Part 1 (Rev. 1): Requirements 5 and 6

Prime responsibility for safety and compliance rests with the holder of an authorisation, typically referred to as the *responsible person* or *licence holder*.

The *Planned Exposure Code* (RPS C-1), is the key document which outlines the responsibilities of persons conducting any planned activity and is a condition of licence for all ARPANSA licences (under regulation 48). Section 2.5 of the RPS C-1 states the role of the Responsible Person. Key points are as follows:

- the Responsible Person will generally be the person who holds the authorisation and will therefore have management responsibility and control
- The Responsible Person has the responsibility for setting up and implementing the technical and organisational measures necessary for protection and safety for the practices and radiation sources for which the relevant regulatory authority provides authorisation
- The Responsible Person may designate a suitably qualified person to carry out tasks relating to these responsibilities but the Responsible Person retains the prime responsibility for protection and safety
- The Responsible Person is responsible for maintaining control over the sources of exposure for the protection of workers who are occupationally exposed, the public, and the environment.

Clause 3.1.1 of the *Planned Exposure Code* states that the Responsible Person must ensure protection and safety in planned exposure situations.

The ARPANS Regulations include provisions such as regulation 49, which assigns prime responsibility for safety to the person or organisation carrying out operations. This is a general condition of licence that states that the licensee must take all reasonably practicable steps to manage the safety of their facilities and sources, including having in place plans and arrangements and ensuring that the plans and arrangements are implemented. Regulations 48 and 49 apply to all types of facilities and activities (and for all stages of the lifetime of these facilities or activities).

Prime responsibility for safety cannot be transferred or delegated as outlined in section 2.5 of the *Planned Exposure Code.* The Code states unequivocally that, "*The Responsible Person may designate a suitably qualified person to carry out tasks relating to these responsibilities but the Responsible Person retains the prime responsibility for protection and safety*".

ARPANSA is empowered under section 35 of the ARPANS Act to enforce compliance with regulations. Under section 35(3) and 35(4), licence holders must allow the CEO or authorised officers to enter and inspect facilities and radioactive sources or radiation apparatus authorised by facility or source licences. Licence holders must comply with any requirement specified in the regulations in relation to such an inspection.

1.5 Coordination of authorities with responsibilities for safety within the regulatory framework

Related to GSR Part 1 (Rev. 1): Requirement 7

Although ARPANSA is the main safety regulator for Commonwealth entities, there are other Commonwealth departments and agencies that are also involved in the safe use, possession or transport of radioactive and nuclear material.

Coordination mechanisms have been established through either memorandum of understanding or meetings. ARPANSA have entered into more than 30 memoranda of understanding, including co-operation agreements and service agreements, with international and national bodies. These arrangements contribute to the elimination or management of areas of uncertainty, or any areas of overlap that could create conflicting requirements for authorised parties.

Authority or agency	Responsibility of authority or agency	Coordination arrangements with ARPANSA
Comcare	Responsible for the regulation of work health and safety and the administration of the workers compensation scheme.	A MoU is in place for consultation, cooperation, assistance and exchange of information where both ARPANSA and Comcare are investigating the same incident.
Australian Safeguards and Non-Proliferation Office (ASNO) – an agency within the Department of Foreign Affairs and Trade (DFAT)	Administers the Safeguards Act, which puts into law Australia's obligations under the Nuclear Non-Proliferation Treaty and related international agreements. Regulates the security of nuclear facilities and material to prevent the unauthorised removal or theft of nuclear material, minimise the risk of sabotage and ensure safeguards meet International Atomic Energy Agency (IAEA) requirements. Issues permits for controlling and protecting nuclear material and items during use and transport. Administers Australia's bilateral nuclear cooperation agreements.	A MoU is in place to provide a framework for information sharing and decision making in view of the fact that both agencies have regulatory responsibilities over nuclear installations operated by ANSTO.
Office of the Supervising Scientist - Department of Environment and Energy (DEE)	The Office of the Supervising Scientist is established under the Environmental Protection (EP) (Alligator Rivers Region) Act 1978. The functions of the Supervising Scientist are identified in the EP (ARR) Act, this includes provision of monitoring and oversight of uranium mining operations in the Alligator Rivers Region of the Northern Territory.	Under the EP (ARR) Act the Alligator Rivers Region Advisory Committee (ARRAC) and the Alligator Rivers Region Technical Committee (ARRTC) are established. ARPANSA, as an agency identified as having an interest in uranium mining operations in the ARR, is invited by the Minister to nominate up to two representatives to ARRAC to provide advice on uranium mining in the region. The ARRTC is a Committee that is comprised of independent technical advisors appointed by the Minister. An ARPANSA staff member is currently an independent technical advisor for radiation on the ARRTC. They are not a formal representative of ARPANSA in this capacity.

Authority or agency	Responsibility of authority or agency	Coordination arrangements with ARPANSA
Department of Environment and Energy (DEE)	Administers the *Environment Protection & Biodiversity Conservation Act 1999 (*EPBC Act) - requires certain nuclear actions to be approved if they have, or are likely to have, a significant environmental impact.	As part of a single environmental assessment and approval process, the Department of Environment and Energy has bilateral agreements in place with all states and territories which provide for the states and territories to assess 'controlled actions' on behalf of the Commonwealth. This includes where those actions are nuclear actions as defined under the EPBC Act. These assessments are then in turn utilised by the Federal Minister for Environment and Energy (or their delegate) in making a decision. Processes are in place for ARPANSA's provision of expert advice on radiation aspects of proposals referred under the EPBC Act.
Bureau of Meteorology	Bureau of Meteorology is the main provider of weather forecasts, warnings and observations to the Australian public. The Bureau maintains a network of field offices across the continent, on neighbouring islands and in Antarctica.	An agreement is in place with the Bureau of Meteorology for provision of weather data for emergency response, see further section 10; and for sampling sites for radionuclide monitoring, see further section 2.
Australian Antarctic Division	The Australian Antarctic Division is responsible for Australia's presence and activities in the Australian Antarctic Territory and the Southern Ocean.	MoU with the Australian Antarctic Division for the location and service of CTBT sampling stations for the airborne radioactivity.

Authority or agency	Responsibility of authority or agency	Coordination arrangements with ARPANSA
Department of Industry, Innovation and Science (DIIS)	Export permits for nuclear materials are granted by the Minister for Resources, Energy and Northern Australia. The Atomic Energy Act permits the Minister to authorise mining in the Ranger Project Area in the Northern Territory and retains Commonwealth ownership of uranium and thorium. Has a role in stewardship of radioactive materials through the development of the National Radioactive Waste Management Facility. The National Measurement Institute (NMI) is responsible for maintaining Australia's units and standards of measurement including reference materials and reference techniques.	There is a formal delegation for export permits to the CEO of ARPANSA or delegate. A communications protocol has been established between ARPANSA and DIIS regarding the planned National Radioactive Waste Management Facility. ARPANSA maintains the national primary standard for absorbed dose under an authorisation from NMI.
Department of Home Affairs	The Department of Home Affairs is the responsible agency as Customs is an agency within the Home Affairs portfolio, but authorised officer for the issue of export and import permits for radioactive material under Regulations 9AD and 4R respectively is CEO ARPANSA or their staff. Emergency Management Australia (EMA), responsible for emergency response coordination	The responsibilities of the Minister and CEO ARPANSA are delineated in the Regulations. Meetings are held between Customs and ARPANSA when the need arises.
Department of Health	The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods. They carry out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances. Food Standards Australia New Zealand (FSANZ).	APRANSA maintains contact with TGA and FSANZ on an as needed bases including regular meetings thorough the Regulatory Science Network. Examples of collaboration include food surveys and analyses of food contamination in case of accidents with radionuclide release such as in the aftermath of the nuclear accident following the East-Japan earthquake and tsunami in 2011.

Authority or agency	Responsibility of authority or agency	Coordination arrangements with ARPANSA
Department of Infrastructure, Regional Development and Cities	Australian Maritime Safety Authority (AMSA) and Civil Aviation Safety Authority (CASA) ensure the safe transport of radioactive materials by air and sea, including the appropriate documentation, classification, packaging, stowage and segregation.	AMSA and CASA meet with ARPANSA intermittently on an as-needs basis at the Transport Regulators Forum.
Department of Defence	Australian Geospatial-Intelligence Organisation (AGO)	An agreement exists for modelling imagery related to emergency response, see further section 10.

Table 2. Overview of key inter-agency cooperation arrangements with Commonwealth departments and agencies

ARPANSA also engages and coordinates with radiation regulators from the States and Territories. This is achieved at a formal level to aid national uniformity through meetings of the RHC. The RHC usually meets three times a year, whereas informal monthly teleconferences take place among participants in the Radiation Regulators' Network (RRN). ARPANSA also coordinates with the States and Territories on an operational level, for example where a source or facility is transferred between a jurisdiction's and ARPANSA's regulatory control.

1.6 System for protective actions to reduce existing or unregulated radiation risk

Related to GSR Part 1 (Rev. 1): Requirement 9, GSR Part 3: Requirement 2, paragraph 2.26 and Requirements 47-49

Situations may arise in regulated activities (planned exposure situations) carried out by controlled persons which entail risks that require urgent regulatory attention. The ARPANS Act provides the CEO of ARPANSA the powers to deal with such situations in section 41. This section provides that the CEO may give directions to a controlled person (that is, any Commonwealth entity or its employees) to take such steps as the CEO considers appropriate, provided the CEO believes on reasonable grounds that a controlled person is not complying with the Act or Regulations, there is a risk of death, serious injury or serious damage to the environment, arising from radiation, in connection with a controlled material, and the CEO believes there is an urgent need to exercise such powers to minimise the risk.

Further, Section 65 of the Act describes powers available to inspectors where they believe it is necessary to exercise powers in order to protect the health and safety of people or to protect the environment. These powers include entering premises, searching premises, seizing hazardous things, and issuing directions (improvement notices) to the controlled persons.

ARPANSA has published documents with principles and guidance on dealing with existing exposure situations, such as unregulated sources of natural and artificial origin. These include:

- Fundamentals for Protection against Ionising Radiation 2014 (RPS F-1)) (see section 4.10), which elaborates on Principle 10 of the IAEA SF-1 (Protective actions to reduce existing or unregulated risks)
- Guide for Radiation Protection in Existing Exposure Situations 2017 (RPS G-2) (*Existing Exposure Guide*), which covers contamination from past activities, post-emergency, commodities (including food and construction materials), natural sources (including radon in workplaces other than planned exposure situations such as uranium mines and other radionuclides of natural origin), and exposure of aircrew to cosmic radiation.

In addition, for contamination from past activities or events, the ARPANS Act provides the CEO of ARPANSA with the power to bring legacy sites under regulatory control. There is only one legacy site that is currently under ARPANSA's regulatory control, being the Little Forest Legacy Site near Lucas Heights in NSW, which is managed by ANSTO. Section 11.3 of this Summary Report provides more information on the Little Forest Legacy Site, and on management of other legacy sites.

ANSTO has the function, under the *Australian Nuclear Science and Technology Organisation Act 1987,* to store and manage unregulated sources at the request of a law enforcement agency or regulatory body. This includes radioactive material that arises from an emergency.

There is limited legislative basis for the regulation and monitoring of environmental and existing exposure situations such as public exposure due to radon indoors, or exposure due to radionuclides in non-food commodities. However, ARPANSA has undertaken a range of scientific studies and other actions which are discussed in section 11.3.

1.7 Provisions for the decommissioning of facilities and the management of radioactive waste and of spent fuel

Related to GSR Part 1 (Rev. 1): Requirement 10, GSR Part 3: Requirements 2 and 31, GSR Part 5: Requirements 1, 2 and 6, SSR Part 5: Requirement 1, GSR Part 6: Requirements 4 and 5

Spent fuel, intermediate level waste and low level waste resulting from the operation of nuclear and other installations at the ANSTO facilities are managed at the Lucas Heights Science and Technology Centre. In addition, waste from Commonwealth activities and from activities under jurisdictional regulation is currently stored in various locations around the country. The most recent report under the terms of the Joint Convention provides a summary. A centralised, national facility for the disposal of low-level radioactive waste and storage of intermediate level material has been proposed by the Commonwealth and a site selection process is currently underway.

Legislation and regulatory framework

The Commonwealth has made regulatory provisions for the safe decommissioning of facilities, safe management and disposal of radioactive waste and the safe management of spent fuel, by prohibiting these conducts unless appropriately licensed under the ARPANS Act.

A controlled facility as defined in section 13 of the ARPANS Act includes nuclear installations, prescribed radiation facilities and prescribed legacy sites. Nuclear installations, defined in section 13, include:

- A radioactive waste storage or disposal facility with an activity greater than the activity prescribed in the regulations (see regulations 7 and 8 of the ARPANS Regulations)
- A plant for storing spent fuel that has been used in a nuclear reactor.

ARPANSA has published detailed guidance for applicants for a waste storage or disposal facility Applying for a licence for a radioactive waste storage or disposal facility together with a stakeholder information document, *Radioactive waste storage and disposal facilities: information for stakeholders*. The Radiation Health Committee recently signed off on the *Code for Facilities for Disposal of Radioactive Waste* (to be published as RPS C-3; the draft document is made available to the IRRS), which gives effect in Australia to the requirements of the IAEA Specific Safety Requirements *Disposal of Radioactive Waste* (SSR-5).

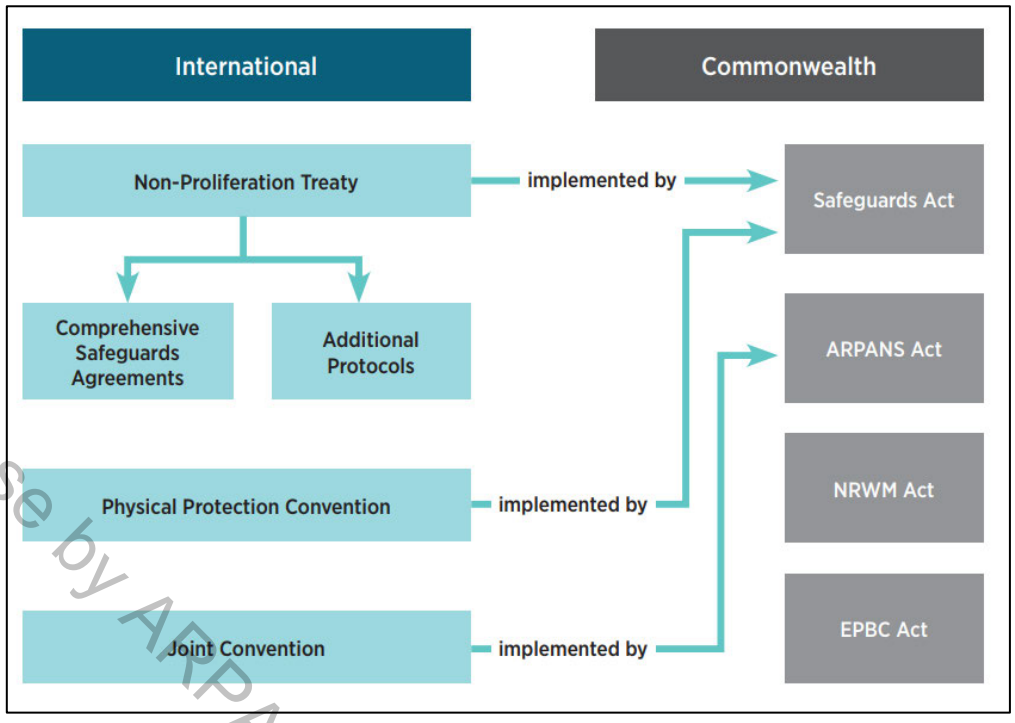

Figure 7. Commonwealth legislative arrangements for managing Australia's radioactive waste

Radioactive waste and spent fuel management policy

The Commonwealth's arrangements for radioactive waste management are outlined in the Australian Radioactive Waste Management Framework (ARWMF) published by the Department of Industry, Innovation and Science in April 2018. The ARWMF contains the principles, policies and institutional arrangements of radioactive waste management in Australia. The policy is stated in section 4 of the document. Key points are as follows:

- The aim of Australia's management of radioactive waste is to safely and securely manage Australia's past and future radioactive waste holdings through appropriate processing, containment and eventual disposal in order to reduce, to as low as practicable and justifiable, the associated health, safety, environmental, financial, security and safeguards risks to current and future generations.
- The current policy, legislative and regulatory framework for the safe management of radioactive waste in Australia includes each jurisdiction licensing radioactive waste management activities
- Radioactive waste management methods must conform to the highest appropriate standards as determined by Commonwealth, State and Territory regulators, and requires acceptance by the general public.
- Implementation of the national framework involves active engagement across a number of key stakeholder groups including government (policy and regulatory), waste producers, and the general public.
- All radioactive waste management activities will be based on best available science and technology and conducted in an open and transparent manner.
- The Commonwealth's approach towards long-term radioactive waste management includes implementing policy to site and establish a centralised, purpose-built National Radioactive Waste Management Facility (NRWMF). This facility will dispose of Australia's domestically produced low level waste, and store intermediate level waste (ILW) for a period of time sufficient for the

Commonwealth to establish a permanent ILW disposal facility, consistent with international obligations and best practice.

- The Commonwealth has also implemented policy, legislation and regulations aimed at ensuring Commonwealth waste holders and producers:
  - adopt measures for minimising the generation of radioactive waste
  - safely manage their waste until it is accepted by a national storage or disposal facility
  - dispose or store their waste at the NRWMF, or dispose waste at the disposal facility for intermediate level waste to the maximum extent possible, rather than in other facilities.

The Commonwealth's policy for the management of spent fuel is outlined in section 6.2.4 of the Framework document. Key points are as follows:

- In Australia, the Commonwealth is the only jurisdiction in which spent fuel is managed. Australia's spent fuel comes from ANSTO's research reactors.
- Australia has no spent fuel arising from nuclear power, military or defence programmes.
- No spent fuel reprocessing facilities exist in, or are proposed for, Australia (note that section 10 the ARPANS Act states that the CEO of ARPANSA must not authorise a reprocessing facility).
- It is the policy of the Commonwealth that spent fuel is sent overseas for reprocessing. The resulting long-lived ILW will be returned to Australia for storage. Ultimately, this waste will be disposed of at an ILW disposal facility.

Most of the waste resulting from reprocessing the spent fuel from the shut-down HIFAR reactor has been returned to Australia. The first batch of spent fuel from the OPAL reactor was recently shipped overseas for reprocessing, i.e. about 12 years after the OPAL reactor commenced operations. In the future, ANSTO intends to ship spent fuel overseas for reprocessing once every six years.

The Government has enacted the *National Radioactive Waste Management Act 2012* to provide for a transparent and voluntary process for the nomination and selection of a site for national radioactive waste management storage and disposal facilities. Although this will be a Commonwealth owned and operated facility, it is intended to be a national facility, i.e. receive waste from other jurisdictions.

Australia is a signatory to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management and ratified it in 2003. Australia has participated in every review meeting of the Convention, including providing successive reports under the terms of the Convention and the general compliance of Australia with the incentives of the Convention.

Diversity between types of radioactive waste

The Framework document takes into account the current and projected volumes of waste and the different types of wastes. These are discussed in sections 3.2 and 6.2 (Australia's radioactive waste types) of the document. Section 6.2 considers the different types of wastes that are generated in Australia and the options for their storage or disposal. The types of wastes that are considered are exempt waste, LLW, ILW, disused sealed radioactive sources and naturally occurring radioactive material (NORM).

Management through an integrated and systematic manner up to disposal

Section 5 of the Framework document discusses the roles and responsibilities of the various parties involved in radioactive waste management in Australia, noting that Australia has a federal system of government with separate jurisdictions exercised by the Commonwealth, six States and two Territories. Many departments and agencies are involved at the Commonwealth level but the Department of Industry, Innovation and Science has policy lead for waste management and the Department of Health has policy lead for public health and health protection. ARPANSA is the independent regulator of waste management by Commonwealth entities. Section 5 of the Framework document also discusses the roles and responsibilities of States and Territory governments, and radioactive waste generators and managers.

Section 5.5 of the Framework discusses the proposed technical coordination arrangements for and integrated approach to waste management to disposal. Key points are as follows:

- The technical coordination function will be performed by a Commonwealth entity. This function includes overseeing the long-term storage and disposal of legacy, current and future radioactive waste, and in the short to mid-term managing the research, development, construction and operation of the NRWMF. The organisation responsible for this technical coordination function may also be the operator of the NRWMF.
- Australia's Radioactive Waste Management Organisation (RWMO), with input from other agencies including waste holders and producers, and regulators, will develop a comprehensive radioactive waste management strategy.
- The strategy (to be developed by the RWMO) will provide detailed, long-term management pathways for individual waste streams over their full life cycle, including disposal pathways for LLW and ILW. The strategy will prioritise radioactive waste management activities across the Commonwealth. It includes defining critical path research, practices and processes that reflect international best practice, and establishing and maintaining a positive radioactive waste management safety culture.
- The RWMO will also monitor and oversee radioactive waste disposal facilities; and maintain an accurate national radioactive waste inventory. The Commonwealth will establish arrangements for providing the resources (financial, technical and human) to sustain these coordination functions, and for the implementation of the radioactive waste management strategy.

Appropriate research and development

The Commonwealth's strategy for research and development in relation to disposal of radioactive waste is provided in section 6.4 of the Framework document. Key points are as follows:

- Research and development will be integral to developing facilities to manage Australia's radioactive waste. International experience shows research and development will be required on waste classification standards, disposal concept development, site characterisation and safety assessment.
- As the NRWMF development progresses through site characterisation, design, safety assessment and community engagement, knowledge gaps will be identified. To ensure such gaps are addressed, the radioactive waste management strategy developed by the RWMO will incorporate a life-time research and development plan, flexible enough to be updated as planning and implementation of waste facilities proceeds and new information comes to light.
- Research and development prioritisation will be guided by NRWMF safety assessments.

- The balance between the level of confidence at any point and additional insights from a continued research and monitoring programme will be a central element in interactions between the RWMO, the NRWMF operators and regulators.
- The RWMO, as the organisation with overall technical responsibility for radioactive waste management functions, will have primary responsibility for ensuring that all necessary investigations of sites and materials are carried out, assessed for suitability and that all data necessary for safety assessment has been obtained.
- The RWMO will also ensure that necessary research and development is carried out so that planned NRWMF technical operations can be practically and safely accomplished and demonstrated; as well as to understand and support the processes on which safe disposal depends.
- A collaborative approach will be taken with Australian and international expertise.

1.8 Competence for safety

Related to GSR Part 1 (Rev. 1): Requirement 11

The Commonwealth does not specify specific competency requirements for persons who have responsibility for safety in radiation protection. However, the Radiation Protection Series outlines roles and responsibilities for a number of specific roles for which each jurisdiction determines the appropriate qualifications and experience. There is significant alignment between the competency requirements for many specific occupations across jurisdictions, including through nationally recognised peak industry bodies. However, as discussed in section 13.3, there is variation between jurisdictions for some occupations.

Holders of a licence issued under the ARPANS Act are, under regulation 49 of the ARPANS Regulations, required to implement their plans and arrangements, which under Schedule 3 of the Regulations should include a safety management plan. Guidance on these requirements is provided in ARPANSA's Regulatory Guide on plans and arrangements. This ensures that applicants provide evidence of how staff competence is managed.

Following the identification of the need for qualified security assessors for the purpose of implementing the nationally adopted Radiation Protection Series publication Code of Practice - Security of Radioactive Sources 2007 (RPS11), ARPANSA in 2013 signed a MoU with the Attorney General's Department Protective Security Training College (PSTC). ARPANSA and PSTC delivered two rounds of a Graduate Certificate training in Radiation Security by 2016 under the National Radiation Security Advisors Accreditation Scheme. This course was also captured under that Australian Skills Quality Framework (ASQA) and is nationally recognised training. ARPANSA provides a list of graduates of the national course to allow jurisdictions to have access to a pool of competent and persons to give effect to RPS 11. ARPANSA regulatory officers with protective security knowledge and experience review and endorse security plans for Commonwealth licence holders. Where there is a potential conflict of interest, ARPANSA will use accredited assessors.

Most Australian jurisdictions mandate qualifications and training as part of the authorisation process (see section 5), for example NSW and QLD. Under this system individual applicants are required to demonstrate they meet a mandatory level of competence prior to obtaining an individual licence. This also includes accredited persons, for example a Certified Radiation Expert (CRE) in NSW who provides independent testing of equipment and verifies shielding requirements and may be subject to audits.

The Australian Radiation Protection Accreditation Board (ARPAB) is the peak professional body responsible for certifying radiation protection professionals, such as Radiation Safety Officers (RSOs) and radiation protection advisors in industry. It is sponsored by three professional bodies, Australian College of Physical Scientists and Engineers in Medicine (ACPSEM), Australian Institute of Occupational Hygienists (AIOH) and the Australasian Radiation Protection Society (ARPS). However ARPAB accreditation is not stipulated as a mandatory requirement for any industry.

A number of universities in Australia offer training and qualification in medical application of radiation, including medical physics. The role of 'qualified expert' is outlined in RPS 14, and specific competence requirements have been agreed by the RHC.

Within the medical profession, the Australian Health Practitioner Regulatory Agency (AHPRA) protects titles of occupations including medical radiation practitioner, diagnostic radiographer, medical imaging technologist, radiographer, nuclear medicine scientist, nuclear medicine technologist, and radiation therapist. To practice as one of these protected titles a person must be registered with AHPRA, which involves demonstrating competence and maintain continuing professional development. Membership with an appropriate professional body and attendance at relevant training course or conferences can be used to demonstrate continuing professional development. Examples include the Royal Australian and New Zealand College of Radiologists (RANZCAR), Australian Society of Medical Imaging and Radiation Therapy (ASMIRT), Australian and New Zealand Society of Nuclear Medicine (ANZSNM) and the Australian College of Physical Scientists and Engineers in Medicine (ACPSEM) for Medical Physicists.

ANSTO provides radiation safety training through a variety of courses. The ANSTO courses include one-day courses for the use of laboratory, X-ray and moisture density gauges, and three and five day courses for Radiation Safety Officers. Other training is available, such as industry training and undergraduate and postgraduate programs in Australian universities (e.g. medical physics degree). ANSTO also provides its own in-house training on nuclear safety and the safety of waste operations. Regular exercises are held by ANSTO to test its emergency preparedness and response capabilities and train its staff. These exercises include many other response organisations, such as law enforcement and conventional emergency services, and also includes ARPANSA.

1.9 Provision of technical services

Related to GSR Part 1 (Rev. 1): Requirement 13, GSR Part 3: Requirement 2, paragraph 2.23

Under paragraph 15(1)(d) of the ARPANS Act, a function of the CEO is to provide services relating to radiation protection, nuclear safety, and medical exposures to radiation.

ARPANSA's Radiation Health Services Branch and Medical Radiation Services Branch provide several technical services relating to radiation protection and medical exposures to radiation. To a variable extent, these services are commercial, cost-recovered, or basically a service to the Australian community for the purpose of promoting protection of health and safety, and protection of the environment; in accordance with the object of the Act.

ARPANSA's services include:

- Personal radiation monitoring service (PRMS) – dosimetry service provider of optically stimulated luminescence (OSL) badges, and other personal dosimetry services
- Australian Clinical Dosimetry Service – audits of linear accelerators used in radiation therapy

- Ultraviolet (UV) monitoring – a network of solar measurements in major Australian cities
- Ultraviolet protection testing services – fabrics, shade cloth, sunglasses, etc.
- Radiofrequency (RF) calibration services - RF hazard meters, gauss meter calibrations
- Diagnostic and protection level calibrations- radiology/medical physics equipment
- Ultraviolet radiation (UVR) instrument calibration – calibration of solar UVR and UVR from artificial sources used in industry
- Radioanalytical services – commercial service for the measurement of radioactivity, such as in food samples
- Hire of radiation meters – magnetic field, ionising radiation and UV meters
- Australian National Radiation Dose Register – national dose register for the storage and maintenance of radiation dose records
- Emergency response – capabilities including field gamma spectroscopy, dose assessment and advice products and, geospatial modelling for operational decision makers

The PRMS supplements services provided by the private sector. ARPANSA maintains this service partly because it broadens the base for dosimetry expertise, a core competency for the agency, as well as provides strategic capability for Australia in the case of major emergencies. The 'neutrality' of the service, from a competitive perspective, is managed.

ARPANSA does not accredit any other technical services. For example, while there are a number of commercial dosimetry services that are used across Australia, only some jurisdictions (such as NSW and SA) require that only approved providers be used. For example, while accreditation from the National Association of Testing Authorities (NATA) is highly regarded, there is no formal requirement for accreditation. Schedule 10 of the National Directory for Radiation Protection (RPS6) is intended to contain a minimum set of nationally agreed accreditation requirements for third-party service providers. However, this schedule has not been finalised at this time. See also section 13.3 of this report, on national uniformity.

1.10 Conclusions and actions

The Commonwealth has established an effective legal framework for safety, applicable to Commonwealth entities, that meets the expectations of the IAEA safety standards. The responsibilities are clearly allocated, including expressly providing for the effective independence of the regulatory body within the legislation. Provisions have been made for coordination between Commonwealth departments and agencies where responsibilities overlap or interface. Prime responsibility for safety is clearly allocated to the person or organisation carrying out the operations.

Likewise, States and Territories have established frameworks which share common key elements captured in the jointly prepared National Directory for Radiation Protection, codes, and relevant jurisdiction legislation.

The actions that have been identified concern practices at ARPANSA, and actions that ARPANSA can initiate in order to promote uniform practices across all jurisdictions, aligned with the IAEA safety standards. Some further actions will be outlined in subsequent sections of this Summary Report.

- There is no single document with a national policy and strategy for safety, and variation remains across jurisdictions. These variations do not undermine Australia's ability to achieve the safety

objective outlined in SF-1; however a proper place for a nationally agreed policy and strategy could be the National Directory for Radiation Protection, jointly developed and maintained by all jurisdictions. The process for implementing the policy and strategy in a nationally (across jurisdictions) consistent and uniform manner could be improved, building on recent initiatives to explore options for establishing a nationally uniform legal framework for safety. See Action Plan item 1

- Across Australian jurisdictions, there are currently no agreed and uniform exemption and clearance levels. The draft 2nd Edition of the NDRP is proposing to incorporate by reference Schedule I of GSR Part 3, which, when implemented, will require all jurisdictions to incorporate the provisions in GSR Part 3 for exemptions and clearance into their legal and regulatory frameworks. See Action Plan item 2.
- The Australian Government has responsibility for providing resources for decommissioning of Commonwealth facilities. However, specific funds for end-of-life are not typically set aside at the commencement of major projects. See Action Plan item 3.
- ARPANSA intends to pursue its project to establish compliance with ISO/IEC 17020, which specifies requirements for the competence of bodies performing inspection and for the impartiality and consistency of their inspection activities; this project should include a formal human resource plan for regulatory activities. See Action Plan item 4.
- Across Australian jurisdictions, there is no agreed and uniform requirements for accreditation for performing technical services, including mandatory qualifications or service providers (e.g. dosimetry or testing); these could be established through the RHC. See Action Plan item 5).

2. Global nuclear safety regime

This section focuses on the Commonwealth. Some additional information is provided on State and Territory arrangements, to provide context.

2.1 International obligations and arrangements for international cooperation

Related to GSR Part 1 (Rev. 1): Requirement 14

The Commonwealth takes advantage of opportunities offered by the Global Nuclear Safety regime for improving the national framework for safety. It does this through meeting its obligations under the conventions and codes of conduct, participation in the development of safety standards, development of recommendations and guidance, arranging and participating in peer reviews on safety and security, and engaging in bilateral and multilateral projects to enhance safety. The activities include significant engagement of ARPANSA with the IAEA, the International Commission on Radiological Protection (ICRP), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), and the World Health Organization (WHO). Australia is a party to the Comprehensive Nuclear-Test-Ban Treaty (CTBT). ARPANSA manages Australia's obligations under the Treaty to operate seven radionuclide monitoring stations in mainland Australia, the Pacific, the Indian Ocean and Antarctica. Two of these (located in Darwin and Melbourne) have noble gas sampling and detection capability in addition to the equipment for detection of particulate activity that is in operation in all stations.

Australia is a party to the following conventions that establish common obligations and mechanisms for ensuring protection and safety (year of Australia's ratification in brackets):

- Convention on Early Notification of a Nuclear Accident (1987)
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1987)
- Convention on Nuclear Safety (1997)
- Convention on Physical Protection of Nuclear Material (CPPNM) and Amendments (2016)
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (2003).

Other international agreements to which Australia is a signatory, and which are required to be considered under section 84 of the ARPANS Act and listed in schedule 2 of the ARPANS Regulations, include:

- Treaty on the Non-Proliferation of Nuclear Weapons (1970)
- Agreement between Australia and the International Atomic Energy Agency for the Application of Safeguards in connection with the Treaty on the Non-Proliferation of Nuclear Weapons (1974)
- Agreement for cooperation between the Government of Australia and the Government of the United States of America concerning technology for the separation of isotopes of uranium by laser excitation, with annexes, exchange of notes and agreed minutes (1999)
- International Convention for the Suppression of Acts of Nuclear Terrorism (2005).

Australia has committed to the implementation of the following codes of conduct that promote the adoption of good practices in the relevant facilities and activities:

- Code of Conduct on the Safety and Security of Radioactive Sources, and the Supplementary Guidance on the Import and Export of Radioactive Sources. In September 2018, Australia will be making a political commitment to the Supplementary Guidance on the Management of Disused Radioactive Sources
- Code of Conduct on the Safety of Research Reactors.

These international obligations are carried out either by ARPANSA, as the Commonwealth regulator for nuclear safety and radiological security, or the Australian Safeguards and Non-Proliferation Office (ASNO) as the regulator for safeguards, nuclear accounting and control, and nuclear security.

Implementation of the Code of Conduct on the Safety and Security of Radioactive Sources has seen some challenges. While Australia had implemented a National Sealed Source Register (NSSR) that was managed by ARPANSA, and this was noted as a strength during the follow-up IRRS Mission, a decision was taken by the RHC in 2016 to abandon the national register. This decision was based on a range of factors including inconsistent automation, duplication of effort, incomplete data and the overall cost in both time and money did not satisfy scrutiny of the cost-benefit in maintaining the register as it had been established. The RHC decided to rely upon the network of jurisdictional source registers that was determined to be a more functional, efficient and timely communications regime, where security enhanced source inventory data is provided to ARPANSA by the jurisdictions during a security incident. This decision was challenged when Australia received a follow up IAEA International Physical Protection Advisory Service (IPPAS) Mission in 2017. The IPPAS team evaluated that the network of jurisdictional registers that remains does not align to the expectations of the Code of Conduct on the Safety and Security of Radioactive Sources. The IPPAS Mission recommended that Australia should establish a national register to improve arrangements for an accurate and real-time national radioactive source register. A similar recommendation was made when Australia received a Joint External Evaluation (JEE) of International Health Regulation Core Capacities of Australia in November 2017 (see section 10.2).

Australia has signed, but not ratified, the Convention for Supplementary Compensation for Nuclear Damage. Australia has not ratified the convention due to the small scale of nuclear activities in Australia and distance from overseas nuclear facilities, which has meant ratification has not been a priority for the Commonwealth. In its submission to the South Australian Nuclear Fuel Cycle Royal Commission, the Commonwealth noted: 'Further involvement in the fuel cycle would require the adoption of nuclear liability legislation to ensure operators are held liable for incidents and are able to provide adequate compensation, and that claims for compensation for an accident in Australia are dealt with in Australia'.

ARPANSA coordinates the national reports submitted under the term of the Convention on Nuclear Safety and the Joint Convention, and represents Australia in the Competent Authorities' Meeting under the Early Notification and Assistance Conventions.

ARPANSA in collaboration with State and Territory regulators represented on the Radiation Health Committee, actively promotes the implementation of the IAEA safety standards in the Australian national context. This is further elaborated on in section 9 of this Summary Report. Australia through ARPANSA has a representative on the IAEA Commission on Safety Standards and on all of the IAEA safety standards committees, i.e.

- Emergency Preparedness and Response Standards Committee
- Nuclear Safety Standards Committee (corresponding member)
- Radiation Safety Standards Committee
- Transport Safety Standards Committee
- Waste Safety Standards Committee.

Australia participates in the work of the IAEA Nuclear Security Guidance Committee through the Australian Safeguards and Non-Proliferation Office (ASNO).

The Commonwealth has undergone international peer reviews of the regulatory control and safety of facilities and activities. This has included an Integrated Regulatory Review Service mission in 2007 and a follow-up mission in 2011, and an International Physical Protection Advisory Service (IPPAS) mission in 2013 and a follow-up mission in 2017. The IRRS and IPPAS missions can be found online. Australia, through ARPANSA, also provides experts to IRRS missions globally, as well as to missions related to emergency preparedness (EPREV), occupational safety (ORPAS) and physical protection (IPPAS).

Australia participates in multilateral and bilateral cooperation that enhances safety by means of harmonised approaches as well as increased quality and effectiveness of safety reviews and inspections. To that end, Australia, through ARPANSA, has memoranda of understanding or cooperative arrangements with nine bilateral partners across eight countries. These are:

- US Nuclear Regulatory Commission
- US National Nuclear Security Administration
- Swedish Radiation Safety Authority
- Norwegian Radiation Protection Authority
- Nuclear Energy Regulatory Agency of Indonesia
- Vietnam Agency for Radiation and Nuclear Safety
- UAE Federal Authority for Nuclear Regulation
- Singapore National Environment Agency
- Public Health England.

Australia, through ARPANSA, further contributes to the promotion of assistance in global safety through the provision of experts to technical meetings and workshops held by the IAEA. The provision of experts is ad hoc, depending on resourcing for agencies involved. Some examples from 2017–18 include:

- Regional Workshop on Establishment and Maintenance of National Dose Registry, in Melbourne, Australia, 24–25 May 2018
- Regional Workshop on Regulatory Inspection Programmes of Research Reactors, in Sydney, Australia 5–9 February 2018

- Workshop on the Use of a Harmonised Safety Culture Framework, Vienna, 23–25 October 2017
- Regional Workshop on the Revised Safety Requirements in Emergency Preparedness and Response, 2–5 October 2017, Melbourne, Australia
- IAEA exercise for the Response and Assistance Network Joint Assistance Team, Japan, 1–6 October 2017
- International Training Course of New and Prospective Points of Contact for the Incident and Trafficking Database (ITDB), Vienna, 24–28 July 2017
- Consultancy Meeting to address Member State comments on 'Revision of Safety Guide WS-G-3.1 on Remediation Process for Areas Affected by Past Activities and Accidents' [DS468], Vienna, 7–11 August 2017
- IAEA Regional Cooperation Agreement Training Course on Sampling and Basic Analytical Techniques, Indonesia, 16–25 August 2017.

2.2 Sharing operating experience and regulatory experience

Related to GSR Part 1 (Rev. 1): Requirement 15

ARPANSA manages and acts as the national point of contact on a number of national and international registers. These include:

- **Australian Radiation Incident Register (ARIR).** Australia's nine jurisdictions report incidents to a central register managed by ARPANSA. ARPANSA analyses the accumulated incident data to identify lessons to be learned and contributing causes. ARPANSA, in consultation with the jurisdictions, professional organisations, and experts, prepares an annual report published on the ARPANSA website. As an example, the 2016 report featured incidents in nuclear medicine.
- **International Nuclear and Radiological Event Scale (INES).** ARPANSA reports relevant incidents to the IAEA to ensure the public, as well as international regulatory bodies, are informed of the occurrence of significant safety events associated with the use, storage and transport of radioactive material and radiation sources. For example in 2012, ARPANSA submitted an INES Event Rating Form (ERF) on the potential exposure of international airplane passengers to gamma radiation from poorly secured Cs-137 sources.

  ARPANSA shares relevant information with licence holders on international incidents on ad hoc basis.
- **Incident Reporting System for Research Reactors (IRSRR).** In addition to ARPANSA, access to the system has been granted to a number of ANSTO personnel, to ensure timely distribution of the information to relevant personnel. Australia regularly posts events to the system at an average rate of one event a year.
- **Incident and Trafficking Database (ITDB).** Through the ITDB ARPANSA shares the analysis of certain regulatory incidents leading to nuclear and other radioactive material falling out of regulatory control, and incidents that have nuclear security implications. The ITDB staff analyses the collection of information reported by participating states. Most incidents relate to unauthorised disposal (e.g. radioactive sources entering the scrap metal industry), unauthorized shipment (e.g. scrap metals contaminated with radioactive material being shipped across international borders), or the discovery of radioactive material (e.g. uncontrolled radioactive sources).

A proportion of ARPANSA's ITDB reporting goes to international organisations such as INTERPOL. ARPANSA also supports IAEA ITDB's requests to further disseminate the lessons learned from a specific incident reported by ARPANSA to other international organisations for safety and security training purposes. ARPANSA facilitates the secure domestic sharing of security-relevant lessons learned from international incidents reported to the ITDB via the Australian Secret Network.

- **The Australian National Dose Registry (ANRDR).** ARPANSA administers a central record keeping register for the storage and maintenance of occupational radiation dose records. From July 2017 the submission of dose records became a mandatory requirement for all Commonwealth licence holders and work is in progress for mandatory submission from state and territory licence holders. Information stored in the ANRDR has been used to provide data to UNSCEAR for occupational exposures reviews. Currently an annual newsletter is produced to provide feedback of analysis of ANRDR data to relevant industries and all Australian regulators.

ARPANSA shares outcomes from national and international meetings and national registers to Australian regulators/operators on an ad-hoc basis through the RHC, conferences, workshops and peak professional bodies. For the ARIR and ANRDR, ARPANSA is currently pursuing additional interfaces and reporting mechanisms such as the use of a web portal to facilitate the sharing of this operational experience with regulatory bodies.

ARPANSA publishes the Regulatory Assessment Reports and Statements of Reasons for major licence decisions on its website. One example is the recent decision to issue ANSTO with a licence to operate the ANSTO Nuclear Medicine Facility (ANM) at the Lucas Heights Science and Technology Centre. ARPANSA also published its assessment of the first periodic safety review for the OPAL reactor.

2.3 Conclusions and actions

Australia has a long history of promoting the international framework for safety and is under the IAEA auspices contributing to progressing international norms in this area. Australia is a founding member of UNSCEAR and ARPANSA is an active participant in major radiation protection and scientific fora, such as ICRP and WHO. ARPANSA sits on all IAEA safety standards committees, is a Regional Collaborating Centre with the World Health Organization, and manages Australia's radionuclide detection network on behalf of the CTBTO.

Australia meets its obligations under conventions, codes of conduct, safety standards and other international arrangements. This includes:

- having a national warning point as specified under the early notification convention
- having a national competent authority as outlined by the early notification and assistance conventions
- making certain capabilities available for assistance in the event of a nuclear accident or radiological emergency
- submitting national reports to the Convention on Nuclear Safety and Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management for peer review, and participating in all review meetings of the conventions
- having representatives on all safety standards committees and implementing those standards as feasible.

Australia is experiencing some challenges in meeting the intent to fully implement the Code of Conduct for safety and security or radioactive sources in relation to establishing and maintaining a National Sealed Source Register.

- ARPANSA will continue to work with the RHC and other stakeholders to improve arrangements for accurate storage and retrieval of information on sources by building on existing arrangements, reiterating the benefits of such a register and strengthening the linkage between safety and security and threat prevention. See Action Plan item 6.

Australia shares experiences relevant to nuclear safety and radiation protection with the international community. This includes running regular workshops on various aspects of regulation or radiation protection and other initiatives to build regional engagement to develop better radiation regulation. ARPANSA intends to leverage its bilateral relationships to further strengthen its regional focus and further build on other international efforts in South-East Asia and the Pacific on nuclear safety and radiation protection.

Within Australia, ARPANSA could further enhance its sharing of international experience through the establishment of formal regular feedback mechanisms. There is currently no formal system for sharing international experience across the organisation and with the other Australian jurisdictions.

- ARPANSA intends to strengthen this function through improved collaboration with other Australian jurisdictions. See Action Plan item 7.

3. Responsibilities and functions of the regulatory body

This section focuses on the Commonwealth regulator, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Information is provided on State and Territory arrangements where they interface or interact with those of the Commonwealth, or to provide context.

3.1 Organisational structure of the regulatory body and allocation of resources

Related to GSR Part 1 (Rev. 1): Requirement 16

The vision and purpose of ARPANSA are stated in the Corporate Plan, the most recent being the plan for 2018 – 2022. ARPANSA's activities are guided by the vision statement:

A safe radiation environment for the Australian community.

The purpose statement reads:

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is the Australian Government's primary authority on radiation protection and nuclear safety. Our purpose is to protect the Australian people and the environment from the harmful effects of radiation, through understanding risks, best practice regulation, research, policy, services, partnerships and engaging with the community.

ARPANSA operates under the authority of the ARPANS Act and is responsible for regulating a range of controlled activities from small radiation sources such as baggage X-ray, to a 20 MW multipurpose nuclear reactor and associated research and radioactive isotope production facilities. ARPANSA is an independent agency under the portfolio of the Commonwealth Department of Health. The establishment of the Office of the CEO of ARPANSA, and of ARPANSA as the regulatory body for Commonwealth entities, was described in section 1.3 of the Summary Report.

The functions of the CEO are set out in section 15 of the ARPANS Act. The functions are:

- to promote uniformity of radiation protection and nuclear safety policy and practices across jurisdictions of the Commonwealth, the States and the Territories;
- to provide advice on radiation protection, nuclear safety and related issues;
- to undertake research in relation to radiation protection, nuclear safety and medical exposures to radiation;
- to provide services relating to radiation protection, nuclear safety and medical exposures to radiation;
- to accredit persons with technical expertise for the purposes of this Act;
- to monitor the operations of ARPANSA, the Council, the Radiation Health Committee and the Nuclear Safety Committee;
- to report on the operations of ARPANSA, the Council, the Radiation Health Committee and the Nuclear Safety Committee;
- to monitor compliance with Division 1 of Part 5 and make recommendations to the Director of Public Prosecutions; and,
- such other functions as are conferred by this Act, the regulations or any other law.

While the ARPANS Act and Regulations set the basic framework under which ARPANSA works, and establish the CEO as the independent regulator of Commonwealth entities using or producing radiation, the policy for ARPANSA's Regulatory Activities sets the direction for ARPANSA's staff when performing regulatory activities. The policy makes the following commitment:

> *The CEO and ARPANSA are committed to providing the highest quality services to the Australian government and community. ARPANSA provides for:*
>
> - *sound and predictable regulatory arrangements, independent of promoting interests;*
> - *a graded approach to the management of radiation risks, so that regulatory actions are commensurate with the level of hazard and risk, are appropriately managed and do not unduly impede on justified activities that involve radiation;*
> - *intergenerational and transboundary protection;*
> - *arrangements for stakeholder engagement; and*
> - *transparency and accountability in regulatory activities including decision making.*
>
> *ARPANSA will, as applicable, implement and act in accordance with the Australian Government Guide to Regulation, the Australian Government's Regulator Performance Framework, and the Australian Government publication International Standards and Risk Assessments; and with other guidance relevant to Commonwealth regulatory activities.*

ARPANSA's regulatory activities are outlined in the Regulatory Management System. In particular, the inspection manual describes how resources are prioritised in accordance with a graded approach to ensure oversight effort is risk informed. The method for ranking regulatory priority for facility licences is based on risk, taking into account controls in place, while the methodology for determining regulatory priority for sources is based on the inherent hazard of the source. Based on cost recovery data, ARPANSA directs four times more effort to medium or higher regulatory priority licences compared to lower regulatory priority licences. To achieve this some low hazard equipment is overseen predominately by self-reporting and through general information sharing, some are subject to interactive e-inspections while higher hazard controlled material, apparatus and facilities are subject to highly detailed inspections undertaken quarterly by a team of inspectors over several days. The ARPANSA website has further information on how it conducts its inspection program and further details are provided in section 6 of this Summary Report.

ARPANSA's regulatory activities have been reviewed by the Australian National Audit Office (ANAO) in 2014, and in the previous IRRS primary (2007) and follow-up (2011) missions. ARPANSA also internally assesses its performance including by an annual self-assessment required by the Australian Government Regulator Performance Framework . All of these assessments stated that ARPANSA's regulatory performance was generally satisfactory and suited to the circumstances, with strengths but also with areas for improvements.

Organisational Structure

The ARPANS Act provides for the employment of staff needed to carry out ARPANSA's role and to recover its regulatory costs by charging licence fees. Other funding is provided through appropriations and fees for services (see section 1.3). ARPANSA has six business groups that carry out activities that support the CEO's functions under the ARPANS Act and Regulations. ARPANSA's business groups deliver components of the agency's strategies and services and enable it to discharge its responsibilities and perform its functions effectively.

Chief Executive Officer (CEO)

Part 6 of the ARPANS Act sets out the matters that are relevant to the appointment of the CEO and the conditions for office. The CEO is appointed by the Governor General for a term of up to five years, and can be reappointed. The functions of the CEO are those set out in section 15 of the ARPANS Act, and can be delegated.

Office of the CEO (OCEO)

The OCEO facilitates, coordinates and supports the activities of the CEO. The office leads collaboration and communication, coordinates stakeholder and international engagement, liaises with the Minister's Office and the Department of Health, and provides advice to the agency and Government on emerging and strategic issues. The OCEO has nine staff members and is led by the Chief of Staff.

Regulatory Services Branch (RSB)

The RSB has main carriage of authorisation, inspection, review and assessment of applications, and enforcement; in relation to the safety and security of Commonwealth radiation sources and facilities. Comprising four sections (Source Safety and Security, National Codes and Standards, Facility Safety and Safety Systems), the branch is ARPANSA's principal driver for delivering regulatory services to Commonwealth entities using or producing radiation, and in promoting uniform regulatory standards across all jurisdictions. The costs for regulatory activities are recovered from application fees and annual licence charges. The RSB has 23 members of staff (including one vacancy) and is led by the Chief Regulatory Officer.

