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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

AUSTRALIA

Yallambie, Australia

5-16 November, 2018

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

Integrated Regulatory Review Service

IRRS

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REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
AUSTRALIA

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INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
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Mission dates:	*5-16 November 2018*
Regulatory body visited:	*Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)*
Location:	*Yallambie, VIC*
Regulated facilities and activities in the mission scope:	*Research Reactor, Waste Management facilities, Decommissioning activities, Radiation sources facilities and activities, Transport of radioactive material, Control of medical exposure, Occupational radiation protection, Public and environmental exposure control*
Organized by:	*IAEA*

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The number of recommendations, suggestions and good practices is in no way a measure of the status of the national infrastructure for nuclear and radiation safety. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

At the request of the Commonwealth Government of Australia, an international team of senior nuclear and radiation safety experts met with representatives of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), Queensland Health, the New South Wales Environment Protection Authority, Victoria's Department of Health and Human Services, South Australia's Environment Protection Authority, Tasmania's Department of Health, Western Australia's Radiological Council, the Northern Territory's Department of Health, and the Australian Capital Territory's Health Protection Service from 5 to 16 November 2018 to conduct an Integrated Regulatory Review Service (IRRS) mission.

The mission took place at ARPANSA's premises in Yallambie (Melbourne, Victoria). The purpose of the IRRS mission was to perform a peer review of Australia's regulatory frameworks for nuclear and radiation safety.

The scope of the IRRS mission to Australia included all modules offered by the IRRS. It included all facilities and activities regulated in Australia, with the exception of the uranium mining industry and the management of waste containing naturally occurring radioactive material (NORM). The mission scope included ARPANSA's role and responsibilities as the Commonwealth regulator for radiation protection and nuclear safety in all modules. In addition, for specific modules (radiation sources control, transport, and medical exposure control), the mission scope included all State and Territory regulatory bodies. The review compared the Australian regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also an opportunity to exchange information and experience between the IRRS team members and the Australian counterparts in the areas covered by the IRRS.

The IRRS team consisted of 15 senior regulatory experts from 13 IAEA Member States, three IAEA staff members and two observers. The IRRS team carried out the review in the areas of: responsibilities and functions of the government; the global safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including authorization, review and assessment, inspection, enforcement, development of regulations and guides including their contents; emergency preparedness and response; control of medical exposures, occupational radiation protection, control of public exposure, environmental monitoring and the interface of safety with nuclear security.

The IRRS mission included a policy issue discussion on national uniformity of radiation protection and nuclear safety policy and practices across the Commonwealth, States and Territories.

The mission included interviews and discussions with staff of the Commonwealth, State and Territory regulatory bodies, with visits limited to the OPAL Research Reactor and ANSTO Health facility at the Lucas Heights Science and Technology Centre (New South Wales), as well as SafeRad SE Asia Pty Ltd and St Vincent's Hospital (Victoria) for observations of regulatory inspection activities. This included discussions with the authorized party personnel and management on regulatory effectiveness. In addition, meetings with Commonwealth policy departments (Health; Industry, Innovation and Science; Foreign Affairs and Trade) were organized.

In preparation for the IRRS mission, each of Australia's radiation safety regulatory bodies conducted self-assessments and identified areas for improvement. ARPANSA prepared a preliminary action plan. The results of the self-assessments and supporting documentation were provided to the team as advance

reference material for the mission. Throughout the mission, the IRRS team was extended full cooperation in the regulatory, technical, and policy issues by all parties in a very open and transparent manner.

The IRRS team acknowledged the outstanding efforts of the Australian governments to engage in this extensive international peer review on nuclear and radiation safety. The participation by the Commonwealth, State and Territory regulatory bodies enabled the team to develop a broad understanding of the regulatory framework resulting in recommendations and suggestions that should benefit nuclear and radiation safety for all of Australia.

This was the first IRRS mission to undertake a comprehensive multi-jurisdictional review of a federated constitution in which all of the jurisdictions are self-governing. This was identified as a good practice by the team and a model that other federal countries may want to consider when planning for future IRRS missions. The IRRS team observed a high level of engagement by participants from the Commonwealth, States and Territories, demonstrating a strong commitment to continuous improvement in nuclear and radiation safety.

Additional good practices identified by the IRRS team included:

- the availability of comprehensive guidance for radiation protection in existing exposure situations;
- ARPANSA's succession planning for all positions;
- ARPANSA's holistic integration of risks in the management processes.

The IRRS team made recommendations and suggestions that indicate where improvements are necessary or desirable to continue enhancing the effectiveness of regulatory functions in line with IAEA safety standards.

The most significant challenge to Australia is establishing a national framework for radiation safety that assures a consistent level of safety and protection of people and the environment across all jurisdictions, in principle and in practice. While there are on-going activities to address consistency in the Australian radiation safety programmes, the IRRS team noted several areas where further efforts are warranted.

The IRRS team recognized that many of its recommendations and suggestions confirmed or elaborated on the actions identified by Australia's jurisdictions as a result of their self-assessments. The IRRS team identified the following key issues warranting attention or improvement and believes that consideration of these would enhance the overall performance of the regulatory systems.

- The Commonwealth Government should make a firm commitment and take actions with specific milestones to address decommissioning of facilities and radioactive waste management by assuring the strategy, programmes, funding and technical expertise for safe completion are in place.
- The Commonwealth Government, in conjunction with State and Territory Governments, should ensure full implementation of the Code of Conduct on the Safety and Security of Radioactive Sources, continuing to promote the safe and secure use of radioactive sources. This will contribute to the safety and security of the domestic and international communities and fulfil Australia's commitment to this important international instrument.
- The Commonwealth, State and Territory governments should ensure that all parties having responsibilities for safety of facilities and regulatory activities have the necessary competence and resources to carry out their responsibilities.

- State and Territory regulatory bodies should establish a strategy and allocate resources to ensure that inspections of facilities and activities are conducted consistently and in accordance with a graded approach.

- Regulatory bodies in all jurisdictions should assess domestic and international experience related to nuclear and radiation safety and evaluate the need for updating their processes for authorization, review and assessment, inspections and regulations.

- ARPANSA should establish criteria to evaluate the effectiveness of licensee's emergency exercises and assign roles and responsibilities for its staff during emergency situations.

- ARPANSA should complete its work on the integrated management system including promotion of leadership and management for safety.

The IRRS team findings are summarized in Appendix V. The IRRS team encourages all Australian parties to collaborate in the development of an action plan to address these findings with due consideration of IAEA safety standards.

An IAEA press release was issued at the end of the IRRS mission and was shared on the ARPANSA website.

I. INTRODUCTION

At the request of the Commonwealth Government of Australia, an international team of senior safety experts met representatives of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), Queensland Health, the New South Wales Environment Protection Authority, Victoria's Department of Health and Human Services, South Australia's Environment Protection Authority, Tasmania's Department of Health, Western Australia's Radiological Council, the Northern Territory's Department of Health, and the Australian Capital Territory's Health Protection Service from 5 to 16 November 2018 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Australian regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Commonwealth Government of Australia in December 2015. A preparatory meeting was conducted from 9 to 10 April 2018 at the IAEA in Vienna to agree the scope, objectives and detailed preparations of the review mission in connection with regulated facilities and activities in Australia and their related safety aspects.

Australia is a federal country, consisting of nine jurisdictions having responsibilities for the regulatory oversight of nuclear and radiation safety. As per the request of Australia, and as agreed at the preparatory meeting, the scope of the IRRS mission to Australia covers all modules offered by the IRRS, namely modules 1 to 12. It also covers all facilities and activities regulated in Australia, with the exception of the uranium mining industry and the management of waste containing naturally occurring radioactive material (NORM). In terms of jurisdictions, the mission scope includes the Commonwealth regulator's role and responsibilities in all modules. In addition, for specific modules (radiation sources control, transport, and medical exposure control), the mission scope also includes all States and Territories regulatory authorities. Each section of the mission report specifies which jurisdictions are included.

The report also adresses the different jurisdictions with the following understanding. "Government" means the Commonwealth Government of Australia; the "Governments" means the governments of the Commonwealth, States and Territories; "regulatory bodies" means the regulatory bodies of all nine jurisdictions.

The IRRS team consisted of 15 senior regulatory experts from 13 IAEA Member States, 2 IAEA staff members, 1 IAEA administrative assistant and 2 observers. Within the defined scope of the mission, the IRRS team carried out the review in the areas of: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, control of medical exposure, environmental monitoring, control of discharges and public exposure control and the interface of safety with nuclear security. In addition, a policy issue on national uniformity of radiation protection and nuclear safety policy and practices across jurisdictions of the Commonwealth, States and the Territories was discussed.

ARPANSA as well as the State and Territory regulatory bodies, where applicable, conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission the IRRS team performed a systematic review of all topics within the agreed scope through review of Australia's advance reference material, conduct of interviews with management and staff from ARPANSA and the State and Territory regulatory bodies, and direct observation of some of the regulatory activities at regulated facilities.

Meetings with Commonwealth policy departments (Health; Industry, Innovation and Science; and Foreign Affairs and Trade) were also held.

Throughout the mission the IRRS team received excellent support and cooperation from all of the Australian counterparts.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review the Australian radiation and nuclear safety regulatory framework and activities against the relevant IAEA safety standards, to report on regulatory effectiveness and to exchange information and experience in the areas covered by the IRRS.

It is expected that this IRRS mission will facilitate regulatory improvements in Australia and other Member States, utilising the knowledge gained and experiences shared between Australian counterparts and IRRS reviewers and the evaluation of the Australian regulatory framework for nuclear and radiation safety, including its good practices.

The key objectives of this mission were to enhance the national legal, governmental and regulatory framework for nuclear and radiation safety, and national arrangements for emergency preparedness and response through:

a) providing an opportunity for continuous improvement of the regulatory bodies through an integrated process of self-assessment and review;

b) providing the host country (regulatory bodies and governmental authorities) with a review of its regulatory technical and policy issues;

c) providing the host country (regulatory bodies and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;

d) promoting the sharing of experience and exchange of lessons learned among senior regulators;

e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS Team members who have experience of other regulatory practices in the same field;

f) providing the host country with recommendations and suggestions for improvement;

g) providing other countries with information regarding good practices identified in the course of the review;

h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);

i) contributing to the harmonization of regulatory approaches among countries;

j) promoting the application of IAEA safety requirements; and

k) providing feedback on the use and application of IAEA safety standards.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Commonwealth Government of Australia, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 9 to 10 April 2018. The preparatory meeting was carried out by the appointed Team Leader Mr Petteri Tiippana, Deputy Team Leader Ms Laura Dudes, the IRRS IAEA Team representatives, Team Coordinator Mr Hilaire Mansoux and Deputy Team Coordinator Mr Zia H. Shah and the ARPANSA representatives.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of ARPANSA represented by Mr Carl-Magnus Larsson, Chief Executive Officer (CEO) of ARPANSA. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Research Reactor;
- Waste Management facilities;
- Decommissioning activities;
- Radiation sources facilities and activities;
- Transport of radioactive material;
- Control of medical exposure;
- Occupational radiation protection;
- Public and environmental exposure control;
- Selected policy issues.

Mr Carl-Magnus Larsson made a presentation on the national context, the current status of the national regulatory infrastructure and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS mission in Australia in November 2018.

The proposed composition of the IRRS team was discussed and tentatively confirmed. Logistics including meeting and work places, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The Liaison Officer for the IRRS mission was confirmed as Mr Ryan Hemsley from ARPANSA.

Australia provided IAEA with the advance reference material (ARM) for the review in September 2018. In preparation for the mission, the IAEA team members reviewed the Austalian advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

The relevant IAEA safety standards, the Code of Conduct on the Safety and Security of Radioactive Sources and the Code of Conduct on the Safety of Research Reactors were used as review criteria. The complete list of IAEA publications used as the references for this mission is provided in Appendix VII.

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday 4 November, 2018 in Melbourne, directed by the IRRS Team Leader. Discussions encompassed the general overview, the scope and specific issues of the mission, clarification of the bases for the review and the background, context and objectives of the IRRS programme. The agenda for the mission was presented to the team. As required by the IRRS Guidelines,

the reviewers presented their initial impressions of the ARM and highlighted issues to be addressed during the mission.

The host country Liaison Officer was present at the initial IRRS team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday, 5 November 2018, with the participation of Senator the Hon Bridget McKenzie, the Minister for Regional Services, Sport, Local Government and Decentralisation, ARPANSA senior management and staff, representatives from Queensland Health, the New South Wales Environment Protection Agency, Victoria's Department of Health and Human Services, South Australia's Environment Protection Authority, Tasmania's Department of Health, Western Australia's Radiological Council, and the Australian Capital Territory's Health Protection Service, the Commonwealth Department of Health, the Australian Safeguards and Non-Proliferation Office, and Department of Defence. Opening remarks were made by Senator McKenzie, Mr Carl-Magnus Larsson, CEO ARPANSA, Mr Petteri Tiippana, IRRS Team Leader and Mr Juan Carlos Lentijo, Deputy Director General of the IAEA, head of the department for nuclear safety and security. Major General David Mulhall, Department of Defence, gave a presentation of the licence holder perspective. Mr Jim Scott, ARPANSA's Chief Regulatory Officer gave an overview of the Australian context and activities, and Mr Ryan Hemsley, Liaison Officier, presented the main results of the pre-mission self-assessment.

During the IRRS mission, a review was conducted for all areas within the agreed scope with the objective of providing Australia with recommendations and suggestions for improvement and where appropriate, identifying good practices. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national legal, governmental and regulatory framework for safety.

The IRRS Review team performed its review according to the mission programme given in Appendix III.

The IRRS exit meeting was held on Friday 16 November 2018. The opening remarks at the exit meeting were presented by Dr Carl-Magnus Larsson, CEO of ARPANSA, Ms Sharon Appleyard, First Assistant Secretary for the Office of Health Protection (OHP) of the Commonwealth Department of Health, and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Petteri Tiippana. Closing remarks were made by Mr Hilaire Mansoux, IAEA Team Coordinator.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

The 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.

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

Australia has not published a national policy and strategy for safety in a single document. However, the Commonwealth has made provisions and commitments in legislation, agreements and other documents that encompass relevant elements of such a strategy, including:

- The alignment of the *Australian Radiation Protection and Nuclear Safety Act 1998* (ARPANS Act) with the fundamental safety principles
- The scope of the governmental, legal and regulatory framework for safety
- The power of the CEO of ARPANSA to engage staff and consultants to assist in the performance of the CEO's statutory functions
- A provision and framework for research and development
- Mechanisms for taking account of social and economic developments
- The promotion of leadership and management for safety, including safety culture.

In order to further enhance these principles, the IRRS team found that Australia could benefit from formalizing and summarizing them in one document. The National Directory for Radiation Protection (NDRP) is currently under revision. The IRRS team was informed that this directory, which is used as a document to promote uniformity in radiation protection between the Commonwealth and the States and Territories, might serve as the platform to contribute to the evolution of a national policy and strategy for safety, noting that in its current form, the NDRP is an operational document rather than policy. The initial action plan also addressed the formation of a national policy and strategy for safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: While Australia has implemented the objectives of a national policy and strategy for safety within its framework for safety, the said strategy is yet to be formalized in a policy document. This has been recognized in the ARM, and is part of the action plan.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 1, para. 2.3 states that** *"National policy and strategy for safety shall express a long-term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy."*
S1	**Suggestion: The Commonwealth Government, in conjunction with State and Territory Governments, should consider formalizing the existing elements of the framework for safety into a comprehensive national policy and strategy for safety.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

Australia is a federal constitutional monarchy 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.

The Commonwealth may only exercise powers given to it under the Australian Constitution or through agreements entered into with States. Each State and the Commonwealth has its own sovereign parliament. The self-governing territories, namely, the Northern Territory and the Australian Capital Territory, have legislative assemblies with limited law making powers but these can be overturned by the Commonwealth Parliament, which has the power to make laws for the Territories. As described, all the States and Territories have their own radiation protection legislation and regulatory bodies. This has resulted in some differences in regulatory requirements and implementation across the Australian jurisdictions, leading to inconsistencies such as those reported under the '*Radiation Health Committee (RHC) options paper - national approach to the regulation of radiation safety and security'*. The IRRS team was informed that national uniformity is an overall challenge across multiple issues within the Australian legal framework. However, there are several ways to resolve harmonization issues in order to promote uniformity. Examples, as expressed within the ARM and through the interviews with the counterparts, are:

- Cooperation through the Council of Australian Governments (COAG) – The COAG is the main intergovernmental forum in Australia. The members of COAG are the Prime Minister, State and Territory First Ministers and the President of the Australian Local Government Association. The Prime Minister chairs COAG. The outcomes of COAG meetings are contained in communiqués published at the end of each meeting. Where formal agreements are reached, these may be embodied in intergovernmental agreements, including National Agreements and National Partnership Agreements.
- National Partnership Agreements – agreements between the Commonwealth and one or more State or Territory on specific areas of competence. Additional funding is provided in return for the establishment of general standards.
- Mirror legislation – a system where draft legislation is developed as a model, most often by a body created for the purpose (usually by the Commonwealth with representatives from each jurisdiction), but could be one jurisdiction enacting a model law, either in consultation with other jurisdictions or of its own account. The model law is then enacted in the same or substantially similar terms by all jurisdictions. Under such a scheme there is generally no central body to administer the legislation, but it is also possible to have mirror legislation with a central administering body.
- Complementary applied law schemes – A complementary applied law scheme is where one jurisdiction (which need not be the Commonwealth) enacts a law on a topic, which is then applied by other jurisdictions as a law of that jurisdiction.
- Referral of State powers to the parliament – Paragraph 51(xxxvii) of the Constitution gives the Commonwealth Parliament power to make laws with respect to matters referred to the Parliament of the Commonwealth, by the Parliament, or Parliaments of any state, or states. Examples of subject areas in relation to which referrals have been given include corporations, workplace relations and counter-terrorism.

The Commonwealth has promulgated a legal framework for safety through the ARPANS Act and Regulations.

Commonwealth, State and Territory radiation safety regulators, through their representation on the Radiation Health Committee, develop Codes, agree on implementation and interpretation, capture them in draft revisions to the NDRP, and subsequently seek the approval of Australia's Health Ministers for them

to be recorded in the NDRP. The establishment of a nationally consistent framework for safety is a complex and often time-consuming process, and its implementation across the nation differs. Initiatives have been taken by the regulators represented on the RHC and by the Commonwealth Government to explore options for achieving a more unified and efficient approach.

The RHC is established by the ARPANS Act and serves as an advisory body to the CEO of ARPANSA. In addition to the CEO, the RHC is comprised of a representative of the Nuclear Safety Committee (NSC), a person to represent the interests of the general public radiation control officers who represent each State and Territory and up to two other members. The radiation control officers are expected to have their jurisdictions' authority to engage in discussions and provide advice for promoting national uniformity. The CEO of ARPANSA invites nominations for all members of the RHC.

The establishment of the National Directory for Radiation Protection (NDRP) approved by COAG sought to increase national uniformity by providing an overall nationally agreed framework for radiation safety. This Directory aims to provide comprehensive guidance to establish and maintain a uniform legislative framework for ionising radiation protection in Australia. Although the NDRP was developed with the needs of radiation safety and protection agencies and regulators in mind, it is acknowledged that the NDRP is also used by all sectors involved in implementing radiation controls, including mining, mineral processing and occupational health and safety regulators.

Currently, the NDRP is undergoing review and the NDRP 2nd edition is expected to be submitted to Australian Health Ministers for consideration in July 2019. While the NDRP 1st Edition led to improvements, the IRRS team noted that many issues regarding uniformity still remain unaddressed. The IRRS team was informed that the transposition and implementation of the nationally agreed standards provided in the NDRP by the Commonwealth, States and Territories have happened to varying degrees. The IRRS team noted that the relevant safety standards have not been implemented consistently by all Australian jurisdictions and harmonization and uniformity within the Australian legal and regulatory framework has not been achieved at the necessary level. This could potentially lead to an impact on the effectiveness of the radiation framework for safety. For example, there are different licensing requirements regarding sources, transport, emergency response and medical applications across the jurisdictions that, though unlikely, carry the potential to compromise safety.

In order to ensure an optimal framework for protection of the workers, public and environment, the principles of the general safety standards need to be applied in a consistent manner across all Australian jurisdictions.
Some examples of actions that could enhance national uniformity include:

- Increasing the consistency and compatibility of the legal framework through the existing harmonization processes;
- Consistent application of regulatory processes such as authorization, review and assessment, inspection, enforcement, and the development of regulations and guides;
- Harmonization of exemption and clearance levels;
- Adopting the NDRP's 2nd edition.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: The Commonwealth, as well as all States and Territories, have jurisdiction in regards to the Framework for Safety. While all jurisdictions have committed to increase the level of national uniformity through instruments like the NDRP, the national codes and guides have not been implemented consistently by all Australian jurisdictions and harmonization and uniformity within the Australian legal and regulatory framework has not been achieved at the necessary level. This could potentially impact the

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
safety of the public, workers and environment. Some mechanisms that were inhibiting progress have been addressed within the draft of the 2nd edition of the NDRP. However, the 2nd edition of the NDRP has not yet been approved by Australian Health Ministers. Additionally, measures regarding authorization, review and assessment, inspection, enforcement, and regulations are not being consistently applied. This has been partly recognized in the ARM, and is part of the action plan.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 2 para. 2.6 states that** *"Where several authorities are involved, the government shall specify clearly the responsibilities and functions of each authority within the governmental, legal and regulatory framework for safety."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 7 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."*
(3)	**BASIS: GSR Part 1 (Rev 1) Requirement 7 para. 2.18 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The Government shall ensure that there is appropriate coordination of and liaison between the various authorities …"*
R1	**Recommendation: The Commonwealth Government, in conjunction with State and Territory Governments, should ensure a consistent level of protection of people and the environment through effective coordination and harmonized implementation of codes and guides by the Commonwealth, States, Territories and regulatory bodies.**

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The Commonwealth, through ARPANSA, as well as the States and Territories, through their respective regulator, have established regulatory authorities for radiation protection.

ARPANSA sits within the Health portfolio but is independent in its regulatory decision making. This was enabled by establishing the CEO of ARPANSA as an independent statutory office holder to be appointed by the Governor-General of Australia for a five year period and who will be the head of a statutory agency called ARPANSA. 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.

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 through the Minister 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.

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.

While the power for reconsidering a licence decision on the request of an eligible person (i.e. a licence holder or applicant for a licence) lies with the Minister, the IRRS team was informed that it is possible for

either ARPANSA or the affected eligible person, being persons whose interests are affected by the decision, to appeal against the Minister's decision to the Administrative Appeals Tribunal (AAT), an independent merits review tribunal with the power to confirm, vary or set aside the reviewable decision. AAT decisions may be appealed to the Federal Court of Australia for judicial review on the grounds of error of law.

Funding is provided within the ARPANS Act through appropriations by the Commonwealth as well as the ability of ARPANSA to charge for its services.

ARPANSA's Radiation Health Services Branch (RHSB) and Medical Radiation Services Branch (MRSB) hold facility and source licences issued on behalf of the CEO of ARPANSA. The assessment for issuing these licences and the inspection of the authorized 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 authorization, 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. The Memorandum of Understanding regulating this oversight by the Queensland Department of Health has expired. This issue is addressed in Suggestion 3 of Section 3.2.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

As stated in the ARPANS Act, the prime responsibility for safety and compliance with requirements rests with the holder of the authorization. The Code for Radiation Protection in Planned Exposure Situations (2016) (the Planned Exposure Code; RPS C-1) is a key document which outlines the responsibilities of persons conducting any planned activity and is a condition of licence for all ARPANSA licences. The prime responsibility for safety cannot be transferred or delegated according to the Planned Exposure Code.

ARPANSA is empowered under the ARPANS Act to enforce compliance with regulations. Licence holders must allow the CEO or authorized officers to enter and inspect facilities and radioactive sources or radiation apparatus authorized by facility or source licenses. 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

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

Coordination mechanisms have been established through either memoranda of understanding or meetings. ARPANSA has entered into more than 30 memoranda of understanding, including cooperation 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 authorized parties.

ARPANSA also engages and coordinates with radiation safety regulators from the States and Territories, especially through RHC, but also on the operational level, for example where a source or facility is transferred between a State or Territory jurisdiction's and ARPANSA's regulatory control.

There are several forums set up to aid national uniformity. The RHC usually meets three times a year, to discuss the development of codes and similar matters. In addition, monthly teleconferences which assist inter-jurisdictional collaboration take place among participants in the Radiation Regulators' Network.

The IRRS team noted an issue regarding the cooperation between the regulatory bodies of all jurisdictions and the Therapeutic Goods Administration (TGA). Medical equipment is controlled by the TGA, and only TGA approved equipment is permitted for supply in the country. The IRRS team was informed that there are no mutual interactions between the supplier of medical equipment and the regulatory bodies responsible for radiation protection. In case of equipment related unusual occurrences that may have implications for protection and safety of users, and implemented corrective actions, the supplier does not always inform the regulatory body. Additionally, the IRRS team was informed that some of the regulatory bodies refer to external websites to gather information regarding the unusual incidents reported by the suppliers, for dissemination to their licence holders. This identifies a need for co-ordination between the regulatory bodies and the TGA to address the above issues.

The IRRS team was informed that the adoption of the national codes and guides and the coordination between the regulatory bodies across the Australian jurisdictions varies, which could potentially lead to an impact on the effectiveness of the framework for radiation safety. This issue is addressed in Recommendation 1 of Section 1.2.

1.6 SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS

The ARPANS Act provides the CEO of ARPANSA the powers to deal with situations that require urgent regulatory attention. 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 has reasonable grounds.

Furthermore, the ARPANS Act describes powers available to inspectors where 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), which elaborates on Principle 10 of the IAEA SF-1 (Protective actions to reduce existing or unregulated risks); and
- 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, the ARPANS Act provides the CEO of ARPANSA with the power to bring legacy sites under regulatory control.

1.7. PROVISIONS FOR THE MANAGEMENT OF RADIOACTIVE WASTE

The Commonwealth is currently the only jurisdiction in which spent fuel is generated and managed. The policy for spent fuel includes on site storage awaiting reprocessing in France, followed by storage of the returned intermediate level waste in dual purpose (transport and storage) casks.

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

national facility for the storage or disposal of radioactive waste. Consequently, low and intermediate-level radioactive waste continues to be stored by Commonwealth, State and Territory government regulators and licensees at over one hundred locations.

The Australian Radioactive Waste Management Framework, published in April 2018, details the principles and long-term goals for radioactive waste management. It reaffirms Australia's commitment to providing for the safety and sustainability of radioactive waste management over generations, and for the adequate allocation of financial and human resources.

As per the framework document, radioactive waste is defined as being "material that no longer has any foreseeable use and contains radioactive materials with activities or activity concentrations at levels that require ongoing management to ensure its safety". Further, the framework document classifies all waste in accordance with a six tier system aligned with the guidance IAEA safety standards document GSG-1. The IRRS team noted that this definition of radioactive waste and the system for classification of radioactive waste were not uniformly applied by all Australian regulatory bodies.

The IRRS team noted that the Australian Radioactive Waste Management Framework commits to the establishment of a low level disposal facility and co-located intermediate level waste store in the medium term and an intermediate level waste disposal facility in the longer term. However, neither the strategy nor the specific arrangements to give effect to these commitments for radioactive waste management have been elaborated in detail.

Additionally, the IRRS team noted that while the Australian Radioactive Waste Management Framework acknowledged the need for and proposed the establishment of a National Radioactive Waste Management Organization (RWMO), the RWMO has not yet been established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Australian Radioactive Waste Management Framework presents the overall principles and long-term goals for radioactive waste management. The document, however, does not address the responsibilities and arrangements to ensure delivery of the commitments with associated timeframes and milestones.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 10 states that** *"The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel."*
(2)	**BASIS: GSR Part 5 Requirement 2 states that "***To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established. The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State, shall indicate the regulatory control required, and shall consider relevant societal factors. The policy and strategy shall be compatible with the fundamental safety principles [2] and with international instruments, conventions and codes that have been ratified by the State. The national policy and strategy shall form the basis for decision making with respect to the management of radioactive waste.***"**
(3)	**BASIS: GSR Part 5 requirement 2, para 3.6. states that** *"The national strategy for radioactive waste management has to outline arrangements for ensuring the implementation of the national policy. It has to provide for the coordination of responsibilities. It has to be compatible with other related strategies such as strategies for nuclear safety and for radiation protection."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(4)	**BASIS: GSR Part 1 (Rev 1) Requirement 2, para 2.5, states that** "*The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:… Responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities;…"*
R2	**Recommendation: The Commonwealth Government should establish and implement a strategy to give effect to the policy principles and goals in the Australian Radioactive Waste Management Framework.**

The IRRS team noted that decommissioning is recognized as a distinct stage in the lifecycle of a facility and formal decommission plans are required in support of the authorization for decommissioning. Additionally, the ARPANS Act includes the requirement that the CEO of ARPANSA must take international best practice in radiation protection and nuclear safety into account when making a licensing decision about decommissioning of a facility. However, there is no formal national policy addressing decommissioning or provision of funding for decommissioning.

The self-assessment undertaken by Australia recognized that 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.

Furthermore, the IRRS team noted that while the High Flux Australian Reactor (HIFAR Research Reactor) was permanently shut down in 2007 and defueled, with the spent fuel being sent for reprocessing, the facility has been under a "possess and control" licence since, with no decommissioning activities commencing in the past 11 years.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Government has not established a national policy and strategy for decommissioning including timing and financial aspects.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 10, states that** *"The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel"*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 10, para. 2.28. states that** *"Decommissioning of facilities …shall constitute essential elements of governmental policy and the corresponding strategy …"*
(3)	**BASIS: GSR Part 6 Requirement 4, states that** *"The government shall establish and maintain a governmental, legal and regulatory framework within which all aspects of decommissioning, including management of the resulting radioactive waste, can be planned and carried out safely. This framework shall include a clear allocation of responsibilities, provision of independent regulatory functions, and requirements in respect of financial assurance for decommissioning."*
(4)	**BASIS: GSR Part 1 (Rev 1) Requirement 2, para 2.5, states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:…*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities;…"
R3	**Recommendation: The Commonwealth Government should establish a national policy and strategy for decommissioning of facilities.**

With regard to the safe management of disused sources, in the absence of a waste repository in a number of jurisdictions in Australia, disused sources either have to be stored or returned to the manufacturer or source supplier. From time to time, orphan sources are discovered and require management by the responsible jurisdiction. So far, jurisdictions have been able to safely manage these cases, using their own resources and bearing the associated financial costs.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: In Australia, with one exception (NSW), there is no legal requirement to establish financial provisions to cover the cost of managing a disused radioactive source. Although the current practice is that disused sources should generally be returned to the manufacturer, there are many disused sources that will have to be appropriately managed. It is expected that the disposal costs will have to be borne by the owners of the sources under the charging models that are in consideration.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 10 para. 2.33 states that** *"Appropriate financial provision shall be made for:* *(a) Decommissioning of facilities;* *(b) Management of radioactive waste, including its storage and disposal;* *(c) Management of disused radioactive sources and radiation generators;"*
(2)	**BASIS: GSR Part 3 Requirement 17 para. 3.60 states that** *"The Registrants and licensees shall ensure that arrangements are made promptly for the safe management of and control over radiation generators and radioactive sources, including appropriate financial provision, once it has been decided to take them out of use."*
(3)	**BASIS: Code of Conduct on the Safety and Security of Radioactive Sources para. 22 states that** *"Every State should ensure that its regulatory body: …* *(b) ensures that arrangements are made for the safe management and secure protection of radioactive sources, including financial provisions where appropriate, once they have become disused;"*
R4	**Recommendation: The Commonwealth Government, in conjunction with State and Territory Governments, should ensure that financial provisions are provided to enable the management of disused radioactive sources.**

1.8. COMPETENCE FOR SAFETY

The Commonwealth does not prescribe specific competency requirements for persons who have responsibility for safety in radiation protection. However, the Radiation Protection Series outlines 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 the Australian jurisdictions, including through nationally recognized industry bodies.

Most Australian jurisdictions mandate qualifications and training as part of the authorization process. 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 CEO of ARPANSA may also accredit persons for the purposes of achieving the objectives of the ARPANS Act.

The Australian Radiation Protection Accreditation Board is one professional body capable of certifying radiation protection professionals, such as Radiation Safety Officers and Radiation Protection Advisors in industry.

A number of universities in Australia offer training and qualifications in medical application of radiation, including medical physics. Within the medical profession, the Australian Health Practitioner Regulation Agency protects titles of occupations including medical radiation practitioner, diagnostic radiographer, medical imaging technologist, radiographer, nuclear medicine scientist, nuclear medicine technologist, and radiation therapist.

