

Australian Government

Australian Radiation Protection and Nuclear Safety Agency



## **Quarterly Report**

# of the

## **Chief Executive Officer of ARPANSA**

## July to September 2021

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ARPANSA 619 Lower Plenty Road Yallambie VIC 3085 email: info@arpansa.gov.au

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#### Acknowledgement of Country

ARPANSA respectfully acknowledges Australia's Aboriginal and Torres Strait Islander communities and their rich culture and pays respect to their Elders past and present. We acknowledge Aboriginal and Torres Strait Islander peoples as Australia's first peoples and as the Traditional Owners and custodians of the land and water on which we rely.

We recognise and value the ongoing contribution of Aboriginal and Torres Strait Islander peoples and communities to Australian life and how this enriches us. We embrace the spirit of reconciliation, working towards the equality of outcomes and ensuring an equal voice.

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### Letter of transmittal

19 November 2021

The Hon Dr David Gillespie MP Minister Assisting the Minister for Trade and Investment Minister for Regional Health PO Box 6022 House of Representatives Parliament House Canberra ACT 2600

#### Dear Minister

The Australian Radiation Protection and Nuclear Safety Act 1998 (the Act) requires the Chief Executive Officer (CEO) of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) to submit to the Minister, at the end of each quarter, a report on:

- the operations during the quarter of the CEO, ARPANSA, the Radiation Health and Safety Advisory Council (the Council), the Nuclear Safety Committee (the NSC) and the Radiation Health Committee
- details of directions given by the Minister to the CEO under section 16 of the Act
- details of directions given by the CEO under section 41 of the Act
- details of improvement notices given by inspectors under section 80A of the Act
- details of any breach of licence conditions by a licensee, of which the CEO is aware
- details of all reports received by the CEO from the Council and the NSC under Part 4, paragraphs 20(f) or 26(1)(d) of the Act, and
- a list of all facilities licensed under Part 5 of the Act.

I am pleased to provide you with a report, meeting the requirements of the Act, covering the period June to September 2021.

Please note that subsection 60(6) of the Act requires you to cause a copy of the report to be laid before each House of the Parliament within 15 sitting days of the day on which this report was given to you.

Yours sincerely

Ivan Williams

## The operations of the CEO and ARPANSA

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

ARPANSA sits within the Department of Health portfolio and has a single outcome, as set out in the 2021-22 Portfolio Budget Statements (PBS):

## Protection of people and the environment through radiation protection and nuclear safety research, policy, advice, codes, standards, services and regulation.

The Radiation Protection and Nuclear Safety Program, contained within the 2021-22 PBS, describes four performance measures, against which ARPANSA seeks to achieve its outcome. These measures are:

- Provide high quality advice to government and the community on health, safety and environmental risks from radiation.
- Provide emergency preparedness and response systems for a radiological or nuclear incident.
- Promote patient safety in radiotherapy and diagnostic radiology.
- Ensure protection of people and the environment through efficient and effective regulation.

The report on the operations of the CEO and ARPANSA focuses on these.

# Provide high quality advice to government and the community on health, safety and environmental risks from radiation

#### Enhanced Electromagnetic Energy (EME) Program

In August 2021, ARPANSA published the EME Program Research Framework which sets out the research priorities and details how research projects will be funded under this program. As part of the program, ARPANSA announced the first call for applications for research funding on 5G and health. The Research Framework is available at: <a href="http://www.arpansa.gov.au/research-and-expertise/electromagnetic-energy-program/eme-program-research-framework">www.arpansa.gov.au/research-and-expertise/electromagnetic-energy-program/eme-program-research-framework</a>.

On 20 August 2021, ARPANSA hosted an online presentation 'Mobile phones and health', as part of National Science Week. The presentation to 130 registered attendees included insights on the science behind mobile phone technology, how ARPANSA's new radiofrequency exposure standard protects human health, and the research initiatives in ARPANSA's four-year EME Action Plan. A recording of the presentation is available at: <a href="http://www.youtube.com/watch?v=NUfMqRuJKE8">www.youtube.com/watch?v=NUfMqRuJKE8</a>.