Radiation Health Services Branch (RHSB)

The RHSB comprises three sections; Monitoring and Emergency Response, Assessment and Advice, and Radiation Protection Services. The branch provides radiation protection advice and assessments to stakeholders including the public and government. It develops and maintains ARPANSA's infrastructure for emergency preparedness and response (EPR). The branch operates a number of national initiatives including an ultraviolet radiation monitoring network, and the Australian National Radiation Dose Register. It operates radiation monitoring stations established under the terms of the Comprehensive Nuclear-Test-Ban Treaty. It also provides services on a fee-for-service basis including the Personal Radiation Monitoring Service, the ultraviolet radiation fabric testing service and a radiofrequency equipment calibration service. The RHSB has 44 members of staff and is led by the Chief Radiation Health Scientist.

Medical Radiation Services Branch (MRSB)

The MRSB provides safety and quality advice on the use of radiation in medicine to all Australians. The branch has three sections – Medical Imaging, Primary Standards Dosimetry Laboratory and Australian Clinical Dosimetry Service. The Medical Imaging section is responsible for dose data collection and advice on patient safety within diagnostic imaging, and it publishes the National Diagnostic Reference Levels for imaging modalities. The Primary Standards Dosimetry Laboratory maintains the Australian National Primary Standard for absorbed dose. By calibrating hospitals' radiation monitors against the primary standard, it ensures that hospital equipment is accurate. The Australian Clinical Dosimetry Service assesses radiation dose delivered by linear accelerators used by radiotherapy providers in Australia, for a fee, verifying that the radiation dose delivered to

patients under treatment is correct. The MRSB has 22 members of staff and is led by the Chief Medical Radiation Scientist.

Office of the General Counsel (OGC)

The OGC provides legal advice and strategic support to the agency with regard to all aspects of the agency's operations and assists the CEO to achieve their statutory mandate. The OGC also provides legal advice and support to all ARPANSA staff to assist them in performing their functions and to ensure that in doing so they are compliant with relevant government policy and legislation. The OGC has two members of staff, one located with the RSB, and led by the General Counsel.

Corporate Office

The Corporate Office comprises four sections; Finance, People and Culture, Digital Technology, and Performance and Governance. The Corporate Office provides an enabling function for the agency, assisting in ensuring the internal systems are in place for maintaining effective and efficient agency performance. The Corporate Office has 34 members of staff and is led by the Head of Corporate who is also the Chief Financial Officer.

The organisational chart is presented below at Figure 8. The CEO is supported by the Executive Group (EG); comprising of the CEO and the Branch and Office Heads., The EG meets monthly to monitor the Agency's performance in relation to plans and obligations. The Strategic Management Committee (SMC) meets four times a year for 1-2 days, to discuss strategic issues. The SMC is comprised of EG members plus one or more (currently two) external members appointed by the CEO. The roles and functions of the advisory bodies, including the Audit and Risk Committee, are explained elsewhere in this Summary Report.

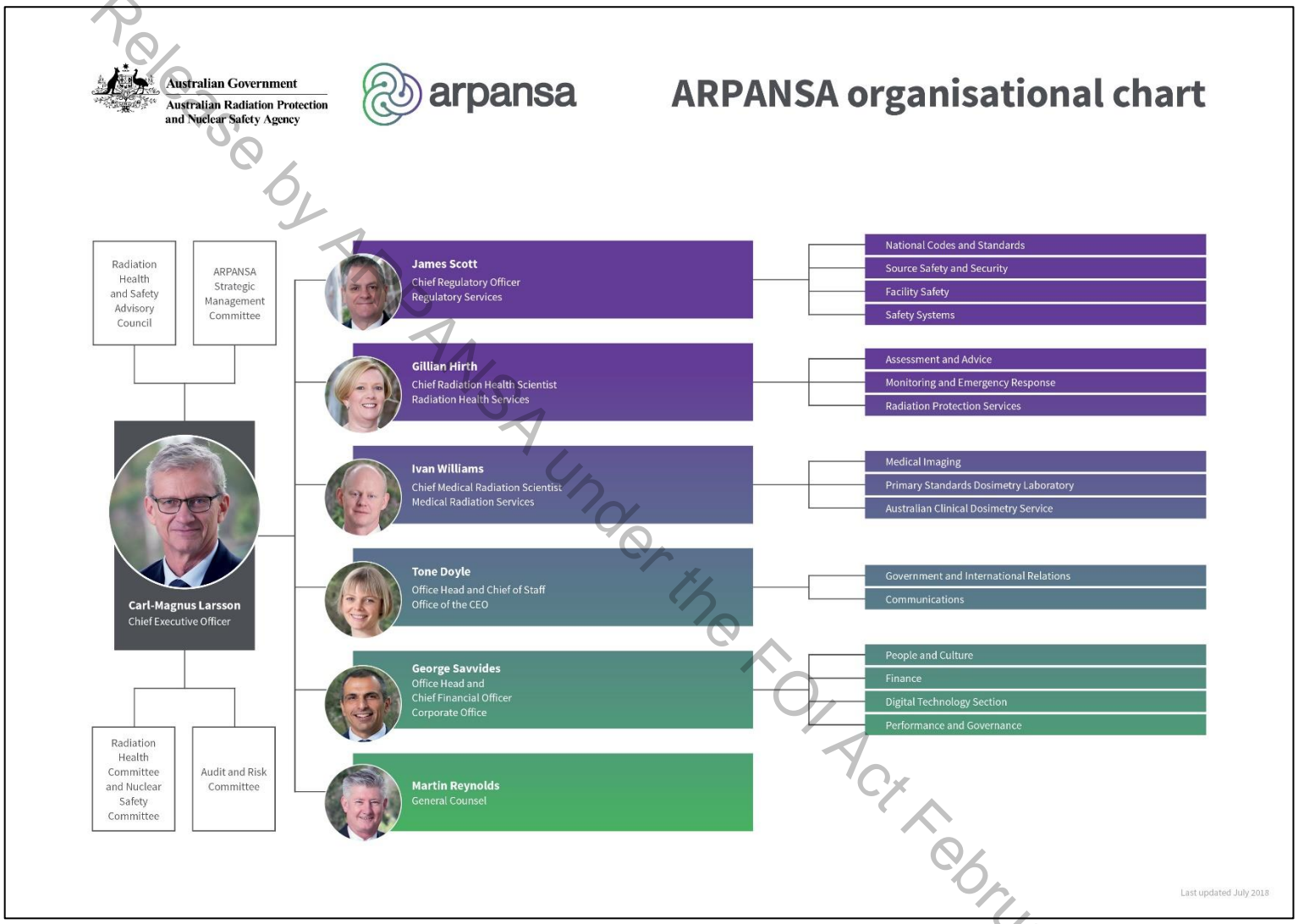

Figure 8. ARPANSA organisational chart

ARPANSA staff are distributed between the agency's Sydney office (about 25 staff including most of RSB) and the Melbourne office and laboratories (>100 staff).

3.2 Effective independence in the performance of regulatory functions

Related to GSR Part 1 (Rev. 1): Requirement 17

ARPANSA is established as an independent regulatory body under the ARPANS Act and maintains a direct reporting line to Parliament through the relevant Minister. This provides operational separation from most licence holders and interested parties.

The establishment of a regulatory body and its independence was discussed in section 1.3, where it was noted that the Minister can direct the CEO and that the CEO must comply with such direction. The Minister can, however, only direct the CEO if it is in the public interest to do so. Furthermore, the Minister must table a direction in Parliament within 15 sitting days. The CEO has so far never received a direction under the ARPANS Act. Regulatory decisions of significance, e.g. licensing of facilities and findings of a licence holder in breach of the Act, are reported to Parliament via the Minister in the Quarterly and Annual Reports.

The Policy for ARPANSA's Regulatory Activities (section 6.4) outlines the commitment of the CEO of ARPANSA to carry out the regulatory function independently. Section 4 of this Policy states that all ARPANSA staff are responsible to ensure that it is followed. The policy states that the CEO of ARPANSA carries out their regulatory and other functions free from political or economic pressures and is empowered and required to give independent advice. While ARPANSA engages with and strives to understand the needs and views of licensees, applicants for an ARPANSA licence, and other stakeholders; the regulatory decisions are taken in the interest of safety and the protection of people and the environment, independent of such interests, but with due consideration to negative consequences for example third parties.

ARPANSA maintains relevant procedures within its Regulatory Management System (RMS), governing the activities of the Regulatory Services Branch. Many of these documents or information based on them, are published on the ARPANSA website, which ensures transparency to license holders and the public. ARPANSA's Quality Policy guides the development, implementation and application of the RMS to all agency activities. The RMS, by adopting agreed policies and procedures, assists in consistency, the integrity of approach, and helps to maintain and improve the quality of service delivery.

Means to ensure personal views or conflicts of interest do not affect the effective functioning of the regulatory body

The CEO and ARPANSA staff are obliged to declare any interests in matters related to regulatory decision making to enable determination whether such interests may constitute a real, potential or perceived conflict of interest. This declaration is required to be made annually. Potential conflicts of interest between the CEO's regulatory and non-regulatory functions are required to be identified and managed appropriately under section 15(2) of the ARPANS Act.

It is normal for professional staff to express differences of opinion in regard to the technical matters of regulatory approaches and functions, or in relation to interpretation of standards. Usually these differences are resolved by discussions within a peer group or with supervisors. The process of expressing differences of opinion and then respectfully working through these to find a consensus resolution is a sign of a healthy workplace culture and is encouraged. Occasionally an employee may express a professional opinion which differs from prevailing staff opinions, or management decisions and which is not resolved through normal

processes. Where a consensus is not achievable, a procedure is in place for managing differing professional opinions. This process involves the preparation of a submission to the Chief Regulatory Officer, or other Branch Head. This is then passed to an independent reviewer to assess the technical issues. A report is prepared by the reviewer and considered by the Chief Regulatory Officer. This decision may be appealed to the CEO of ARPANSA.

Regulatory capture occurs when an inspector, or agency, adopts industry or facility specific thinking that can lead to not properly challenging a controlled activity or advancing a position that benefits the institution above the interest of safety. This can be caused by strong familiarity with a specific institution and its staff. The inspection procedures (Inspection Manual section 1.4) in the RMS, introduces means to avoid this, such as multiple inspectors on major inspections and periodically rotating inspectors to minimise the risk of regulatory capture.

ARPANSA operates under the *Public Service Act 1999* and associated legislative framework, which requires that suitable Australian citizens are recruited over foreign nationals. As a result of the small size of the nuclear industry in Australia, ARPANSA may need to recruit persons from overseas on special visa arrangements, or persons previously employed by a licence holder. During the recruitment process, applicants must declare any potential conflicts of interest, which are considered and managed by ARPANSA.

In practice, ARPANSA staff carefully mentor and supervise new staff. New staff are quarantined from any decision-making roles associated with their previous employer for a reasonable period. However, ARPANSA does not currently have a formal procedure in place for the recruitment and training of staff from license holders. ARPANSA is currently developing an approach to staffing that meets the requirements of ISO 17020 'Conformity assessment – Requirements for the operation of various types of bodies performing inspection'.

Inspection and assessments of high risk sources and facilitates are undertaken by teams and there are peer review systems in place for the review and approval of all regulatory tasks. This helps ensure that regulatory decisions are not unduly influenced by a single inspector's view.

Means to maintain effective independence and integrity

ARPANSA undertakes a number of tasks that intersect with its regulatory responsibilities. This includes areas such as regulation of sources controlled by ARPANSA, emergency response, and the provision of services such as dosimetry. An overview of how ARPANSA manages these intersections is provided on the ARPANSA website for public transparency.

Two branches of ARPANSA hold a licence issued by the CEO of ARPANSA, and are subject to regulatory control by the Regulatory Services Branch. These licences allow ARPANSA to carry out dealings with controlled apparatus and controlled material under the ARPANS Act. To ensure the independence of the ARPANSA decision making process when issuing and managing these licences, oversight by third parties, such as a State or Territory radiation regulator, is used. Inspections of ARPANSA licence holders are also overseen by a State or Territory radiation regulator as outlined in the inspection manual.

ARPANSA does not engage in industry promotion roles, and restricts its role to ensuring safety. Promotion of nuclear-related activities and waste management are, at the Commonwealth level, typically undertaken by the Department of Industry, Innovation and Science. For example, ARPANSA has clearly demarcated its role in the proposed national waste management facility in online communication, information documents and regulatory guides.

The ARPANS Act establishes three advisory bodies to support and advise the CEO to carry out ARPANSA functions (see section 1.3). These bodies can provide the CEO with independent advice on regulatory matters, and include:

- The Nuclear Safety Committee (NSC) for matters relating to nuclear safety and the safety of controlled facilities.
- The Radiation Health Committee (RHC) for matters relating to radiation protection, including formulating draft national policies, codes and standards.
- The Radiation Health and Safety Advisory Council (RHSAC) for identifying emerging issues and provides advice on radiation protection and nuclear safety.

ARPANSA regularly reviews and audits its performance through various means, including:

- ARPANSA has established an Audit and Risk Committee (A&RC) to provide independent advice and assurance to the CEO on ARPANSA's financial and performance reporting responsibilities, risk oversight and management, and system of internal control. The A&RC has been established in accordance with section 45 of the *Public Governance, Performance and Accountability Act 2013* (PGPA Act) and section 17 of the of the *Public Governance, Performance and Accountability Rule 2014 (PGPA Rule)*. The chair and two members are non-ARPANSA staff, and one additional member is appointed from within ARPANSA.
- In 2014, the Australian Government required all Commonwealth Regulators to conform to the requirements of its Regulator Performance Framework (RPF), including the conduct of an annual self-assessment of regulatory performance. The assessments demonstrated a high level of compliance with the RPF requirements, noted gradual improvements in relation to the key performance indicators and also identified a number of opportunities for further improvements. Such opportunities are recorded in a register for implementation when practicable. In undertaking this assessment, ARPANSA has gone beyond RPF requirements to bring in external experts and a licence holder representative. Experts have included staff from the US Nuclear Regulatory Commission, and Commonwealth and State regulators. Past RPF self-assessment Reports are available online.

Intervention measures

ARPANSA has a range of intervention options available to deal with non-compliance of legislative requirements (see further section 8 of this Summary Report). The options are tiered in a graded approach, and ARPANSA strives to use the proportionate option to achieve the desired outcome based on the evidence observed, as described in the internal Compliance and Enforcement Manual and related regulatory guide. When required, ARPANSA will intervene in situations of significant risk to ensure safety outcomes. Sometimes these interventions require a licence holder to allocate significant resources to an issue, and therefore are only used when necessary. Some recent examples of interventions that have significantly affected licence holder operations include:

- Following the discovery of materials out of regulatory control, an improvement notice was issued requiring a licence holder to undertake a comprehensive inventory check of material holdings, a detailed risk assessment and to store materials securely in accordance with legislated requirements.

- A direction was issued to a licence holder to take immediate steps to initiate an external and independent review into safety practices; the direction was prompted by a series of events with safety implications, including one rated at level 3 on the INES scale.

3.3 Staffing and competence of the regulatory body

Related to GSR Part 1 (Rev. 1): Requirement 18

The Regulatory Services Branch (RSB) of ARPANSA employs 23 staff (one position is vacant at the time of preparation of this report), with most staff performing inspections as part of their duties. Most of the RSB staff are based in ARPANSA's Sydney Office.

Within the RSB, ARPANSA expertise includes nuclear operations, engineering including nuclear engineering, transport, medical physics, emergency preparedness and response, radiation protection and nuclear security. In addition, RSB staff have been trained and have experience in other areas important to safety, including human and organisational factors.

RSB can draw on a significant pool of expertise from other branches and offices in ARPANSA when needed. This support may include expertise in radiation protection, dose reconstruction, health assessments, medical radiation, radiation measurements, environmental monitoring and protection, stakeholder engagement, communication and emergency response. Expertise is regularly sought for the preparation of emergency preparedness and response-related hazard assessments of facilities and geospatial products that capture large data sets. The Office of the General Counsel has a legal officer working in the Sydney Office, providing advice on regulatory decisions. The CEO is based in the ARPANSA Sydney Office and devotes about a third of their time to regulatory activities.

At times, ARPANSA invokes the MoUs or other arrangements with other regulators or competent authorities for their advice (such as with ASNO on nuclear security matters for material that is both nuclear and radiological), which is also of benefit to licence holders, as recommendations or advice is harmonised and consistent between the relevant authorities.

If ARPANSA requires specialist technical advice to support regulatory activities that do not exist within the agency, financial resources and contacts are available to source that expertise externally.

The Policy for ARPANSA's Regulatory Activities states that: '*Branches and Offices work collaboratively in carrying out activities that support the CEO's regulatory functions including promotion of national uniformity. Special care is taken with regard to licensing and enforcement decisions, which in terms of legality, potential conflicts and other aspects are properly vetted, e.g. by the ARPANSA General Counsel. Additionally, the CEO of ARPANSA is advised by three independent statutory external bodies and may seek independent advice via contractual arrangements from third parties as necessary, ensuring that any conflicts of interest are identified and addressed during those processes. ARPANSA maintains the core expertise to obtain, assess and implement advice from external bodies or third parties'.*

As indicated in the abovementioned Policy, ARPANSA may draw on the advice from the RHSAC, the NSC and the RHC. This can include advice on issues related to radiation protection, nuclear safety, and community engagement. For more information on the advisory bodies, see section 1.3.

Overall, ARPANSA has been able to capitalise on resources across the Agency to deliver regulatory outcomes without jeopardising regulatory integrity. Examples are the recent review and assessment of ANSTO's application to operate the ANSTO Nuclear Medicine Mo-99 Facility (ANM), and the pre-licensing

activities carried out in relation to the planned National Radioactive Waste Management Facility. The NSC and the RHSAC has had an important role in these activities. Although these arrangements do impact on other activities, it demonstrates 'institutional strength-in-depth' in the spirit discussed by the International Nuclear Safety Group (INSAG) in its Publication *Ensuring Robust National Nuclear Safety Systems – Institutional Strength in Depth* (INSAG 27).

The ARPANSA Workforce Plan (2017–2021) supports the identification, development and maintenance of competency requirements, and is supported by succession planning. ARPANSA's succession planning process aims to identify the likelihood of a vacancy and the consequence or impact of the vacancy on the agency. This succession planning process was applied to the RSB in 2017. When a vacancy is identified, the People and Culture Section of the Corporate Office works with the relevant business area to review the specific requirements of the role and amend the position description and recruitment process as required. This process is undertaken on an as needs basis, taking account of the succession planning process that has previously been undertaken.

ARPANSA has identified the adoption of ISO 17020 or equivalent arrangements for all regulatory processes as desirable. ARPANSA has developed and implemented a Qualification Card system with associated defined competencies that all regulatory officers must meet before being becoming an Authorised Inspector. The ARPANSA Workforce Plan and Regulatory Management System processes provide overall guidance and assistance. This includes formal and ongoing identification of agency knowledge gaps and necessary training consistent with the development of ISO17020, which is to be extended to all regulatory processes.

Staffing levels in State and Territory regulatory bodies

Each jurisdictions allocates resources to the regulatory body based on the priorities and resources available to the jurisdiction. This leads to significant variation in the staffing and other resources available to the regulatory body. Some jurisdictions have indicated that reductions in the number of staff over time, and the loss of some experienced staff, has impacted their volume of work and response times. Information relevant to jurisdictional regulatory bodies are summarised below.

Jurisdiction	Resources	Approximate size of jurisdiction
ARPANSA	23 positions within the regulatory services branch RSB of ARPANSA. Approximately 20 staff are technical staff/inspectors. ARPANSA in total has approximately 130 staff, including a range of radiation expertise.	Licences: 100, including approximately 60 source licences and 40 facility licences including one research reactor. These licenses are issued to agencies/entities and cover a large number of individuals.
ACT	2 technical/inspector positions within the ACT Health Radiation Safety Section, and a Manager with responsibility for both the Radiation and Environment regulatory groups within the ACT. Additionally, the Radiation Council has 7 members and is a decision-making body which has delegated some of their functions to ACT Health Directorate.	Possession licences: 200 User licences: 1200 Percentage population: 2%

Jurisdiction	Resources	Approximate size of jurisdiction
NSW	7 staff work directly in radiation regulation. This includes 5 operational (2 senior) and 2 policy (1 senior) staff.	Possession licences: 3500 User licences: 15 000 Percentage population: 32%
QLD	14 staff work in the Radiation Health Unit undertaking regulatory, technical and professional advisory roles, and interacting with governments, public companies, members of the public etc. The Radiation Health Unit also operates Queensland's radioactive waste store and manages emergency response in Queensland. Routine licence applications are considered via a systematised process by around 6 officers in another unit. About 110 persons are appointed as inspectors under the Radiation Safety Act 1999.	Possession licences: 2,443 User licences: 17 990 (including transport) Percentage population: 20% Other Authorisations issued: • 1507 individuals holding radiation safety officer or accreditation certificates • 5705 sealed radioactive substances are registered and tracked • 10 857 radiation apparatus are registered and tracked.
SA	15 staff work directly in radiation regulation, including two administrative officers. These are supported by other staff in areas such as business support, investigation, legal advice, and community engagement. The regulatory body overall has approximately 230 staff, covering environmental as well as radiation regulation.	Possession licences: 750, including uranium mining. Radiation sources: 3500 User licences: 6700. Percentage population: 7%
TAS	4 permanent staff - 3 regulatory physicists and a licensing officer.	Licences: 500, authorising around 3000 persons to use approximately 3000 radiation sources. 600 registered places where sources are stored and used. Percentage population: 2%
VIC	11 staff work in the Victorian Department of Health and Human Services Radiation Safety Team within the Health Protection Branch, who have backgrounds in physics, medical physics, health physics, nuclear medicine, radiography and environmental health. Many of these personnel have both government and non-government experience within their respective areas of expertise. This specialist team is further resourced by a centralised administrative support/customer service team, database administration officer, investigations office, project and management support as well as a number of public health physicians.	Possession licences: 2 688 User licences: 14 365 Percentage population: 26%

Jurisdiction	Resources	Approximate size of jurisdiction
WA	10 staff involved in regulatory activities (1 technical and 9 scientific and policy staff)	Registered premises (equivalent to possession licences): 2,000 (including mining and milling of radioactive ores) Use licences: 7000 Percentage population: 10%
NT	2.5 staff involved in regulatory activities (2 scientific, 0.5 administrative)	1,300 licensees (use and possession) Percentage population: 1%

Table 3. Staffing levels and number of licences across jurisdictions

3.4 Liaison with advisory bodies and support organisations

Related to GSR Part 1 (Rev. 1): Requirement 20

ARPANSA uses a broad range of sources of information to make regulatory decisions. These include internal technical staff, advisory bodies, external contractors, and information sharing arrangements with other government agencies.

Regulatory officers who lead inspections or assessments determine whether ARPANSA has the required competencies and capacity available to undertake the task. If a gap is identified, ARPANSA evaluates what additional expertise is required, and sources it as appropriate. ARPANSA does not have a formal policy or guidance that details the circumstances when it calls on external expertise. However, when reviewing complex licence applications, preference favours establishing a multi-disciplinary review team in order to ensure that all of safety, security and emergency response considerations are carefully and appropriately integrated into the review process. A recent example is the ANM operating licence application. A project may be established in accordance with ARPANSA's Project Management Framework.

There are no designated technical support organisations in Australia. Instead, ARPANSA uses its internal resources, primarily the RHSB and MRSB, and also external consultants when required. External experts have been used in a variety of contexts, including to assess seismic faults, manufacturing processes for components manufactured overseas, and reactor environmental analysis for shock and vibration. An example of a recent use of external expertise was in the assessment of an application to increase the power limit of the OPAL reactor. External contactors were used to conduct an independent evaluation of temperature variation, and to undertake a review of the implication of this change to the Operating Limits and Conditions and Safety Analysis Report.

ARPANSA also uses external consultants to support its facility inspection programme. This may be where a specialist knowledge is required but is more often used to provide an alternative perspective and provide continued development. As previously mentioned ARPANSA always includes an inspector from a State or Territory regulator when an inspection or assessment of ARPANSA's internal licence holders is undertaken.

Additionally, the ARPANS Act establishes three independent advisory bodies to support the CEO with advice to carry out ARPANSA's functions. The advisory bodies' functions and membership are defined in the Part 4 of the ARPANS Act. The bodies act in accordance with the Roles and expectations for advisory bodies which outlines the scope of each body and requirements such as conflicts of interest. The functions are further explained in this report (section 1.3) on the ARPANSA Website, and are summarised below:

- The Nuclear Safety Committee (NSC) advises the CEO and the Council on matters relating to nuclear safety and the safety of controlled facilities, including developing and assessing the effectiveness of standards, codes, practices and procedures. The NSC is frequently used to provide advice or review particular licencing considerations or ARPANSA publications related to the regulation of facilities.
- The Radiation Health Committee (RHC) advises on matters relating to radiation protection, including formulating draft national policies, codes and standards for consideration by the Commonwealth, states and territories.
- The RHSAC issues and provides advice on radiation protection and nuclear safety, including advice on the adoption of recommendations, policies, codes and standards.

Similar arrangements exist in the States and Territories. For example, the principal source of expert advice to the NSW EPA is the Radiation Advisory Council, established under s.29 of the Radiation Control Act 1990 (NSW). This comprises 17 members appointed by the Minister and apart from the Council Chair, none are EPA staff. Members are drawn from a variety of specialist fields as well as legal and community representatives. The Council may establish committees to examine specific issues to provide advice, assistance and support to the EPA on a variety of matters, including the development of technical guidance documents.

3.5 Liaison between the regulatory body and authorised parties

Related to GSR Part 1 (Rev. 1): Requirement 21

In addition to formal inspections and review processes, ARPANSA maintains frequent contact with authorised parities.

ARPANSA strives for all liaison with licence holders and applicants to be appropriate and professional and carried out openly and transparently, as stated in the Policy for ARPANSA's Regulatory Activities. This helps to achieve high levels of consistency, predictability and trust in its regulatory service. To achieve this, ARPANSA implements its practices and processes, many of which are publicly available, so that stakeholders can understand and also comment on the regulatory standards and expectations that must be met. ARPANSA also publishes the regulatory assessment reports and the reasons for issuing licences for any major applications, and inspection reports except where security restrictions apply.

Specific activities to support good communication practices include:

- information sharing meetings with licence holders. The purpose of these meetings is to keep up to date with activities of the licence holder and any significant regulatory issues. For some licence holders this includes quarterly meetings where their quarterly reports are discussed, or to discuss upcoming applications or changes
- site visits supplement the ARPANSA's inspection program for facility licences and build inspector familiarity with a site or processes outside of formal assessments, and provide an opportunity to discuss and clarify regulatory expectations
- an annual Licence Holder Forum (LHF) which is used to highlight topical issues and which provides an opportunity for licence holders to form networks and share information on safety and regulatory compliance. The 2017 LHF was attended by over 80 licence holder representatives, and included a panel discussion on the recent *Planned Exposure Code* (RPS C-1) and other changes affecting licence holders

- liaison forums with individual major licence holders, such as the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and the Department of Defence to facilitate discussion about issues relevant to these licence holders
- lead inspectors are assigned to each licence and are responsible to be the primary contact point for the licence. Licence holders also nominate a staff member to be the primary regulatory affairs liaison with ARPANSA. This ensures effective channels of communication can be maintained, as people are familiar with whom to talk to in the organisation
- inspection reports, unless classified on security grounds, are published on the ARPANSA website. This provides transparency for license holders and for the public. Inspection reports outline performance including areas for improvement, potential non-compliance and good practices. Each report explains the basis for any potential non-compliance with the Act
- extensive communication occurs in relation to non-compliances with legislative requirements. Prior to making a determination of whether a breach has occurred, the licence holder is invited to provide any comments, identify extenuating circumstances and mitigating actions, and outline any proposed corrective actions related to the potential non-compliance. This ensures that ARPANSA has considered the full range of evidence and circumstances before reaching a decision. Once a breach has been confirmed, a letter is sent that explains the basis for the breach finding and, where applicable, acceptance of the corrective actions proposed
- licensing decisions are communicated formally via a letter. For major applications, including new licences, the letter will include the basis for the decision in a 'statement of reasons'. These are published on the ARPANSA website for Major Facilities
- consultation with stakeholders on any new codes and standards or significant changes to regulatory policies and procedures, including through the have your say section of the website
- seeking regular feedback on its interactions with licence holders through a variety of surveys and a register of compliments and complaints.

3.6 Stability and consistency of regulatory control

Related to GSR Part 1 (Rev. 1): Requirement 22

ARPANSA has a Regulatory Management System (RMS), forming part of the Integrated Management System (IMS) – currently under development – that supports the provision of a consistent and predictable regulatory assessments and decisions that are based on an evaluation of applicant and licence holder performance against published codes, standards and regulatory guidance. Section 5 of ARPANSA's Regulatory Policy outlines this commitment. The process to meet the commitment is defined in manuals, supporting procedures and instructions that describe how staff undertake review and assessment, peer review, make regulatory decisions and, as necessary, take enforcement actions. The procedures within the 'inspection manual', 'licensing and assessment manual', and 'enforcement manual' implement the core regulatory process. Development and revision of these modules within the RMS involve consultation with the branch, and training during the annual information and training day. The RMS and document revision is further described under section 4.

The CEO of ARPANSA (or when necessary, the CEO's delegate, the Chief Regulatory Officer) makes formal regulatory decisions, such as licence approvals or breach findings. This ensures that key decisions are consistent and in accordance with internal procedures and advice from various sources. ARPANSA ensures consistency through a number of measures and procedures. These include:

- inspection reports are subject to peer review by a second inspector, and approval by the section director and for inspections identifying potential non-compliances, the Chief Regulatory Officer. An additional quality control check ensures consistency of reports (see section 6)
- documentation, including the Licensing and Assessment Manual and regulatory guides, provides guidance to ensure consistent decision-making
- regulatory decisions are rarely made in isolation, and major decisions are only made after appropriate consultation. Regulatory officers work in a team environment where information is shared and consensus is generally sought. A Lead Inspector is assigned to each licence and is supported by an alternate inspector who also maintains oversight of the licence. Additionally, the branch is made aware of important regulatory decisions and activities, such as through regular section and branch executive meetings, and the annual information and training day for inspectors.
- all assessments must be documented and most types of assessment require peer reviews by an alternative regulatory officer and then the Section Director. It is then subject to a quality review and, where applicable, review by the Office of the General Counsel. This process is further described in sections 5 and 6
- inspection outcomes from reports are also reviewed and categorised for learning and development purposes to identify trends and potential issues
- if there are differences in opinions between approaches these can be resolved in accordance with an established procedure for managing differences of opinion
- the Regulatory Assessment Report and Statement of Reasons for major applications are published online. These provide the basis for regulatory decisions for a range of audiences including other regulators
- any changes in regulatory policy, including changes to the regulations or national guidance requires the impacts to be assessed, and where relevant, requires consultation with affected parties. These changes are typically also placed on the have your say section of the website. For more information, see section 9.1 of regulations and guides.

3.7 Safety related records

Related to GSR Part 1 (Rev. 1): Requirement 35

Requirements for regulatory management of records are captured in the Regulatory Management System and is compliant with the Archives Act 1983 and associated record keeping requirements. ARPANSA maintains detailed records including:

- all documents and records, including incoming communications are stored in the **electronic records management system (HPE)**. This includes inspection notes, reports, findings, and letters. Any documents or records originating from the licence holder that are acquired by ARPANSA for the purposes of regulatory oversight or as part of applications are also stored. Any paper records, including hand written notes, are scanned into this system. HPE includes version tracking and retrieval. Users' access rights are managed centrally by authorised records officers. For example, depending on access rights, users are typically unable to delete records or access sensitive records unrelated to their duties. These documents are periodically backed up and are transferred to archives for storage or disposal as required

- a **Licence Administration Database (LAD)** provides a tool for business intelligence across all licences. This provides important information on each licence and licence holder including records of applications, inspections, performance reports, details of sealed sources and generators (updated periodically) and details of licence holder contacts. It provides management reports to assist regulatory officers to manage specific licences and for ARPANSA management to measure internal performance
- the **Australian National Radiation Dose Register (ANRDR).** ARPANSA administers a central record database that is used for the storage and maintenance of occupational radiation dose records. The ANRDR was established in 2010 primarily for the uranium mining industry, and now contains dose records from workers from all Australian uranium mines. The ANRDR has progressively expanded and now includes dose records for some mineral sand mining companies. From July 2017 the submission of dose records from all Commonwealth licence holders became a licence condition. The States and Territories have agreed to make ANRDR the national dose record depository (final decision from WA pending) and work is underway to put necessary arrangements in place. A first delivery of dose records to be stored in the ANRDR has recently been delivered from the medical sector.

Authorised parties, licence holders, are required to have plans and arrangements in place that detail the controlled activity. Regulation 50 of the ARPANS Regulations requires that these plans and arrangements are reviewed by the licence holder at least every three years and that the licence holder must maintain records of any changes. This is confirmed during inspections.

All Commonwealth licence holders (which includes ARPANSA) have legal responsibilities under Commonwealth law (Archives Act 1983 and associated record keeping requirements) to store and maintain any records that they create. Applicable codes, standards (which may be a condition of licence) and regulatory guidance describe expectations for licence holder record keeping for specific aspects of operations. Regulatory guidance is provided on records for training, transport, doses, security and EPR.

The Planned Exposure Code, which is a condition of all ARPANSA licences, includes the following requirement:

3.1.20 The Responsible Person must ensure that a record keeping system is implemented that includes the following:

(a) authorisations granted by the relevant regulatory authority

(b) the radiation management plan

(c) details of training courses and of participation by occupationally exposed persons

(d) details of radiation monitoring and dose assessment

(e) inventories of radiation sources and radioactive waste

(f) details of incidents and accidents involving exposure to radiation and of corrective measures taken.

This list reflects most of the requirements listed under Requirement 35 of GSR Part 1: Registers of sealed radioactive sources and radiation generators, records of doses from occupational exposure, records relating to the safety of facilities and activities, records of events including non-routine releases of radioactive material to the environment, inventories of radioactive waste and of spent fuel.

ARPANSA does not collect and maintain an independent register of licence holder information such as waste or safety records. However, the *Planned Exposure Code* requires that these records are available for inspection by the regulatory body and, when a practice terminates, the licence holder must pass to the relevant regulatory body the records of radiation doses and any other records specified by the relevant regulatory body.

The adequacy of the licence holders' records is assessed as part of the inspection assessment process. Any issues identified in the records are addressed in the inspection report. For example, the Performance Objectives and Criteria (PO&C), which form the basis for each inspection (see further section 7 of this Summary Report), include requirements on:

- configuration management in regard to change control and internal safety reviews
- inspection, testing and maintenance in regard to reviews of scheduled maintenance frequencies
- training in regard to the frequency of training and in accuracy of training material
- radiation protection in regard to dose records and setting dose constraints
- security and emergency preparedness and response in regard to hazard, threat and vulnerability assessments.

There is currently no single 'all encapsulating' requirement to maintain records within the ARPANS Act or Regulations or in regulatory guidance. The Plans and Arrangements guide has explicit record keeping requirements for training (2.41), transport (3.77), dose records (4.11), Security (6.7) and EPR (7.42). However, there is currently no explicit requirement on facility safety documentation (i.e. engineering plant, design variations, operations logs). This information may be requested for the shutdown, decommissioning, or closure of facilities in accordance with the regulatory guide *Decommissioning of Controlled Facilities*, which is due to be published shortly.

3.8 Communication and consultation with interested parties

Related to GSR Part 1 (Rev. 1): Requirement 36

ARPANSA has extensive consultation and information sharing arrangements in place and publish a variety of documents online on its regulatory approaches. A dedicated communications team provides support and facilitates communication with stakeholders and the public.

Examples of processes to inform and consult with interested parties include:

- the have your say section on the ARPANSA website lists ARPANSA publications and other documents, and relevant international documents such as IAEA drafts, for consultation. All RPS Codes and Guides go through a public consultation process as do other ARPANSA guidance documents. Depending on the national Code or Guide being developed engagement with special interest groups and professional bodies is also undertaken. For example, the draft Medical Exposure Code (RPS C-5) recently underwent public consultation, and consultation with professional bodies

- a range of fact sheets and information documents from the Regulation and Licensing page of the ARPANSA website that describe how, what and why ARPANSA regulates. These pages are written for the public and media but may also assist licence holders in their dealings with ARPANSA

- the Talk to a Scientist program offers the public an opportunity to find answers to science-related questions that they have been unable to find using other resources
- as part of ARPANSA's formal accountability mechanisms, ARPANSA prepares Annual and Quarterly Reports to the Minister and Parliament. These reports cover ARPANSA's activities and describe the safety performance of licence holders including incidents and breaches, and includes information on major licencing decisions. Reports and other key accountability documentation is available to the public via the Corporate Publications page of the ARPANSA website. This includes any special reports to Parliament, which are also made available to the public. Documents tabled in parliament provide oversight and accountability of ARPANSA's activities, as well as those of Commonwealth licence holders
- requirements for prior notice and consultation on receipt of facility applications are outlined in regulation 40 of the ARPANS Regulations. ARPANSA invites public submissions on applications for nuclear installations through the website and as otherwise stipulated regulation 40, and hold public forums where applicable. A table addressing any comments received, including resolution, is published on the website
- extensive information is on the Major Facilities page of the website, including a summary of related regulatory decisions, and the basis for the decision in the 'Statement of Reasons'
- information for stakeholders is developed on as needed basis. For example, information was developed specifically related to the National Radioactive Waste Management Facility (NRWMF). Whilst no application for a licence has been received, ARPANSA has been proactively engaging with potentially affected communities and providing relevant information to stakeholders, using the ARPANSA website and also through visits to the communities. ARPANSA's engagement has assisted those communities to understand ARPANSA's role as regulator and the integrity of the regulatory process. A 'communications protocol' has been established to describe the demarcation between ARPANSA and the Department of Industry, Innovation and Science (the proponent of the facility) in pre-licensing activities
- the NSC (which provides independent advice to the CEO) must, under the ARPANS Act, include a person to represent the local government or the local administration of an area affected by the safety of a controlled facility, as well as a member representing the interests of the general public. Similarly, the 'public' is represented on the RHC and the RHSAC. The member representing the interests of the general public facilitates the interaction between the advisory bodies and the public. The member is expected to report, as a matter of routine at the meetings, on any specific contacts made by members of the public relevant to the functions of the advisory body. The minutes of these meetings are made public. See section 1.4 on the advisory bodies
- licence holders that have activities with the potential for off-site consequences are required to have emergency plans in place for emergencies including those with off-site consequences that include public advice and notifications

3.9 Conclusions and actions

ARPANSA, the Commonwealth regulator, is independent from operators and policy areas of government, and the CEO of ARPANSA has a direct reporting line to the relevant Minister and to Parliament. The Agency's organisational structure and internal arrangements support the discharge of its responsibilities efficiently and with integrity. ARPANSA performs annual self-assessments under the Regulator Performance

Framework, involving licence holders and external regulators in the process. The self-assessment is published on ARPANSA's website.

The regulatory process follow specified policies, principles and associated criteria as outlined in the manuals maintained in the management system. This helps to ensure stability and consistency of regulatory control.

ARPANSA has a strong culture of transparency and of engagement with authorised entities and other stakeholders. This is evidenced in regular license holder forums, liaison group meetings with major license holders, and community consultation programs such as before and during review of licence applications.

Areas that can be improved:

- formalisation within the staff training framework of the existing process to recruit and train staff that have come from a licence holder to preserve the integrity of the regulatory processes. ARPANSA is currently working on an ISO 17020 project which will improve succession planning and training requirements for inspectors (see Action Plan item 4).
- ARPANSA has established mechanisms for obtaining and maintaining records relating to the safety of facilities and activities. However, this could be further enhanced to ensure that all relevant information outlined in GSR Part 1 revision 1 section 4.63 is captured in ARPANSA guidance, and can be requested in relation to decommissioning of facilities. ARPANSA will also work towards inclusion of relevant documentation in Schedule 3 Part 1 of the ARPANS Regulations – *information that may be requested by the CEO*. See Action Plan item 8.

4. Management system of the regulatory body

This section focuses on the Commonwealth regulator, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

4.1 Responsibility and leadership for safety

Related to GSR Part 2: Requirements 1 and 2

The ARPANSA Integrated Management System (IMS) that is currently in development is intended to capture all regulatory processes as well as processes that support regulatory activities. This system comprises of quality, safety, security, risk, compliance and corporate governance areas. ARPANSA's Work Health and Safety Policy (WHS Policy), WHS Manual and supporting procedures and processes are a fundamental component for safety. Processes associated directly to the provision of ARPANSA's regulatory service are captured in the Regulatory Management System (RMS) that is a component of the IMS.

The WHS Policy outlines the agency's management commitment to providing a safe environment for all employees, contractors and visitors with the prioritisation of safety to achieve business objectives without undue risk. The ARPANSA Risk Management Framework outlines the roles and responsibilities for the effective management of risks to ARPANSA, to its staff and to the Australian community. The Risk Management Framework applies to all ARPANSA employees, contractors and consultants undertaking activities and processes associated with the operations of ARPANSA. The *Work Health and Safety Management Manual* (WHS Management Manual) describes the systematic process of hazard identification, risk assessment, and risk control with the aim of providing a safe work environment for employees, contractors and visitors at ARPANSA.

As part of the WHS Policy there is a commitment to maintain safety systems and set measurable objectives and targets to ensure continued improvement aimed at the elimination of risks. These encompasses both lead and lag safety indicators, such as scheduled WHS inspections, number of report cards submitted, documents reviewed, and incident/injury statistics.

The WHS Policy and the WHS Management Manual incorporate values and expectations and includes work health and safety performance objectives and targets. Performance against the WHS Objectives and Targets is reported to ARPANSA's Executive Group, Work Health and Safety Committee, and the Audit and Risk Committee, to ensure continual monitoring as well as high-level visibility of safety progress across the entire agency. Each ARPANSA section (business group) is required to support these objectives and targets by encouraging all workers to actively contribute to and participate in the WHS program of work to enhance safety performance. This commitment to WHS flows through to individual staff performance agreements. These are actively promoted and compliance is reviewed within ARPANSA.

The WHS Management Manual outlines the roles, responsibilities and accountabilities across all levels of the agency. It clearly defines the responsibilities of senior management, managers, supervisors, workers, contractors and ARPANSA's Work Health and Safety Advisor in relation to the agency's activities. These responsibilities reflect the object of the Commonwealth *Work Health and Safety Act 2011*.

ARPANSA has a *Planning and Performance Framework* (in draft, pending EG endorsement and CEO approval) which enables ARPANSA to define its purpose and strategic objectives and assists the agency in making decisions on allocating resources to pursue its purpose and strategic objectives. Effective implementation of the framework ensures that the agency operates efficiently and that work is completed

in accordance with requirements, expectations, plans and resources. It also allows ARPANSA to develop accurate and reliable performance information to help officials, ministers, the parliament and the public form judgements on whether the agency is delivering on its intended results, as identified in the *ARPANSA Portfolio Budget Statement 2018-19* and the *ARPANSA Corporate Plan 2018-2022*.

The WHS Policy fosters a culture of internal reporting of hazards and incidents with a view to improve safety performance and to learn from incidents and near misses. ARPANSA sets reporting targets, as outlined in the *WHS Objectives and Targets*, whereby the reporting of hazards is encouraged and measured as a lead safety indicator.

The ARPANS Act established the CEO of ARPANSA as the regulator of Commonwealth entities. The Regulatory Services Branch (RSB) of ARPANSA has delegated responsibilities for regulatory activities that support the CEO's regulatory function. RSB staff, led by the Chief Regulatory Officer, is accountable to the CEO. The Branch has established quality management procedures which are aligned with the Policy for ARPANSA's Regulatory Activities and associated performance objectives of corporate and branch planning documents. ARPANSA is currently enhancing its regulatory management system (RMS) towards a management system that complies with *ISO:17020 Conformity Assessment – Requirements for the operation of various types of bodies performing inspection*. The regulatory policy, key processes and guidelines are described or provided on the ARPANSA website for external transparency and guidance of licence holders.

The WHS Policy is translated to licence holders through the Policy for ARPANSA's Regulatory Activities, and the components of the RMS. The overarching principles of this key policy document are reflected in the RMS, and in training and the culture of the regulatory organisation.

ARPANSA *Regulatory Services Branch Business Plan 2018-19* has a range of performance indicators, some of which emphasise leadership and management for safety. For example, to gauge ARPANSA's effect on the safety culture of licence holders there is a performance indicator that the number of self-reported non-compliances should be greater than those detected during ARPANSA routine compliance monitoring including inspections. Another performance indicator is for improvements that are implemented in the ARPANSA regulatory framework and systems of work.

ARPANSA's regulatory processes emphasise that the responsibility for safety rests with the licence holder. ARPANSA has risk informed quarterly or six monthly licence holder reporting requirements that promote openness and transparency. ARPANSA's *Compliance and Enforcement Manual* has an escalating enforcement strategy that rewards licence holders that identify and report their own problems.

4.2 Responsibility for integration of safety into the management system

Related to GSR Part 1 (Rev. 1): Requirement 19 and GSR Part 2: Requirements 3, 4 and 5

The ARPANSA Corporate Plan is the primary planning document that outlines ARPANSA's vision, mission, objectives and performance information. The Corporate Plan is aligned with the six strategic objectives that assist ARPANSA to protect the Australian people and the environment from the harmful effects of radiation. These objectives are:

- protect the public, workers and the environment from the harmful effects of radiation
- promote radiological and nuclear safety and security, and emergency preparedness
- promote the safe and effective use of ionising radiation in medicine

- ensure risk informed and effective regulation
- enhance engagement with community, industry and government
- enhance organisational innovation, capability and resilience.

The Policy for ARPANSA's Regulatory Activities outlines the agency's commitment to undertake its regulatory functions free from other pressures and for the continual improvement of all regulatory processes and procedures.

The Agency business plans and individual performance agreements are aligned with the Corporate Plan to ensure that individuals and teams contribute to achievement of ARPANSA's strategic objectives. ARPANSA's planning documents incorporate information on the strategies that will be employed to deliver on the objectives, the activities and projects that will aid in this delivery, and the measures used to assess success.

As part of the WHS Policy, there is a commitment to maintain safety systems and set measurable objectives and targets which reflect the agency's commitment to safety. The WHS *Objectives and Targets Procedure* encompasses both lead and lag safety indicators.

ARPANSA's WHS Policy and WHS Management Manual describes responsibilities and accountabilities of staff at all levels within the agency. The WHS Committee is responsible for establishing and maintaining the WHS Policy and WHS Objectives and Targets, which are reviewed annually and endorsed by the Executive Group. The WHS Committee is also responsible for maintaining the WHS Management Manual and supporting procedures.

ARPANSA's *Quality Policy* guides the development, implementation, application and continuous improvement of the management system. ARPANSA's management system is maintained in accordance with the *Documentation Management Procedure* and the *Documentation Change Control Procedure*, which describe the processes for preparing , reviewing and updating documents, approving updated documents, issuing approved updated documents and cancelling obsolete documents.

ARPANSA's planned performance is contained in the *Portfolio Budget Statements 2018–2019*, as performance measures. These performance measures set out the high-level activities ARPANSA will undertake in order to achieve our purpose, to protect the Australian people and the environment from the harmful effects of radiation through understanding risks, best practice regulation, research, policy, services, partnerships and engaging with the community.

Under the Commonwealth Government's Regulator Performance Framework, ARPANSA is required to undertake an annual self-assessment against a common set of six key performance indicators to allow for a comprehensive assessment of regulator performance. The outcomes of the self-assessment support a continuous improvement cycle by the critical analysis of ARPANSA's regulatory performance and identification of good practices and areas for improvement. In the interests of openness, and to maximise learning from the self-assessment process, ARPANSA goes further than required by the framework by including one external, independent person and another that is a senior manager from a licence holder on the five-person self-assessment team. An annual Self-Assessment Report against the requirements of the RPF is published on the ARPANSA website.

Progress against the measures and other commitments outlined in the Portfolio Budget Statement, Corporate Plan and Agency Business Plans are periodically reviewed and reported to ARPANSA's Strategic Management Committee and the Audit and Risk Committee. ARPANSA's reported results for the year against the performance criteria detailed in the Corporate Plan are published in the Annual Performance

Statement, as part of the ARPANSA Annual Report. In addition, WHS activities, issues and performance is reported to ARPANSA's Executive Group and the Audit and Risk Committee quarterly. Actions are taken where necessary by the ARPANSA Executive Group to address any deviations from performance targets.

ARPANSA's key strategies, plans and performance measures are reviewed annually as part of the Agency's integrated planning and performance cycle.

ARPANSA's WHS Policy encompasses the adoption of a holistic (systemic) safety approach that was developed to reflect the latest safety science of human and organisational factors. This best practice system comprises of seven overlapping characteristics that together help to identify and reduce vulnerabilities to common contributing causes of accidents. The seven characteristics are; human factors; non-technical skills; resilience; defence in depth; management systems; safety culture and security culture. This approach assists ARPANSA staff and licence holders to appreciate the interactions between human, organisational and technological factors. The holistic approach to safety has been extensively promoted to licence holders through conferences, meetings and ARPANSA's general oversight programme. There is extensive guidance and tools for assessing holistic safety on the ARPANSA website.

With regard to ARPANSA's regulatory approach to applicants and licence holders, ARPANSA has a range of guidance to outline regulatory requirements and expectations on its website. This is further communicated through written communication, information sharing, forums, inspections and other interactions.

4.3 The management system

Related to GSR Part 2: Requirements 6, 7 and 8

Integrated Management System

ARPANSA's Integrated Management System (IMS) is being developed and implemented incrementally across the agency. The overarching *IMS Framework* (in draft) will capture all regulatory processes as well as processes that support regulatory services, including quality, safety, security, risk, compliance and corporate governance. The IMS Framework outlines the organisational roles, responsibilities and authorities to maintain and improve the performance of ARPANSA's safety and regulatory functions through the development, application, maintenance and continuous improvement of its management system. The IMS Framework also defines the scope of the IMS and the services provided by the agency's different branches, offices and sections.