The Australian Nuclear Science and Technology Organisation (ANSTO) provides radiation safety training through a variety of courses and 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 organizations, such as law enforcement and conventional emergency services, and also includes ARPANSA.

Efforts have been made to build and maintain competence of all parties having responsibilities in relation to the safety of facilities and activities, however, significant variation in implementing radiation protection programmes across the Australian jurisdictions continues to exist. The IRRS team was informed that in some jurisdictions, the regulatory bodies have indicated that their current staffing levels and sometimes the competence of the existing staff was not commensurate with the licensing tasks to be performed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: While efforts to build and maintain competence of all parties having responsibilities for safety have been made in some areas across the Australian jurisdictions, significant variation in implementing radiation protection programmes continues to exist. Additionally, the majority of regulatory bodies have indicated that their current staffing level and sometimes their technical competence for the breadth of radiation practices which are regulated across Australia was not commensurate with the range of regulatory tasks to be performed, taking into account the relatively high number of regulated entities.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 2 para. 2.6 states that** *"Where several authorities are involved, the government shall specify clearly the responsibilities and functions of each authority within the governmental, legal and regulatory framework for safety.*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 7 para. 2.35 states that** *"the building of competence shall be required for all parties with responsibilities for safety of facilities and activities, including authorized parties, the regulatory body and organizations shall be built, in the context of the regulatory framework for safety, by such means as:* *-technical training* *-learning through academic institutions and other learning centres* *-research and development work."*
(3)	**BASIS: GSR Part 1 (Rev 1) Requirement 18 states that** *"the regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R5	**Recommendation: The Governments should ensure that all parties having responsibilities for safety of facilities and regulatory activities have the necessary competence and resources to carry out their responsibilities.**

1.9. PROVISION OF TECHNICAL SERVICES

According to the ARPANS Act, one of the functions of the CEO is to provide services relating to radiation protection, nuclear safety, and medical exposures to radiation. Accordingly, 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 a government funded 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 related to ionizing radiation 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;
- Diagnostic and protection level calibrations – radiology/medical physics equipment;
- Radioanalytical services – capabilities in radioanalytical analysis which includes a commercial service for the measurement of radioactivity, such as in food samples;
- Hire of radiation meters;
- Australian National Radiation Dose Register – national dose register for the storage and maintenance of radiation dose records; and
- Emergency response – capabilities including field gamma spectroscopy, dose assessment and advice products and geospatial modelling for operational decision makers.

1.10. SUMMARY

The IRRS team reviewed the responsibilities and functions of the Government. While the focus lays mainly on the Commonwealth level, in certain areas observations have been made to the responsibility and functions of the States and Territories. Overall, the IRRS team found that Australia is in good alignment with IAEA safety standards. However, observations have been made in regards to the uniform and consistent application of the safety standard across all jurisdictions.

The IRRS team found some areas for improvement related to the formalization of the national policy and strategy for safety, the consistent application of the safety standards by all Australian jurisdictions and harmonization and uniformity within Australia's legal and regulatory framework, the responsibilities and arrangements to ensure an Australian framework for radioactive waste management, financial provisions to cover the cost of managing disused radioactive sources, and building and maintaining competence of all parties regarding nuclear and radiation safety.

1.11 POLICY ISSUE DISCUSSION

The Commonwealth and each of the States and Territories have their own legal framework on radiation protection and have established separate regulators for the licensing and regulatory control of the safety of

radiation sources, associated facilities and activities. These arrangements have resulted in a variance in the implementation of the safety requirements and have established different inspection regimes forregulators across Australia. Regulatory bodies at the States and Territories level are usually established within a department of health or environment protection authority. Hospitals, dental practices, universities and industries using radioactive sources are the entities most commonly regulated. Unlike the Commonwealth radiation safety regulator, ARPANSA, State and Territory regulators deal with a far greater number of these entities.

To encourage national consistency, the ARPANS Act provides that the CEO of ARPANSA is "to promote uniformity of radiation protection and nuclear safety policy and practices across jurisdictions of the Commonwealth, the States and the Territories". The primary pathways available to the CEO for the promotion of national regulatory uniformity are via the RHC (members appointed by the CEO) and its work outputs such as the codes and guides, as well as the NDRP.

The discussion focused on the approach in Australia to support national uniformity and harmonization in regulating facilities and activities. The IRRS team shared models and mechanisms used by different countries with a federal structure to support a consistent legislative and regulatory framework and discussed their respective policies, strategies, resources and practices that help provide a common platform to all regulatory bodies operating within their country. The countries expressed various ways and means aimed at promoting harmonization such as having a consistent legislative and regulatory framework, a shared commitment to harmonization, and mechanisms for sharing of information, training and competency development. The IRRS team highlighted the importance of harmonized regulation and its consistent implementation to provide equal assurance of the health and safety of the public, the patients, the workers and the environment across the nation. The team encouraged open dialogue both with fellow regulators and with authorized parties, and leveraging those discussions to identify priority areas of misalignment or gaps of regulatory expectations, processes and practices that do not contribute to nuclear and radiation safety.

Regulators from States and Territories signalled their commitment to the common objective of national uniformity through harmonized approaches, but recognized the challenges and limitations of this commitment. In particular, regulators noted the resource challenges that are faced by many, and the complexity of their legislative systems to effect quick and real change in their respective jurisdictions. The participants recognized the important role of the RHC in achieving this outcome, in particular through its work to develop a comprehensive system of national codes and the NDRP.

The Environmental Health Standing Committee (enHealth) is a standing committee under the COAG structure in Australia. enHealth has recognized the challenges faced by regulators of radiation safety, noted commonalities with other sectors across Australia as well as the importance of a national code, and that the maintenance of their respective legislative frameworks may be achieved through mechanisms such as automatic adoption. EnHealth has signalled its capacity to support the further promotion of national uniformity initiatives, in particular to bridge the radiation safety regulators with decision makers within the COAG framework (i.e. Australian Health Ministers).

2. THE GLOBAL SAFETY REGIME

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

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Australia, through the Commonwealth, takes advantage of opportunities offered by the Global Nuclear Safety regime for improving the national framework for safety 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, the United Nations Scientific Committee on the Effects of Atomic Radiation, and the World Health Organization. Australia is a party to the Comprehensive Nuclear Test-Ban Treaty. ARPANSA manages Australia's obligations under the Treaty to operate nine radionuclide monitoring stations in mainland Australia, the Pacific, the Indian Ocean and Antarctica.

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 and Amendments (2016)
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (2003).

Other relevant international agreements to which Australia is a signatory of 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 Code of Conduct on the Safety and Security of Radioactive Sources. On 21 May 2004, the Department of Foreign Affairs and Trade transmitted a letter of political commitment regarding this Code of Conduct to the IAEA, stating '*While the Australian Government acknowledges that the Code is a non-legally binding commitment, it confirms that the commitment will be backed by steps to improve the security of source at a national level*'. However, the IRRS Team observed that the Code of Conduct is not being implemented fully across all Australian jurisdictions. Examples of non-compliance include: the discontinuation of a National Sealed Source Register (NSSR), variability in financial provisions for disused sources and other observations from sections 5 to 9 of this report that provide further evidence of implementation inconsistencies. Furthermore,

the consistent implementation of measures to determine, as appropriate, the trustworthiness of individuals involved in the management of radioactive sources was not found to be readily available. The IRRS team was informed that both the re-establishment of the NSSR and the issue of the trustworthiness of individuals are being addressed within the RHC's working programme.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: While Australia has committed to the implementation of the Code of Conduct on the Safety and Security of Radioactive Sources not all principles described therein have been established across Australia. For example, the existing National Sealed Source Register has been discontinued. However, there are additional items within the Code of Conduct that need to be addressed to achieve full implementation of the Code of Conduct. This has been partly recognized in the ARM and is part of the action plan.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 14 states that** *"The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews and promote international cooperation and assistance to enhance safety globally.*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 14, para. 3.2 (b) states that** *"The features of the global safety regime include: Codes of Conduct that promote the adoption of good practices in the relevant facilities and activities.*
(3)	**BASIS: CoC on the Safety and Security of Radioactive sources, II. Scope and Objectives, para. 5 (b) states that** *"These objectives should be achieved through the establishment of an adequate system of regulatory control of radioactive sources, applicable from the stage of initial production to their final disposal, and a system for the restoration of such control if it has been lost.*"
(4)	**BASIS: CoC on the Safety and Security of Radioactive sources, III. Basic Principles, para. 14 states that** *"Every State should establish a national register of radioactive sources. This register should, as a minimum, include Category 1 and 2 radioactive sources as described in Annex 1 to this Code. The information contained in that register should be appropriately protected. For the purpose of introducing efficiency in the exchange of radioactive source information between States, States should endeavour to harmonize the formats of their registers."*
R6	**Recommendation: The Commonwealth Government, in conjunction with State and Territory Governments should ensure full implementation of the Code of Conduct on the Safety and Security of Radioactive Sources.**

Australia, on the Commonwealth level, 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.

In December 2015, Australia requested an IRRS mission to review the arrangements for radiation protection and nuclear safety in Australia. The intended scope for the review was 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.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Australia has requested a comprehensive review of their nuclear and radiation safety framework. The scope of the IRRS mission includes the Commonwealth as well as the other national jurisdictions. States and Territories actively participated in the review of their authorization, inspection, review and assessment, enforcement, regulation of sources, medical applications and transport. In addition, national uniformity was chosen as the topic for the policy issue. Australia is the first country with a federal system of government to invite such a comprehensive review with participation from all national jurisdictions.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 14 states that** *"The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 14, para. 3.2 states that** *"The features of the global safety regime include:…* *(d) International peer reviews of the regulatory control and safety of facilities and activities, and mutual learning by participating States; …"*
(3)	**BASIS: GSR Part 1 (Rev 1) Requirement 7 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."*
GP1	**Good Practice: Demonstrating a commitment to enhancing national uniformity and consistency, the Australian Governments have actively engaged in a comprehensive, multijurisdictional international peer review. The active engagement by Commonwealth, State and Territory regulatory bodies, allowed the IRRS team to develop recommendations and suggestions that should contribute to the safe use of radiation for the benefit of all Australians. This is the first IRRS mission that included a holistic review of the nuclear and radiation safety framework across multiple regulatory jurisdictions.**

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Australia, through ARPANSA, manages and acts as the national point of contact on a number of national and international registers, which are additionally used to share operating and regulatory experience domestically and internationally, such as the:

- Australian Radiation Incident Register (ARIR)
- International Nuclear and Radiological Event Scale
- Incident Reporting System for Research Reactors
- Incident and Trafficking Database
- Australian National Radiation Dose Register (ANRDR)

Australia participates in multilateral and bilateral cooperation that enhances safety by means of harmonized 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. The IRRS team was informed that through these agreements the exchange of operating experience and regulatory experience is being encouraged.

ARPANSA shares outcomes from national and international meetings and national registers with Australian regulators/operators on an informal basis through the RHC, conferences, workshops and professional bodies.

ARPANSA manages the ARIR. All regulatory bodies report incidents to this centralized register, even though no reporting timeline is established. For 2017 almost 600 events, mostly related to medical practices, were reported to the ARIR. This enables information sharing among all Australian regulatory bodies. An annual report, giving statistics and highlighting some events and their lessons learned, is published. It also includes a feature topic (nuclear medicine in 2016, computed tomography for the upcoming 2017 report). In its self-assessment, ARPANSA identified an action to establish and implement a formal system for sharing relevant international information (including registers) to a broader audience. This also includes the existing projects for the dissemination of ARIR and enhancement to increase the use of these resources. An example of learning opportunities is described in Section 6.2.

Information and regulatory experience from the international and national level is shared in different ways as described above, not least of which is an agenda item about international affairs on each RHC meeting schedule. However, the IRRS team was informed that overall, the sharing of experience gained by the regulatory bodies across the Australian jurisdictions could be improved upon, especially through bodies like the RHC and using modern technological approaches, workshops and conferences and by external peer reviews like the previous IRRS mission and its follow up mission, as well as the IPPAS and WHO Joint External Evaluation (JEE) missions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Operating and regulatory experience is being shared between the regulatory bodies of Australia, through the RHC, conferences, workshops and professional bodies. However, the existing methods need improvement to better disseminate national and international experience gained by the regulatory bodies across the Australian jurisdictions. This has been recognized in the ARM and is part of the action plan.	
(1)	**BASIS: GSR Part 1 (Rev 1) requirement 15 states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities*.
(2)	**BASIS: GSR Part 1 (Rev 1) requirement 15, para 3.4 states that** *"The regulatory body shall establish and maintain a means for receiving information from other States, regulatory bodies of other States, international organizations and authorized parties, as well as a means for making available to others lessons learned from operating experience and regulatory experience.*
S2	**Suggestion: ARPANSA, in conjunction with the State and Territory regulatory bodies, should consider improving on the methods to better disseminate national and international experience gained by the regulatory bodies across the Australian jurisdictions.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: An annual report summarising events reported in ARIR is published by ARPANSA. No structured assessment is conducted by any regulatory bodies regarding the need to update their respective regulatory requirements or guidance or review and assessment or inspection and licensing processes as a result of the lessons learned from these events.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 15 states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 15 para 3.5 states that** *"To enhance the safety of facilities and activities globally, feedback shall be provided on measures that have been taken in response to information received via national and international knowledge and reporting networks. Such measures could comprise promulgating new regulatory requirements or making safety enhancing modifications to operating practices or to equipment in authorized facilities and activities…"*
R7	**Recommendation: Regulatory bodies should assess the need for updating regulatory requirements or guidance, review and assessment, inspection and licensing processes after considering the events reported in ARIR, especially the noteworthy events highlighted in the annual ARIR report.**

2.3 SUMMARY

The IRRS team reviewed the global safety regime. Australia, through the Commonwealth, is a very active participant in the international community to promote global safety.

The IRRS team found some areas of improvement related to the implementation of the Code of Conduct on the Safety and Security of Radioactive Sources, the improvement of the sharing of national and international experience gained by the regulatory bodies and to learn from regulatory experience.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

This section of the report is limited to the Commonwealth regulatory body, ARPANSA, and does not address the State and Territory regulatory bodies.

3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES

ARPANSA is the Commonwealth Government's primary authority on radiation protection and nuclear safety. The ARPANS Act specifies the breadth of regulated activities that are overseen by ARPANSA, that includes a range of controlled activities from small radiation sources such as baggage X-ray units, to a 20 MW multipurpose nuclear research reactor and associated research and radioactive isotope production facilities. ARPANSA is an independent agency under the portfolio of the Commonwealth Department of Health.

The CEO of ARPANSA is an independent statutory office holder, responsible to the Minister, and is empowered to establish a structure for the organization and manage its available resources to fulfil its obligations effectively. The regulatory functions of ARPANSA are largely performed by the Regulatory Services Branch (RSB). The RSB may access the expertise of other branches, including the Radiation Health Services Branch and the Medical Radiation Services Branch. In addition, support of their regulatory functions is provided from the Corporate Office, Office of the CEO and the Office of the General Counsel. In the interest of continuous improvement, the RSB has recently undergone a strategic realignment. This realignment included a review of ARPANSA's operations and resulted in a number of structural changes aimed at improving their effectiveness. This realignment is largely complete and an assessment of the success of the initiative is planned.

Resources for ARPANSA are assigned under the Department of Health portfolio and ARPANSA operations are funded both through appropriations from government and costs recovered from the provision of regulatory and other services. ARPANSA has authority to reinvest revenue generated from their services. When significant changes to their workload arise, mechanisms are available for ARPANSA to seek additional resources from within the Department of Health overall resourcing allocation set by the Commonwealth Government. This has been done in practice, for example, when the Australian Clinical Dosimetry Service (ACDS) transitioned to a cost recovered service for which ARPANSA sought and received an increase in its staffing cap.

ARPANSA has a well-developed risk management framework and has documented guidance to assess the relative risk of a regulated facility or activity and assign an appropriate level of regulatory scrutiny. This has been identified as a good practice in Section 4.3. Facility oversight is based on a three-year inspection programme, while source oversight is based on a six-year inspection programme. The framework goes beyond IAEA requirements, and integrates the base risk of an activity with an assessment of the level of control that the licence holder has over their operations. This assessment is based on a variety of factors including the strength of their radiation safety programmes, the results of recent inspections and an assessment of other planned (compliance) and unplanned (incidents) reports. These factors are integrated into an overall judgement of regulatory priority, with a consequential assignment of regulatory scrutiny (i.e. inspection frequency). This judgement is reviewed on an annual basis or if triggered by incidents or inspection results.

ARPANSA, as a Commonwealth entity, has a robust performance management framework. This framework sets performance targets for their regulatory duties and monitors performance against these targets, thus ensuring the effectiveness of their oversight activities. With respect to assigned inspection frequencies, ARPANSA has mechanisms to monitor performance on a quarterly basis. Performance against performance indicators are reported publicly. This system is discussed further in Section 4.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

ARPANSA is 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.

ARPANSA has formalized their commitment to carry out its regulatory functions independently in the Policy for ARPANSA's Regulatory Activities. Specifically, the Policy documents the commitment to carry out their duties free from political or economic pressures and sets the expectation to provide independent advice. The Policy goes on to recognize the importance of engaging with authorized parties and other interested parties, while noting the expectation that regulatory decisions be taken independent of such interests, in the interest of safety and the protection of people and the environment.

As a Commonwealth agency, ARPANSA is subject to the *Public Governance, Performance and Accountability Act 2013* and the *Public Service Act 1999*. The latter documents the public service's code of conduct, and the obligation for all staff to take reasonable steps to avoid any conflict of interest (real or perceived) in connection with the employee's employment; and disclose details of any material personal interest of the employee in connection with the employee's employment. In practice, staff are required to declare any real or perceived conflicts of interest or that no conflicts exist, and their supervisors are required to ensure that any declared real or perceived conflicts are appropriately managed, in consultation with ARPANSA's General Counsel. These declarations are required to be completed on an annual basis, or as soon as possible after circumstances change. In addition, ARPANSA is subject to the *Public Interest Disclosure Act 2013*, which provides mechanisms for internal and external disclosure of potential wrongdoing, and protection of public interest disclosers. The IRRS team was informed that as part of their onboarding process, new employees are informed of their obligations to avoid real or perceived conflict of interest, and any potential conflicts are managed through controls of work assignment. The IRRS team was further informed that in cases where staff are recruited from regulated entities, work is assigned to manage any potential conflict of interest.

Informal and formal mechanisms are in place to support the objectivity of ARPANSA's regulatory activities. Work is assigned to a lead regulatory officer, however, for risk-significant activities, the work is carried out by a team, who are expected to arrive at a consensus on the regulatory position taken as an outcome of that work. Authorization, review and assessment, and inspection processes include the expectation for peer review of the work, which is verified through the approval process.

In addition, to mitigate long-term regulatory capture, the ARPANSA Inspection Manual also documents the commitment to periodically rotate licences amongst ARPANSA regulatory officers, considering their respective expertise. In practice, work assignment is expected to be reviewed every three years, however this frequency is not formally documented and there are no mechanisms to monitor performance against this objective. ARPANSA may consider updating the Inspection Manual to include these aspects.

ARPANSA undertakes some activities itself that require regulatory oversight under the ARPANS Act, including the operation of radiation generators and the possession and use of radioactive sources. These activities are regulated by the Regulatory Services Branch (RSB), however in order to mitigate potential conflicts of interest, State and Territory regulatory bodies are invited to review and/or participate in RSB's inspection and review and assessment activities related to ARPANSA facilities and activities. A memorandum of understanding (MOU) was in place with Queensland Health, which formally documented their participation in RSB's inspection activities. However, the MOU has expired.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: ARPANSA has mechanisms to provide for independent review of regulated activities undertaken by ARPANSA through inclusion of state regulators to participate in regulatory oversight activities. An MOU was in place with the Queensland authority, which documented their independent oversight of inspections of ARPANSA activities (though was lacking provisions for review and assessment). However, the MOU has expired.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 7, para. 4.7 states that** *"The regulatory body shall prevent or duly resolve any conflicts of interests or, where this is not possible, shall seek a resolution of conflicts within the governmental and legal framework."*
S3	**Suggestion: ARPANSA should consider formalizing its arrangements to independently review its oversight of regulated facilities and activities undertaken by ARPANSA, including their authorization, review and assessment, and inspection.**

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

ARPANSA has 23 positions in the RSB that are directly dedicated to their regulatory functions. About twenty of these positions have competency in a wide variety of technical fields related to radiation protection and nuclear safety. RSB can also draw on the expertise in other sections of ARPANSA in order to discharge its regulatory duties. If ARPANSA requires specialist technical advice to support regulatory activities that do not exist within the agency or in other partner organizations, financial resources and contracts are available to source that expertise externally.

Overall, ARPANSA has been able to leverage resources across the organization to perform their regulatory functions, including the review of several complex files such as the ANSTO Nuclear Medicine Mo-99 Facility and the licensing and oversight of the OPAL research reactor. ARPANSA has developed a Workforce Plan (2017–2021) which notes the identification, development and maintenance of competency requirements. In addition, in 2017, ARPANSA undertook a comprehensive review of all positions in the organization as part of their succession planning. This includes identification of vulnerable areas and priority areas for strengthening resilience of some key competencies.

The IRRS team was informed that ARPANSA has initiated a process to adopt ISO 17020 or equivalent arrangements for all regulatory processes. As a part of that work, ARPANSA has developed and implemented a Qualification Card system with associated defined competencies that all regulatory officers must meet before becoming an Authorized Inspector. Competencies of the Authorized Inspector candidate are formally assessed prior to their designation.

Many of the elements of a comprehensive human resources plan are in place and additional work continues. As discussed in Section 3.1, ARPANSA completed a review of the functions of the regulatory services branch. However, ARPANSA has not yet completed a systematic analysis of their regulatory duties in order to identify the number of staff necessary and the essential knowledge, skills and abilities for them to effectively perform their regulatory functions.

ARPANSA has several elements necessary to support development and maintenance of employee competencies. As noted above, the succession plan included an employee by employee assessment, and the IRRS team was informed that all staff have individual learning plans that identify learning both for development in current role and for future development. ARPANSA has also developed a four-year learning strategy that includes many deliveries focused on knowledge sharing, career development, people management, enterprise capabilities and learning management.

ARPANSA provides training and development to staff, both through formal and experiential based learning. Induction courses provide an overview of the operations of the regulatory body and key processes, and technical courses offered both in house or externally are used to ensure competence in the necessary technical areas. However, ARPANSA has not yet completed the development of a comprehensive training programme that is based on an analysis of the necessary competence and skills.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: ARPANSA has many elements of a human resources plan, including a robust succession programme. ARPANSA has not assessed the number and capabilities of staff required to effectively perform their regulatory and emergency response duties, including a training programme that is based on an analysis of the necessary skills and competencies. This has been recognized in the ARM, and is part of the action plan.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 18, para. 4.11 states that** *"A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions"*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 18, para. 4.13 states that** *"This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements."*
R8	**Recommendation: ARPANSA should enhance its human resource management to include an assessment of the number and capabilities of staff required to effectively perform their regulatory and emergency response duties and enhance their training programme based on an analysis of the necessary skills and competencies.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: In order to identify potential future resource risks, ARPANSA has systematically assessed every position in the organization to identify knowledge management and succession risks and identify mitigation measures to address any risks. These measures have been prioritized based on the risk of losing an essential competency.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 18, para. 4.12 states that** *"4.12. The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."*
GP2	**Good Practice: ARPANSA has a well-developed strategy to compensate for the departure of qualified staff that systematically assessed succession risks for every position in the organization and prioritised the development of competencies that were found to be vulnerabilities to the long-term capability of the organization.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

ARPANSA serves as its own technical support organization and maintains competence of a broad range of technical areas both within the RSB as well as in the other branches and offices that can be called upon as

needed. Further ARPANSA is empowered to bring in external expertise from domestic or international sources to support its regulatory functions.

Three advisory bodies are established through the ARPANS Act:

- The Radiation Health and Safety Advisory Council (RHSAC) advises the CEO on radiation protection and nuclear safety, including advice on the adoption of recommendations, policies, codes and standards. Members are appointed by the Minister following consultation with the CEO and consumer and environmental groups as appropriate.
- 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. Members are appointed by the CEO following consultation with the Council.
- The Radiation Health Committee (RHC) advises the CEO on matters relating to radiation protection, including formulating draft national policies, codes and standards for consideration by the Commonwealth, States and Territories. The RHC, which includes radiation control officers representing all State and Territory radiation regulators, is also a key element of Australia's move towards regulatory uniformity. Members are appointed by the CEO following consultation with the Council. However, the CEO can only appoint radiation control officers that have been nominated by the States and Territories.

The ARPANS Act specifies the objects and membership of each advisory body, and their operations are prescribed in the ARPANS Regulations. All members must provide real or perceived conflict of interest declarations at the beginning of their appointment and it is their duty to ensure that this declaration is updated if circumstances change during the term of appointment. All three advisory bodies have a principal objective to provide advice to the CEO. The RHC and the NSC also support the development of a nationally uniform system of national codes and guides. All advisory bodies operate transparently, minutes and formal advisory documents available on the ARPANSA website. In addition, each advisory body has a member who is accountable to serve as the representative of public interest.

ARPANSA has demonstrated that it makes effective use of the advisory bodies and external experts to support its regulatory functions. ARPANSA has leveraged this capability on complex technical analyses, while maintaining the ultimate decision-making authority and the necessary competency to operate as an intelligent customer.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

ARPANSA uses both formal and informal mechanisms to interface with authorized parties and, consistent with its commitment to transparency, makes most of its dealings with authorized parties available on its public website. In addition to formal inspections and review processes, ARPANSA liaises with authorized parties in a variety of ways. In particular, ARPANSA uses site visits as a vehicle to maintain open discussions with individual licence holders. These site visits supplement the inspection programme and maintain open dialogue with the licence holders on developments in their organization and facilities, as well as providing an opportunity to dialogue on regulatory developments. Similarly, informal meetings are held with licence holders to discuss matters of mutual interest, providing a forum for licence holders to keep the regulatory body apprised of recent developments and long-term plans. It is worthy to note, however, that an independent review following a series of significant events encouraged an improved interface between ANSTO and ARPANSA.

Inspection reports, unless classified on security grounds, are published on the ARPANSA website. This provides transparency for licence 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. In addition, ARPANSA's process to decide on a breach or non-compliance, includes a comment period available to the licence holder, and for natural justice processes, to present any additional information that may be relevant to the determination of non-compliance, the decision of which rests with the CEO or their delegate. 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.

Further, once a decision is made on a licence application, the decision is communicated to the authorized party. All decisions are accompanied by a 'statement of reasons' that outlines the basis for the decision. This statement is usually included in the letter informing the authorized party, but for complex decisions, or decisions which may have significant public interest, it may be in a separate document which is published on the ARPANSA website.

ARPANSA also has mechanisms to engage with the whole licence holder community, hosting an annual Licence Holder Forum 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. In addition, ARPANSA holds periodic regional outreach sessions to engage with local licence holder communities or to target subsets of licence holder groups. In addition, ARPANSA uses the 'have your say' section of its website to invite comment on proposed codes and guides. Finally, ARPANSA seeks feedback on its interactions with licence holders through surveys and maintains a register of compliments and complaints.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

ARPANSA's regulatory approach is described in a regulatory delivery model, and its website provides an overview of its regulatory policy regarding the oversight of facilities and activities. ARPANSA has provided a description of the different regulatory tools that are used by the regulatory body. ARPANSA's regulatory functions are managed through its Regulatory Management System, that includes the Licensing and Assessment Manual, the Inspection Manual and the Compliance and Enforcement Manual. The manuals outline the core regulatory processes and provide the framework that supports consistent and predictable regulatory assessments and decisions. ARPANSA also has a strong practice of engaging staff in the development of new policies and processes. This includes a formal consultation with staff, as well as formal disposition of comments received, prior to approval of the policy or procedure. This step should support engagement with staff in new policy development and help ensure alignment in its application.

ARPANSA's regulatory assessments are performed against published criteria and guidance, helping to ensure that their decisions are predictable and consistent. ARPANSA has published Performance Objectives and Criteria, that form the foundation against which licensee performance is assessed during compliance activities. In order to support consistent application of its regulatory expectations, ARPANSA has an internal process for review, approval and quality control of all assessment and inspection reports. This process includes team and peer reviews and approvals that help ensure that regulatory control is consistent. In addition, as discussed in Section 3.5, reasons for decisions are documented for all licence decisions and inspection findings are provided to authorized parties with supporting facts and findings.

Section 9.1 of this report provides additional details on the processes used to develop and update regulatory requirements. Of relevance to this section, this process includes a formal assessment of the potential impacts of new or amendments to existing codes and regulations.

3.7. SAFETY RELATED RECORDS

As a public entity, ARPANSA is subject to the *Archives Act 1983* and the associated record keeping requirements which together ensure that ARPANSA maintains all official records, including those associated with the facilities and activities that it regulates. All records are maintained in an electronic records management system. In addition, ARPANSA manages licence holder information in their Licence Administration Database (LAD) and supporting systems, which maintain key information for all licence holders. The LAD includes information on ARPANSA's licence holder inventories of sealed sources, radiation devices and waste.

ARPANSA maintains certain national databases: the Australian National Radiation Dose Register (ANRDR), a central record database for occupational radiation dose records and the Australian Radiation Incident Register (ARIR), which records radiation incidents across the country. The ANRDR was established in 2010 primarily for the uranium mining industry, and now contains dose records from workers from all Australian uranium mines. In 2017, it became mandatory for all ARPANSA licence holders. States and Territories have also signalled their intent to promote the register. The ANRDR is discussed further in Section 11.1. The ARIR receives reports on incidents that occur across all nine jurisdictions of Australia. These reports are analysed and trends in reports are reviewed. ARPANSA produces an annual report that outlines trends in reported events, highlighting common root causes and corrective actions. This report provides a tool for licence holders to identify potential improvements to their own programmes and practices.

ARPANSA's records management system contains all records received from licence holders including all records related to the safety of facilities and activities. The records management system would also include any records that might be necessary for the shutdown and decommissioning (or closure) of facilities.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

There is a clear commitment to transparency in ARPANSA's activities, with a well-developed and comprehensive website including a variety of information from general radiation information to regulatory assessment reports and inspection reports. ARPANSA's website also includes the complete regulatory framework, including applicable codes and guides. ARPANSA also supports direct engagement, hosting "Talk to a Scientist" sessions twice a week that invite direct questions from the public in addition to providing general contact information. Further, ARPANSA has a presence on social media, including YouTube, Facebook and Twitter.

ARPANSA has demonstrated a recognition of the importance of engagement with the Australian public and has held information and outreach sessions with interested members of the public when considering the authorization of major projects. Material and outcomes of these meetings are also available on their website. Further, the regulatory body makes major licensing decisions and reasons for those decisions available on their website. The "Have Your Say" section of the website is used to engage with authorized parties and interested parties in order to solicit input to proposed regulatory codes and guides. This is discussed further in Section 9. In addition, as noted in Section 3.7, summary reports on event and incident trends are made available on an annual basis.

It is worthy to note that despite ARPANSA's evident effort to provide transparent regulatory information, there are currently no requirements on authorized parties to provide the same. There would be a benefit to requiring licence holders to have similar outreach and engagement activities that are targeted directly to the communities in which they operate.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: ARPANSA has a robust and transparent approach to communicating with interested parties. However, ARPANSA does not have requirements for authorized parties to undertake similar communication activities, other than during emergency situations. Some evidence of licensee's communications with interested parties does exist.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 36, para. 4.66 states that** *"The regulatory body shall establish, either directly or through authorized parties, provision for effective mechanisms of communication."*
(2)	**BASIS: GSG-6, para. 3.2 states that** *"The regulatory body should place requirements on authorized parties to inform and, when appropriate, consult interested parties about the radiation risks associated with the operation of a facility or the conduct of activities, including the results of the safety assessment. The regulatory body should also place requirements on authorized parties to make available to relevant interested parties decisions with regard to measures for protection and safety. These requirements should be specified in regulations promulgated by the regulatory body, in the authorization or by other legal means."*
(3)	**BASIS: GSR Part 2 Requirement 5 states that** *"Senior management shall ensure that appropriate interaction with interested parties takes place."*
S4	**Suggestion: ARPANSA should consider developing and implementing requirements for authorized parties to establish effective mechanisms of communication with interested parties.**

3.9. SUMMARY

The IRRS team reviewed the responsibilities and functions of the regulatory body, focusing, for this section, on the Commonwealth regulatory body, ARPANSA. Overall, the IRRS team found that ARPANSA is a mature and competent regulator, with strong practices to develop their competencies, ensure consistent and comprehensive regulatory oversight and effectively engage with authorized and other interested parties.

The IRRS team found some areas for improvement related to the need to formalize external reviews of its self-regulation, strengthen human resource management and training and develop and implement requirements for authorized parties to engage with the public. The IRRS team also found a good practice with respect to ARPANSA's comprehensive succession planning framework.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

This section of the report is limited to the Commonwealth regulatory body, ARPANSA, and does not address the State and Territory regulatory bodies.

