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

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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.

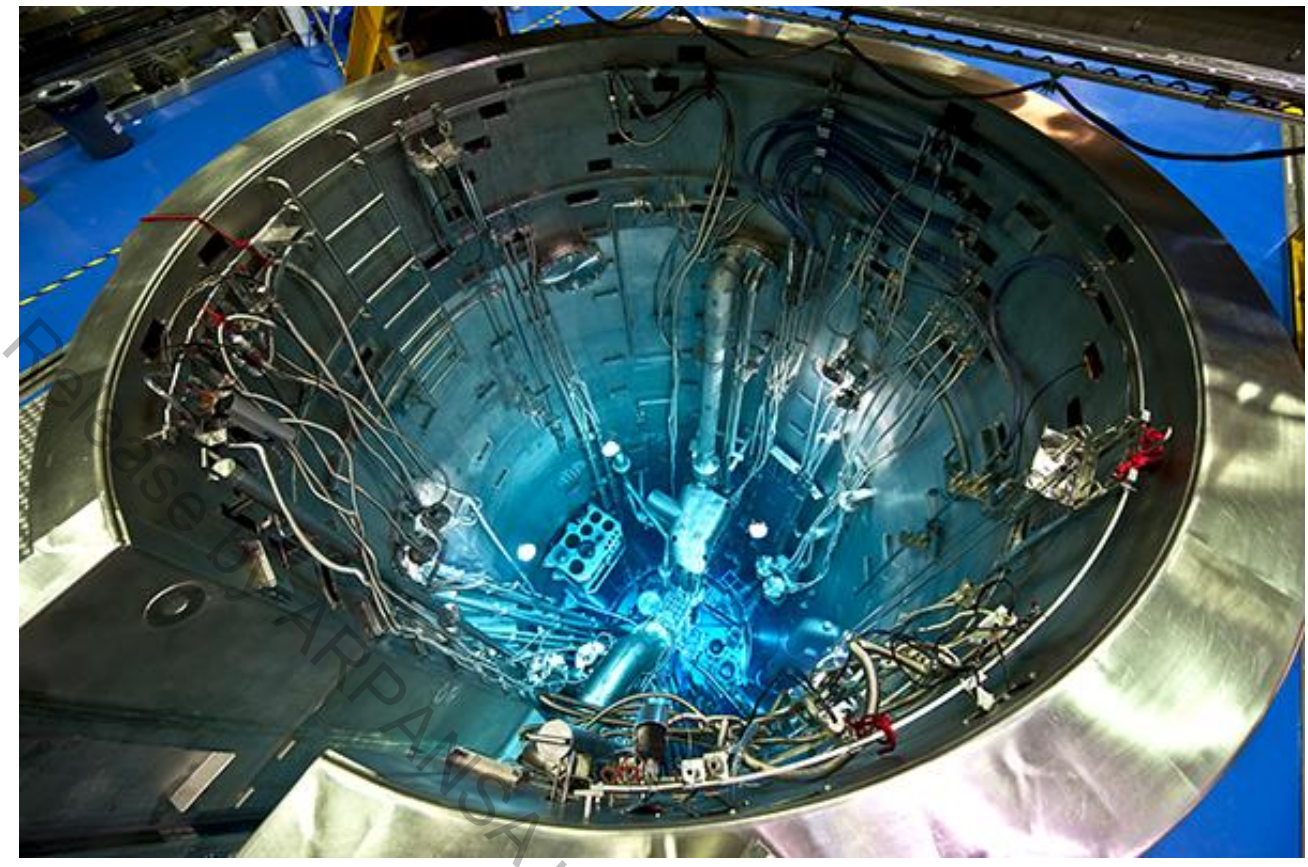

Figure 3. OPAL Reactor at ANSTO's Lucas Heights Facility

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.