ARPANSA's organisational structures, processes, responsibilities, accountabilities, and levels of authority are specified in the following high-level documents that will form part of the IMS:

- ARPANSA Organisational Chart
- ARPANSA Committee Governance Framework
- ARPANSA Compliance Framework
- ARPANSA Risk Management Framework
- ARPANSA Planning and Performance Framework
- Policy for ARPANSA's Regulatory Activities
- Quality Policy
- Work Health and Safety Policy

- Protective Security Policy.

Risk management

ARPANSA's *Risk Management Framework* is the core of the IMS. Radiation risk is central to ARPANSA's role in the community, and thus risk management is a key element of ARPANSA's business planning and is central to the way ARPANSA manages its operations and how the IMS is structured. Effective risk management holds a focus on managing risk to ARPANSA's performance outcomes, whereby risk management processes provide the link between ARPANSA's stated strategic objectives and the operational business plans to achieve these objectives.

Our framework deals with three main types of risks:

- risks to our ability to carry out our statutory functions (such as funding, legal, government, policy, staffing level and competence obligations)
- risks to our people and assets (such as a safe work environment and practices, protective security, and asset management)
- radiation risks to the Australian people and environment (such as risks to workers, the public, patients undergoing medical procedures, and the environment), which ARPANSA is responsible for managing under the ARPANS Act.

Our framework, together with supporting WHS procedures, considers the hazards and magnitude of the potential risks associated with the health and safety of our people and environment. In particular, the ARPANSA risk matrix within the framework takes into account the possible consequences for safety if a failure or an unanticipated event occurs or if an activity is improperly conceived or executed.

Governance

The CEO is the ultimate decision maker in all matters that relate to the CEO's functions, as set out in section 15 of the ARPANS Act. The CEO is accountable to Parliament and reports to Parliament via the Minister. The CEO is, in carrying out their functions, supported by a number of advisory bodies and committees, some of which are internal, and some of which are statutory under relevant legislation.

One of the key components of the IMS is the ARPANSA *Committee Governance Framework* which outlines the role and function of the statutory and internal committees and how responsibilities assigned to the regulatory body are properly discharged. The Committee Governance Framework is supported by terms of reference documents which describe the specific functions of each of the committees and groups that form ARPANSA's governance structure. In particular, ARPANSA's Strategic Management Committee, Executive Group, Audit and Risk Committee, Work Health and Safety Committee, Radiation Safety Committee, Agency Security Group, Project Management Advisory Group, and Branch Quality Committees all have a role to play in the development, application, maintenance and continuous improvement of the management system.

The functions of these committees are aligned with, and contribute to the achievement of the WHS objectives and targets and continuous improvement of the WHS management system.

The relationship between ARPANSA's statutory and internal committees is illustrated in Figure 9.

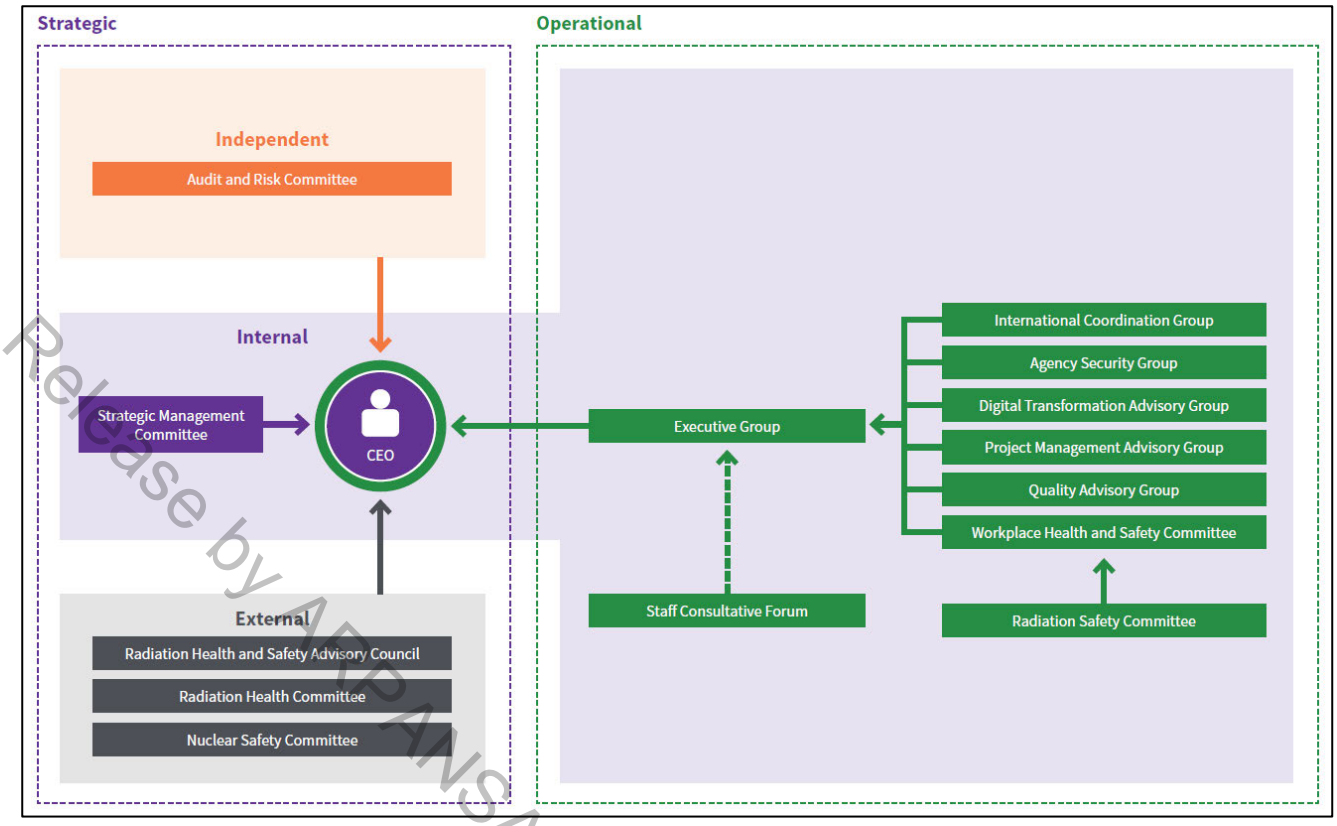

Figure 9: ARPANSA Committee Governance Structure

Compliance

The ARPANSA *Compliance Framework* outlines the process for identifying, monitoring, assessing and recording the agency's compliance requirements. This framework forms a key component of the IMS to achieve effective corporate governance through the implementation of integrated risk and compliance processes across the agency. The Compliance Framework describes how ARPANSA complies with all regulatory requirements that apply to the agency and the responsibilities and accountabilities for establishing and maintaining an effective compliance framework. This document is available on the staff intranet.

Planning and performance

ARPANSA has a well-established planning and performance process which enables ARPANSA to define its vision and strategic objectives and to assist the agency in making decisions on allocating resources to pursue its purpose to protect the Australian people and the environment from the harmful effects of radiation. The ARPANSA *Planning and Performance Framework* is under review and is currently in draft form. Effective implementation of the framework ensures that the Agency operates efficiently and that work is completed in accordance with requirements, expectations, plans and resources. It also allows ARPANSA to develop accurate and reliable performance information to help officials, ministers, the parliament and the public form judgements on whether the agency is delivering on its intended results, as identified in our key planning documents, namely the ARPANSA Portfolio Budget Statement and the ARPANSA Corporate Plan.

Regulatory processes

The *Policy for ARPANSA's Regulatory Activities* outlines the commitment of the CEO to carry out their regulatory functions, and of ARPANSA to carry out activities that support the CEO's regulatory functions under the ARPANS Act and the ARPANS Regulations. ARPANSA will, as applicable, implement and act in accordance with the *Australian Government Guide* to Regulation and the Australian Government's *Regulator Performance Framework*, and the Australian Government publication *International Standards and Risk Assessments*, and with other guidance relevant to Commonwealth regulatory activities.

ARPANSA's Regulatory Services Branch (RSB) has established quality management procedures within the Regulatory Management System (RMS) which are aligned with the Policy for ARPANSA's Regulatory Activities and associated performance objectives of corporate and branch planning documents. As previously mentioned, ARPANSA is currently enhancing its RMS towards a management system that complies with *ISO: 17020 Conformity Assessment – Requirements for the operation of various types of bodies performing inspection*.

The RMS incorporates an approach to ARPANSA's regulatory activities that ensures a graded approach is implemented that is informed by hazard and risk. A key process to achieve this is the determination of the regulatory priority for each licence and is explained in the ARPANSA *Inspection Manual*. Source licences are graded based on the inherent hazard of the source, in accordance with its categorisation in the ARPANS Regulations. Facility licences have a more complex ranking system that is based on the categorisation of a facility but that also takes account of the level of safety controls built into the facility, past regulatory performance and the licence holder knowledge of and approach to holistic safety. This process provides the basis for setting the frequency, scope and depth of baseline inspections. A key document for planning and conduct of inspections is the ARPANSA Performance Objectives and Criteria (PO&C) that are designed to be used in a graded manner. ARPANSA can also undertake additional 'augmented' inspections in response to poor performance or specific safety issues, incidents or accidents.

The ARPANSA *Compliance and Enforcement Manual* is another RMS document that clearly articulates a risk informed and graded approach to regulation. The manual describes the range of interventions available to correct matters of non-compliance up to licence cancellation or legal action. ARPANSA always strives to use the lowest form of enforcement needed to restore compliant behaviour.

In practice, while RMS has the same or very similar processes in place for regulatory activities regardless of the hazard/risk that they present, a graded approach is applied to all regulatory work and this is easily shown through a time tracking system used by Regulatory Services Branch. Whilst most licences represent hazards/risks at the lower end, around 80% of activities that can be ascribed to the management of specific licences, relate to medium or higher hazard/risk licences.

Occasionally an employee may express a professional opinion in regard to technical matters, regulatory approaches or functions, which differs from prevailing staff opinions, or management decisions and which is not resolved through normal processes. ARPANSA's *Procedure for Managing Differing Professional Opinions* within the RMS describes the actions and responsibilities for expressing, documenting and arbitrating differing professional opinions related to technical or legal issues. Usually these differences are resolved by discussions within a peer group or with supervisors. Where they are not resolved, there is a process for respectively working through them to find a resolution, which is further discussed in section 3.2 of this report. This is a sign of a healthy workplace culture and is encouraged.

Supporting processes

ARPANSA has developed the required policies and supporting procedures that govern day-to-day operations to ensure that quality, safety and security elements are aligned with organisational goals and are integrated into the management system.

Quality

ARPANSA's Quality Policy guides the development, implementation, application and continuous improvement of the integrated management system. ARPANSA's quality management procedures sit within the overarching IMS Framework and aim to be consistent with the requirements of *ISO 9001:2015 Quality management systems – Requirements*.

Control of documents within the IMS are managed in accordance with ARPANSA's quality system. The procedures for the ARPANSA records management system (HPERM) support this process. The ARPANSA document control process is defined in the Documentation Management Procedure, whereby all documents are controlled, and are allocated a unique documentation identification number. Documents are maintained digitally and their access is controlled within HPERM. For security and commercial-in-confident reasons access is granted on a need-to-know basis but generally all regulatory staff have open access to regulatory documents.

The *Documentation Management Procedure* and *Documentation Change Control Procedure* outlines the process for preparing , reviewing and updating documents, approving updated documents, issuing approved updated documents and cancelling obsolete documents. Work instructions exist for each of these tasks and are available within the ARPANSA quality system and on the staff intranet.

The creation and revision of documents occur within HPERM whereby an audit log exists for each record which documents all actions which have occurred. This audit log displays the time and date of all changes to documents as well as the user who performed these changes. Previous revision of documents can be viewed from HPERM also.

All controlled documentation within the ARPANSA quality system are required to be reviewed at intervals of no greater than 24 months. All documents go through the same approval process regardless of whether they are newly created documents or they are documents which have been revised. This approval process is documented in the *Documentation Change Control Procedure* and in work instruction *Develop, Review and Approve Documents*.

The management system has been developed to comply with ARPANSA's *Recordkeeping Policy*. This policy provides the overarching framework for all of ARPANSA's recordkeeping practices and procedures, including within individual work area where all guidelines and work instructions must be consistent with the policy. All documents are maintained in HPERM with quality documents being saved with the record type 'Quality Documents' and appropriate metadata fields are used to store information about the records (e.g. document ID).

The RMS is documented in accordance with the requirements of the ARPANSA quality system and it provides procedures and instructions that detail the full range of regulatory interactions with ARPANSA licence holders. The RMS is documented in HPERM and a *Register of Document Status* provides a list of all records management system documents and their history.

Safety

ARPANSA's Work Health and Safety Policy (WHS Policy) underpins the agency's approach to achieving goals safely, enhancing safety and fostering a strong safety culture as outlined in the following policy commitments:

- Prioritise safety with other organisational goals and thereby achieving business objectives without undue risk.
- Ensure that continuous improvements are measured, evaluated and reported against the agency goals and objectives.
- Embed safety systems across the whole organisation and nurture a safety culture.

The WHS Policy outlines the fundamental safety objectives of the agency. As part of the WHS Policy there is a commitment to maintain safety systems and set measurable objectives and targets to ensure continued improvement aimed at the elimination of risks. ARPANSA sets annual work health and safety performance targets and objectives, which reflect the agency's commitment to safety. The *WHS Objectives and Targets Procedure* encompasses both lead and lag safety indicators.

The WHS Management Manual and supporting procedures sit within the overarching IMS Framework and provide the mechanism for achieving policy commitments by outlining the key elements for managing safety, which are relevant to the operations of the agency.

Decisions made in relation to internal safety arrangements are communicated via ARPANSA's Executive Group, WHS Committee and the Staff Consultative Forum. The minutes of these meetings are made available to staff via the ARPANSA intranet.

Security

The Australian Government is committed to effectively managing the protective security risks to Government business and building increased trust, confidence and engagement with the Australian people and our international partners. The Government requires agency heads to have in place effective protective security arrangements to ensure:

- their respective agency's capacity to function
- the safety of those employed to carry out the functions of government and those who are clients of government
- official resources and information the agency holds in trust, both from and for the public, and those provided in confidence by other countries, agencies and organisations, are safeguarded.

To achieve this, the CEO of ARPANSA applies the Protective Security Policy Framework (PSPF). The PSPF is based on principles of public sector governance including:

- accountability – being answerable for decisions and having meaningful mechanisms in place to ensure the entity adheres to all applicable protective security standards
- transparency – clearly defining roles and responsibilities within entities for protective security functions and clear procedures for making decisions and exercising authority
- efficiency – effectively using resources to implement risk-based protective security strategies

- leadership – achieving an entity-wide commitment to protective security through effective leadership.

The CEO appointed a Security Executive at the senior executive service level, an Agency Security Adviser (ASA) and an IT Security Adviser (ITSA) in order to establish and maintain an effective protective security program for ARPANSA. The ASA and ITSA are required to maintain their knowledge and skill levels relevant to their positions, to ensure the effective management of protective security within ARPANSA, such as in protective security technical competence (in physical security, personnel security and information security), security risk assessment and management including cost-benefit analysis, developing and delivering security awareness training and security incident investigations.

The protective security policy, plan and procedures are established in the *ARPANSA Protective Security Document Framework* and are to be adhered to by all ARPANSA employees, contractors and consultants engaged by ARPANSA. They underpin the dynamic nature of ARPANSA's work domestically and internationally, providing the necessary protection to enable ARPANSA to function effectively ensuring our information and assets are not compromised.

The ARPANSA Protective Security Policy (APSP) outlines the overarching protective security policies that reflect the requirements necessary to maintain an appropriate standard for protecting our assets, that being our people, information, intellectual property, activities and facilities. The APSP maintains, as a minimum, the requirements of the PSPF.

The ARPANSA Agency Security Plan outlines ARPANSA's security risk profile and details our approach to managing protective security, including the expected activities and treatments that will meet APSP and PSPF compliance requirements and, more importantly, ensure the continuous protection of ARPANSAs people, information and assets against the identified risks and assessed business impact levels.

The CEO submits the required annual PSPF compliance reports to the portfolio Minister every year.

4.4 Management of resources

Related to GSR Part 2: Requirement 9

Regulatory resourcing requirements are addressed through business and strategic planning which is led by senior management.

Section 4 of the ARPANSA *Inspection Manual* identifies the core competencies (skills, knowledge and attitudes) for Inspectors and this is taken into account in the recruitment and personnel development processes. Recruits are hired with pre-existing competencies which are then supplemented with on-the-job and other training that allows them to fully participate in the regulatory business.

The future adoption of *ISO 17020:2012 Conformity assessment – Requirements for operation of various types of bodies performing inspection* and equivalent arrangements for all regulatory processes and the ARPANSA Workforce Plan supports the identification, development and maintenance of competency requirements. This will be incorporated into the work to develop agency wide competencies as part of HR processes. ARPANSA has tested a 'Qualification Card' system with associated defined competencies that all regulatory officers must meet before becoming an Authorised Inspector.

Senior management ultimately determines which competences and resources the regulatory body needs to discharge its responsibilities. Senior management also determines which competences and resources the regulatory body has to retain or has to develop internally, and which competences and resources may be obtained externally. Competences to be sustained in-house by the regulatory body include competences for leadership at all management levels.

The ARPANSA Executive Group has approved the implementation of a *People Manager Capability Framework* for initial application to the Executive Group. The framework comprises people management performance expectations for APS and Executive Level people managers, Directors, and Branch/Office Head roles. The performance expectation descriptors are aligned with the Australian Public Service Work Level Standards.

ARPANSA's *Work Health and Safety Policy* articulates the adopted values and behavioural expectations that the organisation places on safety. This, alongside ARPANSA's holistic approach to safety, which includes the characteristic of safety culture, reinforces the importance of safety in the work place and normalises safe attitudes in the workplace. Competencies for safety are determined as part of job and task descriptions and are delivered through group training or where appropriate individual development plans. The determination of training needs is undertaken wherever safety matters are reported or through risk assessment. ARPANSA's aim is to continuously build safety competencies in its workforce through these processes. All regulatory officers have been provided training in safety culture and holistic safety so that they are able to identify weaknesses in the safety culture of licence holders.

This includes formal and ongoing identification of agency knowledge gaps and necessary training consistent with the development of ISO17020 extended to all regulatory processes. Branch training is conducted on a regular basis and each staff member commits to an individual development plan as part of their annual performance review. This plan, which is developed between the staff member and supervisor, identifies any individual training needs to maintain and extend personnel competencies and meet the strategic direction of the agency.

In February 2018, ARPANSA launched LearnHub, an electronic learning management system, which has the functionality to store records of capabilities, and courses aligned to capabilities, as well as the completion of courses by individual employees.

4.5 Management of processes and activities

Related to GSR Part 2: Requirements 10 and 11

Regulatory services are delivered in accordance with the RMS and the overarching ARPANSA management system. There are procedures and instructions relating to the delivery of all regulatory services. The key documents in this regard are:

- Inspection Manual
- Licensing and Assessment Manual
- Compliance and Enforcement Manual.

Supporting quality documents are hyperlinked from within these manuals and include a range of instructions, templates and forms. A full list of RMS documents and their history is found in the ARPANSA Register of Document Status.

Any changes to the RMS are subject to consideration of the Regulatory Services Branch (RSB) Quality Committee and are authorised by the Branch Head (the RSB Quality Committee is made up of each RSB Director, the Branch Quality Coordinator and the ARPANSA Quality Manager). The delivery of regulatory services is also subject to regular performance monitoring, review, assessment and feedback which should identify any procedural problems affecting the quality of services.

As previously mentioned in section 4.3, control of documents is managed in accordance with the ARPANSA quality system. The procedures for the ARPANSA electronic records management system (HPERM) support this process.

An orientation and training program occurs for all new employees. This includes discussing local work practices specific to that work area. Relevant supervisors are responsible to ensure that their staff are aware of and adhere to the ARPANSA quality system policies and procedures within. The Quality Manager has defined responsibility and authority for ensuring that the ARPANSA management system related to quality is implemented and followed.

As outlined in the *Documentation Management Procedure*, all ARPANSA staff undergo regular mandatory training in relation to recordkeeping policies and procedures and specific subject-based training is available where required and requested.

Guidance, procedures and staff training for archiving statutory requirements and records management in general are in place.

ARPANSA manages procurement in accordance to the *Public Governance, Performance and Accountability Act 2013,* the *Public Governance, Performance and Accountability Rule 2014* and the Commonwealth Procurement Rules 2018.

This overarching legislation and guidance is communicated to ARPANSA staff through the *Procurement Accountability Authority Instruction* (AAI), which is published on the Agency's intranet where all staff are able to access it.

ARPANSA is obliged to make use of the Commonwealth Contracting Suite (CCS) for all procurements under $200,000 unless certain exemptions apply. The CCS is an online interactive suite of smart forms designed to assist procurement officials prepare procurement documentation for Commonwealth procurement valued under $1 million. The CCS reflects Government policy to streamline business between the public and private sector and has standard terms and conditions to ensure consistency and ease of use. CCS standard contracts include clauses for security and Work Health and Safety (WHS).

All procurements over $10 000 must include the preparation of a *Procurement Plan – over $10 000* form where safety considerations must be listed in consultation with the WHS Advisor. Evaluations of quotes and tenders take place by cross–representational teams after first completing a Tender evaluation panel – conflict of interest declaration form. Any procurement of contractors and labour hire workers where the value of the contract exceeds the procurement threshold that results in the need to tender for services, will invoke the *Work Health and Safety Contractor Assessment and Selection Procedure*. The procedure allows for the review and assessment of the tenderer's ability to meet their obligations in relation to work health and safety, which ensures that any products or services procured are safe and fit for purpose.

Ongoing management and monitoring of contractors in relation to safety is detailed in accordance with the *Work Health and Safety Contractor Inspection Procedure*, which outlines the parameters for monitoring performance and the required frequency based on the level of risk.

A number of external experts have been identified and utilised to provide services in the form of advice when needed. While there is no formal process that details the circumstances when it calls upon external expertise it is the responsibility of regulatory officers, working with the Corporate Office, to determine the specific requirements needed in any contract and to work with the Corporate Office. There are networks available through IAEA activities and the following independent advisory committees:

- The Nuclear Safety Committee advises the CEO and the Council on matters relating to nuclear safety and the safety of controlled facilities, including developing and assessing the effectiveness of standards, codes, practices and procedures.
- The Radiation Health Committee advises on matters relating to radiation protection, including formulating draft national policies, codes and standards for consideration by the Commonwealth, states and territories.
- The Radiation Health & Safety Advisory Council identifies emerging issues and provides advice on radiation protection and nuclear safety, including advice on the adoption of recommendations, policies, codes and standards.

The advisory bodies' functions and membership are defined in Part 4 of the ARPANS Act. The functions are further explained on the ARPANSA website.

4.6 Culture for safety

Related to GSR Part 2: Requirement 12

ARPANSA's definition of safety culture is consistent with the established IAEA safety culture model but includes an additional attribute of integration across organisational boundaries. It includes a direct reference to the safe behaviours that come from shared values and beliefs. ARPANSA influences licence holders by identifying behavioural expectations, which are found in ARPANSA's Holistic Safety Guidelines. This goes beyond the IAEA model with the inclusion of other modern safety science principles such as non-technical skills and resilience. The holistic approach also integrates safety and security principles wherever feasible. The principles of holistic safety are emphasised throughout ARPANSA's PO&Cs which are used during the planning and implementation of regulatory inspections. Safety culture is one of three cross cutting areas of the PO&Cs. ARPANSA's ability to identify 'areas for improvement' during inspections is a powerful tool to help improve safety culture of licence holders even if there is insufficient evidence of non-compliance. The PO&C are also available on the ARPANSA website for stakeholders to use pro-actively.

Safety is a key value for all ARPANSA staff and is directly driven from ARPANSA's mission to protect people and the environment from the harmful effects of radiation. WHS promotion within the agency includes safety moment/issues as part of all important meetings including weekly managers meetings, and senior leadership meetings, such as the Strategic Management Committee, Executive Group and Audit and Risk Committee. The WHS Committee, which is chaired by the CEO, actively encourages and supports individuals to achieve safety goals and the ARPANSA intranet is used to support this.

There is extensive consultation on the development of all processes and policies amongst staff. All staff are able to raise suggestions for performance improvements including safety. This is usually done via the section managers, but Branch and Office Heads and the CEO have an 'open door' policy to staff. Staff are also able to participate in localised and agency wide enhancements to safety performance via the following forums:

- participation and contribution in the Hazard Identification, Risk Assessment and Management (HIRAM) process
- Work Health Safety Committee
- Staff Consultative Forum
- Consultation on the development/review of policies and procedures via the ARPANSA intranet
- Report Card process.

The WHS Policy promotes safety culture by employing a holistic safety approach in accordance with the ARPANSA Holistic Safety Guidelines. The WHS Policy and WHS Management Manual encourages staff to raise safety concerns in accordance with the *Work Health and Safety Act 2011*. A number of activities and initiatives, including WHS induction training for new staff and contractors, WHS training for supervisors, WHS inspection program, participation and contribution in the HIRAM process, report card process and promotion of a safe and healthy workplace through newsletter articles and staff presentations.

The WHS Management Manual outlines the mechanisms by which staff can actively participate in the raising of issues and being involved in decision making in relation to safety. Hazard report cards provide workers with a way to report both positive observations and opportunities for improvement in relation to safety, which can be submitted anonymously if people wish to do so.

The agency also measures a questioning and learning attitude towards safety through positive performance indicators that are included as part of the agency's WHS Objectives and Targets.

4.7 Measurement, assessment and improvement

Related to GSR Part 2: Requirements 13 and 14

The *WHS Objectives and Targets Procedure* provides a mechanism for the agency to measure safety performance and a commitment to continuous improvement in safety. The *WHS Safety and Objectives Targets and Procedures* are reported to the Executive Group on a quarterly basis to ensure that senior management have visibility of the agency's safety performance. The Executive Group comprises members from each Branch and Office of the agency, which means that safety performance results are disseminated across the agency. Safety performance results are also reported to the Work Health and Safety Committee, Audit and Risk Committee and Staff Consultative Forum on a quarterly basis. ARPANSA's regulatory performance is also required to be reviewed annually under Australian Government Regulator Performance Framework that strives to ensure that all Commonwealth regulators are effective and efficient.

The draft ARPANSA Planning and Performance Framework outlines the Agency's approach to business planning and performance monitoring.

ARPANSA's planning documents incorporate performance information, including the strategies that will be employed to deliver on these, and the activities and projects that will aid in this delivery. This includes outcomes-based key performance indicators as required by the RPF, which encourages regulators to undertake their functions with the minimum impact necessary to achieve regulatory objectives and to effect positive ongoing and lasting cultural change within regulators. Progress against the measures and other commitments outlined in the Corporate Plan and Agency Business Plans are monitored and reported to ARPANSA's Strategic Management Committee and the Audit and Risk Committee on a quarterly basis.

ARPANSA's results for the year against the performance criteria detailed in the Corporate Plan are published in the Annual Performance Statement, as part of the ARPANSA Annual Report.

ARPANSA undertakes an annual self-assessment against the requirements of the Australian Government's RPF. The outcomes of the self-assessment support a continuous improvement cycle by the critical analysis of ARPANSA's regulatory performance and identification of good practices and areas for improvement.

All regulatory services are undertaken in accordance with the Regulatory Management System (RMS) that lies under the overarching ARPANSA management system. The RMS was established more than a decade ago and stipulates the activities necessary to carry out the regulatory activities as required by the ARPANS Act and Regulations. ARPANSA has established a Safety Systems Section within RSB, the functions of which include managing the RMS including internal performance monitoring, customer satisfaction surveys, annual training, reporting and continuous improvement. Safety Systems works closely with the ARPANSA Corporate Office that has responsibility for the overarching ARPANSA quality system. Safety Systems Section also undertakes the annual self-assessment required under the Australian Government RPF.

Progress against the measures and other commitments outlined in the Portfolio Budget Statement, Corporate Plan and Agency Business Plans are periodically reviewed and reported to ARPANSA's Strategic Management Committee and the Audit and Risk Committee. ARPANSA's results for the year against the performance criteria detailed in the Corporate Plan, are published in the Annual Performance Statement, as part of the ARPANSA Annual Report.

ARPANSA's key strategies, plans and performance measures are reviewed annually as part of the Agency's integrated planning and performance cycle.

The RSB Safety Systems Section evaluates performance on an ongoing basis and recommends improvement in regulatory processes as required.

The agency's management systems are subject to both internal and external reviews at defined intervals. Internal assessments are undertaken in accordance with the ARPANSA quality system and the WHS management system within particular areas i.e. monthly workplace inspections. Periodic external assessments are undertaken in accordance with the Audit and Risk Committee's requirements, whereby an external entity is engaged to conduct internal audits. The agency has also participated in external audits of the Work Health and Safety Management System that are undertaken by Comcare, the Commonwealth work health and safety regulator. ARPANSA has participated in both the initial and intermediate level audits, which resulted in a number of safety improvements as part of the audit findings.

ARPANSA has engaged external consultants to undertake a comprehensive review of the agency's radiation safety system (Radiation Safety Management System Review). The review commenced in July 2018 and is scheduled to be completed by November 2018 with the revised system to be fully implemented by July 2019. A snapshot report was provided in August 2018, which provides an overview of what has been identified so far and how opportunities for improvement will be managed as the project progresses. The aim of the review is to ensure that the Agency has an effective and contemporary radiation safety system that is the exemplar for domestic licence holders, which is recognised both locally and internationally. Internal audits from both a quality and safety perspective are undertaken by suitably qualified auditors who are independent from the work areas being audited and are given appropriate authorisation to access all relevant information to undertake the audit.

All audit findings are entered into the Issues Management Register, which allows findings to be tracked and actioned in a timely manner in accordance with the quality management procedures. The register is

internally available to all staff via the intranet so that other areas of the agency can access information and implement learnings from other areas of the organisation.

ARPANSA has an internal audit program provided by a third party designed to ensure the Agency's compliance with relevant legislation and standards. The ARPANSA Strategic Internal Audit Plan outlines the audit program to provide assurance to ARPANSA's Executive Group and Audit and Risk Committee about the Agency's processes, governance, and systems of internal control and risk management.

4.8 Conclusions and actions

ARPANSA has a draft framework for the implementation of an IMS. Documented procedures, policies and record management practices are in place to allow the regulator to effectively discharge their functions within the RMS. The ARPANSA documentation of the management system is controlled, usable, readable, clearly identified and readily available at the point of use. The effectiveness of the management system is also assessed as part of internal audits and reviews such as the Regulatory Performance Framework Self-Assessment.

In ARPANSA's continued efforts to firmly establish and further develop the integrated management system, the following actions are a priority:

- The management system does not currently integrate across the agency and across functional objectives. Additionally the current system functionality is only capable of limited analysis of data and so information which may aid decision making and improvement activities may not always be available. Several initiatives are currently being pursued as part of the IMS project (see Action Plan item 9) and a project to replace the current system for the management of regulatory information including authorisations and compliance monitoring, is currently being considered (see Action Plan item 10).
- The ARPANSA training for inspectors and learning system could be enhanced. Several initiatives are under development for competency requirements, training for inspectors and learning opportunities could be enhanced. These enhancements form part of the ISO 17020 project (see Action Plan item 4).
- Individuals in the organisation, from senior managers downwards, are passionate about having a strong influence on safety. Senior management has recently commissioned an assessment of the culture for safety at ARPANSA. This assessment shall help to drive improvement and measure the effectiveness of enhancements which may be identified (see Action Plan item 11).

5. Authorisation

This section includes responses from all Australian jurisdictions on generic issues (5.1), and from most jurisdiction on sources, facilities and activities (5.2) and transport (5.6).

The sections on research reactors (5.3), waste management (5.4) and decommissioning (5.5) relate to the Commonwealth regulator, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

5.1 Generic issues

Related to GSR Part 1 (Rev. 1): Requirement 4, paragraph 2.12; Requirements 23 and 24
Related to GSR Part 3: Requirements 6, 7, 8 and 13, GSR Part 4: Requirement 21

Authorisations overview

In Australia, a person (individual or corporation) is prohibited from dealing with a radiation source unless they are covered by a licence or an exemption, under the relevant jurisdictional legislation. Most jurisdictions also authorise or accredit experts to perform certain functions such as equipment verification (e.g. a compliance test), or to provide certain services. Additionally, notifications or approvals are required for some activities such as specific types of disposal, transport or management of incidents. ARPANSA manages the authorisation of import and export permits for radiation sources on behalf of the Department of Home Affairs. Only ARPANSA authorises nuclear installations (as defined in the ARPANS Act).

ARPANSA authorisations

Sections 30 and 31 of the ARPANS Act specifies that a controlled person must not undertake certain activities without authorisation in the form of a licence. Section 10 of the Act specifies that the CEO must not authorise the construction or operation of a nuclear fuel fabrication plant; a nuclear power plant; an enrichment plant; or, a reprocessing facility.

In taking a decision on authorisation in the form of a facility or source licence, the CEO (or delegate) of ARPANSA must take into account international best practice in relation to radiation protection and nuclear safety (sections 32 and 33 of the Act). The CEO must also take into account matters that are specified in regulations 41 and 42 of the ARPANS Regulations.

All applications received by ARPANSA are assigned to a regulatory officer and processed in accordance with the procedures outlined in the Regulatory Management System (RMS). The CEO of ARPANSA, or delegate, makes decisions based on advice from staff and, where applicable, advice from external sources such as the Nuclear Safety Committee (NSC).

There are a number of different types of applications processed:

- ARPANSA issues source and facility licenses under sections 32 and 33 of the ARPANS Act. These authorisations are issued to Commonwealth entities and cover 'controlled persons' as defined in section 13 of the Act. A licence is required to deal with any radiation source or facility, which includes possession or disposal of non-exempt material. In line with a graded approach, requirements on demonstration of safety are more detailed for higher hazard/risk facilities than for lower hazard/risk source licences (see section 5.2 and section 6)

- in addition to generic exemptions (such as exempt dealings in schedule 2 of the Regulations), persons may apply for a specific exemption such as from the requirement to hold a licence under regulation 37. For example, ARPANSA has exempted siting licences (pre-construction activities) for accelerators at existing facilities where adequate measures are in place. In addition, ARPANSA may exempt specific dealings under regulation 38(5) subject to certain requirements
- individual approval is required for most types of disposal, under regulation 53, while notification is required for the transfers of sources between authorised parties. Additionally, a licence may authorise regular discharges, or clearance, below levels set in the licence without further approval
- transport plans for security enhanced sources, and certain types of shipment and packaging require approval under *Code of Practice for the Security of Radioactive Sources 2007* (RPS 11) and *Code of Practice for the Safe Transport of Radioactive Material* 2014 (RPS C-2). Compliance with both Codes is a condition of licence (see section 5.6)
- source security plan approvals, issued by ARPANSA (the regulatory body) or accredited security experts, are required under RPS11, which is a condition of licence
- any change with significant implications for safety requires approval under regulation 51, while non-significant changes require notification under regulation 52. A regulatory guide has been prepared to assist licence holders with this determination and submission (see section 5.2)
- approval to construct a safety item is required under regulation 54, for any item that is important for the safety of a controlled facility, as identified in a safety analysis report.

As ARPANSA does not licence individuals, no application or notification requires specific qualifications of authorised personnel. However, training and staffing form part of general licence requirements as laid out in the Regulatory Guide: Plans and Arrangements for Managing Safety, the arrangements for which are reviewed during authorisation and verified through inspection. These are also required to be reviewed by the licence holder on a periodic basis under regulation 50.

The CEO may impose conditions (section 35 of the Act) and may amend a licence (section 36 of the Act) at any time, by written notice to licence holder. Licences that are not time limited will be in force until the licence is suspended, cancelled (section 38) or surrendered (section 39).

All licence decisions, including issuing or refusing a licence, are eligible for review. Under section 40 of the Act, an eligible person may request the minister to review the decision of the CEO and may apply to the Administrative Appeals tribunal to review the decision of the minister.

Import and export applications

A permit is required under the Customs (Prohibited Exports) Regulations 1958 to export high activity radioactive sources – which are defined in the Regulations – out of Australia, and under the Customs (Prohibited Imports) Regulations 1956 to import any (no minimum activity or concentration limit) radioactive substances into Australia. Permits are valid for single shipments or for a period of 12 months.

To obtain a permit, an application must be submitted to ARPANSA with details on the importer/exporter's licence status, the details of the sources, and end user information. Non-medical import applications require information on storage; medical import requires information on product registration; and for export permits transport information is also required.

Disposal

Disposal includes apparatus and material that is transferred, material which is placed in permanent disposal, or apparatus which is destroyed. ARPANSA requires the prior approval for disposal of most sources (ARPANS Regulation 53), and notification only for transfer between two Commonwealth licence holders. Information on this process is provided in a regulatory guide.

State and Territory authorisations

In most States and Territories, activities requiring authorisation are limited to dealing with sources, as such site preparation or construction are typically not licensable activities until a source is possessed or used. However, the construction of facilities is licenced in some jurisdictions including VIC and SA. In QLD and VIC an approval is required prior to acquiring a source. Additionally, arrangements are in place in all jurisdictions, such as shielding plan/requirements and sale/supply licences or restrictions on supply, which effectively introduce controls on the construction and supply phases. For example, there may be a requirement only to sell a radiation source to a person who holds an appropriate licence or exemption.

Applications and notifications include:

- applications for management and possession licences, for individuals or companies, are required in all jurisdictions (see section 5.2)
- user licences, for individuals dealing with sources, require an application in most jurisdictions. This includes maintenance, service, and testing (see section 5.2)
- registration of individual sources require an application in most jurisdictions and notification in other jurisdictions (see section 5.2)
- disposal of sources, for individual sources, require notification in most jurisdictions, and approval in others, while routine disposal via discharges of radioactive material requires an appropriate licence
- varying an authorisation previously granted, or where the particulars of the applicant have changed
- supply/service notification may be required, depending on the local jurisdiction, as a condition of licence
- mining regulations and environmental legislation may require additional applications and notifications that are not covered under the radiation regulatory bodies' mandate (outside of scope for this IRRS).

Accreditation is the formal recognition of a person to perform a safety related function. Where this function involves dealing with radiation source an authorisation (licence) may also be required. Examples of accreditations or approvals granted by some jurisdiction include:

- security plan/transport security plan approved assessors (e.g. VIC)
- compliance testers (e.g. VIC, NSW, SA, TAS, QLD)
- shielding plans (typically included in compliance testing accreditation)
- dosimetry service provider (e.g. NSW)
- training courses (e.g. NSW, VIC, QLD)
- radiation Safety Officer (e.g. QLD)
- medical physicists/qualified experts (e.g. VIC, QLD).

Information on documentation that is required to be submitted to the regulatory body prior to authorisation, including safety assessments such as those that are covered by the radiation management plans, is provided on the jurisdictions' websites (e.g. NSW, TAS, QLD, VIC, WA).

The States and Territories generally document their review and assessment using checklists (see section 6 on review and assessment). Depending on the application, this assessment may include review by an advisory body to the regulator. During this process the regulatory body may apply conditions to any authorisation.

Applicants can appeal the decisions of a regulatory body through the minister and/or the relevant administrative appeals tribunal as defined in the relevant legislation.

Disposal

For individual apparatus, most jurisdictions such as NSW require notification of disposal within a set period, typically 14 days. Some jurisdictions, require prior approval depending on the type of disposal. Disposal of sealed sources generally requires approval and disposal of unsealed material is typically through a licence that permits disposal.

For example in QLD, notification within 7 days is required after the disposal of x-ray equipment or laser apparatus. No notification/approval is required for radioactive substances that are below a prescribed concentration level, whereas for the disposal of radioactive substances above that level, an approval is required. QLD has a prior approval requirement in place for any radiation source that is being relocated out of the jurisdiction.

Compliance test

In the States and Territories, individual sources, as applicable, are tested by persons accredited to perform such tests by the regulatory body. These tests are performed against specific requirements set by the relevant jurisdiction's regulatory body and vary across jurisdictions. Typically, this includes all medical equipment, and most industrial equipment. The requirements are usually based on Australian standards or, where applicable, international standards. Testing protocols or required outcomes are available on the relevant jurisdiction's website.

In most jurisdictions that have source registration (such as the ACT), evidence of a satisfactory compliance test is required prior to use, as part of the registration process. In other jurisdictions (such as QLD) sources are registered and require periodic testing as a separate process. Either a certificate submitted or, in other jurisdictions, the full report with test results is required. In most jurisdictions these tests are required at either a set frequency or when re-applying for registration (renewal). For example, in WA, the Radiological Council's 'Fixed Industrial Gauges Compliance Testing Program' requires the triennial testing of fixed industrial gauges for compliance with the program's requirements and results must be submitted to the regulator prior to registration.

5.2 Authorisation of radiation sources, facilities and activities

Related to GSR Part 1 (Rev. 1): Requirements 23 and 24, GSR Part 3: Requirements 6, 7 and 8

All jurisdictions maintain records of applications and authorisations within their records management system. This includes the use of a database, and the use of digital records and paper records, in accordance with the relevant jurisdiction's records management requirements. For ARPANSA, licences are issued as a certificate, with key information maintained in a database (see section 4).

ARPANSA authorisations

Facility licences

Facility licenses include higher hazard/risk uses such as the research reactor, irradiation facilities, medical isotope production facilities, large accelerators and legacy sites. Controlled facilities are defined in section 13 of the ARPANS Act, which includes the radiation facilities prescribed under division 2 and 3 of the Regulations. A facility licence may also authorise dealings with sources.

Authorisations of facility licences (controlled facilities) are staged as follows: site preparation, construction, possession or control, operation, de-commissioning, remediation of a legacy site, and abandonment (section 30 of the Act; Schedule 3 Part 1 of the Regulations). Additionally, conditions may apply or be imposed by the CEO (section 35 of the Act), e.g. to introduce additional hold points such as requiring the submission and review of commissioning results.

Information required to be submitted with all facility applications, which includes requirements for safety assessments (required under regulation 39), is listed in Schedule 3 of the Regulation. Additionally, the CEO may require further information to satisfy the relevant requirements. Examples of information which may be required under schedule 3 of the regulations are shown in Table 4.:

Licence type	Examples of evidence required
General information	Plans and arrangements describing how the applicant proposes to manage the controlled facility to ensure the health and safety of people, and the protection of the environment including the following information: • the applicant's arrangements for maintaining effective control of the facility • the safety management plan for the controlled facility • the radiation protection plan for the controlled facility • the radioactive waste management plan for the controlled facility • the security plan for the controlled facility • the emergency plan for the controlled facility • the environment protection plan for the controlled facility.
Authorisation for preparing a site for a controlled facility (siting)	A detailed site evaluation establishing the suitability of the site. The characteristics of the site, including the extent to which the site may be affected by natural and man-made events. Any environmental impact statement requested or required by a government agency, and the outcome of the environmental assessment.

Licence type	Examples of evidence required
Operate	A final safety analysis report that demonstrates the adequacy of the design of the controlled facility and includes the results of commissioning tests. The operational limits and conditions of the controlled facility. The arrangements for commissioning the controlled facility. The arrangements for operating the controlled facility.

Table 4. Evidence required for a license

For a facility application, regulation 40 requires the CEO to publish a notice in a daily newspaper and in the *Gazette*, and, in the case of a nuclear installation, the CEO must invite submissions on the application. A regulatory officer will prepare a Regulatory Assessment Report (RAR) to review the application and inform the decision maker, the CEO of ARPANSA or their delegate. Depending on the complexity of the application, a Statement of Reasons (SoR) which is a public document outlining the consideration on the decision. See section 6 of this Summary Report.

Source licences

For ARPANSA, most source licences cover a range of risks from baggage x-ray scanners, to industrial radiography, small laboratories, and medical use. Source licences also include non-ionising radiation source, e.g. lasers. Source licences provide for authorisation of source types, which are categorised by hazard (group 1, 2 or 3) according to schedule 3C of the ARPANS Regulations. Source licences typically authorise lower hazard/risk applications than facilities, for example for unsealed material:

- Group 1: A laboratory or premises with less than 100 times the exemption level (activity limit in schedule 2 of ARPANS Regulations)
- Group 2: A laboratory or premises with more than 100, but not more than 10 000 times the exemption level (activity limit in schedule 2 of ARPANS Regulations)
- Group 3: A laboratory or premises with more than 10 000, but not more than 1 000 000 times the exemption level (activity limit in schedule 2 of ARPANS Regulations)
- Prescribed Radiation Facility: Premises with more than 1 000 000 times the exemption level (activity limit in schedule 2 of ARPANS Regulations).

In line with a graded approach, source licences are not staged over the lifetime of the authorisations. Source licences instead permit dealing with sources, which includes possession, use and disposal. However, conditions may be used to introduce additional hold points such as requiring the submission and review of commissioning results.

The information required (under regulation 39) to be submitted with all source licence applications is stated in Schedule 3 of the Regulations. In line with a graded approach, these are less onerous and less specific than facility requirements. However, the CEO may require further information to ensure that relevant requirements for protection of health and safety of people, and protection of the environment, are met.

Examples of information which can be required under schedule 3 of the regulations include, but are not limited to:

Description	Examples from Schedule 3 (not exhaustive)
General information	Plans and arrangements describing how the applicant proposes to manage the controlled material or apparatus to ensure the health and safety of people and the protection of the environment including the following information: a) the applicant's arrangements for maintaining effective control of the controlled material or controlled apparatus b) the safety management plan for the controlled material or controlled apparatus c) the radiation protection plan for the controlled material or controlled apparatus d) the radioactive waste management plan for the controlled material or controlled apparatus e) the plan for ultimate disposal or transfer of the controlled material or controlled apparatus f) the security plan for the controlled material or controlled apparatus g) the emergency plan for the controlled material or controlled apparatus.
Dealing involves a sealed source of a controlled material	• The nuclide, activity, chemical form, encapsulation material and physical form of the sealed source • The purpose and identification details of the sealed source • The place where the sealed source is located • A copy of any sealed source certificate for the sealed source

Table 5. Examples from Schedule 3 of the Regulations

A regulatory officer will prepare a RAR, which will make a recommendation to the CEO (or delegate) about whether to issue a licence and may recommend imposing licence conditions.

Application and notification of certain changes

In addition to applying to vary a licence or authorisations, when a licence holder makes any change, notification or approval may be required. Any changes which are significant, and would affect safety, the licence holder must obtain prior approval from ARPANSA before making the change. Other changes must be notified to ARPANSA within three months. The guide *When to seek approval to make changes under Regulation 51* provides guidance on the subject. These changes require a similar level of evidence to be submitted as a new application, however only information relevant to the change is required.

State and Territory authorisations

User licences

In addition to possession and management licences described below, State and Territory jurisdictions issue licences to individual users who are authorised to deal with radiation. These applicants must submit sufficient evidence of qualification, training and experience to satisfy the regulator. Requirements for supporting evidence is listed on the relevant jurisdiction's website.

Management and possession licences

A possession licence permits the possession of types of sources (e.g. dental x-ray) for a specific purpose. Each individual source requires an authorisation (registration), and users typically require a separate 'use' licence.

A management licence may also authorise specific pieces of equipment, and in some cases may authorise persons working at a practice. In some jurisdictions, such as TAS, the possession and use licences are in a single document which also covers the registration of radiation sources.

Requirements for supporting evidence is captured in relevant jurisdictional legislation. Similar to the requirement under the ARPANS Regulations for 'Plans and Arrangements' (see Regulation 49), States and Territories have requirements for 'Radiation Management Plans' (RMP) or equivalent. This is the key safety document, or document within the organisation's management system, which outlines how safety is implemented and managed.

The RMP encompasses the safety case[2], which is submitted with new applications for approval by the regulator. In accordance with a graded approach, RMPs vary in sophistication depending on the risk-ranking of the radiation source. Some jurisdictions such as TAS, QLD, and ACT have templates for low risk applications such as for dental and veterinary radiography practices. More complex practices, such as radiation therapy, may submit an overarching document to the regulator that references internal documents used by the practice. This avoids the regulator needing to store and update a large numbers of controlled documents, which are held by practices. The controlled documents are considered in conjunction with the Radiation Management Plan during the authorisation process and examined during audits.

The criteria to be assessed against are outlined in the relevant jurisdiction's legislation, which include the principles of justification, optimisation and where applicable limitation.

The assessment of applications for licences can be comprehensive or staged. For example, a complex therapy facility where acquisition, storage (in an appropriately constructed and registered place) and use, are granted incrementally after the appropriate safety analysis has been made by the regulator. This is achieved via conditions of licence or registration.

Registration of sources

In most States and Territories (including ACT, NT, NSW, TAS, SA, QLD and WA) individual sources are registered with the regulator. The registration is a form of authorisation in addition to the management or possession licence, and generally requires the submission of compliance test results for that source or place (not applicable to all source types). This differs from ARPANSA's approach in that approval is required prior to use, whereas ARPANSA requires notification on a quarterly basis. In QLD and TAS, the possession licensee must apply for an approval to acquire prior to obtaining the source.

[2] The safety case is the collection of arguments and evidence in support of the safety of a facility, source or activity.

5.3 Authorisation of research reactors

Related to SSR-3: paragraphs 3.4 – 3.5 and Requirements 1 to 6 and to NS-R-3

As described in section 5.1 of this report, the ARPANS Act applies to 'Commonwealth entities' and 'controlled person' as defined in section 13 of the Act. This ensures that all persons covered by the authorisation are subject to regulatory oversight by ARPANSA. The facility authorisation process includes licences covering stages (site preparation, construction, possession or control, operation, decommissioning, remediation of legacy site, and abandonment) as well as safety significant changes (regulation 51) and the construction of safety items (regulation 54). There are no additional legislated requirements for licensing of research reactors. The legislation requires certain documentation to be submitted with each stage of the application.