# Provide emergency preparedness and response systems for a radiological or nuclear incident

#### National capability and capacity building in emergency preparedness and response

ARPANSA has initiated a project to better understand national capacity and capability to respond to a nuclear or radiological accident, with a survey across all jurisdictions being undertaken through the National Health Emergency Management Subcommittee, a standing committee of the Australian Health Protection Principal Committee. While COVID restrictions have reduced the ability to engage directly, remote engagement has meant that responses have been received from New South Wales, Queensland, Victoria, and the Commonwealth, with others anticipated before the end of 2021. This will help identify areas where national capacity and capability require strengthening and inform a proposal for a national training and exercise program with national and international partners.

#### Promote patient safety in radiotherapy and diagnostic radiology

#### Australian Clinical Dosimetry Service

During this quarter, ARPANSA's Australian Clinical Dosimetry Service (ACDS) initiated 27 active remote optically stimulated luminescence detector audits covering 77 linear accelerators (linacs) and performed 14 on-site audits. Of the on-site audits, 6 supported the clinical introduction of new linacs including the new Magnetic Resonance Linear Accelerator (MR-linac) in Victoria and a new treatment facility in Queensland. The ACDS audit program measures and evaluates the radiation dose delivered to radiation oncology patients by treatment units (linacs), ensuring that accurate radiation doses are delivered. The service is scheduled to audit 99 per cent of Australian and 50 per cent of New Zealand providers for the 2021-22 period and is finalising agreements with a few outstanding organisations. The audit schedule has been impacted by COVID-19 lockdowns and travel restrictions however staff redeployments to avoid regular border crossings will support rescheduling for delayed audits in the next quarter.

In July, ARPANSA added the stereotactic ablative body radiotherapy audit, one of the most advanced and comprehensive in the world, to the standard audit subscription. This audit measures and evaluates dose delivery for radiotherapy treatments where highly focused and comparatively large doses of radiation are administered to very small areas of the body. This makes it particularly important to verify that the dose delivered to the patient is correct and delivered accurately to the location of the tumour. Incorrect treatment has the potential to significantly and adversely affect the patient's quality of life.

ARPANSA staff were key authors for a published international journal article regarding the underestimation of dose in organs at risk by a class of dose calculation algorithm, which was observed through analysis of ACDS audit results. The article adds to a growing body of knowledge influencing radiation oncology dose prescription practices. The article is available at: <a href="https://aapm.onlinelibrary.wiley.com/doi/10.1002/mp.15123">https://aapm.onlinelibrary.wiley.com/doi/10.1002/mp.15123</a>.

#### Primary Standards Dosimetry Laboratory

ARPANSA has commenced a 3-year project to build a new primary standard for radiation dosimetry for Australia. The primary standard allows for a highly accurate calibration of equipment which underpins radiation measurements in all areas of science and medicine, but particularly in radiotherapy and other

medical uses of radiation. The first components for this instrument (a water calorimeter) were purchased and shipped to Canada for assembly. Once tested and compared with equivalent international instruments, this water calorimeter will replace ARPANSA's existing graphite calorimeter. The new calorimeter will be more accurate, easier to use, and accessible for repair. In addition, it is configurable for use in particle beams, which will support radiation measurements in new radiotherapy treatments such as proton beams.

#### Ensure risk-informed and effective regulation

#### Significant regulatory activities

ARPANSA routinely assesses licence applications and requests for approval to make changes to facilities and associated activities which may have significant implications for safety.

A licence application was submitted by the Australian Nuclear Science and Technology Organisation (ANSTO) to site a new Intermediate Level Solid Waste (ILSW) facility. ILSW is a by-product from the production of molybdenum-99 (Mo-99) at the ANSTO Nuclear Medicine (ANM) facility. ARPANSA will host a virtual public forum into the site licensing of this facility in October 2021.