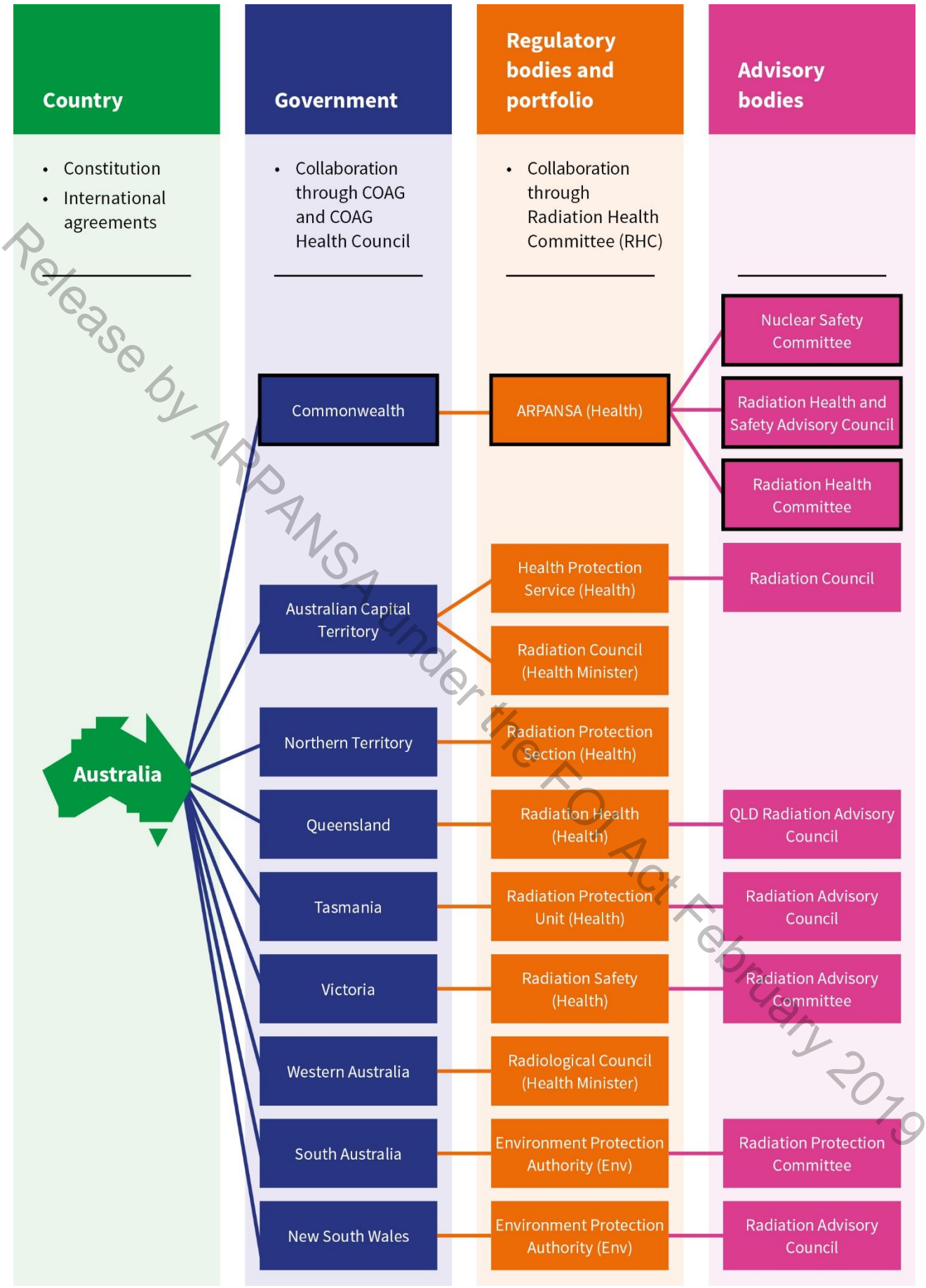

Figure 4. Overview of primary radiation safety regulatory bodies in Australia

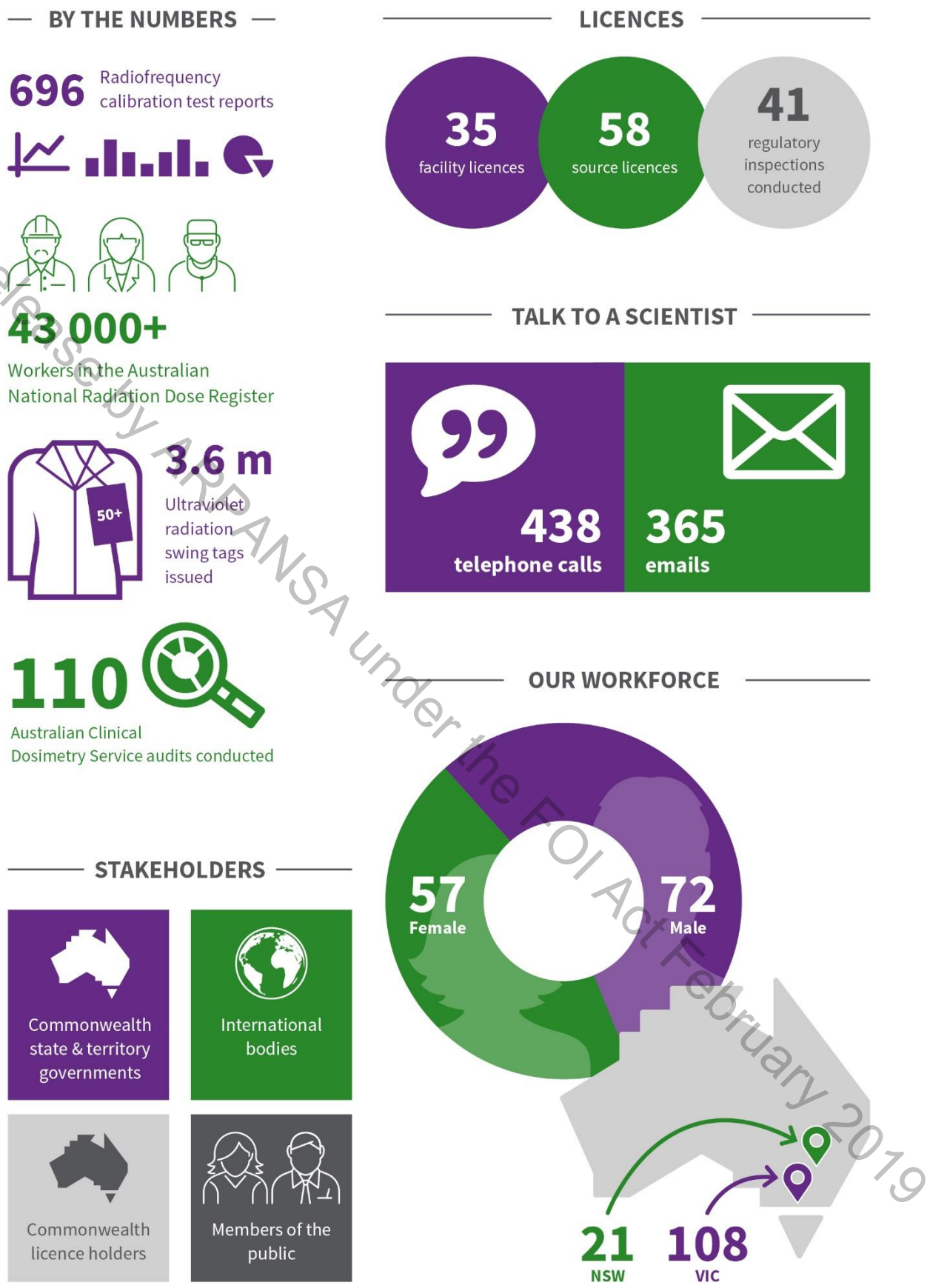

Figure 5. Statistics for the Commonwealth regulator, ARPANSA, for the 2017-18 financial year.

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).

