



Australian Government
**Australian Radiation Protection
and Nuclear Safety Agency**



Quarterly Report
of the
Chief Executive Officer of ARPANSA

April to June 2021



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and Nuclear Safety Agency**



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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.

Printed by:

CanPrint Communications Pty Ltd
16 Nyrang Street
Fyshwick ACT 2609

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Letter of transmittal

15 September 2021

The Hon Dr David Gillespie MP
Minister Assisting the Minister for Trade and Investment
Minister for Regional Health
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 1 April to 30 June 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



Carl-Magnus Larsson
CEO of ARPANSA

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 2020-21 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 2020-21 PBS, describes four performance criteria, against which ARPANSA seeks to achieve its outcome. These criteria are:

- Provide high quality advice to the government and 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 criteria.

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

Enhanced Electromagnetic Energy (EME) Program

In May 2021, ARPANSA and the University of Auckland published a study that found that there is no link between mobile phone use and salivary gland cancers. The study looked at the number of salivary gland cancers occurring in Australia from 1982 to 2016, which coincides with the rise of mobile phone use. The findings of the study remain consistent with international assessments, that exposure to radiofrequency electromagnetic energy within safety limits, has no adverse health effects on the human body. The study is available at www.sciencedirect.com/science/article/abs/pii/S1877782121000783?dgcid=author%5d.

Medical imaging

ARPANSA finalised the 2020 annual data collection for diagnostic reference levels (DRLs) in computed tomography (CT) through the National Diagnostic Reference Level Service (NDRLS). NDRLS surveys are completed by participating imaging facilities that collect ionising radiation dose data from CT imaging. ARPANSA uses this data to calculate Australian DRLs, which reflect the indicative dose used in current practice for common types of CT scans in Australia. In 2020, a record total of 5078 surveys were received from 722 scanners, across 8 common scan types. DRL data indicated that survey medians were consistent with or lower, than the published DRLs. The DRLs help to avoid excess radiation dose to patients by providing a point of comparison between imaging facilities and encouraging the refinement of diagnostic imaging practices. The increase in survey participation among imaging facilities provides greater confidence that the levels ARPANSA determines, reflect common practice across Australia. Statistics for 2020 have been published on ARPANSA's website at www.arpansa.gov.au/research-and-expertise/surveys/national-diagnostic-reference-level-service/mdct/statistics.

Primary Standards Dosimetry Laboratory (PSDL)

ARPANSA completed calibrations for seven radiotherapy facilities this quarter. ARPANSA's PSDL calibrates equipment used in hospitals to ensure the correct dose is delivered during radiotherapy. ARPANSA operates two medical linear accelerators (linacs), which allow calibration of equipment to ensure the safe delivery of radiation services in Australia and contributes to world-class research and education. Linacs are the medical devices used to deliver radiation therapy in highly targeted dosages. The older linac, installed in 2009 and nearing end-of-life, has been modified to match the newer machine enabling it to be utilised for the rest of its operational life. This enables ARPANSA's services to be provided more efficiently with minimal disruption.

Australian Clinical Dosimetry Service (ACDS)

The ACDS continues to cover 100 per cent of Australian radiotherapy providers and this quarter we achieved a New Zealand (NZ) subscription rate of 50 per cent via cost-recovered service. The ACDS delivered an above-average number of on-site audits this quarter due to the 2020 COVID-19 disruption to service increasing 2021 demand. Despite multiple COVID-19 lockdowns this quarter, the ACDS performed 40 on-site audits. Only 1 audit for FY 2020/21 was unable to be completed due to travel restrictions. This facility was able to be issued an interim Statement of Compliance due to the ACDS working with the Radiation Oncology Health Program Grants scheme and the facility to find a solution in performing a postal

audit. The Australian-NZ travel bubble opened on 19 April 2021, allowing ARPANSA to complete four NZ audits with assistance from a local external auditor.

ARPANSA's ACDS audit program measures and evaluates the radiation dose to patients from medical treatment. This is to ensure that the dose delivered is as close to the prescribed and planned treatment dose as possible, improving patient safety and providing confidence in treatment outcomes.