The rigour of the evidence to be submitted with an application is reflected in ARPANSA regulatory guides, including *Plans and Arrangements for Managing Safety*. As with all applications, the applicant will be required to submit information to meet regulatory requirements and must consider international best practice (IBP) as well as matters specified in regulation 41.

The recently retired ARPANSA guide Regulatory Assessment Principles (RAPs) consolidated design and operational requirements, including for research reactors. However, the Commonwealth has made a commitment to align with or use trusted international standards and risk assessments where possible and deemed appropriate, to reduce the regulatory burden. In keeping with this commitment and for practical reasons, a decision was made not to maintain this, now outdated, ARPANSA guidance. Instead, relevant IAEA safety standards and other sources of international best practice are considered to replace the RAPs and possibly other ARPANSA guides. A complete gap analysis is underway to identify if all requirements previously captured in RAPs are acceptably covered by the relevant international standards. The use of international best practice is further discussed in section 9, including an item for the Action Plan relevant to the (retired) Regulatory Assessment Principles.

The RAPs included the expectations for the research reactor Safety Case and the Safety Analysis Report (SAR). This is now contained in the IAEA Specific Safety Guide No. SSG-20 and the safety principles and design criteria of the IAEA Specific Safety Requirements No. SSR-3.

Plans and Arrangements for Managing Safety (section 2, Safety Management) outlines the hierarchy of the safety policies, organisational responsibilities, management and personnel responsibilities, documentation and control, change control, learning and improvement, training and competencies of personnel – in particular operational personnel with safety functions, and licence holders' review process and committees. International standards also include guides such as *GS-G-3.1 Application of the Management System for Facilities and Activities, GS-G-3.5 The Management System for Nuclear Installations, NS-G-4.5 The Operating Organization and the Recruitment, Training and Qualification of Personnel for Research Reactor.*

5.4 Authorisation of radioactive waste management facilities

Related to GSR Part 5: Requirements 3 and 4, SSR-5: Requirements 2, and 12–19

The long-term plans for management of Australia's radioactive waste are outlined in the Australian Radioactive Waste Management Framework, which was described in detail in section 1.7 of this Summary Report.

A Commonwealth operated, national facility has been proposed for disposal of Australia's low level radioactive waste, and for storage of intermediate level waste – the National Radioactive Waste Management Facility(NRWMF). The process for selecting and establishing the NRWMF, which is intended to manage all radioactive waste in Australia, is set out in the *National Radioactive Waste Management Act 2012* (NRWM Act).

The Commonwealth is committed to a voluntary site nomination process. Nominated sites are first evaluated using a desktop assessment and a multi-criteria site analysis methodology. Considerations during this initial stage include community support, the stability and protection of the environment, economic viability, health, safety, security and equity (how equally the risks and benefits are shared by the community). There is a minimum 60 day consultation period and a survey to gauge the level of community support. The Minister will determine if any sites should progress to the technical site assessment stage.

As part of the technical assessment stage, a comprehensive and independent assessment of cultural heritage is carried out in collaboration with the traditional owners. Assessment is also carried out for environmental impacts including assessment of ground and surface water and flora and fauna.

Three sites in South Australia are under detailed consideration by the Department of Industry, Innovation and Science. These are the Wallerberdina Station near Hawker; and the Napandee and Lyndhurst properties near Kimba. At the time of preparation of this Summary Report, a final decision has not been made with regard to site selection, and the voluntary nomination process is still open.

The proposed site will require licensing and approval under Commonwealth legislation, including the *Environment Protection and Biodiversity Conservation Act 1999* and the ARPANS Act.

The national requirements for establishment of disposal facilities are outlined in the draft *Code for Disposal Facilities for Radioactive Waste (RPS C-3)*. This Code was agreed by jurisdictional regulators at the July 2018 meeting of the Radiation Health Committee. It is intended to be published as RPS C-3 and will in effect implement the IAEA Specific Safety Requirements No. SSR-5 *Disposal of Radioactive Waste* in Australia.

The ARPANSA licensing process is further described in the Regulatory guide: Applying for a licence for a radioactive waste storage or disposal facility and the Information for Stakeholders: Radioactive Waste Storage and Disposal Facilities. The information document also describes interrelations with the *Nuclear Non-Proliferation (Safeguards) Act 1987* (the Safeguards Act), the EPBC Act and the NRWM Act.

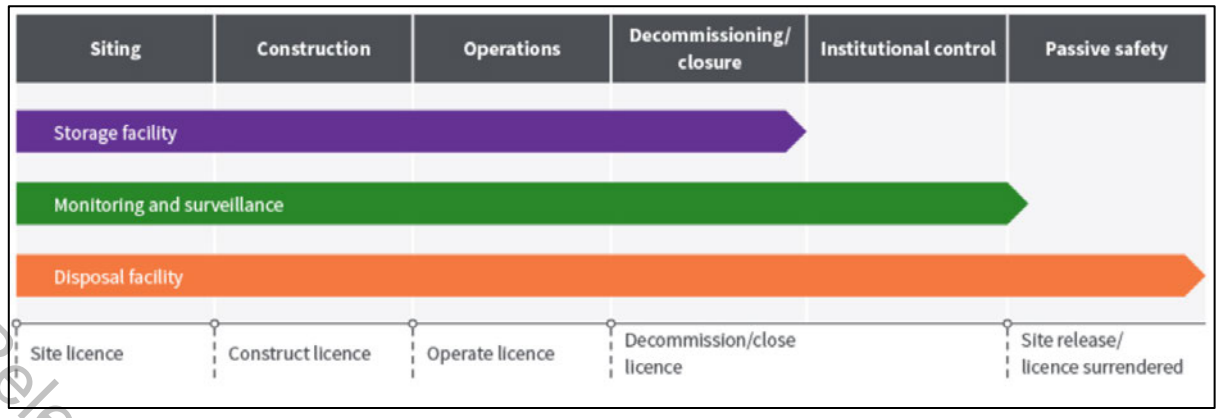

Figure 10. Overview of the staged licensing over the lifetime of any proposed facility

The ARPANSA Regulatory Guide specifies information to be supplied to demonstrate that the proposed conduct can be carried out without undue risk to the health and safety of people and the environment. This information is contained in the safety case, which is a collection of scientific, technical, administrative and managerial arguments and evidence in support of the safety of a facility. It covers the suitability of the site and the design, construction and operation, the assessment of radiation risks, and assurance of the adequacy and quality of all of the safety related work that is associated with the facility

ANSTO operates several facilities for managing liquid and solid radioactive waste arising from its routine operations (see section 6.4). Different facilities are used depending on radiation levels and the method of ultimate disposal, where this can be anticipated. This includes material in interim storage awaiting final disposal in a NRWMF. Some waste undergoes treatment during its period of management. For example, intermediate-level liquid waste is treated and solidified for interim storage. The Interim Waste Store at ANSTO, Lucas Heights houses a single TN-81 cask containing vitrified waste product from reprocessing of HIFAR spent fuel.

ANSTO is also licensed to possess and control the Little Forest Legacy Site (LFLS), which is a secure, shallow land burial site used by the former Australian Atomic Energy Commission for the disposal of some wastes (both radioactive and non-radioactive) up until 1968. The facility was licensed as a 'Prescribed Legacy Site' under the revised ARPANS Act in July 2016, becoming the first site licensed under this new classification. Under the licence, ANSTO has to provide the CEO of ARPANSA with a plan for the medium and long-term management of LFLS by mid-2018. A recent request for an extension of this date out to December 2019 was approved by the CEO of ARPANSA. A project was established in 2016 to examine the options related to the future safe management of the facility and the waste inventory contained therein.

In addition to the facilities managed by ANSTO, the Commonwealth is also responsible for:

- a number of small stores for waste at several CSIRO laboratories located around Australia
- a dedicated waste store operated by the Australian National University in Canberra
- a radioactive waste disposal facility in the Kakadu National Park in the Northern Territory containing low level uranium and thorium wastes from remediation of former exploration sites and mine in the 1950s
- a store for Commonwealth radioactive waste is located at Evatt's Field on the Woomera Prohibited Area, South Australia. It contains approximately 10,000 200 litre drums of predominantly contaminated soil remediated from a former research site that undertook studies into uranium and thorium ore processing

- a small waste store located at ARPANSA's Yallambie, Victoria, premises.

A significant part of this waste is destined for the NRWMF, according to the current plans for establishment of this facility.

The authorisation for small-scale local waste management activities is as described in this section. However, jurisdictional environmental legislation may also apply to such facilities. Additionally, the requirements under the Environment Protection and Biodiversity Conservation Act 1999.

Jurisdictions typically have a small store of radiation sources. Each State and Territory government, as the result of past practices, acquired these legacy sources. Jurisdictional regulators manage these stores, only some of which (such as WA and QLD) are accepting new material. Western Australia operates a near-surface and bore-hole waste disposal facility, the Mt Walton East Intractable Waste Disposal Facility, which is available for holders of radioactive materials regulated by the WA regulatory body.

Previously, disposal of very low level waste was carried out at authorised landfills in accordance with RHS 13, *Code of practice for the disposal of radioactive wastes by the user* (1985). However, under the new requirements for user disposal in the National Directory for Radiation Protection (schedule 14) authorisation by the regulator may no longer be required for some of these disposals (note that schedule 14 is in the process of being republished as a stand-alone Code, RPS C-6).

5.5 Authorisation of decommissioning activities

Related to GSR Part 6

Under section 30 of the ARPANS Act, a controlled person must not decommission, dispose of or abandon a controlled facility without an authorisation under the ARPANS Act. In other jurisdictions, dealing with radioactive materials requires a licence, which may include a facility being decommissioned. In some jurisdictions, such as VIC, the decommissioning of facilities is explicitly captured in the legislation, while other jurisdictions can use other mechanisms to regulate activities in a staged manner.

The information required by the ARPANS Regulations (Schedule 3) is listed by the type and life stage of authorisation and includes decommissioning. In the case of decommissioning, the CEO may request a decommissioning plan and a schedule for decommissioning of the controlled facility. For abandoning a controlled facility (the release of a site from regulatory control), the information that may be requested includes the results of decommissioning activities and details of any environmental monitoring program proposed for the site.

The CEO is required to consider international best practice when deciding whether to issue a licence. For decommissioning this includes guidance such as the IAEA *General Safety Requirements No. GSR Part 6 Decommissioning of Facilities* and *WS-G-5.2 Safety Assessment for the Decommissioning of Facilities Using Radioactive Material.*

A Regulatory Guide on Decommissioning of Controlled Facilities has undergone public consultation and is under publication, which provides more specific requirements. The Guide builds on the General Safety Requirements No. GSR Part 6 *Decommissioning of Facilities* and the Draft IAEA Safety Guide: *Decommissioning of Nuclear Installations*. It includes specific requirements on funding, resourcing and staffing which are captured under regulation 41 which requires an applicant to demonstrate capacity to comply with relevant regulatory requirements and conditions of the licence. Decommissioning has been

considered in the recent construction and operation licence decisions for the ANSTO Nuclear Medicine Facility (ANM). ARPANSA plans to pursue an update of the ARPANS Regulations to formally require decommissioning arrangements as part of the initial siting, construction and operation applications and the submission of a decommissioning safety analysis report.

Other national codes, such as the *Planned Exposure Code* (RPS C-1) and ARPANSA Regulatory Guides, such as *Plans and Arrangements for Managing Safety*, apply to decommissioning as well as to other stages of the facility life-cycle.

Prior to issuing a licence to abandon/surrender a site, ARPANSA will verify that all regulatory requirements and end state criteria, as specified in the final decommissioning plan and in the authorisation for decommissioning have been met.

5.6 Authorisation of transport activities

Related to SSR-6

Package design, certification, and special arrangements

ARPANSA is one of the competent authorities in Australia for the certification of package design (including special form radioactive material, low dispersible radioactive material, packages containing 0.1 kg or more of uranium hexafluoride, packages containing fissile material, Type B(U) packages, Type B(M) packages, Type C packages), validations of certificates, and special arrangements shipments.

While some jurisdictions carry out these functions from time to time, other jurisdictions (such as the ACT) rely on ARPANSA to provide these authorisations, or request assistance in their review and assessment. Although all jurisdictions recognise ARPANSA issued authorisations, there is currently no formal documented arrangement in place. A formal arrangement would provide clarity on the expectations and level of service provided.

Guidance and checklists for applicants submitting requests for transport approval is available on the ARPANSA website, see section 9.6 of this Summary Report.

Routine transport

In each jurisdiction, authorisations which cover transport require compliance with the *Code of Practice for the Safe Transport of Radioactive Material* (2014) (RPS C-2) published by ARPANSA on behalf of all Australian jurisdictions, or the previous version of this code. The Code is currently being updated to reflect the most recent edition of the IAEA Specific Safety Requirements No. SSR-6 *Regulations for the Safe Transport of Radioactive Material* Rev 1.

A person seeking to transport radioactive material must do so under the authorisation from the local jurisdiction. A person transporting material across state/territory borders must be authorised in all relevant jurisdictions where the material is transiting. This does not apply to ARPANSA licence holders, who are not required to hold State and Territory authorisation as ARPANSA's jurisdiction covers controlled persons irrespective of which state they are in.

Depending on the jurisdiction, transport authorisations may be covered by the management licence of the organisation responsible for the material, the organisation transporting the material, or the individual transporting the package, as summarised below.

Transport is covered under possession/management licences only	Transport is covered under a licence of transporting organisation	Each individual must be licensed for transport	Transport requirements apply, but no licence is required for transport
ARPANSA	VIC	ACT	NSW
NT^	TAS	QLD	SA
	WA*		NT

Table 6. Transport authorisations

** For WA, at least one individual must hold a transport licence, and transport may be conducted under the general supervision of the licensee.*

^ For NT, the owner is responsible for licencing of the transport of ores and concentrates.

For example, in QLD, if a radioactive substance is being transported by road, the individual in charge of the vehicle must hold a transport licence to transport the substance (section 14 of the Radiation Safety Act 1999). This individual must apply for a licence and provide evidence of appropriate training. If a radioactive substance is being transported by a way other than by road, the person, who may be an individual or a corporation, must be the holder of a transport licence (section 15). In this case, the person must apply for a licence and provide evidence of appropriate training to staff who will be involved in the transport radioactive substances.

In some jurisdictions (e.g. VIC), the organisation which transports material is required to hold a licence rather than individual transporters.

In the NT, RPS C-2 is an approved Code of Practice for transport but in addition, the *Radioactive Ores and Concentrates (Packaging and Transport) Act* requires the owner of ores and concentrate to apply for storage and transport.

In other jurisdictions (e.g. NSW), no specific (individual) authorisation is required. However, the management (possession) licence holder must ensure that transport is conducted in accordance with RPS C-2. This is similar to ARPANSA where the licence holder must ensure that transport is in accordance with RPS C-2.

In addition to the regulatory bodies of the jurisdictions, the Civil Aviation Safety Authority (CASA) is the competent authority for shipment by air, while the Australian Maritime Safety Authority (AMSA) is the competent authority for seaborne transport. For example, CASA is the competent authority for approval of radioactive materials in special form and of Type B containers for air transport. A detailed application based on the current edition of the International Atomic Energy Agency Regulations for the Safe Transport of Radioactive Material will be required, including all required supporting test, design and safety data. The application is assessed using IAEA guidance documents and decisions are based on a safety case, international standards and compliance with RPS C-2.

In addition to radiation safety requirements, other safety requirements and guidance may apply to the transport of radioactive material. These requirements complement the radiation safety requirements and are well aligned to radiation specific requirements. Examples include the *Australian Dangerous Goods Code* and *Load Restraint Guide* from the National Transport Commission, and Safely transporting dangerous goods by WorkSafe Victoria.

Transport of security enhanced sources

A security enhanced source may not be transported without authorisation. The *Code of Practice for the Security of Radioactive Sources* (2007) RPS 11 requires that for security enhanced source a Source Transport Security Plan is prepared that demonstrates how the Responsible Person will satisfy the requirements of RPS 11 in relation to the source. An assessor accredited for this purpose by the relevant jurisdiction regulatory body, which may be the radiation regulator, must endorse this plan. The plan must in all cases be submitted to the radiation regulator.

5.7 Conclusions and actions

Australian jurisdictions generally meet the expectations set out in the IAEA safety standards. Authorisations are required for any dealing with a source or facility that is not exempted. While the system for authorisations differ among jurisdictions, applicants are required to provide an adequate demonstration of safety in support of an application for authorisation. There are guidelines available to applicants that clarify the requirement on the information that has to be submitted with the application.

A number of areas where improvements can be made have been identified, that primarily relate to ARPANSA:

- An improvement opportunity is identified for ARPANSA to prescriptively (e.g. in the ARPANS Regulations), capture the requirement to provide a decommissioning plan at early stages of the facility life cycle (i.e. with the siting and construction applications for the facility), and to request a safety analysis for decommissioning activities. The requirements could be included in Schedule 3 Part 1 Table 1 of the ARPANS Regulations. See Action Plan item 3.
- Currently no formal arrangement in place between the Commonwealth (ARPANSA) and States and Territories for the certification of package design, validations of certificates, and special arrangements shipments. The provision of a formal arrangement may help to set clear expectations on roles and acceptability of assessments in all jurisdictions, and provide for cross-jurisdictional acceptance of certificates, validations and approvals. See Action Plan item 12.

6. Review and assessment

This section includes responses from all Australian jurisdictions on generic issues (6.1), and from most jurisdiction on sources, facilities and activities (6.2), and transport (6.6).

The sections on research reactors (6.3), waste management (6.4) and decommissioning (6.5) relate to the Commonwealth regulator, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

6.1 Generic issues

6.1.1. Management of review and assessment

Related to: GSR Part 1 (Rev. 1): Requirements 25 and 26, paragraphs 4.40–4.48, GSR Part 3 Requirement 13, GSR Part 4: Requirements 1–4

In Australia, a person (or controlled person) intending to deal with a radiation source, or – if relevant – operate a facility, must apply for and hold a licence with the relevant jurisdiction, or otherwise be covered by a licence or exemption (see section 5). Prior to granting such an authorisation, when varying the authorisation and at certain other instances, the relevant regulatory body will perform review and assessment. Other applications and notifications also require review and assessment.

All jurisdictions follow documented procedures for review and assessment of applications, which are maintained in their respective quality systems. This includes the use of assessment checklists, or pro-forma, and are carried out through delegations of authority. At ARPANSA, requirements are captured in the Regulatory Services *Licensing and Assessment Manual*, which includes the preparation of a regulatory assessment report.

In all jurisdictions, 'management' or 'possession' licences are required to possess radiation sources, including radioactive material. The application for this type of licence require documented plans and arrangements such as a radiation management plan, transport plans or equivalent documents to be submitted. Assessment of this information is performed to ensure:

- that the use of the source is justified
- that measures are implemented to ensure protection is optimised so that exposures, the number of exposed persons and the likelihood of incurring exposures are as low as reasonably achievable (social and economic factors taken into account)
- that dose limits are complied with where applicable
- jurisdictional regulatory requirements are complied with
- that the applicant has the capacity to comply with the requirements.

These requirements are captured in jurisdictional legislation or in licence conditions. In accordance with a graded approach, more detailed information is required for applications in relation to higher hazard/risk facilities, sources or activities. National agreements on requirements are compiled in the Radiation Protection Series No.6 *National Directory for Radiation Protection* (NDRP), as agreed by jurisdictional regulators at the July 2018 meeting of the Radiation Health Committee. Where applicable, the agreed requirements of the NDRP are considered during the review and assessment.

The requirements and demonstration of safety is less onerous for low hazard/risk activities, such as dentistry, for which the regulatory requirements are covered by the Radiation Protection Series *Code of Practice and Safety Guide for Radiation Protection in Dentistry 2005 (*RPS 10), than for higher hazard/risk applications such as nuclear medicine, which is covered by the Radiation Protection Series *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation 2008*(RPS 14). Where applications are particularly complex or are considered non-routine, they may be reviewed by an advisory body to the regulator. For example, the ACT Radiation Council delegates to the ACT Health Directorate Health Protection Service the power to approve licences that match specific dealings (e.g. operate veterinary X-ray) or specific experience (e.g. degree/registration with the Veterinary Board) for certain occupations (e.g. veterinarian), which will be issued subject to specified conditions (e.g. compliance with the Radiation Protection Series Code of Practice & Safety Guide for Radiation Protection in Veterinary Medicine 2009 (RPS 17). The Radiation Council reviews and assesses and, as appropriate, approves all other applications. For ARPANSA, complex facility applications typically involve a review and assessment of some aspects of the application by the Nuclear Safety Committee.

In the States and Territories, individual sources must be registered, which may be part of the process to obtain a management licence. Additionally, a compliance test must be performed prior to use for most equipment (see section 5.1). The equipment (type of sources) or premises requiring tests, as well as the nature and scope of the tests, vary between jurisdictions.

For ARPANSA, individual sources, or pieces of equipment that are acquired by the licence holder, need to be notified to the regulator as part of annual, biannual or quarterly reports. At this time, an assessment is made to ensure that the source is a permitted source type under the authorisation of the licence.

In QLD and TAS, an approval to acquire a source is required. The QLD regulator reviews that the recipient is authorised and has considered disposal and security of the source. At this time, the regulator ensures that the source type that is permitted to be possessed by the licence holder. Additionally, in TAS the regulator reviews the source for compliance with standards as part of the authorisation process.

State and Territory jurisdictions also issue individual 'use' licences. For these licences, the qualification, training and experience of applicants is reviewed. Most jurisdictions, e.g. NSW, maintain a list of approved qualifications and training (e.g. accreditation or registration with professional bodies, tertiary qualifications or approved courses) which are considered sufficient to obtain a specific type of licence. The issue of national competency requirements is currently addressed by jurisdictional regulators through the Radiation Regulators' Network with the intention of national agreement through the Radiation Health Committee and subsequent updating of the NDRP.

ARPANSA manages the authorisation of import and export permits on behalf of the Department of Home Affairs. A permit is required under the Customs (Prohibited Imports) Regulations 1956 to import any radioactive substances into Australia, and under the Customs (Prohibited Exports) Regulations 1958 to export high activity radioactive sources out of Australia.

6.1.2. Organisation and technical resources for review and assessment

Related to GSR Part 1 (Rev. 1): Requirement 4, paragraph 2.8; Requirement 11, paragraphs 2.34–2.38; Requirement 15, paragraphs 3.3–3.5; Requirement 16, paragraph 4.4–4.5; Requirement 17, paragraph 4.6; Requirement 18, paragraphs 4.11–4.13 and Requirement 20, paragraphs 4.18–4.22

As described in section 3.3 of this Summary Report, staffing and competence of the regulatory body, each regulator has resources available for review and assessment. For ARPANSA, this includes approximately 20 regulatory staff who perform review and assessment with support from a significant number of staff sourced from across the agency, with expertise in dosimetry, health, communication and other areas relevant to regulatory review and assessment. Where appropriate, such as when there is a gap in expertise, ARPANSA engages contractors to assist in inspection and assessment.

As previously stated, advisory bodies, committees and councils are used by the regulatory bodies where additional external expertise are desirable, such as for complex applications or policy decisions. For ARPANSA, the primary advisory body for this purpose is the Nuclear Safety Committee. In some jurisdictions, such as ACT, the council holds powers to approve authorisations, and therefore perform reviews and assessments where applicable. For more information on advisory bodies to ARPANSA, see section 0.

6.1.3. Basis for review and assessment

Related to GSR Part 1 (Rev. 1): Requirements 23 and 24, paragraphs 4.33–4.34; Requirements 25 and 26, paragraphs 4.40–4.41, GSR Part 4: Requirements 14–15

The principal basis for all review and assessment is the relevant jurisdictional legislation, and the national codes that are adopted in a jurisdiction, which apply to the type of application. The national codes are listed on the website, and for ARPANSA licence holders a list is provided of which codes are applicable to different types of sources and facilities. See section 9 on the development and adoption of national codes and other guidance.

	Example requirement
***Code for Radiation Protection in Planned Exposure Situations 2016*, Radiation Protection Series C-1 (RPS C-1)**	3.1.4 The Responsible Person must ensure that the radiation management plan: a) adopts objectives for protection and safety in accordance with the requirements of this Code b) applies measures for protection and safety that are commensurate with the radiation risks associated with the exposure situation both in normal operation and in the event of an incident or accident c) is adequate to ensure compliance with the requirements of this Code. 3.1.5 The Responsible Person must ensure the radiation management plan addresses protection commensurate with the level of radiation risk that it seeks to mitigate of: (a) occupationally exposed persons (b) members of the public (c) the environment.

	Example requirement
***Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation* 2008 (RPS 14)**	Schedule A: The Radiation Management Plan must address the following: a) work practices and protocols for all procedures involving medical exposure to ionizing radiation, including those: (i) to ensure that the prescribed radiation procedure is performed on the correct patient; (ii) for the proper planning and delivery of radiotherapy doses; (iii) for preparation and dispensing of radiopharmaceuticals; (iv) for optimising the protection of the patient consistent with section 2 of this Code; and (v) for observation 11 of the patient by the operator throughout procedures where the dosimetry or image quality could be affected by patient movement b) construction and shielding of the medical facility or premises so that dose constraints acceptable to the relevant regulatory authority are applied for occupationally exposed persons and members of the public c) the action to be taken if the radiation doses to occupationally exposed persons or members of the public are found to exceed the dose constraints d) optimisation of the shielding so that external radiation exposure rates are kept as low as reasonably achievable, economic and social factors being taken into account e) arrangements for appropriate isolation of hospital in-patients undergoing treatment with sealed or unsealed radioactive sources f) the training, qualifications and supervision of the staff of the medical facility and their roles and responsibilities g) the licensing requirements of the radiation regulatory authority h) personal radiation monitoring requirements for persons involved in the use of radiation i) personal protective equipment to be worn by persons involved in the use of radiation ...see RPS14 for additional requirements...

	Example requirement
Code of Practice and Safety Guide for Portable Density/Moisture Gauges Containing Radioactive Sources 2004 (RPS 5)	2.1 Each Responsible Person, supplier or service provider who deals with a portable density/moisture gauge must ensure that a Radiation Management Plan is developed, documented, implemented and regularly reviewed to ensure safety in all applicable dealings with the portable density/moisture gauge, including: a) work practices b) roles and responsibilities c) radiation monitoring requirements, including details of how the availability or accessibility requirements for the monitoring equipment are to be achieved d) control of an incident involving the gauge (section 4.3) e) storage of the gauge (section 5.1) f) transport of the gauge (section 5.2) g) repairs and maintenance of the gauge (section 6.1) h) what to do with the gauge (e.g. sale, transfer, disposal) when it is no longer required (Sections 6.2 and 6.3) i) accountability and records (section 6.4) j) any other requirement that may have a bearing on safety.

Table 7. Examples of requirements under Codes

For source and facility applications under the Commonwealth, State and Territory legal frameworks, safety assessments are part of the Radiation Management Plan, or similar documentation of plans and arrangements. This may include attached documents, such as shielding plans, and an assessment by the licence holder of typical doses, and doses likely to be received as part of abnormal events. This assessment may take into account complex modelling, personal dosimetry data or typical radiation doses for the industry, depending on the complexity of the application.

All jurisdictions have the ability to request additional information if not satisfied by the information provided in the application. For ARPANSA, information which may be requested is listed in schedule 3 of the Australian Radiation Protection and Nuclear Safety Regulations 1999 (the Regulations). For example, for a facility operating licence, the CEO of ARPANSA may require 'A final safety analysis report that demonstrates the adequacy of the design of the controlled facility and includes the results of commissioning tests.'

In addition to regulatory requirements and Australian guidelines, when considering an application the CEO of ARPANSA must under sections 32 and 33 of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act) take into account international best practice. The international standards listed on ARPANSA's website are a key basis for ARPANSA's review and assessment, particularly were there are no relevant Australian codes, guides or other documents.

Further guidance on the criteria of assessment is available in:

- the 'regulatory assessment criteria for the design of new controlled facilities and modifications to existing facilities', which has been earmarked for revision as some of the documentation referenced is not current. However, the principles remain relevant and continue to be used until the document is updated

- the 'regulatory assessment principles for controlled facilities' which is provided for historical purposes only. New applications will be assessed against relevant current international best practice. For more information on guides, see section 9.

The international standards listed on the website include the IAEA safety standards. For example, while there is no Australian specific guidance on safety assessments, the following documents are can be drawn on to support safety assessments:

- GSR Part 4 Safety Assessment for Facilities and Activities
- GS-G-4.1 Format and Content of the Safety Analysis Report for Nuclear Power Plants
- SSG-2 Deterministic Safety Analysis for Nuclear Power Plants
- SSG-3 Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants
- SSG-4 Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants
- WS-G-5.2 Safety Assessment for the Decommissioning of Facilities Using Radioactive Material
- SSG-20 Safety Assessment for Research Reactors and Preparation of the Safety Analysis Report
- SSG-27 Criticality Safety in the Handling of Fissile Material
- GSG-3 The Safety Case and Safety Assessment for the Predisposal Management of Radioactive Waste

6.1.4. Performance of review and assessment

Related to GSR Part 1 (Rev. 1): Requirements 25 and 26, paragraphs 4.43–4.48, GSR Part 4: Requirements 2–21

When a person applies to for an authorisation from the regulatory body within the relevant jurisdiction, prior to granting such an authorisation, an assessment is performed by the regulator against relevant documents detailing the requirements, as described in the previous section.

In all jurisdictions where changes to the authorisation occurs, e.g. in relation to any particulars that appear on a licence, an application to amend the authorisation is required. In some jurisdictions, such as QLD, changes to the radiation management plan require prior approval. These changes are assessed in the same manner as a new application.

State and Territory authorisations are issued for a fixed term, being one year or up to three years in most jurisdictions. Once the authorisation expires, a re-application or renewal is required. The licence holder is required to identify any review of plans and arrangements and submit the information as applicable. This provides an opportunity to review the operations of the licence, the radiation management plan and associated documentation where changes have occurred. Most sources require periodic certificates of compliance at certain intervals – from one to three years depending on jurisdiction and hazard/risk of the source. In some jurisdictions, this certification and re-authorisation processes are linked, while in other jurisdictions certification is on a separate cycle to the authorisation.

For ARPANSA, authorisations (licenses) can be time-limited but are often not. Any changes with significant safety implications, which change the details in the application, or modify the source or facility, require

prior approval. These changes are assessed in accordance with internal procedures and may include an amendment of the licence or conditions. Non-safety-significant changes require notification within three months, which provides the opportunity for regulatory review should this be warranted.

In accordance with a graded approach, detailed periodic reviews by the licence holder that are assessed by the ARPANSA, are only required for the highest hazard/risk sources or facilities, such as the research reactor.

For example, the following condition applies to the OPAL reactor:

> *A detailed plan for the next Periodic Safety and Security Review (PSSR) of the OPAL Reactor must be submitted to the CEO of ARPANSA and to the Director General of the Australian Safeguards and Non-proliferation Office (ASNO) no later than 30 November 2019. The conduct of the PSSR must follow relevant ARPANSA and ASNO regulatory guidance and include the results of an international peer review on the safety and security of the OPAL Reactor. The report on the findings of the PSSR and resulting action plan must be submitted to the CEO of ARPANSA no later than 30 November 2021 in a form stipulated in the regulatory guidance.*

While the following condition applies to all source and prescribed radiation facility licences:

> *The licence holder must comply with applicable codes and standards and must, at least once every three (3) years, conduct a self-assessment against each applicable code and standard to ensure compliance. Applicable codes and standards can be found on the ARPANSA website at: www.arpansa.gov.au/codes-standards-for-sources.*

Reviews are performed as part of the inspection process, see also section 6 of this Summary Report. For example, ARPANSA maintains a three-year baseline inspection schedule for facilities and a six-year baseline inspection schedule for sources. The frequency is set based on the hazard only for sources, and by the hazard and level of control for facilities ('risk').

In addition to scheduled inspections, additional inspections are carried out when a need is identified, such as following a report of a safety concern, or following an event with safety implications such as a reported incident. When a regulatory inspection is performed, review and assessment of the requirements, including any requirements under national codes or commitments is made in the plans and arrangements. This can include verification of requirements on certification, maintenance and record keeping. This is typically using a checklist or a pro-forma in accordance with the requirements of the regulatory body's management system.

Appropriate enforcement actions are taken, as and if necessary, as described in section 8.

6.2 Review and assessment for radiation, sources facilities and activities

Related to GSR Part 1 (Rev. 1): Requirements 23, 25 and 26, GSR Part 3: Requirements 10-13

As described in the preceding sections, authorisations, including licences for the possession and use of sources and facilities, require detailed assessment by the relevant jurisdiction's regulatory body. These assessments focus heavily on the 'plans and arrangements' or 'radiation management plan' which outlines the commitments made by the applicant or licence holder. Compliance with this plan is generally a condition of licence.

ARPANSA review and assessment

Once an application has been received by ARPANSA, the application will be examined to ensure that all the necessary information has been included, that it is properly signed by a person authorised to submit an application, and that the application fee has been paid. If so, the applicant will receive a letter of acknowledgment. However, if any of the mandatory information is not included, the applicant may be contacted for further information or the application and application fee may be returned with a covering letter describing the omission. Applications are then forwarded to a Regulatory Officer for assessment. Where matters require clarification, the Regulatory Officer will contact the applicant or the licence holder's nominee. The Regulatory Officer may also consider that an inspection or site visit is necessary and may contact the applicant to make arrangements.

Once the Regulatory Officer has reviewed and assessed all the information provided, a Regulatory Assessment Report (RAR) is produced. This report will address the matters to be taken into account by the CEO of ARPANSA in accordance with subsection 32(3) of the Act, namely international best practice in relation to radiation protection and nuclear safety and the matters specified in the regulations. Regulations 41 and 42 of the Regulations specify the matters to be taken into account by the CEO. For a facility licence they are:

a) whether the application includes the information asked for by the CEO

b) whether the information establishes that the controlled apparatus or material can be dealt with without undue risk to the health and safety of people, and to the environment

c) whether the applicant has shown that there is a net benefit

d) whether the applicant has shown that the magnitude of individual doses, the number of people exposed, and the likelihood that exposure will happen, are as low as reasonably achievable, having regard to economic and social factors

e) whether the applicant has shown a capacity for complying with the Regulations and the licence conditions that would be imposed under section 35 of the Act

f) whether the application has been signed by an office holder of the applicant, or a person authorised by an office holder of the applicant

g) in the case of a nuclear installation, the content of any submissions made by members of the public about the application.

The RAR will make a recommendation to the CEO (or delegate) about whether to issue a licence and may recommend the licence conditions to be imposed under section 35 of the Act. All relevant documentation is sent to the decision maker. The applicant will be advised in writing of the decision. For major facility licences, e.g. for nuclear installations, a Statement of Reasons is prepared which outlines matters which the CEO took into account. The Statement of Reasons is published on the ARPANSA website.

The workflow for review and assessment of an application for a licence for a nuclear installation (which includes public consultation, is schematically outlined below (note that time scales can vary considerably).

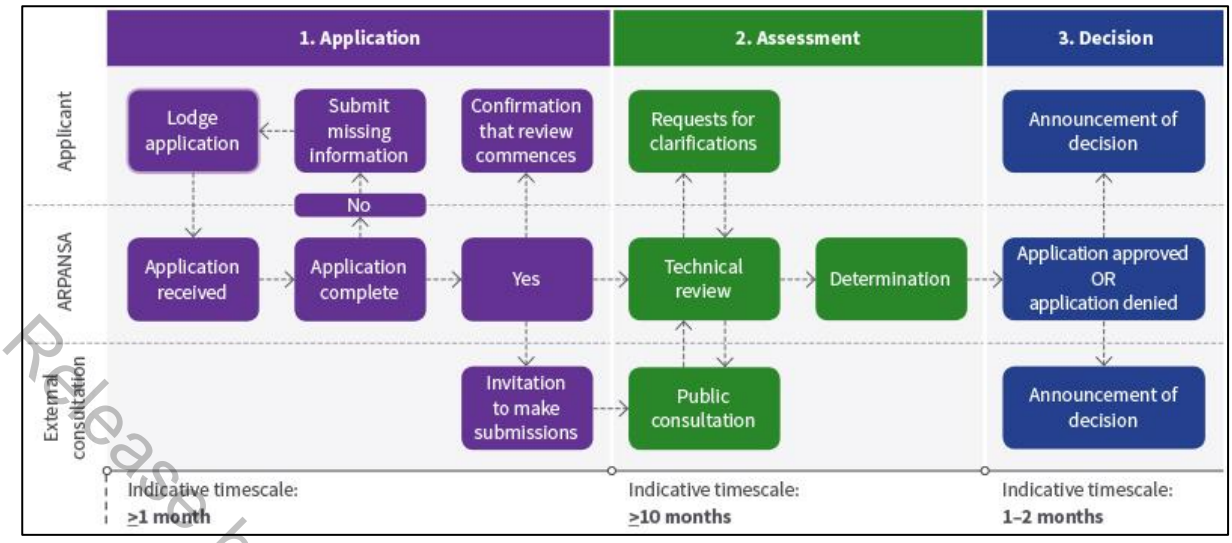

Figure 11. Workflow for review and assessment

State and Territory authorisations

In each jurisdiction, the regulatory body must consider the justification of the practice as part of the application process, similar to the ARPANSA process described above. Detail on the justification must be supplied in the Radiation Management Plan or as evidence in other supporting documentation. The level and detail of information supplied in support of the application is based on a graded approach. Any authorisations for activities with higher potential consequence (hazard) or an unusual application require more detail in support of the application, including the justification of the practice.

For example, the ACT Radiation Council, under the *Radiation Protection Act 2006*, must not issue a licence unless they are satisfied that it is in the public interest to do so. They must also consider any competence, security, or similar requirements set out in the NDRP. However, the graded approach is not applied uniformly across jurisdictions for different source types. For example a dentist in one state may be expected to submit more information than one in another jurisdiction.

Strategies for optimisation must be described in the radiation management plan, and where applicable in the shielding plan.

The requirements for shielding and equipment standards vary by jurisdiction. This is further discussed in section 13.

6.3 Review and assessment for research reactors

Related to SSR-3: Requirements 1 and 5

Reviews and assessments of research reactors are carried out over the lifecycle of the reactor and are, in principle, carried out following the same or similar procedures as used for review and assessment of other controlled facilities.

The licence application requirements are set under the Act and in the Regulations (Schedule 3, Part 1), for each stage in the life cycle (see section 5.3 of this report). ARPANSA performs reviews against the requirements in the Act and Regulations, and in ARPANSA regulatory guides including *Siting of Controlled Facilities* and *Plans and Arrangements for Managing Safety*. In addition, for areas that are not specifically

covered by ARPANSA guides, relevant IAEA documents are used. International best practice (IBP) is required to be considered under the Act, which in ARPANSA's approach includes the IAEA Specific Safety Requirements *Safety of Research Reactors (SSR3)*, the General Safety Requirements Part 1, 2, 3, 4 and 7, and Specific Safety Guides such as SSG-20, SSG-22, and NS-G-2.11.

For example, the Safety Case and Safety Analysis Report (SAR) are reviewed against IAEA SSG-20 and the fundamental safety principles, and design criteria are stated in SSR-3. These documents also contain the requirements on the Operating Limits and Conditions (OLCs) content and structure.

The recently retired ARPANSA guide Regulatory Assessment Principles (RAPs) consolidated design and operational requirements which applied to specific practices including research reactors. However, the RAPs became outdated and the decision was made not to maintain this guide. Instead, the relevant international standards (for both radiation and nuclear safety and nuclear security) replace the RAPs. This guidance and the use of international standards and risk assessments is further discussed in section 9.3.

As with all applications handled by ARPANSA, reviews and assessments are recorded in the ARPANSA record management system. A regulatory officer prepares a RAR, which summarises the review and assessment. For new research reactor applications, and complex changes or licence variations, the CEO of ARPANSA issues a Statement of Reasons (SOR) which is a public document outlining the decision making process and the factors taken into account to reach the licensing decision. For example, a SOR was prepared for the original operating licence, modified fuel design and licence amendment following the periodic safety review.

As a condition of licence, the OPAL reactor is subject to a periodic review every 10 years (or if necessary, earlier) in line with the guide *Periodic Safety and Security Review for Research Reactors*. In addition to this mandatory periodic safety review, and the requirement to review plans and arrangements every three years, regulatory approval is required for changes with significant implications for safety (regulation 51 of the Regulations). Examples of safety significant changes are found in the *Regulatory Guide: When to seek approval to make changes under Regulation 51*. These changes are assessed against the same requirements as new applications, including international standards that form part of international best practice.

Periodic reporting is required quarterly for research reactors as a condition of licence, this includes notification of any other changes (regulation 52 of the Regulations), as well as incidents and similar information. During ARPANSA inspections, a review of the licence holders' assessment of their changes is performed. Non-inspection meetings with licence holders also allow for discussion of these changes.

6.4 Review and assessment for waste management facilities

Related to GSR Part 6: paragraph 3.3

ARPANSA currently licenses a number of licence holders who store radioactive material temporarily, which may be disposed of in future disposal facilities. This includes a number of waste management facilities which are operated by ANSTO at the Lucas Height Science and Technology Centre. ANSTO's radioactive waste management facilities comprise:

- a low-level solid waste store
- a decontamination centre
- a low-level solid waste compaction facility

- a low-level liquid waste treatment facility
- a delay and decay facility for decay of short-lived waste
- an intermediate-level liquid waste storage facility
- a 'hot cells' facility
- an interim intermediate-level solid waste store facility
- a waste treatment and packaging facility
- spent fuel ponds
- a dedicated redundant source store and storage hot cells
- an Interim Waste Store housing a single TN-81 cask containing vitrified waste product from reprocessing of HIFAR spent fuel, and cemented technological waste arising from the reprocessing (pipework etc.).

ARPANSA also licences a prescribed legacy site, the Little Forest Legacy Site at Lucas Heights, and a facility for the disposal of low level material from past mining practices in the Alligator River region in the NT. These facilities are discussed in section 11.3.

For construction of all facilities, Item 12 of Part 1 of Schedule 3 of the Regulations requires the applicant to provide the arrangements of testing and commissioning of the facility. Further, ARPANSA *Regulatory Assessment Criteria for the Design of New Facilities and Modifications to Existing Facilities* (design criteria 235, 237-242) recommends that design of the safety systems needs to ensure that they can be tested, inspected and maintained before operation and throughout the OLCs of the facility to assure acceptability for service. Testing of safety systems determines or verifies the capability of such systems to meet specified requirements by subjecting the systems to a set of physical, chemical, environmental or operational conditions.

The design of a facility is approved through a construction licence and construction of an item important for safety is subject to regulatory approval under regulation 54 of the Regulations. ARPANSA *Regulatory Guide for Construction of an item important for safety* provides guidance on principles and criteria to be followed for construction of an item important for safety. This includes verification and validation criteria to be followed. Item 15 and Item 16 of Part 1 of Schedule 3 of the Regulations require the following:

- Item 15: A description of the structures, components, systems and equipment of the controlled facility as they have been constructed
- Item 16: A final safety analysis report that demonstrates the adequacy of the design of the controlled facility, and includes the results of commissioning tests.

The commissioning results demonstrating that the design objectives have been achieved are considered in the regulatory assessment for granting the operating licence of a facility.

The documented arrangements for operating a facility are required under Item 19 of Part 1 of Schedule 3 of the Regulations. Such arrangements include periodic maintenance, testing and inspection of safety systems. In addition, Item 17 of Part 1 of Schedule 3 of the Regulations requires the provision of the OLCs and condition of the facility derived from the safety analysis that defines the safety envelope of the facility. It is a licence condition for operation of a facility to comply with OLCs and conditions at all times.

Radioactive waste that is also nuclear material is to be managed then the security systems and infrastructure protecting the nuclear material will need to comply with the requirements under the Amendment to the *Convention on the Physical Protection of Nuclear Material* and the IAEA *Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities*. This is managed under the *Nuclear Non-Proliferation (Safeguards) Act 1987* by the Australian Safeguards and Non-Proliferation Office (ASNO).

There is currently no centralised national waste management facility for interim storage or disposal in Australia. Sections 1.7 and 5.4 of this Summary Report provide detailed information on the plans and framework supporting the establishment of a national facility. ARPANSA has provided significant guidance on the requirements and review and assessment that will take place once an application for a national waste management facility for storage and disposal of radioactive waste is made (see sections 5.4 and 9.4). This assessment is in line with other facilities described in this section, and includes requirements for the applicant to demonstrate effective systems and processes:

- that provide assurance that the controlled facility can be sited, constructed, operated, decommissioned and closed in a way that does not pose undue risk to the health and safety of people and to the environment
- that the controlled facility provides an overall net benefit
- that protection of workers is optimised during operation and decommissioning and that worker protection is optimised during monitoring and remedial works including in the post-closure phase of a disposal facility
- that prevent unauthorised access, theft and acts with malicious intent including actions that would contribute to proliferation of nuclear material considering the security vulnerabilities of the controlled facility and entire system for waste management
- that maintain adequate capacity for the full lifecycle of the controlled facility and records are established and preserved for the future.

6.5 Review and assessment for decommissioning activities

Related to GSR Part 6: paragraph 3.3

ARPANSA requires licences for the decommissioning stage of facilities, and a licence holder must apply for authorisation to abandon a facility. ARPANSA has previously issued such authorisations, however there are currently no facilities that hold an ARPANSA decommissioning licence. The application process is described in the preceding sections, see section 5.5. To support decommissioning applications detailed information is required, which is reviewed and assessed prior to making a licensing decision. In addition to decommissioning, an approval is required under regulation 53 of the Regulations for the disposal of radiation sources. In other jurisdictions, such approval or notification is also required.

The ARPANSA Guide *Surrender of a Facility Licence and Release from Regulatory Control* is based on IAEA Safety Standards *Release of Sites from Regulatory Control on Termination of Practices WS-G-5.1 2006*. This guide contains further guidance to assist the determination of whether the CEO should accept the surrender of a facility licence following decommissioning, and release it from regulatory control. A Regulatory Guide on *Decommissioning of Controlled Facilities*, which is based on the IAEA General Safety Requirements GSR Part 6 *Decommissioning of Facilities*, is in its final stages of publication. Relevant international standards, which are taken into account during review and assessment, also include *WS-G-5.2 Safety Assessment for the Decommissioning of Facilities Using Radioactive Material.*

Further information is provided in section 5.5 of this Summary Report.

6.6 Review and assessment for transport activities

Related to SSR-6

Routine transport

Authorisation is required for the transport of radioactive material. The information submitted by the applicant is assessed against the codes applied by relevant jurisdiction legislation. For ARPANSA the application is reviewed against the requirements of *Code for the Safe Transport of Radioactive Material 2014*, Radiation Protection Series C-2 (RPS C-2), and RPS C-1. This is part of the licensing process described in the preceding sections.

Special arrangements, package validation and other transport approvals

Previously, the ARPANSA Regulatory Guide *Safety Guide for Approval Processes for the Safe Transport of Radioactive Materials (2012)*, Radiation Protection Series No.2.2 (RPS 2.2) was used in the review of transport approvals. This document was replaced with direct reference to the guidance: *Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (*SSG-26), and *Schedules of Provisions of the IAEA Regulations for the Safe Transport of Radioactive Material 2012 Edition (SSG-33).*

ARPANSA's assessment of package design, shipment approval, and validation of designs includes identification, consideration and tracking of the serial numbers of approved package designs. Validated package design data is recorded by ARPANSA in the document management system, which includes details of the original design certificate and serial numbers of packages. ARPANSA is informed of the serial number of each packaging manufactured to a design approved under paragraphs 808, 811, 814 and 820 of RPS C-2 (direct adoption of IAEA SSR-6 *Regulations for the Safe Transport of Radioactive Material*).

Applications for approval are assessed against all relevant regulatory requirements. The results of assessment determine whether an approval certificate will be issued. The approval process also takes into account that the applicant and subsequent consignors and carriers have adequate provisions in place for preparedness for and response to an emergency in the transport of radioactive material.

When considering applications for approval of shipments under special arrangement, ARPANSA takes into account the demonstration by the applicant that the overall level of safety provided by the design of the package and the supplementary operational controls during transport is at least equivalent to that which would be achieved if all applicable regulatory requirements were met.

ARPANSA considers special arrangement to be exceptions, to be applied on a case-by-case basis where it is impracticable to demonstrate compliance with specific clauses of the SSR-6. Approvals are granted to single shipments with controls and measures strengthened to meet the standard that would otherwise be expected and achieved.

Security enhanced transport

Under the ARPANSA *Code of Practice for the Security of Radioactive Sources 2007*, Radiation Protection Series No.11 (RPS 11) a Source Transport Security Plan must be provided to the relevant regulatory body at least seven days in advance of the proposed date of each shipment of a Category 1 source; for Category 2 or 3 sources, notification is required at least seven days in advance of the shipment, or the first shipment if shipments are to be frequent.

This plan must contain the information required in Schedule A2 of RPS 11, which includes:

- a description of the source to be transported including: nuclide, activity (including date of measurement), physical and chemical form, serial number, transport packaging and the categorisation
- details of the conveyance in which the source will be transported and the arrangements for securing the shipment during transport and any stops on the route
- the name, address and business and after hours contact details for the consignor, consignee, carrier and, where used, guard or police service
- specific security concerns to be addressed, for example theft or sabotage, or mechanical or electronic failure of a physical security measure
- the physical and procedural security measures in place
- arrangements for review and revision of the Source Transport Security Plan.

Personal doses during transport

Persons involved with high activity radiation sources such as those used in industrial radiography, borehole logging and geotechnical measurements are typically required to wear a personal radiation dosimeter to record their dose, including when they are using or transporting the radioactive sources. In most jurisdictions, monitoring is required if there is potential for exposure to be greater than 1 mSv. Some jurisdictions, e.g. TAS, issue specific guidance on monitoring frequency in relation to potential doses. In other jurisdictions, including Commonwealth, while there is no specific guidance, such as a level at which monitoring is required, the requirement is effectively implemented under RPS C-1, applicants must outline dose-monitoring techniques in their application and there is an expectation of monitoring workers who may potentially incur higher exposures. Depending on the individual circumstances, the potential to exceed the annual effective dose limit for members of the public of 1mSv is typically applied as the threshold where monitoring is required, consistent with the guidance of other jurisdictions. Where determined to be required, dynamic monitoring during carriage of particularly hazardous loads could be undertaken on a specific need basis. However, this is not typically required. Similarly, independent verification of transport worker doses is typically not undertaken.