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

The CEO of ARPANSA has regulatory functions under the ARPANS Act for the management of radiation risks. The leadership for and commitment to safety by the senior management is stated in the ARPANSA´s Work Health and Safety (WHS) Policy and the WHS Manual, which are fundamental components for ARPANSA safety. The WHS policy outlines the management commitment related to safety, such as to provide a safe environment for employees, contractors and visitors; prioritise safety with other organizational goals and thereby achieve business objectives without undue risk; the safety of all ARPANSA activities through the promotion of core values, beliefs and behaviors; ensure that continuous improvements are measured, evaluated and reported against the agency goals and objectives; consult with key stakeholder, experts and the workforce for safety improvements; and report, investigate and learn from all workplace incidents and near misses.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

ARPANSA has developed a holistic approach to safety that encompasses technological, human and organizational factors through seven key characteristics: human factors; non-technical skills; resilience; defence in depth; management systems; safety and security culture. ARPANSA's own commitment to holistic safety is stated in the WHS policy and is communicated to applicants and licence holders through ARPANSA's website, published regulatory guides, written communication, inspections and other interactions. However, the IRRS team found that, although mentioned in policy documents and plans, interested parties have not yet been identified in the Integrated Management System (IMS) that is currently under development. Moreover, at this stage ARPANSA does not have a well documented strategy for interactions with every interested party.

The IRRS team was informed that ARPANSA has an integrated planning, budgeting and performance reporting process that is risk-informed with defined linkages between the strategic priorities, key planning documents and the business plans. All these documents are reviewed against the safety objectives according to the yearly planning cycle.

4.3. THE MANAGEMENT SYSTEM

ARPANSA has multiple management systems, such as the Regulatory Management System, Work, Health and Safety Management Manual, and separate quality management systems for each of the laboratories. These systems cover many of the specific requirements in GSR Part 2 and align with ISO9001 and ISO45001. Some of the ARPANSA laboratory services are also accredited against ISO17025. Within these systems there is a range of policies, objectives, plans and procedures. ARPANSA's regulatory business is undertaken in accordance with a Regulatory Management System (RMS) that includes arrangements for regulatory functions and its own administration and continuous improvement.

In October 2016, ARPANSA started an agency project to design and implement an IMS, with the vision for the IMS being "one agency, one system, one outcome". ARPANSA applies a top down strategy in the development with the objective to connect all of ARPANSA´s systems and processes into one complete framework. The objective is to achieve their strategic objectives, while integrating elements such as quality,

safety, security and risk. The IMS project also includes updating, centralising and organising documentation to ensure that information is up to date and can be easily accessed. The IRRS team was informed that progress is regularly communicated to staff through presentations, ARPANSA Newsletters, and the Intranet (ISAAC).

The IRRS team concluded that the first phase of the work was recently completed, and that several over-arching frameworks and manuals are now in place. Regulatory processes contained within the RMS will be integrated during the second phase of the IMS project. An "IMS page" on ISAAC, is a new portal for identifying information, needed to do the work, including policies, procedures forms etc. The IRRS team found other items in the IMS incomplete such as: the identification of interested parties and an appropriate strategy for interaction with them (see 3.8); processes being satisfactorily identified, defined and described (see 4.5); management of organizational changes; and an implemented procedure for the management review of the IMS.

The ARPANSA Risk Management Framework being the core of the IMS, embraces a range of risks such as; risks to the ability to carry out the statutory functions; risk to employees and assets; and radiation risks to people and environment. The risk management processes provide the link between ARPANSA´s strategic objectives and the operational business plans and sets the foundation upon which the performance management framework is based. The IRRS team found this framework to be a comprehensive way of integrating all types of risks in the management processes, the regulatory activities, and in day-to-day work activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: ARPANSA´s Risk Management Framework is the core of the IMS while it is embracing a range of risks such as; risks to the ability to carry out the statutory functions; risk to employees and assets; as well as radiation risks to people and the environment. This comprehensive way of integrating all types of risks sets the foundation for how the performance management framework is built.	
(1)	**BASIS: GSR Part 2, Req. 7 para 4.15 states that** *"The criteria used to grade the development and application of the management system shall be documented in the management system. The following shall be taken into account:* *…* *b) The hazards and the magnitude of the potential impacts (risks) associated with the safety, health, environmental, security, quality and economic elements of each facility or activity;* *….*
GP3	**Good Practice: ARPANSA applies a holistic and comprehensive way of integrating all types of risks in the management processes, the regulatory activities, and day-to-day work activities, providing a strong foundation for their performance management framework.**

4.4. MANAGEMENT OF RESOURCES

To ensure that ARPANSA can deliver intended objectives, regulatory resourcing and other requirements are addressed through business and strategic planning led by senior management in accordance with the ARPANSA Planning and Performance Framework. The IMS project is being developed and implemented using the ARPANSA Project Management Framework. This framework is applied on projects meeting certain criteria, which includes cost, duration of the project, complexity, risk, strategic or political importance, and impact on the organization. The ARPANSA Executive Group provide governance and oversight of this kind of Agency projects, including project approval. A fundamental principle of the IMS

project, the IRRS team found, is executive leadership and commitment to the project by ensuring sufficient resources are provided for the development of the management system.

The IRRS team was informed that staff training is conducted on a regular basis and each staff member commits to an individual plan as part of the annual performance review with the target to meet ARPANSA´s strategic direction. Regulatory officers have been provided training in, among other things, holistic safety so that they are able to identify weakness in human, organizational and technological factors including the safety culture of licence holders. ARPANSA has recently launched an electronic learning management system, LearnHub, which has the functionality to store records of capabilities, courses available aligned to capabilities, as well as the completion of courses by individual employees. Recently a module was available in LearnHub to introduce staff to the concept of safety culture.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

ARPANSA´s Regulatory Services Branch (RSB) has an established Regulatory Management System (RMS), which includes procedures for core regulatory activities such as Inspections; Licensing and Assessment; and Compliance and Enforcement. These procedures support ARPANSA´s Policy for Regulatory Activities, which constitutes an over-arching framework for ARPANSA's regulatory functions.

Documents are managed and controlled in accordance with the ARPANSA quality system, supported by the ARPANSA record management system. The IRRS team was informed that documents and records within the records management system are at present controlled separately in accordance with the requirements of the RMS. In the record management system there is a compilation of quality documents present in the RMS and a procedure for managing the RMS, which includes the review of documents such as procedures and ARPANSA regulatory guidance. The RMS is controlled and maintained within the RSB, with clear accountability and authority.

The IRRS team was informed that the integrated management system (IMS) is intended to capture all regulatory processes as well as processes that support regulatory activities. However, the IRRS team found that some of the regulatory functions for instance; a process for establishing, promoting, reviewing and updating ARPANSA guides, were not defined, described and integrated into the IMS.

Although ARPANSA has a range of policies, objectives, plans and procedures in place, methods for the identification, development and modification of processes within the IMS are lacking. The IRRS team concluded that ARPANSA´s core and supporting processes are not comprehensively identified, defined and implemented. As a consequence, the interactions between processes are not fully elaborated. The objective of the ongoing work to develop and implement an IMS is to incorporate and connect existing systems for quality management, and to provide for continual improvement across all processes, procedures and functional areas.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: ARPANSA has completed the first phase in the development and implementation of an integrated management system (IMS) that incorporates and connects existing systems for quality management and integrates all regulatory functions, but the work is not finalized. Regulatory processes will be integrated during the second phase of the IMS project. ARPANSA has not developed methods for the identification, development and modification of its processes within the IMS. ARPANSA´s core and supporting processes are not comprehensively identified, defined and implemented across the agency, and the interactions between processes are not fully elaborated. This has been partly recognized in the ARM and is part of the action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**GSR Part 2, Requirement 10 states that** *"Processes and activities shall be developed and shall be effectively managed to achieve the organization´s goals without compromising safety."* *4.32 Each process or activity that could have implications for safety shall be carried out under controlled conditions, by means of following readily understood, approved and current procedures, instructions and drawings. These procedures, instructions and drawing shall be validated before their first use and shall be periodically reviewed to ensure their adequacy and effectiveness. Individuals carrying out such activities shall be involved in the validation and the periodic review of such procedures, instructions and drawings."*
(2)	**GSR Part 2, Req. 10 para 4.28 states that** *"Each process shall be developed and shall be managed to ensure that requirements are met without compromising safety. Processes shall be documented…"*
(3)	**GSR Part 2, Req. 10 para 4.29 states that** *"The sequencing of a process and the interactions between processes shall be specified so that safety is not compromised. Effective interaction between interfacing processes shall be ensured. Particular consideration shall be given to interactions between processes within the organization, and to interactions between interactions between processes conducted by the organization, and to interactions between processes conducted by external service providers."*
(4)	**GSR Part 2, Req. 10 para 4.32 states that** *"Each process or activity that could have implications for safety shall be carried out under controlled conditions, by means of following readily understood, approved and current procedures, instructions and drawings. These procedures, instructions and drawing shall be validated before their first use and shall be periodically reviewed to ensure their adequacy and effectiveness. Individuals carrying out such activities shall be involved in the validation and the periodic review of such procedures, instructions and drawings."*
R9	**Recommendation: ARPANSA should further define, develop, and document its processes including sequencing of the processes and the interactions between interfacing processes within the IMS.**

4.6. CULTURE FOR SAFETY

ARPANSA´s WHS policy promotes a positive safety culture. The policy states that safety is everyone's responsibility. The CEO chairs the ARPANSA WHS Committee and ARPANSA's Executive Group has additional responsibilities to allocate resources, provide instruction and ensure compliance. The IRRS team was informed that safety is a key value for all ARPANSA staff and addressed at different occasions and meetings where the CEO encourages and supports individuals to achieve safety goals. The importance of safety is a key component in the induction programme for new employees. All members of staff are expected to be actively engaged in safety matters and are encouraged to raise safety concerns and report hazards and incidents by using a Report Card form or a Hazard and Incident form available on the intranet. Staff are also welcome to participate in different forums which aim to enhance safety performance, e.g. the consultation process on the development of policies and procedures via the ARPANSA intranet.

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The IRRS team was informed that the *WHS Safety and Objectives and Targets Procedure* provides a mechanism for the agency to measure safety performance and a commitment to continuous improvement in safety. Reporting to the Executive Group is done on a quarterly basis to ensure that senior management

has visibility of the agency's safety performance. Safety performance results are also reported to the Work Health and Safety Committee, Radiation Safety Committee, Audit and Risk Committee and Staff Consultative Forum on a quarterly basis.

The ARPANSA Planning and Performance Framework outlines the Agency's approach to business planning and performance monitoring. In accordance with this framework ARPANSA´s performance is reported on a quarterly basis to the Strategic Management Committee and the Audit and Risk Committee. In addition, ARPANSA is required to undertake an annual assessment of its regulatory performance under the Australian Government Regulator Performance Framework.

The IRRS team was informed that ARPANSA has an on-going internal audit programme 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 programme that provides assurance to ARPANSA's Executive Group and Audit and Risk Committee about the Agency's processes, governance, performance reporting and systems of internal control and risk management. However, the documented procedure for internal audits is still in draft. The team was informed that the details of "management review" of the management system are still to be developed.

The Non-Conformance and Continuous Improvement Management procedure provides the framework to ensure that all non-conformances are systematically reported and investigated in a timely manner to establish the root cause(s) and evaluate their effects on the safety and effectiveness of the service, product and processes. All non-conformances, corrective and preventative actions and continuous improvements including all audit findings are recorded in the Issue Management Register available to all staff members.

To date, ARPANSA has not undertaken a full assessment of the organization´s safety culture. However, a decision has been made to carry out an assessment of leadership and safety culture of ARPANSA´s regulatory functions, and funding has been provided. Employing external expertise at this stage, the key objective will be to build internal capacity to undertake further assessments in the future. The planned assessment will be undertaken in early 2019 and will provide ARPANSA with a baseline of the current safety culture. The team was informed that, after an evaluation of the project has occurred, ARPANSA will extend the assessment across all functions of ARPANSA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: ARPANSA has made a commitment to conduct an assessment of leadership and safety culture of ARPANSA´s regulatory functions, however, this assessment does not cover all levels and functions of the organization. This has been recognized in the ARM and is part of the action plan.	
(1)	**BASIS: GSR Part 2, Requirement 14 states that** *"The senior management shall regularly commission assessments of leadership for safety culture in its own organization."*
(2)	**BASIS: GSR Part 2, Req. 14 para 6.9 states that** *"Senior management shall ensure that self-assessment of leadership for safety and of safety culture includes assessment at all organizational levels and for all functions in the organization. Senior management shall ensure that such self-assessment makes use of recognized experts in the assessment of leadership and of safety culture."*
(3)	**BASIS: GSR Part 2, Req. 14 para 6.10 states that** *"Senior management shall ensure that an independent assessment of leadership for safety and of safety culture is conducted for enhancement of the organizational culture for safety (i.e. the organizational culture as it relates to safety and as it fosters a strong safety culture in the organization)."*
(4)	**BASIS: GSR Part 2, Req. 14 para 6.11 states that** *"The results of self-assessments and*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	independent assessments of leadership for safety and of safety culture shall be communicated at all levels in the organization. The results of such assessments shall be acted upon to foster and sustain a strong safety culture, to improve leadership for safety and to foster a learning attitude within the organization."
R10	**Recommendation: ARPANSA should undertake an independent assessment of leadership for safety and safety culture covering all organizational levels and all functions in the organization.**

4.8. SUMMARY

The IRRS team reviewed the management system of the regulatory body. The leadership for and commitment to safety are stated in ARPANSA´s over-arching policies. ARPANSA is applying a Risk Management Framework, which embraces and integrates all types of risks. This comprehensive framework sets the foundation upon which the performance management framework is based. This approach goes beyond standard international practice.

ARPANSA has identified a need to develop an IMS and has completed the first phase of its development. While regulatory processes are documented within the Regulatory Management System, further work is needed to comprehensively identify, define and implement all core processes within the IMS. ARPANSA has adopted a holistic safety approach including human factors, non-technical skills, resilience, defence, in-depth management systems, safety and security culture, however, it has not yet undertaken a full assessment of its safety culture.

5. AUTHORIZATION

This section covers all Australian jurisdictions on generic issues (5.1), and from most jurisdictions 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 ARPANSA only.

5.1. GENERIC ISSUES

As per legislation in Australia, the responsible 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. Overall, there are more than 13 000 radiation licences allowing possession and more than 50 000 individual radiation use licences. These cover a range of medical, industrial and commercial applications. Each jurisdiction's regulatory body grants authorization under its specific jurisdiction legislation.

Within all jurisdictions, there is a level of independence between the appropriate regulatory bodies for radiation safety and other areas within organizations dealing with spent fuel or radioactive waste management, with the exception that the regulatory bodies all have some sources and store a small quantity of radioactive waste. Some jurisdictions have a form of executive management, independent of the regulatory body that can make decisions upon the safe management of facilities belonging to the regulatory body.

Within each jurisdiction the legislation enables the regulator to refuse to grant an authorization if the applicant is not a fit and proper person and it is necessary to do so in the interests of public health and safety; or the proposed use of radiation is inappropriate or unjustified. Further, the jurisdictional legislation enables the regulator to suspend, vary or cancel an authorization in specific situations. The Commonwealth, States and Territories have all agreed, via the NDRP processes, that whenever a regulatory body makes a decision to suspend, vary or cancel an authorization, all other relevant regulators within and outside of its jurisdiction should be advised of the decision.

ARPANSA manages the authorization of import and export permits for radiation sources on behalf of the Department of Home Affairs. While an import permit is required for any radioactive substance, an export permit is only required for Category 1 or Category 2 radioactive sources. Before granting an import permit, ARPANSA consults the regulatory body controlling the proposed end-user. ARPANSA also considers the contractual arrangements set to repatriate security enhanced sealed sources. While these arrangements demonstrate an adequate implementation of the provisions of the Code of Conduct on the Safety and Security of Radioactive Sources, ARPANSA has noted that the different criteria between imports and exports of radioactive materials does not currently provide visibility of all movements of radioactive material.

Most regulatory bodies also authorize or accredit experts to perform certain functions such as equipment verification (e.g. a compliance test), or to provide certain services. Licence conditions may be imposed, as needed. Additionally, notifications or approvals are required for some activities such as specific types of disposal, transport or management of incidents.

ARPANSA and all State and Territory regulatory bodies maintain records of applications and authorizations within their records management systems. 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. NSW and TAS regulatory bodies indicated that their IT systems were effectively fulfilling their needs. As a result of the self-assessment, ARPANSA identified an action to investigate options to enhance its current system for the management of regulatory information associated with licence holders and regulatory activities.

Several regulatory bodies in States and Territories (e.g. VIC, QLD, WA) indicated that their current IT systems do not meet their needs for an efficient processing of licence application and management of licences and that enhancement would be desirable, to, amongst other things, allow applicants and licence holders to directly upload data related to their licence. Victoria and Queensland indicated that they currently had projects underway to replace or enhance their existing systems.

The Mutual Recognition Act (1992), has been established in all jurisdictions, to facilitate the business of companies working in several jurisdictions. Once a company has been licensed in one jurisdiction (State A for example), it can complete a request for recognition in another jurisdiction (State B for example) and immediately start working in State B. The regulatory body of State B has one month to determine whether the licence issued in State A is equivalent to a licence issued in State B. Several regulatory bodies indicated that it would be valuable to clarify, for example through a publication in the NDRP framework, the equivalences between States and Territories. To this end, a comparison across all jurisdictions of licence wording for typical practices is encouraged. This is discussed in Section 1.2 of this report.

For ARPANSA licence holders any change with significant implications for safety requires prior approval and may also require an amendment of the licence, while non-significant changes require only notification to the regulatory body.

Under the ARPANS Act, ARPANSA issues authorization for each stage of the life cycle of controlled facilities, and dealing with (possession, control, use or operation, and disposal) of controlled material or controlled apparatus. The ARPANS Act contains provisions specifically prohibiting the issuance of a licence for: a nuclear fuel fabrication plant; a nuclear power plant; an enrichment plant; a reprocessing facility.

5.2. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

ARPANSA issues source and facility licences for practices identified in the ARPANS Act, i.e. to Commonwealth entities and their contractors. Source licences cover a range of risks from baggage x-ray scanners, to industrial radiography, small laboratories, and medical use. These are categorised by their inherent hazard into three groups, which are specified in 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. 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).

In most States and Territories, activities requiring authorization are limited to dealing with sources. As such, site preparation or construction are typically not licensable activities until a source is possessed or used. Additionally, arrangements are in place in all jurisdictions, such as shielding plan requirements and sale or supply licences or restrictions on supply, which effectively introduce controls on the construction of facilities where radiation sources are employed. Applications and notifications include:

- applications for management and possession licences, for individuals or companies, are required in all jurisdictions;
- user licences, for individuals dealing with sources, require an application in most jurisdictions, which includes maintenance, service and testing;
- registration of individual sources requires an application in most jurisdictions and notification in other jurisdictions;

- 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 authorisation.

The licensing requirements vary between jurisdictions as indicated in the table below:

	NSW	VIC	TAS	SA	QLD	ACT	NT	WA	Commonwealth
Management licence	✓	✓	✓	#	×	×	×	✦	✓
Possession licence	*	*	*	✓	✓	✓	✓	✦	*
Equipment/place registration	*	*	*	✓	✓	✓	✓	✦	× Notification only
User licensing	✓	✓	✓*	✓	✓	✓	✓	✓	×

* Captured under management licence (e.g. individually listed on licence)
✦ In WA, registrations may include possession and management licence requirements
In SA, licences associated with mining are considered 'management licences' these are Licence to carry out mining and mineral processing, Licence to test for developmental purposes and a Facilities licence.

Accreditation is the formal recognition of a person to perform a safety related function. For some safety related functions which involve dealing with radiation sources, a personal authorization (accreditation) may also be required. Examples of accreditations or approvals granted by some jurisdictions include:

- security plan/transport security plan approved assessors
- compliance testers
- shielding plans
- radiation safety officers
- medical physicists/qualified experts.

Each jurisdiction's laws and regulations establish the contents of applications to be submitted for initial, and where applicable, renewal of the authorization. Information on documentation that is required to be submitted to the regulatory body prior to authorization, including safety assessments such as those that are covered by the radiation management plans, is provided on the jurisdictions' websites.

In most jurisdictions that require source registration, evidence of a satisfactory compliance test is required prior to use, as part of the registration process. These tests are required at either a set frequency or when re-applying for registration (renewal).

The assessment of applications for licences may be 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 reviewed by the regulator. This is achieved via licence conditions or registration or via staged facility licences, depending on the jurisdiction and source.

In States and Territories, authorizations are issued for a fixed term, being one year or up to three years in most jurisdictions. All regulatory bodies have the legal basis to include conditions in an authorization.

In all jurisdictions, where changes to the authorization occur, e.g. in relation to any particulars that appear on a licence, an application to amend the authorization is required. With respect to terminating or surrendering a licence or disposal of a radioactive source, all jurisdictions have regulatory processes to control this step. This allows implementation of a cradle to grave approach.

In most States and Territories, processing applications for new, modified or renewed licences results in a significant workload. The IRRS team was informed that, in a number of cases, the assessment was largely administrative and impacted the ability to devote time to perform inspections (see Section 7.2).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Several State and Territory regulatory bodies indicated that amendments of licences in order to update the list of sources or apparatus or renew user licence, result in a significant workload, more often as a result of administrative rather than technical issues. In some jurisdictions, the maximum duration of authorization is set by the law.	
(1)	**BASIS: GSR Part 1 (Rev 1) para. 2.5 states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following: …* *(3) The type of authorization* that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach; …* *(8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach …"* ** Authorization' includes approval, written permission, licensing, certification or registration*
(2)	**BASIS: GSR Part 3 defines registration as** *"A form of authorization for practices of low or moderate risks whereby the person or organization responsible for the practice has, as appropriate, prepared and submitted a safety assessment of the facilities and equipment to the regulatory body. The practice or use is authorized with conditions or limitations as appropriate.* *The requirements for safety assessment and the conditions or limitations applied to the practice would be less severe for registration than those for licensing."*
(3)	**BASIS: GSG-13 para. 3.76 states that** *"The concepts of notification, authorization by registration, and authorization by licensing broadly represent a graded approach to regulatory control based upon the levels of risk or the nature of the facility or activity"*
S5	**Suggestion: The State and Territory regulatory bodies should consider reviewing their requirements for authorization (authorization by licence vs authorization by registration and duration of an authorization), based on their regulatory experience and risks, with the goal of making better use of existing regulatory resources.**

5.3. AUTHORIZATION OF RESEARCH REACTORS

The OPAL reactor, a 20 MW multi-purpose pool type reactor, is currently the only operational research reactor in Australia. The OPAL facility construction licence was issued in April 2002. The licence authorizing operation of the reactor, including hot commissioning, was issued in July 2006.

The HIFAR reactor, a tank type reactor rated at 10 MW, was operated for 49 years and was shutdown permanently on 30 January 2007. The reactor has been de-fuelled. Additionally, the Moata reactor, an Argonaut type reactor, was shut down in 1995 and has been decommissioned.

According to the ARPANS Regulation 1999, the authorization process applicable to research reactors is divided into site preparation, construction, possess or control, operation, decommissioning and abandonment. The safety of research reactor design is reviewed at construction licence stage. The safety of commissioning is reviewed during both the construction and operation licence stages.

ARPANSA has made a commitment to align its regulatory framework with international standards. Where possible and deemed appropriate, relevant IAEA safety standards and other sources of international best practice are used in conjunction with ARPANSA regulatory guides. A complete gap analysis is underway to identify if all requirements previously captured in the outdated guide are covered by the relevant international standards.

The IRRS team noted that while ARPANSA has adopted IAEA Safety Standard SSR-3, the safety case for the OPAL reactor does not address extended shutdown of the reactor. ARPANSA should determine the regulatory criteria to be met by the licensee during extended shutdown of the OPAL Reactor. ARPANSA is encouraged to review this matter during the next periodic safety review.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: In ARPANS Regulations there is no authorization Stage for extended shutdown. An analysis comparing the ARPANSA requirements and guidance against current safety standards is currently underway and was described in the ARM.	
(1)	**BASIS: GSR Part 1 (Rev 1), para. 4.29 states that** "For a facility, the stages in the lifetime usually include: site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure)."
(2)	**BASIS: Code of Conduct on the Safety of Research Reactors, Code 20** states that "The regulations and guidance established by the State or the regulatory body according to national arrangements should (t) Where necessary in national circumstances, establish criteria for the safety of research reactors in extended shutdown".
(3)	**BASIS: SSR 3 requirement 87 states that:** *If an extended shutdown is planned or occurs, the operating organization for a research reactor facility shall establish and implement arrangements to ensure the safe management, planning, effective performance and control of work activities during the extended shutdown.*
S6	**Suggestion: ARPANSA should consider revising the regulation and guidance for licensing of research reactors to include extended shutdown and associated submission requirements.**

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Regulation of spent fuel management is only undertaken within the Commonwealth jurisdiction by ARPANSA. Spent fuel management is regulated under a facility licence authorising the operation of the relevant facilities.

The legislative framework established by all Australian jurisdictions prohibits the use of non-exempt radioactive material (including radioactive waste) and ionising apparatus without an authorization or exemption. This requires the material/apparatus/premises to be registered, or the subject of a licence condition requiring a detailed inventory to be maintained, and subject to regulatory compliance monitoring, including inspection. In most jurisdictions, licensing is also required for radioactive waste stores operated by the regulator.

5.5. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

Within the Commonwealth, in accordance with the provisions of the ARPANS Act, a controlled person must not decommission, dispose of or abandon a controlled facility except under the authority of a licence issued by ARPANSA. The ARPANS Regulations specify that a decommissioning plan and a schedule for

decommissioning of the controlled facility are mandatory in support of an application for a decommissioning licence. For abandonment (the release of a site from regulatory control) of a controlled facility, the information that may be requested includes the results of decommissioning activities and details of any environmental monitoring programme proposed for the site. Prior to issuing a licence to abandon/surrender a site, ARPANSA verifies that all regulatory requirements and end state criteria, as specified in the final decommissioning plan and in the authorization for decommissioning, have been met.

The IRRS team noted that there is no explicit legislative requirement for an initial decommissioning plan as part of the siting or construction phase of a new facility or nuclear installation. Decommissioning plans are only required prior to the start of decommissioning and in support of the decommissioning licence application. ARPANSA has developed a regulatory guide, "Decommissioning Guide for Controlled Facilities" that explicitly requests decommissioning plans throughout the different licensing stages. ARPANSA plans to include the guide as a condition of licence and will in the longer term seek to update the ARPANS Regulations with regard to decommissioning requirements.

The IRRS team noted that there was consideration of decommissioning during the construction licence approval granted for the OPAL Reactor and ANSTO Nuclear Medicine (ANM) Facility.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: ARPANS regulations only specify submission of a decommissioning plan for a decommissioning licence application. ARPANSA has developed a decommissioning guide which requires a decommissioning plan for all licensing stages of a facility. The need to implement this as a requirement has been recognized in the ARM and is part of the Action Plan.	
(1)	**BASIS: GSR PART 6 Requirement 5: Responsibilities of the regulatory body for decommissioning states that** *"The regulatory body shall regulate all aspects of decommissioning throughout all stages of the facility's lifetime, from initial planning for decommissioning during the siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning. The regulatory body shall establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall adopt associated regulations and guides. The regulatory body shall also take actions to ensure that the regulatory requirements are met."*
	Basis GSR PART 6 paragraph 7.5 states that *"The decommissioning plan shall be updated by the licensee and shall be reviewed by the regulatory body periodically (typically every five years or as prescribed by the regulatory body), or when specific circumstances warrant, such as if changes in an operational process necessitate significant changes to the plan. The decommissioning plan shall be updated as necessary in the light of relevant operational experience gained, available lessons learned from the decommissioning of similar facilities, new or revised safety requirements, or technological developments relevant to the selected decommissioning strategy. If an accident occurs or a situation arises with consequences relevant for decommissioning, the decommissioning plan shall be updated by the licensee as soon as possible and shall be reviewed by the regulatory body."*
S7	**Suggestion: ARPANSA should consider revising the conditions of licence to require decommissioning plans for all life stages of the facility.**

5.6. AUTHORIZATION OF TRANSPORT

There are eleven competent authorities for transport of radioactive material in Australia, as listed in the Code of Practice for the Safe Transport of Radioactive Material RPS C-2. These are ARPANSA, State and Territory regulatory bodies, the Civil Aviation Safety Authority and the Australian Maritime Safety Authority. Responsibilities are assigned by mode of transport, relation of the shipment to Commonwealth entities and the jurisdiction where the shipment takes place. All these competent authorities may issue the approvals specified in the IAEA Regulations for the Safe Transport of Radioactive Material (SSR-6). Some competent authorities carry out these functions from time to time, but most rely on ARPANSA to provide these approvals, or they request assistance from ARPANSA in their review and assessment. All jurisdictions recognize ARPANSA issued authorizations, even if this is not formally agreed.

Additionally, a person seeking to transport radioactive material must do so under the authorization legislation of the local jurisdiction. Therefore, a person transporting material across several States or Territories must be authorized in each applicable jurisdiction where the material is transiting, except for ARPANSA licence holders who are not required to hold State and Territory authorization as ARPANSA's jurisdiction covers controlled persons irrespective of which State or Territory they are in.

Depending on the jurisdiction, transport authorizations may be covered by the management licence of the organization responsible for the material, the organization transporting the material, or the individual transporting the material.

5.7. SUMMARY

The IRRS team reviewed the regulatory framework for authorization in Australia. The IRRS team noted that while all jurisdictions have the legal basis to perform authorization, the implementation of the individual systems is not consistent across all jurisdictions.

Identified areas for improvement include the effectiveness of the current authorization processes, in the States and Territories, in the light of operational experience and application of a graded approach, updating regulatory requirements to address extended shutdown for research reactors and decommissioning of facilities in the Commonwealth during all licensing stages.

6. REVIEW AND ASSESSMENT

This section covers all Australian jurisdictions on generic issues (6.1), and most jurisdictions 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 ARPANSA only.

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

In Australia, a responsible 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 authorization, when varying the authorization and at certain other instances, the relevant regulatory body will perform a 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 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 National Directory for Radiation Protection (NDRP), as agreed from time to time by jurisdictional regulators at meetings of the RHC and subsequently by Australian Health Ministers. Where applicable, the agreed requirements of the NDRP are considered during the review and assessment.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

While each regulator has resources available for review and assessment, the number of assessors varies amongst the regulatory bodies. Recommendations with regard to the uniform or harmonized application of requirements during review and assessment as well as competence of regulatory staff have been made in sections 1.2 and 1.8 respectively.

ARPANSA has approximately 20 regulatory staff who perform review and assessment. The Regulatory Services Branch is supported by ARPANSA staff in other branches with expertise in radiation protection, dosimetry, emergency preparedness, risk assessment, legal, communications and other relevant areas as required Additionally, where necessary, ARPANSA engages experienced contractors to assist in the undertaking of review and assessment activities.

Advisory bodies, committees and councils are used by the regulatory bodies where additional external expertise are desirable, such as for complex applications or policy decisions. For ARPANSA, the primary advisory body for this purpose is the Nuclear Safety Committee. In some jurisdictions, such as ACT, a statutory body approves authorizations and performs reviews and assessments where applicable.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

The principal basis for review and assessment include the relevant jurisdictional legislation, and the national and international codes or standards that may or may not be formally adopted in a jurisdiction but which apply to the type of application under consideration. The applicable national codes are available on the

ARPANSA website, together with a listing of the relevant codes for each of the different types of sources and facilities.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

National agreements on requirements are compiled in the NDRP, as agreed from time to time by jurisdictional regulators at the RHC and, subsequently, by Australian Health Ministers. Where applicable, the requirements of the NDRP are considered during the review and assessment. ARPANSA staff may undertake site visits and hold regular meetings, to confirm information required for review and assessment.

In accordance with a graded approach, periodic reviews by the licence holder that are assessed by ARPANSA, are only required for the high hazard facilities. The IRRS team was informed that the frequency of the periodic review varies between 5 and 10 years. This requirement is not documented in regulatory requirements but is included as a condition of licence on a case by case basis. However there is also a requirement on licence holders under Regulation 50 of the Regulations to review their plans and arrangements for managing safety at least once every three years.

6.2. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Assessment of applications is performed to ensure that:

- the use of the source is justified – in each jurisdiction, the regulatory body considers the justification of the practice as part of the application process. Detail on the justification must be supplied in the radiation management plan or as evidence in other supporting documentation. The level and detail of information supplied in support of the application is based on a graded approach;
- measures are implemented to ensure protection is optimized;
- dose limits are complied with where applicable;
- jurisdictional regulatory requirements are complied with;
- the applicant has the capacity to comply with the requirements.