ARPANSA'S ACDS continues to develop new audits to meet contemporary therapy developments, and this quarter completed a stereotactic ablative body radiotherapy (SABR) audit, enabling a new audit program to go live. This audit measures and evaluates dose for high-dose treatment delivery techniques where there is an increased likelihood and consequence of adverse effects from incorrect treatment delivery.

The ACDS national audit program has commenced work on the design and development of a specialised auditing software tool, Data Analysis and Integrated Scientific sYstem (DAISY). The tool aims to improve data integrity and alleviate staff and client workload for complex audits and specialised procedures.

Ensure protection of people and the environment through efficient and effective regulation

Significant regulatory activities

ARPANSA collaborated with the United Kingdom nuclear regulator, the Office for Nuclear Regulation, for the inspection of radioactive waste containers, set to return to Australia from the Sellafield Reprocessing Plant. The waste relates to the processing of spent fuel sent to the UK in earlier years from Australia's former research reactor.

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

During the quarter, regulatory approvals were provided to:

- Commonwealth Scientific and Industrial Research Organisation (CSIRO) Health and Biosecurity Division to store and use increased amounts of the radioisotope thorium-228. This will allow further research into the use of the radioisotope lead-212 for cancer treatment.
- Australian Nuclear Science and Technology Organisation (ANSTO) to increase the Open Pool Australian Lightwater (OPAL) reactor's annual tritium airborne discharge notification level. This will not have any significant impact on offsite radiation doses to the general public.
- ANSTO to modify the pre-amplifier electronics of the OPAL First Reactor Protection System to provide improved coverage across the whole range of operating conditions.
- ANSTO to undertake rhenium-188 production for treatment of skin cancer in conjunction with Oncobeta GmbH (Germany).
- Director of National Parks to transfer nominee responsibility of the South Alligator Disposal Facility to the Supervising Scientist (in the Department Agriculture, Water and the Environment). The application proposed changes including revised plans and arrangements. A licence condition relating to environmental monitoring was also amended.

ARPANSA also provided ANSTO feedback on its plan for rectification and mitigation of the OPAL riser defects discovered in November 2020. A licence condition was added to the OPAL licence on 31 May 2021, requiring ANSTO to regularly report on defect inspections and analysis of observations and measurements.

Significant event reporting

As indicated last quarter, on 15 March 2021, an event occurred when the OPAL First Reactor Protection System electronics did not function as designed to shut down the reactor. The reactor was instead safely shutdown by the Second Reactor Protection System. This event did not result in any adverse nuclear or radiological consequences. As a result, the event was determined to be at level 1 on the International Nuclear and Radiological Event Scale (INES) which is recognised as an 'anomaly'.

A request to modify the electronics of the OPAL First Reactor Protection System was submitted to ARPANSA, which included the replacement of a capacitor. ARPANSA provided approval to ANSTO on 27 April allowing the OPAL reactor to return to power. ARPANSA imposed a licence condition which requires ANSTO to redesign the First Reactor Protection System electronics by 29 October 2021 to ensure full functional performance across the entire range of operating conditions.

Inspections

ARPANSA conducted 10 inspections and 2 site visits 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.

Regulatory guidance development

ARPANSA published the *Regulatory Guide: Preparation of the safety analysis report for non-reactor facilities* on ARPANSA's website. This guide is used to assess licence applications at each stage of life for facilities under regulatory control. It will assist licence holders to prepare safety analysis reports in accordance with international best practice and comply with the ARPANS Act and Regulations. It is available online at www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides.

Stakeholder engagement

ARPANSA met with ANSTO to discuss the establishment of an emergency response exercise schedule for its high-risk facilities. This undertaking will allow ARPANSA to identify and inspect exercises of interest.

ARPANSA attended meetings with the South Australian Environment Protection Authority (EPA) as part of the project steering committee regarding licensing activities relating to a proposed proton radiotherapy unit. ARPANSA's support to the EPA has included a review of the Preliminary Safety Analysis Report for the unit and provided advice on this and potential licence conditions for construction and operation.