6.7 Conclusions and actions

Australian jurisdictions perform review and assessments of applications for authorisation in a manner that generally meets the expectations set out in the IAEA safety standards. The regulatory body reviews and assesses relevant information including from applications and submissions to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorisation. Review and assessment of information is performed over the lifetime of the facility and is commensurate with the radiation risks, in accordance with a graded approach.

Requirements and processes for regular, periodic review and assessment by the licence holder are included in licence conditions, regulations and regulatory guidance. The regulatory body will perform an assessment of the initial application and when significant changes are made that may impact safety. Notification of changes and routine updates provide the opportunity for review: this occurs in States and Territories on re-application, and through regular reporting in the case of ARPANSA. Additional reviews may occur as part of the inspection process.

ARPANSA maintains a high level of transparency in its review and assessment. This includes publishing online major assessments, including relevant regulatory assessment reports and statements of reason.

7. Inspection

This section includes responses from all Australian jurisdictions on generic issues (7.1), and from most jurisdiction on sources, facilities and activities (7.2), and transport (7.6).

The sections on research reactors (7.3), waste management (7.4) and decommissioning (7.5) relate to the Commonwealth regulator, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

7.1 Generic issues

Related to GSR Part 1 (Rev. 1): Requirements 27–29, paragraphs 4.50 and 4.53

Inspections are performed by each jurisdiction's regulatory body in accordance with the legal framework of each jurisdiction. Inspectors are authorised to carry out inspections of licence holders or in relation to suspected unauthorised possession or use and to investigate reported non-compliance. staffing and competence of the regulatory body is described in section 3.3.

The inspections are carried out, utilising a graded approach, of licence holder facilities, sources, and activities. Both scheduled and reactive inspections may be performed by all jurisdictions. Unannounced inspection are carried out judiciously as they may be more disruptive to the licence holder and third parties, e.g. patients in a medical setting, and key staff may not be available.

In addition to formal inspections, site visits and meetings may be undertaken. Generally, site visits are used by inspectors to familiarise themselves with processes, procedures or personnel, to follow up on specific progress, or as part of educative and consultative campaigns. Meetings also include scheduled meetings such as to discuss licence holder quarterly reports or project updates.

Inspections are planned and carried out in accordance with written procedures and focus on a number of topical areas. Inspection results are discussed with and provided to the licence holder - or as relevant the operator, owner, or site occupier. This includes inspection outcomes and request for actions, as necessary.

7.2 Inspection of radiation sources facilities and activities

Related to GSR Part 1 (Rev. 1): Requirements 27–29 and GSR Part 3: Requirement 3

Related to GSR Part 1 (Rev. 1): Requirement 29, paragraphs 4.51 and 4.52

ARPANSA inspections

ARPANSA inspections are scheduled and carried out in accordance with long term schedules, which are based on hazard or risk, or are carried out for a specific cause (augmented inspections). Scheduled physical inspections include prior notification to the licence holder, entrance meetings to discuss scope, and exit meetings to review findings. The inspection reports are, following licence holder review for factual correctness and internal approval, placed on the ARPANSA website (except for security sensitive material). Once the report is published online a survey is sent to the licence holder's representatives that were present during all or part of the inspection to seek feedback on the inspection.

The ARPANSA inspection process, as summarised in this section, is also provided on ARPANSA's website to ensure that licence holders are aware of processes and expectations. Specific procedures are captured in ARPANSA's *Inspection Manual*, which is maintained in the Regulatory Management System (RMS) and published online.

The CEO appoints inspectors under the *Australian radiation Protection and Nuclear Safety Act 1998* (the Act) (see section 3.3 of this report on regulatory body resources including numbers of inspectors). Part 7 of the Act sets the powers available to inspectors to inspectors, which include the power of entry and inspection at any time, search, seize, inspect, take samples, take photographs or records, and require the occupier to answer questions or produce records.

Types of inspections

The types of Inspection carried out include:

- scheduled physical inspections - Routine inspections are scheduled in accordance with a hazard/risk informed frequency
- scheduled e-inspections - Licence holders with lowest hazard sources and low hazard sources located in remote locations may be asked to provide evidence of effective control in the form of documentation and photographs for desktop review as an alternative to an inspector visiting the site. As an example, e-inspections may be carried out for an X-ray baggage scanner located overseas at an Australian embassy
- unannounced inspections - These may be performed with the consent of the occupier or, if the licence holder refuses, with a warrant
- augmented inspections – These are performed with notice, but in addition to any inspections due according to a scheduled frequency, and are typically in response to a specific issue or incident.

An inspection may be performed at any premises to assess compliance with the Act or the Australian Radiation Protection and Nuclear Safety Regulations 1999 (the Regulations), which could include where the inspector believes that activities or dealings are being undertaken which require authorisation, and is not limited to the inspection of the licence holder's premises.

Site visits and meetings supplement the inspection program but are not inspections. Generally, site visits are used by inspectors to familiarise themselves with processes, procedures or personnel. The information gathered is often used to inform a decision-making process such as licence application assessment, requests for approval to undertake a change with significance for safety under regulation 51 of the Regulations, or other required approval. Site visits may also be used to share information with a licence holder or educate them on regulatory matters relevant to the activities they undertake. Observations and information are recorded in a Site Visit Report. There is no requirement to provide the site visit report to the licence holder or for its publication. However, observations are discussed with the licence holder's management and personnel during the site visit. Meetings are also held, including regularly scheduled meetings to discuss quarterly or sixth monthly report outcomes, or project updates.

Frequency of inspections and graded approach

ARPANSA adopts a graded, risk or hazard-informed approach to compliance monitoring and inspection. Inspection frequency ranges from quarterly to six yearly. For some low hazard sources, ARPANSA utilises non-inspection based compliance monitoring and reporting. Inspection schedules are maintained in the RMS.

For facility licences, ARPANSA applies a risk ranking methodology to prioritise inspection effort, and to determine inspection frequency. For source licences, an inherent source hazard methodology is applied based on the hazard groupings of sources. These methods are outlined in ARPANSA's *Inspection Manual.*

Inspection frequency	Facility		Source	
	Regulatory priority	Examples	Regulatory priority	Examples
3 months	Very high	Research reactors	Not applicable	-
1 Year	High	Waste storage facility	1	Industrial radiography
1-2 Years	Medium	Large accelerator facilities	2	High level laboratory
3-4 Years	Low	Small irradiator facilities	3	Portable gauges
4-5 Years	Very low	-	4	Medical apparatus
5-6 years (or alternative arrangement)	-	-	5,6	Baggage scanners, UV source

Table 8. Inspection frequency summary

All facilities and sources with Regulatory Priority 1 are inspected by 2 or more inspectors.

Inspection areas

Areas of inspection are outlined in the Performance Objectives and Criteria (PO&C). These are detailed in section 1.9 of ARPANSA's *Inspection Manual*. Prior to inspection, facility or site-specific questions are developed to assess adherence to the PO&C. While source licence inspections cover all modules of the PO&C, facility licence inspections will sometimes focus only on specific modules. Each module is broken down into smaller sub-modules to focus on specific areas. Source licences utilise the same approach as facilities using a condensed PO&C format. A summary of the PO&C areas is provided below:

- **1 – Performance reporting and verification.** This module addresses the reporting culture, both internally and externally, including discrepant or unreported performance data, performance indicator verification, compliance with the operating limits and conditions.
- **2 – Configuration management.** This module addresses the knowledge of and control of physical configuration and operational methods. It includes evaluation of changes (Regulations 51 & 52 the Regulations), equipment alignment, operability determinations, temporary facility modifications, safety and security system design and capability.
- **3 – Inspection, testing and maintenance.** This module addresses the regime of inspection, testing and maintenance that ensures the safety of the controlled activity. It includes post-maintenance testing, in-service testing and inspection, surveillance testing, maintenance, management arrangements.
- **4 – Training.** This module addresses the systematic use of personnel training, authorisation and accreditation to ensure that all workers are suitably qualified and experienced thus ensuring that the controlled activity is undertaken safely and securely.

- **5 – Event protection.** This module addresses the licensee's consideration and implementation of controls to manage and mitigate the effects of outside influences including adverse weather, fire protection including bush fires, flooding, and land management.
- **6 – Security.** This module addresses the security arrangements and requirements to prevent unauthorised access or damage; loss, theft or unauthorised transfer; and unauthorised use, of controlled apparatus or radioactive sources.
- **7 – Radiation protection.** This module addresses the access control, dosimetry, optimisation, radiation monitoring instrumentation, effluent system monitoring, radioactive material processing and transportation etc., that protect people and the environment from the harmful effects of radiation.
- **8 – Emergency preparedness and response.** This module addresses the anticipation of hazards and threats, the assessment of consequences and the preparation of appropriate systems and measures to ensure an effective, timely, integrated, controlled and coordinated response to a nuclear or radiological emergency. It includes exercises and drills, emergency response organisation testing, and notification testing.
- **Cross Cutter 1 – Safety culture.** This module addresses the shared values and beliefs, throughout an organisation, that produce behavioural norms that provide an appropriate and demonstrable attention to safety.
- **Cross Cutter 2 – Human performance.** This module addresses the standards and expected behaviour of workers and the organisational features that are in place to ensure that the organisation maximises the strengths and minimises the weaknesses of human performance by providing workers with appropriate policies, processes, practices and equipment.
- **Cross Cutter 3 – Performance improvement.** This module addresses how the organisation monitors and learns from operational experience. It covers the understanding of how deviations from expected performance are understood, the identification, evaluation and solution of problems; and the implementation of opportunities for improvement.

Inspection reporting

Inspection reports are prepared and, following licence holder review for factual correctness and internal approval, placed on the ARPANSA website.

The inspection report provides observations and findings and may include areas for improvements or potential non-compliances identified during the inspection. These help the licence holder to review the issues and identify potential strategies to address their causes.

When ARPANSA identifies a potential non-compliance, the licence holder is given an opportunity to respond before a determination is made whether the licence holder has been in breach of the Act. Once a non-compliance has been confirmed as a breach of the Act, it is placed in a register and tracked to ensure relevant corrective actions have been performed by the licence holder.

Inspection outcomes are also analysed and distributed:

- internally, to staff quarterly via emailed reports and annually as part of internal training. This provides for an opportunity to change regulatory processes, and raises awareness of issues from across the regulatory body

- externally, at licence holder forums, and summarised on the ARPANSA website. This helps licence holders to be aware of common findings, which may assist in driving improvement in practice and culture
- where a past incident is identified during an inspection, they are also recorded in the Australian Radiation Incident Register (ARIR). ARIR reporting requirements apply to all jurisdictions and are specified in Schedule 13 of the *National Directory for Radiation Protection*. ARPANSA publishes yearly summaries of the over 300 incidents reported to the register annually.

Independence, conflict of interest and joint inspections

As outlined in the Policy for ARPANSA's Regulatory Activities, ARPANSA acts independently of any other interests in carrying out its regulatory activities. This includes independent advice, overseeing licence holder activities, and ensuring that the prime responsibility rests with the licence holder.

ARPANSA staff, including the CEO, are obliged to declare any interests in matters related to regulatory decision making to enable determination whether such interests may constitute a real, potential or perceived conflict of interest.

ARPANSA's Regulatory Services Branch (RSB) engages internal staff from other branches (if appropriate) or external subject matter experts for particular inspections. External inspectors (currently from Queensland Department of Health) are engaged to provide independent oversight of inspection activities by performing joint inspections with RSB staff where ARPANSA is also the licence holder. These processes are captured in procedures such as ARPANSA's *Inspection Manual*.

ARPANSA collaborates with other agencies, including joint inspections with:

- Comcare – the Commonwealth workplace health and safety regulator
- Australian Safeguards and Non-Proliferation Office (ASNO) – the nuclear security and safeguards regulator.

States and Territories

Scope

State and Territory inspections focus on compliance with relevant jurisdiction requirements and licence conditions, which may include adherence to codes and standards. In general, the inspections concentrate on ensuring that the minimum requisite safety standard is achieved. In addition, where an issue is identified which may indicate that a licensee does not demonstrate a capacity or willingness to comply with requirements, further actions may be taken.

Some State and Territory inspections do not typically investigate the practices of a possession licensee against international best practice or considerations such as safety culture. However, authorised parties are encouraged to improve practices.

Areas of inspection are dependent on the source and the relevant codes which apply to these sources. For example, inspection categories may include:

- medical imaging practices
- medical practices involving nuclear medicine

- medical practices involving interventional fluoroscopic apparatus
- veterinary practices
- operations involving mining, including mineral sands mining, and processing
- practices involving industrial radiography equipment
- practices involving portable density/moisture gauges.

Types of inspections

The relevant jurisdictional legislation allows for both announced and unannounced inspections, which may be in accordance with a schedule or where a need is identified. Inspections are typically performed with consent of the owner or occupier, but may also be performed under a warrant if circumstances so require.

In many situations, particularly with medical practices, scheduled (routine) inspections are announced inspections. Therefore, prior to inspection, the licence holder (or representative) and the regulator agree a mutually convenient time to undertake the inspection. Prior notice varies by jurisdiction and inspection type. With regard to medical practices, negotiation of timeframes helps to minimise interruptions to the workplace and patient flow, as well as ensures that relevant staff and equipment are available.

In most jurisdictions, unannounced inspections are typically only undertaken as the result of a suspected or confirmed non-compliance or an incident and may form part of a formal investigation process. This could be part of enquiries and complaints regarding potential environmental contamination or health risks caused by radiation sources or activities. In some jurisdictions (e.g. QLD) certain types of inspections are scheduled and carried out as unannounced inspections.

Graded approach and frequency of inspections

Each jurisdiction sets their inspection program in accordance with local jurisdiction resources and priorities. These take into consideration the risk and context of the source. For example, the SA regulatory body performs 100 inspections per year across the diagnostic medical, industrial and scientific areas, prioritising higher activity sources and higher risk applications such as uranium mining (with quarterly inspections).

Inspections on a targeted industry or practice modality may also be conducted as part of a campaign, for example due to a change in requirements or reported non-compliance.

Many source types, including medical sources, are also inspected through third-party compliance testing to assess whether the equipment meets certain criteria. This testing frequency depends on the type of source and the jurisdiction in which the equipment is located. See compliance tests in this section.

Inspections may be carried out where non-compliance is suspected, including where a licence holder has not renewed their authorisations by the due date, or where incidents have occurred.

Some jurisdictions have experienced significant staff reductions, which have affected the risk-based-informed compliance monitoring practices. As such, these jurisdictions focus on reactive (based upon incidents, complaints or notifications) rather than proactive inspections (in line with long-term inspection schedule). However, other jurisdictions (e.g. VIC) have been actively enhancing their in-field presence with a target of 480 inspections per year.

Inspection reporting

The regulatory inspections assess the licence holder's compliance with the legal responsibilities, including compliance with national codes and standards. This may result in recommendations, areas for improvement or findings of non-compliance.

Recommendations generally do not reflect a non-compliance with legislative requirements, but identify areas where practice could be improved. The recommendations, or areas for improvement, are usually based on best practice radiation regulation, for example found in the ARPANSA Radiation Protection Series (RPS) publications. The licence holder is provided with educative material to consider. Implementation is typically tracked though site visits or other non-inspection contacts or activities.

Breaches of acts and regulations, which typically require actions to be taken to return to compliance, may, depending on the type or severity, include enforcement actions (see section 8 of this Summary Report).

Third-party inspections (compliance tests)

In addition to inspections by the regulator, jurisdictions accredit persons to assess the compliance of sources, or places where sources are kept, against criteria set by the jurisdiction. For example, the NSW regulatory body requirements for testing medical diagnostic X-ray equipment is published in Guideline 6 - Registration requirements & industry best practice for ionising radiation apparatus used in diagnostic imaging. This is organised by the licence holder directly with the third party who submits evidence of compliance outcomes to the regulator directly or through the licence holder. There is considerable variation in frequency, types of tests and what needs to be tested across the jurisdictions, which introduces uniformity issues for sources which are moved between jurisdictions (see section 13.5 on national uniformity).

Third-party compliance testers may be audited by the local jurisdiction regulatory body to ensure that standards are being maintained.

7.3 Inspection of research reactors

Related to SSR-3 paragraphs 3.13–3.16

Related to GSR Part 1 (Rev. 1): Requirement 29, paragraphs 4.51 and 4.52

The ARPANSA general inspection process is followed for the inspection of research reactors. This is described on the ARPANSA website and detailed information is provided in section 7.2 of this Summary Report. In addition to the inspection requirements that apply to all sources and facilities, some requirements apply only to the ANSTO OPAL Research Reactor.

The eight functional inspection areas that are covered by the program, plus three additional cross-cutting areas that are applicable to all functional areas, apply to the inspections of the OPAL reactor. For the OPAL reactor, on average, one or more functional areas are inspected per quarter. The eight functional areas and three cross-cutting areas are described in section 7.2.

The regulatory expectations are further detailed and supplemented by additional information and guidelines in the ARPANSA regulatory guides (e.g. Periodic Safety and Security Review for Research Reactors). The international best practice documents which apply to research reactors includes IAEA Specific Safety Requirements *Safety of Research Reactors* (SSR-3), and supersede many principles of the

now archived Regulatory Assessment Principles guide and are also applicable to the requirements for research reactor design. These documents cover safety aspects such as control of radiation exposure, restricting probability of events, mitigating consequences, reactivity control, heat removal, and application of defence in depth.

There is one ARPANSA inspector dedicated to the OPAL research reactor, supported by an alternate inspector who maintains general oversight of the facility. Both of these inspectors are senior regulatory officers who have experience in the nuclear industry and regulation. Inspectors are periodically rotated with regard to their assigned facilities to develop skills and reduce the risk of regulatory capture. Additional support is provided as needed from other RSB officers or other experts appointed internally or externally. See section 3.3 for further information on staffing and competence of the regulatory body.

As with all facility inspections (described in section 7.2), inspection results are discussed, reviewed, reported, published online, and corrective actions followed up. Site visits supplement the inspection program. These are regular, frequent and informal visits to the premises of a licence holder for the purpose of familiarisation with a facility or source, associated processes or procedures, and personnel. The site visits of the OPAL research reactor are conducted in 2-3 week intervals. There are no research reactor specific additional requirements for inspections.

7.4 Inspection of waste management facilities

Related to GSR Part 5: paragraphs 4.22, 5.14, 5.15, 5.20

Related to SSR-5: paragraphs 3.15, 3.48, 5.19

Related to GSR Part 1 (Rev. 1): Requirement 29, paragraphs 4.51 and 4.52

There are a number of waste management facilities managed by the Commonwealth, as previously discussed in sections 5.4 and 6.4. Among the Commonwealth waste management facilities, ANSTO operates the largest number of facilities (see section 6.4 of this Summary Report). ANSTO is also responsible for a legacy waste site from the 1960s containing radioactive waste produced by its predecessor, the Australian Atomic Energy Commission.

For storage of radioactive waste, it is ARPANSA's expectation that there should be documented procedures for inspection, maintenance and monitoring as described in the ARPANSA Regulatory Guide: Plans and arrangements for managing safety (section 4). The review for adequacy for storage capacity is stipulated through facility licence conditions, and review of performance assessment of the facility is required to be undertaken at least every three years.

ARPANSA undertakes inspection in accordance with the ARPANSA *Inspection Manual* applying the PO&C as described in section 7.2 above. There are no other specific instructions for inspection of waste facilities.

7.5 Inspection of decommissioning activities

Related to GSR Part 6: paragraph 8.5

Related to GSR Part 1 (Rev. 1): Requirement 29, paragraphs 4.51 and 4.52

There are currently no decommissioning licences issued by ARPANSA. ARPANSA has, in the past, licensed the decommissioning of the Moata research reactor and the National Medical Cyclotron (NMC).

The Moata research reactor was a 100kW Argonaut class reactor that operated for more than 30 years. It was decommissioned in 2009, during which it was subject to an extensive inspection program to verify that the requirements of the decommissioning safety case were met. Prior to the surrender of the Moata licence, ARPANSA inspected the disposal routes for all radioactive waste from the facility and verified that the building that had housed the reactor had activity levels consistent with the building prior to the operation of the reactor.

The same process was conducted for the decommissioning of the NMC, the licence for which was surrendered in 2012 (licence F0230). In this instance a new cyclotron was installed at the refurbished facility (licence F0251). Copies of these licenses are found in the evidence folder of the decommissioning module.

ARPANSA also licences the permanently shutdown 10 MW HIFAR research reactor under a Possess or Control licence (F0184). Under this licence the operator must care and maintain the reactor including refurbishment were needed. Subject to approval, the operator may undertake activities to radiologically characterise it in preparation for decommissioning. However, the operator is not permitted to remove any radioactive components from that facility before it applies for and is issued with a decommissioning licence. The HIFAR research reactor is also subject to regular inspections to ensure that the requirements of the Possess and Control licence are met.

Inspection of decommissioning stage facilities are planned and executed as per other inspections. Inspections will in in accordance with the PO&C and will verify whether or not any conditions of licence are met. This will include an assessment against appropriate standards relating to decommissioning.

7.6 Inspection of transport activities

Related to SSR-6: paragraphs 302, 306, 503,582, 801

Compliance monitoring includes two aspects:

- confirming that transport has been appropriately authorised, and that relevant provisions have been made in the consignor's management system. Requirements on these provisions are part of the licence of the organisation who controls or transports the material
- that transport arrangements are carried out in accordance with the *Code for the Safe Transport of Radioactive Material 2014,* Radiation Protection Series C-2 (RPS C-2). In some jurisdictions, such as QLD and WA, the individuals transporting material by road will have individual licences.

In line with a graded approach, inspections are targeted at the areas of highest risk. Australian regulatory bodies do not generally consider the routine transport of radioactive material as a high risk to public health or the environment in Australia. Consequently, inspections that target facilities and activities related to transport of radioactive material are rare in most jurisdictions and such inspections would typically only be conducted in case of suspected non-compliance, e.g. following complaints or input from informants.

ARPANSA

ARPANSA's authorisations cover the licence holder organisation (including staff and contractors), who may transport material.

ARPANSA inspects transport arrangements as part of the routine inspection program where applicable. ARPANSA's PO&C include checking that transport of radioactive material is carried out in accordance with RPS C-2. ARPANSA may undertake announced or unannounced inspections of any phase of transport, including transport providers, transit storage and dispatch. The majority of transport shipments that occur involving ARPANSA's licence holders are of a routine or low risk nature. As a consequence, no recent inspections have been performed specifically of these routine transports. Inspections focus on management arrangements and authorisations of licence holders, rather than on compliance of individual shipments. Joint campaigns with other transport authorities have been undertaken as needed. For example, ARPANSA and the Civil Aviation Safety Authority (CASA) undertook a joint inspection on airborne transport in Sydney, based on information provided by CASA.

For specific high profile shipments ARPANSA works with the licence holder to ensure appropriate regulatory oversight. For example, in July 2018, ANSTO shipped four casks of spent fuel from the OPAL reactor at ANSTO to France for reprocessing. The shipment approval was granted by ARPANSA. ARPANSA validated three French casks for use within Australia, while the fourth cask of the same design was granted design approval as a B(U)F package. An ARPANSA inspector was in attendance during the first leg of the transport routine from Lucas Heights to the designated port for loading onto the vessel prior to embarking into international waters en route to France.

Guidance on areas to cover during transport is provided in an appendix to the ARPANSA Regulatory Guide: Transport of Radioactive Material. However, this guide has not been reviewed since 2013 and provides limited practical guidance for ARPANSA licence holders transporting radioactive material.

States and Territories

Inspections are performed of licence holders, and cover transport where applicable. Victoria is proposing to monitor compliance by participation in joint transport operations to be delivered in conjunction with other regulators of the transport of hazardous materials. These operations are run as short term targeted interventions to monitor transport vehicles in busy transport routes. This is considered to be an efficient and effective measure of monitoring whether transporters are complying with the requirements to hold a management licence and comply with RPS C-2.

In several jurisdictions, including VIC, there are requirements on monitoring through personal dosimetry for personnel who are predicted to be above 1 mSv per annum. While this would not typically apply to general transport, personnel who perform transport as part of their activities, such as industrial radiographers, are subject to these monitoring requirements.

7.7 Conclusions and actions

Australian jurisdictions perform inspections in a manner that generally meets the expectations set out in the IAEA safety standards.

Regulatory bodies carry out inspections of facilities and activities to verify that the authorised party is in compliance with the regulatory requirements and with the conditions specified in the authorisation. Jurisdictions, including ARPANSA, have an inspection program that, in line with the graded approach, justifies the type and frequency of inspections carried out. However, there is significant variation between the jurisdictions in inspection frequencies and scope. A number of jurisdictions have risk ranking methodologies to inform inspection frequency, such as the matrix provided in ARPANSA's *Inspection Manual*. However these have not been harmonised across jurisdictions. Some jurisdictions do not have a formal schedule of inspections, or similar document, which outline inspection frequencies. The uniformity of inspection processes is further discussed in section 13.

In addition to the core regulatory elements, regulatory bodies play an important role in promoting positive culture for safety amongst licence holders. For ARPANSA, this is reflected in the inspection cross cutting PO&C and the finding of areas for improvement which are not non-compliances but which may assist the licence holder in improving safety.

As a means of carrying out inspections in remote areas and overseas territories, ARPANSA has developed an electronic inspection (e-inspection) program to satisfy the inspection program. These e-inspections are for low risk sites and sources, in line with the graded approach.

All jurisdictions have the power to carry out both announced and unannounced inspections. Many jurisdictions, including ARPANSA, make use of unannounced inspections as required rather than on a regular, scheduled, basis.

An improvement opportunity has been identified to enhance APRANSA inspection oversight of transport activities:

- ARPANSA inspects compliance with RPS C-2 as part of routine inspections; however, this program does not currently confirm routine transport arrangements of material after it has left the premises. See action plan item 13.

8. Enforcement

This chapter includes responses from all Australian jurisdictions.

8.1 Enforcement policy and processes

Related to GSR Part 1 (Rev. 1): Requirements 30 and 31, paragraphs 4.54, 4.57–4.60

Each jurisdiction's legal framework defines the compliance monitoring, and investigative and enforcement activities which may be undertaken. This includes the appointment of authorised officers, scope of authority, identification, powers to require information or records, powers the authorised officers have at premises, and powers to question and identify persons.

When a non-compliance has been identified, inspectors may use a range of options under their respective acts. These range from informal measures, through formal warnings and improvement notices, to prohibition notices or directions. Inspectors may seize radiation sources and evidence. Each regulatory body has the powers to suspend or cancel authorisations as well as to impose conditions on the authorisation. The regulatory body may also initiate prosecution of alleged offenders, typically through the jurisdictional department of public prosecution. However, in accordance with a graded approach, typically, the minimum regulatory action would be taken which will provide for a return to compliance.

In addition to managing non-compliance, the regulatory body may make recommendations or suggestions which assist the licence holder in applying best practice, while being mindful of not overstepping the demarcation between the responsibility of the operator and the responsibility of the regulator.

ARPANSA enforcement

ARPANSA's *Compliance and Enforcement Strategy* describes the promotion and monitoring of compliance and a graded response to non-compliance. The ARPANSA Regulatory Guide *Graded Approach to Dealing with Licence Holder Non-Compliance,* complements the policy and is targeted at licence holders. Both the strategy and guide are published on ARPANSA's website. The considerations on which enforcement tool should be used include the safety consequences, nature of the discovery, impact, the licence holder level of intent, their compliance history and other factors. The potential actions are graded below:

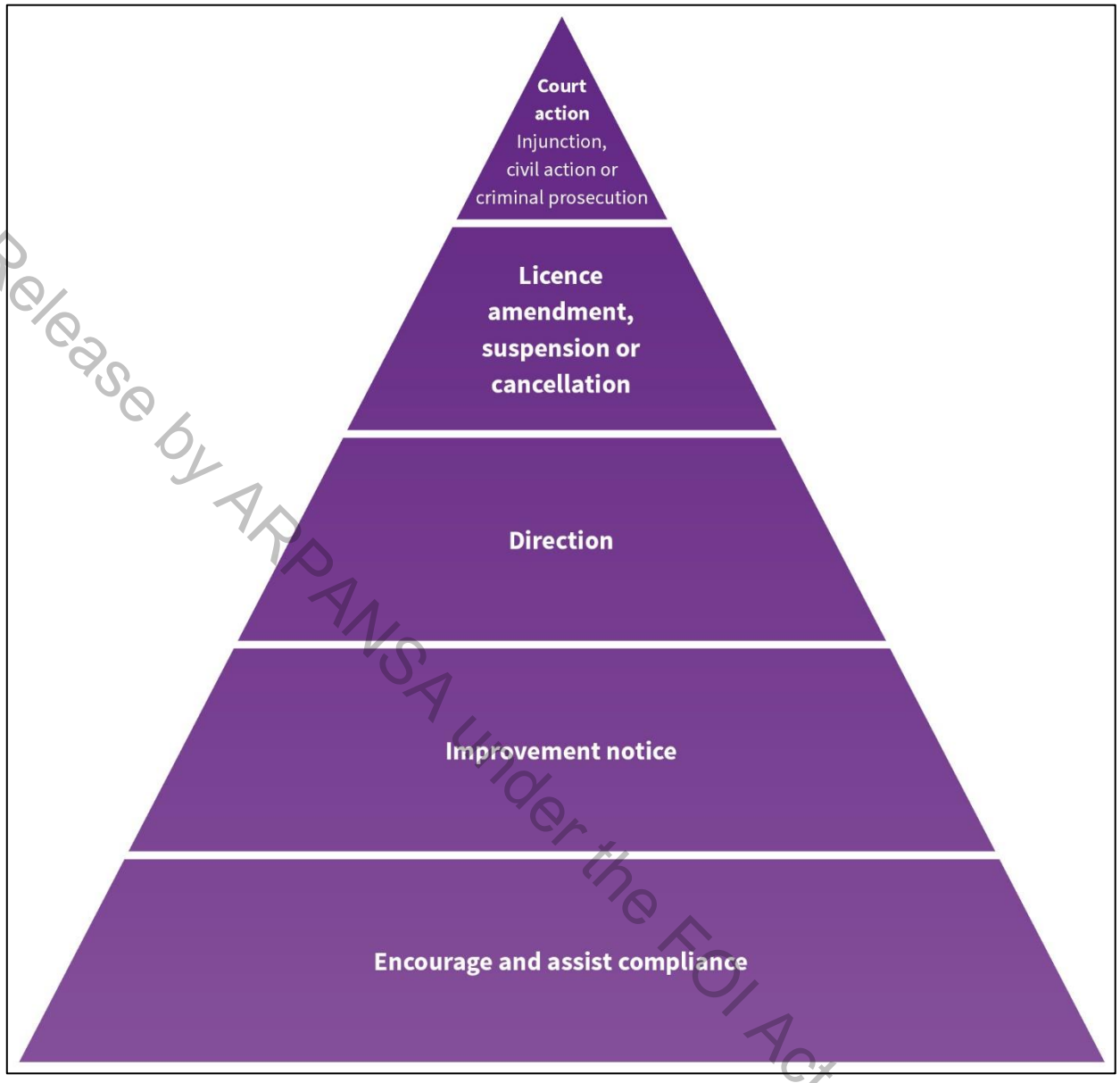

Figure 12. Potential enforcement grades

Under ARPANSA's Regulatory Management System, actions required by the licence holder to return to compliance are also followed up by inspectors, using a graded approach. For example, an improvement notice must be complied with within the timeframe specified, while the rectification of a finding in an inspection report may, in some instances, not be confirmed until the next scheduled inspection. Informal contact is generally used as part of encouragement and assistance. A follow-up register is used by ARPANSA officers to track actions associated with non-compliances.

The licence holder is required under regulation 46 of the Australian Radiation Protection and Nuclear Safety Regulations 1999 to investigate any non-compliance. In accordance with ARPANSA procedures, the licence holder is allowed 28 days to respond to any potential non-compliances identified in a report before ARPANSA makes a determination on whether the licence holder was non-compliant and what further actions to take. At this time, the licence holder is requested to identify actions and timeframes to implement those actions. Non-compliances that do not have significant safety implications are reported without naming the licence holder in the statutory quarterly and annual reports to Parliament. All other

non-compliances with potentially significant safety implications are reported to Parliament with the licence holder identified. The determination of a breach is made by the CEO of ARPANSA or their delegate, the Chief Regulatory Officer.

Inspectors may issue an improvement notice that requires the licence holder to remedy a non-compliance or prevent a likely non-compliance from occurring. An improvement notice may be used when resolution at the lower levels has failed to result in a return to compliance; there is immediate and significant safety implications; multiple or recurrent non-compliance of the same nature; or the licence holder refuses to take action in response to identified areas for improvement that are considered likely to lead to non-compliance.

The CEO may issue a direction to protect the health and safety of people or to avoid damage to the environment if the CEO on reasonable grounds believes that a controlled person is not complying with the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act).

In addition to non-compliances, ARPANSA issues areas for improvement (AFI), which are in the form of recommendations or suggestions that assist the licence holder in applying best practice. ARPANSA follows up within three months to evaluate if action is being taken for the areas of improvement. AFIs and potential non-compliances are listed in the inspection reports.

8.2 Enforcement implementations

Related to GSR Part 1 (Rev. 1): Requirement 31, paragraphs 4.55–4.56

In all jurisdictions, the regulator has access to a number of enforcement options. Including for inspectors to seize radiation sources, and either take, or recommend that their regulatory body take disciplinary action. Disciplinary actions include informal resolution or reprimanding; a requirement for specific actions or training to be undertaken such as through an improvement notice; imposing or varying conditions; and licence suspension or cancellation. Prosecution may also be pursued, such as through a recommendation to the State or Territory director of public prosecutions. NSW, NT and TAS have the power to issue Penalty Infringement Notices, which require the payment of a fine. A graded approach is used in implementing different enforcement actions.

ARPANSA enforcement actions

As described in section 8.1, powers under the Act enable or include:

- AFIs, which are in the form of recommendations or suggestions that assist the licence holder in applying best practice and avoiding potential non-compliances
- resolution of non-compliances though informal or formal communication, and the publication of non-compliances in annual and quarterly reports. Resolution actions and timeframes are recorded in the Breach Register and followed up
- improvement notice issued by an inspector under section 80A of the Act
- directions, given by the CEO under section 41 of the Act
- licence amendment, cancellation or suspension under sections 36 and 38 of the Act
- referring matters to the Director of Public Prosecutions. However, the ability to prosecute under the Act is limited; section 4 of the Act states that nothing in the Act renders the Crown liable to be prosecuted for an offence.

When an inspector identifies a potential non-compliance, through inspection or notification from the licence holder, the potential non-compliance is graded in accordance with the Regulatory Guide: *Graded Approach to Dealing with Licence Holder Non-Compliance*. Inspectors, after considering any comments from licence holders, provide the CEO with a recommendation to determine if a non-compliance occurred. The use of directions and improvement notices was discussed in section 8.1.

ARPANSA statistics for	2016-17	2017-18*
Areas for improvement (not a non-compliance)	154	97
Minor non-compliances (no or minor safety implications)	8	13
Significant non-compliances (significant safety implications)	2	4
Improvement notices	1	0
Directions, suspensions, Injunctions	0	1

*The 2017-18 annual report has not yet been completed and final reported numbers may vary from the presented data.

Table 9. ARPANSA enforcement statistics for last two financial years

APRANSA identifies AFI and potential non-compliances in inspection reports, which are published online. ARPANSA's practice is to follow-up within three months to evaluate if action is being taken for the areas of improvement. This helps in evaluating the effectiveness of the recommendations made, as well as provides information on the performance of the licence holder. For non-compliances, follow up is conducted on an individual basis, within negotiated timeframes as recorded in a breach register.

As part of internal education and training, ARPANSA prepares quarterly and annual inspection outcome reports, which analyse the types of AFIs and potential non-compliances found and any feedback received from licence holders. This information is also summarised and placed on the ARPANSA website and discussed at ARPANSA Regulatory Services Branch annual training days.

State and Territory enforcement actions

Most of the regulatory bodies have specific guidance on compliance and enforcement for their regulatory officers. For example, in QLD, the guidance document *Radiation Safety Act 1999*: Strategy to achieve compliance includes an enforcement guidance tool to guide consistent and supported enforcement actions to remedy identified non-compliance. Other jurisdictions, such as Victoria, have draft documents, which are being developed for this purpose.

These documents outline procedures for investigating non-compliance, determining the level of risk, identifying the enforcement options to most effectively improve compliance, and deciding on follow up actions.

For example, the NSW Environmental Protection Authority, during 2016-17 financial year, took the following actions:

NSW EPA Regulatory enforcement statistics for 2016-17	
Advisory letters	41
Show cause	3
Formal warning	1
Official cautions	19
Penalty infringement notices (fine)	2

8.3 Conclusions and actions

Regulatory bodies across Australia have established and implemented enforcement policies and practices in accordance with the legal framework of each jurisdiction, meeting the expectations of the IAEA safety standard in this area. ARPANSA has comprehensive documentation on the implementation of a graded approach to non-compliances, which is available to stakeholders.

The policies allow for enforcement measures to be taken according to the significance and severity of non-compliance, including taking immediate action in some situations (a graded approach).

9. Regulations and guides

This section considers Commonwealth arrangements, and the collaboration between all jurisdictions to develop nationally consistent regulatory documents; it does not consider the specifics of the State and Territory regulations and guides.

9.1 Generic issues

Related to GSR Part 1 (Rev. 1): Requirements 32–34, paragraphs 4.61–4.62, GSR Part 3: Requirement 3

Regulations and legislative change

Legislative change in each jurisdiction of Australia must pass through that jurisdiction's parliament. These parliaments act independently of each other. In general, a bill to create or amend an Act must be passed by both houses (the House of Representatives and the Senate for the Commonwealth; the Legislative Assembly and Legislative Council for States and Territories except QLD, which only has one house of parliament) and ratified by the Governor General or governor. Regulation, and other subordinate legislation, is made by the executive branch of government and authorised by parliament. The executive branch of government is drawn from the legislature.

The Federal Executive Council, which in practice gives legal effect to the decisions of the cabinet, comprises the Prime Minister and Ministers of State who advise the Governor-General. For more information see section 1. The relevant jurisdiction legislation is listed in *Appendix A – Reference Documents.*

For the Commonwealth, a Regulation Impact Statement (RIS) is required for any policy proposal or other decision designed to introduce, amend or abolish regulation and that may have an impact on businesses, community organisations or individuals, unless the proposed change is a minor or machinery in nature. The RIS outlines the potential impacts and opportunities which may be created by an approach and considers alternative approaches. The Australian Government Guide to Regulation outlines this process, with specific guidance such as Australian Government RIS Preliminary Assessment Form: Is a RIS required? The Office of Best Practice Regulation (OBPR) advises on, and assesses, Regulation Impact Statements and Post-Implementation Reviews, as well as prepares regular compliance reports, which are published on its website.

States and Territories have similar requirements, see e.g. the ACT Best Practice Guide for Preparing Regulatory Impact Statements. These require that the impact of introducing new requirements on business and individuals be assessed and communicated appropriately, which may include public consultation. Where there are differences in the requirements of the different jurisdictions, national uniformity issues may arise, as described in section 13 of this Summary Report.

National regulatory documents

ARPANSA, on behalf of all jurisdictions, publishes a range of documents to promote nationally consistent approaches to safety. Foremost in these publications is the Radiation Protection Series (RPS) suite of publications.

These include the *National Directory for Radiation Protection* (NDRP), which was first published in 2004 with regulatory principles and requirements and a process for the development and adoption of national codes and standards for radiation protection. The current NDRP is due to be replaced by a revised

2nd edition of the NDRP, which has been endorsed by the regulators from all Australian jurisdictions in July 2018, through the Radiation Health Committee. It is in an advanced stage of the national approval process and is expected to be approved by the Health Ministers by mid-2019.

Apart from the NDRP, which is a stand-alone depository for agreed regulatory principles and approaches, publication categories within the RPS are *Fundamentals*, *Codes*, and *Guides*:

- Fundamentals set the basic principles for radiation protection and describe the fundamental radiation protection, safety and security objectives. They are written in an explanatory and non-regulatory style and describe the basic concepts and objectives based on international standards and best practice.
- Codes are regulatory in style and may be referenced by regulations or conditions of licence. They contain either general safety or security requirements which may be applicable for all dealings with radiation, or practice-specific requirements. They provide overarching requirements and are expressed as 'must' statements which are to be satisfied to ensure an acceptable level of safety.
- Guides provide guidance on how to comply with the Codes or apply the principles of the Fundamentals. They are written in an explanatory and non-regulatory style and indicate the measures recommended for good practice. They are generally expressed as 'should' statements.

All codes that could potentially be used by regulators as conditions of licence or registration are subject to the Council of Australian Governments (COAG) Best Practice Regulation - A Guide for Ministerial Councils and National Standard Setting Bodies (Oct 2007). This means that such publications are treated as 'quasi-regulation' and are required to undergo a process of regulatory impact assessment to the satisfaction of the Office of Best Practice Regulation. The process includes public consultation.

The Radiation Health Committee (RHC) (see section 1.4) oversees the preparation of RPS documents which are produced in accordance with agreed priorities. This is a function of the RHC under section 23 of the Act:

- to develop policies and to prepare draft publications for the promotion of uniform national standards of radiation protection
- from time to time, to review national policies, codes and standards in relation to radiation protection to ensure that they continue to substantially reflect world best practice.

The RHC approves the RPS documents. ARPANSA will then, on behalf of all jurisdiction, seek the view of the Radiation Health and Safety Advisory Council (RHSAC) to endorse the publication, which is then published on the ARPANSA website. RHSAC includes representation from industry, public health, and health care and research. Endorsement from the RHSAC can provide additional assurance that community concerns, emerging issues, and adoption requirements have been taken into account.

National adoption of amendments to the NDRP and codes that have been referenced in Schedule 11 of the NDRP, require agreement by Health Ministers represented on the COAG (Council of Australian Governments) Health Council. They can then be implemented in the legal framework, e.g. as mandatory conditions of licence. For example, ARPANSA lists a number of Codes in Regulation 48 as mandatory licence conditions, and additional specific RPS publications on the website.

The RPS suite of publications also includes 'standards' and 'recommendations'. The matters covered in these publications will be updated within the structure of Fundamentals, Codes and Guides with time, and RPS will no longer refer to 'standards' and 'recommendations.

In addition, ARPANSA publishes RHC statements on particular issues, all of them on behalf of the jurisdictions and other RHC members.

The codes, standards and guides are updated taking into account international best practice such the IAEA safety standards. For example, the *Code for Radiation Protection in Planned Exposure Situations (2016)* (RPS C-1), and *Code for Radiation Protection in Medical Exposure* (RPS C-5) (under development) update pre-existing RPS documents by taking into account IAEA GSR Part 3. The Guide for Radiation Protection in Existing Exposure Situations (RPS G-2) is a new RPS publication based largely on GSR Part 3.

A list of the publications is provided under codes and guidance documents, in *Appendix A – Reference Documents.*

Regulatory guides for ARPANSA licence holders

ARPANSA regulatory guides are published on the website to give specific guidance to licence applicants and licence holders.

These documents provide guidance on ARPANSA's regulatory requirements. Interested parties are notified of changes through ARPANSA website and email, and have been consulted beforehand. ARPANSA holds a Licence Holder Forum annually to, among other things, inform licence holders about the updated status of regulations, Codes and Guides. For example, the 2017 feature topic was the *Code for Radiation Protection in Planned Exposure Situations* (RPS C-1), and the forum included a panel discussion between licence holders as well as a fulsome presentation on the RPS C-1.

These codes and guides have been developed drawing on past experience, best practice and international standards such as the IAEA safety standards. These guides are part of the Regulatory Management System (RMS) and as such subject to periodic review.

ARPANSA Regulatory Guides include:

- guides to assist prospective licence holders, which demonstrate a graded approach, requiring more detail for complex applications (graded approach):
    - How to apply for a source licence - October 2017
    - How to apply for a licence for a prescribed radiation facility - May 2016
    - How to apply for a facility licence for a nuclear installation - May 2016
    - Applying for a licence for a radioactive waste storage or disposal facility – May 2017
- Plans and Arrangements for Managing Safety – This guide sets out the requirements that should be demonstrated in an applicant's or licence holder's plans and arrangements. It may also assist licence holders in their review of plans and arrangements required under Regulation 50.
- Transfer or disposal of sources - August 2015 - This guide provides information on how to apply for approval to dispose of controlled apparatus or controlled material or transfer controlled apparatus or controlled material out of Commonwealth jurisdiction.
- How to determine whether a UV source is a controlled apparatus - October 2017 - This guide is provided to assist controlled persons determine whether a UV source falls within the definition of a controlled apparatus under the ARPANS regulations. It is valid for both pulsed and continuous sources of ultraviolet radiation where the exposure duration is not less than 0.1 ms. It does not apply to ultraviolet lasers.
- Inspections website – This site provides information for licence holders on inspection processes, outcomes, and what to expect during inspections.

- Graded approach to dealing with licence holder non-compliance - This document provides guidance to staff and stakeholders about ARPANSA's regulatory response to licence holder non-compliance (enforcement).

International best practice (IBP)

Under sections 32 and 33 of the Act, the CEO must consider international best practice in relation to radiation protection and nuclear safety when deciding whether to issue a licence. In addition, the Commonwealth Government proposed, in the Industry Innovation and Competitiveness Agenda: An Action Plan for a Stronger Australia, and subsequently adopted the policy principle that 'if a system, service or product has been adopted under a trusted international standard or risk assessment, then our regulators should not impose any additional requirements for approval in Australia, unless it can be demonstrated that there is a good reason to do so.'

An international standard and risk assessment does not become 'trusted' before its relevance and applicability in the Australian context has been assessed, documented and decided. The Commonwealth's policy (and ACC Guidance) on international standards and risk assessment states that portfolios need to work with stakeholder groups to identify criteria that take into account a number of considerations, including the applicability in the Australian context, and whether any necessary Australian specific conditions or circumstances warrant distinct regulatory standards and risk assessment processes.

ARPANSA promotes implementation in Australia of relevant international standards and risk assessments, in consultation with stakeholders. Two parallel but interconnected processes are being followed: one that is directly related to Commonwealth entities regulated by ARPANSA and one that develops codes and guides to be used nationally across all jurisdictions and, as relevant, referenced in the National Directory for Radiation Protection (NDRP). The RHC plays a key role in the latter process.

The ARPANSA website lists international best practice documents that represent international consensus on risks and what constitutes a high level of safety and protection of people and the environment from the harmful effects of radiation. The documents are considered in regulatory review and assessment, as well as in inspections and other activities. ARPANSA considers these documents within the Australian context and determines whether all requirements and guidance is applicable in the Australian regulatory environment, and whether any Australian-specific conditions or circumstances require further requirements or guidance.

As stated earlier, some of these international documents are referenced in ARPANSA's regulatory guides. For example IBP requirements on Management Systems, includes the requirements document GSR Part 2 Leadership and Management for Safety and associated safety guides which including G-3.1 Application of the Management System for Facilities and Activities, GS-G-3.5 The Management System for Nuclear Installations, TS-G-1.4 The Management System for the Safe Transport of Radioactive Material.

The ARPANSA guide Regulatory Assessment Principles (RAPs), which consolidated design and operational requirements, was recently retired in favour of direct reference to IBP documents. An analysis of international standards in the Australian context, as a replacement for the RAPs, is under way.

Regulatory guides for States and Territories licence holders

Similarly, State and Territory regulators publish information on their website, including but not limited to compliance testing requirements, shielding requirements, guidance on applications and the preparation of management plans. National uniformity is further discussed in section 13.

9.2 Regulations and guides for radiation sources, facilities and activities

Related to GSR Part 1 (Rev. 1): Requirements 32-34

The overarching document Fundamentals for Protection Against Ionising Radiation (2014) (RPS F-1) provides the protection objective and the basis for the regulatory requirements. This adopts the IAEA Fundamental Safety Principles SF-1 and underpins all further considerations.

In addition to the ARPANS Act and Regulation, the following codes apply to all licences:

- *Code for Radiation Protection in Planned Exposure Situations* (2016) (RPS C-1) based on requirements in IAEA GSR Part 3
- *Code for the Safe Transport of Radioactive Material* (RPS C-2) directly adopts the IAEA Transport Code SSR-6 & associated safety guides SSG-26 and SSG-33
- *Code of Practice - Security of Radioactive Sources* (RPS 11) which covers security arrangements for sealed sources
- *Code of Practice for the Disposal of Radioactive Wastes by the User* (1985) [for licences which allow dealing with Sources] – note that this has been superseded by Schedule 14 in the NDRP; the RHC has also agreed that this will be published a separate Code in the RPS suite of publication (RPS C-6).

Additionally, specific codes and guides are provided for industries or sources, such as:

- *Code of Practice and Safety Guide for Portable Density/Moisture Gauges Containing Radioactive Sources* (2004)
- *Code of Practice and Safety Guide for Radiation Protection in Dentistry* (2005).

For ARPANSA the website lists which specific codes apply to specific sources and facilities. In other jurisdictions, these are listed in the applicable licence condition.

ARPANSA also provides guidance for licence holders on topics such as applying for authorisations, plans and arrangements, and specific requirements and applies international best practice in its review, assessment and decisions, in relation to licence applications or in other regulatory activities This has been covered under 9.1 above.