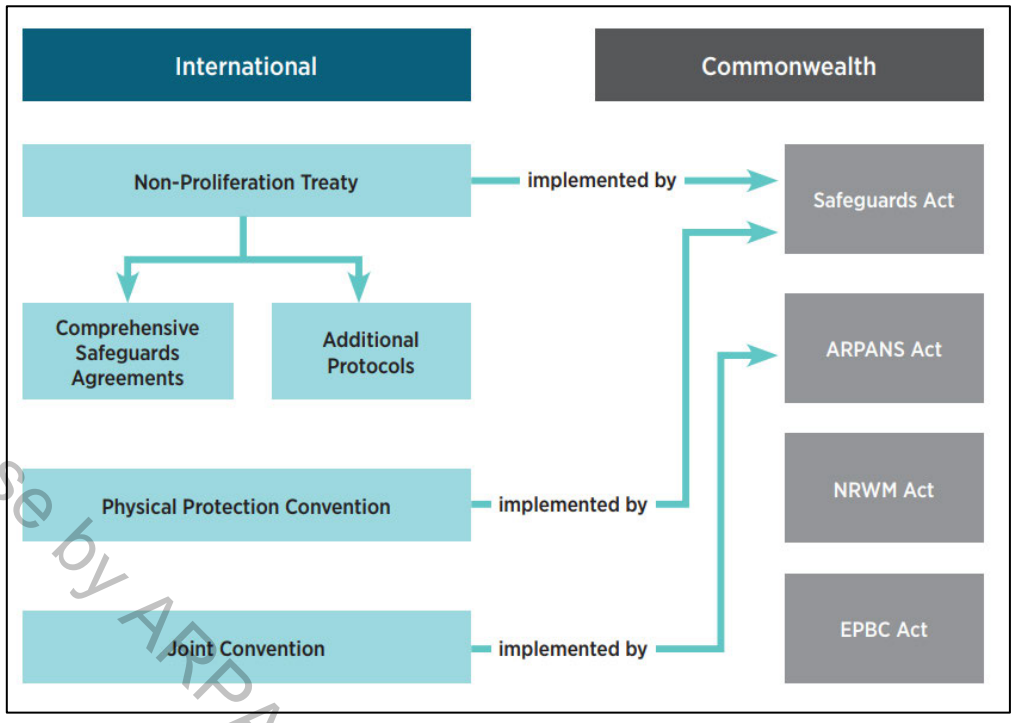

Figure 7. Commonwealth legislative arrangements for managing Australia's radioactive waste

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.