Where applicable, consistency with the codes and guidance in the NDRP is considered. The principal basis for all review and assessment is the relevant jurisdictional legislation, and the national codes that are adopted in a jurisdiction, which apply to the type of application. These assessments focus heavily on the "plans and arrangements" or "radiation management plan" which outlines the commitments made by the applicant or licence holder, recognizing that compliance with this plan is generally a condition of licence.

All regulatory bodies have the ability to request additional information. All follow documented procedures for review and assessment of applications, which are maintained in their respective quality systems. Their level of detail varies. For example, at ARPANSA, requirements related to review and assessment are captured in the ARPANSA Licensing and Assessment Manual. Before issuing a licence or granting a significant variation, ARPANSA documents its review and assessment in a Regulatory Assessment Report (RAR). Templates for the RAR have been developed, taking into account a graded approach.

The State and Territory regulatory bodies generally document their review and assessment using checklists. Depending on the application, this assessment may include review by an advisory body to the regulator. Applications for non-standard practices receive additional scrutiny and often result in exchanges with the applicant.

Applications for significant changes to an existing licence are reviewed and assessed in the same manner as a new application. Review and assessment of an application to renew a time limited licence is generally done in a simpler way, largely administrative, when there are no changes compared to the current licence. This is especially true for user licences. As some licences issued by ARPANSA may not be time limited, ARPANSA performs a review of each licence every 3 years to ensure there is no obvious need for update. For this periodic review, a short checklist is used to perform and document the review.

As mentioned in Section 2.2, learning from events reported by licensees, including events recorded in the ARIR, is of key importance for continuous improvement for both the licensees and the regulatory bodies. During the interviews, the IRRS team was informed of the ongoing actions related to events that occurred at the ANSTO Health facility producing Mo-99. Following four events with safety implications, the first one being in August 2017 and rated level 3 in the International Nuclear and Radiological Event Scale, ARPANSA directed ANSTO to have an external safety review performed. ARPANSA also initiated additional inspections of the facility and increased scrutiny on its operation. The external review report was submitted to ARPANSA in October 2018; it identified many areas of improvement for ANSTO Health and a few for ARPANSA. ARPANSA has decided to initiate a dedicated project to monitor ANSTO Health progress in implementing the 85 recommendations identified in the report. ARPANSA is considering additional actions to capture lessons learned from these events from a regulatory perspective.

With regards to its regulatory processes, ARPANSA has already decided to:

- produce a regulatory triage and response procedure providing guidance on actions to be taken following an incident or accident, including when and when not to intervene;
- developing guidance on expectations regarding the preservation of the scene during events;
- reintroduce aspects of the "thematic" inspection programme, focusing on risk assessment verification, radiation protection, incident reporting, safety culture etc. with a view to prevention of accidents;
- incorporate guidance on reviewing possible trends in triggers and contributing factors to near misses in its proposed revision of the Performance Objectives and Criteria for inspections; and
- devote the main topic of the 2018 Licence Holder Forum to "Risk Assessment".

ARPANSA is considering additional actions to capture lessons learned from these events from a regulatory perspective.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: ARPANSA has acknowledged the need to review its regulatory oversight in the light of last year's events at ANSTO Health facility. Some actions have already been initiated but ARPANSA has not completed a comprehensive evaluation to determine whether its current regulatory measures (regulations and guides, review and assessment, inspection and licensing) require modification, based on the lessons learned, including but not limited to those identified in the recently published ANSTO independent safety review report, with respect to the events that occurred at the ANSTO Health facility.	
(1)	**BASIS: GSR Part 1 (Rev 1) requirement 15 states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities."*
(2)	**BASIS: GSR Part 1 (Rev 1) para. 4.43 states that** *"The regulatory body shall assess all*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	radiation risks associated with normal operation, anticipated operational occurrences and accident conditions, prior to operation of the facility or conduct of the activity, and periodically throughout the lifetime of the facility or the duration of the activity, to determine whether radiation risks are as low as reasonably achievable."
(3)	**BASIS: GSR Part 1 (Rev 1) para. 4.46 states that** *"For an integrated safety assessment, the regulatory body shall first organize the results obtained in a systematic manner. It shall then identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of activities where relevant. Feedback information shall be provided to the authorized party. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach."*
(4)	**BASIS: GSR Part 1 (Rev 1) para. 4.53 states that** "*In conducting inspections, the regulatory body shall consider a number of aspects, including:* *—Structures, systems, components and materials important to safety;* *—Management systems;* *—Operational activities and procedures;* *—Records of operational activities and results of monitoring;* *—Liaison with contractors and other service providers;* *—Competence of staff;* *—Safety culture;* *—Liaison with the relevant organization for joint inspections, where necessary*."
R11	**Recommendation: ARPANSA should conduct a comprehensive evaluation to determine whether its current regulatory oversight measures (regulations and guides, review and assessment, inspection and licensing) should be modified, based on lessons learned, including but not limited to those identified in the ANSTO independent safety review report, of the events that occurred at the ANSTO Health facility.**

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

The licence application requirements for research reactors are set out in the ARPANS Act and Regulations.

The IRRS team was informed that relevant IAEA safety standards are used as a basis for conducting regulatory review and assessment. The safety case and safety analysis report are reviewed against IAEA SSG-20 and the fundamental safety principles and design criteria stated in SSR-3. As a condition of licence, the OPAL reactor is subject to a periodic safety review every 10 years (or if necessary, earlier) in line with the guide Periodic Safety and Security Review for Research Reactors.

In addition to the mandatory periodic safety review, ARPANSA has a standing requirement to review plans and arrangements every three years. Furthermore, regulatory approval is required for changes with significant implications for safety (regulation 51 of the ARPANS Regulations). Regarding approval to make changes under regulation 51, these changes are assessed against the same requirements as new applications, including international standards that form part of international best practice.

The IRRS team noted that the full range of accidents, including severe accidents and design extension conditions are not analysed as required by SSR-3. In accordance with IAEA safety standards a set of design

extension conditions for a research reactor shall be derived for the purpose of enhancing the safety of the research reactor by enhancing its capabilities to withstand, without unacceptable radiological consequences, accidents that are either more severe than design basis accidents or that involve additional failures. The regulatory guidance does not fully address these issues and should consequently be updated.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: ARPANSA has not required the licensee to conduct full range of accident analysis including severe accident analysis and design extension condition as part of the safety analysis report.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 26 Paragraph 4.43 states that** *"The regulatory body shall assess the radiation risks associated with normal operation, anticipated operational occurrences and accidents, including possible events with a very low probability of occurrence, prior to operation of the facility or conduct of the activity, and periodically throughout the lifetime of the facility or the duration of the activity, to determine whether radiation risks are as low as reasonably achievable."*
(2)	**SSR-3 Requirement 22 states that:** *"A set of design extension conditions for a research reactor shall be derived for the purpose of enhancing the safety of the research reactor by enhancing its capabilities to withstand, without unacceptable radiological consequences, accidents that are either more severe than design basis accidents or that involve additional failures…."*.
S8	**Suggestion: ARPANSA should consider requiring the licensee to perform severe accident analysis, assess design extension conditions and update final safety analysis accordingly.**

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The review and assessment process for waste management facilities follows that for all facilities licensed by ARPANSA as described in Section 6.1.

ARPANSA requires that each safety case includes documented arrangements for operating a facility include periodic maintenance, testing and inspection of safety systems, operating limiting conditions and conditions of the facility derived from the safety analysis that defines the safety envelope of the facility.

6.5. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

The review and assessment process for decommissioning activities follows that for all facilities licensed by ARPANSA as described in Section 6.1.

There are currently no active decommissioning projects authorized by ARPANSA. The HIFAR research reactor was shut down in 2007 and following removal of the fuel from the reactor for reprocessing, the facility has been authorized under a possess or control licence. The only activities that are permitted to be undertaken at the site involve site characterisation and activities not involving removal of radioactive material. An application for decommissioning has not been submitted by the licence holder.

6.6. REVIEW AND ASSESSMENT FOR TRANSPORT

As part of the licensing process the information submitted by the applicant is assessed against the Transport Code (RPS C-2) applied by relevant jurisdiction legislation.

Applications for approval of package designs and special form radioactive materials, validation of foreign package design approvals, special arrangements and other transport approvals are required to be assessed against the requirements of RPS C-2. Based on the results of the assessment, a decision on the granting (or refusal) of an approval/validation certificate is made.

Assessment of package design and special form radioactive material design is a complex process and requires combined knowledge in transport regulations and guides as well as in several technical areas. In Australia, there are eleven competent authorities that may issue such approvals, as listed in Schedule B of RPS C-2. There are no measures established ensuring that applications for approvals of package design and special form radioactive material design are assessed in a consistent manner by all competent authorities in Australia, making use of the national and international knowledge in this area and building up national experience.

When considering applications for approval of shipments under special arrangement, the applicant has to demonstrate that the overall level of safety provided by the package design and the supplementary operational controls during transport is at least equivalent to that which would be achieved if all applicable regulatory requirements were met. Special arrangement is considered by exception and is to be applied only on a case-by-case basis, where it is impracticable to demonstrate compliance with specific clauses of the SSR-6. Approvals are granted to single shipments with specific additional controls and measures to meet the safety level that would have been achieved by compliance with those specific clauses.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no measures to ensure a consistent review of applications for approval of package design and special form radioactive material design by different regulatory authorities. This may have consequences beyond Australia as such approval may also enable use of the package in foreign countries. This has been recognized in the ARM and is part of the Action Plan.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 22 states that** *"The regulatory body shall ensure that regulatory control is stable and consistent."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 7 states that:** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."*
(3)	**BASIS: GSR Part 1 (Rev 1) Requirement 20 states that:** *"The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities."*
(4)	**BASIS: GSR Part 1 (Rev 1) Requirement 15 states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities."*
R12	**Recommendation: Regulatory bodies as well as the Civil Aviation Safety Authority and**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	the Australian Maritime Safety Authority, should coordinate to ensure consistent review of applications for approval of package design and special form radioactive material design.

6.7. SUMMARY

The IRRS team reviewed the framework for review and assessment in Australia. The review considered the general practices related to the regulatory review and assessment including the management, organization and technical resources, technical basis and performance of regulatory activities under this aspect.

Overall, the IRRS team found that the implementation of regulatory review and assessment is consistent with the recommendations in IAEA safety standards. Some areas of improvement were noted and recommendations related to evaluation of the review process and supporting activities based on lessons learnt, as well as coordination among competent authorities responsible for transport package design approvals were made. Additionally a suggestion for inclusion of requirements addressing analysis of severe accidents and design extension conditions for research reactors was made.

7. INSPECTION

This section covers all Australian jurisdictions on generic issues (7.1), on sources, facilities and activities (7.2) and transport (7.6) inspections. The sections on research reactors (7.3), waste management (7.4) and decommissioning (7.5) relate only to inspection by ARPANSA.

7.1. GENERIC ISSUES

7.1.1. INSPECTION PROGRAMME

All regulatory bodies that conduct inspections indicated that inspection priorities consider the following:

- licence holder facilities, sources, and activities in the jurisdiction;
- a graded approach with the risk posed;
- inspections performed in the past years;
- geographical constraints;
- available regulatory resources.

An inspection schedule is not established in all jurisdictions (see Section 7.2).

In the States and Territories, in addition to inspections performed by the regulatory body, 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 as well as most industrial equipment. The requirements are usually based on Australian standards or, where applicable, international standards.

In most jurisdictions that have source registration (such as the ACT), evidence of a satisfactory compliance test is required prior to use. In other jurisdictions (such as QLD) sources are registered and require testing prior to first use and periodic testing thereafter as separate processes. 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).

7.1.2. INSPECTION PROCESS AND PRACTICE

Inspectors are authorized to carry out routine inspections of licensed sources or facilities, suspected unauthorized possession or use, and to investigate possible or actual non-compliance. Both scheduled and reactive inspections may be performed by all jurisdictions. Unannounced inspections may be carried out but could be disruptive and ineffective if key licensee staff are unavailable at the time the inspection is performed. Therefore, in the majority of cases, announced inspections are carried out.

The inspection scope is either general or focussed on one or several topic areas. They are generally performed by one inspector however, when needed, multi-disciplinary integrated teams may be established, such as for facilities and higher risk activities. Inspection methods include consulting documentation or records, interviews, walk-downs and observing facilities and activities, taking technical measurements or taking pictures. At the end of an inspection, an exit meeting informs the licence holder of areas for improvement, potential regulatory non-compliances and confirms the facts.

Inspections are generally carried out in accordance with written procedures. Inspection results are discussed with and provided to the licence holder - or if relevant the operator, owner, or site occupier. After an

inspection, a formal report/letter is sent to the licence holder. Findings are usually categorized in two groups:

- those that constitute a potential non-compliance with the legally binding requirements. This gives an opportunity to the licence-holder to express its views on the situation and his/her intended course of action before a breach is confirmed;
- the "areas for improvement" where, although not meeting the threshold of a potential non-compliance, the licence holder does not meet the expected level of performance.

Areas of good performance may also be recognized.

The IRRS team noted that ARPANSA uses different databases to capture information from inspections. The IRRS team found a lack of consistency and systematic tracking of inspection findings to ensure the taking of prompt and appropriate actions to correct inspection findings and prevent recurrence. It was however noted that lead inspectors were required to review whether the licensee had initiated action within a period of three months of the inspection report being issued to the licensee. It was further observed that the various databases are not integrated and there are gaps in the information contained in the various databases. ARPANSA publishes inspection reports on its website for transparency, while State and Territory regulatory bodies do not. Finally, once the ARPANSA inspection report has been issued, a survey is sent to the licence holder's representatives that were present during all or part of the inspection to seek feedback on the inspection.

7.1.3 INSPECTORS

In all jurisdictions, the regulatory framework provides the authority to perform inspections and related actions (powers of access, to seize materials). The IRRS team noted that, in addition to conducting inspections, inspectors also perform review and assessment activities as part of the authorization processes.

Training requirements and associated actions needed to be appointed as an inspector depends on each jurisdiction. In some jurisdictions, including the Commonwealth, inspectors are required to obtain formal qualifications prior to being appointed as an inspector.

7.2. INSPECTION OF RADIATION SOURCES, FACILITIES AND ACTIVITIES

Each jurisdiction's legal framework enables the compliance monitoring, and investigative and enforcement activities which may be undertaken. This includes the appointment of authorized inspectors, scope of authority, identification, powers to require information or records, access premises, seize materials and to question and identify persons.

For all regulatory bodies, inspection tasks are performed by staff who also perform review and assessment. Inspections performed by the regulatory body are essentially announced inspections but unannounced inspections occasionally occur. Reactive inspections may be performed following an event or a complaint.

Only ARPANSA's and QLD's regulatory bodies have a multi-year inspection schedule, derived from explicit inspection frequencies by types of practices:

- ARPANSA methodology 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 which governs the frequency and the intensity of the inspection;

- QLD's regulatory body is re-evaluating its inspection strategy, to respond to the inherent risk of the various practices and the effectiveness and reliability of control measures, not just the radiation hazard in the practices.

To facilitate establishing priorities for inspections, a unified national approach to rank radiation sources and facilities according to their inherent risks could be established.

While several regulatory bodies have experienced significant staff reductions, many now focus on reactive (based upon incidents, complaints or notifications) inspections rather than proactive inspections (in line with long-term inspection schedule) as shown in the following table.

Jurisdiction	Licensees	Regulatory Body resources	Inspections performed		
			2015	2016	2017
ARPANSA	58 source licences and 34 facility licences. These licenses are issued to agencies/entities and cover a large number of individuals.	In ARPANSA Regulatory Service Branch: 17 staff are technical staff/inspectors.	47 [2]	83 [4]	59 [4]
ACT	Possession licences: 200 User licences: 1200	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	3	9	6
NSW	Possession licences: 3500 User licences: 15 000	7 staff work directly in radiation regulation. This includes 5 operational (2 senior) and 2 policy (1 senior) staff.	51 [3]	29 [10]	27 [0]
NT	1,300 licensees (use and possession)	2.5 staff involved in regulatory activities (2 scientific, 0.5 administrative)	Not provided	Not provided	Not provided
QLD	Possession licences: 2,443 User licences: 17 990 (including transport) 1507 individuals holding radiation safety officer or accreditation certificates.	14 staff work in the Radiation Health Unit. About 110 persons are appointed as inspectors under the Radiation Safety Act 1999	599 [0]	157 [7]	77 [8]
SA	Possession licences: 750 (including uranium mining) Radiation sources: 3500 User licences: 6700.	15 staff work directly in radiation regulation, including two administrative officers	Not provided	Not provided	Not provided
TAS	Licences: 500, authorising around 3000 persons to use approximately 3000 radiation sources. 600 registered places where sources are stored and used.	4 permanent staff - 3 regulatory physicists and a licensing officer.	91 [1]	219 [0]	237 [1]
VIC	Possession licences: 2 688 User licences: 14 365 Approved tester : 48 Security plan approved assessor : 13	11 staff work in the Victorian Department of Health and Human Services Radiation Safety Team within the Health Protection Branch,	419 [5]	483 [4]	481 [31]

WA	Registered premises (equivalent to possession licences): 2,000 (incl mining/milling of radioactive ores) Use licences: 7000	10 staff involved in regulatory activities (1 technical and 9 scientific and policy staff)	71 [2]	19 [0]	13 [0]
Number written as [xx] are inspections on industrial radiography TAS: Total number of inspections by the regulator is accurate but the majority are desktop and interview/phone/email as we work through reviewing radiation management plans. WA: These inspections are 'in-person' facility inspections and do not include desk top or other virtual type QLD: In 2015, 432 inspections were primarily of laser and IPL businesses during a trial to assess the effectiveness of using other resources to perform compliance inspections. QLD subsequently trained an additional 100 inspectors during 2017-2018.					

Several regulatory bodies have directed their resources to performing licensing activities rather than inspection activities. It may be worthwhile for them to assess whether the balance between licensing and inspection activities is appropriate.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Several Regulatory Bodies of States or Territories recognized that currently they do not perform a sufficient number of inspections, due to a lack of staff and the geographical size of their respective jurisdictions. Resources are primarily allocated to perform licensing related tasks. A yearly inspection programme has not been developed in some jurisdictions where inspections are only performed when a significant event occurs or a complaint is filed (reactive inspection).	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 27 states that** *"The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 28 states that** *"Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced."*
(3)	**BASIS: GSR Part 1 (Rev 1) para 4.50 states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."*
(4)	**BASIS: GSR Part 1 (Rev 1) Requirement 3 states that** *"The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities."*
R13	**Recommendation: The State and Territory regulatory bodies should develop an inspection strategy and carry out a resource allocation assessment.**

Inspections are carried out in accordance with written procedures and focus on a number of topical areas. For ARPANSA, these are presented in ARPANSA's *Inspection Manual*: inspection frequency ranges from quarterly to six yearly, taking into account a risk or hazard-informed approach. Areas of inspection are outlined in the Performance Objectives and Criteria (PO&C), common to any radiation source practice, and further refined in checklists specific to types of practices. PO&C covers performance reporting verification (3 criteria), Configuration control (4 criteria), Inspection, testing and maintenance (2 criteria), Training (4

criteria), Event protection (2 criteria), Security (3 criteria), Radiation protection (10 criteria), EPR (10 criteria), Safety culture (2 criteria), Human performance (4 criteria), Performance improvement (5 criteria).

ARPANSA also performs scheduled "e-inspections": licence holders with the lowest hazard sources and low hazard sources located in remote locations may be asked to provide evidence of effective control in the form of submitting targeted documentation and photographs for desktop review as an alternative to an inspector visiting the site. Some State and Territory regulatory bodies have similar practices.

The IRRS team had the opportunity to observe two inspections carried out by the VIC Regulatory Body, one at an industrial radiography workshop, the other at a hospital in the Melbourne area. The inspectors conducted both inspections in an effective and professional manner, using the pre-established inspection protocols and recording facts as the inspection progressed. Review of records and practice procedures, interview and observations were the primary means used to collect facts even if some records or procedures were consulted. Each inspection ended with an exit discussion summarizing the key findings. The inspection was also an opportunity to discuss potential modifications to the licence and to give information on recent/upcoming changes to regulatory requirements.

7.3. INSPECTION OF RESEARCH REACTORS

The eight functional inspection areas that are covered by the periodic inspection programme, plus three additional cross-cutting areas that are applicable to all functional areas, apply to the inspections of the OPAL reactor. The cycle through the eight functional areas and three cross-cutting areas in the inspection programme takes approximately two years.

All inspection activities for safety of research reactors are prepared and implemented based on the Inspection Manual. This manual provides guidance for inspection procedures, radiation monitoring equipment, inspector competencies, inspector health, safety and security, and review of the inspection programme. It stresses that at no time does an inspection diminish the licence holder's primary responsibility for safety.

Most inspections are performed according to the yearly inspection plan. No unannounced inspections have been undertaken recently but can be performed if deemed necessary.

There is one ARPANSA inspector assigned to the oversight of the OPAL research reactor, supported by an alternate inspector who maintains general oversight of the facility. Both of these inspectors are senior regulatory officers who have experience in the nuclear industry and regulation. Inspectors are periodically rotated with regard to their assigned facilities to develop skills and reduce the risk of regulatory capture. Additional support is provided as needed from other ARPANSA staff or external experts.

In support of review and assessment, site visits are also undertaken to verify commitments made by the licensee in the safety case. Inspectors obtain information about the facilities through the site visits, and have discussions on safety related issues. There are regular, frequent and informal visits to the premises of a licence holder for the purpose of familiarization with a facility or source, associated processes or procedures, and personnel qualifications. The site visits of the OPAL research reactor are conducted every two to three weeks.

The IRRS team had the opportunity to observe an inspection of ANSTO Health at ANSTO's Lucas Heights nuclear facility. ARPANSA inspectors conducted a routine inspection addressing training, radiation protection, records, emergency preparedness and response, and security. Inspectors followed their process and conducted the inspection in an effective and professional manner. The observations were limited to the training portion of the inspection. In addition, the IRRS team members visited the following nuclear and

radiation facilities: OPAL reactor, ANM Mo-99 facility, Neutron Scattering Experiment facility and the Interim Waste Store.

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

Waste management facilities licensed by ARPANSA are inspected according to the inspection schedule applicable to all licensees. The inspection dates are agreed upon with licence holders. ARPANSA can perform unannounced inspections; however, such inspections have not been carried out in recent years. As for the research reactor, the suite of 8 inspection functional areas are covered every two to three years on average. The inspection process for waste management facilities follows the same process as for research reactors.

7.5. INSPECTION OF DECOMMISSIONING ACTIVITIES

There are currently no Commonwealth facilities undergoing active decommissioning.

The HIFAR reactor is authorized under a possess or control licence. Inspections at this facility are currently conducted once every 18 months, based on the graded approach and regulatory priority ranking for the facility. Topical areas to be inspected are similar to the functional areas mentioned in Section 7.3, are to be verified on a three-year cycle. The inspection process is similar to that of waste management facilities and research reactors.

7.6. INSPECTION OF TRANSPORT

All jurisdictions have the legal basis to perform inspections. However, in several jurisdictions, only very few inspections are actually performed.

Several types of inspections are carried out in Australia that cover transport of radioactive material:

- Compliance review for holders of licences for transport or use of radioactive material as part of the licensing process;
- Inspections of the stowage of packages on the vehicle, especially those for industrial radiography, borehole logging and portable density moisture gauges, motivated not only by radiation safety and protection expectations, but also by security considerations;
- Joint inspection by ARPANSA and the Civil Aviation Safety Authority or the Australian Maritime Safety Authority of certain shipments;
- General inspections of dangerous goods transport on the road.

In some jurisdictions, after noteworthy incidents, campaigns of inspections of shipments of mobile sources like industrial radiography devices, borehole logging devices and portable density moisture gauges have been carried out, targeted on secure stowage on the vehicle. Such inspections should be carried out on a regular basis, since shipments of these safety significant sources occur frequently and may present risks if not done appropriately. Regarding ARPANSA, the intention to implement a system for inspection of handling and stowage of packages by consignors and carriers is part of the action plan.

There is a recommendation in Section 7.2 that the State and Territory regulatory bodies should develop inspection strategies to better balance the resource allocation between inspection and licensing.

7.7. SUMMARY

The IRRS team reviewed the inspection processes in Australia. All jurisdictions have the legal basis to perform inspections. However, in several jurisdictions, only very few inspections are actually performed. For jurisdictions where numerous inspections will occur during the year, an inspection schedule is established. When inspections are performed, inspection protocols are followed and findings are formally communicated to the licence-holder, requiring improvement actions when needed.

8. ENFORCEMENT

This section covers all Australian jurisdictions.

8.1. ENFORCEMENT POLICY AND PROCESS

The Commonwealth and the States and Territories have identified within their respective legal frameworks, the authority that is necessary to conduct compliance verification, investigations, and enforcement activities. These authorities include the ability to take action when non-compliances are identified or there is a concern for the safety and security of the public, workers and the environment. Prosecution may also be initiated.

From an administrative perspective, enforcement actions can include suspension, cancellation, amendment, or revocation of licences. All enforcement actions taken by a regulatory body are subject to review prior to implementation, while providing the licence holders with legislative appeal mechanisms in all circumstances.

Inspectors have been provided with a range of measures under their respective legal frameworks to address non-compliances. The measures can escalate from written notices to "improvement notices", to directions in circumstances where more escalated actions are required. Prosecution can also take place.

The ARPANS Regulations and regulatory guides describe the licence holder obligations with respect to non-compliances identified and a process for determining when a non-compliance has occurred. The resulting actions of a non-compliance based on either safety significance or administrative nature, can range from the publication in statutory quarterly and annual reports to Parliament to further escalated actions such as the issuance of a direction or prosecution. For non-compliances that are identified, the licence holder has 28 days to respond to the notification prior to ARPANSA reaching a final decision and any actions are taken. In addition to the escalated enforcement actions discussed above, inspectors can issue an AFI (areas for improvement), in situations where the regulator considers that it is appropriate for the licence holder to apply best practices in the application of an activity or the use of radioactive sources.

ARPANSA has published a *Compliance and Enforcement Strategy* that describes the graded approach that is taken in response to any non-compliance. In addition, further guidance regarding the enforcement strategy is provided in the Regulatory Guide, *Graded approach to Dealing with Licence Holder Non-Compliance*, available to inspectors and licence holders.

In the case of the States and Territories, only some jurisdictions have enforcement strategies in place to provide guidance to authorized officers. This guidance reflects a graded approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Some regulatory bodies indicated that they did not have a formal enforcement policy describing the approach used to determine which enforcement measures should be used for various types of situations.	
(1)	**BASIS: GSR Part 1 (Rev 1) requirement 30 states that** *"The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization."*
R14	**Recommendation: State and Territory regulatory bodies should have an enforcement policy to provide staff direction in the application of enforcement actions commensurate**

	to the significance and nature of any regulatory non-compliance.

8.2. ENFORCEMENT IMPLEMENTATIONS

Examples of the application of a graded approach to enforcement were presented in the documentation reviewed and interviews undertaken.

Recommendations or actions to improve compliance can be escalated due to severity and response by the licence holder. This is the case with the issuance of an improvement notice issued by an inspector which can be escalated to a "direction" issued by the CEO of ARPANSA. In instances where health and safety concerns have been identified, licences can be amended, suspended or cancelled as appropriate; a prosecution of a civil or criminal nature can be initiated in the most serious circumstances. In general, the enforcement strategy of ARPANSA employs a graded approach and working alongside of the licence holder to address any non-compliance identified.

An example of an ARPANSA escalated action is the direction issued to ANSTO Health on 29 June 2018 due to four events with safety implications that occurred within the past year, one (contamination of the hands of a worker, resulting in a localised skin exposure of about 20 Gy) rated INES level 3, in one facility (radionuclide production) within less than a year. This direction, publicly available on ARPANSA website, comprises 6 actions, with associated deadlines, including performing an external review, the terms of reference of the review being approved by ARPANSA.

With respect to State and Territory jurisdictions, administrative non-compliances are the majority of non-compliances that trigger enforcement actions. Escalated approaches to enforcement are described in enforcement strategies where they exist and within the legislative framework of all jurisdictions. Enforcement actions can involve such measures as meetings with licence holders, written notices, the issuance of an AFI. The current enforcement measures provide some flexibility to respond to any potential non-compliance.

For the most part, non-compliances that are reported to or identified by the jurisdictions are administrative in nature such as expiry of management and possession licences, to late or lack of responses to the regulatory bodies. In some States and Territories, the need for an increased variety of enforcement options was raised to ensure that the enforcement tool chosen is commensurate with the level of risk. This issue is addressed in Recommendation 14 of Section 8.1.

8.3. SUMMARY

The IRRS team reviewed the enforcement processes in Australia. Legislation has been established to take enforcement actions when non-compliances are identified. The measures in place generally provide for a graded application by inspectors as well as authorized authorities that are identified in the various jurisdictions.

Enforcement actions are reviewed systematically prior to implementation and licence holders are provided through the regulatory framework the opportunity to challenge the validity of a proposed enforcement action.

9. REGULATIONS AND GUIDES

This chapter covers all Australian jurisdictions on generic issues (9.1), and from most jurisdictions on source facilities and activities (9.2) and transport (9.6). The sections on research reactors (9.3), waste management (9.4) and decommissioning (9.5) relate to ARPANSA only.

9.1. GENERIC ISSUES

Australia has a national approach to regulations and guides that is described in the National Directory for Radiation Protection (NDRP). This is supported by a series of national codes referenced in Schedule 11 of the NDRP and supporting national guides. In addition, ARPANSA publishes guides for their Commonwealth regulated parties. Together, these provide a comprehensive regulatory framework for nuclear and radiation safety including technical codes on a variety of facilities and activities, as well as ARPANSA guides that specify the form and content of licence applications. The IRRS team, however, identified gaps or areas where changes were needed to fully align with IAEA requirements. These are discussed in the following sections.

In addition, all nine jurisdictions have their own radiation protection legislation and regulations. In practice, this creates differences in regulatory requirements and their implementation across jurisdictions. As a result, there are inconsistencies across the different jurisdictions. The RHC has launched an initiative, the "report a national uniformity issue" to manage these inconsistencies. This is discussed further in Section 1.2.

There are a range of publications that promote practices to protect human health and the environment from harmful effects of radiation. These publications form the national framework to manage radiation risks. Foremost in this framework is the Radiation Protection Series (RPS) of documents. Publication categories within the RPS are Fundamentals, Codes, and Guides:

- Fundamentals set the basic principles for radiation protection and describe the fundamental radiation protection, safety and security objectives. They are written in an explanatory and non-regulatory style and describe the basic concepts and objectives of international best practice.
- Codes are regulatory in style and may be referenced by regulations or conditions of licence. They contain either general safety or security requirements which may be applicable for all dealings with radiation, or practice-specific requirements. They provide overarching requirements and are expressed as 'must' statements which are to be satisfied to ensure an acceptable level of safety and/or security.
- Guides provide recommendations and guidance on how to comply with the Codes or apply the principles of the Fundamentals. They are written in an explanatory and non-regulatory style and indicate the measures recommended for good practice. They are generally expressed as 'should' statements.

National codes and guides are developed and revised based on direction provided by the RHC. In addition to publishing the national codes and guides on behalf of the RHC, ARPANSA develops guides for its regulated entities. However, ARPANSA does not have a documented process for the development of their Guides, and the RHC process for developing national codes and guides has not been integrated into their management system. This is discussed further in Section 4.5. Notwithstanding, many of the necessary elements of this process are in place; ARPANSA on behalf of the RHC consults publicly with stakeholders during the development, and there are internal review and approval mechanisms prior to finalizing and presenting elements of the regulatory framework. The disposition of comments received on public consultations is made available at the time of publication.

National codes and guides are under the purview of the RHC and form a part of the NDRP framework. Amendments are subject to approval of the RHC, and new national codes and guides are subject to regulatory impact assessment by the Office of Best Practice Regulation. Codes and guides are approved by the RHC, however approval of the Australian Health Ministers is required for them to be integrated into the NDRP. Policy analysis of new or existing codes and guides include consideration of potential impacts on regulated bodies as well as developments in the international regulatory framework and best practice. The IRRS team was advised by regulatory bodies that the final validation by COAG was cumbersome and at times introduced a significant delay to final approval. Further, regulatory bodies advised that their internal processes to adopt new codes and guides was inefficient, presenting a challenge to national uniformity.