9.3 Regulations and guides for research reactors

Related to SSR-3: paragraphs 3.1 to 3.4

Codes that apply to all facilities also apply to research reactors, including relevant Radiation Protection Series documents. There are no specific additional requirements under the Act or Regulations, which apply only to research reactors. However, ARPANSA has prepared guidance documents for these licence holders, such as Regulatory guide - Periodic Safety and Security Review of Research Reactors. The preparation of a periodic review, normally every 10 years but otherwise as necessary or requested by the CEO, is a licence condition on the OPAL reactor

As with all licence applications, the CEO of ARPANSA must consider how IBP is applied. For research reactors, international best practice is carefully considered and commitments to follow IBP documents are part of the licence holders plans and arrangements. The following IAEA documents are listed on the IBP page and are used as the regulatory basis for review and assessments of research reactors:

Safety requirements

- SSR-3 Safety of Research Reactors

Safety guides

- SSG-20 Safety Assessment for Research Reactors and Preparation of the Safety Analysis Report
- SG-24 Safety in the Utilization and Modification of Research Reactors
- NS-G-4.1 Commissioning of Research Reactors
- NS-G-4.2 Maintenance, Periodic Testing and Inspection of Research Reactors
- NS-G-4.3 Core management and Fuel Handling for Research Reactors
- NS-G-4.4 Operational Limits and Conditions and Operating Procedures for Research Reactors
- NS-G-4.5 The Operating Organization and the Recruitment, Training and Qualification of Personnel for Research Reactors
- NS-G-4.6 Radiation Protection and Radioactive Waste Management in the Design and Operation of Research Reactors
- SSG-22 Use of a Graded Approach in the Application of the Safety Requirements for Research Reactors
- SSG-10 Ageing Management for Research Reactors
- NS-G-2.11 A System for the Feedback of Experience from Events in Nuclear Installations
- NS-G-2.13 Evaluation of Seismic Safety for Existing Nuclear Installations
- SSG-37 Instrumentation and Control Systems and Software Important to Safety
- SSG-38 Construction of Nuclear Installations

9.4 Regulations and guides for waste management facilities

Related to GSR Part 5: Requirements 2, 6, 8, 9, 10, 11 and 12, SSR-5: Requirements 5, 7, 10, 15, 19, 20, 22 and 26

Plans are in place for establishing a National Radioactive Waste Management Facility for disposal of low level waste and storage of intermediate level waste. The framework governing these activities also includes plans for finding a site, and establishment of a facility, for disposal of intermediate level waste (see section 1.7; Australian Radioactive Waste Management Framework, April 2018). To assist in the preparation of such a site ARPANSA has published Regulatory guide: Applying for a licence for a radioactive waste storage or disposal facility - May 2017 and Information for Stakeholders: Radioactive Waste Storage and Disposal Facilities.

For routine disposal of waste in all jurisdictions, the requirements of RHS 13, *Code of practice for the disposal of radioactive wastes by the user* (1985), was essentially superseded by the incorporation of user disposal requirements in Schedule 14 of the *National Directory for Radiation Protection* (RPS 6) in 2017. As explained in section 9.2, RHC has agreed to republish Schedule 14 as a stand-alone Code, RPS C-6.

ARPANSA in collaboration with State and Territory Regulators has prepared the *Code for Facilities for Disposal of Solid Radioactive Waste* (RPS C-3), which in an advanced stage of the approval process (it has been approved by the RHC), and which will replace the current Radiation Health Series 35 - *Code of practice for the near-surface disposal of radioactive waste in Australia* (1992). It expands the scope of the 1992 Code to include disposal of solid radioactive waste in all types of disposal facilities (not just near-surface disposal). The publication will inform potential applicants for a licence to dispose of radioactive waste in a disposal facility, other stakeholders and the public of the issues that will have to be addressed by the applicant. The Code describes objectives for protection of human health and of the environment, drawing upon international best practice in relation to radiation protection and radioactive waste safety, e.g. the IAEA *Disposal of Radioactive Waste* (SSR-5).

Additionally, ARPANSA in collaboration with State and Territory regulators has published a Safety Guide for the Predisposal Management of Radioactive Waste (2008) and Safety Guide for Classification of Radioactive Waste (2010). This provides guidance to all Australian licence holders who may generate waste and are required to manage this waste until a disposal solution is in place.

9.5 Regulations and guides for decommissioning activities

Related to GSR Part 6

While some jurisdictions, including ARPANSA, can issue explicit licences for decommissioning under the relevant legislation, other jurisdictions can achieve the safety objective through, e.g., the use of licence conditions (see section 5).

As with all applications to ARPANSA, the CEO is required to consider international best practice, which includes requirements and guidance such as *GSR Part 6 Decommissioning of Facilities* and *WS-G-5.2 Safety Assessment for the Decommissioning of Facilities Using Radioactive Material.* These provide expectations of what to include with an application.

ARPANSA guidance on decommissioning includes the ARPANSA Guide Surrender of a Facility Licence and Release from Regulatory Control.

ARPANSA has prepared the Regulatory Guide: Decommissioning of Controlled Facilities which is being finalised for publication. This guide will provide guidance to licence holder and other interested parties on planning, conducting and completing the decommissioning of nuclear installations. It aims to assist in ensuring that the decommissioning of these facilities is conducted in a safe and environmentally acceptable manner in accordance with international best practice. This document will also be used for regulatory assessment of a licence application for decommissioning a controlled facility.

Once the draft guide has been approved and published, the plans and arrangements guide will be updated to ensure it references all applicable provisions such as decommissioning strategies and resource arrangements.

Sites that have been contaminated, including with radiation, by past activities are typically identified at the closure of the activity or discovered during changes to land use – for example, from industrial to residential use. In most cases these can be managed at the time that the change of land use occurs. In rare cases, some sites are found to present an unacceptable risk to human health or to the environment and must be dealt with as a priority. Guidance on legacy situations is contained in in RPS G-2 Guide for Radiation Protection in Existing Exposure Situations (2017), developed in collaboration with State and Territory regulators, and approved by the RHC.

9.6 Regulations and guides for transport activities

Related to SSR-6

In Australia, the *Code for the Safe Transport of Radioactive Material* 2014 (RPS C-2) provides the nationally agreed framework and requirements for safe transport of radioactive material. RPS C-2 adopts the IAEA's Regulations for the Safe Transport of Radioactive Material, 2012 Edition (SSR-6). Additionally, the *Code of Practice for the Security of Radioactive Sources* 2007 (RPS 11) contains requirements for the transport of security enhanced (sealed) sources.

These requirements are implemented by the relevant jurisdiction's listed in Schedule B of Radiation Protection Series C-2 and on the website. However, some jurisdictions are still using the previous 2008 or 2001 version of the code within the relevant jurisdiction legislation.

Previously ARPANSA maintained RPS 2.1 *Safety Guide for the Safe Transport of Radioactive Material (2008 Edition)*, and RPS 2.2 *Safety Guide for Approval Processes for the Safe Transport of Radioactive Materials (2012)*. However, as of 2016, ARPANSA directs all stakeholders to:

- SSG-26 *Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material*
- SSG-33 *Schedules of Provisions of the IAEA Regulations for the Safe Transport of Radioactive Material (2012 Edition).*

Additionally ARPANSA maintains checklists on the ARPANSA website, to assist persons making applications:

- Approval of Special Form Radioactive Material & Low Dispersible Radioactive Material Checklist
- Special Arrangement Approval Checklist
- Shipment Approval Checklist
- Package Design Approval Checklist
- Validation of Certificate Approval Checklist.

9.7 Guides for promotion of safety culture or 'holistic safety'

ARPANSA approaches the need for a strong safety culture through a holistic approach, a best practice, systemic, approach to safety that is consistent with the requirements of GSR Part 2 requirements 2 and 12. ARPANSA has published a range of information and guidance on its holistic safety webpages and has also engaged with stakeholders through meetings, forums and conferences to encourage a proactive approach to holistic safety.

ARPANSA's holistic approach was developed to address vulnerabilities that are associated with common contributing causes of accidents. Drawing on modern safety science ARPANSA has emphasised the following seven characteristics for holistic safety which address technical, human and organisational factors of safety in an overlapping and integrated manner:

- human aspects – competency and training, equipment and process design, operational environmental design
- non-technical skills – communication, leadership, team working, decision making and situational awareness

- defence in depth – conservative and proven design, control and limiting systems, safety systems, accident mitigation, and off-site response
- management system – integration of safety management requirements into all business processes
- resilience – the abilities to respond, monitor, anticipate and learn
- safety culture – based on INSAG 15 with an additional attribute of integration across organisational boundaries
- security culture – security management should be informed and integrated.

ARPANSA's Holistic Safety Guide discusses the characteristics and attributes of organisations that have good holistic safety practices. This is supported by another guide providing examples of questions that licence holders can ask themselves to explore their own organisations performance. ARPANSA has also published tools that can be used or adapted by organisations to help them identify strengths and weaknesses in key aspects of holistic safety.

The characteristics of holistic safety have also been woven into the inspection Performance Objectives and Criteria, (PO&Cs) and are examined through the ARPANSA inspection programme. The PO&Cs are published on the ARPANSA website to enable licence holders to proactively identify and address weaknesses before they are identified by inspectors.

9.8 Conclusions and actions

Australia generally meets the expectations of the IAEA safety standards with regard to regulation and guides.

The RHC develops, jointly and with the support of ARPANSA staff, a number of national Codes, and Guides for adoption across Australia. These are published by ARPANSA as part of the Radiation Protection Series and made available on the website. There is national agreement on regulatory elements and basic principles and approaches, captured in the National Directory for Radiation Protection, which also adopt certain Codes by reference, for national implementation. Consultation is undertaken for all these documents, as well as an assessment of the impact on businesses, persons and other stakeholders.

These national documents, together with relevant jurisdiction legislation which is periodically reviewed and revised, specify the principles, requirements and criteria for safety upon which regulatory judgements, decisions and actions are based.

The RHC has agreed to, as applicable and practicable in the Australian context, implement what broadly is referred to as international standards in Codes and Guides; ARPANSA links to international best practice on its website to provide guidance to license holders on appropriate international standards that may be considered.

ARPANSA has developed regulatory guides on a variety of topics for Commonwealth licence holders, which build on international best practice such as the IAEA safety standards. The documents also communicate the requirements for safe operations and protection of people and the environment, to a broader audience. As an example, to provide clear guidance on the regulatory process for the proposed national radioactive waste management facility, ARPANSA has been in regular contact with stakeholders and provided guidance documents on the website – including Information for Stakeholders: Radioactive Waste Storage and Disposal Facilities.

ARPANSA actively promotes safety culture with licence holders through initiatives such as the holistic safety guidelines and the Performance objectives and criteria, which are used during inspections as well as review and assessment.

The ARPANSA guide Regulatory Assessment Principles (RAPs), which consolidated design and operational requirements for ARPANSA licence holders, was recently retired in favour of direct reference to international best practice documents. An action on ARPANSA has been identified as follows:

- a comprehensive analysis on which international standards (and similar) documents are applicable to which facilities, and any gaps, has commenced but is not yet completed; it should be pursued in order to ascertain appropriate consideration of international standards' in ARPANSA's licensing activities. See Action Plan item 14.

10. Emergency preparedness and response (EPR)

This section focuses on the Commonwealth arrangements, with additional information provided on State and Territory arrangements where relevant.

The Australian Government Crisis Management Framework

The Australian Government Crisis Management Framework (the Crisis Framework) version 2.2 (December 2017) outlines the arrangements enabling the Australian Government's 'all hazards' crisis management approach. This approach is a continuum of: prevention, preparedness, response and recovery. The Crisis Framework covers a range of crises, including terrorist incidents, health pandemics, natural disasters and other incidents (including radiological and nuclear); and covers incidents affecting Australians and Australian interests domestically and overseas. The Crisis Framework provides ministers and senior officials with guidance on their respective roles and responsibilities. It also sets out the arrangements that link ministers and the work of key officials, committees and facilities, within the Australian Government, and guides the interfaces between jurisdictions in the Australian Federal System. The Crisis Framework is overseen by the Commonwealth Department of Prime Minister and Cabinet.

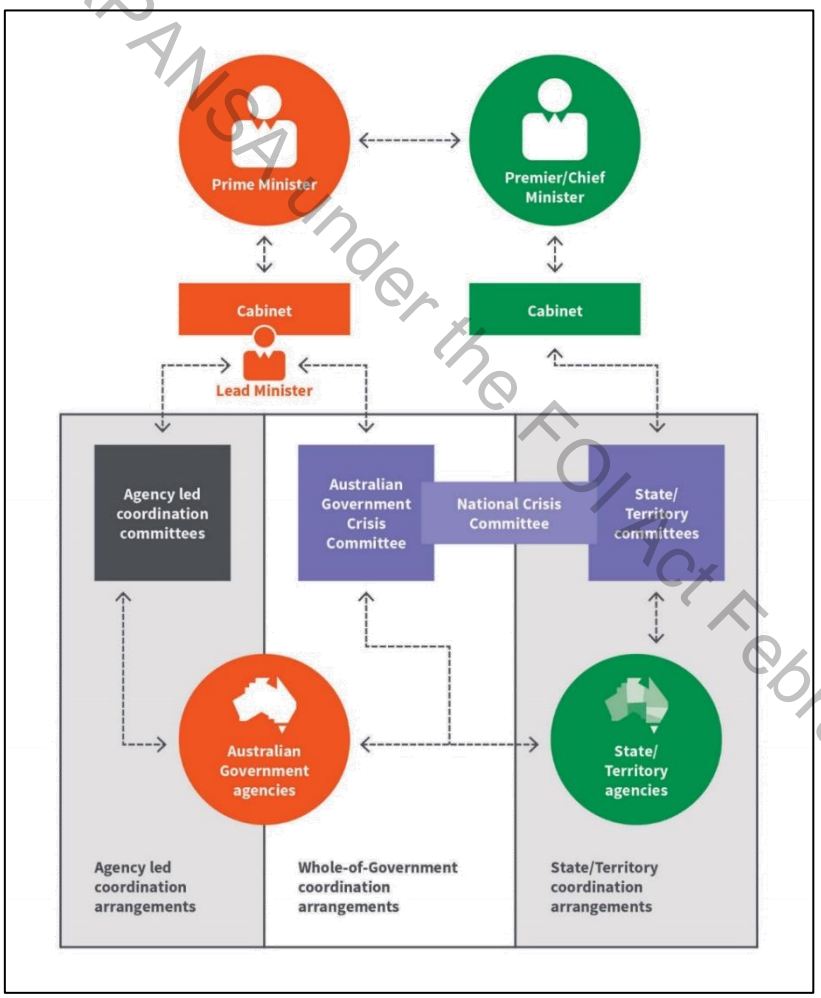

Figure 13. Crisis coordination arrangements (December 2017).

The Crisis Framework does not replace existing crisis plans on specific hazards or functions. Rather it sets out the guidelines for the Australian Government's response to any crisis. The Crisis Framework also identifies the Responsibilities of the Commonwealth and State and Territory governments.

State and Territory responsibilities

Under the Crisis Framework the States and Territories have legislated responsibility for the protection of life, property and the environment within the bounds of their jurisdiction. They control most functions essential for effective crisis prevention, preparedness, response and recovery. The nature of the response is recorded in specific State or Territory emergency plans. The response can cover a range of functions, including health, law and order, energy supplies, transport, water and local government. Where crises involve actual or potential national consequences there may be a need for a high level of collaboration and coordination within and across all levels of government (for example: response to potential nuclear emergencies, such as an offsite release from the OPAL reactor or a nuclear powered warship).

Commonwealth Responsibilities in a crisis

The Commonwealth Government responsibilities in a crisis and how they relate to the State/Territory who have the primary responsibility for first response, are summarised in figure 14. The Commonwealth also provides financial assistance to states and territories to support prevention and preparedness activities, including crisis management exercises, and national leadership and coordination on policy and capability through the Council of Australian Governments (COAG) Committees, such as the Australia-New Zealand Emergency Management Committee, the Australian Health Protection Principal Committee (AHPPC) and the Australia-New Zealand Counter-Terrorism Committee (ANZCTC).

Supporting role	Joint management	Primary responsibility
Providing support to the states and/or territories where the need of a response overwhelms resources and Australian Government coordinated assistance has been requested	Working together with the states and/or territories to manage a crisis that has potential to affect, or has affected, more than one jurisdiction, the broader community or an Australian Government area of responsibility	Managing any crisis that is not the responsibility of a state or territory
Financial assistance		
Providing financial assistance to state and territory governments and individuals affected by a major crisis		

Figure 14. Commonwealth Government responsibilities (December 2017)

Commonwealth agencies also develop national plans and maintain a national exercise program which is delivered through the Commonwealth Department of Home Affairs. This Department, through Emergency Management Australia, operates the Crisis Coordination Centre (CCC). Through the CCC, EMA are able to coordinate the execution of Commonwealth plans in accordance with the Crisis Framework and facilitate the formal communication channels between the jurisdictions and the Commonwealth Government during a crisis. EMA is also responsible for initiating and hosting the Australian Government Crisis Committee and the National Crisis Committee (see Figure 13). Additionally, the Department of Foreign Affairs and Trade and the Department of Defence manage a program for incidents that may affect Australians or Australian interests overseas. The CCC also acts as the National Contact Point identified by the Australian Government in relation to the Emergency Notification and Assistance Conventions for radiological and nuclear emergencies and ARPANSA is the designated National Competent Authority.

Response plans related to nuclear or radiological incidents

There are a number of Australian Government plans that may relate to a nuclear or radiological incident, including:

- Australian Government Disaster Response Plan (COMDISPLAN)
- National Counter Terrorism Plan (NCTP)
- Australian Government Space Re-Entry Debris Plan (AUSSPREDPLAN)
- National Health Emergency Response Arrangements (and sub-plan the Health Chemical, biological, radiological and nuclear Incident Response Plan (Health CBRN Plan)
- National Plan for Maritime Environmental Emergencies.

These plans are drafted and reviewed through a range of committees, including the

- Chemical Biological, Radiological and Nuclear Security Sub-Committee (CBRNSSC)
- Australian Health Protection Principal Committee (AHPPC)
- Australian Government Planning Group (AGPG)
- National Plan Strategic Coordination Committee (NPSCC).

There are also other Commonwealth plans and arrangements that relate to more specific nuclear or radiological activities and interface with multiple plans across jurisdictions. These include:

- ANSTO Emergency Management Plan; this plan interfaces with a range of state based plans including the NSW State Emergency Plan, the NSW State Lucas Heights Emergency Sub-Plan and the NSW State CBRN Hazardous Materials Emergency Sub-Plan
- Defence Operations Manual: Visits to Australia by Nuclear-Powered Warships (OPSMAN 1, Edition 10). This manual sets out the requirements for emergency plans that must be developed at the jurisdiction level for ports receiving visits by nuclear-powered warships, it also guides Commonwealth response responsibilities and interfaces with COMDISPLAN and the Health CBRN Plan.

As the National Competent Authority and Commonwealth Regulator, the role of ARPANSA domestically would depend on the type of emergency and which emergency plan is activated. ARPANSA, as a Commonwealth agency, may be called on as part of a wider Commonwealth involvement in an incident or emergency, as liaison officers, or to support State or Territory emergency response.

ARPANSA's contribution in the event of a radiological or nuclear incident may include:

- location and characterisation of likely sources of radiological threat
- collection and analysis of monitoring data
- prediction of dispersion of radioactive substances
- technical analysis and assessment of simulated and actual data
- provision of expert advice including radiation protection and nuclear safety and security advice.

ARPANSA's support to State and Territory governments would mainly be provided to the relevant regulatory body in the jurisdiction who holds primary responsibility under the relevant State or Territory legislation. ARPANSA may provide staff and specialist resources, or support in the form of radiation protection advice, technical advice, detachment of liaison officers, or technical products provided by electronic means. The regulatory bodies in each jurisdiction play a key part in preparedness and response in relation to radiological and nuclear emergencies.

10.1 Authority and responsibilities for regulating on-site EPR of operating organisations

Related to GSR Part 7: Requirements 2, 20 and 25, GSR Part 1 (Rev. 1): Requirements 16, 26 and 27

All States and Territories have emergency management requirements established by the radiation regulator under the relevant jurisdiction legislation, and additional requirements under emergency response legislation such as fire and rescue services. These requirements aim to be consistent with national codes and guides (see section 10.2). The current nationally adopted guide is the *Recommendations for Intervention in Emergency Situations Involving Radiation Exposure* (2004) RPS 7, which is intended to be replaced with *Guide for Radiation Protection in Emergency Exposure Situations*, RPS G-3. RPS G-3 is currently in an advanced stage of preparation for publication which is likely to occur towards the end of 2018. These guides are further discussed below.

ARPANSA's regulation of EPR

ARPANSA is the Commonwealth regulator for safety, security and EPR of Commonwealth use of radiation sources, radioactive materials, nuclear installations and radiation facilities. The responsibilities of ARPANSA under the ARPANS Act and Regulations are reviewed in section 3 of this Summary Report.

Even though radiological emergencies can be considered to be low probability events among Commonwealth licence holders, there is potential for high radiation exposures of people and impact on the environment if such an emergency were to occur. As such, it is part of ARPANSA's mandate to regulate licence holder's implementation of EPR systems, and also to promote national uniformity in this area (see the ARPANS Act, section 15, 1a).

Commonwealth agencies with radiation protection expertise and additional radiation emergency response capabilities, such as ARPANSA, ANSTO and Defence, can act in support of the States and Territories when requested. Information on ARPANSA's role in EPR is provided publicly on the ARPANSA website.

Operators of nuclear installations, which may have radiological consequences in an emergency, are regulated by ARPANSA.

ARPANSA verifies compliance of on-site arrangements through the review and assessment of documentation during the licensing process, including the emergency plans. Inspections are carried out by ARPANSA on EPR arrangements of the operator and ARPANSA also observes some emergency exercises conducted by the operator. These operations are integrated into the routine compliance monitoring discussed below and in sections 5, 6, 6 and 8 of the Summary Report.

ARPANSA is an observer on the Sutherland Shire Council Emergency Planning Committee, which consists of ANSTO, the Council and various emergency response organisations including NSW Police, fire brigade, ambulance, etc. These meetings improve the coordination and organisation of interactions during exercises and actual emergencies. ARPANSA provides independent guidance and support on compliance with GSR Part 7 for the on-site and off-site interfaces.

In addition to the regulation of nuclear installations by ARPANSA, the Defence Operations Manual: Visits to Australia by Nuclear-Powered Warships (OPSMAN 1, Edition 10) also details the requirements for emergency plans that must be developed at the jurisdiction level for ports receiving visits by nuclear-powered warships. These requirements are developed and maintained by an inter-departmental committee, the Visiting Ships Panel (Nuclear) (VSP(N)), which involves a number of agencies, including ARPANSA, at the Commonwealth and State/Territory level. The implementation of these plans and arrangements are exercised, reviewed and validated on a regular basis (at least 2 yearly). Any new port requested for use by a nuclear powered warship must be validated by the VSP(N) prior to any visit being undertaken. Information on these visits is also provided on the ARPANSA website.

10.2 Regulations and guides on on-site EPR of operating organisations

Related to GSR Part 7: Requirements 2 and 8, GSR Part 1 (Rev. 1): Requirement 2

The Radiation Health Committee (RHC), develops draft national codes and guides which are ultimately published by ARPANSA. Through the National Directory for Radiation Protection (NDRP), jurisdictions agree to implement the codes within their jurisdiction.

ARPANSA has published, or is in an advanced stage of drafting, the following documents which provide guidance on EPR nationally:

- Fundamentals for Protection Against Ionising Radiation (2014) [RPS F-1]
- Code for Radiation Protection in Planned Exposure Situations (2016) [RPS C-1]
- Recommendations for Intervention in Emergency Situations Involving Radiation Exposure (2004) [RPS7]
- Guide for Radiation Protection in Emergency Exposure Situations (DRAFT) [RPS G-3].

Regulatory Guides, which establish emergency arrangements expectations for ARPANSA licence holders, include:

- Plans and arrangements for managing safety (Section 7)
- How to apply for a source licence (section 7 – Emergency Plan)
- How to apply for a licence for a prescribed radiation facility (section 6 – Emergency Plan)
- How to apply for a licence for a nuclear installation (section 6 – Emergency Plan)
- Periodic safety and security review for research reactors (Safety Factor 13 – Emergency Planning).

ARPANSA maintains a list of international best practice documents, which may be considered in the regulatory process. These include:

- GSR Part 3 Radiation Protection and Safety of Radiation Sources: Basic Safety Standards
- GSR Part 7 Preparedness and Response for a Nuclear or Radiological Emergency
- NSS-13 Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities (INFCIRC/225/Revision 5)
- NSS-14 Nuclear Security Recommendations on Radioactive Material and Associated Facilities
- NSS-15 Nuclear Security Recommendations on Nuclear and Other Radioactive Material out of Regulatory Control.

The Regulations (Schedule 3, part 1, Item 4(f)) require the licence holder to include an emergency plan in the application for a facility licence, which will be subject to ARPANSA's review during the licensing process. A graded approach is applied, where the level of scrutiny is commensurate to the level of hazard/risk. Examples of licences that have required emergency plans include:

- OPAL – The Open Pool Australian Lightwater Reactor (OPAL) licence required detailed emergency plans. Resources are coordinated and exercised with the NSW Government for off-site response. The next revision of these plans will reflect the requirements of GSR Part 7
- ANM – ANSTO Nuclear Medicine. These plans refer to the on-site response and are in alignment with GSR Part 7
- spent fuel transport operations.

Specific regulation and guidance

The draft *Guide for Radiation Protection in Emergency Exposure Situations*, RPS G-3, which is planned for publication by the end of 2018 has been developed to implement the requirements of GSR Part 7 and provides advice on:

- a National Hazard Assessment for all jurisdictions (part 1, section 2.4) as well as the requirement for performing a hazard assessment (part 1 with further details in part 1, sections 3.1 and 3.1.18 to 3.1.26)
- emergency plans that are based upon the outcomes of the hazard assessment and the graded approach (part 2, planning and preparedness)
- declaration of a nuclear or radiological emergency (part 3, section 3.1). This includes application of the graded approach, further advice on response time objectives, the beginning of the emergency response, including initiation of on-site response
- planning of emergency zones (see part 2, section 3.3)
- protective measures, including urgent protective actions (part 3, section 3.2.2)
- measures to protect emergency workers and helpers (part 3, section 3.2.3)
- the mitigating actions for on-site and off-site response (part 3, section 3.1 and 3.2), including a General Emergency, a Site Area Emergency, a Facility Emergency or an Alert
- protective measures, including urgent protective actions (part 3, section 3.2.2)
- communication of the response organisations that are providing support, including off-site notification point, to ensure suitable, reliable communication using diverse means
- measures to protect emergency workers and helpers are specifically considered (part 3, section 3.2.3)
- communication with the public (part 1, 3.2.69 to 3.2.75 and part 3, section 8)
- waste management (part 1, 3.2.84 to 3.2.88)
- transition (section 4) and termination (section 5)
- development of capability to effectively respond in an emergency (part 1, 3.3.16 to 3.3.21) including training, drills and exercises (see part 1, 3.3.28 to 3.3.33)
- management of documentations (see part 1, 3.3.34 to 3.3.39).

For Commonwealth licence holders, these requirements are expanded in section 7 of the regulatory guide plans and arrangements for managing safety. This includes detailed requirements for:

- emergency plans for any conduct or dealing that could give rise to a need for emergency intervention. The plan, based on an assessment of the consequences of reasonably foreseeable accidents or incidents, should aim to minimise the consequences and ensure the protection of on-site personnel, the public and the environment
- comprehensive emergency procedures, to be prepared in accordance with the objectives of the emergency plan for any conduct or dealing which could give rise to the need for emergency intervention
- emergency preparedness arrangements, including ensuring that all organisations identified in the emergency plan are prepared for such emergencies, including that adequate facilities and equipment are available and maintained.

While the Regulatory Guide *Plans and Arrangements for Managing Safety* includes the key elements described above, it currently refers to RPS 7 rather than RPS G-3 which has not yet been formally adopted and published. Following publication of RPS G-3, the guide will be revised to include RPS G-3 including:

- expectation of response time objectives and emergency action levels in operator plans (extent depends on hazard)
- general, site area, facility and alert levels of classification
- requirement for redundancy/diversity in off-site communications in the Plans and Arrangements Guide
- consideration of waste generated in an emergency.

Whilst this advice is in place, and is consistent with RPS-7, the application of protective measures for workers is inconsistent throughout Australia. In some states, emergency workers are treated as members of the public with regard to dose limits. This inconsistency was identified as an area for priority action in the recommendations (for radiation emergencies) from the Joint External Evaluation (JEE) of International Health Regulation Core Capacities of Australia undertaken in November 2017.

Australia in general terms has a comprehensive system in place for communication with the public in emergencies, across Commonwealth, state and territory governments and this was confirmed in Australia's JEE Mission Report. However the public continues to seek information from more sources, particularly social media. Many emergency response agencies, have social media strategies that have been effectively implemented during events such as tropical cyclones (QLD), there is inconsistent or slow adoption of social media in some parts of government, where a preference for more traditional media prevails.

In the case of radiological emergencies in Australia, there are formal elevation procedures that ARPANSA must follow for communications from the Commonwealth (by traditional means) there is currently no procedure in place to implement fast social media messaging. However, the JEE Mission report also recommended three areas for priority action in Australia, these are:

- *implement a risk communication training programme for communications staff, emergency response employees, senior management decisions-makers and other relevant staff to establish a common understanding and expertise*
- *develop guidance for the strategic use of social media in emergencies that includes protocols for coordination among jurisdictions, sectors and stakeholders*

- *establish a mechanism that monitors community engagement activities across jurisdictions and shares lessons learned to inform risk communication planning and message development in emergencies.*

ARPANSA is now working closely with the Commonwealth Department of Health who have the lead on developing and implementing National Action Plan for Health Security to address the JEE report recommendations, including the three Risk Communication recommendations above.

10.3 Verifying the adequacy of on-site EPR of operating organisations

Related to GSR Part 7: Requirements 2 and 25, GSR Part 1 (Rev. 1): Requirements 26-31

ARPANSA verifies compliance of on-site arrangements through a variety of means, which are documented below

Review and assessment of documentation elaborating operator's emergency arrangements during licensing process

The operator's emergency plan is specifically required by the ARPANS Regulations, in Schedule 3 part 1. For more information on this process, see section 6 on review and assessment.

IAEA GSR Part 7 forms the high-level basis for reviewing the appropriateness of the EPR Plans. The inspection Performance Objectives and Criteria (PO&C) are also used to assess the effectiveness of EPR Plans. During review and assessment international best practice, such as specific details in guides such as IAEA GSG 2.1 are also used by the regulator to review a plans adequacy.

Examples include:

- OPAL reactor licensing, the emergency plan was reviewed against international standards (note IAEA GSR2 and IAEA GSR Part 7 were not published at that time [2004])
- ANSTO Nuclear Medicine (ANM) facility application, both onsite and off-site response plans were reviewed, which resulted in ANSTO revising the plan taking into account the (draft) Emergency Exposure Guide and for consistency against GSR Part 7.

In the case of the OPAL reactor, the emergency and preparedness review is scheduled biennially. However, due to the reactor sharing the site with other facilities, segments of the site EPR arrangements are inspected more often under those facility inspection programs. The review assures that the external organisations as well as internal service providers are involved in exercises so the coordination interfaces are well developed.

Inspections of EPR arrangements of operator

EPR is periodically inspected for all licences with a graded approach applied (see section 6 for more information on the inspection process). Inspectors examine the EPR plans and arrangements periodically according to the inspection schedule. In line with a graded approach, the OPAL reactor EPR arrangements are examined at two-year intervals. In addition to the scheduled inspections, augmented inspections may be carried out if there is the potential that the EPR performance or effectiveness has been diminished. The inspection is performed against the PO&C, which has been developed based on international standards and guides.

PO&C - BM8 – Emergency preparedness and response: This module addresses the anticipation of hazards and threats, the assessment of consequences and the preparation of appropriate systems and measures to ensure an effective, timely, integrated, controlled and coordinated response to a nuclear or radiological emergency. It includes exercises and drills, emergency response organisation testing, and notification testing.

For high consequence facilities (including nuclear installations), ARPANSA's licencing regime covers siting, construction, operation and decommissioning. Hot/cold commissioning, which is normally staged e.g. through conditions of licence, is usually the stage where ARPANSA observes or assesses the results of emergency tests.

Enforcement actions are taken in accordance with section 8.

Evaluating emergency response exercises conducted by operator

ARPANSA observes exercises by the operator on a regular basis. Every exercise that ARPANSA observes is evaluated and recorded, such as through a site visit report. However, not all are evaluated against a formal set of criteria. Evaluation may include considering outcomes against international best practice and the objectives of the exercise. ARPANSA records actions arising from the exercises and ensures that the operator appropriately raises and enters these into their action tracking system. ARPANSA typically monitors the implementation of the actions through inspections, site visits and meetings as applicable.

Integration of requirements

ARPANSA gives guidance to licence holders on the integration of safety and security in the Regulatory Guide Plans and Arrangements for Managing Safety. Other guidance on security and safety interfaces, including integration of security terms such as 'Unacceptable Radiological Consequences', is provided in the Emergency Exposure Guide. This has recently been applied in the licensing process for the ANM facility.

Security and safety are considered in the review and assessment of the operator's EPR plans, using the PO&C during inspection, and during the Periodic Safety and Security Review (PSSR), which also requires integration with onsite and offsite organisations. Integration of safety and security plans and arrangements (contingency plans) are reviewed in parallel with EPR plans to ensure integration.

The EPR considerations for nuclear installations are a key focus area for ARPANSA. However, ARPANSA also considers EPR for radioactive material and other sources. This can have national significance such as the coordination between jurisdictions for transportation of radioactive materials. Nationally, requirements on the transportation of materials and the associated EPR is detailed in the *Code for Safe Transport of Radioactive Material* (RPS C-2; based upon IAEA SSR-6), and the *Code of Practice - Security of Radioactive Sources* (RPS 11) for security enhanced sources. More information can be found on the ARPANSA website.

10.4 Roles of the regulatory body in a nuclear or radiological emergency

Related to GSR Part 7: Requirements 2, 20-26, GSR Part 1 (Rev. 1): Requirements 3 and 8

As outlined in section 10.1, activation of any plan within the Australian Government Crisis Management Framework can involve a large number of stakeholders and in a nuclear or radiological emergency the role of the agencies is based on the scenario. These arrangements are captured in local jurisdictional emergency plans. For example, the Queensland state disaster management plan and Radiological disaster plan clearly define roles of the regulator during an emergency and how interactions with other parties is managed. For radiological emergencies in Queensland (such as an event involving a nuclear powered warship visit to the Port of Brisbane), Queensland Health will be the lead agency while the Queensland Fire and Rescue Service's Fire Controller, in liaison with Queensland Health, will be responsible for the identification and establishment of hazardous material safe operating zones.

ARPANSA's functions

ARPANSA administers the conventions on Early Notification of a Nuclear Accident and Assistance in the case of a Nuclear Accident or Radiological Emergency (ENAC). As the National Competent Authority and Commonwealth Regulator the role of ARPANSA domestically would depend on the type of emergency and which emergency plan is activated.

In the event of a radiological or nuclear incident, as described in section 10.1, ARPANSA may be involved in a range of actions:

	**Release Scenario** • Collection and analysis and assessment of simulated and actual data to aid: o early: implement urgent protective actions o intermediate: restriction of food stuff and dose reconstruction o long-term: ongoing monitoring.
	**Lost/stolen or orphan source (search)** • wide area mapping • localised search and survey • unknown container assessments
	**National strategic or special event** • room searches • venue clearance • choke point detection

Figure 15. ARPANSA's functions in different scenarios

ARPANSA adopts an evidence-based and risk-informed approach to decisions and advice. To achieve this, ARPANSA performs technical analysis and consequence modelling, assesses the exposure pathways from accidents, recommends protective actions and advises on potential health consequences.

ARPANSA primarily provides support to each State and Territory government's relevant regulatory body that holds primary responsibility under the relevant State or Territory legislation. ARPANSA support may be in the form of liaison officers or technical products provided by electronic means. Elevated response may be requested by States or Territories. Examples of ARPANSA's response for various domestic incidents include:

- the response to a missing well-logging source in WA 2006, where ARPANSA provided a search team to assist the authorised officers of the Radiological Council in the search
- search team provided support of the Victorian Department of Health and Human Services in 2008 to search a scrap yard for two sources improperly disposed of by a state licence holder
- search teams deployed to support Special Events such as the Commonwealth Games and meetings of the G20.

As the ENAC designated National Competent Authority, ARPANSA is notified of radiological or nuclear emergencies though the Australian Government Crisis Coordination Centre (CCC), operated by the department of Home Affairs. The CCC is a 24/7 staffed facility that provides situational awareness for all of the Commonwealth on any hazard. The CCC acts as the 'National Warning Point' to receive, and coordinate the further distribution of emergency notifications from the Incident and Emergency Centre (IEC) at the IAEA. While ARPANSA's duty officer will also receive direct notifications from the IAEA in the event of a radiological or nuclear emergency, our duty officer is a 24/7 on-call arrangement. The CCC will contact the duty officer to ensure notifications are received from the IAEA. In addition to IAEA alerts, the CCC will also provide updates on terrorist events and natural disasters such as earthquakes or tsunamis that may lead to a nuclear emergency.

In the case of an international radiological or nuclear emergency ARPANSA would be the primary source of advice to the Australian Government, but would not be the lead agency. An example of this situation was the response provided in relation to the Fukushima Daiichi nuclear accident and radiological release in 2011, where modelling and radiation protection advice were provided to the Commonwealth Government and Australians abroad. ARPANSA coordinated closely with both the Department of Foreign Affairs and Trade and the Department of Health in this situation.

ARPANSA also hosts a World Health Organisation (WHO) Collaborating Centre for Radiation Protection, and is a member of the WHO's Radiation Emergency Medical Preparedness and Assistance Network.

As noted earlier, for visits to Australian ports by nuclear powered warships (NPW), an inter-departmental committee, the Visiting Ships Panel (Nuclear) (VSP(N)) oversees the arrangements. VSP(N) involves a number of agencies at the State/Territory and Commonwealth level including the Commonwealth Departments of Defence, Department of Health, ARPANSA, ANSTO and Emergency Management Australia. Specific roles and responsibilities relating to visits from Nuclear Powered Warships, including monitoring, are detailed in the Naval Operations Manual OPSMAN1, and the port specific safety plans, which vary according to the jurisdiction responsible for the port. ARPANSA provides OSL monitors and analyses marine samples. In the event of a NPW accident, ARPANSA would provide additional teams and the Commonwealth Technical Advisor to support the State response through the COMDISPLAN.

ARPANSA is also in the process of establishing a memorandum of understanding (MoU) with the Australian Maritime Safety Authority (AMSA) who are responsible for the day-to-day management of the Arrangements outlined in the National Plan for Maritime Environmental Emergencies (NPMEE). While this plan makes no specific mention of radiological or nuclear emergencies, AMSA is supportive of establishing an MoU with ARPANSA in order to conduct joint exercises and training, and understand how ARPANSA's assistance could be requested via COMDISPLAN and interface with the NMPEE in a radiological or nuclear emergency. This MoU will be drafted before the end of 2018.

ARPANSA also takes part in table top emergency exercises, which combine Safety and Security, including those associated with the Global Initiative to Combat Nuclear Terrorism (http://www.gicnt.org/) and Australian Crisis Coordination Centre.

Coordination and integration of emergency arrangements is tested through emergency exercises. An example of this is Exercise Pacific Protector 2017, involving the Australian Border Force, ARPANSA, ANSTO, Royal Australian Navy and other Commonwealth and international participants.

ARPANSA's capability and resourcing

ARPANSA has established a Radiation Emergency Coordination Centre in Melbourne, which provides 24 hour access to expert radiation protection advice in the event of a radiological or nuclear incident. This service is utilised when receiving a request for international assistance (such as through the IAEA's Response and Assistance Network), or at the request of Commonwealth Licence holders and jurisdictional regulators. ARPANSA's dedicated EPR staff are recruited to fulfil specialist roles, and have been assessed on their capacity to perform during an emergency. Each of the three positions within the EPR Group are allocated a position description aligned to the EPR Program brief and broader Branch and section programs. While other staff within ARPANSA do not currently have EPR expertise identified in their roles, ARPANSA can draw on all staff during emergencies. Staff expertise include nuclear physics, nuclear engineering, environment monitoring, mathematics and chemistry.

ARPANSA maintains equipment and expertise to operate as an integrated capability that will provide the measurement and analysis requirements for all postulated radiological and nuclear emergencies within Australia, and abroad. Specialised radiation monitoring capability supports the assessment of radiation levels and the extent of radioactive contamination in the event of a radioactive release from a nuclear or radiological emergency. These capabilities include:

- gamma and neutron search
- health physics survey
- portable radio-isotope identification devices
- portable high purity germanium gamma spectroscopy
- low and high volume air sampling
- general environmental sampling.

The capabilities and roles of these teams are consistent with the requirements of the IAEA Response Assistance Network (RANET) capabilities.

ARPANSA also maintains laboratory-based facilities for the detailed analysis of environmental samples and for the measurement of radioactivity in contaminated people, and has in recent years established the Australasian Radioanalytical Laboratory Network (ARLN). The ARLN aims to strengthen capacity and

capability within Australia and New Zealand for the testing of radioactivity in food and environmental samples. This need is particularly important in the event of a radiological or nuclear emergency when potentially many samples will require analysis and laboratories may be overwhelmed.

10.5 Conclusions and actions

The Commonwealth, States and Territories have an established an effective framework for responding to radiological and nuclear emergencies. Roles and responsibilities are clearly articulated within the Australian Government Crisis Management Framework and are underpinned by legislation within jurisdictions and a range of supporting plans. Processes for coordination between Commonwealth departments and agencies at all levels of government are in place with the key outcome always focussed on the protection of life, property and the environment.

ARPANSA has a proven track record of providing high quality advice as the competent authority on emergency preparedness and response to radiological and nuclear events, for example during the response to the nuclear accident after the Great East-Japan Earthquake and Tsunami in 2011.

As an outcome of our learnings from the Fukushima accident and other subsequent exercises ARPANSA has implemented a range of initiatives, including the implementation of the Australasian Radio-analytical Laboratory Network (ARLN). The ARLN has been established in order to maintain critical capabilities, and to address vulnerabilities in the system of EPR in Australia. There are also other actions that ARPANSA has initiated but not yet completed such as the development of the Automated Radiation Monitoring System and establishment of a Memorandum of Understanding with the Australian Maritime Safety Authority.

The new national guide, RPS G-3, is in an advanced stage of drafting to enhance compliance to emergency preparedness requirements in GSR Part 7. While the ARPANSA Plans and Arrangements Guide includes the key elements described above, it currently refers to RPS 7 rather than RPS G-3, which has not yet been formally adopted and published.

- Following publication of RPS G-3 the Plans and Arrangements Guide will need to be revised (see Action Plan item 15**Error! Reference source not found.**) to incorporate aspects of RPS G-3, including:
    - expectation of response time objectives and emergency action levels in operator plans (extent depends on hazard)
    - general, site area, facility and alert levels of classification.
    - requirement for redundancy/diversity in off-site communications in the Plans and Arrangements Guide
    - consideration of waste generated in an emergency.

The plans and arrangements for nuclear powered warship visits will also need to be reviewed following the release of RPS G-3. Following the publication of RPS G-3 and subsequent implementation of this guidance there will be a need for ARPANSA to consider how effectively these new aspects are implemented and addressed by the operating organisations. It is foreseen that this would be done as part of emergency exercise evaluations. Currently, there is no formal methodology or criteria developed that would assist the inspectors during an exercise evaluation. This may be an area of work for ARPANSA to consider prior to the implementation of RPS G-3.

More broadly ARPANSA is also involved in developing the Action Plan that the Commonwealth, State and Territory governments are currently in the process of finalising to address the WHO JEE Mission recommendations (i.e. Australia's National Action Plan for Health Security (NAPHS)). Within the NAPHS ARPANSA has been identified as the lead agency for addressing the recommendations identified for the radiation emergencies core competencies. The three recommendations are:

- *enhance the interoperability of Federal and state/territory radiation operations through broad multisectoral/multijurisdictional exercises*
- *develop federal guidance for jurisdictional first responder occupational exposures*
- *conduct a national hazard assessment, to include creating an inventory of radiation sources, and establish a national radiation capability register.*

Some of the work towards addressing these recommendations will be achieved with the publication of RPS G-3, however the longer term implementation of RPS G-3 will present a significant body of work and ARPANSA will need to work cooperatively with the Radiation Health Committee (RHC) and other stakeholders to achieve these outcomes.

The third of these recommendations provides a more significant challenge for ARPANSA following the RHC decision in 2016 to abandon the previous National Sealed Source Register. In 2017 Australia received a follow up IAEA International Physical Protection Advisory Service (IPPAS) Mission and the IPPAS team challenged the RHC decision and evaluated that the network of jurisdictional registers that remains does not align to the expectations of the Code of Conduct on the Safety and Security of Radioactive Sources. The IPPAS Mission recommended that Australia should establish a national register to improve arrangements for an accurate and real-time national radioactive source register. ARPANSA will continue to work with the RHC and other stakeholders to improve arrangements for accurate storage and retrieval of information on sources by building on existing arrangements, reiterating the benefits of such a register and strengthening the linkage between safety and security and threat prevention.

ARPANSA will also be a stakeholder in implementing a number of other JEE recommendations including:

- *consider simultaneous reporting to states and territories and IHR NFP from national reference laboratories, chemical sector and radiation sector for urgent and high risk hazards (Core competency: National Legislation, Policy and Financing)*
- *enhance the existing public health exercise program to address all IHR-relevant hazards and to integrate multisectoral and multijurisdictional elements (Core competency: Emergency Response Operations)*
- *use existing data sources, including relevant accreditation schemes, to define the public health workforce for conducting forward planning, recruitment of appropriate categories of staff (including toxicology and radiation specialists) and development of future credentialing schemes (Core competency: Workforce Development)*
- *work with states and territories to ensure sustainable mechanisms for epidemiologists and other public health professionals at state, territory and local level (Core competency: Workforce Development)*
- *ensure public health emergency response plans at multiple levels and multiple sectors are linked appropriately and efficiently to facilitate a coordinated response across the country and across the agencies (Core competency: Preparedness)*

- *implement a risk communication training programme for communications staff, emergency response employees, senior management decisions-makers and other relevant staff to establish a common understanding and expertise (Core competency: Risk Communication)*
- *develop guidance for the strategic use of social media in emergencies that includes protocols for coordination among jurisdictions, sectors and stakeholders (Core competency: Risk Communication)*
- *establish a mechanism that monitors community engagement activities across jurisdictions and shares lessons learned to inform risk communication planning and message development in emergencies (Core competency: Risk Communication).*

*Establish clear mechanisms for coordinating regular information sharing and joint risk assessments across health and security agencies at the Australian Government, state and territory levels. (Core competency: Linking Public Health and Security Authorities)*Australia's NAPHS to address the JEE recommendations will be implemented on a priority basis over the next five years.

- An identified action is to continue the implementation of the recommendation from the JEE. This is captured in the Action Plan, item 16.

11. Additional areas

This section includes responses from most Australian jurisdictions on medical exposure (11.1).

The sections on occupational exposure (11.2), and 'discharges, materials for clearance, and existing exposure situations; environmental monitoring for public radiation protection' (11.3) relates to the Commonwealth regulator, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

11.1 Control of medical exposures

Related to GSR Part 3, Requirements 34-42, paragraphs 3.145-3.185

ARPANSA has published *the Code of Practice for Radiation Protection in the Medical Applications of Ionising Radiation 2008* (RPS 14) and the *Code of Practice for the Exposure of Humans to Ionising Radiation for Research Purposes 2008* (RPS 8). The Codes were developed in collaboration with the States and Territories under the auspices of the Radiation Health Committee (RHC). These Codes are supported by four guidance documents:

- Recommendations for the Discharge of Patients Undergoing Treatment with Radioactive Substances (2002) RPS 4
- Safety Guide for Radiation Protection in Diagnostic and Interventional Radiology 2008 (RPS 14.1)
- Safety Guide for Radiation Protection in Nuclear Medicine 2008 (RPS 14.2)
- Safety Guide for Radiation Protection in Radiotherapy 2008 (RPS 14.3).

Additionally ARPANSA has published two practice specific codes; the *Code of Practice and Safety Guide for Radiation Protection in Dentistry 2005* (RPS 10) and the *Code of Practice for Radiation Protection in the Application of Ionizing Radiation by Chiropractors 2009* (RPS 19).

The requirements for dental imaging facilities, clinicians and other staff in RPS 10 are similar to the requirements in RPS 14 for diagnostic imaging. RPS 10 also outlines responsibilities for referrers and for persons supplying, installing and servicing equipment. RPS 10 includes equipment compliance standards, requirements for film handling and processing, and procedural requirements for radiation safety.

RPS 19 is an abbreviated version of RPS 14 with the requirements relating to radiotherapy and nuclear medicine removed and some terminology altered to reflect chiropractic practice.

All of these codes and guidance documents were developed and approved by the RHC, which includes representation from all jurisdictions. In 2018, the RHC is revising RPS 14 to achieved better alignment to GSR Part 3 (see below on draft RPS C-5).

RPS 14 contains many of the technical requirements which are applied within the jurisdictional regulatory frameworks. The Commonwealth, Queensland, TAS, VIC, NSW and the ACT all adopt a requirement to adhere to RPS 14 as a condition of licences allowing for medical use or possession. South Australia and Western Australia have specific requirements within the local regulations which are broadly consistent with these requirements, except where noted below.

RPS 14 section 3 clearly defines the roles and responsibilities for the responsible person, medical practitioners, operators (medical radiation technologists) and qualified experts (medical physicists) in relation to the safety of individuals undergoing medical treatment or research.

All jurisdictions, other than ARPANSA, assess qualifications, training or experience required for users, including medical radiation practitioners, physicists and radiologists, to deal with medical sources via separate authorisations (use licences). For example, NSW publishes the competence requirements on their website. ARPANSA only regulates a small number of medical sources, and has generic requirements that the licence holder ensure staff are adequately trained and experienced. Additionally, the Australian Health Practitioner Regulatory Agency (AHPRA) protects titles of occupations including medical radiation practitioner, diagnostic radiographer, medical imaging technologist, radiographer, nuclear medicine scientist, nuclear medicine technologist, and radiation therapist. To use a protected title a person must be registered with AHPRA, which involves demonstrating relevant qualifications or competence.