The Western Australia (WA) Department of Health radiation regulator requested ARPANSA's support to review the updated safety case for Tellus' proposed WA Sandy Ridge waste management facility, a near-surface geological waste repository intended to accept various hazardous wastes including radiological.

The ARPANSA-ANSTO Liaison Forum was held in Miranda, NSW on 21 April 2021. It included discussions on OPAL First Reactor Protection System, OPAL riser defects, review of the ANSTO Little Forest Legacy Site Best Available Technology report and follow up on the Independent Safety Review of ANSTO Health. Summaries of liaison forum meetings are available at www.arpansa.gov.au/regulation-and-licensing/licensing/information-licence-holders/ansto-arpansa-liaison-forum.

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.

Permits issued this quarter:

Type of permits	Urgent (single shipment)	Standard (single shipment)	12 months
Import of non-medical radioisotope	55	60	3
Import of medical radioisotope	0	141	9
Export of high activity source	-	8	-

Transport of radioactive material

ARPANSA approves certain plans and packages 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 safety and security considerations, including the transport arrangements and route, are suitable for the shipment.

ARPANSA issued two validation certificates to ANSTO for a:

- Type B(U)F transport package, this package will be used for transport of OPAL fresh fuel.
- Type B(U) package, this package will be used to transport specific special form radioactive material.

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's CEO Dr Carl-Magnus Larsson participated in the Main Commission (MC) of the International Commission on Radiological Protection (ICRP), an independent, international, non-governmental organisation whose recommendations form the basis of radiological protection policy, regulations, guidelines and practice worldwide. With Dr Larsson retiring at the end of this term, ARPANSA's Deputy CEO and Chief Radiation Health Scientist, Dr Gillian Hirth, was elected to be on the MC for the 2021–2025 term. ARPANSA's Chief Medical Radiation Scientist, Adjunct Assoc Prof Ivan Williams, was also elected as a member of the Committee 3 Radiological Protection in Medicine, which is focussed on the protection of persons and unborn children when ionising radiation is used in medical diagnosis, therapy, and biomedical research, as well as protection in veterinary medicine.

The Department of Foreign Affairs and Trade invited ARPANSA to attend two separate virtual briefings on 3 and 9 June to the Pacific Islands Forum (PIF), from the International Atomic Energy Agency (IAEA) and the Japanese government respectively. The briefings were initiated following Japan's announcement of plans to discharge into the sea the accumulated treated wastewater from the clean-up of the Fukushima-Daiichi Nuclear Power Plant. ARPANSA has an ongoing role in the provision of advice to the Australian Government and community around the potential health and environmental impacts from the discharge. The PIF had released a statement raising their concerns with the plan and the IAEA and Japanese government have committed to ongoing engagement as part of their respective work.

ARPANSA's Deputy CEO was invited to co-chair the IAEA's International Conference on the Safety and Security of Radioactive Sources: Accomplishments and Future Endeavours, 20-24 June 2022 in Vienna. Radioactive sources are extensively used for beneficial purposes around the world in medical, industrial, agricultural, research and educational applications. Their safety and security remain a matter of global attention with significant improvements and advancements in recent decades. This important conference provides an opportunity for regulators, competent authorities and many other stakeholders to foster cooperation and exchange experiences on lessons learnt and anticipated future developments on how to establish and maintain a high level of safety and security of radioactive sources throughout their life cycle.

ARPANSA's Deputy CEO participated virtually in the 49th Session of the IAEA's Commission on Safety Standards (CSS), a standing body of senior government officials holding national regulatory responsibilities, which has a special overview role of the IAEA's safety standards and advises the IAEA Director General. The CSS endorsed eight draft standards and approved a draft Document Preparation Profile Safety Guide on the Investigation of Site Characteristics and Evaluation of Radiation Risks to the Public and the Environment in Site Evaluation for Nuclear Installations. Australian Safety Standards representatives with coordination of wider comments will ensure this advice is appropriate for applying to the siting of installations in Australia.