Furthermore, once a new/revised code has been included in the NDRP, the regulatory bodies enact it through different processes. This may be through, for example, regulation or licence condition. Depending on the process used in the jurisdiction, this can lead to delays in the code's adoption.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The process for obtaining Australian Health Minsters' approval to adopt a new national code risks delaying implementation of national codes that may be important to nuclear and radiation safety. The draft second edition of the NDRP addresses this. Further, implementation of new codes and standards is inconsistent amongst regulatory bodies. This can lead to significant delays in implementing new requirements.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained."*
(3)	**BASIS: GSG-13 para. 3.61 states that** *"The process of developing regulations and guides should be described in procedures and should be sufficiently flexible to permit timely revisions to be made to take account of changes in technological, legal and practical conditions."*
S9	**Suggestion: The Commonwealth Government, in conjunction with State and Territory Governments should consider revising the process to maintain and update the NDRP and the means for implementing codes in order to support timely adoption and implementation of new national codes.**

Despite the comprehensiveness of the regulatory framework, the RHC does not have a documented practice of regularly reviewing and updating existing codes and guides. However, the IRRS team was advised that the draft version 2 NDRP will require these to be reviewed every five years, which includes a review of the codes referenced in schedule 11 of the directory. Further, at the request of the RHC, ARPANSA has undertaken a holistic review of their regulatory framework and identified gaps or areas of misalignment with international requirements. The IRRS team was informed that the RHC supported this analysis and requested that a working group of the committee review and prioritize the identified deficiencies.

After the 2007 IRRS mission, ARPANSA made a comprehensive, readily available list of regulatory guidance documents, and a central repository for regulatory guidance has been created on the ARPANSA public website.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Many codes and guides exist, however the RHC has not completed a holistic review of the national regulatory framework to ensure it is comprehensive and provides adequate coverage commensurate with the radiation risks associated with the facilities and activities. This work is currently underway.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 32, para. 4.63 states that** *"…The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach."*
S10	**Suggestion: ARPANSA, in conjunction with the State and Territory regulatory bodies should consider completing a review of the regulatory framework and prioritizing identified gaps to ensure that it is comprehensive and provides adequate coverage commensurate with the radiation risks associated with the facilities and activities in accordance with a graded approach.**

9.2. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

All nine jurisdictions have their own radiation protection regulations and guides with some differences in regulatory requirements, for example:

Design constraint when calculating the shielding required for a diagnostic X-ray apparatus				
Description	NSW	NT	QLD	WA
Occupational design constraint	100 µSv per week (should)	Less than 0.1 mSv per week (fraction of 5mSv per year) for controlled areas	40 µSv per week in occupational areas outside of the radiation source room or behind protective barriers (e.g. at operator consoles).	10% of the effective dose limit (2mSv per year)
Member of Public design constraint	20 µSv per week (must)	Less than 0.02mSv per week (fraction of 1mSv per year) for uncontrolled areas	10 µSv per week (in any area able to be accessed by members of the public)	50% of the public effective dose limit (0.5 mSv per year)

Examples of competency requirements to be eligible for a use licence			
Occupation	QLD	NSW	VIC
Dentist	*[fast track applications]* Recognized Degree (e.g. BDS), and registered as a Dentist with the Australian Health Practitioner Regulation Agency (AHPRA).	Exempt for intraoral – for OPG registered as a dentist with the Australian Health Practitioner Regulation Agency (AHPRA).	Must be registered as a dentist with the Australian Health Practitioner Regulation Agency (AHPRA).
Dental assistant	*[fast track applications]* Certificate IV in Dental Assisting (Radiography Specialisation)	Certificate IV in Dental Assisting (HTL43012)	Certificate IV in Dental Assisting (HTL43012)

Dental (CBCT)	*[fast track applications]* Registered dentist holding a certificate of Proficiency in dental CBCT issued by an oral and maxillofacial radiologist approved by Radiation Health	Dentists, Dental hygienists/therapists/ assistants/nurses (Above and) training course (1 listed) **or** manufacturer, **or** in-house training by licenced person.	Dentists, dental hygienists/therapists/ assistants/nurses (Above and) training course (3 listed) and applications training (12 listed)
Industrial radiography	• Approved course in radiation safety • Log book of 300 supervised practice hours (by a licensed person) • Statement of level of competency	Training course (10 listed)	Training course (5 listed)
Portable density/moisture gauges	• Approved course in radiation safety • Log book of 20 supervised practice hours (by a licensed person) • Provision of Certificate of Competency from an approved person	Training course (18 listed)	Training course (3 listed)

As discussed in Section 1.2, a set of shared expectations across all jurisdictions is the cornerstone of ensuring consistent regulation and national uniformity. There would be a benefit to reviewing the frameworks in each jurisdiction against the shared expectations in the NDRP and supporting codes and guides. Inconsistencies should be identified, prioritized and systematically addressed while addressing Recommendation 1 of Section 1.2.

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

In addition to requirements and guides of general application, ARPANSA has developed guidance documents for licence holders of research reactors. These include regulatory guide *How to Apply for a Facility Licence for a Nuclear Installation*, *Construction of an Item Important for Safety - Regulation 54*, *Decommissioning of Controlled Facilities* and *Periodic Safety and Security Review (PSSR) of Research Reactors*. This latter document outlines expectations for PSSR. In accordance with this guidance, a PSSR of the OPAL reactor is conducted every 10 years.

For research reactors, international best practice is considered and ARPANSA expects commitments to follow International Best Practice documents as part of the licence holder's plans and arrangements. Many IAEA documents are used as the regulatory basis for review and assessments of research reactors.

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

In anticipation of a licence application for the planned National Radioactive Waste Management Facility (NRWMF) for low level waste disposal, ARPANSA has recently updated its regulatory framework for waste management facilities. The regulatory guide "Applying for a licence for a radioactive waste storage or disposal facility", was published in May 2017. In addition, ARPANSA produced a publication targeting interested parties: "Information for Stakeholders: Radioactive Waste Storage and Disposal Facilities." Schedule 14 of the NDRP (RPS-6, June 2017) provides guidance on the requirements and limits for the disposal of radioactive waste by the user. The IRRS team was informed that ARPANSA in collaboration

with State and Territory regulators, has now published Schedule 14 of NDRP (RPS-6) as a standalone document RPS-C-6 Code for Disposal of Radioactive Waste by the User in September 2018.

The RHC has prepared the Code for Disposal Facilities for Solid Radioactive Waste (RPS C-3), which was published in October 2018. This replaces the previous code on radioactive waste disposal that had been published in 1985.

9.5. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

ARPANSA has published a guide on Decommissioning of Controlled Facilities. The guide is based on the IAEA General Safety Requirements No. GSR Part 6 Decommissioning of Facilities and the draft IAEA Safety Guide: Decommissioning of Nuclear Installations. The guide includes a discussion of the different decommissioning options for controlled facilities and provides guidance on the selection of the preferred option for decommissioning. However, neither the guide nor any other policy or instrument specifies that immediate dismantling is the preferred option as required by GSR Part 6, para. 5.1.

Other Australian national codes, such as the Planned Exposure Code (RPS C-1) and ARPANSA regulatory guides, such as Plans and Arrangements for Managing Safety, are also applicable to the decommissioning stage.

Further, the IRRS team noted that ARPANSA plans to update the current 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. This is addressed in Suggestion 7 of Section 5.5.

9.6. REGULATIONS AND GUIDES FOR TRANSPORT

In Australia, the Code for the Safe Transport of Radioactive Material 2014 (RPS C-2) provides the nationally agreed framework and requirements for safe transport of radioactive material. This Code was developed by the RHC. It consists of a copy of the IAEA transport regulations SSR-6 (2012 Edition) together with a chapter stating the scope of applicability in Australia, some explanations and deviations from SSR-6 applicable to Australia and a list of all Australian competent authorities. The Code covers road, rail and waterways under the jurisdiction of States and Territories in Australia. In order to have legal effect in each jurisdiction, it must be enacted by ARPANSA and the States and Territories through regulations or licence conditions.

The Australian Dangerous Goods Code, Edition 7.5 points to the current Edition of the United Nations Recommendations on the Transport of Dangerous Goods, effectively embedding the transport of radioactive material into the framework for transport of dangerous goods. Additionally, regulations for the air and sea transport of radioactive material implement the current revisions of the ICAO TI and the IMDG Code, respectively. Australia is member of ICAO and IMO.

Regarding guidance for the application of the transport regulations, ARPANSA has created links on its website to IAEA SSG-26, SSG-33, and has made a regulatory guide and checklists for completeness of applications available for several types of approvals.

The IRRS team noted some inconsistencies in the application of requirements. For example:

- some States still apply the previous version of the Code, pointing to the 2005 edition of the IAEA Regulations
- some jurisdictions adopt the Code as regulations but others, implement the code as a licence condition to licensees involving transport of radioactive material.

The IRRS team recognized that the time for adoption of new codes may vary with the different jurisdictions depending on their respective legislative practices. This may lead to inconsistent transport requirements across the different jurisdictions.

In addition, competent authorities should ensure that compliance with the latest version of the Code is mandatory for all parties and operations related to the transport of radioactive materials. This should include all persons involved in the design, manufacture, maintenance and repair of packaging, and the preparation, consigning, loading, carriage including in-transit storage, unloading and receipt at the final destination for consignments of radioactive material and packages. If implemented solely through licence conditions, some entities who are not licence holders but involved in the above activities, may not be subject to the requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Some States apply an outdated version of the Code for the Safe Transport of Radioactive Material, which may lead to conflicts during transport crossing more than one jurisdiction or including air or international sea shipments. Additionally, in several jurisdictions, the Code is introduced not as regulation but as condition of transport-related licences. This creates a risk that not all operations included in the scope of the IAEA Transport Regulations SSR-6 are adequately addressed.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
(1)	**BASIS: SSR-6 Para 106 states that** *"These Regulations apply to the transport of radioactive material by all modes on land, water, or in the air, including transport that is incidental to the use of the radioactive material. Transport comprises all operations and conditions associated with, and involved in, the movement of radioactive material; these include the design, manufacture, maintenance and repair of packaging, and the preparation, consigning, loading, carriage including in-transit storage, shipment after storage, unloading and receipt at the final destination of loads of radioactive material and packages"*
R15	**Recommendation: Regulatory bodies should ensure that their regulations for the safe transport of radioactive material align with the latest revision of the Code for the Safe Transport of Radioactive Material (Radiation Protection Series C-2) and ensure that these regulations apply to all operations specified in the scope of the IAEA Regulations for the Safe Transport of Radioactive Material SSR-6.**

9.7. SUMMARY

The IRRS team reviewed the regulatory framework of regulations, codes and guides in Australia. The review considered the general practices related to the review, development and implementation of codes and standards, as well as the completeness and adequacy of the regulatory framework for applicable facilities and activities. Overall, the IRRS team found that there is a comprehensive system of codes and guides that generally aligns well with international requirements.

The IRRS team found some areas for improvement related to completing a holistic review of its framework and streamlining some processes.The team also identified the need to update certain regulations, codes and guides in order to fully align with IAEA requirements.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

This section of the report is limited to the Commonwealth regulatory body, ARPANSA, and does not address the State or Territory regulatory bodies, with additional information provided on States' and Territories' arrangements where relevant.

10.1. AUTHORITY AND RESPONSIBILITIES FOR REGULATING ON-SITE EPR OF OPERATING ORGANIZATIONS

Under schedule 3 of the ARPANS Regulations, ARPANSA has the authority to request emergency plans for controlled facilities, controlled material and controlled apparatus in the Commonwealth jurisdiction.

The three ARPANSA regulatory guides:

- Applying for a Source licence;
- Applying for a Licence for a Prescribed Radiation Facility; and
- How to Apply for a Facility Licence for a Nuclear Installation,

require that emergency arrangements are developed for all foreseeable emergencies such as dispersion of materials, overexposure of operators and theft or loss of controlled material. These guides require that the responsibilities of all parties in the event of an emergency, contact arrangements, emergency procedures, emergency equipment and reporting arrangements are included and, where necessary, arrangements for involving external agencies such as police and other emergency services. In addition, details must be provided on testing the emergency arrangements through regular reviews and exercises and rectifying any deficiencies found in the emergency plans. Emergency plans are reviewed against the current ARPANSA guidance and GS-G-2.1. The ANSTO Nuclear Medicine (ANM) emergency plan was reviewed using GSR Part 7 at the licence application stage.

ARPANSA uses a graded approach for regulating emergency preparedness and response (EPR). All EPR plans are reviewed at the licence application stage. Following this, ARPANSA regulatory inspectors examine the EPR plans and arrangements periodically in accordance with the inspection schedule. In line with a graded approach, the OPAL reactor EPR arrangements are examined at two-yearly intervals. However, due to the reactor sharing the site with other facilities, segments of the site EPR arrangements are inspected more often under those facility inspection programs. ARPANSA has so far not undertaken a holistic inspection of EPR arrangements for the ANSTO Lucas Heights site.

States and Territories each have their own regulatory bodies and emergency management legislation. During the IRRS mission a short meeting was held with all the State and Territory regulatory bodies to discuss their roles in regulating EPR and in emergency response. The team noted that the degree to which EPR is included in regulatory processes varies between jurisdictions. In addition, each jurisdiction has its own emergency response arrangements and the mechanism for coordination of response for an emergency which affects more than one jurisdiction is not routinely practised for radiation emergencies.

10.2. REGULATIONS AND GUIDES ON ON-SITE EPR OF OPERATING ORGANIZATIONS

The RHC has drafted a new guide for Radiation Protection in Emergency Exposure Situations (RPS G-3) based on GSR Part 7. As well as making the draft guide available for comments on the ARPANSA website, ARPANSA also undertook a stakeholder mapping exercise and identified approximately 120 key stakeholders in Australia and abroad e.g. IAEA IEC, who were requested to review the three-part document. In October 2017, following an IAEA regional GSR Part 7 training course hosted by ARPANSA, a workshop

on the new guide was held for State and Territory regulatory bodies. Larger states (Queensland, Victoria and New South Wales) also sent representatives from fire services. A second workshop was held in July 2018 in Melbourne in conjunction with the Victorian Regulator where first responders in Victoria (fire services, Emergency Management Victoria, ambulance and hospitals) and Commonwealth licence holders operating in Victoria were invited and encouraged to provide comments. The draft guide has also been promoted at international meetings and through the Australasian Radiation Protection Society. The guide is expected to be approved by the RHC before the end of 2018.

ARPANSA's regulatory guides such as "Plans and Arrangements for Managing Safety" and "Periodic Safety and Security Review of Research Reactors" are based on the current emergency exposure guide (Intervention in Emergency Situations Involving Radiation Exposure RPS-7), but in some areas refer to the draft RPS G-3. When the new emergency exposure guide, RPS G-3, is published, these regulatory guides will need to be updated to reflect the new requirements such as:

- expectation to establish emergency action levels, other physical observables and response time objectives in operator plans (extent depends on hazard);
- general, site area, facility and alert levels of emergency classification;
- requirement for redundancy/diversity in off-site communications in the Plans and Arrangements Guide; and
- consideration of waste generated in an emergency.

This has been recognized in the ARM and is part of the action plan.

Inconsistencies in emergency response arrangements across Australia such as the treatment of emergency workers was identified during the WHO Joint External Evaluation (JEE) of *International Health Regulations (2005)* core capacities of Australia undertaken in November 2017. An action plan addressing recommendations from the JEE is being developed by the Commonwealth Department of Health. As well as contributing to the implementation of certain actions, ARPANSA has responsibility for leading on the implementation of three of the actions by 2023 including to:

- enhance the interoperability of Federal and State/Territory radiation operations through broad multi-sectoral/multijurisdictional exercises;
- develop federal guidance for jurisdictional first responder occupational exposures; and
- conduct a national hazard assessment, to include creating an inventory of radiation sources, and establish a national radiation capability register.

This has been recognized in the ARM and is part of the action plan.

A new code on industrial radiography (RPS-C4) was published recently which includes requirements for EPR. This will be adopted by the Commonwealth, States and Territories.

The IRRS team noted that ARPANSA plans to develop guidance for licence holders on carrying out hazard assessments and on preparing, conducting and evaluating table top and field emergency exercises.

10.3. VERIFYING THE ADEQUACY OF ON-SITE EPR OF OPERATING ORGANIZATIONSORGANIZATIONS

An EPR module is included in ARPANSA inspections to check that the licence holder anticipates hazards and threats, assesses their consequences and prepares associated systems and measures to ensure an effective, timely, integrated, controlled and coordinated response to any nuclear or radiological emergency. ARPANSA uses a graded two-tiered approach for inspection depending on whether the facility is in

Emergency Preparedness Category II or Emergency Preparedness Category III or IV. Performance Objectives and Criteria which form the basis for inspections are currently under review against GSR Part 7.

ARPANSA inspectors observe some emergency exercises organised by ANSTO at the Lucas Heights Science and Technology Centre. However, no criteria are available for evaluating these exercises. Exercises are not observed at any other sites. Some ANSTO exercises were observed through the inspection process while other exercises were observed as site visits. ARPANSA inspectors follow up on all actions identified by ANSTO following operational events, drills and exercises undertaken as part of a licence condition to ensure any lessons learned are actioned. However, this may not always be the case when exercises are observed as site visits or associated with a site-wide exercise that is not explicitly associated with one specific licence (e.g. a site licence). The IRRS team noted that ARPANSA observed a site-wide emergency exercise organised by ANSTO in 2016 which was based on a scenario agreed with ARPANSA. The purpose of this exercise was to test emergency response arrangements across the ANSTO site and the effective coordination of the on-site and off-site response. However, ARPANSA does not routinely review the nature of ANSTO exercises to ensure that the scenarios are sufficiently challenging or that all functional areas are exercised over time.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: ARPANSA observes some emergency exercises at the ANSTO facilities as part of the inspection process and as site visits but no criteria to evaluate these exercises have been developed and there is limited input into the scope of the exercises to ensure all aspects of the emergency plan are exercised. This has been partly recognised in the ARM.	
(1)	**BASIS: GSR Part 7 para. 6.30 states that** *"Exercise programmes shall be developed and implemented to ensure that all specified functions required to be performed for emergency response, all organizational interfaces for facilities in category I, II or III, and the national level programmes for category IV or V are tested at suitable intervals. These programmes shall include the participation in some exercises of, as appropriate and feasible, all the organizations concerned, people who are potentially affected, and representatives of news media. The exercises shall be systematically evaluated (see para. 4.10(h)) and some exercises shall be evaluated by the regulatory body. Programmes shall be subject to review and revision in the light of experience gained (see paras 6.36 and 6.38)."*
(2)	**BASIS: GSR Part 7 para. 6.33 states that "***The conduct of exercises shall be evaluated against pre-established objectives of emergency response to demonstrate that identification, notification, activation and response actions can be performed effectively to achieve the goals of emergency response (see para. 3.2)."*
R16	**Recommendation: ARPANSA should develop criteria for evaluation of licensee exercises, to include the observation of exercises as part of the inspection process and ensure that licensees exercise all aspects of their emergency plan over an agreed time period and in line with a graded approach.**

10.4. ROLES OF THE REGULATORY BODY IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

ARPANSA is the designated National Competent Authority under the Early Notification and Assistance Conventions and maintains equipment and expertise in the Melbourne offices which is registered with RANET. Some of this equipment is located offsite in case of an on-site emergency at ARPANSA. ARPANSA also maintains a well-equipped laboratory for the analysis of environmental samples and has

established the Australasian Radioanalytical Laboratory Network (ARLN) to increase measurement capacity in an emergency.

Under Australian constitutional arrangements, each State and Territory has primary responsibility for emergency preparedness and response in its own jurisdiction. If they cannot respond to an emergency within their own resources they may request support from ARPANSA. ARPANSA's response capabilities are specified in the following national plans:

- Australian Government Disaster Response Plan
- National Counter Terrorism Plan

In addition, emergency response roles have been assigned to ARPANSA in:

- Australian Government Space Re-Entry Debris Plan
- Department of Defence Operations Manual – Visits to Australia by Nuclear-Powered Warships
- Health CBRN Plan – Domestic Health Response Plan for Chemical, Radiological or Nuclear Incidents of National Significance

However, the role of ARPANSA in a nuclear or radiological emergency at licensee or national level is not specified in legislation or any overarching emergency response framework such as the Australian Government Crisis Management Framework. The mechanism for the coordination of response between ARPANSA and the regulatory bodies in the States Territories during emergency response is not always defined or practiced.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The roles and responsibilities of ARPANSA in emergency preparedness and response have not been clearly assigned for nuclear and radiological emergencies. The mechanism for the coordination of response between ARPANSA and the regulatory bodies in the States Territories during emergency response is not always defined or practised.	
(1)	**BASIS: GSR Part 7 para. 4.7 states that** *"The government shall ensure that all roles and responsibilities for preparedness and response for a nuclear or radiological emergency are clearly allocated in advance among operating organizations, the regulatory body and response organizations."*
(2)	**BASIS: GSR Part 7 para. 6.30 states that** "*Exercise programmes shall be developed and implemented to ensure that all specified functions required to be performed for emergency response, all rganizational interfaces for facilities in category I, II or III, and the national level programmes for category IV or V are tested at suitable intervals."*
R17	**Recommendation: The Commonwealth Government, in conjunction with State and Territory Governments should ensure that the roles and responsibilities of ARPANSA in emergency preparedness and response both for incidents involving its own licensees and for incidents in the States and Territories are clearly assigned and exercised.**

While ARPANSA's role in an emergency involving a nuclear-powered warship is clear, there are no plans setting out ARPANSA's responsibilities in other radiological maritime emergencies, with the exception of the Australian Augmented Maritime Task Force (AMATF) arrangements led by the Royal Australian Navy.

ARPANSA is planning to develop a Memorandum of Understanding (MoU) with the Australian Maritime Safety Authority (AMSA) to set out ARPANSA's role in a radiological or nuclear emergency.

Although ARPANSA's response roles may not be clear for all nuclear and radiological emergencies, ARPANSA takes an active role in EPR which was demonstrated in its response to the Fukushima accident in 2011. ARPANSA has the tools, instruments, supplies, equipment, communication systems, facilities and documentation along with the knowledge, skills and abilities for effective emergency response. The team noted that ARPANSA has expertise in atmospheric dispersion modelling but that these resources could be overwhelmed in a prolonged emergency. ARPANSA should consider ways to increase atmospheric dispersion modelling capacity in an emergency. This issue is addressed in Recommendation 8 of Section 3.3.

ARPANSA has developed an in-house emergency response plan called the Incident Management Plan (IMP) which sets out the different roles required in an emergency and the coordination mechanisms. These roles would generally be carried out by the staff who undertake this work routinely but the roles in the IMP are not assigned to staff in the preparedness phase. Assigning staff to specific response roles would allow additional staff to be identified for emergency response roles and facilitate easier tracking of staff training.

ARPANSA has established a Radiation Emergency Coordination Centre in its Melbourne office where emergency response staff will be based in the event of a radiological or nuclear incident. This facility was used during the ConvEx-3 (2017) exercise.

Standard Operating Procedures (SOPs) are available for many EPR processes in ARPANSA. These procedures are currently being transferred into ARPANSA's Integrated Management System on the intranet.

ARPANSA regularly carries out exercises to test their emergency response capabilities. The ConvEx-3 exercise in 2017 was carried out over 72 hours. Lessons learned from participation in the ConvEx-3 exercise e.g. the need for a dedicated incident management system, were captured, but not included in the Integrated Management System. The IMP was not updated accordingly. In addition, the team noted that ARPANSA has never held a field exercise to test their IMP for an incident at the ANSTO site which could include deployment of staff from Melbourne to Sydney.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Staff are not formally assigned response roles in advance in ARPANSA's Incident Management Plan. While emergency exercises are held, there is no system in place to evaluate lessons learned and update plans and procedures accordingly. Not all elements of ARPANSA's Incident Management Plan are exercised.	
(1)	**BASIS: GSR Part 7 para. 6.28 states that** *"The operating organization and response organizations shall identify the knowledge, skills and abilities necessary to perform the functions specified in Section 5. The operating organization and response organizations shall make arrangements for the selection of personnel and for training to ensure that the personnel selected have the requisite knowledge, skills and abilities to perform their assigned response functions. The arrangements shall include arrangements for continuing refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities in an emergency response undergo the specified training."*
(2)	**BASIS: GSR Part 7 para. 6.30 states that** "*Exercise programmes shall be developed and implemented to ensure that all specified functions required to be performed for emergency response, all organizational interfaces for facilities in category I, II or III, and the national level programmes for category IV or V are tested at suitable intervals."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(3)	**BASIS: GSR Part 7 para. 6.38 states that** *"The operating organization and response organizations shall make arrangements to review and evaluate responses in actual events and in exercises, in order to record the areas in which improvements are necessary and to ensure that the necessary improvements are made (see Requirement 19)."*
R18	**Recommendation: ARPANSA should strengthen its Incident Management Plan by assigning roles and responsibilities, ensuring all elements of the Plan are tested and addressing lessons learned following exercises or real events.**

10.5. SUMMARY

The IRRS team reviewed the regulatory aspects of the emergency preparedness and response processes in Australia. ARPANSA is the Commonwealth regulator for emergency preparedness and response for Commonwealth use of radioactive materials, nuclear facilities and associated activities. EPR plans are required for all licence applications. There is an inspection module dedicated to EPR which uses a graded approach and some exercises are observed at the Lucas Heights Science and Technology Centre. Criteria for evaluating exercises are required.

ARPANSA has developed a new three-part comprehensive guide for Radiation Protection in Emergency Exposure Situations (RPS G-3) based on GSR Part 7 which should be published in 2019. ARPANSA undertook a detailed stakeholder engagement process including stakeholder mapping and dedicated workshops to promote and encourage feedback on the plan. Following publication, some regulatory guides will need to be updated.

The role of ARPANSA as a response agency both at the licensee and national levels requires clarification. Despite this, ARPANSA has an in-house incident management plan, good facilities, excellent technical expertise and a comprehensive suite of tools and equipment to fulfil the roles envisaged in the incident management plan. Some work is required to ensure staff are assigned roles in the plan and that all aspects of the plan are exercised at regular intervals.

11. ADDITIONAL AREAS

This Section includes all jurisdictions for Section 11.1 and only ARPANSA for Sections 11.2 and 11.3.

11.1. CONTROL OF MEDICAL EXPOSURES

Responsibilities of the Government

The regulatory oversight responsibility for the use of radiation sources for medical purposes is assigned to ARPANSA and the regulatory bodies in the States and Territories. For medical applications there are 4 Codes:

- RPS 14 – Radiation Protection in the Medical Applications of Ionizing Radiation
- RPS 8 – Exposure of Humans to Ionizing Radiation for Research Purposes
- RPS 10 – Radiation Protection in Dentistry
- RPS 19 – Radiation Protection in the Application of Ionizing Radiation by Chiropractors

The IRRS team was informed that ARPANSA has completed a mapping of IAEA safety standard requirements, which identified necessary revisions to RPS 14 and a new code, the *Code for Radiation Protection in Medical Exposure* (RPS C-5), is being developed to replace RPS 14. The proposed revision will address many of the requirements as per GSR Part 3. The current draft has completed public consultation and the analysis of comments received are being considered. The IRRS team was informed that the new code is expected to be approved by the RHC by the March 2019 meeting, and will subsequently be submitted for approval by the Australian Health Ministers.

Dose constraints are considered in different guides, exposures of carers and comforters are addressed in RPS 4 - *Discharge of Patients Undergoing Treatment with Radioactive Substances*, individuals participating in a research programme are addressed in the Guide RPS 8 - *Exposure of Humans to Ionizing Radiation for Research Purposes*.

RPS 14 establishes responsibilities for the licensee, which includes consideration as mandatory, the implementation of the Diagnostic Reference Levels (DRL). However, ARPANSA has only established DRL for practices involving computed tomography and nuclear medicine, including positron emission computed tomography which are published on its website; other DRLs are under development.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Code of Practice RPS 14 requires and establishes DRL for radiodiagnostic and nuclear medicine diagnostic practices, however, DRL for interventional and other procedures are not yet established. This is identified in the action plan of ARPANSA and encompassed in the draft *Code for Radiation Protection in Medical Exposure*, (RPS C-5).	
(1)	**BASIS: GSR Part 3 Requirement 34 para. 3.148 states that** *"The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality, to enable the requirements of para. 3.169 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	wide scale surveys or on published values that are appropriate for the local circumstances."
R19	**Recommendation: ARPANSA, in collaboration with professional bodies, should establish DRLs for medical exposures incurred in medical imaging, including image guided interventional procedures, where practicable.**

Responsibilities of the Regulatory Authorities

ARPANSA is the regulatory body for Commonwealth entities including Defence, Indian Ocean Territories Health Service, and Home Affairs (which includes the functions for customs and immigration), which have equipment for radiodiagnosis and fluoroscopy. The States and Territories regulate all other medical facilities.

RPS 14 prescribes the authorization for medical practitioners and operators by the relevant regulatory body. As a part of the authorization, all jurisdictions take into account the qualifications of users including medical practitioners as recommended in the relevant Safety Guides published by ARPANSA. However, the competencies related to radiation protection and safety are not always specified in regulation. Although some regulatory bodies specify additional competency requirements in radiation safety and protection, others have not specified them.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The qualification of professionals engaged in the use of radiation sources for medical purposes is specified in the relevant regulatory guidance. However, their competency requirements with respect to radiation protection and safety are not specified.	
(1)	**BASIS: GSR Part 3 Requirement 3 para. 2.32 states that** *"The regulatory body shall ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety."*
(2)	**BASIS: GSR Part 3 Requirement 35 para. 3.150 states that** *"The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals with specific duties in relation to the radiation protection of patients) to assume the responsibilities specified in these Standards only if they:* *(a) Are specialized in the appropriate area;* *(b) Meet the respective requirements for education, training and competence in radiation protection, in accordance with para. 2.32;"*
(3)	**BASIS: SSG 46 para 2.123 states that** *"The institutes and organizations that provide education and training in radiation protection to health professionals should use GSR Part 3 [3] and this Safety Guide as resources on the requirements for radiation protection and safety in medical uses of radiation."*
S11	**Suggestion: The Governments should consider developing common competency requirements for relevant medical professionals in radiation protection and safety and ensuring consistent application across the jurisdictions.**

Responsibilities of registrants and licensees

Roles and responsibilities for registrants and licensees, medical practitioners, operators (medical radiation technologists) and qualified experts (medical physicists) are provided in RPS 14 and the associated guides. Registrants and licensees are required to adhere to RPS 14 as a licence condition by some regulatory bodies while others have incorporated its elements into their regulations. A Radiation Management Plan (RMP) is required during the licensing stage which should cover the licensee's work practices and protocols for all procedures involving medical exposure.

The individual regulatory bodies stipulate different requirements with respect to dose constraints for shielding design, radiation safety training requirements, compliance testing requirements and their frequency. In addition, the sufficiency of medical and paramedical personnel is not addressed in legislation.

Justification of medical exposures

RPS 14 requires that the referring physician and radiological medical practitioner be involved in the justification of medical exposures for individual patients and prohibits procedures being performed without a written referral. Western Australia has made guidelines available (Diagnostic Imaging Pathways), however no other regulatory bodies have adopted referral guidelines to assist in the justification of individual patient exposures, which should be used as a clinical decision support tool for diagnostic imaging examinations.

Justification of medical exposure as part of a programme of biomedical research is addressed in RPS 8, which also provides dose constraints for diagnostic investigations. The researcher must obtain approval of the Human Research Ethics Committee of the relevant institution and an independent assessment of effective dose to the participant is required to be carried out by a medical physicist. The researcher must provide the research participant with sufficient written information about the purpose, methods, radiation dose, associated risks and any discomforts of the radiation exposure to enable the research participant to give informed consent.

Optimization of medical exposures

Only TGA approved medical equipment meeting the national/international standards is allowed for supply and use across all the jurisdictions, although some regulatory bodies may place additional test requirements for acceptance.

The procedures for optimization are required to be addressed in the RMP of the licensee, which is typically incorporated as a condition for licence. Schedule A of RPS 14 provides the format of the RMP, covering various aspects of optimization. The responsible person is required to arrange for tests related to patient dosimetry, calibration and quality assurance of radiotherapy equipment by, or under, the supervision of a qualified expert. However, there is no requirement for patient dosimetry to be performed under the supervision of a medical physicist for other medical practices.

RPS14 makes no specific mention of a medical physicist but specifies that a qualified expert be available for consultation on optimization, dosimetry and quality assurance and to give advice on radiation protection. The Safety Guides (RPS 14.1, 14.2 and 14.3) recommends that a medical physicist would be the qualified expert. This is further clarified by a '*Statement on Expectations for a Qualified Expert in relation to the Medical Code (RPS 14)'* issued by the RHC.

DRL are required to be taken into account for diagnostic procedures. While there is a requirement for a review of procedures in cases where the doses consistently exceed the DRL, there is no such requirement if the doses are significantly below the DRL.