The radiation protection principles of justification, optimisation and limitation are captured in section 2 of RPS14. Medical exposure must be justified and optimised in accordance with specific requirements in the Code. In general, the Code requires a medical radiation procedure to be justified (section 3.1.3) and approved (section 3.1.15), including through referrals. Section 3.2.1c states that a radiation medical practitioner who approves a procedure involving the exposure of a patient to ionising radiation must ensure that the radiation exposures are justified (section 3.2.2) and optimised (section 3.2.5).

RPS 14 (section 3.2.2) defines what the radiation medical practitioner must take into account in determining the net benefit of a medical radiation procedure. RPS 14 allows for procedures to be generically justified by a radiation medical practitioner or by an acknowledged professional college or authority. However, Australia does not have national referral guidelines, or national requirements on the role of the referring medical practitioner. The term 'referrer' is defined in RPS14 to include 'medical practitioner, dentist or other health professional who is entitled to refer individuals to the radiation medical practitioner' but no specific responsibilities or qualifications are outlined as referrers are not licenced by the radiation regulatory bodies. To assist referring medical practitioners in determining the appropriate examination, programs such as Diagnostic Imaging Pathways (DIP), which is widely rolled out in WA, may be used. ARPANSA provides an online short educational module on radiation protection of the patient, targeted at general practitioners to raise awareness of the risks and benefits of medical imaging. This ensures that participating practitioners have been trained in the risk/benefit analysis required for justification. Some jurisdictions, such as Queensland, define which radiation medical practitioners are authorised to request a diagnostic procedure or prescribe a therapeutic procedure.

To assist in the optimisation of patient protection while achieving the desired diagnostic outcome, RPS 14 (section 3.1.8) requires a licence holder to develop a program to compare their patient dose metrics against any established national Diagnostic Reference Levels (DRLs). ARPANSA establishes the national DRLs and maintains a program to allow institutions to submit data for comparison to the DRLs for multi-detector computed tomography and for nuclear medicine. DRLs for additional modalities are planned to be rolled out in the future.

Compliance programs under which an accredited third party tests equipment are a regulatory requirement in all States and Territories. Information is provided on relevant regulators' websites, for example Victoria. Satisfactory compliance test results are either linked to the authorisation requirements or required under licence conditions. Standards are set by the relevant jurisdiction regulatory body, based either on Australian standards, national codes, professional body standards (such as the radiation oncology practice standards), or international guidance. While compliance tests before use are mandated across Australia, the frequency of any periodic tests as well as the scope of the tests varies significantly between jurisdictions. This is further discussed in section 13 of this Summary Report, on national uniformity.

For radiation oncology, a national independent dosimetry program, the Australian Clinical Dosimetry Service (ACDS), was established by ARPANSA under a Memorandum of Understanding with the Department of Health (Commonwealth), and with departmental funding. The ACDS is an ISO 17025 accredited audit service which offers dosimetry audits to meet Australian Radiation Oncology Practice standards, Australian Government funding conditions, and jurisdictional radiation licence requirements. It is now operated by ARPANSA on a fee-for service basis and covers well over 90% of the linear accelerators (linacs) used in Australia.

RPS 14 (section 3.2.2e) requires that in determining the net benefit from a medical radiation procedure, the radiation medical practitioner must take into account the pregnancy status of a female patient of child bearing capacity. RPS 14 (section 3.2.2f) requires that the radiation medical practitioner must take into account the breast-feeding status of a female patient to be administered a radiopharmaceutical if there is the potential for a radiation dose of more than 1 mSv to a breast-fed child.

The radiation medical practitioner (RPS 14 section 3.2.7) must ensure that, where a radiation procedure is likely to result in a radiation dose of more than 1 mSv to an embryo or fetus, reasonable steps are taken immediately before the commencement of the procedure to establish whether the patient is pregnant. For a therapeutic nuclear medicine administration, the pregnancy status of a patient of childbearing capacity must be established with a definitive biochemical test within 24 hours before the commencement of the treatment. Where a pregnancy has been established, the expected dose to the fetus must be estimated and the risks and benefits explained before a procedure takes place (RPS 14 schedule B).

The radiation medical practitioner must take reasonable measures to ensure that any exposure of children is eliminated or minimised when a radiopharmaceutical is administered to a breast-feeding patient (RPS14 section 3.2.9), or a therapeutic radiopharmaceutical is administered to a patient who is providing close care of a child (RPS14 section 3.2.10).

For patient discharged while undergoing treatment with a radioactive implant, or with a therapeutic quantity of radiopharmaceutical, the radiation medical practitioner must, under RPS 14 (section 3.2.6), ensure that the patient, carer or the patient's legal guardian is, before leaving, provided with written information and instructions that address:

a) the risks associated with ionizing radiation exposure to carers and other persons
b) how to restrict exposures to carers and other persons that could result from proximity to the patient, if relevant
c) storage or disposal of any dislodged radioactive sources, if relevant
d) prevention of contamination, if relevant.

Additionally, RPS 4 on *Discharge of Patients Undergoing Treatment with Radioactive Substances* contains specific information related to radiation protection for people interacting with discharged patients. Dose constraints for carers of patients are provided in section 2.1 of RPS 4. All jurisdictions, with the exception of SA, refer to the use of RPS 4 for guidance on dose constraints of carers. SA refers to dose constraints that are specified in an organisation's approved radiation management plan.

All jurisdictions in Australia require, through their legislation or licence conditions, to ensure that all practical measures are taken to minimise the likelihood of an incident, and must report, investigate and implement appropriate controls for any incidents that do occur. Certain incidents are reported to the Australian Radiation Incident Register (ARIR), which is maintained by ARPANSA. The National Directory for Radiation Protection Schedule 13 captures this agreement and provides details on the national incident-reporting framework and defines the type of incidents that requires reporting to the ARIR. Legislation in each jurisdiction requires notification of radiation incidents to the regulatory body, who passes this information on to ARPANSA where relevant.

RPS 14 outlines responsibilities relating to equipment failures and for the investigation and reporting of incidents in sections 3.1.11-3.1.12 and 3.3.10-3.3.11.

In regard to the review of plans, RPS 14 requires the development, documentation, and review of a Radiation Management Plan that addresses work practices and arrangements for protection and safety. Specifically under section 3.1.1 the organisation must ensure that:

a) a Radiation Management Plan that incorporates the components listed in section A1 of Schedule A of RPS 14 is developed, documented, resourced, implemented and regularly reviewed

b) the Radiation Management Plan describes the management and reporting arrangements that enable the radiation medical practitioner and the operator to discharge their obligations under RPS 14

c) all persons affected by the Radiation Management Plan follow and comply with the Radiation Management Plan.

Jurisdictions may have specific requirements for the frequency of review. For example, under Regulation 50 ARPANSA requires reviews to be carried out every three years.

RPS 14 requires records be kept, including the following:

- radiation doses associated with types of medical procedures (3.1.7)
- radiation doses associated with occupational exposure (3.1.9c)
- radiation incidents (3.1.12)
- radiation shielding (3.1.17)
- records of the work performed on radiation producing equipment or equipment containing radioactive source(s) following any repair, maintenance or modification on that equipment (3.1.30)
- equipment faults and corrective maintenance performed (3.1.31b)
- estimates of the expected radiation dose to an embryo or fetus (B1.3).

Revision of RPS 14, draft Code for Radiation Protection in Medical Exposure (RPS C-5)

ARPANSA and the RHC have recently released a public consultation draft of the new *Code for Radiation Protection in Medical Exposure* (RPS C-5). It was released for public comment on 23 February 2018. At the time of preparation of this Summary Report, work was ongoing to resolve the 430 comments received during consultation.

It is expected that RPS C-5 will further enhance the alignment with the requirements of GSR Part 3 and contains explicit references to that document.

RPS C-5 is intended to cover medical exposures involving ionising radiation, including exposure to carers and comforters and to volunteers in medical research, and also including intended, unintended and accidental exposures. It will not apply to dentistry or to chiropractors, where the existing practice-specific codes will continue to apply.

Major changes introduced in RPS C-5 include: requirements to inform the patient, or their legal authorised representative, of the benefits and risks of an intended radiological procedure; including the referrer in the justification process; requiring the use of relevant referral guidelines in justification; extending equipment calibration requirements to all medical uses, not just radiotherapy; changing terminology from qualified expert to medical physicist; and explicitly requiring radiological reviews. Appendix 1 of RPS C-5 indicates the links between the clauses in the code and GSR Part 3.

11.2 Occupational radiation protection

Related to GSR Part 3, Requirements 19-28, paragraphs 3.68 to 3.116, and Requirements 45, paragraphs 4.12-4.19

The structure of authorisations, including licensing and registration, is discussed in section 5 of this report. In general, no person may deal with radiation unless authorised to do so (e.g. in a licence) or an exemption has been granted under the relevant jurisdiction legislation. The responsible person is responsible for safety and has responsibilities that cannot be delegated. In addition, in most jurisdictions, individual sources must be registered with the regulatory body.

ARPANSA published the *Code for Radiation Protection in Planned Exposure Situations*2016 (RPS C-1) in the Radiation Protection Series of publications. This document, along with the Fundamentals for Protection against Ionising Radiation 2014 (RPS F-1), comprise Australia's occupational radiation protection standards. These currently apply to all Commonwealth bodies and they have been agreed to be adopted into the *National Directory for Radiation Protection (NDRP)*. The national adoption of RPS C-1 is still pending and jurisdictions are still in the process of adjusting to the new Code, e.g. as a condition of licence. ARPANSA has implemented RPS C-1 as a condition of licence through the ARPANS Regulations, effective July 2017.

RPS C-1 contains detailed requirements including roles and responsibilities, dose assessment, monitoring and training. For example, section 3.1.24 (b) requires the responsible person to provide a copy of dose records of an occupationally exposed person to that person periodically, on request and on termination of employment. Compliance by workers in section 3.2.3 (f) on employment, provide to the responsible person, or assist the responsible person, to obtain details of their prior occupational radiation exposure, as necessary.

IAEA GSR Part 3 requirement	RPS C-1 section	
Requirement 1	Application of the principles of radiation protection	3.1.2
Requirement 4	Application of the principles of radiation protection, Radiation Management Plan, Information, instruction and training	3.1.1, 3.1.4, 3.1.6, 3.1.8, 3.1.14, 3.2.9
Requirement 5	Radiation Management Plan, Management for protection and safety	3.1.5, 3.1.9-3.1.10
Requirement 7	Management for protection and safety	3.1.11
Requirement 9	Optimisation of protection and safety, Record keeping, Information, instruction and training	3.1.12, 3.1.20-3.1.21, 3.2.10
Requirement 11	Optimisation of protection and safety	3.1.13-3.1.14
Requirement 12	Dose limits	3.1.2(c) and (d)
Requirement 13	Safety assessment	3.1.17-3.1.19
Requirement 14	Record keeping	3.1.22-3.1.23
Requirement 15	Prevention and mitigation of accidents	3.1.15
Requirement 16	Prevention and mitigation of accidents	3.1.16
Requirement 17	Radiation generators and radioactive sources	3.1.25
Requirement 18	Human imaging using radiation for purposes other than medical diagnosis, medical treatment or biomedical research	3.1.26
Requirement 21	Responsibilities of the Responsible Person for the protection of workers	3.2.1-3.2.2
Requirement 22	Compliance by workers	3.2.3
Requirement 23	Cooperation between Responsible Persons	3.2.4
Requirement 24	Application of the principles of radiation protection, Radiation Management Plan	3.1.3, 3.1.7
Requirement 25	Assessment of occupational exposure and workers' health, Record keeping	3.1.24, 3.2.5-3.2.6
Requirement 26	Information, instruction and training	3.2.7-3.2.8, 3.2.10
Requirement 27	Conditions of service	3.2.11
Requirement 28	Special arrangements for protection and safety for female workers and for persons under 16 years of age	3.2.12-3.2.13
Requirement 31	Radioactive waste and discharges	3.3.1-3.3.2
Requirement 32	Monitoring and reporting	3.3.3

Table 10. Comparison of GSR Part 3 and RPS C-1 as provided in the appendix of RPS C-1

In addition to radiation safety requirements, each jurisdiction in Australian has their own workplace health and safety (WHS) legislation. Safework Australia developed Model WHS laws, which have been adopted in all jurisdictions. These requirements include consultation with workers for safety matters, review of control measures, and establishment of safety policies and procedures.

These requirements align well with the radiation safety requirements and provide specific responsibilities. For example:

- the WHS Act (part 2 division 4 section 28 Duties of Workers) states that while at work, a worker must take reasonable care for his or her own health and safety and take reasonable care that his or her acts or omissions do not adversely affect the health and safety of other persons

- the RPS C-1, (section 3.2.3: Compliance by Workers) states that the Responsible Person must ensure that each occupationally exposed person in their employ complies, to the extent that the occupationally exposed person is capable, with all reasonable measures to control and assess exposure to radiation in the workplace.

Health surveillance is not specifically required for personnel occupationally exposed to ionising radiation in Australia, with the exception of South Australia. There is a general requirement in the WHS Regulations (Commonwealth, 2016), Chapter 3 Part 3.1, for an employer to identify hazards and manage them using the hierarchy of controls. Health surveillance can form a part of the mitigating controls for a hazard if the risk is considered significant for the employer. IAEA draft document DS 453 details requirement health surveillance of occupational exposed workers and ARPANSA will consider incorporating the requirements of this document once published.

ARPANSA operates and maintains the Australian National Radiation Dose Register (ANRDR). Initially established for the uranium industry in 2010 the ANRDR has been expanded to cover other organisations and industries. In July 2017 the implementation of RPS C-1 saw the submission of dose records to the ANRDR from Commonwealth licence holders become a licence condition. ARPANSA has also recently been engaging with the medical sector in Australia for their submission of dose records to the ANRDR with one major hospital having started submissions. Currently the ANRDR holds dose records for over 44 000 individuals.

Given the multi-jurisdictional nature of Australia ARPANSA continues to work with jurisdictional regulators to encourage them to implement RPS C-1 and make the submission of dose records from their licence holders to the ANRDR a licence condition.

ARPANSA is working to ensure that the ANRDR meets the needs of all stakeholders so that it can be a useful tool for jurisdictional regulators, submitting organisations and workers. The provision of ANRDR access to jurisdictional regulators is intended to allow them to review dose records for organisations submitting within their jurisdiction to compare industry, workgroup or individual exposures with national averages and maximums. Changes to the current organisational access is proposed to ensure that the ANRDR captures all relevant dosimetry information and that the ANRDR can be used as an acceptable record management system for an organisations dose records. There are also plans in place to provide workers with direct online access to their dose records to align the system with current societal expectations.

ARPANSA has also been engaged internationally with the IAEA through a practical arrangements agreement that has seen APRANSA take a leading role in promoting best practice occupational radiation protection within the Australasian region. This has seen ARPANSA provide resources for the development of guidance, delivery of training, auditing and advice within the region over the last four years. Examples include; hosting an IAEA workshop for the development and maintenance of national dose registers in May 2018; providing staff for an IAEA expert mission for the development of a national dose register in the United Arab Emirates in February 2018 and providing an expert for the delivery of training in occupational radiation protection in Japan in October 2017. An ongoing commitment for continuing work in occupational radiation protection has been recently signed between ARPANSA and the IAEA.

11.3 Control of discharges, materials for clearance, and existing exposure situations; environmental monitoring for public radiation protection

Control of discharges, materials for clearance

Related to GSR Part 3 Requirement 8, paragraphs 3.10-3.12,

The *National Directory for Radiation Protection (NDRP)* establishes that disposal can occur without regulatory approval provided they occur in accordance with Schedule 14 'Requirements and limits for the disposal of radioactive waste by the user', by sewer, air or landfill. These requirements were published in June 2017 and are to be adopted by jurisdictions, but have not yet been adopted in all jurisdictions, including the Commonwealth. These limits are based on potential exposure scenarios as described in the document. This form of disposal is to apply without the need for authorisation or notification to the regulatory body. When revising the NDRP and promulgating the 2nd edition of the NDRP, the RHC decided to re-publish Schedule 14 as a stand-alone *Code for the Disposal of Radioactive Waste by the User*, to be published as RPS C-6.

Additionally, the *Code for Disposal Facilities for Solid Radioactive Waste* (RPS C-3) is in an advanced stage of draft and expected to be published in the near future. It is ARPANSA's intention to make both RPS C-3 and RPS C-6, once they are published, mandatory licence conditions and as such listed in regulation 48.

ARPANSA exempt dealings and exemption limits are established in the ARPANS Regulations (schedule 2), additionally a specific exemption may be applied for (regulation 37-38). No specific clearance levels are established in regulation. Further exemptions are listed in the 2nd edition of the NDRP, which also refers to GSR Part 3 as regards clearance levels.

Related to GSR Part 3 Requirements 29, 32, 33,

Requirements for regulation of public exposure have been established in *the Code for Radiation Protection in Planned Exposure Situations* (2016) (RPS C-1). Complying with this code is a condition of licence for all licences issued under the ARPANS Act.

Dose limits for public exposure are established in the relevant jurisdictional legislation, including the Commonwealth (regulation 59) and in RPS C-1 (Schedule B). These include 1 mSv in a year for effective dose, with an annual equivalent dose to the lens of the eye of 15 mSv and 50 mSv for skin.

Where an application is received requesting authorisation to discharge above the exempt values, these are assessed by the regulatory body on a case by case basis. This can be in the form of a licence allowing discharge, or the granting of a specific exemption.

ARPANSA has granted an airborne discharge authorisation to ANSTO based upon an assessed dose to a hypothetical critical group of individuals. The objective for radiation dose to a member of the public due to airborne radioactive discharges from all conducts and dealings is 20 microsieverts effective dose per year. To assist in keeping these doses as low as reasonably achievable the doses are monitored through discharge notification levels and reported to ARPANSA. The quarterly notification level is set at 50 per cent of the annual level, and a four weekly notification level is set at 20 per cent of the annual level.

The discharge of liquid wastes is managed through individual agreements with the local authority for waterways and sewers, such as NSW trade waste agreements. The waste discharged must comply with drinking water standards. The drinking water reference activity concentrations correspond to an annual

constraint of 0.1 mSv/year and are based on the methodology specified in the World Health Organisation's (WHO) *Guidelines for Drinking Water Quality (2004)* and using the conversion factors specified in the International Atomic Energy Agency *International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources Safety Series No. 115 (1996*).

The holder of an ARPANSA licence must ensure, under Regulation 58(4), that radiation protection and safety relating to the licence are optimised in order to ensure that the doses, the number of people exposed and the likelihood of incurring the exposure are as low as reasonably achievable after taking into account economic and societal factors.

Under the *Code for Radiation Protection in Planned Exposure Situations*, RPS C-1 (section 2.5), the Responsible Person must ensure that:

(a) a monitoring program, sufficient to verify and demonstrate compliance with the authorisation, is implemented to confirm that public exposure due to any radiation source within the practice is adequately assessed

(b) the monitoring program specified in sub-clause (a) includes monitoring of, as appropriate:
  (i) external exposure due to such sources
  (ii) discharges
  (iii) radioactivity in the environment
  (iv) other parameters important for the assessment of public exposure

(c) appropriate records are maintained of:
  (i) the results of the monitoring program
  (ii) estimated doses to members of the public

(d) the results of the monitoring program are reported or made available to the relevant regulatory authority at approved intervals, including, as applicable:
  (i) the levels and composition of discharges
  (ii) dose rates at the site boundary and in premises open to members of the public
  (iii) results of environmental monitoring
  (iv) retrospective assessments of doses to the representative person

(e) any levels exceeding the operational limits and conditions relating to public and occupational exposure are reported promptly to the relevant regulatory authority in accordance with reporting criteria established by the relevant regulatory authority

(f) any significant increase in dose rate or concentrations of radionuclides in the environment that could be attributed to the authorised practice is reported promptly to the relevant regulatory authority in accordance with reporting criteria established by the relevant regulatory authority

(g) a capability is maintained to conduct monitoring:
  (i) in an emergency
  (ii) in the event of an unexpected increase in radiation levels, or
  (iii) of concentrations of radionuclides in the environment due to an accident or other unusual event attributed to the authorised radiation source or facility

(h) the adequacy of the assumptions made for the assessment of public exposure and the assessment for radiological environmental impacts is verified by a qualified expert

(i) results from radiation source monitoring and environmental monitoring programs and assessments of doses from public exposure are made available on request, as appropriate.

ARPANSA does not make specific provision for independent monitoring of discharges. However, ARPANSA requires regular reporting from licence holders, which may be verified as needed. ARPANSA has verified environmental measurements provided by licence holders through its own laboratories when required. ARPANSA has the capacity to perform monitoring where the need is identified, typically as part of a scientific study rather than for regulatory compliance monitoring.

Consumer products that contain radioactive material of greater than the exemption limit are subject to regulatory control. For these practices, licensing or exceptions would be required, and as such the regulator would ensure that consumer products are not made available to the public unless their use by members of the public has been justified, and either their use has been exempted or their provision to the public has been authorized.

Existing and chronic exposure

Related to GSR Part 3 Requirements 47-52, paragraphs 5.2-5.33,

The Guide for Radiation Protection in Existing Exposure Situations (RPS G-2), jointly developed and approved by the Radiation Health Committee, establishes the framework to ensure existing exposure situations, when identified, can be managed for the purpose of protection and safety, and so that appropriate reference levels can be established.

Guidance on existing exposure situations

RPS G-2, section 3.2.4 provides for:

- the identification of those persons or organisations responsible for the contamination of areas and those responsible for financing the remediation program, and the determination of appropriate arrangements for alternative sources of funding if such persons or organisations are no longer present or are unable to meet their liabilities and be found in section 3 clause 3.2.4(a)
- the designation of persons or organisations responsible for planning, implementing and verifying the results of remedial actions can be found in section 3 clause 3.2.4 (b)
- the establishment of any restrictions on the use of or access to the areas concerned before, during and, if necessary, after remediation can be found in section 3 clause 3.2.4 (c)
- an appropriate system for maintaining, retrieval and amendment of records that cover the nature and the extent of contamination; the decisions made before, during and after remediation; and information on verification of the results of remedial actions, including the results of all monitoring programs after completion of the remedial actions can be found in section 3 clause 3.2.4 (d).

Remediation of existing exposure situations

An example of ARPANSA regulatory oversight of remediation and control of a legacy site is the South Alligator River Valley in Kakadu National Park in the Northern Territory, which was the target of rehabilitation work.

Government uranium mining operations in the 1960s occurred at 13 sites in this region. There were no formal environmental regulations throughout this period and no requirement for complete rehabilitation of

any of these sites. Consequently, they were generally abandoned, including a small mill and solvent extraction plant, contaminated process ponds, roads and tracks as well as open cut mines and mineshafts. Since operations ceased, several phased rehabilitation projects occurred in the late 1980s and two projects were completed in 1992 and 2000. These produced material which was stored for disposal. In 2006, the Commonwealth Government provided $7.4 m to Parks Australia North to clean up all remaining sites within the South Alligator River Valley to an acceptable standard.

The South Alligator Containment Facility (SACF) was purpose built in 2009 to encapsulate various waste from abandoned uranium mines in the region. The CEO of ARPANSA granted a licence to possess or control the South Alligator Disposal Facility. Monitoring of the SACF is undertaken via collection of data from one automatic weather station and three soil monitoring stations equipped with an extensive array of sensors throughout the facility profile. These automatically collected data is supplemented with other manually collected information such as ^{222}Rn flux densities plus water chemistry and seepage of surrounding ground waters. The purpose of the collection and interpretation of all these data is to gain an understanding of the facility's behaviour in the context of the goals and objectives of the facility, and to guide annual operational management activities.

Another example is the remediation and ongoing oversight of the former nuclear weapons test site at Maralinga in South Australia. Between 1952 and 1963 the Maralinga Lands were used by the UK for the testing and development of nuclear weapons. The UK made three attempts to clean up Maralinga but only the last was intended to leave the site in a state where no further security control would be necessary. Following concerns about the level of contamination and a subsequent Royal Commission into the matter in 1985, the Maralinga Rehabilitation Technical Advisory Committee was established in 1993 to oversee the Australian Government rehabilitation of the Maralinga test site.

For the rehabilitation of Maralinga, a 'reference' annual committed effective dose (which can now be referred to as a reference level) of 5 mSv per year was agreed upon with interested parties. Following the successful rehabilitation, dose assessments have shown that most of the contaminated areas at Maralinga fall well within the clean-up standards applied for unrestricted land use, meaning that in most areas activities and land uses such as hunting, mining exploration and construction could proceed. There are still restrictions on permanent occupancy within a 'restricted land-use' (non-residential) boundary surrounding Taranaki, a former test-site at Maralinga. These restrictions are precautionary in nature and are in place as control measures designed to contain any remaining contamination at the site and to discourage accidental intrusion into the burial trenches.

In November 2009 the Australian and South Australian Governments and Maralinga Tjarutja (the traditional owners of the land) signed the Maralinga Nuclear Test Site Handback Deed, which gave effect to the return of the test site and Maralinga Village to Maralinga traditional owners. ARPANSA continues to provide information, advice and environmental monitoring through the Maralinga Land and Environment Management Plan, including completing regular radiological surveys and dose assessments. Maralinga is now licensed by the South Australian government.

ARPANSA regulates a former disposal facility known as the Little Forest Legacy Site (LFLS) which is maintained by ANSTO. The LFLS was originally constructed as a disposal facility, but was first licensed by ARPANSA in 2015 under a possess or control licence as a nuclear waste storage facility.

The facility was established by the former Australian Atomic Energy Commission for the near surface burial of low level wastes. The facility was operational between 1960 and 1968. During this time, a number of shallow trenches were excavated and about 1600 cubic metres of material was buried. The material

consisted of equipment and waste contaminated with radioactive substances of low activity, effluent sludge, chemicals and beryllium. After emplacement of the waste, a one metre thick layer of local clay-rich soil was used to cover the waste.

The licence was then reissued in November 2016 as a possess or control licence for a prescribed legacy site which was a new category of licence introduced into the ARPANS Act and Regulations to cover legacy sites. A licence condition was imposed on ANSTO to produce a medium and long term plan for the management of the site, including potential remediation. The timeline for production of this plan was recently extended to December 2019, with interim progress reports due at six monthly intervals.

ARPANSA undertakes a scheduled inspection programme at Little Forest Legacy Site with 3 sites visits and one inspection having been undertaken since 2016. Annual reports are submitted to ARPANSA by ANSTO providing relevant information such as integrity of the containment cover, results of groundwater analysis etc.

Radon exposure to the public

Information on exposure due to radon is available on the ARPANSA website. A national reference level for radon of approximately 10 mSv per year effective dose, corresponding to an annual residential indoor radon concentration of approximately 200 Bq/m^3, is in place in Australia for all jurisdictions.

A nationwide survey was first published in a technical report by ARPANSA's predecessor organisation, the Australian Radiation Laboratory, in 1990. A total of 10,000 dwellings were selected from a random sample taken from the electoral districts in each State or Territory. Subsequently approximately 3,900 dosimeters were sent to those responding to the invitation and the monitors were exposed for a period of 12 months. Approximately 3,400 monitors were returned and analysed. Averages were determined by postcode, State and Territory and for Australia. This radon map is available online.

From this data, an overall average for Australian homes of 11 Bq/m^3 was determined and that an estimated one in a thousand of Australian homes could have levels of radon exceeding 200 Bq/m^3, the level where remedial actions should be considered.

It is ARPANSA's judgement, on the basis of information available, that a national action plan to control public exposure to radon indoors is not justified in Australia at this time. ARPANSA is presently undertaking studies to characterise possible radon prone areas and the national radon protection strategy is currently under development by ARPANSA. It is anticipated that the strategy will state that a national action plan is not justified due to the low average level of radon in Australian homes.

11.4 Conclusions and actions

Australia generally meets the expectations of the IAEA safety standards in medical, occupational, and existing exposure situations. However, some areas for improvement have been identified.

Medical exposure

Across Australia, there is a nationally recognised code for medical exposures, RPS14, that has been endorsed by all States and Territories. Adherence with the code is a legal requirement in all but two jurisdictions. Additionally, a new draft *Code for Radiation Protection in Medical Exposure* (RPS C-5) is currently in advanced stages of development, which will further enhance the alignment with the requirements of GSR Part3. Within RPS14 the roles and responsibilities of the Referring medical practitioner/Referrer are not defined, nor are there detailed referral requirements such as referral guidelines. While the referrer is often not within the scope of radiation safety regulatory bodies functions, some jurisdictions apply restrictions on professions or individuals who can issue a valid referral.

- An action item has been identified which aims at strengthening uniformity in referral guidelines, which will be part of promulgation of the draft Medical Code, to be published as RPS C-5. See Action Plan item 18)

ARPANSA has established National Diagnostic Reference levels for multi-detector CT and nuclear medicine procedures. This includes a system that allows institutions to establish their facility reference levels for CT and compare these with other institutions across Australia.

- DRLs for image-guided interventional procedures are being developed and the efforts to expand DRL coverage of other modalities should continue to be pursued. See Action Plan item 19**Error! Reference source not found.**).

A lack of national uniformity for authorisations, testing and design of medical equipment may negatively affect the mobility of business or professionals across Australia. For example, a similar practice in two different jurisdictions may have differing requirements on shielding, or the use of safety devices such as foot switch accidental activation protection. Additionally, there is no national uniformity for the responsibilities of the referring medical practitioner or generic justification guidelines.

Occupational exposure

Australia has strong harmonised workplace health and safety legislation for the protection of all workers. Radiation protection requirements set out in the new *Code for Radiation Protection in Planned Exposure Situations* (2016) (RPS C-1), is adapted from and contains specific reference to the GSR Part 3 requirements.

- ARPANSA does not require mandatory health surveillance for radiation workers, or provide specific guidance on this topic. However, one jurisdiction (South Australia) does have requirements for uranium mining workers. (See action plan 20).

Control of discharges, materials for clearance, and existing exposures situation

Australia has in place a guide on existing exposure situations based on GSR Part 3 requirements. This guide has been agreed by all jurisdictions. ARPANSA has developed further guidance for stakeholders on implementation of the existing exposure guide. Australia has developed national guidance on the transition from an emergency situation to an existing exposure situation. Australia was one of the first Member States to do this.

- The national radon protection strategy is currently under development by ARPANSA and is expected to state that a national action plan is not justified. Additionally, ARPANSA is presently undertaking studies to characterise possible radon prone areas. (See action plan 17).

There are varying standards of regulation surrounding remediated sites and controlling existing exposure situations. National uniformity is further discussed in section 13.

Environmental monitoring for public radiation protection

- While licence holders are required to have environmental monitoring programs as applicable (e.g. ANSTO), ARPANSA does not provide for an independent monitoring programme of and assessment of public doses due to authorised facilities or activities. Therefore, these results are also not made publicly available (See action plan 21).

However, ARPANSA is establishing an Australian radiation monitoring network related to the visit of nuclear powered warships. The real-time data generated by this system will be accessible to the public via an interactive chart that will be available on our website once the network is installed.

12. Interface with nuclear security

This section focuses on Commonwealth arrangements.

12.1 Legal basis

Related to GSR Part 1 (Rev. 1): Requirement 12, paragraph 2.39

ARPANSA is the competent authority to ensure the safety and control of radioactive material for the Commonwealth, while jurisdictional regulatory bodies are responsible for their jurisdictions across Australia. The Australian Safeguards and Non-proliferation Office (ASNO) is the competent authority for ensuring Australia's compliance with the Comprehensive Safeguards Agreement and Additional Protocol with the IAEA, and with the amended Convention on the Physical Protection of Nuclear Material. This is done through the accounting and control of nuclear material and the regulation of physical protection (nuclear security) for all jurisdictions. These authorities have separated functions though separate Acts (see section 1). There is an information sharing arrangement in place under a memorandum of understanding (MoU) between ASNO and ARPANSA. Information is extensively shared between ARPANSA and other jurisdictions' regulatory bodies, including through the Radiation Health Committee.

The Australian Federal Police and local emergency response agencies generally have roles defined through the emergency plans (see section 9), or transport plans (see section 5.6, 6.6, 9.6) associated with specific tasks or scenarios. The Australian Government Crisis Management Framework recognises that emergency response organisations require integration into multidisciplinary teams for safety- and security-initiated events.

12.2 Regulatory oversight activities

Related to GSR Part 1 (Rev. 1): Requirement 12, paragraphs 2.39–2.40

Under the ARPANS Act, security is considered incidental under the objectives of the Act, and so does not explicitly require interfaces between safety and security to be considered. The ARPANSA website lists international best practice documentation including NSS-13, NSS-14, NSS-15 and IAEA-TECDOC-1801 *Management of the Interface between Nuclear Safety and Security for Research Reactors*. All of these documents refer to interfaces between safety and security, are promoted by ARPANSA as best practice, and may be considered during application and review.

ARPANSA has also listed GSR Part 7 as international best practice and its requirements are considered in regulatory decisions and guidance. This includes emergency response arrangements for licence holders.

As part of the inspection program, Performance Objectives and Criteria (PO&C) Baseline Module (BM) 6.3 states: 'The organisation has effective security management arrangements that are supported by a good security culture. An integrated approach is taken to Safety and Security'. This is further expanded upon under BM 6.3.4 which states: 'Safety and security measures are developed so that they do not compromise each other. Safety and security are seen as complimentary and processes are designed so that measures for one complement the other'.

Similarly, Paragraph 18 of the compliance code attached to ANSTO's permit to possess nuclear material, granted by ASNO under the Safeguards Act, states that 'The Permit Holder shall manage the nuclear security interface with nuclear safety and nuclear material accountancy and control arrangements in a manner to ensure that they do not adversely affect each other and to the degree possible, they are mutually supportive'.

12.3 Interface among authorities

Related to GSR Part 1 (Rev. 1): Requirement 12, paragraphs 2.39–2.40

ARPANSA and ASNO have jointly developed the regulatory guide Periodic Safety and Security Review of Research Reactors (PSSR), which specifically requires consideration of the interfaces between safety and security when conducting a periodic review. Periodic reviews are usually required every 10 years or when there is a significant change in the safety and/or nuclear security environment.

ARPANSA and ASNO have established a Joint Physical Protection and Security Working Group where there are shared responsibilities and any issues with the interfaces between safety and nuclear security can be resolved.

Additionally, co-operative meetings are held on security issues, on an as need basis. For example, at a recent meeting in early 2018 ARPANSA met with the Australian Federal Police (AFP), ASNO and ANSTO to discuss protective security arrangements at the Lucas Heights Science and Technology Centre.

12.4 Conclusions and actions

Integration of safety and security is explicitly covered in regulatory guidance (such as PSSR documents) and the ARPANS inspection program (PO&Cs). Additionally, the primary nuclear regulators ASNO and ARPANSA have regular joint meetings with affected parties, including licence holders, and exchange information under a MoU.

While a strict legal basis is not apparent for the initiatives that are being carried out to ensure integration of safety and security, Australia's requirements are significantly integrated through a variety of mechanisms. These functions are integrated in a similar manner to all other areas such as transport, or disposal. As such, the provisions for special legal requirements to ensure integration would have limited benefit.

13. National uniformity

This section includes responses form the regulatory bodies of all jurisdictions. It provides for a discussion on areas where regulatory bodies have implemented different approaches, providing a number of examples of challenges and issues experienced in establishing and implementing a national consistent legal framework for radiation protection in Australia. The material supports a discussion on matters that broadly relate to 'uniformity'. The section does not generate items for the Action Plan per se, and there is no corresponding IRRS module. However, a number of the actions identified in the modules are impacted by differences in jurisdictional approaches, or require a nationally uniform response.

As mentioned in the Background to this Summary Report, Australia has a federal system of government that encompasses nine jurisdictions, being the Commonwealth (the national-level Australian Government), the six States and two self-governing Territories. The States and Territories vary significantly in population, land area, and economic activities, which affects priorities and resourcing levels within a jurisdiction. A summary of the population and land area of each State and Territory is provided below:

State/Territory	Population 2017 (million)	% of Australian population	Land area (million km^2)	% of Australian land area
Australian Capital Territory	0.4	2%	<0.1	<1%
New South Wales	7.8	32%	0.8	10%
Northern Territory	0.2	1%	1.4	18%
Queensland	4.9	20%	1.7	23%
South Australia	1.7	7%	1.0	13%
Tasmania	0.5	2%	0.1	1%
Victoria	6.3	26%	0.2	3%
Western Australia	2.6	10%	2.5	33%
Australia (rounded)	25 million	-	7.7 million km^2	-

Table 11. Comparison of Australian States and Territories

The Commonwealth may only exercise powers given to it under the Australian Constitution or though agreements entered into with States. Each State and the Commonwealth has its own sovereign parliament. The self-governing territories, namely, the Northern Territory and the Australian Government Territory, have legislative assemblies with limited law making powers but these can be overridden by the Australian Parliament, which can also make laws for the Territories.

All nine jurisdictions have their own radiation protection legislation and regulatory bodies. This may create differences in regulatory requirements and implementation across jurisdictions, leading to inconsistencies such as those reported under the RHC initiative *report a national uniformity issue*.

One of the functions of the Commonwealth regulator, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), is to promote national uniformity, which is enshrined in the *Australian Radiation Protection and Nuclear Safety Act 1998* (the ARPANS Act). Lack of national uniformity or inconsistency in the implementation of radiation protection legislation can adversely impact the effectiveness and efficiency

of the administration of safety of radiation practices across jurisdictions. In particular, lack of national uniformity in licensing, registration or exemption provisions for different occupations and radiation sources may pose difficulties for users operating across jurisdictions or relocating from one jurisdiction to another. If this occurs, it will result in higher costs being incurred to businesses, end users, and ultimately to the community.

Australia has made a consistent, yet gradual approach to addressing national uniformity. The principal body that addresses national uniformity is the Radiation Health Committee (RHC). The functions and membership of the RHC is set out in the ARPANS Act, and discussed in section 1.4 of this Summary Report. One of the key functions is 'to develop policies and to prepare draft publications for the promotion of national uniform standards of radiation protection' (section 23(1) of the ARPANS Act). The RHC is comprised of representatives of each jurisdiction, who must be 'radiation control officers', a senior position in a regulatory body. The RHC, through ARPANSA, publishes national codes and guides and agrees on national implementation of regulatory elements as outlined in the National Directory for Radiation Protection. Note that the first edition of the NDRP (RPS 6), including amendment 7, is still in force) but is intended to be superseded by the 2nd edition that was approved by the RHC in July 2018.

In late 2016, the RHC agreed to aspire towards 'a seamless regulatory experience for the safe use of radiation'. The aim is to:

- enable individuals and businesses conducting radiation practices or using radiation sources across Australia to do so seamlessly with no barriers to the transfer of their authorisations
- facilitate the adoption of agreed national radiation protection codes and standards in a consistent manner in all jurisdictions
- work towards a national register of radiation practices and sources, and inspection and incident database.

A number of options were explored by the RHC, which were outlined in an RHC Options Paper – provided in the reference material. The paper considered several options, including a more proactive implementation of the NDRP, model legislation (identical radiation legislation in each jurisdiction), and single legislation (one legislation for the whole country administered by ARPANSA and implemented by every jurisdiction). RHC resolved to adopt the first option of proactively implementing the NDRP, while working towards model or single legislation.

The Commonwealth Government, through the Department of Health, is pursuing a similar initiative, so far mainly in consultation with other Commonwealth departments under the terms of an Interdepartmental Committee (IDC). ARPANSA provides technical advice to the IDC and the RHC has been informed of the initiative. This issues paper has many similarities with the paper developed by the RHC, but has not been provided as a reference for the IRRS team at this time.

The Radiation Regulators' Network (RRN) has been established to facilitate operational discussions on regulatory issues affecting all jurisdictions, for example, discussing and arriving at a possible national position on the authorisation of new radiation equipment and the development of a single national set of competency requirements for the issue of user licences to medical radiation practitioners and industrial radiographers. The RRN is not administrated through the ARPANS Act. However, several members of RHC sit on the RRN.

13.1 Authorisations – licencing, registrations, exemptions

Related to GSR Part 1 (Rev. 1): Requirement 1, 2

Authorisations issued in Australian jurisdictions, which must be applied for and granted prior to dealing with a radiation source, may include:

- user licences (allowing an individual to deal with radiation sources)
- possession licences (allowing a corporation or individual to own or control sources)
- registration (each individual equipment or place where radioactive material is used)
- management licences (a combination of the above authorisations). For example, a management licence in TAS can cover the use and possession of a number of sources. This means, a dentist may hold a licence which allow them to own and use 4 dental X-ray apparatus, which are listed on the licence, each additional dentist at the practice will also hold a use licence. In TAS, a management licence for supply or repair may authorise multiple persons at a business.

	NSW	VIC	TAS	SA	QLD	ACT	NT	WA	Commonwealth
Management licence	✓	✓	✓	#	×	×	×	ϕ	✓
Possession licence	*	*	*	✓	✓	✓	✓	ϕ	*
Equipment/place registration	*	*	*	✓	✓	✓	✓	ϕ	× Notification only
User licensing	✓	✓	✓*	✓	✓	✓	✓	✓	×

* Captured under management licence (e.g. individually listed on licence)

ϕ In WA, registrations may include possession and management licence requirements.

\# In SA, licences associated with mining are considered 'management licences' these are *Licence to carry out mining and mineral processing*, *Licence to test for developmental purposes* and a *Facilities licence*.

Table 12. Summary of authorisation types

In accordance with a graded approach, certain dealings with radiation sources are exempted in different jurisdictions. For example, use licences are not required for baggage scanner (X-ray apparatus) in TAS or QLD, or for the use of intra-oral radiography by dentists in NSW and WA. However, other jurisdictions require these persons to hold a licence.

The differences among jurisdictions' legislation and their administration result in some inconsistencies in terms of the licensing requirements and can add complexity that makes it harder for businesses, practices and individuals to move between jurisdictions or establish themselves in a new jurisdiction. For example, an industrial radiographer who owns practices in one jurisdiction, and wishes to expand their business to a new jurisdiction, will need to become familiar with the requirements and may not be able to replicate the same setup used in the first jurisdiction.

To address this issue, the RHC has prepared the Regulatory expectations for users of radiation sources seeking to obtain authorisations in more than one jurisdiction. This statement was issued by the RHC following endorsement by a majority of the regulatory bodies. The document sets out what applicants can expect when seeking authorisations (licences or registrations) for the same activity in multiple jurisdictions.

Every jurisdiction also has a *Mutual Recognition Act 1992*, which allows for, among other things, the recognition of an existing user licence of an equivalent occupation while applying for authorisation in a second jurisdiction. See section 13.9

Graded approach

Authorisations are in some cases graded differently by jurisdictions, and there is no national agreement on what constitutes a high priority source or facility.

For example, NSW categorises sources into four groups (A-D), while ARPANSA categorises sources into three groups (schedule 3C of the ARPANS Regulations), split into six regulatory priority groups. NSW classifies sealed sources based on security category (D-value), while ARPANSA bases its categorisation on multiples of the exemption limits (ARPANS Act). While there is broad consistency in low risk sources such as dental X-ray, and high risk sources used in industrial radiography, some source types do not align. For example, the NSW Group B contains ARPANSA lowest (Group 1) and highest (Group 3) priority group sources.

Source type	NSW licence group	ARPANSA group (regulatory priority)
Dental	Group A	Group 1
Mobile medical	Group B	Group 1
Fixed medical	Group B	Group 2
Fixed gauges (Cat 4)	Group B	Group 2
Radiotherapy	Group B	Group 3
Industrial radiography	Group C	Group 3

Table 13. Categorisation of radiation sources examples

13.2 Scope of regulation

Related to GSR Part 1 (Rev. 1): Requirements 23

The types of sources covered by regulatory requirements vary across jurisdictions. In addition to exemptions, some sources are explicitly covered only by some jurisdictions. For example, jurisdictions independently introduced regulation of cosmetic tanning beds (solarium), followed by jurisdictions banning the practice. This was done with national consultation but was not done as part of a national strategy. An example for laser/IPL is given below.

Example: Regulation of lasers and non-ionising radiation sources

There is no national agreement to regulate lasers or intense pulsed light (IPL) sources. However, four jurisdictions currently regulate some types of lasers.

Jurisdiction	Medical lasers	Cosmetic laser	Industrial laser	Laser pointer	IPL
ARPANSA	✓	✓	✓	✓	×
TAS	✓	✓	✓	✓	✓
WA	✓	✓	✓	*	×
QLD	✓	✓	*	*	×
ACT, NSW, VIC, SA, NT	×	×	*	*	×

* Industrial and handheld lasers are also regulated under the Work Health and Safety legislation, and weapons restrictions may apply for laser pointers of a certain power. Under the Radiation Safety Act 1999, Queensland regulates class 4 lasers designed for use on persons.

Table 14. Current regulation of lasers

The RHC, through ARPANSA, ran a survey in 2012 to consider the best regulation options for laser and IPL, especially in the cosmetic industry. ARPANSA prepared a Regulatory Impact Statement (RIS), Intense Pulsed Light sources [IPLs] and Lasers for Cosmetic or Beauty Therapy consultation draft in May 2015. A technical paper (TR177) was released in 2017 on the analysis of the consultation. RHC considered there is insufficient information to warrant a decision. Therefore, there is no national agreement on the regulation of lasers and IPL.

13.3 Competency requirements for radiation occupations/service providers

Related to GSR Part 1 (Rev. 1): Requirement 11

There is limited agreement on national competencies such as the level of qualification, training and experience required to deal with radiation sources, or to be a Radiation Safety Officer.

Most jurisdictions maintain a list on their website of approved qualification and training (e.g. accreditation or registration with professional bodies, tertiary qualifications or approved courses) which are considered sufficient to obtain a specific type of licence.

While there is broad consensus on many common occupations, there are differences which can affect the eligibility of applicants. Theoretically, under the *Mutual Recognition Act 1992* (see section 13.9) such an applicant could apply for and receive a licence in a jurisdiction with less stringent requirements, then apply under mutual recognition and receive a licence in the second jurisdiction. As such, these differences do not limit persons from obtaining a licence but add additional hurdles. In recognition of this, some jurisdictions (e.g. ACT) state on their website that they accept applications where the applicant can demonstrate eligibility in any jurisdiction.

Occupation	QLD	NSW	VIC
Dentist	*[fast track applications]* Recognised Degree (e.g. BDS), and registered as a Dentist with the Australian Health Practitioner Regulation Agency (AHPRA).	Exempt for intraoral – for OPG registered as a dentist with the Australian Health Practitioner Regulation Agency (AHPRA).	Must be registered as a dentist with the Australian Health Practitioner Regulation Agency (AHPRA).
Dental assistant	*[fast track applications]* Certificate IV in Dental Assisting (Radiography Specialisation)	Certificate IV in Dental Assisting (HTL43012)	Certificate IV in Dental Assisting (HTL43012)
Dental (CBCT)	*[fast track applications]* Registered dentist holding a certificate of Proficiency in dental CBCT issued by an oral and maxillofacial radiologist approved by Radiation Health	Dentists, Dental hygienists/therapists/ assistants/nurses (Above **and**) training course (1 listed) **or** manufacturer, **or** in-house training by licenced person.	Dentists, dental hygienists/therapists/ assistants/nurses (Above **and**) training course (3 listed) **and** applications training (12 listed)
Industrial radiography	• Approved course in radiation safety • Log book of 300 supervised hours (by a licensed person) • Statement of level of competency	Training course (10 listed)	Training course (5 listed)
Portable density/moisture gauges	• Approved course in radiation safety • Log book of 20 supervised hours (by a licensed person) • Provision of Certificate of Competency from an approved person	Training course (18 listed)	Training course (3 listed)

Table 15. Examples of competency requirements

13.4 Adoption of codes

Related to GSR Part 1 (Rev. 1): Requirements 32

The process to adopt codes in Australia further highlights challenges in national uniformity. Generally, RHC will draft a code on a particular issue, with assistance from ARPANSA and generally building on 'standards' and risk assessments published by the IAEA, WHO, ICRP, UNSCEAR and others, as applicable. The drafting process includes public consultation hosted on the ARPANSA website. Following RHC approval and recommendation from the Radiation Health and Advisory Council to adopt the Code, ARPANSA publishes it on its website and steps are taken to include the Code in Schedule 11 of the NDRP. RHC has agreed that once a Code is listed in Schedule 11, all jurisdictions will take steps to give it legal effect either through amendment to legislation or implementation as a licence condition.

Currently the listing of a code in Schedule 11 of the NDRP can be significantly delayed as any amendment to the NDRP must be approved by the Council of Australian Governments' (COAG) Health Council, which comprises the Health Ministers of every jurisdiction. The amendment process can take up to 18 months. To rectify this situation, as part of the approval process for the 2nd edition of the NDRP, it will be proposed that Ministers devolve the authority to approve most amendments to the NDRP to the RHC.

While formally the Codes listed in the NDRP should be adopted in each jurisdiction, there may be delays and some variation in how the Codes are implemented. For example, the WA Radiological Council (Council) actively applies the requirements of several ARPANSA Codes of Practice relevant to radiation exposure in medical situations. However, whilst the Council has agreed to adopt the Medical Code (RPS 14), the requirement to comply with RPS 14 has not yet been adopted into the Regulations and thus some requirements of this Code are not legislated in WA. A condition of registration that requires adherence to RPS 14 has been drafted and approved by the Council, but has not yet been applied to registrations. However, some specific licences have a condition applied requiring adherence with RPS14.

Codes may be subject to the preparation of Regulatory Impact Statements (RIS) if the Office of Best Practice Regulation (OBPR; see section 9.1) decides that a RIS is necessary because of the impact and cost burden of the code on stakeholders. Even where the OBPR decides that a RIS is not necessary that does not mean that the decision must be accepted by every State and Territory. A State or Territory may require a RIS before a code is implemented in its jurisdiction. This disconnect between the jurisdictional requirements on the need for a RIS can make it difficult to adopt codes into local legislation. Furthermore, because consultation is to be undertaken at the jurisdictional level, there is the expectation that changes would be made to account for any public comment received, which may lead to inconsistencies across jurisdictions.