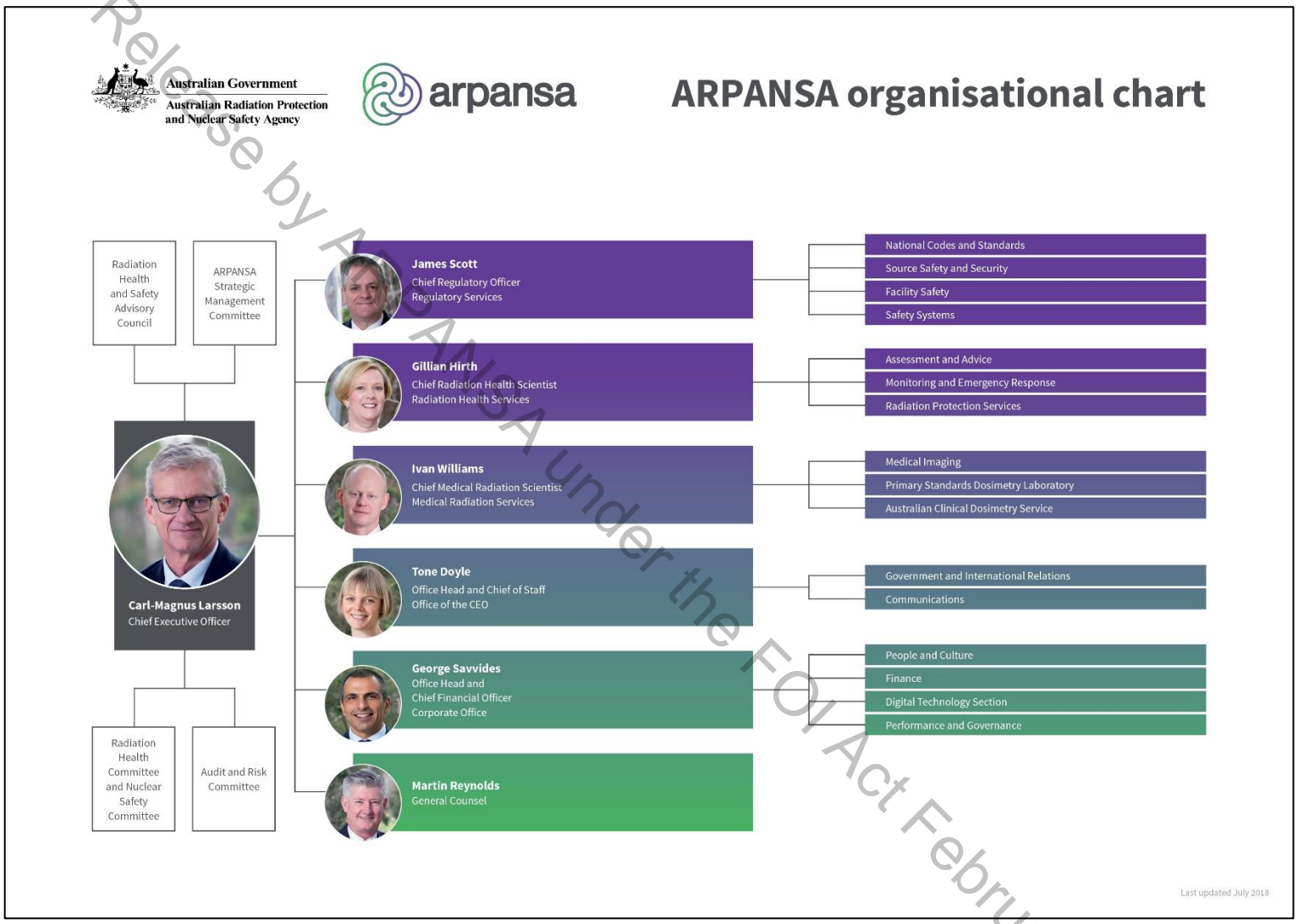

Figure 8. ARPANSA organisational chart

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.