During the quarter, 7 regulatory approvals were issued, including for:

- The routine use of a back-up dissolution hot cell at the ANSTO Nuclear Medicine Facility. The review of the safety of the back-up hot cell was already underway when a failure occurred in the main hot cell. ARPANSA prioritised the review and approval of operation of the back-up hot cell to minimise the disruption in nuclear medicine supply to the Australian community. The main hot cell remains off-line and is discussed below under 'Significant Event Reporting'.
- The storage of an additional TN-81 transport and storage package in the Interim Waste Store at ANSTO, Lucas Heights. TN-81 is a forged steel transport and storage cask, that is used in nuclear shipments. This approval was required to safely store the package which is to be shipped from the UK. The waste which will return is radiologically equivalent to the spent fuel, from the High Flux Australian Reactor (HIFAR), that was sent to the UK for reprocessing in 1996.
- A request from ANSTO to surrender the Radiotracer Facility licence. This facility had been used to store radioisotopes for environmental studies but has not been used for several years. Surrendering unused licences allows the redirection of resources to higher priority matters for both the licence holder and regulator.
- An upgrade to the valves and transfer pipes associated with the storage tanks at the ANSTO waste operations facility. The tanks store legacy Intermediate Level Liquid Waste (ILLW) from nuclear medicine production and the upgrade will facilitate the transfer of the ILLW from the existing tanks to new tanks which are to be installed in the future.
- The removal of a licence condition on the ANSTO Camperdown facility relating to optimisation of
  radiation protection. ANSTO has announced its intention to close the Camperdown facility and has
  advised ARPANSA of its intention to submit a decommissioning licence application for the facility in
  mid-2022. A new licence condition was applied which requires ARPANSA approval to operate if
  ANSTO should decide to restart the facility. This avoids unnecessary work being undertaken to
  address operational matters which are no longer required. The Camperdown facility comprises of a
  cyclotron used to produce short-lived radioisotopes used for medical research.

#### Significant event reporting

ANSTO reported an event at the Open-Pool Australian Lightwater (OPAL) reactor whereby 2 staff members were splashed with tritiated heavy water and inhaled the associated vapour, with doses subsequently estimated to be significantly below the statutory dose limit. Tritium is a radioactive isotope of hydrogen that is generated in heavy water within the reactor. It requires careful handling by workers to avoid contamination. The event happened in a room processing heavy water from the reactor reflector vessel. As the estimated doses were low, ARPANSA will monitor ANSTO's own investigation of the event to ensure that any lessons are learned, and safe working practices are improved as appropriate.

Advice was received from ANSTO of an event rendering the primary ANSTO Nuclear Medicine (ANM) facility dissolution hot cell inoperable, but without any release of radioactive material or exposure of staff. The dissolution hot cells are used for the dissolution of targets irradiated in the OPAL reactor to extract the Mo-99 radiopharmaceutical. ARPANSA subsequently provided approval to ANSTO for the routine operation of the back-up dissolution hot cell. An investigation was undertaken by ANSTO, concluding that the event was due to human error. ARPANSA will maintain oversight of the recovery plan and prioritise the assessment of any subsequent application that may be required to restore the main hot cell to normal operation.

#### Inspections

ARPANSA conducted five inspections and one site visit during the quarter. ARPANSA undertakes a program of scheduled inspections of licence holders to monitor compliance with the Act and the ARPANS Regulations. The scope and frequency of inspections is risk-informed, accounting for a range of factors including licence holder safety performance. Inspections play an important part in ARPANSA's compliance and performance monitoring program providing assurance that licence holders are operating safely. The inspection reports can be found at: www.arpansa.gov.au/regulation/inspections/reports.

#### Stakeholder engagement

ARPANSA met with ANSTO to discuss the development of their emergency preparedness and response schedule. This schedule takes into consideration the requirements of the Guide for Radiation Protection in Emergency Exposure Situations (RPS-G3) and ensures that ARPANSA can commence inspections of the performance of ANSTO during planned exercises. ANSTO has advanced significantly in their planning, and as soon as COVID conditions allow, ARPANSA will undertake inspections of exercises.

ARPANSA had a virtual meeting with ANSTO and its International Peer Review Team for the safety-related elements of the OPAL Periodic Safety and Security Review (PSSR). The PSSR is a ten-yearly comprehensive review to ensure that the OPAL Reactor safety case remains valid. The review team comprised individuals with extensive research reactor operational and regulatory experience from the United States, the Netherlands, South Africa and Argentina. The review team presented its overview of the findings arising from its review with a strong endorsement of many of the OPAL processes and practices across the fifteen safety factors, as well as identifying several areas for improvement.