Codes, such as the new *Code for Radiation Protection in Planned Exposure Situations* (2016) (RPS C-1), contain requirements which are open to interpretation. This means that implementation of requirements by each jurisdiction may differ in practice. For example, RPS C-1 requires that radiation management plans be reviewed. For ARPANSA, the mandatory review period is set at three years (regulation 50). However, requirements in other jurisdictions range from annual to five yearly review, or there is no fixed requirement. The interpretation and implementation of the Planned Exposure Code is currently a topic for discussion within the RRN.

New technologies and emerging practices

New technologies and emerging practices can arise before relevant codes address the issue. This may cause jurisdictions to implement requirements that are specific to their jurisdiction, which subsequently makes it harder to achieve national uniformity.

For example, cone-beam computed tomography (CBCT) dental equipment increased rapidly in Australia due to the availability of low cost equipment and a high rate of charge through Medicare (government subsidised health care). However, regulatory bodies in Australia captured these units differently with some jurisdictions applying orthopantomogram (OPG) equipment standards while some applied CT standards. Operator requirements are also not consistent with some jurisdictions limiting their use to qualified dentists while other jurisdictions accept dental assistants with manufacturer provided applications training (see section 13.3).

The use of lasers and intense pulsed light in the health and cosmetic industries is another example of an emerging technology that has established itself in the mainstream, but is not yet subject to consistent national requirements or regulation.

13.5 Radiation source compliance testing programs

Related to GSR Part 1 (Rev. 1): Requirements 29

Compliance tests are performed on sources to confirm that they are operating in accordance with agreed requirements. They typically focus on operational factors such as radiation output, but can include signage or operational considerations such as quality assurance activities. Additionally, some jurisdictions, such as TAS and QLD require testing of certain premises or places.

Each jurisdiction has its own set of compliance standards. These differences include:

- standards to be tested against
- frequency of tests
- which sources need testing.

Tests from one jurisdiction are not formally recognised in other jurisdictions, which hinders the seamless transfer of equipment. Generally, if a source moves from one jurisdiction to another, even if it is within the testing frequency of the States, the original test is not recognised and a test in the new jurisdiction will need to be performed. This is an issue for portable sources such as medical screening programs, which are delivered across Australia using sources in mobile vans. These services often need to be tested and authorised in multiple jurisdictions which introduces a financial burden.

Description	NSW	VIC	QLD
Timer Accuracy	The accuracy of the timer controls must be within ±5% or ± one pulse of the indicated time, whichever is greater. The coefficient of variation of at least three consecutive measurements at the same timer setting must not exceed 0.05.	The exposure timer accuracy for timer settings across a clinical range must be within: • ±10% of the indicated value for exposure times greater than or equal to 0.1 seconds* • ±20% ± 1 pulse of the indicated value for exposure times less than 0.1 seconds*.	The measured irradiation time must be within: • ±10% percent of the indicated value for irradiation times 100 milliseconds or greater • ±20 percent of the indicated value for irradiation times less than 100 milliseconds. Measurements should be performed at approximately 70 kVp and 100 mA using at least 5 irradiation time settings.
KVP Accuracy	The kVp accuracy for kVp settings across the clinical range must be within ± 5% of the measured value. The coefficient of variation of at least five consecutive measurements at the same kVp setting must not exceed 0.02.	kVp settings across the clinical range must not exceed ±5% or 5kVp, whichever is greater of the indicated value.	The measured kVp: • should be within ± (5 percent + 1 kVp) of the indicated value • must be within ±10 percent of the indicated value.

Table 16. Differences in standards, examples from plain film (medical) radiography testing requirements

Some requirements on equipment apply only in certain jurisdictions, such as a guard on footswitches to prevent accidental activation. This can affect the sale of equipment across borders. Additionally, for medical apparatus, only TGA registered devices can legally be sold in Australia. TGA have agreements with EU which means IEC Standards typically apply. Any local variation in technical requirements that differ from TGA registration (IEC) requirements could cause issues.

Requirement	NSW	VIC	QLD	ACT, SA
Plain film radiographic	5 yearly	2 yearly	3 yearly	Testing is only required after new installation or significant repair.
Fluoroscopic	2 yearly	2 yearly	12 months	
CT	2 yearly	12 months	12 months	

Table 17. Testing frequency, examples

Description	VIC	NSW	QLD	WA
Dental apparatus	✓	✓	✓	✓
Baggage Scanners	×	✓	✓	✓
Indusial (fixed) gauges	×	✓	✓	✓
Non Destructive Testing (Industrial Radiography) apparatus	×	×	✓	×
Premises for unsealed Radioactive material (Laboratory)	×	×	✓	×

Table 18. The types of apparatus/premises to be tested, examples

One jurisdiction (WA), concluded that in order to maintain oversight with reduced resources, the compliance testing program could be extended to include activities usually associated with security enhanced sources, such as borehole logging and industrial radiography, or those activities with high numbers of users and sources, such as portable density/moisture gauges.

13.6 Shielding and design requirements

Related to GSR Part 1 (Rev. 1): Requirements 24

Each jurisdiction sets requirements on shielding and design.

Several jurisdictions have radiation shielding guidance or requirement documents that are publicly available, including:

- NSW: Radiation Guideline 7 - Radiation shielding design assessment and verification requirements
- TAS: Standard for Radiation Place for radiation Apparatus - X-ray [RPA0501]
- QLD: Radiation Safety Standard PR100:2010 Standard for Premises – Ionising Radiation Sources
- WA: Structural Radiation Protection Guidance Notes.

The underpinning reference documents include the National Council on Radiation Protection and Measurements (NCRP) Report No. 147 - Structural shielding design for medical X-ray imaging facilities (2004) and the Australian Standard AS 2243.4 Safety in laboratories – Part 4: Ionizing radiations.

An example of the variations between jurisdictions is in the design constraint, which is the level to which shielding is designed. For example when calculating the shielding required for a diagnostic X-ray apparatus. This level is set below the occupational and public exposure limits.

Design constraint, examples

Description	NSW	NT	QLD	WA
Occupational design constraint	100 µSv per week (should)	Less than 0.1 mSv per week (fraction of 5mSv per year) for controlled areas	40 µSv per week in occupational areas outside of the radiation source room or behind protective barriers (e.g. at operator consoles).	10% of the effective dose limit (2mSv per year)
Member of Public design constraint	20 µSv per week (must)	Less than 0.02mSv per week (fraction of 1mSv per year) for uncontrolled areas	10 µSv per week (in any area able to be accessed by members of the public)	50% of the public effective dose limit (0.5 mSv per year)

Signage requirements, examples

State	Requirement	Implementation method
TAS	All entrances to individual rooms or areas where a radiation apparatus - X-ray is to be usually or primarily used must bear a radiation warning sign. This sign must consist of a trefoil, in black on a yellow background, with an appropriate warning. Signs must be in compliance with the requirements of Australian Standard AS 1319-1994 Safety signs for the occupational environment.	Premises standard compliance with which is assessed by authorised persons.
VIC	*Dependent on source type, for medical applications:* Each entrance to the radiation source room must display a conspicuous radiation warning sign which contains the following information: • radiation warning symbol (trefoil) • words to the effect of 'caution – X-rays'. The symbol and lettering must be black on a yellow background. Note: This requirement does not apply to: a) radiation source rooms in which only intra-oral dental diagnostic radiography equipment is used or b) rooms that can only be accessed from the radiation source room or c) entrances to the radiation source room where a person must, prior to entering the room, pass through a control area, provided that a radiation warning sign is placed at the outside entrance to the control area.	Licence holder responsibilities (condition of licence)

State	Requirement	Implementation method
NSW	*Dependant on source type, for fluoroscopy:* A radiation warning sign complying with Schedule 5 of the Regulation must be displayed on the outside of the entry doors to any room: a) in which a fixed apparatus is installed or b) designated as the room in which a mobile or portable apparatus is permanently used. A radiation warning light must be positioned at the entry doors to all rooms, except in the case of 1.4.1 (b) or where a CRE has determined that not to do so would not pose a risk to the safety of any person. Where a radiation warning light is provided, it must light whenever the X-ray tube is placed in the preparation mode before exposure and when fluoroscopy is in progress. The light must remain illuminated for the duration of the exposure and must bear the words 'X-RAYS—DO NOT ENTER' or similar. Immediate illumination must be ensured.	Regulation, compliance checked during compliance testing.

13.7 Identification and security checking for security enhanced sources

Related to GSR Part 1 (Rev. 1): Requirements 23 and 24

In response to a recommendation of the Council of Australian Governments' CBRN Security Strategy, ARPANSA published the *Code of Practice for the Security of Radioactive Sources* (RPS 11) in 2007, which jurisdictions agreed to adopt in their regulatory framework. The Code stated that a person responsible for a security enhanced source as defined in the Code should undergo a security background check including an Australian Security Intelligence Organisation (ASIO), and security assessment and criminal history checks by the Australian Federal Police (AFP) and all State and Territory police services.

ARPANSA subsequently (2010 - 2011) drafted several iterations of a Security Background Checking Framework which was reviewed, with concerns and issues raised by several jurisdiction and statutory bodies including NSW Environment Protection Authority, Australian Security Intelligence Organisation and the Department of the Prime Minister and Cabinet. One of the principal objections raised was that the framework was predicated on each State and Territory (and the Commonwealth) implementing their own radiation security background checking schemes.

The RHC proposed that national scheme for security checking operated by Auscheck may be suitable for the purpose. Auscheck is a Commonwealth body that performs backgrounds checks nationally for aviation, maritime and health security regimes. It has existing arrangements and relations with all relevant police and security organisations. An RHC working group including ARPANSA is continuing to liaise with Auscheck regarding the legislative framework for implementation.

13.8 National information and databases

Related to GSR Part 1 (Rev. 1): Requirements 35

Jurisdictionally based regulation has led to a lack of national registers or databases of, e.g., radiation sources or of those assessed to be competent to use those sources. There is no national register of places

in which radiation practices are authorised to be conducted nor is there a national register of the people and organisations authorised to conduct radiation practices. In other areas, national databases have been established or are under establishment. Some examples of information-databases are given below.

Public registers

Some jurisdictions are required under their legislation to maintain public registers (such as NSW and QLD) which discloses the licence, the type of dealings permitted, and status of the authorisation. Other jurisdictions (such as ACT) have specific provisions requiring the protection of such information within their Act.

Transport and storage of security enhanced sources

Under the *Code of Practice for the Security of Radioactive Sources* 2007 (RPS 11), each security enhanced source requires a Source Transport Security Plan to be prepared. This plan demonstrates how the Responsible Person will satisfy the requirements of RPS 11, and includes information such as the shipping routes and potential incident response scenarios.

These considerations are an important part of transport arrangements as a poor choice of transport route could increase the likelihood of mechanical failure or accidents. Transport routes can cover multiple jurisdictions and be thousands of kilometres long which makes maintaining knowledge of all possible routes difficult. For example, shipments from Brisbane (QLD) to Melbourne (VIC) would cover more than 1,500km and pass through NSW.

Under RPS 11 (section 5.1) the Source Transport Security Plan must be provided to the relevant regulatory body either 7 calendar days in advance of the shipment of security enhanced sources, or for Category 2 or 3 sources where frequent shipment will occur, at least 7 calendar days in advance of the first shipment.

As such, each regulator should be aware of the sources that are stored or transported in their jurisdiction. However, this information is not currently logged or shared through any national systems. While the wider sharing of this information may enhance the response capabilities and aid in the effective oversight of transport arrangements, this information is not in a form that is conducive to wider distribution.

Australian Radiation Incident Register

The regulatory bodies report incidents to a central register managed by ARPANSA, the Australian Radiation Incident Register (ARIR). ARPANSA analyses the accumulated incident data to identify lessons and contributing causes. ARPANSA, in consultation with the jurisdictions, professional organisations, and experts, prepares an annual report published on the ARPANSA website.

The register and the report provide an effective platform to analyse submitted incidents and through the report share learnings with the community. This information could be more effectively targeted, shared and promoted if reports where made directly into the ARIR by the end user. This would require a redesign of the database and web system, but may save regulatory time and promote national uniformity through a uniform system for the collection, review, and assessment of radiation incidents.

13.9 Moving between jurisdictions

Differences in radiation legislation and regulatory policy among the nine jurisdictions can sometimes prove problematic for users of radiation sources operating in more than one jurisdiction. This includes

requirements to hold multiple licences with potentially differing requirements on competency, reporting and documentation required to be submitted (e.g. Radiation Management plans). To reduce the likely burden on users, ARPANSA with the radiation regulatory bodies of NSW, NT, QLD, SA, TAS and VIC have endorsed the Regulatory expectations for users of radiation sources seeking to obtain authorisations in more than one jurisdiction. The document sets out what applicants can expect when seeking authorisations (licences or registrations) for the same activity in multiple jurisdictions. It endeavours to further the objectives of nationally uniform radiation protection outcomes, and to minimise unnecessary regulatory burden.

Every jurisdiction has a Mutual Recognition Act and Trans-Tasman Mutual Recognition Act. These Acts set out certain rights for individuals seeking an occupational licence or registration in a state or territory on the basis that they are already licensed or registered for an 'equivalent occupation' in another state, territory or New Zealand. Essentially, once a mutual recognition licence application is lodged, an eligible person is deemed to hold a licence until the second jurisdiction makes a licence determination. The Acts also limit the jurisdictional regulatory body in the things they may consider, such as qualifications of the applicant as the first jurisdiction has already assessed this. More details are available on the NSW EPA 'Guideline for the Operation of the Mutual Recognition Legislation for Licensing and Accreditation under the Radiation Control Act 1990' and by the commonwealth government.

Appendix A – Reference documents

This list is not an exhaustive list of all documents referenced in the summary report. Documents that do not have links to a website may not be publicly available. Other documents are still in a draft form and have not been published. These documents have been included as part of the advance reference material and uploaded to the SharePoint site.

Codes and guidance documents

Radiation Protection Series:

RPS F-1	Fundamentals for Protection Against Ionising Radiation (2014)
RPS C-1	*Code for Radiation Protection in Planned Exposure Situations (2016), Planned Exposure Code*
RPS C-2	*Code for the Safe Transport of Radioactive Material (2014)*
RPS No. 3	*Radiation Protection Standard for Maximum Exposure Levels to Radiofrequency Fields - 3 kHz to 300 GHz (2002)*
RPS No. 5	*Code of Practice and Safety Guide for Portable Density/Moisture Gauges Containing Radioactive Sources (2004)*
RPS No. 8	*Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005)*
RPS No. 9	*Code of Practice and Safety Guide for Radiation Protection and Radioactive Waste Management in Mining and Mineral Processing (2005)* **Associated safety guide:** RPS 9.1 - *Safety Guide for Monitoring, Assessing and Recording Occupational Radiation Doses in Mining and Mineral Processing (2011)*
RPS No. 10	*Code of Practice and Safety Guide for Radiation Protection in Dentistry (2005)*
RPS No. 11	*Code of Practice for the Security of Radioactive Sources (2007)*
RPS No. 12	*Radiation Protection Standard for Occupational Exposure to Ultraviolet Radiation (2006)*
RPS No. 13	*Code of Practice and Safety Guide for Safe Use of Fixed Radiation Gauges (2007)*
RPS No. 14	*Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)* **Associated safety guides:** RPS 14.1 - *Safety Guide for Radiation Protection in Diagnostic and Interventional Radiology (2008)* RPS 14.2 - *Safety Guide for Radiation Protection in Nuclear Medicine (2008)* RPS 14.3 - *Safety Guide for Radiation Protection in Radiotherapy*
RPS No. 17	*Code of Practice and Safety Guide for Radiation Protection in Veterinary Medicine (2009)*
RPS No. 19	*Code of Practice for Radiation Protection in the Application of Ionizing Radiation by Chiropractors (2009)*

Safety guides:

RPS G-1 *Guide for Radiation Protection of the Environment (2015)*

RPS G-2 *Guide for Radiation Protection in Existing Exposure Situations (2017)*

RPS 4 *Recommendations for the Discharge of Patients Undergoing Treatment with Radioactive Substances (2002)*

RPS 7 *Recommendations for Intervention in Emergency Situations Involving Radiation Exposure (2004)*

RPS 15 *Safety Guide for the Management of Naturally Occurring Radioactive Material (NORM) (2008)*

RPS 16 *Safety Guide for the Predisposal Management of Radioactive Waste (2008)*

RPS 18 *Safety Guide for the Use of Radiation in Schools (2012)*

RPS 20 *Safety Guide for Classification of Radioactive Waste (2010)*

Other publications:

RPS 6 *National Directory for Radiation Protection (NDRP) June 2017*

Radiation Health Series publications

Regulatory Guides (for ARPANSA Licence Holders and Applicants)

Holistic Safety Guidelines

Policy and procedures published online:

- Licensing & Assessment Manual [REG-LA-MAN-240]
- Compliance & Enforcement Manual [REG-COM-MAN-270]
- Inspection Manual [REG-INS-MAN-280]

Key documents provided as part of the submission (not public documents):

- Draft National Directory for Radiation Protection Version 2
- RHC Options Paper for National Uniformity
- Work Health and Safety Management Manual (WHS Management Manual)
- Work Health and Safety Objectives and Targets Procedure
- Compliance Framework
- Procedure for Managing Differing Professional Opinions
- Documentation Management Procedure

Legislation (Commonwealth)

National Radioactive Waste Management Act 2012

Environment Protection and Biodiversity Conservation Act 1999

Australian Nuclear Science and Technology Organisation Act 1987

Nuclear Non-Proliferation (Safeguards) Act 1987

Legislation (ARPANSA)

Australian Radiation Protection and Nuclear Safety Act 1998 (ARPANS Act)

Australian Radiation Protection and Nuclear Safety Regulations 1999

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

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

Australian Radiation Protection and Nuclear Safety (Consequential Amendments) Act 1998

Legislation (State and Territory)

Collectively, with the ARPANS legislation above, these are referred to as 'relevant jurisdiction legislation' in this document.

Australian Capital Territory (ACT)	Radiation Protection Act 2006
	Radiation Protection Regulation 2007
New South Wales (NSW)	Radiation Control Act 1990
	Radiation Control Regulation 2013
Northern Territory (NT)	Radiation Protection Act - NT Legislation
	Radiation Protection Regulations
Queensland (QLD)	Radiation Safety Act 1999
	Radiation Safety Regulation 2010
South Australia (SA)	Radiation Protection and Control Act 1982
	Radiation Protection and Control (Ionising Radiation) Regulations 2015
	Radiation Protection and Control (Transport of Radioactive Substances) Regulations 2003
Tasmania (TAS)	Radiation Protection Act 2005
	Radiation Protection Regulations 2016
Victoria (VIC)	Radiation Act 2005
	Radiation Regulations 2017
Western Australia	Radiation Safety Act 1975
	Radiation Safety (General) Regulations 1983
	Radiation Safety (Qualifications) Regulations 1980
	Radiation Safety (Transport of Radioactive Substances) Regulations 2002
	Nuclear Waste Storage and Transportation (Prohibition) Act 1999

Defined terms and abbreviations

ARPANSA – Australian Radiation Protection and Nuclear Safety Agency, the radiation safety regulator for the Commonwealth government use of radiation sources.

Apparatus, or controlled apparatus, (radiation generators) refers to a device that may emit radiation.

Authorisation - a written permission granted by the Authority for an operating organisation to perform specified practices. The form of an authorisation can include a licence, registration, or accreditation

ASNO - Australian Safeguards and Non-proliferation Office - Commonwealth body responsible for nuclear safeguards and security, and obligations related to non-proliferation.

ANSTO – Australian Nuclear Science and Technology Office - Commonwealth nuclear organisation which operates the OPAL reactor, produces nuclear medicine and supports government nuclear initiatives.

COAG - The Council of Australian Governments - the peak intergovernmental forum in Australia. Its role is to manage matters of national significance or matters that need co-ordinated action by all Australian governments.

Commonwealth Government (also referred to as the Australian Government, the Commonwealth Government, or the Federal Government) - the government of the Commonwealth of Australia, a federal parliamentary constitutional monarchy. It is separate and independent from *State governments*.

Controlled material - radioactive material that is captured under the relevant jurisdiction legislation, and includes sealed sources and unsealed material.

Jurisdiction regulatory body – one of the radiation safety regulatory bodies including federal, State and Territory bodies. That is, ARPANSA, Australian Capital Territory Health Protection Service and Radiation Council, Northern Territory Radiation Protection Section, Queensland Radiation Health Unit, Tasmanian Radiation Protection Unit, Victorian Radiation Safety Section, Western Australia Radiological Council, South Australian Environment Protection Authority and NSW Environment Protection Authority.

Licence - an authorisation granted by the Authority allowing a person to carry out a practice involving radiation.

Licence Holder - the holder of an authorisation by ARPANSA issued under section 33 or 34.

National Code, National Guide – A document which is intended for adoption within jurisdictions across Australia. This includes the Radiation Protection Series.

Nuclear installation - a nuclear fuel fabrication plant, nuclear reactor (including critical and subcritical assemblies), research reactor, nuclear power plant, spent fuel storage facility, enrichment plant or reprocessing facility.

Nuclear Safety Committee (NSC) - one of the three advisory bodies to the CEO of ARPANSA established under the ARPANS Act. The NSC advises the CEO and the RHSAC on matters relating to nuclear safety and the safety of controlled facilities, including developing and assessing the effectiveness of standards, codes, practices and procedures.

Performance Objectives and Criteria (PO&C) – the set of criteria which underpin the ARPANSA inspection processes. They include eight functional areas (e.g. security) and three cross-cutting areas (e.g. Safety Culture).

Permitted persons - persons who are neither Commonwealth nor Commonwealth contractors, who are engage in dealings using the facilities, sources, or apparatus licensed by the CEO of ARPANSA. For example, researchers who undertake a study under an arrangement with a Commonwealth agency that is licensed by ARPANSA.

Radiation Heath Committee (RHC) – One of the three advisory bodies to the CEO of ARPANSA established under the ARPANS Act. The RHC advises the CEO and the RHSAC on matters relating to radiation protection, including formulating draft national policies, codes and standards for the promotion of uniform national standards of radiation protection for consideration by the Commonwealth, states and territories.

Radiation Health and Safety Advisory Council (RHSAC) - one of the three advisory bodies to the CEO of ARPANSA established under the ARPANS Act. The RHSAC advises the CEO on emerging issues and matters of major public concern relating to radiation protection and nuclear safety.

Registration - an authorisation by the Authority for a radiation apparatus or sealed source apparatus, or a premises, in which radiation sources are used.

Regulatory Guide – a guidance document published by ARPANSA for ARPANSA Licence holders or applicants. Separate from *national guide*.

Relevant jurisdiction legislation – the applicable radiation safety legislation of the jurisdiction in question. These are listed in the previous section.

Sealed source - radioactive material that is permanently sealed in a capsule or closely bound and in solid form.

Source (Radiation Source) – Radioactive material or apparatus, which may be subject to regulatory control.

State Government – Is the government of one of the sovereign States, distinct from *Commonwealth Government*.

Unsealed material - radioactive material other than in a sealed source.

State and Territory the six states - New South Wales (NSW), South Australia (SA), Queensland (QLD), Tasmania (TAS), Victoria (VIC), Western Australia (WA) - and two independent territories - Australian Capital Territory(ACT), Northern Territory (NT).

Action plan

This section focuses on the Commonwealth, in particular the Australian Radiation Protection and Nuclear Safety Agency. Issues which affect national uniformity and may require a multi-jurisdictional approach are highlighted in green below.

The Action Plan lists proposed actions to be taken to improve alignment with the IAEA safety standards, as relevant in the Australian context. The Action Plan should be considered a draft, which will be finalised subsequent to receiving the IRRS report. However, some of the actions are already ongoing.

Action number	Short description		
1.	**National policy and strategy [national uniformity]**		
IRRS module number	1	**Summary report section**	1.1; 13
IAEA safety standard requirement(s)	**GSR Part 1 (Rev. 1) - Requirement 1: National policy and strategy for safety** The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals. 2.3 National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy. **GSR Part 1 (Rev. 1) – Requirement 2: Establishment of a framework for safety** 2.5 The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following: [2.5 (1) to 2.5 (19) of GSR Part 1 list the elements of a framework for safety]		
Context	Across Australia, there is no single document with a national policy and strategy for safety. However, the elements of the national policy are largely described in jurisdiction and Commonwealth documentation, including the NDRP. Nevertheless, despite having strong networks in place and 20 years of experience of operating under the ARPANS Act, and a legislative directive to promote national uniformity, and of jurisdictional collaboration in the Radiation Health Committee, significant variation remains.		

	This action has synergies with recommendation 2 'Undertake an analysis of policies related to the International Health Regulations (2005) (IHR) to identify gaps and potential overlap in existing policies.' from the WHO Joint External Evaluation (JEE) Mission that was made in relation to the core competency 'National Legislation, Policy and Financing'. The scope of a national policy and strategy for safety and the recommendation by the JEE Mission have significant overlap.
Action to perform	ARPANSA to initiate and promote, in collaboration with the RHC and the Commonwealth Department of Health, actions aimed at drafting a national policy and strategy for safety, and to strengthen a uniform framework for safety and health protection to be included in the National Directory for Radiation Protection, or be otherwise reflected in the legal framework in Australia.
Deadline	Actions have commenced and will be ongoing with a number of milestones over a 3-5 year time frame
Organisation/person responsible	ARPANSA/RHC/Commonwealth Department of Health (e.g. in relation to JEE recommendations)

Action number	Short description		
2.	**Exemption and clearance levels [national uniformity]**		
IRRS module number	1	**Summary report section**	1.1; 11.3; 13.1
IAEA safety standard requirement(s)	**GSR Part 1 (Rev. 1) - Requirement 2: Establishment of a framework for safety** 2.5 The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following: [...] (17) The criteria for release from regulatory control **GSR Part 3 - Requirement 8: Exemption and clearance:** 3.12 The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from regulatory control, using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels specified by the regulatory body on the basis of these criteria. By means of this approval, the regulatory body shall ensure that sources that have been cleared from regulatory control do not again become subject to the requirements for notification, registration or licensing unless it so specifies.		
Context	Across Australia, there are no unified/agreed exemption and clearance levels. For example, there are no exemptions on import and there are variations in the exemption levels between States. Jurisdictions typically determine clearance levels only upon application.		
Action to perform	The draft NDRP 2nd Edition is proposing to incorporate by reference Schedule I of GSR Part 3, which, when implemented, will require all jurisdictions to incorporate the provisions in GSR Part 3 for exemptions and clearance into their legal and regulatory frameworks. ARPANSA to facilitate the national adoption of the exemption and clearance levels as part of its function to promote national uniformity. ARPANSA to propose that the ARPANS Regulations be amended to give effect to provisions for clearance outlined in GSR Part 3.		
Deadline	Mid 2020		
Organisation/person responsible	RHC/ARPANSA		

Action number	Short description		
3.	**Decommissioning requirements**		
IRRS module number	1, 5a	**Summary report section**	1.1; 5.5; 1.7
IAEA safety standard requirement(s)	**GSR Part 6 - Requirement 4: Responsibilities of the government for decommissioning** The government shall establish and maintain a governmental, legal and regulatory framework within which all aspects of decommissioning, including management of the resulting radioactive waste, can be planned and carried out safely. This framework shall include a clear allocation of responsibilities, provision of independent regulatory functions, and requirements in respect of financial assurance for decommissioning. **GSR Part 6 - Requirement 5: Responsibilities of the regulatory body for decommissioning** The regulatory body shall regulate all aspects of decommissioning throughout all stages of the facility's lifetime, from initial planning for decommissioning during the siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning. The regulatory body shall establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall adopt associated regulations and guides. The regulatory body shall also take actions to ensure that the regulatory requirements are met.		
Context	Decommissioning and the management of associated waste should be recognised elements of a facility life cycle and should therefore be considered in the early planning stage.		
Action to perform	• Following publication of the Regulatory Guide *Decommissioning of Controlled Facilities*, update the Regulatory Guide *Plans and Arrangements for Managing Safety* and review the Performance Objectives and Criteria (PO&C) to reflect the content of the decommissioning guide. • Include *Decommissioning Plan* under 'General information', and Safety Analysis Report under 'Authorisation for decommissioning a controlled facility'; in Schedule 3 Part 1 of the ARPANS Regulations (Information that may be requested by the CEO). • Promote formal mechanisms to ensure funds for decommissioning are set aside at the commencement of major nuclear projects.		
Deadline	Mid 2020		
Organisation/person responsible	ARPANSA		

Action number	Short description		
4.	**Human resource plan**		
IRRS module number	1; 3; 4	**Summary report section**	1.8; 3.2; **3.3Error! Reference source not found.**; 4.4
IAEA safety standard requirement(s)	**GSR Part 3 - Requirement 17: Effective independence in the performance of regulatory functions** 4.8 To maintain the effective independence of the regulatory body, special consideration shall be given when new staff members are recruited from authorized parties, and the independence of the regulatory body, regulatory aspects and safety considerations shall be emphasized in their training. The regulatory body shall ensure that its staff operate professionally and within its remit in relation to safety. **GSR Part 3 - Requirement 18: Staffing and competence of the regulatory body** 4.11 The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions.		
Context	ARPANSA is currently developing a system to ensure that its regulatory functions including staffing and competence and other resourcing is consistent with the requirements of ISO:17020:2012 *Conformity assessment – Requirements for operation of various types of bodies performing inspection.* This includes a Qualification Card system to check-off when a person employed as a regulatory officer meets minimum competency standards to become an authorised Inspector. ARPANSA currently identifies core competencies for Inspectors and this is taken into account in the recruitment and personnel development processes, and is underway to establish resource plans. Recruits are hired with pre-existing competencies which are then supplemented with on-the-job and other training that allows them to fully participate in the regulatory business. The action should also consider the particular issues surrounding recruitment and training of staff from licence holders, as well as other factors that contribute to the integrity of the regulatory activities. There are cross-linkages between this action item and the actions resulting from the Joint External Evaluation of Core Competencies under the World Health Regulations (WHO), referred to in action item 1.		
Action to perform	A formal human resource plan is under development and will contribute to, and be informed by, the ISO 17020 project, which takes into account at least the factors mentioned above under 'Context' and is integrated with the ARPANSA-wide arrangements for managing the Agency's human capital.		
Deadline	End 2019		

Action number	Short description
Organisation/person responsible	ARPANSA

Action number	Short description		
5.	**Accreditation competencies**		
IRRS module number	6	**Summary report section**	1.9; 13
IAEA safety standard requirement(s)	**GSR Part 1 - Requirement 13: Provision of technical services** 2.41 Technical services do not necessarily have to be provided by the government. However, if no suitable commercial or non-governmental provider of the necessary technical services is available, the government may have to make provision for the availability of such services. The regulatory body shall authorize technical services that may have significance for safety, as appropriate.		
Context	Across Australian jurisdictions, there is no agreed and uniform requirements for accreditation for performing technical services, including mandatory qualifications or service providers (e.g. dosimetry or testing, or any other service or profession); these could be established through the RHC. Criteria could be based on international and national standards, and other reference documentation.		
Action to perform	ARPANSA to initiate and support the identification of competencies and suitable means for accreditation, or similar approval, in collaboration with jurisdictions, professional bodies and key stakeholders. These accreditation competencies following agreement by jurisdictions, should be listed in the NDRP.		
Deadline	Part of business as usual, but a first set of competencies should be agreed prior to the end of 2020.		
Organisation/person responsible	RHC/ARPANSA		

Action number	Short description		
6.	**National sealed source register [national uniformity]**		
IRRS module number	2; 10	**Summary report section**	2.1; 10.5
IAEA safety standard requirement(s)	***GSR 7 Requirement 4 – Hazard Assessment*** *The government shall ensure that a hazard assessment is performed to provide a basis for a graded approach in preparedness and response for a nuclear or radiological emergency (4.18, 4.21, 4.22)* ***GSR Part 1 (Rev. 1): Requirement 14 - International obligations and arrangements for international cooperation and assistance*** 3.2 The features of the global safety regime include: [...] (b) Codes of conduct that promote the adoption of good practices in the relevant facilities and activities.		
Context	Australia is experiencing challenges in meeting the intent to fully implement the Code of Conduct for safety and security or radioactive sources in relation to establishing and maintaining a National Sealed Source Register (NSSR). Despite previously establishing the NSSR, the RHC decided in 2016 to abandon the NSSR and revert to utilising a network of jurisdictional registers. This decision was challenged when Australia received a follow up IAEA IPPAS Mission in 2017. It was that Australia (ARPANSA) establish a national register of sources to improve arrangements for an accurate and real-time national radioactive source register as the arrangements were not meeting the intent of the Code of Conduct for safety and security of radioactive sources (SSRS). In 2017 when Australia received a Joint External Evaluation (JEE) of International Health Regulation Core Capacities of Australia a similar recommendation was received. The JEE recommendation stated that Australia (all jurisdictions) should *Conduct a national hazard assessment, to include creating an inventory of radiation sources.* ARPANSA has been tasked with leading the implementation of this action, in cooperation with the RHC. This action is already captured in the NAPHS, but work is yet to commence.		
Action to perform	ARPANSA and the RHC to establish arrangements (i.e. NSSR) for accurate storage and retrieval of information on radioactive sources to meet the expectations of the code of conduct for SSRS and strengthen the linkage between safety and security and threat prevention.		
Deadline	2022		
Organisation/person responsible	ARPANSA/RHC and JEE NAPHS stakeholders		

Action number	Short description		
7.	**Sharing of international and national experience [national uniformity]**		
IRRS module number	1; 2; 11d	**Summary report section**	1.2; 2, 5
IAEA safety standard requirement(s)	**GSR Part 1 - Requirement 15: Sharing of operating experience and regulatory experience** The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities.		
Context	ARPANSA shares outcomes from national and international meetings and registers to Australian regulators/operators on an ad-hoc basis through the Radiation Health Committee (RHC), conferences and peak professional bodies. There is no single point or method of contact for reporting and receiving information, and currently no formal system for sharing this type of information across the organisation and with the other Australian jurisdictions.		
Action to perform	Establish and implement a formal system for sharing relevant international information (including registers) to a broader audience including the States and Territories. This may include the expanded use of the Radiation Regulators' Network (RRN) and the RHC. Identify opportunities to further utilise and share non-Commonwealth expertise in international and national forums. This also includes the existing projects for the dissemination of ARIR and ANRDR registers, and enhancements of the registers to increase the use of these resources.		
Deadline	Mid 2022		
Organisation/person responsible	ARPANSA to lead with participation of RHC		

Action number	Short description		
8.	**Safety records**		
IRRS module number	3	**Summary report section**	3.7
IAEA safety standard requirement(s)	**GSR Part 1 - Requirement 35: Safety related records** 4.63 The regulatory body shall make provision for establishing and maintaining the following main registers and inventories: • [...] • Records relating to the safety of facilities and activities; • Records that might be necessary for the shutdown and decommissioning (or closure) of facilities; • [...]		
Context	ARPANSA specifies a number of records that must be maintained by the licence holder, including within the Regulatory Guide *Plans and Arrangements for Managing Safety*. However, this does not currently include is currently explicit requirement on facility safety documentation including engineering plant, design variations, operations logs, which may in particular be required to make informed regulatory decisions in the decommissioning state of major facilities.		
Action to perform	To ensure records are maintained, the Regulatory Guide *Plans and Arrangements for Managing Safety* should be updated to include documents relating to safety of plant, equipment and operation for the purpose of past, present and future operations, including decommissioning and disposal.		
Deadline	Following the approval of the draft decommissioning guide.		
Organisation/person responsible	ARPANSA		

Action number	Short description		
9.	**Integrated Management System**		
IRRS module number	4	**Summary report section**	4
IAEA safety standard requirement(s)	GSR Part 2 - Requirement 6: Integration of the management system The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised. 4.9. The management system shall be applied to achieve goals safely, to enhance safety and to foster a strong safety culture by: (a) bringing together in a coherent manner all the necessary elements for safely managing the organization and its activities (b) describing the arrangements made for management of the organization and its activities (c) describing the planned and systematic actions necessary to provide confidence that all requirements are met (d) ensuring that safety is taken into account in decision making and is not compromised by any decisions taken.		
Context	ARPANSA is developing an integrated management system. Documented procedures, policies and record management practices are in place to allow the regulator to effectively discharge their functions. However, the management system does not integrate completely across the agency and across all functional objectives. Additionally, reporting and analytical functionality is limited which impacts on ARPANSA's ability to effectively review licence holder operations.		
Action to perform	Continue to develop the IMS project.		
Deadline	Continuous improvement post-IRRS		
Organisation/person responsible	ARPANSA		

Action number	Short description		
10.	**Regulatory information management**		
IRRS module number	4	**Summary report section**	4
IAEA safety standard requirement(s)	**GSR Part 1 - Requirement 26: Graded approach to review and assessment of a facility or an activity** 4.46. For an integrated safety assessment, the regulatory body shall first organize the results obtained in a systematic manner. It shall then identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of activities where relevant. Feedback information shall be provided to the authorized party. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach. **GSR Part 2 - Requirement 13: Measurement, assessment and improvement of the management system** 6.7. The management system shall include evaluation and timely use of the following: (a) Lessons from experience gained and from events that have occurred, both within the organization and outside the organization, and lessons from identifying the causes of events; (b) Technical advances and results of research and development; (c) Lessons from identifying good practices.		
Context	While the current system acts as a store of this information, it has limited reporting functionality and is not integrated into operational methods. An enhanced system would help to improve quality and ensure decisions are effectively and efficiently made based on the analysis of data and information.		
Action to perform	ARPANSA is investigating options to enhance the current system for the management of regulatory information associated with licence holders and regulatory activities. This includes applications, licences, inspections, enforcement records. ARPANSA has commenced the project planning phase and is consulting with stakeholders including licence holders and regulatory staff. A scope of work has been drafted which will be finalised when funding is allocated.		
Deadline	As part of operational activities and improvement measures.		
Organisation/person responsible	ARPANSA		

Action number	Short description		
11.	**Safety culture assessments**		
IRRS module number	4	**Summary report section**	4.6
IAEA safety standard requirement(s)	**GSR Part 2 - Requirement 14: Measurement, assessment and improvement of leadership for safety and of safety culture** 6.9 Senior management shall ensure that self-assessment of leadership for safety and of safety culture includes assessment at all organizational levels and for all functions in the organization. Senior management shall ensure that such self-assessment makes use of recognized experts in the assessment of leadership and of safety culture. 6.10. Senior management shall ensure that an independent assessment of leadership for safety and of safety culture is conducted for enhancement of the organizational culture for safety (i.e. the organizational culture as it relates to safety and as it fosters a strong safety culture in the organization). 6.11. The results of self-assessments and independent assessments of leadership for safety and of safety culture [1] shall be communicated at all levels in the organization. The results of such assessments shall be acted upon to foster and sustain a strong safety culture, to improve leadership for safety and to foster a learning attitude within the organization.		
Context	A positive safety culture across the Agency is promoted through a number of activities and initiatives, including WHS induction training, WHS training for supervisors, adoption of 'safety moments' at the commencement of key meetings, WHS inspection program, participation and contribution in the HIRAM process, report card process and by employing a holistic safety approach in accordance with the ARPANSA Holistic Safety Guidelines.		
Action to perform	ARPANSA is establishing a system for the systematic assessment of the culture of the regulator which can be utilised to foster and sustain a strong safety culture, drawing on external expertise The first area to undertake this survey is intended to be the Regulatory Services Branch, followed by other Branches and Offices.		
Deadline	Project has commenced. First analysis, focusing on the Regulatory Services Branch, to be completed mid-2019.		
Organisation/person responsible	ARPANSA		

Action number	Short description		
12.	**Transport package approval [national uniformity]**		
IRRS module number	11c	**Summary report section**	5.6
IAEA safety standard requirement(s)	**GSR Part 1 - Requirement 7: Coordination of different authorities with responsibilities for safety within the regulatory framework for safety** 2.18. Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as: ... (11) Safety in the transport of dangerous goods, including nuclear material and radioactive material; ... This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other's experience.		
Context	ARPANSA certifies of package design (including special form radioactive material, low dispersible radioactive material, packages containing 0.1 kg or more of uranium hexafluoride, packages containing fissile material, Type B(U) packages, Type B(M) packages, Type C packages) and validations of certificates. States and Territories also perform these functions or may request ARPANSA to provide these authorisations, or assistance in the review and assessment of these applications.		
Action to perform	Establish a formal process for the management of transport certification for use by all jurisdictions. For example a register of all certificates issued in Australia and maintain this information in a readily accessible format. Additionally the arrangements whereby jurisdictions recognise or perform authorisations on behalf of a jurisdiction are to be documented to ensure clarity.		
Deadline	2020		
Organisation/person responsible	RHC/ARPANSA		

Action number	Short description		
13.	**Transport inspection and verification**		
IRRS module number	11c	**Summary report section**	7.6
IAEA safety standard requirement(s)	**SSR-6, 307-308** 307. The competent authority shall assure compliance with these Regulations. 308. The relevant competent authority shall arrange for periodic assessments of the radiation doses to persons due to the transport of radioactive material, to ensure that the system of protection and safety complies with the Basic Safety Standards [2]. **GUIDE TS-G-1.5 Compliance Assurance for the Safe Transport of Radioactive Material:** 2.5. Through the compliance assurance programme, the competent authority should obtain assurance that all transport requirements are being met in practice by the users of the Transport Regulations. Monitoring of the effectiveness of compliance is generally performed by routine, periodic inspections (announced or unannounced) of the user's activities. For consignors, such inspections are generally examinations of the procedures before, during or after the transport. For carriers, such inspections are generally performed during or after the transport. The frequency of inspection should be established by taking into account the scope and potential importance to safety of the user's activities		
Context	ARPANSA complies with the standard. However, ARPANSA has not implemented the recommendations of the safety guide.		
Action to perform	ARPANSA to implement a system for inspection of handling and stowage of packages by consignors and carriers of packages while in transit.		
Deadline	Mid 2019		
Organisation/person responsible	ARPANSA		

Action number	Short description		
14.	**Regulatory assessment principles review**		
IRRS module number	9	**Summary report section**	9.1
IAEA safety standard requirement(s)	**GSR Part 1 (Rev. 1) - Requirement 33: Review of regulations and guides** *Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained.*		
Context	The ARPANSA guide Regulatory Assessment Principles (RAPs), which consolidated design and operational requirements for ARPANSA licence holders, was recently retried in favour of direct reference to IBP documents.		
Action to perform	A comprehensive analysis on which documents are applicable to which facilities and any gaps has commenced but not yet completed; it should be pursued in order to ascertain appropriate consideration of 'international best practice in ARPANSA's licensing activities. As necessary, revise the Performance Objectives and Criteria (PO&C) to reflect the Regulatory Assessment Principles.		
Deadline	Mid 2019		
Organisation/person responsible	ARPANSA		

Action number	Short description		
15.	**Emergency plans**		
IRRS module number	10 (5,9)	**Summary report section**	10.2 (5)
IAEA safety standard requirement(s)	**GSR Part 7**		
Context	While the ARPANSA Plans and Arrangements Guide includes the key elements described above, it currently refers to RPS7 rather than RPS G-3 which has not yet been formally adopted and published.		
Action to perform	Following publication of RPS G-3 ARPANSA's Regulatory Guide *Plans and Arrangements for Managing Safety* will need to be revised to include RPS G--3 guidance including: • expectation of response time objectives and emergency action levels in operator plans (extent depends on hazard) • general, site area, facility and alert levels of classification • requirement for redundancy/diversity in off-site communications in the Plans and Arrangements Guide • consideration of waste generated in an emergency. The Performance Objectives & Criteria to be reviewed and as necessary also revised in the light of the changes to the plans and arrangements.		
Deadline	Following publication of RPS G-3		
Organisation/person responsible	ARPANSA		

Action number	Short description		
16.	**Implement actions from JEE for radiation emergencies**		
IRRS module number	10; 5; 9	**Summary report section**	10.2; 5
IAEA safety standard requirement(s)	***GSR Part 7***		
Context	Australia received a Joint External Evaluation (JEE) of International Health Regulation Core Capacities of Australia in 2017 and a number of recommendations were made that related to radiation emergencies. ARPANSA has been tasked with leading the implementation of the action plan for 3 recommendations and contributing to other recommendations in the NAPHS.		
Action to perform	ARPANSA continue to action Implementation of the JEE recommendations as identified in NAPHS.		
Deadline	2023		
Organisation/person responsible	ARPANSA (in cooperation with RHC, and other Commonwealth, State and Territory agencies as required)		

Action number	Short description		
17.	**Radon strategy/radon action plan**		
IRRS module number	5e	**Summary report section**	11.3
IAEA safety standard requirement(s)	**GSR Part 3 - Requirement 50: Public exposure due to radon indoors** 5.21. The government shall assign responsibility for: (a) Establishing and implementing the action plan for controlling public exposure due to ^{222}Rn indoors; (b) Determining the circumstances under which actions are to be mandatory or are to be voluntary, with account taken of legal requirements and of the prevailing social and economic circumstances.		
Context	ARPANSA has guidance and advice on radon. However, Australia has no Radon Strategy or Radon Action Plan in place.		
Action to perform	The national radon protection strategy is currently under development by ARPANSA and will assess the need for a national action plan. Additionally, ARPANSA is presently undertaking studies to characterise possible radon prone areas.		
Deadline	End 2019		
Organisation/person responsible	ARPANSA		

Action number	Short description		
18.	**Referring medical practitioner [national uniformity]**		
IRRS module number	11d	**Summary report section**	11.1
IAEA safety standard requirement(s)	**GSR Part 3 - Requirement 4: Responsibilities for protection and safety** 2.41. Other parties shall have specified responsibilities in relation to protection and safety. These other parties include: (c) Referring medical practitioners; **GSR Part 3 - Requirement 37: Justification of medical exposures** 3.158. Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure. *[Introduction 1.14: The specific objectives of the exposure, the clinical circumstances and the characteristics of the individual involved have to be taken into account by means of referral guidelines developed by professional bodies and the health authority.]*		
Context	There is a lack of uniformity on the responsibilities of, and guidance available to, the referring medical practitioner.		
Action to perform	Engage with jurisdictional regulators to publish and adopt a revised Code for Medical Exposure (RPS C-5) which includes a requirement to ensure that relevant referral guidelines are taken into account for the justification of diagnostic medical exposures.		
Deadline	June 2019 (for publication of RPS C-5)		
Organisation/person responsible	ARPANSA/RHC		

Action number	Short description		
19.	**Diagnostic reference levels**		
IRRS module number	11d	**Summary report section**	11.1
IAEA safety standard requirement(s)	**GSR Part 3 - Requirement 34: Responsibilities of the government specific to medical exposure** 3.148. The government shall ensure, as part of the responsibilities specified in paragraph 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality, to enable the requirements of para. 3.169 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances.		
Context	Diagnostic reference levels are established for MDCT and nuclear medicine and in consultation with relevant professional bodies are being developed for image-guided interventional procedures.		
Action to perform	Establish and monitor diagnostic reference levels for appropriate modalities.		
Deadline	Ongoing		
Organisation/person responsible	ARPANSA		

Action number	Short description		
20.	**Health surveillance [national uniformity]**		
IRRS module number	11e	**Summary report section**	11.2
IAEA safety standard requirement(s)	**GSR Part 3 - Requirement 32: Monitoring and reporting** 3.76. Employers, registrants and licensees shall ensure, for all workers engaged in activities in which they are or could be subject to occupational exposure, that: (f) Necessary workers' health surveillance and health services for workers are provided;		
Context	ARPANSA does not require mandatory health surveillance for radiation workers, or provide specific guidance on this topic. However, there is a general requirement in the WHS Regulations for this to be considered. IAEA draft document DS 453 will detail requirement health surveillance of occupational exposed workers		
Action	Jurisdictions to consider applying the requirements of DS453 once published.		
Deadline	Following publication of IAEA DS 453.		
Organisation/person responsible	ARPANSA/RHC		

Action number	Short description		
21.	**Independent monitoring/public data**		
IRRS module number	5e	**Summary report section**	11.3
IAEA safety standard requirement(s)	**GSR Part 3 - Requirement 32: Monitoring and reporting** The regulatory body and relevant parties shall ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available. 3.135. The regulatory body shall be responsible, as appropriate, for: (c) Making provision for an independent monitoring programme. 3.136. The regulatory body shall publish or shall make available on request, as appropriate, results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure		
Context	Licence holders have monitoring programs in place. However, ARPANSA does not provide for an independent monitoring programme and assessment of public doses due to authorised facilities or activities. Therefore, these results are not made publicly available by ARPANSA, but may be made available by the licence holder.		
Action to perform	ARPANSA is establishing the Australian Radiation Monitoring System (ARMS) to monitor the environment when Australian ports receive a visiting nuclear-powered vessel. In the unlikely event of an accident, Australia has adopted arrangements which require radiation monitoring of the nuclear-powered vessel while it is berthed at port. This monitoring program has two components: environmental monitoring to detect the release of any radioactive material to the environment; and direct radiation monitoring of the vicinity of the nuclear-powered vessel to provide warning of any malfunction which may result in a release of radioactivity. The automated system will be an early warning system in the event of a radiological release from a visiting vessel and will be able to provide valuable data before, during and after a nuclear accident. The real-time data generated by ARMS will be accessible to the public via an interactive chart that will be available on our website once the network is installed. ARPANSA is currently installing ARMS stations in Western Australia, Northern Territory and Queensland. ARPANSA will also establish an ARMS station at the ANSTO Lucas Heights site. This will be one component of an independent environmental monitoring program that is currently being developed for the Lucas Heights site.		
Deadline	End of 2018 for ARMS, end of 2019 for an environmental monitoring including environmental sampling for Lucas Heights.		
Organisation/person responsible	ARPANSA		