ARPANSA provides service through the Australian Clinical Dosimetry Services (ACDS) which conducts a comprehensive audit of radiotherapy treatment doses and a reference dosimetry audit, Treatment Planning System planned measurements and end-to-end audit. In 2018, 100% of radiotherapy clinics in Australia

subscribe to ACDS and this type of audit is now mandatory in some States and Territories. The IRRS team acknowledges that this programme provides confidence and a commitment for patient protection and supports accurate dose delivery in radiotherapy using advanced treatment modalities. In addition, ARPANSA maintains a primary standard dosimetry laboratory and disseminates the standards to a majority of clinical therapy facilities.

Pregnant Women and Breast Feeding Women

RPS 14 requires the appropriate precautions considering all medical practices, for female patients who undergo radiological procedures in case of pregnancy or breast feeding. The IRRS team was informed that all jurisdictions consider these specific requirements as licensing conditions.

Release of patients after radionuclide therapy

RPS 14 requires the provision of written information and instructions before releasing patients with a permanent radioactive implant or with a therapeutic quantity of radiopharmaceutical. The conditions for release of patients with a permanent radioactive implant or with a therapeutic quantity of radiopharmaceutical are recommended in RPS 4.

The guidance in RPS 4 is not included as a licence conditions of all jurisdictions. The IRRS team was informed that in some jurisdictions, the licensee is responsible for determining its own conditions for release of patient, which must be described in the Radiation Management Plan. This may be an example of a lack of national uniformity. This issue is addressed in Recommendation 1 of Section 1.2.

Unintended and accidental medical exposures

In the case of an unintended and accidental medical exposure, RPS 14 establishes requirements for:

- prompt investigation
- submission of written report in a specified period to the regulatory authority
- determination of measures to be implemented to minimize a recurrence.

However, there is no requirement for licensees to provide measures that will be taken to minimize the likelihood of unintended or accidental medical exposure as a result of human error.

Reporting requirements for incidents related to medical exposures are described in the NDRP. Further, some regulatory authorities have additional incident reporting criteria.

Review and Records

There are requirements in RPS 14 for maintenance of records related to patient doses, procedures and equipment faults. There are no requirements for maintenance of records on QA tests and calibrations, or for the period of maintenance of relevant records including patient records.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: The current RPS 14 is not consistent with the requirements as per IAEA Safety Standards GSR Part 3 in relation to medical exposure control. Missing requirements include establishing requirements for sufficiency of medical and paramedical personnel, independent audits and periodicity of QA programmes, calibration of non-radiotherapy equipment, availability of national referral guidelines, period of maintenance of relevant records. This has been partly recognized in the ARM and is part of the action plan. A new code, RPS C-5, is being developed to replace RPS 14. The proposed revision will address many of the requirements as per GSR Part 3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
(2)	**BASIS: GSR Part 3 Requirement 36, para. 3.154 (c), (e) states that** *"Registrants and licensees shall ensure that:* *(c) Sufficient medical personnel and paramedical personnel are available as specified by the health authority* *(e) For diagnostic radiological procedures and image guided interventional procedures, the requirements of these Standards for medical imaging, calibration, dosimetry and quality assurance, including the acceptance paras 3.167, 3.168(a) and (b), 3.169, 3.170 and 3.171, are fulfilled by or under the oversight of or with the documented advice of a medical physicist, whose degree of involvement is determined by the complexity of the radiological procedures and the associated radiation risks".*
(3)	**BASIS: SSG-46 para. 2.54 states that** *"Adequate numbers of radiological medical practitioners, medical radiation technologists, medical physicists and other health professionals with responsibilities for patient radiation protection should be available for a medical radiation facility to function correctly and safely. This includes sufficient capacity to cover absences of key personnel through sickness, leave or other reasons. The health authority, through its policy making role, should set clear standards for acceptable medical practice."*
(4)	**BASIS: GSR Part 3 Requirement 41, para. 3.179 (d) states that** *" Registrants and licensees, in accordance with the relevant requirements of paras 2.51, 3.41–3.42 and 3.49–3.50, shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error …"*
(5)	**BASIS: GSR Part 3 Requirement 42, para. 3.183 (b) states that** *"Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following personnel records :* *b) Records of training of personnel in radiation protection (as required in para. 3.150(b))*
(6)	**BASIS: GSR part 3 Requirement 42 para 3.184 states that "***Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records of calibration, dosimetry and quality assurance……(a) records of results of the calibrations……..(d) Records associated with the quality assurance programme, as required in para. 3.171(d)."*
(7)	**BASIS: GSR part 3 Requirement 38 para 3.172 states that** *"Registrants and licensees shall ensure that regular and independent audits are made of the programme of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks."*
(8)	**BASIS: GSR part 3 Requirement 37 para 3.158 states that "***Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(9)	**BASIS: GSR part 3 para 3.169:** Registrants and licensees shall ensure that …. *A review is conducted to determine whether the optimization of protection and safety for patients is adequate, or whether corrective action is required if, for a given radiological procedure …(ii) Typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.*
R20	**Recommendation: The Governments should ensure the new Code for Radiation Protection in Medical Exposure is consistent with IAEA Safety Standards GSR Part 3 and take steps to adopt and implement it.**

11.2. OCCUPATIONAL RADIATION PROTECTION

Legal and regulatory framework

Australia has established a legal and regulatory framework for radiation safety which includes provisions for protection of workers exposed to radiation in their workplace. The Commonwealth has relevant legal requirements for the control of occupational exposures in the ARPANS Act and the *Work Health and Safety Act* 2011. The ARPANS Act establishes the functions of ARPANSA regarding the protection of the workers. ARPANSA is responsible for the regulatory control of occupational exposures in all Commonwealth entities. The Work Health and Safety Act, applicable to all Commonwealth workplaces, establishes the health and safety duties, in particular the primary duty of care for workers, the duty of care for control of all factors of a workplace and the duty of workers.

In 2016, ARPANSA published the *Code for Radiation Protection in Planned Exposure Situations* (RPS C-1) on behalf of the Australian radiation regulators. This publication has been adopted into the *National Directory for Radiation Protection (NDRP)*. ARPANSA has implemented RPS C-1 through the ARPANS Regulations, effective July 2017.

The ARPANS Regulations:

- establish the principles of justification, optimisation of protection and limitation of risks.
- provide occupational radiation protection requirements on the responsibility of the responsible person who will be, generally, the person who holds the authorization to deal with a radiation source.
- provide annual limits on effective dose and on equivalent dose to the hands, the skin and the extremities for workers, for persons under the age of 16 years and for pregnant and breast-feeding female workers.
- establish requirements for occupational exposure of pregnant and breast-feeding women.
- require employers to provide a worker with alternative work in circumstances where symptoms of a disease related to the effects of ionizing radiation have been identified, or it is confirmed or suspected that a dose limit has been exceeded.

The established dose limits are in compliance with GSR Part 3, with the exception of apprentices and students of 16 to 18 years, who are not specifically considered. Taking into account the circumstances in Australia, the RHC decided that persons between the ages of 16 and 18 years will be treated as adults for dose limitation purposes.

ARPANS Regulations do not require that the conditions of service of workers be independent of whether they are, or could be, subject to occupational exposure and that no compensatory arrangements or preferential considerations can exist. The IRRS team was informed that benefits can be offered to the exposed workers however, they are neither to be granted nor used as substitutes for measures for protection and safety.

Exposure of aircrew due to cosmic radiation is currently considered in the Guide for Radiation Protection in Existing Exposure Situations published by ARPANSA in 2017.
The IRRS team was informed that ARPANSA together with State and Territory regulatory bodies intends to adopt the national reference level for aircrew exposure provided in the Guide for Radiation Protection in Existing Exposure Situations, which is included in the draft 2nd edition of the NDRP.

General responsibilities of registrants, licensees and employers

ARPANS Regulations assign the responsibilities for the protection of workers to the responsible person, in compliance with GSR Part 3. However, the ARPANS Regulations do not require mandatory health surveillance for exposed workers. The IRRS team was informed that medical surveillance of exposed workers is performed on a case by case basis, based on a risk assessment.

General responsibilities of workers

The WHS Act attributes responsibilities to workers, such as taking reasonable care for his or her own health and safety and taking reasonable care that his or her acts or omissions do not adversely affect the health and safety of other persons.

Requirements for radiation protection programmes

The ARPANS Regulations require the responsible person to ensure protection from exposure to radiation by the application of administrative controls through work procedures, training and installation of warning signs and labels, and restricting access to radiation by designation of controlled and supervised areas. The responsible person shall also ensure that a qualified expert, who may be an employee of the responsible person, is identified and is consulted.

Monitoring programmes and technical services

The requirements in the ARPANS Regulations for monitoring programmes and technical services are compliant with GSR Part 3; the responsible person must arrange for appropriate radiation monitoring to assess external radiation doses, intakes of radionuclides and associated committed effective doses and maintain the necessary records. The responsible person must also ensure that records of doses assessed to have been received by an occupationally exposed person, including details of monitoring results and dose calculation methods.

ARPANSA administers the Australian National Radiation Dose Register (ANRDR) for the storage and maintenance of occupational radiation dose records. The ANRDR was originally developed for workers in the uranium mining industry. It includes provisions for recording external and internal effective doses, equivalent doses to the lens, the skin and the extremities and doses due to radon. Since July 2017, the submission of dose records is also a mandatory requirement for Commonwealth licence holders. Work is in progress for mandatory submission from State and Territory licence holders, depending on the adoption of RPS C-1 by the jurisdictional regulators. ARPANSA is currently working to provide jurisdictional regulators and workers with online access to dose records. Licensees provide individual dose records to ARPANSA for entry in the ANRDR.

There is no agreed and uniform requirement across Australian jurisdictions for accreditation for performing technical services, including mandatory qualifications of service providers. The IRRS team was informed

that Schedule 10 of the NDRP, will contain a minimum set of nationally agreed accreditation requirements for third-party service providers. Although this schedule has not yet been finalized, the IRRS team was informed that personal dosimetry provider accreditation could be based on the accreditation system of National Association of Testing Authorities (NATA).

ARPANSA services include the Personal Radiation Monitoring Service (PRMS). The PRMS is accredited by NATA and provides optically stimulated luminescence (OSL) badges, neutron dosimeters, extremity monitors and radon monitors. The PRMS dosimetry services is one of four dosimetry service providers in Australia.

ARPANSA maintains the primary standards for the dosimetry of ionisation radiation for Australia. The Australian Nuclear Science and Technology Organisation (ANSTO) and some hospitals perform internal dosimetry for their own workers with a risk to be exposed to internal contamination.

Training of Workers and Training Services

The ARPANS Regulations require that all personnel who may be exposed to radiation in their work have appropriate education, training and qualification. The responsible person must provide training, refresher training and other relevant information to occupationally exposed persons and maintain records of the details of training courses and participation by occupationally exposed persons.

ARPANSA requires that training service providers must be registered by the Australian Skills Quality Authority (ASQA) or, in some cases, a state regulator. Courses must also be accredited by ASQA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: ARPANS Regulations do not provide specific dose limits for apprentices and students from 16 to 18 years of age; and requirements on the exposure of aircrew due to cosmic radiation. Additionally, they do not require that the conditions of service of workers have to be independent of whether they are or could be subject to occupational exposure and that no compensatory arrangements or preferential considerations can exist; health surveillance for exposed workers; authorization or approval of dosimetry services for the exposed workers. This has been partly recognized in the ARM and is part of the Action Plan.	
(1)	**BASIS: GSR Part 3 Schedule III states that** *" For occupational exposure of apprentices of 16 to 18 years of age who are being trained for employment involving radiation and for exposure of students of age 16 to 18 who use sources in the course of their studies, the dose limits are:* *(a) An effective dose of 6 mSv in a year;* *(b) An equivalent dose to the lens of the eye of 20 mSv in a year;* *(c) An equivalent dose to the extremities (hands and feet) or to the skin of 150 mSv in a year."*
(2)	**BASIS: GSR Part 3 Requirement 27 Para 3.111 states that** *"The conditions of service of workers shall be independent of whether they are or could be subject to occupational exposure. Special compensatory arrangements, or preferential consideration with respect to salary, special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits, shall neither be granted nor be used as substitutes for measures for protection and safety in accordance with the requirements of these Standards."*
(3)	**BASIS: GSR Part 3 Requirement 52 para 5.30 states that** *" The regulatory body or other relevant authority shall determine whether assessment of the exposure of aircrew due to cosmic radiation is warranted."*
(4)	**BASIS: GSR Part 3 Requirement 52 para 5.31 states that** *" Where such assessment is*

	deemed to be warranted, the regulatory body or other relevant authority shall establish a framework which shall include a reference level of dose and a methodology for the assessment and recording of doses received by aircrew from occupational exposure to cosmic radiation."
(5)	**BASIS: GSR Part 3 Requirement 25 states that** *"Employers, registrants and licensees shall be responsible for making arrangements for assessment and recording of occupational exposures and for workers' health surveillance".*
(6)	**BASIS: GSR Part 3 Requirement 20 subparagraphs 3.73 (a) and (c) states that** *"The regulatory body shall be responsible, as appropriate, for: (a) … (c) Authorization or approval of service providers for individual monitoring and calibration services"*
R21	**Recommendation: ARPANSA, in conjunction with State and Territory regulatory bodies, should revise the current requirements on occupational radiation protection to ensure compliance with IAEA Safety Standards GSR Part 3.**

11.3. CONTROL OF RADIOACTIVE DISCHARGES, MATERIALS FOR CLEARANCE, AND EXISTING EXPOSURES SITUATIONS; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

Control of radioactive discharges and materials for clearance

The NDRP specifies that the values included in Schedule 14 represent the activities and concentration below which no approval for disposal and discharge is required.

For facilities and activities authorized, radioactive discharges and materials for clearance are assessed on a case-by-case basis during authorization and licence conditions include notification thresholds on airborne discharges. The IRRS team found that licence conditions do not specify discharge limits. However, the licences of the major nuclear installations specify notification levels based on an objective set to ensure the discharges to the environment for nuclear installations related to the representative individual level of 20μSv per annum, which is significantly below the annual limit of exposure to the public of 1mSv.

Additionally, the liquid discharges from a site to the sewer system is governed by a trade waste agreement, such as the one between ANSTO and Sydney Water, and the discharge limits for liquid discharges are set on the basis of WHO drinking water guidelines.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The current licences issued by ARPANSA require notification to the regulator if certain levels are exceeded. However, the licences do not include a specific limit on discharges.	
(1)	**BASIS: GSR Part 3 Requirement 31: Para's 3.123 states that** *"The regulatory body shall establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharges..."*
S12	**Suggestion: ARPANSA should consider applying nuclide specific discharge limits as part of the approved operating limits and conditions.**

Currently, there are no prescribed clearance values. However, NDRP schedule 14 values represent a level below which material can be cleared from authorized sites. The IRRS team was informed that ARPANSA intends to adopt the clearance levels provided in GSR Part 3 which is intended to be included in the 2nd edition of the NDRP.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no unified or agreed clearance levels for all radionuclides for use in Australia. While the draft NDRP (2nd Edition) proposes the use of the values as per GSR Part 3, this document has not yet been approved. This was acknowledged in the ARM and is part of the action plan.	
(1)	**BASIS: GSR Part 3 Requirements 8 states that** *"The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards. The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control."*
R22	**Recommendation: The Commonwealth Government, in conjunction with the State and Territory Governments, should progress the adoption and implementation of uniform clearance levels.**

Environmental monitoring for public radiation protection

ARPANSA requires licence holders to undertake a monitoring programme of their discharges including reporting of monitoring results to the regulator. However, ARPANSA does not undertake any independent monitoring of the environment to support the authorizations granted. The independent monitoring should include the nuclides that contribute significantly to public doses. This conclusion was also recognized in the ARM.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: ARPANSA does not undertake independent monitoring of operator discharges into the environment. This has been recognized in the ARM and is part of the action plan.	
(1)	**BASIS: "GSR Part 3 Requirement 32 Para 3.135 states that** *"The regulatory body shall be responsible, as appropriate, for…. (c) Making provision for an independent monitoring programme. (d) Assessment of the total public exposure due to authorized sources and practices in the State on the basis of monitoring data provided by registrants and licensees and with the use of data from independent monitoring and assessments."*
(2)	**BASIS: RS-G-1.8 Environmental and Source Monitoring for Purposes of Radiation Protection, Section 5.6 states that** *"….the monitoring programme should pay particular attention to the critical pathways and the critical radionuclides."*
R23	**Recommendation: ARPANSA should make provision for an independent monitoring programme to confirm the monitoring results submitted by licensees and should consider basing the programme on an assessment of the nuclides that make a major contribution to public dose.**

Existing exposure situations, including remediation of areas contaminated with residual radioactive material.

ARPANSA, in conjunction with State and Territory regulatory bodies, has developed a holistic framework for the management and control of existing exposure situations. The guidance is found in the *Guide for Radiation Protection in Existing Exposure situations* (RPS G-2) which aligns with the latest international ICRP and IAEA recommendations (GSR Part 3).

RPS G-2 provides coherent and qualitative guidance on defining legacy and other existing exposure situations including reference levels. The guide develops a methodology to establish site specific reference levels for further remediation. In addition, the guide outlines a methodology for transitioning from emergency to existing exposure situations.

RPS G-2 establishes clear guidance that is consistent with modern IAEA safety standards, addressing the management of existing exposure situations including the recognition, identification of reference levels and explaining their application to stakeholders.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Radiation Protection in Existing Exposure Situations (RPS G-2) and Radiation Protection in Emergency Exposure Situations (RPS G-3, draft) effectively engaged key stakeholders and provide a comprehensive national framework for effective management of emergency and existing exposure situations.	
(1)	**BASIS: GSR PART 3 para 5.3 states that** *"The government shall include in the legal and regulatory framework for protection and safety (see Section 2) provision for the management of existing exposure situations. The government, in the legal and regulatory framework, as appropriate:* *(a) Shall specify the exposure situations that are included in the scope of existing exposure situations;* *(b) Shall specify the general principles underlying the protection strategies developed to reduce exposure when remedial actions and protective actions have been determined to be justified;* *(c) Shall assign responsibilities for the establishment and implementation of protection strategies to the regulatory body and to other relevant authorities51 and, as appropriate, to registrants, licensees and other parties involved in the implementation of remedial actions and protective actions;* *(d) Shall provide for the involvement of interested parties in decisions regarding the development and implementation of protection strategies, as appropriate."*
GP4	**Good Practice: ARPANSA, in conjunction with State and Territory regulatory bodies, has established comprehensive guidance that addresses existing exposure situations including the methodology to be uses for the identification of legacy sites, the establishment of appropriate reference levels and explaining their application to stakeholders. The guide also addresses the transition from an emergency situation to an existing exposure situation and the strategies for effective management of legacy situations.**

Radon

Australia has completed a comprehensive survey of radon that found very low levels of radon in Australian homes. On this basis, ARPANSA had initially concluded that there is no need for a national radon action plan. However following consideration of the new ICRP dose coefficients for radon, ARPANSA is re-considering their position and a review of the radon strategy has been included in the ARPANSA corporate plan.

11.4. SUMMARY

The IRRS team reviewed the regulatory framework and practices for the control of medical, occupational and public exposures in Australia. The team found good alignment with international requirements, and identified areas for improvement relating to each of the focus areas.

With respect to medical, occupational and public exposure situations, the team found that while there are provisions for nearly all aspects of radiation protection, the identified gaps should be addressed in order to fully comply with GSR Part 3.

The IRRS team also identified a good practice with respect to the framework for radiation protection in existing exposure situations.

12. INTERFACE WITH NUCLEAR SECURITY

This section of the report is limited to the Commonwealth regulatory body, ARPANSA, and does not address the State and Territory regulatory bodies.

12.1. LEGAL BASIS

While ARPANSA is the Commonwealth regulatory body for safety and security of radioactive materials, the Australian Safeguards and Non-proliferation Office (ASNO) is the competent authority for ensuring Australia's compliance with the Comprehensive Safeguards Agreement and Additional Protocol with the IAEA, and with the amended Convention on the Physical Protection of Nuclear Material. This is done through the accounting and control of nuclear material and the regulation of physical protection (nuclear security) for all jurisdictions. There is an information sharing arrangement in place under a memorandum of understanding (MoU) between ASNO and ARPANSA.

The Australian Federal Police and local emergency response agencies generally have roles defined through the emergency plans, or transport plans associated with specific tasks or scenarios. The Australian Government Crisis Management Framework recognizes that emergency response organizations require integration into multidisciplinary teams for safety and security-initiated events.

12.2. REGULATORY OVERSIGHT ACTIVITIES

The ARPANSA website lists international best practice documentation including NSS-13, NSS-14, NSS-15 and IAEA-TECDOC-1801 Management of the Interface between Nuclear Safety and Security for Research Reactors. All of these documents refer to interfaces between safety and security, are promoted by ARPANSA as best practice, and may be considered during application and review.

ARPANSA has also listed GSR Part 7 as international best practice and its requirements are considered in regulatory decisions and guidance. This includes emergency response arrangements for licence holders.

As part of the inspection programme, Performance Objectives and Criteria (PO&C) Baseline Module (BM) 6.3 states: 'The organization has effective security management arrangements that are supported by a good security culture. An integrated approach is taken to Safety and Security'. This is further expanded upon under BM 6.3.4 which states: 'Safety and security measures are developed so that they do not compromise each other. Safety and security are seen as complementary and processes are designed so that measures for one complement the other'.

Similarly, Paragraph 18 of the compliance code attached to ANSTO's permit to possess nuclear material, granted by ASNO under the Safeguards Act, states that 'The Permit Holder shall manage the nuclear security interface with nuclear safety and nuclear material accountancy and control arrangements in a manner to ensure that they do not adversely affect each other and to the degree possible, they are mutually supportive'.

The IRRS team noted that in practice multi-disciplined safety and security teams are established to review applications and inspect the siting, construction and operation of a facility.

12.3. INTERFACE AMONG AUTHORITIES

ARPANSA and ASNO have jointly developed the regulatory guide Periodic Safety and Security Review of Research Reactors (PSSR), which specifically requires consideration of the interfaces between safety and security when conducting a periodic review.

ARPANSA and ASNO have established a Joint Physical Protection and Security Working Group where there are shared responsibilities and any issues with the interfaces between safety and nuclear security can be resolved.

Additionally, co-operative meetings are held on security issues, on an as-needed basis. For example, at a recent meeting in early 2018 ARPANSA met with the Australian Federal Police (AFP), ASNO and ANSTO to discuss protective security arrangements at the Lucas Heights Science and Technology Centre.

12.4. SUMMARY

The IRRS team reviewed the interfaces with nuclear security. Integration of safety and security is explicitly covered in regulatory guidance (such as PSSR documents) and the ARPANS inspection programme (PO&Cs). Additionally, the primary nuclear regulators ASNO and ARPANSA have regular joint meetings with affected parties, including licence holders, and exchange information under a MoU.

While a strict legal basis is not apparent for the initiatives that are being carried out to ensure integration of safety and security, Australia's requirements are integrated through a variety of mechanisms. In addition the safety and security interface is prescribed through a permit condition as described in Section 12.2

APPENDIX I LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS			
1.	TIIPPANA Petteri	Radiation and Nuclear Safety Authority (STUK), FINLAND	Petteri.Tiippana@stuk.fi
2	DUDES Laura	U.S. Nuclear Regulatory Commission (USNRC), UNITED STATES OF AMERICA	Laura.Dudes@nrc.gov
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5.	FERON Fabien	Autorite de Surete Nucleaire, FRANCE	fabien.feron@asn.fr
6.	RABSKI Henry	Canadian Nuclear Safety Commission (CNSC), CANADA	henry.rabski@canada.ca
7.	OHLEN Elisabeth	Swedish Radiation Safety Authority (SSM), SWEDEN	Elisabeth.Ohlen@ssm.se
8.	PATHER Thiagan	National Nuclear Regulator (NNR), SOUTH AFRICA	TPather@nnr.co.za
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12.	SMITH Veronica	Environmental Protection Agency, IRELAND	V.Smith@epa.ie
13.	PERRIN Marie Line		marie-line.perrin@wanadoo.fr
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15.	TEIXEIRA Flavia Cristina	National Nuclear Energy Commission (CNEN), BRAZIL	flavia@cnen.gov.br

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17.	SU Wendy	National Environment Agency (NEA), SINGAPORE	wendy_su@nea.gov.sg
IAEA STAFF MEMBERS			
1.	MANSOUX Hilaire	Division of Radiation, Transport and Waste Safety	H.Mansoux@iaea.org
2.	SHAH Zia	Division of Nuclear Installation Safety	Z.H.Shah@iaea.org
3.	DOETSCH Rebeka	Division of Radiation, Transport and Waste Safety	R.Doetsch@iaea.org
LIAISON OFFICER			
1.	HELMSLEY Ryan	Director Government and International Relations Office of the CEO	ryan.hemsley@arpansa.gov.au

APPENDIX II LIST OF MAIN COUNTERPARTS

IRRS EXPERTS	ARPANSA COUNTERPARTS
RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	
REISNER Dominik DUDES Laura	LARSSON Carl-Magnus
GLOBAL SAFETY REGIME	
REISNER Dominik DUDES Laura	HELMSLEY Ryan
RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	
MOSES Colin	WARD John
MANAGEMENT SYSTEM	
OHLEN Elisabeth	COLLETT Sarsha
AUTHORIZATION	
FERON Fabien RABSKI Henry PATHER Thiagan SNEVE Malgorzata SHIN Dae Soo REICHE Ingo	KALAIZIOVSKI Alex SARKAR Samir WIGNEY Fran MOTTL Vaz TEMPLETON John
REVIEW AND ASSESSMENT	
FERON Fabien RABSKI Henry PATHER Thiagan SNEVE Malgorzata SHIN Dae Soo REICHE Ingo	KALAIZIOVSKI Alex SARKAR Samir WIGNEY Fran MOTTL Vaz TEMPLETON John
INSPECTION	

IRRS EXPERTS	ARPANSA COUNTERPARTS
FERON Fabien RABSKI Henry PATHER Thiagan SNEVE Malgorzata SHIN Dae Soo REICHE Ingo	KALAIZIOVSKI Alex SARKAR Samir WIGNEY Fran MOTTL Vaz TEMPLETON John
ENFORCEMENT	
FERON Fabien RABSKI Henry PATHER Thiagan SNEVE Malgorzata SHIN Dae Soo REICHE Ingo	KALAIZIOVSKI Alex SARKAR Samir WIGNEY Fran MOTTL Vaz TEMPLETON John
REGULATIONS AND GUIDES	
FERON Fabien RABSKI Henry PATHER Thiagan SNEVE Malgorzata SHIN Dae Soo REICHE Ingo	KALAIZIOVSKI Alex SARKAR Samir WIGNEY Fran MOTTL Vaz TEMPLETON John
EMERGENCY PREPAREDESS AND RESPONSE	
SMITH Veronica	GRZECHNIK Markus
ADDITIONAL AREAS - Medical Exposure	
MAHALAKSHMI Sivaramakrishnan TEIXEIRA Flavia Cristina	THOMAS Peter
ADDITIONAL AREAS - Occupational Exposure	
PERRIN Marie-Line	LAWRENCE Cameron
ADDITIONAL AREAS - Control of Radioactive Discharges, Materials for Clearance, and Existing Exposures Situations; Environmental Monitoring for Public Radiation Protection	

IRRS EXPERTS	ARPANSA COUNTERPARTS
SNEVE Malgorzata	CHARALAMBOUS Fiona MCCORMICK Andrew
INTERFACE WITH NUCLEAR SECURITY	
REISNER Dominik DUDES Laura	CASTLE Loch

APPENDIX III MISSION PROGRAMME

IRRS AUSTRALIA MISSION PROGRAMME		
Sunday Nov 4, 2018		
IRRS Initial Team Meeting		
13:30 - 19:00	Opening remarks by the IRRS Team Leader Introduction by IAEA Self-introduction of all attendees IRRS Process (IAEA) Report writing (IAEA) Schedule (Team Coordinator, IAEA) Administrative arrangements (host country Liaison Officer, IAEA): Detailed Mission Programme First impression from IRRS Team members arising from the Advance Reference Material (all team members): Presentations Groups preparation for interviews	Venue: Hotel Mantra on Russell Participants: IRRS Team + Liaison Officer (LO)
19:00 - 21:00	IRRS Team dinner	
Monday Nov 5, 2018		
IRRS Entrance Meeting		
09:30 - 12:00	09.30 Arrival and registration 10.00 Welcome and acknowledgement of country, Tone Doyle 10.05 Opening Remarks • CEO ARPANSA, Carl-Magnus Larsson • IAEA Deputy Director General, Juan Carlos Lentijo • Team Leader, IRRS Mission, Petteri Tiippana • Minister for Regional Communications, Rural Health and Sport, Senator the Hon Bridget McKenzie	Venue: Heidelberg Golf Club Participants: High Level Government Official, RB Management and staff, officials from relevant organisations, IRRS Team + the LO

IRRS AUSTRALIA MISSION PROGRAMME		
	10.35 Introduction of IRRS team members and counterparts, Experts and counterparts 11.00 Overview of the regulation of nuclear safety and radiation protection in Australia, Jim Scott 11.20 Main findings of the self-assessment , Liaison Officer, Ryan Hemsley 11.35 Perspective of a license holder, Major General, David Mulhall 11.50 Management of the IRRS, Ryan Hemsley and Tone Doyle	
12:00 - 13:00	Group photo Lunch	Venue: Heidelberg Golf Club
13:00 - 17:00	Interviews and Discussions with Counterparts (parallel discussions) Module 1 Responsibilities and functions of Government Module 3 Responsibilities and Functions of the Regulatory Body Module 4 Management system of the regulatory body Modules 5 to 9 Waste Management Facilities and Decommissioning Modules 5 to 9 Radiation Sources Modules 5 to 9 Research Reactors Modules 5 to 9 Transport Module 10 EPR Module 11 Patient Protection Module 11 Environment & Control of Discharges, Public Exposure, Existing Exposure Situations Module 11 Occupational Exposure & Control	Venue: ARPANSA Rooms Participants: Experts and counterpart
17:00 - 18:00	Daily IRRS Team meeting	Venue: Yarra Room Participants: IRRS Team + the LO

IRRS AUSTRALIA MISSION PROGRAMME		
Tuesday Nov 6, 2018		
08:30 - 09:00	Daily morning brief	Petteri Tiippana, Carl-Magnus Larsson, Laura Dudes, Jim Scott, Gillian Hirth, Hilaire Mansoux, Zia Shah, Ryan Hemsley
09:00 - 12:00	Interviews and discussions with counterparts (parallel discussions) Module 1 Responsibilities and functions of Government Module 3 Responsibilities and Functions of the Regulatory Body Module 4 Management system of the regulatory body Modules 5 to 9 Waste Management Facilities and Decommissioning Modules 5 to 9 Radiation Sources Modules 5 to 9 Research Reactors Modules 5 to 9 Transport Module 10 EPR Module 11 Patient Protection Module 11 Environment & Control of Discharges, Public Exposure, Existing Exposure Situations Module 11 Occupational Exposure & Control	Venue: ARPANSA Rooms Participants: Experts and counterpart
12:00 - 13:00	Lunch	
13:00 - 17:00	Interviews and discussions with counterparts (parallel discussions) – as above + meetings with policy departments	Venue: ARPANSA Rooms Participants: Experts and counterpart
17:00 - 18:00	Daily IRRS Team meeting	Venue: Yarra Room Participants: IRRS Team + the LO
18:00	Departure for site visit to Lucas Heights	
Wednesday Nov 7, 2018		
08:30 - 09:00	Daily morning brief	Petteri Tiippana, Carl-Magnus Larsson, Laura Dudes, Jim Scott,

IRRS AUSTRALIA MISSION PROGRAMME		
		Gillian Hirth, Hilaire Mansoux, Zia Shah, Ryan Hemsley
09:00 - 12:00	Interviews and discussions with counterparts (parallel discussions) Module 2 Global nuclear safety regime Module 3 Responsibilities and Functions of the Regulatory Body Module 4 Management system of the regulatory body Modules 5 to 9 Waste Management Facilities and Decommissioning Modules 5 to 9 Transport (States & Territories) Module 10 EPR Module 11 Environment & Control of Discharges, Public Exposure, Existing Exposure Situations Module 11 Occupational Exposure & Control	Venue: ARPANSA Rooms Participants :Experts and counterpart
09:00 - 16:30	Site-visits	Venue :Lucas Heights; Williamstown; St Vincent Hospital – Participants : D. Shin, P. Tiippana for Lucas Heights; F.Feron, H. Rabski, M.L. Perrin, L. Mahalalshmi, F. Teixeira+ Victoria RB for Williamstown; St Vincent Hospital
12:00 - 13:00	Lunch	
13:00 - 17:00	Interviews and discussions with counterparts (parallel discussions) Module 3 Responsibilities and Functions of the Regulatory Body Module 4 Management system of the regulatory body Modules 5 to 9 Waste Management Facilities and Decommissioning Module 11 Environment & Control of Discharges, Public Exposure, Existing Exposure Situations Module 11 Occupational Exposure & Control	Venue: ARPANSA Rooms Participants :Experts and counterpart