The annual Defence-ARPANSA Liaison Forum (DALF) meeting was held virtually. The DALF allows strategic engagement between Defence and ARPANSA's senior leadership. ARPANSA and Defence communicated the challenges associated with COVID-19 and how this has impacted physical inspection programs, respectively. ARPANSA and Defence agreed that the campaign-style inspections conducted in Western Australia had worked well for both organisations and would be an effective model to adopt as state border

restrictions are eased. Defence also communicated that several source and facility licence applications are pending.

ARPANSA engaged with ANSTO to update its security plan policies and procedures to better align with international best practice and harmonise arrangements across their site. This will have implications across a number of ANSTO's source and facility licences. ANSTO will update and re-issue security plans for ARPANSA's endorsement or approval where required. This continues to be a strong focus for both agencies.

ARPANSA attended the Australian Mobile Telecommunications Association EME Symposium. The Symposium explored the latest research, standards and technology developments related to 5G with Australian experts. ARPANSA presented on its work on EME for the last ten years, the new EME research framework and its review of millimetre waves and health.

#### Radioactive material import and export permits

The import and export of radioactive material to and from Australia requires permission under Regulation 4R of the Customs (Prohibited Imports) Regulations 1956 and Regulation 9AD of the Customs (Prohibited Exports) Regulations 1958. Under these regulations, ARPANSA officers are authorised to issue import and export permits. Permits ensure that radioactive material entering and exiting the country is subject to appropriate regulatory control. This includes a requirement that the end user is authorised to deal with the material, and that it is subject to appropriate safety and security provisions en route and at its final destination. This material is used for a wide range of medical, industrial, and scientific purposes.

Type of permits	Urgent (single shipment)	Standard (single shipment)	12 months
Import of non-medical radioisotope	47	63	5
Import of medical radioisotope	0	140	8
Export of high activity source	-	7	-

Permits issued this quarter:

#### Transport of radioactive material

ARPANSA approves certain plans for licence holders to transport significant quantities of radioactive material. Under the Code of Practice for the Security of Radioactive Sources (RPS 11, 2019), security-enhanced sources are assessed to ensure the security considerations, including the transport arrangements and route, are suitable for the shipment.

Non-Australian Type B(U) package design requires validation by the Australian competent authority for use in Australia. This is to enable assessment of compliance with local regulatory requirements and to ensure that, should an incident or accident occur involving such material and package, relevant information will be readily available for an appropriate regulatory and emergency response.

ARPANSA issued two validation certificates to ANSTO for a:

• Type B(U), model F-431 transport package. This package will be used for transporting blood irradiators.

• Type B(U)F, model TN-81 transport package. This package will be shipped from the Sellafield facility in the UK in 2022 and will contain vitrified waste of radiological equivalence to waste arising from processing of HIFAR reactor spent fuel.

#### International engagement

ARPANSA's international engagement provides the agency with the means of influencing the international radiation protection and nuclear safety and security framework, and to take stock of international developments to ensure ARPANSA's regulatory framework and radiation protection standards are based on international best practice. ARPANSA did not undertake any international travel during the quarter due to the ongoing impact of COVID-19 travel restrictions. However, ARPANSA continues to maintain international relations through a range of virtual means, which has meant it has been able to participate in a wider range of international events than previously. A sample of these engagement activities is outlined below.

ARPANSA attended virtual meetings of the International Atomic Energy Agency (IAEA) Radiation Safety Standards Committee (RASSC), the Waste Safety Standards Committee (WASSC), and a joint session of WASSC and the Emergency Preparedness and Response Standards Committee (EPReSC). These meetings aimed to discuss the management of radioactive waste in emergency exposure situations, the transitioning from an emergency to an existing exposure situation, and future areas for international collaboration. ARPANSA's membership of the IAEA Safety Standard Committees is a key platform for the agency's international engagement, as their strategic work priorities complement and support ARPANSA's work program to develop and apply nationally uniform radioactive waste safety standards in Australia.