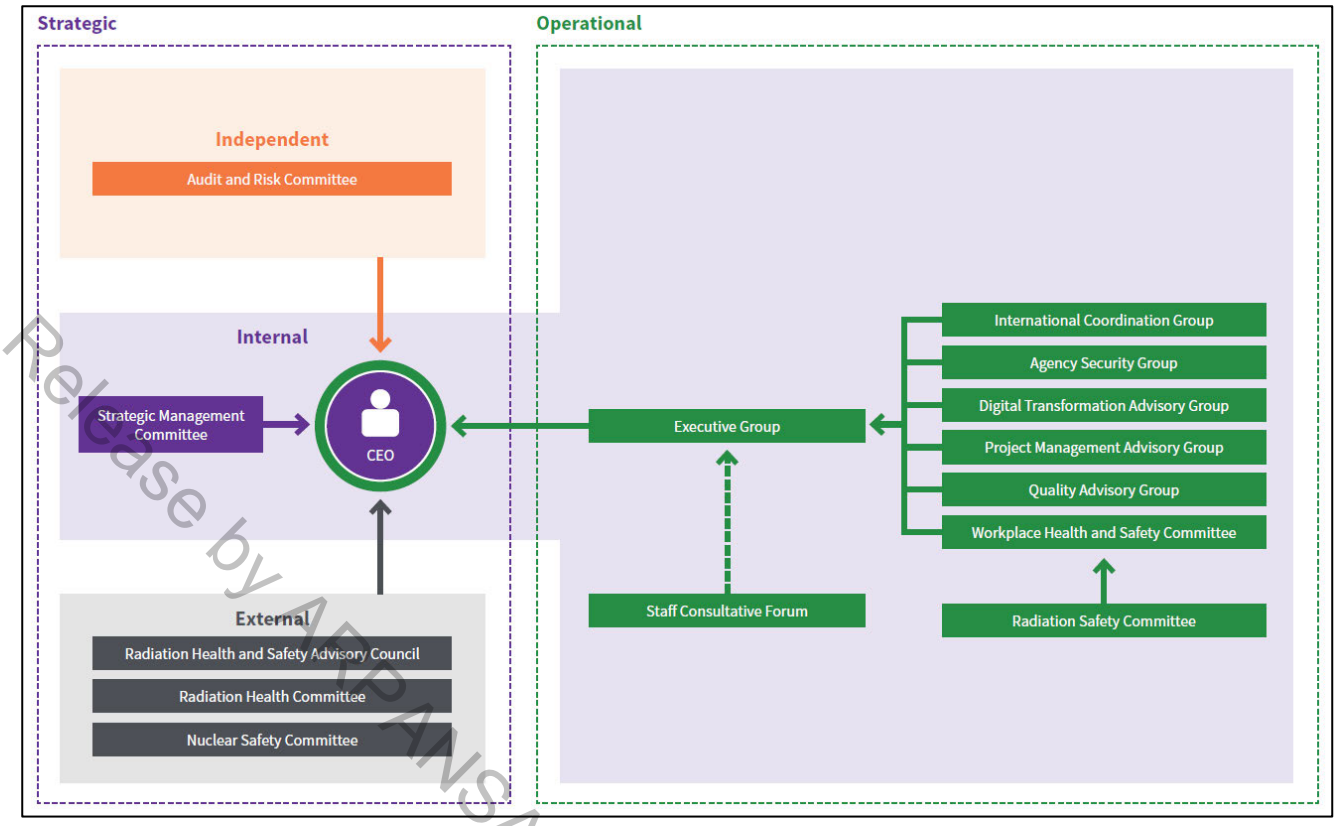

Figure 9: ARPANSA Committee Governance Structure

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.

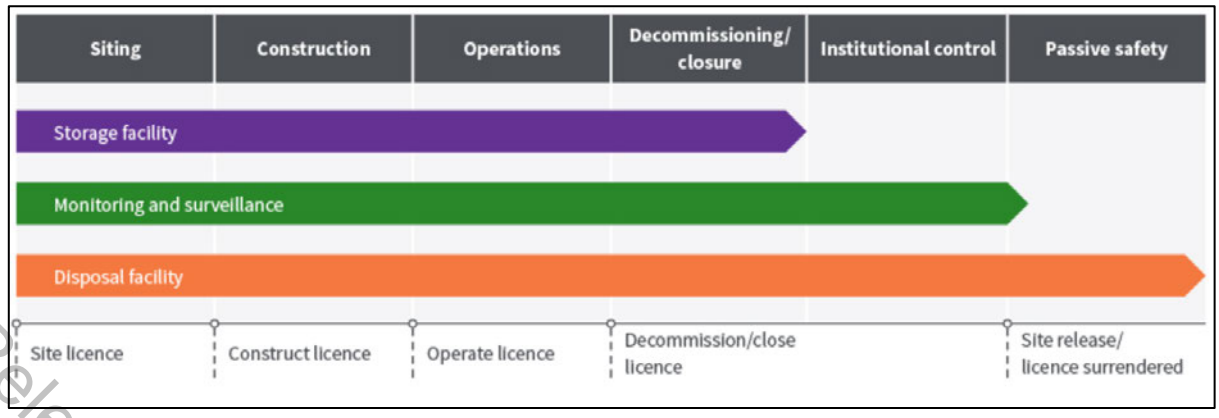

Figure 10. Overview of the staged licensing over the lifetime of any proposed facility

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.