IRRS AUSTRALIA MISSION PROGRAMME		
	Module 12 Interfaces with nuclear security	
17:00 - 18:30	Daily IRRS Team meeting	Venue: Yarra Room + video conference with Miranda site Participants: IRRS Team + the LO
Thursday Nov 8, 2018		
08:30 - 09:00	Daily morning brief	Petteri Tiippana, Carl-Magnus Larsson, Laura Dudes, Jim Scott, Gillian Hirth, Hilaire Mansoux, Zia Shah, Ryan Hemsley
09:00 - 10:00	Follow-up interviews and discussions with counterparts (parallel discussions), as needed	Venue: ARPANSA rooms Participants: IRRS Team and Counterparts
10:00 - 12:00	Policy issue Discussion: National Uniformity	Venue: Yarra room Participants: IRRS Team and Counterparts
12:00 - 13:00	Lunch	Venue :ARPANSA
13:00 - 16:00	Report preparation, preliminary findings (recommendations, suggestions, good practices)	Venue :ARPANSA Participants: IRRS Team
16:00 -17:00	Preliminary findings delivery and compilation	Venue :ARPANSA Participants: IRRS Team
17:00 - 18:30	Daily IRRS Team Meeting: recommendation, suggestions and good practices	Venue: ARPANSA Participants: IRRS Team + the LO
Friday Nov 9, 2018		
08:30 -09:00	Daily morning brief	Petteri Tiippana, Carl-Magnus Larsson, Laura Dudes, Jim Scott, Gillian Hirth, Hilaire Mansoux, Zia Shah, Ryan Hemsley
09:00 - 13:00	Follow-up Interviews as needed Report preparation	Venue: ARPANSA rooms Participants: IRRS Team
13:00 - 14:00	Lunch	Venue: ARPANSA

IRRS AUSTRALIA MISSION PROGRAMME		
14:00 - 16:00	Report preparation	Venue: ARPANSA rooms Participants: IRRS Team
16:00 - 18:30	Daily IRRS Team Meeting: report preparation: finalize observations, basis, recommendations, suggestions and good practices	Venue: Yarra room Participants: IRRS Team + the LO
Saturday Nov 10, 2018		
09:00 - 18:30	• IRRS Team members draft the report and finalize recommendations, suggestions and good practices • Draft report cross reading • Finalization of the report by the entire IRRS Team	Venue: Yarra Room Participants :IRRS Team
20:00 - 22:00	IRRS Team Lead and IAEA Coordinators edit draft report	Venue: Mantra on Russell Participants: TL, DTL, TC, DTC
Sunday Nov 11, 2018		
IRRS Team rest day		
Dinner with ARPANSA and IRRS team		Venue: The Mess Hall
Monday Nov 12, 2018		
08:30 - 09:00	Daily morning brief	Petteri Tiippana, Carl-Magnus Larsson, Laura Dudes, Jim Scott, Gillian Hirth, Hilaire Mansoux, Zia Shah, Ryan Hemsley
09:00 - 12:00	Parallel individual review and discussions of the report sections with the counterparts. Report writing	Venue: ARPANSA rooms Participants: IRRS Team, Counterparts
12:00 - 13:00	Lunch	Venue: ARPANSA
13:00 - 17:00	Report finalising by the IRRS Team	Venue: ARPANSA rooms Participants: IRRS Team

IRRS AUSTRALIA MISSION PROGRAMME		
17:00 - 18:30	IRRS Team Lead and IAEA Coordinators finalize draft report editing	Venue; ARPANSA rooms Participants: TL, DTL, TC, DTC
Tuesday Nov 13, 2018		
09:00 - 10:00	Finalize report text and submit draft report to ARPANSA	Venue: Mantra on Russell Participants: IRRS Team
10:00 - 18:00	ARPANSA organises the review of the draft by all national counterparts and start review	
10:00 - 18:00	IRRS Team Lead and IAEA Coordinators draft: executive summary and prepare exit presentation and press release	Venue: Mantra on Russell Participants: TL, DTL, TC, DTC
Wednesday Nov 14, 2018		
09:00 - 17:00	ARPANSA finalises the review of the draft report and submit written comments to the IRRS Team	
12:00 - 13:00	Lunch	
17:00 - 21:00	IRRS Team reviews Host's comments and finalizes draft report. Handover of the report to ARPANSA	Venue: Mantra on Russell Participants: IRRS Team
Thursday Nov 15, 2018		
08:30 - 09:00	Daily morning brief	Petteri Tiippana, Carl-Magnus Larsson, Laura Dudes, Jim Scott, Gillian Hirth, Hilaire Mansoux, Zia Shah, Ryan Hemsley
09:00 - 12:00	Discussions with hosts on findings	Venue: Yarra Room Participants: IRRS Team and host counterparts
12:00 - 13:00	Lunch	

IRRS AUSTRALIA MISSION PROGRAMME		
13:00 - 17:00	Team meeting for report finalization based on discussions with the hosts Submission of the final draft report to ARPANSA	Venue: Yarra room Participants: IRRS Team
Friday Nov 16, 2018		
11:00 - 12:00	IRRS Exit meeting (IAEA) Main findings of the IRRS mission (Team Leader) Remarks by the host in response to the mission findings Closing remarks (IAEA)	Venue: ARPANSA Participants: Government Official, RB Management and staff, the IRRS Team + the LO
12:00 - 14:00	Farewell lunch	Venue: ARPANSA Participants: All

APPENDIX IV SITE VISITS

SafeRad SE Asia (Industrial Radiography facility)

St. Vincent's Hospital Fitzroy

Lucas Heights Science and Technology Centre

APPENDIX V RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**	S1	The Commonwealth Government, in conjunction with State and Territory Governments, should consider formalizing the existing elements of the framework for safety into a comprehensive national policy and strategy for safety.
		R1	The Commonwealth Government, in conjunction with State and Territory Governments, should ensure a consistent level of protection of people and the environment through effective coordination and harmonized implementation of codes and guides by the Commonwealth, States, Territories and regulatory bodies.
		R2	The Commonwealth Government should establish and implement a strategy to give effect to the policy principles and goals in the Australian Radioactive Waste Management Framework.
		R3	The Commonwealth Government should establish a national policy and strategy for decommissioning of facilities.
		R4	The Commonwealth Government, in conjunction with State and Territory Governments, should ensure that financial provisions are provided to enable the management of disused radioactive sources.
		R5	The Governments should ensure that all parties having responsibilities for safety of facilities and regulatory activities have the necessary competence and resources to carry out their responsibilities.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
2.	GLOBAL SAFETY REGIME	R6	The Commonwealth Government, in conjunction with State and Territory Governments should ensure full implementation of the Code of Conduct on the Safety and Security of Radioactive Sources.
		GP1	Demonstrating a commitment to enhancing national uniformity and consistency, the Australian Governments have actively engaged in a comprehensive, multijurisdictional international peer review. The active engagement by Commonwealth, State and Territory regulatory bodies, allowed the IRRS team to develop recommendations and suggestions that should contribute to the safe use of radiation for the benefit of all Australians. This is the first IRRS mission that included a holistic review of the nuclear and radiation safety framework across multiple regulatory jurisdictions.
		S2	ARPANSA, in conjunction with the State and Territory regulatory bodies, should consider improving on the methods to better disseminate national and international experience gained by the regulatory bodies across the Australian jurisdictions.
		R7	Regulatory bodies should assess the need for updating regulatory requirements or guidance, review and assessment, inspection and licensing processes after considering the events reported in ARIR, especially the noteworthy events highlighted in the annual ARIR report.
3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	S3	ARPANSA should consider formalizing its arrangements to independently review its oversight of regulated facilities and activities undertaken by ARPANSA, including their authorization, review and assessment, and inspection.
		R8	ARPANSA should enhance its human resource management to include an assessment of the number and capabilities of staff required

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			to effectively perform their regulatory and emergency response duties and enhance their training programme based on an analysis of the necessary skills and competencies.
		GP2	ARPANSA has a well-developed strategy to compensate for the departure of qualified staff that systematically assessed succession risks for every position in the organization and prioritised the development of competencies that were found to be vulnerabilities to the long-term capability of the organization.
		S4	ARPANSA should consider developing and implementing requirements for authorized parties to establish effective mechanisms of communication with interested parties.
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**	GP3	ARPANSA applies a holistic and comprehensive way of integrating all types of risks in the management processes, the regulatory activities, and day-to-day work activities, providing a strong foundation for their performance management framework.
		R9	ARPANSA should further define, develop, and document its processes including sequencing of the processes and the interactions between interfacing processes within the IMS.
		R10	ARPANSA should undertake an independent assessment of leadership for safety and safety culture covering all organizational levels and all functions in the organization.
5.	**AUTHORIZATION**	S5	The State and Territory regulatory bodies should consider reviewing their requirements for authorization (authorization by licence vs authorization by registration and duration of an authorization), based on their regulatory experience and risks, with the goal of making better use of existing regulatory resources.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		S6	ARPANSA should consider revising the regulation and guidance for licensing of research reactors to include extended shutdown and associated submission requirements.
		S7	ARPANSA should consider revising the conditions of licence to require decommissioning plans for all life stages of the facility.
6.	**REVIEW AND ASSESSMENT**	R11	ARPANSA should conduct a comprehensive evaluation to determine whether its current regulatory oversight measures (regulations and guides, review and assessment, inspection and licensing) should be modified, based on lessons learned, including but not limited to those identified in the ANSTO independent safety review report, of the events that occurred at the ANSTO Health facility.
		S8	ARPANSA should consider requiring the licensee to perform severe accident analysis, assess design extension conditions and update final safety analysis accordingly.
		R12	Regulatory bodies as well as the Civil Aviation Safety Authority and the Australian Maritime Safety Authority, should coordinate to ensure consistent review of applications for approval of package design and special form radioactive material design.
7.	**INSPECTION**	R13	The State and Territory regulatory bodies should develop an inspection strategy and carry out a resource allocation assessment.
8.	**ENFORCEMENT**	R14	State and Territory regulatory bodies should have an enforcement policy to provide staff direction in the application of enforcement actions commensurate to the significance and nature of any regulatory non-compliance.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
9.	**REGULATION AND GUIDES**	S9	The Commonwealth Government, in conjunction with State and Territory Governments should consider revising the process to maintain and update the NDRP and the means for implementing codes in order to support timely adoption and implementation of new national codes.
		S10	ARPANSA, in conjunction with the State and Territory regulatory bodies should consider completing a review of the regulatory framework and prioritizing identified gaps to ensure that it is comprehensive and provides adequate coverage commensurate with the radiation risks associated with the facilities and activities in accordance with a graded approach.
		R15	Regulatory bodies should ensure that their regulations for the safe transport of radioactive material align with the latest revision of the Code for the Safe Transport of Radioactive Material (Radiation Protection Series C-2) and ensure that these regulations apply to all operations specified in the scope of the IAEA Regulations for the Safe Transport of Radioactive Material SSR-6.
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	R16	ARPANSA should develop criteria for evaluation of licensee exercises, to include the observation of exercises as part of the inspection process and ensure that licensees exercise all aspects of their emergency plan over an agreed time period and in line with a graded approach.
		R17	The Commonwealth Government, in conjunction with State and Territory Governments should ensure that the roles and responsibilities of ARPANSA in emergency preparedness and response both for incidents involving its own licensees and for incidents in the States and Territories are clearly assigned and exercised.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R18	ARPANSA should strengthen its Incident Management Plan by assigning roles and responsibilities, ensuring all elements of the Plan are tested and addressing lessons learned following exercises or real events.
11.1	**CONTROL OF MEDICAL EXPOSURES**	R19	ARPANSA, in collaboration with professional bodies, should establish DRLs for medical exposures incurred in medical imaging, including image guided interventional procedures, where practicable.
		S11	The Governments should consider developing common competency requirements for relevant medical professionals in radiation protection and safety and ensuring consistent application across the jurisdictions.
		R20	The Governments should ensure the new Code for Radiation Protection in Medical Exposure is consistent with IAEA Safety Standards GSR Part 3 and take steps to adopt and implement it.
11.2	**OCCUPTIONAL RADIATION PROTECTION**	R21	ARPANSA, in conjunction with State and Territory regulatory bodies, should revise the current requirements on occupational radiation protection to ensure compliance with IAEA Safety Standards GSR Part 3.
11.3	**CONTROL OF RADIOACTIVE DISCHARGES, MATERIALS FOR CLEARANCE, AND EXISTING EXPOSURES SITUATIONS; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION**	S12	ARPANSA should consider applying nuclide specific discharge limits as part of the approved operating limits and conditions.
		R22	The Commonwealth Government, in conjunction with the State and Territory Governments, should progress the adoption and implementation of uniform clearance levels.
		R23	ARPANSA should make provision for an independent monitoring programme to confirm the monitoring results submitted by licensees

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			and should consider basing the programme on an assessment of the nuclides that make a major contribution to public dose.
		GP4	ARPANSA, in conjunction with State and Territory regulatory bodies, has established comprehensive guidance that addresses existing exposure situations including the methodology to be uses for the identification of legacy sites, the establishment of appropriate reference levels and explaining their application to stakeholders. The guide also addresses the transition from an emergency situation to an existing exposure situation and the strategies for effective management of legacy situations.

APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

ADVANCE REFERENCE MATERIAL	
ARMS Summary Report	
1.	IRRS ARM Summary Report - Australia 2018.pdf
Australia Saris Report	
2.	5 - ACT - Response.docx
3.	5 - NSW - Response.PDF
4.	5 - QLD - Response - Authorization_final.docx
5.	5 - SA - Response - Authorisation_SA EPA-Final.docx
6.	5 - TAS - Response - Authorization.docx
7.	5 - VIC - Response - Authorisation.docx
8.	5 - WA - Response - Authorization.docx
9.	6 - ACT - Response.docx
10.	6 - NSW - Response.PDF
11.	6 - QLD - Response -Review and Assessment_final.docx
12.	6 - SA - Response - Review and Assessment_SA EPA-Final.docx
13.	6 - TAS - Response - Review and Assessment.docx
14.	6 - VIC - Response - Review and Assessment.docx
15.	6 - WA - Response - Review and Assessment.docx
16.	7 - ACT - Response.docx
17.	7 - NSW - Response.PDF
18.	7 - QLD - Response - Inspection_final.docx
19.	7 - SA - Response - Inspection_SA EPA-Final.docx
20.	7 - TAS - Response - Inspection.docx
21.	7 - VIC - Response - Inspections.docx
22.	7 - WA - Response - Inspection.docx
23.	8 - ACT - Response.docx
24.	8 - ARPANSA - Response 2018-sep-13 Enforcement.DOCX
25.	8 - NSW - Response.PDF
26.	8 - QLD - Response - Enforcement_final.docx
27.	8 - SA - Response - Enforcement_SA EPA-Final.docx
28.	8 - TAS - Response - Enforcement.docx
29.	8 - VIC - Response - Enforcement.docx
30.	8 - WA - Response - Enforcement.docx
31.	9 - ARPANSA - Response - Module 9 Regulations and Guides - final - DH.DOCX

32.	ACT - Response.docx
33.	ACT - Response.docx
34.	ARPANSA - Response - IRRS Module 11c Transport_Final.DOCX
35.	ARPANSA Response Module 11d Control of Medical Exposure.docx
36.	FINAL Response Module 11a - Safety Requirements for Radiation Sources_CM....DOCX
37.	MED - ACT - Response.docx
38.	MED - NSW - Response.PDF
39.	MED - QLD - Response -Medical Exposure - Safety Requirements_final.docx
40.	MED - SA - Response - Control of Medical Exposure_SA EPA-Final.docx
41.	MED - TAS - Response - Safety of Medical Exposure.docx
42.	MED - VIC - Response - Safety of medical exposure - radiation.docx
43.	MED - WA - Response - Safety Requirements for Medical Exposure.docx
44.	Module 1 Response - Responsibilities and Functions of Government - Final.DOCX
45.	Module 2 The Global Safety Regime - Responses - amended post-review - Jan 2018.DOCX
46.	Module 3 Response.DOCX
47.	Module 5b Disposal of Radioactive Waste.DOCX
48.	mrsr-management-licence-holders-obligations-pdf.pdf
49.	NSW - Response.PDF
50.	NSW - Response.PDF
51.	NSW EPA Self Assessment Report for Radiation Safety.pdf
52.	Primary Module 11b Research Reactors - core questions and responses.DOCX
53.	Primary Module 5 Authorisation - core questions and responses - final.DOCX
54.	Primary Module 6 Review and Assessment - Core Questions and responses (IRRS).DOCX
55.	QLD - Response - - Safety Requirements_final.docx
56.	QLD - Response -Radiation Sources - Safety Requirements_final.docx
57.	QLD IRRS Self Assessment.pdf
58.	R18_03188 Overview Assessments.xlsx
59.	Response Module 10 Emergency Preparedness and Response - Final.DOCX
60.	Response Module 11e Occupational Radiation Protection - Final.DOCX
61.	Response Module 12 Interface with nuclear security (FINAL 22OCT2018).DOCX
62.	Response Module 5a - Regulation of decommissioning of facilities.DOCX
63.	Response Module 5c Chronic Exposure and remediation.DOCX
64.	Response Module 5d - Safety Requirements for Predisposal Management of R....DOCX
65.	Response Module 5e - Safety Requirements for the Control of Public Expos....DOCX
66.	Response Module 7 - Inspection.DOCX
67.	Response Module 8 - Enforcement.DOCX
68.	Response to Module 4 - Management System for the Regulatory Body.DOCX
69.	SA - Response - Regulation of Radiation Sources_SA EPA-Final.docx
70.	SA - Response - Transport_SA EPA-Final.docx
71.	SA EPA Self-Assessment Report - SA - REPORT.DOCX
72.	TAS - Response - Regulation of Transport of Radioactive Material.docx

73.	TAS - Response - Safety Requirements for Radiation Sources.docx
74.	VIC - Response - Regulation of radiation sources.docx
75.	VIC - Response - Transport of radioactive material.docx
76.	WA - Response - Safety Requirements for Radiation Sources.docx
77.	WA - Response - Safety Requirements for Transport of Radioactive Material.docx
78.	WA IRRS Self Assessment Report.pdf
Australia reference documents:	
79.	Australian Radiation Protection and Nuclear Safety Act 1998 (ARPANS Act).PDF
80.	Australian Radiation Protection and Nuclear Safety Regulations 1999 (ARPANS Regs).PDF
81.	Australian Radioactive Waste Management Framework.PDF
82.	Causes of complex legislation and strategies to address these.PDF
83.	Compliance and Enforcement Manual (REG-COM-MAN-270).DOCX
84.	Draft National Directory for Radiation Protection - for public consultation.docx
85.	enHealth Agenda Paper - Regulation of radiation protection and nuclear safety activities in Australia Aug 2018.docx
86.	Facility Licence F0157 - ANSTO - Operate the Replacement Research Reactor, OPAL.PDF
87.	ARPANSA - SOURCE Licence S0002.PDF
88.	ARPANSA - SOURCE Licence S0003.PDF
89.	ARPANSA Organisational Chart - May 2018.PDF
90.	Australian Radiation Protection and Nuclear Safety (Licence Charges) Act 1998.PDF
91.	Australian Radiation Protection and Nuclear Safety (Licence Charges) Regulations 2000.PDF
92.	Radiation Health Committee NU Options Paper - endorsed.pdf
93.	Radiation Protection Series - Fundamentals for Protection Against Ionising Radiation (RPS F-1).PDF
94.	Radiation Protection Series - Guide for Radiation Protection in Existing Exposure Situations (RPS G-2).pdf
95.	Radiation Protection Series - National Directory for Radiation Protection (RPS 6).PDF
96.	Radiation Protection Series - Radiation Protection in Planned Exposure Situations (RPS C-1).PDF
97.	Radiation Protection Series - Radiation Protection of the Environment (RPS G-1).PDF
98.	Radiation Protection Series - Safe Transport of Radioactive Material (RPS C-2).PDF
99.	Radiation Protection Series - Safe Use of Fixed Radiation Gauges (RPS 13).PDF
100.	Radiation Protection Series - Security of Radioactive Sources (RPS 11).PDF
101.	Regulator Performance Framework.PDF
102.	Regulatory Assessment Criteria for the Design of New Controlled Facilities and Modifications RG-5 (RB-STD-43-00 Rev 1).PDF
103.	Inspection Manual (REG-INS-MAN-280).DOCX
104.	Licensing and Assessment Manual (REG-LA-MAN-240).DOCX
105.	Performance Objectives and Criteria (POandC).PDF
106.	Policy for ARPANSA's Regulatory Activities (ARPANSA-POL-002).PDF
107.	Public Governance, Performance and Accountability Act 2013.PDF

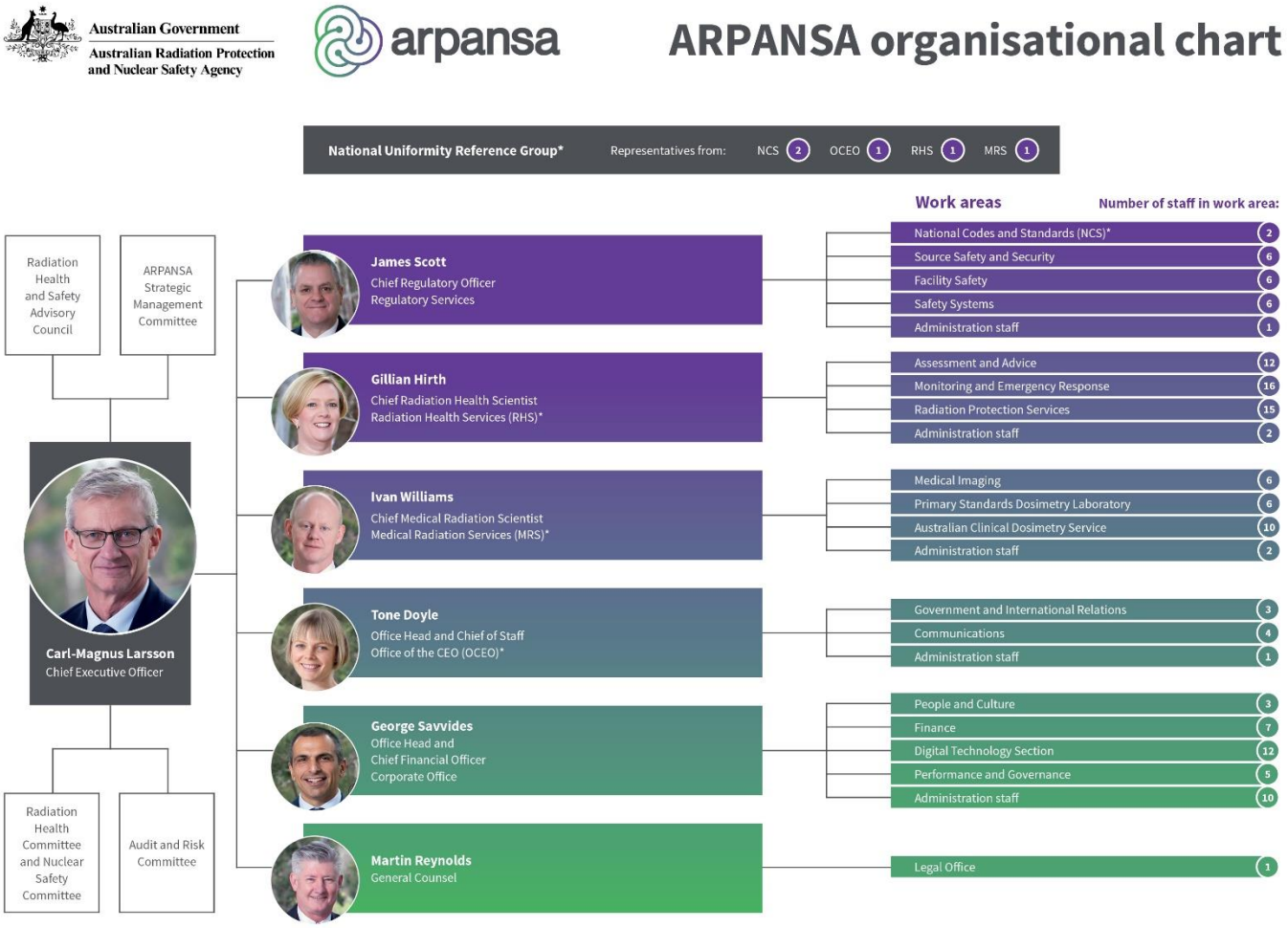
108.	Regulatory Guide - Applying for a Licence for a Prescribed Radiation Facility (REG-LA-SUP-240F).PDF
109.	Regulatory Guide - Applying for a licence for a radioactive waste storage or disposal facility (REG-LA-SUP-240L).PDF
110.	Regulatory Guide - Applying for a source licence (REG-LA-SUP-240E).PDF
111.	Regulatory Guide - Construction of an Item Important for Safety - Regulation 54 (REG-RC-SUP-254A).PDF
112.	Regulatory Guide - Graded approach to dealing with licence holder non compliance (REG-COM-SUP-270J).PDF
113.	Regulatory Guide - Holistic Safety (REG-COM-SUP-240U).PDF
114.	Regulatory Guide - How to Apply for a Facility Licence for a Nuclear Installation (REG-LA-SUP-240G).PDF
115.	Regulatory Guide - Human Imaging for Security Screening Purposes Using Ionising Radiation (REG-LA-SUP-240R).DOCX
116.	Regulatory Guide - Periodic Safety and Security Review of Research Reactors (REG-COM-SUP-270I).PDF
117.	Regulatory Guide - Plans and Arrangements for Managing Safety Sept 2017 (REG-LA-SUP-280B).PDF
118.	Regulatory Guide - Possess or Control of a Controlled Facility, Apparatus or Material (REG-LA-SUP-240X).PDF
119.	Regulatory Assessment Principles for Controlled Facilities (RB-STD-42-00 Rev 1).PDF
120.	Regulatory Delivery Model.DOC
121.	Regulatory Guide - Reporting Compliance (REG-COM-SUP-270B).dotx
122.	Regulatory Guide - Siting of Controlled Facilities (REG-LA-SUP-240L).PDF
123.	Regulatory Guide - Transfer or Disposal of Sources (REG-RC-SUP-252A).DOCX
124.	Regulatory Guide - Transport of Radioactive Material (REG-TR-SUP-360A).DOCX
125.	Regulatory Guide - When to seek approval to make changes under Regulation 51 (REG-RC-SUP-250A).PDF
126.	Regulatory Guide - Reporting an Accident (REG-COM-SUP-274A).PDF

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

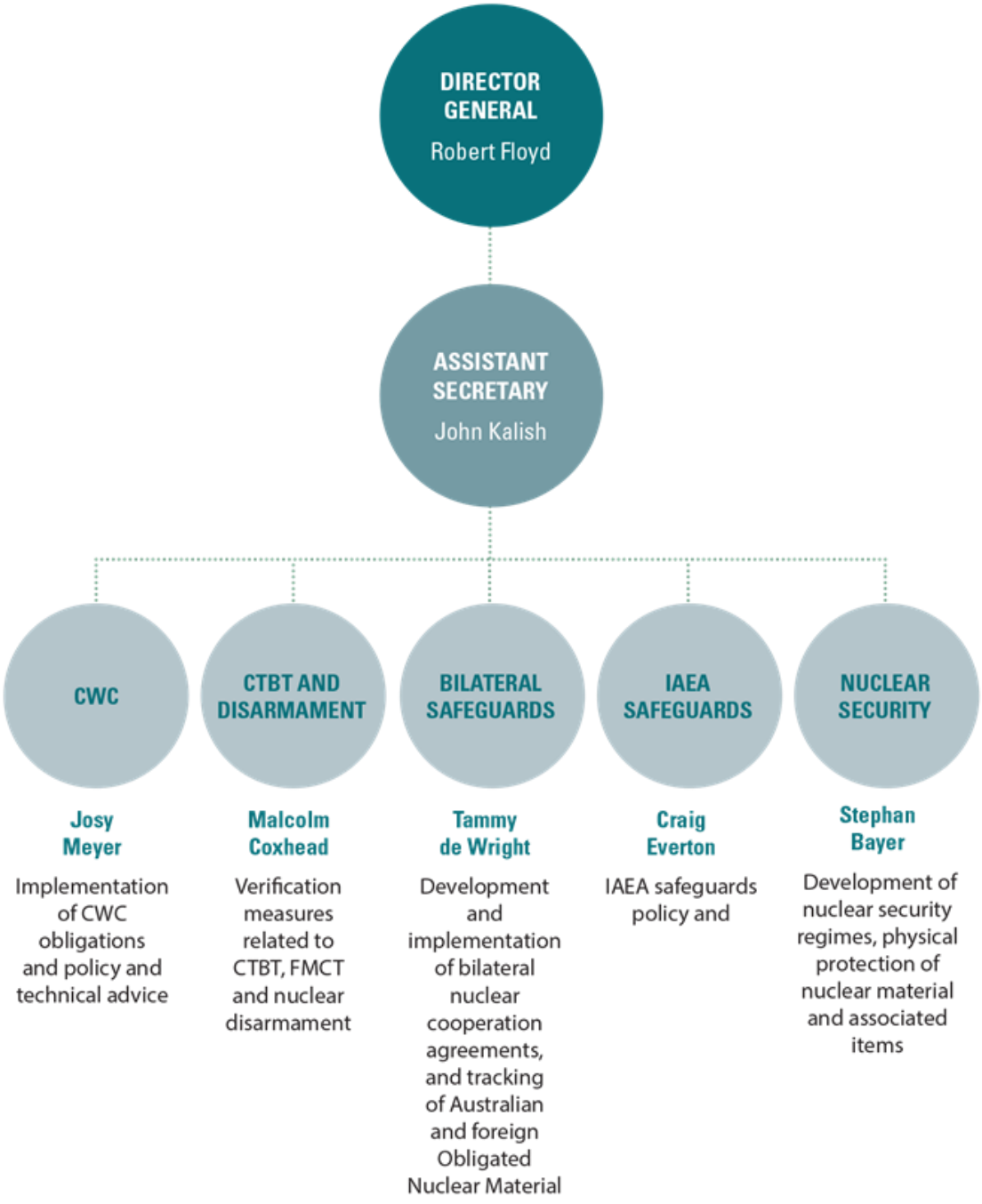
1. INTERNATIONAL ATOMIC ENERGY AGENCY - Fundamental Safety Principles, Safety Fundamentals No. SF-1, IAEA, Vienna (2006)
2. INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016)
3. INTERNATIONAL ATOMIC ENERGY AGENCY- Leadership and Management for Safety, General Safety Requirements No. GSR Part 2, IAEA, Vienna (2016)
4. INTERNATIONAL ATOMIC ENERGY AGENCY – Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements No. GSR Part 3, Vienna, (2014)
5. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for Facilities and Activities, General Safety Requirements No. GSR Part 4 (Rev 1), IAEA, Vienna (2016)
6. INTERNATIONAL ATOMIC ENERGY AGENCY – Predisposal Management of Radioactive Waste General Safety Requirements No. GSR Part 5, IAEA, Vienna (2009)
7. INTERNATIONAL ATOMIC ENERGY AGENCY – Decommissioning of Facilities General Safety Requirement Part 6, No. GSR Part 6, IAEA, Vienna (2014)
8. INTERNATIONAL ATOMIC ENERGY AGENCY – Preparedness and Response for a Nuclear or Radiological Emergency General Safety Requirements No. GSR Part 7, IAEA, Vienna (2015)
9. INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Research Reactors, Specific Safety Requirements No. SSR-3, IAEA, Vienna (2017)
10. INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste Specific Safety Requirements No. SSR-5, IAEA, Vienna (2011)
11. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides, General Safety Guides No. RS-G-1.2, IAEA, Vienna (1999)
12. INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to External Sources of Radiation Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)
13. INTERNATIONAL ATOMIC ENERGY AGENCY - Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide Series No. RS-G-1.4, IAEA, Vienna (2001)
14. INTERNATIONAL ATOMIC ENERGY AGENCY – Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
15. INTERNATIONAL ATOMIC ENERGY AGENCY – Regulatory Control of Radioactive Discharge to the Environment, Safety Guide Series No. WS-G-2.3, IAEA, Vienna (2000)
16. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No. WS-G.5.2, IAEA, Vienna (2009)
17. INTERNATIONAL ATOMIC ENERGY AGENCY – Regulations for the Safe Transport of Radioactive Material, Specific Safety Requirements No. SSR-6, IAEA, Vienna (2012)
18. INTERNATIONAL ATOMIC ENERGY AGENCY – Radiation Protection and Safety in Medical Uses of Ionizing Radiation, Specific Safety Guides No. SSG-46, IAEA, Vienna (2018)
19. INTERNATIONAL ATOMIC ENERGY AGENCY, Environmental and Source Monitoring for Purposes of Radiation Protection, General Safety Guides No. RS-G-1.8, IAEA, Vienna (2005)