ARPANSA virtually attended the first IAEA conference on managing naturally occurring radioactive material (NORM). Participants agreed that a holistic framework is needed in order to implement sustainable and effective management of NORM. A follow-up workshop raised valuable perspectives on this topic which will be shared with the international community in a subsequent webinar, summarising the main findings of the conference and workshop, to provide countries with a roadmap to implement a framework covering policy, regulation and NORM waste-disposal. NORM is important to Australia due to the impact international requirements have on our mineral export industry. ARPANSA needs to ensure that Australian interests are represented in international work, and we adopt an approach that is aligned with Australian stakeholders and best practice.

ARPANSA staff attended Nuclear Energy Agency (NEA) virtual meetings on radioactive waste management, decommissioning and legacy management, and extended storage and transport of waste. These meetings discussed various regulatory and operational issues and the outcomes will be put to the NEA's Radioactive Waste Management Committee, Committee on Decommissioning of Nuclear Installations and Legacy Management, and Regulators Forum (a forum of senior regulators for radioactive waste management and decommissioning) in March 2022. This engagement provides ARPANSA and Australia with an opportunity for open discussion and learning about national experience and good practice in regulation.

ARPANSA was part of the assessment team on a (virtual) expert mission to the Philippines under the auspices of the IAEA. The mission provided the Philippine regulator with technical assistance on reviewing the commissioning program of their subcritical assembly facility. The scope of the mission covered the licensing process, regulatory inspection for commissioning, safety assessment, commissioning program, and operational limits and conditions. Participation in international peer reviews provides ARPANSA with an opportunity to promote safety in the region and internationally and learn from the experience of other regulatory bodies.

ARPANSA initiated a series of ongoing virtual meetings with international regulators to explore practices for the regulation of human and organisational factors important to ensuring radiation safety. The meetings have been held virtually with France, Finland, and the UK. Information from these meetings will be used to further develop ARPANSA's holistic approach to safety which informs radiation regulation in Australia.

ARPANSA attended Organisation for Economic Co-operation and Development (OECD) Nuclear Energy Agency (NEA) meetings of the Committee on Safety of Nuclear Installations (CSNI) Working Groups on Human and Organisational Factors, and Safety Culture. These consultative groups' objectives are to improve the understanding and treatment of human and organisational factors and safety important to radiation protection. These meetings offer an opportunity to discuss and share ideas between international experts from regulators, researchers, and others. ARPANSA's participation in these groups helps deliver best practice regulation and safety in Australia.

ARPANSA virtually attended the 5th International UV and Skin Cancer Prevention Conference 2021 run by EUROSKIN, The European Society of Skin Cancer Prevention. The conference fostered discussions and summarised knowledge into shared recommendations, which will help to improve future skin cancer prevention. Skin cancer from ultraviolet radiation (UVR) is a leading health concern in Australia. This annual conference provides ARPANSA staff with the opportunity to maintain and develop expertise and supports succession planning by learning from and sharing experiences with other countries.

ARPANSA attended a virtual meeting with the US National Nuclear Security Administration Nuclear Security Women's Initiative. This initiative seeks to promote the role and visibility of women in nuclear security, provide education, training, research, and other professional development opportunities to women in the field. The initiative believes that a more diverse and inclusive nuclear security workforce will lead to greater effectiveness in meeting today's nuclear security challenges.

ARPANSA attended a meeting of the New Zealand Interagency Committee on the Health Effects of Non-Ionising Radiation. ARPANSA provided an update on Australian activities including the EME Program. This program is researching the health effects of EME from new and emerging communications technology and publishing a new radiofrequency standard. This meeting is an opportunity to share information on research and policy activities related to electromagnetic fields in both Australia and New Zealand.

ARPANSA participated in an ongoing International Energy Agency (IEA) scientific expert group, which is leading some of the work into the health-related impacts of solid-state lighting. This will influence solid-state lighting standards in Australia for lighting in our homes, buildings and outdoor areas. This work fits with ARPANSA's work to review the health-impacts of light emitting diodes, including from ultraviolet-C lamps commonly sold for sterilising applications.