20. INTERNATIONAL ATOMIC ENERGY AGENCY– Communication and Consultation with Interested Parties by the Regulatory Body, General Safety Guides No. GSG-6, IAEA, Vienna (2017)
21. INTERNATIONAL ATOMIC ENERGY AGENCY– Functions and Processes of the Regulatory Body for Safety, General Safety Guides No. GSG-13, IAEA, Vienna (2018)
22. INTERNATIONAL ATOMIC ENERGY AGENCY– Code of Conduct on the Safety and Security of Radioactive Sources, IAEA, Vienna (2004)

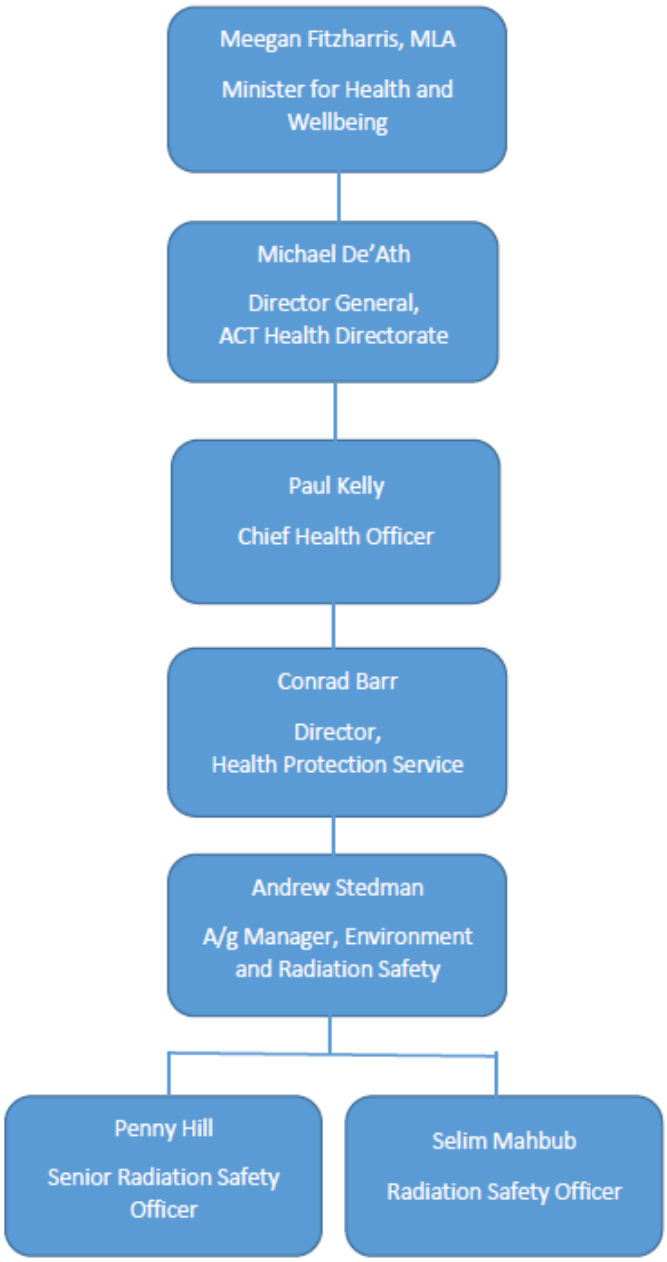
APPENDIX VIII ORGANIZATION CHARTS



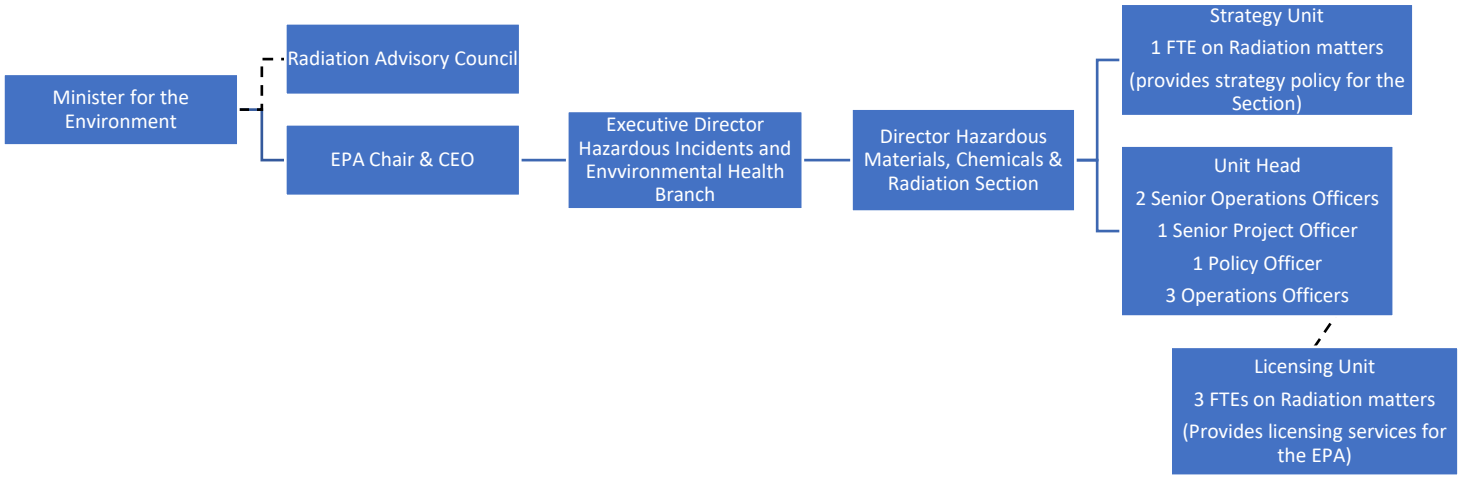
Australian Safeguards and Non-proliferation Office (ASNO)



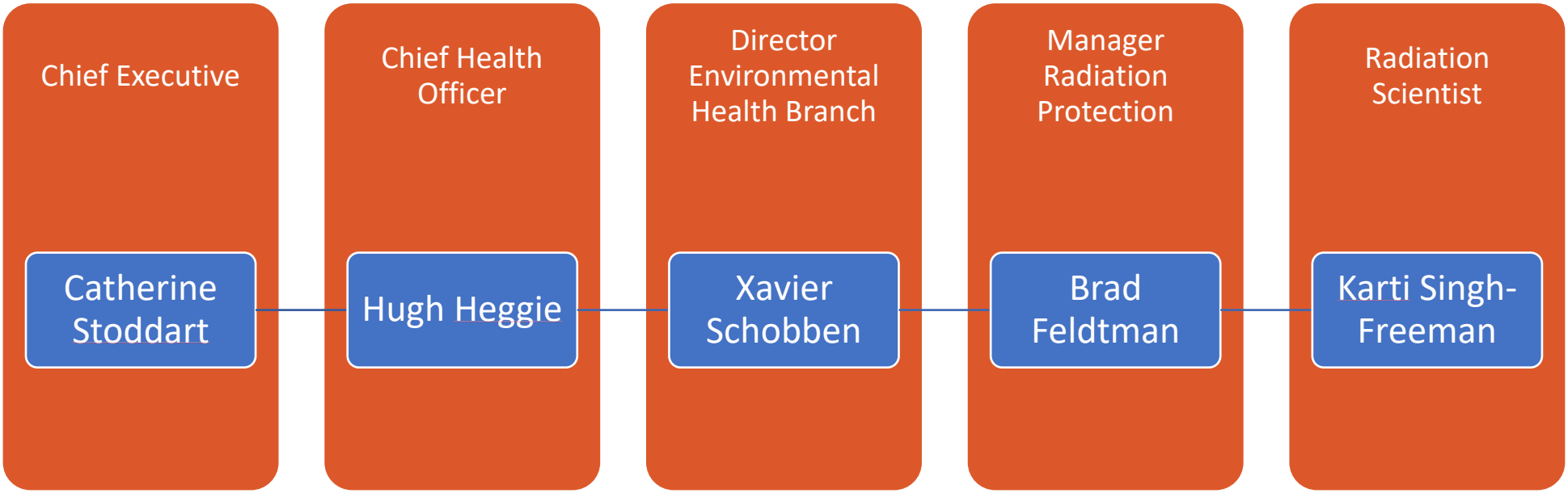
Reporting Structure for the ACT Radiation Safety Section



NSW EPA Radiation Regulation Unit Organisation Chart

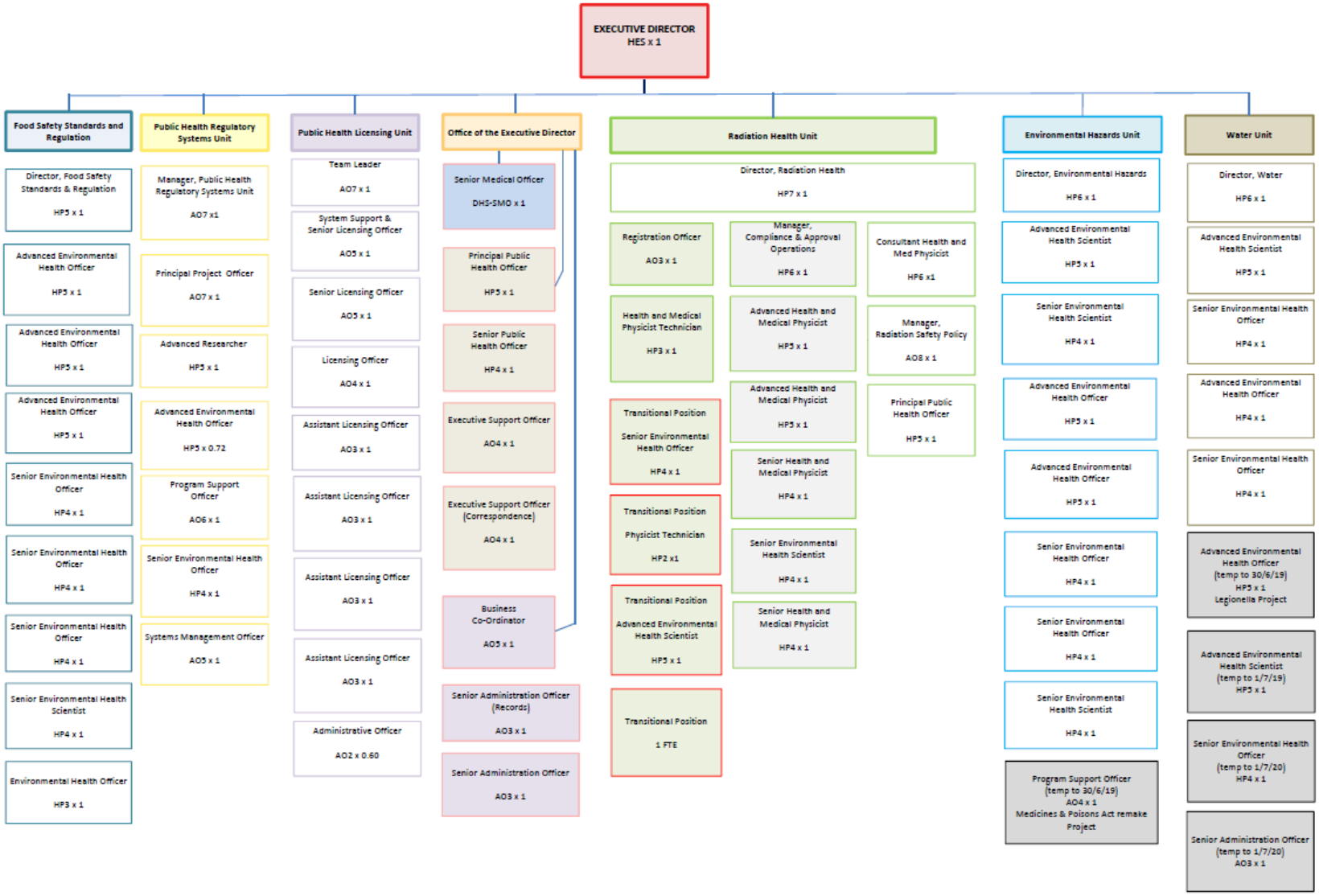


Radiation Protection Functional Chart



HEALTH PROTECTION BRANCH ORGANISATIONAL CHART

Queensland Government



Department of Health organisational structure

Director-General

Chief Auditor (for functional reporting purposes)

Office of the Director-General
- Cabinet and Parliamentary Services
- Secretariat Services

- Office of Health Statutory Agencies
- Ministerial and Executive Services Unit
- Health Innovation, Investment and Research Office
- Ethical Standards Unit

DDG & ODDG Corporate Services Division

Finance Branch
- Budget & Analysis Unit
- Statutory & Advisory Services Unit
- Finance Solutions Unit
- Finance Transactional Services Unit

Human Resources Branch
- Recruitment & Capability
- Employment Relations
- HR Intelligence & Strategy
- People, Safety & Performance

Legal Branch
- Legal Services Unit
- Mental Health Court Registry

Capital & Asset Services Branch
- Capital Infrastructure & Delivery Unit
- Engineering & Technical Services
- Operations
- Asset & Facility Services
- Capital Procurement Services
- Capital Project Delivery

Strategic Communications Branch
- Marketing
- Content & Media
- Communication
- Strategy & Insights
- Online

Risk, Assurance & Information Management Branch
- Internal Audit Unit
- Risk & Business Continuity Unit
- Governance Unit
- Information Management Unit
- Privacy and Right to Information

Business Partnerships & Improvement Branch
- Divisional Engagement & Communication
- Change & Culture Leadership
- Portfolio Management
- Priority Projects

DDG & ODDG Strategy Policy & Planning Division

Strategic Policy & Legislation Branch
- Legislative Policy Unit
- Social Inclusion & Connected Care Unit
- Strategy, Children & Families Unit

Infrastructure Strategy & Planning Branch
- Infrastructure Planning Unit
- Infrastructure Policy and Strategy Unit

System Planning Branch
- Health Service Research Analysis & Modelling Unit
- Statewide Planning
- System Planning

Funding Strategy & Intergovernmental Policy Branch
- State Funding Unit
- Intergovernmental Policy & Funding Unit
- Health Expenditure and Funding Analysis Unit

Statistical Services Branch
- Statistical Analysis & Linkage
- Statistical Collections & Integration
- Statistical Reporting & Coordination
- Statistical Standards & Strategies Unit

Aboriginal & Torres Strait Islander Health Branch
- Whole-of-Government & Regional Engagement Unit
- Strategy, Performance & Investment

Workforce Strategy Branch
- Aboriginal & Torres Strait Islander Workforce
- Strategic Design
- Strategic Pathways & Capability
- Workforce Analytics & Planning
- WorkMAPP

DDG & ODDG Healthcare Purchasing & System Performance Division

Contracting & Performance Management Branch
- Service Agreement Management Unit
- Service Agreement Strategy Unit
- Surgery Connect Unit

Healthcare Purchasing & Funding Branch
- Healthcare Purchasing Strategy Unit
- Purchasing Models & Support Unit
- Funding & Costing Unit

Community Services Funding Branch
- Contract Management Unit
- Procurement Unit

System Performance Branch
- Performance Reporting Unit
- Data & Technical Analysis Unit
- Insights Reporting Unit

Commissioner Queensland Ambulance Service

Chief Executive Health Support Queensland

Chief Executive eHealth QLD

Chief Health Officer & DDG Prevention Division

Health Protection Branch
- Environmental Hazards Unit
- Food Safety Standards & Regulation Unit
- Radiation Health Unit
- Water Unit
- Public Health Licensing Unit

Communicable Diseases Branch
- Blood Borne Viruses & Sexually Transmissible Infections Unit
- Communicable Diseases & Infection Management Unit
- Immunisation Program
- Epidemiology & Research Unit
- ICT Portfolio Management Unit
- Systems Management

Chief Medical Officer & Healthcare Regulation Branch
- Healthcare Legislation Improvement Unit
- Medicines Regulation and Quality Unit
- Medication Services Queensland
- Office of Medicinal Cannabis
- Private Health Regulation Unit
- Medicines Compliance & Human Tissue Unit
- Healthcare Approvals & Regulation Unit
- Medical Advisory & Prevocational Accreditation Unit

Aeromedical Retrieval & Disaster Management Branch
- Health Disaster Management Unit
- Retrieval Services Queensland
- Aeromedical Contracts Management & Support Unit
- Telehealth Emergency Management Support Unit

Preventive Health Branch
- Health & Wellbeing Unit
- Cancer Screening Unit

DDG & ODDG Clinical Excellence Division

Assistant DDG & Chief Clinical Information Officer

Patient Safety & Quality Improvement Service
- Rapid Response & Improvement Unit
- Analytics & Systems Unit
- Programs & Survey & Audit Unit
- Assurance & Support Unit

Centre for Leadership Excellence
- Healthcare Leadership Unit
- Project and Client Support Office

Mental Health, Alcohol & Other Drugs Branch
- Office of the Chief Psychiatrist
- Strategy, Planning & Partnerships Unit
- Clinical Systems, Collections & Performance Unit

Healthcare Improvement Unit
- Clinical & Operational Improvement
- Healthcare Systems & Information Improvement
- Clinician-led Improvement

Office of the Chief Dental Officer

Office of the Chief Nursing & Midwifery Officer

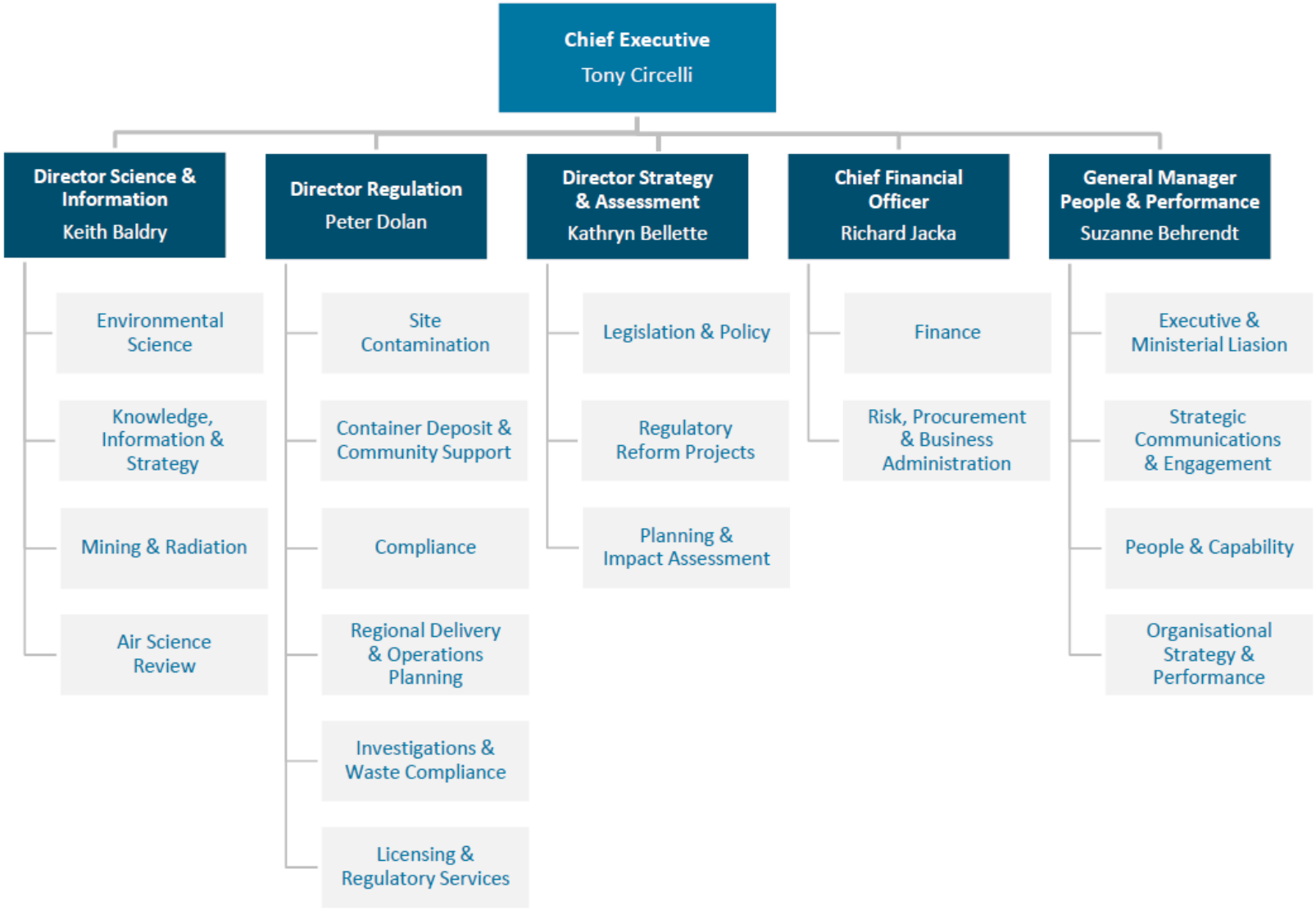
Allied Health Professions Office of Queensland

Last updated November 2018

Queensland Government

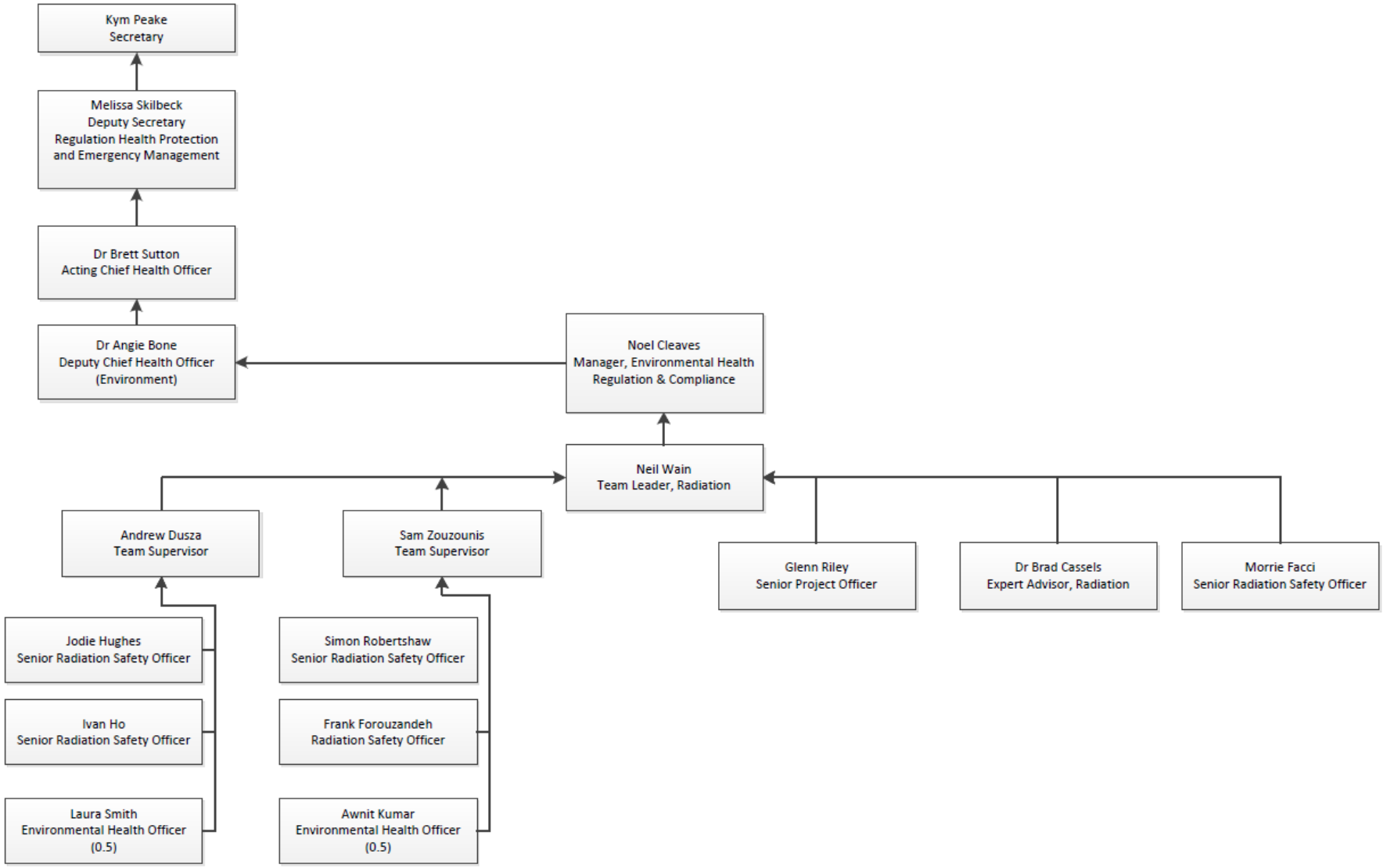
Environment Protection Authority

Organisational Chart

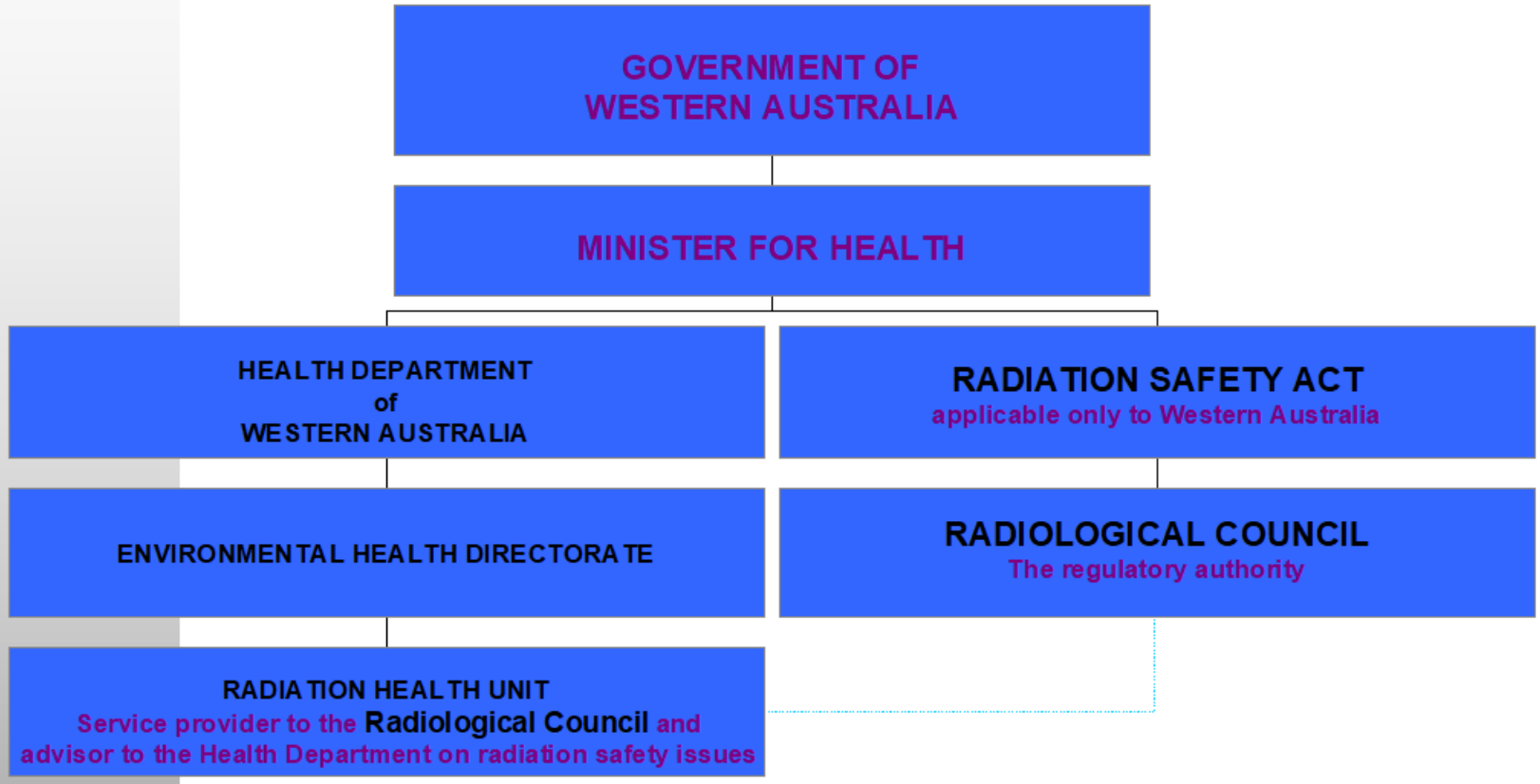


Victorian Department of Health & Human Services

Reporting arrangements for regulation of radiation safety

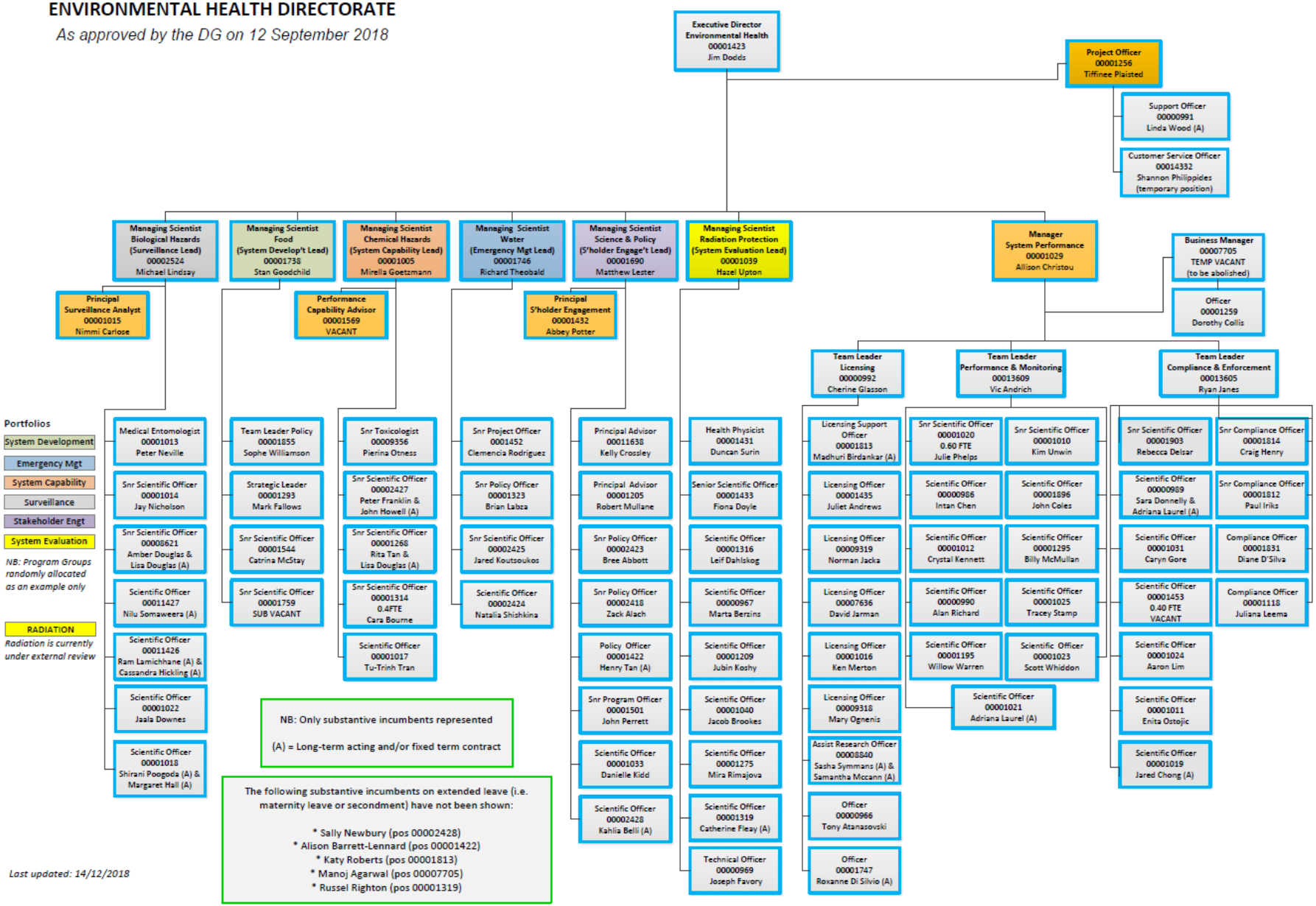


The Radiological Council



ENVIRONMENTAL HEALTH DIRECTORATE

As approved by the DG on 12 September 2018



Last updated: 14/12/2018