In August, ARPANSA presented at the virtual International Atomic Energy Agency (IAEA) Dosimetry Audit Network meeting held in Vienna, Austria, detailing the organisational structure and audit program of the ACDS. The invitation to present recognises internationally the success of DRL and ACDS work programs. Together, these activities ensure the safe delivery of radiation for diagnosis and treatment to the Australian population.

### Details of directions given by the Minister

No directions were given by the Minister under section 16 of the Act.

### Details of directions given by the CEO

No directions were given by the CEO under section 41 of the Act.

### Details of improvement notices given by inspectors

No improvement notices were issued by ARPANSA under section 80A of the Act.

### Details of any breach of licence conditions by a licensee

ARPANSA categorises breaches of licence conditions based on whether the implications for safety (the potential risks to safety) were either significant or minor. Breaches with significant safety implications typically occur where there is a high risk of potential radiation exposure or actual radiation exposure to people or the environment. Breaches with minor safety implications or administrative failures can occur for a variety of reasons including failing to label equipment properly, submit documentation on time, complete scheduled training, keep up-to-date inventories, or conduct scheduled reviews of plans and arrangements. ARPANSA publishes performance history of licence holders on the ARPANSA website: www.arpansa.gov.au/regulation-and-licensing/regulation/our-regulatory-services/who-we-regulate/licence-holder-performance.

There were no breaches with significant safety implications this quarter.

There were two breaches in the quarter with minor safety implications or administrative failures to meet regulatory requirements:

- During an inspection of the Gamma Technology Research Irradiator (GATRI) at ANSTO, it was
  determined that the licence holder had failed to comply with a licence condition which requires a
  self-assessment, at least once every three (3) years, against each applicable code and standard to
  ensure compliance. This was not done for all relevant codes and standards within the required time
  period.
- During an inspection of the Commonwealth Scientific and Industrial Research Organisation (CSIRO) Minerals and Resources, it was determined that the licence holder had not fully implemented the requirements of Security of Radioactive Sources (RPS11) as required by paragraph 59(3)(b) of the Regulations; specifically, the security system does not have immediate detection and assessment measures in place.

### Facilities licensed under Part 5 of the ARPANS Act

No facility licences were issued in the period.

### The operations of the Council and committees

#### **Radiation Health and Safety Advisory Council**

The Radiation Health and Safety Advisory Council (RHSAC) met virtually on 4 and 5 August 2021. The Council received updates from ARPANSA on their progress in the areas of UVR and NORM, following the Council's earlier advice. The Council noted that ARPANSA's response in these areas has been impacted by the COVID-19 pandemic, but progress has continued on the initiatives outlined in the Council's recommendations.

The member representing the interests of the public raised for discussion several questions from the public on topics including, regulation of the Department of Industry Innovation and Science's plans for a National Radioactive Waste Management Facility and ANSTO's plans for the return of reprocessed nuclear fuel to Australia in 2022. The Council voted to close their existing working groups on medical imaging and lasers, pending further developments, following their submission of letters of advice to the CEO of ARPANSA. The Council also received updates from ARPANSA on the increase in regulatory work they are experiencing. This was largely attributed to an increase in applications for authorisations from ANSTO. The Council discussed ARPANSA's plans to address this rise in regulatory workload and avoid delays.

The minutes of past meetings are on ARPANSA's website at <u>www.arpansa.gov.au/rhsac</u>. The next meeting is scheduled for the 16 and 17 December 2021.

#### Reports to the CEO from the RHSAC under paragraph 20(f) of the Act

The RHSAC did not provide any reports to the CEO during this quarter.

#### **Radiation Health Committee**

The Radiation Health Committee (RHC) did not meet during the quarter. The next meeting of the RHC is scheduled for 10 October 2021.

#### **Nuclear Safety Committee**

The Nuclear Safety Committee (NSC) did not meet during the quarter.

The next meeting of the NSC is scheduled for 26 November 2021.

#### Reports to the CEO from the NSC under paragraph 26(1)(d) of the Act

The NSC did not provide any reports to the CEO during this quarter.