ARPANSA attended virtual meetings of the IAEA Radiation Safety Standards Committees during the quarter, including the Transport Safety Standards Committee, the Radiation Safety Standards Committee, the Emergency Preparedness and Response Standards Committee and the Nuclear Safety Standards Committee. These committees influence and recommend standards for member States and Territories to adopt. ARPANSA also participated virtually in IAEA webinars on: Preparedness and Response Phases for Radioactive Source Search and Recovery, Naturally Occurring Radioactive Material (NORM) focusing on working towards a holistic framework in member states and Nuclear Security Detection and Response in Maritime Areas with the objective of effectively managing potential nuclear security threats along maritime borders. ARPANSA continues to be active in international discussions and drafting guidance in these areas.

ARPANSA's Adjunct Associate Professor Ken Karipidis, as a member of the Main Commission (MC) of the International Commission on Non-Ionizing Radiation Protection (ICNIRP), participated in its annual general meeting. Updates were provided on ICNIRP's work program including projects on low frequency guidelines, radiofrequency dosimetry, laser guidelines, short waves, chronic ultraviolet exposure, environmental protection and ultrasound. ICNIRP's international guidelines set the basis for ARPANSA's development of Australian guidance and standards, which apply to technologies such as 5G telecommunications.

ARPANSA staff participated in the 68th Session of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) between the 21-25 June. ARPANSA's Deputy CEO was re-elected as UNSCEAR Chair and the scientific annex *Occupational exposures to ionizing radiation* was approved for publication. UNSCEAR also considered progress reports for three ongoing projects on second primary cancer after radiotherapy, epidemiological studies of radiation and cancer, and public exposure to ionizing radiation from natural and other sources.

ARPANSA presented at a virtual meeting of the Organisation for Economic Cooperation and Development (OECD) Nuclear Energy Agency (NEA) Radioactive Waste Management Committee's Ad Hoc group on Extended Storage and Transport of Radioactive Waste, on 30 June – 1 July 2021. The OECD-NEA is a non-political forum dedicated to sharing and disseminating knowledge in the field of nuclear energy. Discussion centred around the challenges associated with the use of transport and storage casks and the regulatory requirements around extending the design life of storage casks for radioactive waste and spent fuel. This is relevant to ARPANSA's regulatory oversight of the waste containers that are currently stored or expected to be stored at the ANSTO Lucas Heights site.

ARPANSA attended a virtual IAEA Technical Meeting on Lessons Learned from the Disposal of Low-Level Waste from 7–18 June 2021. It focused on countries' experiences gained over the full lifecycle of low-level waste disposal facilities, from initial siting and concept development through construction, operation and finally closure of these facilities. Similar aspects of intermediate level waste disposal facilities were also discussed. Members agreed to develop a technical document on 'Closure design for near-surface disposal facilities with a period of institutional control', which will be relevant to ARPANSA's regulatory assessment and management of Australia's proposed National Radioactive Waste Management Facility.

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

ARPANSA issued one improvement notice to ANSTO under section 80A of the Act. ARPANSA determined that, in several areas, ANSTO had failed to comply with the *Code of practice for the design and safe operation of non-medical irradiation facilities (1988) (RHS 24)* at their Gamma Technology Research Irradiator facility. ANSTO performed a self-assessment of compliance with the code and identified a

number of areas of non-compliance. ANSTO had been made aware of these issues at previous inspections, however had not taken action to address these non-compliances. The improvement notice issued related to the use of a single multi-purpose key to prevent entry to the irradiation area while radiation is present, as well as the other non-compliances with RHS 24. On this basis, ARPANSA informed ANSTO that they must take appropriate action to remedy the contravention to ensure compliance and comply with the improvement notice by 31 December 2021.

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 minor or significant.

Breaches with minor safety implications are typically administrative failures to meet regulatory requirements. For example: 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. As a matter of policy, ARPANSA has not publicly named entities for minor breaches although that policy will change from July 2021 in accordance with ARPANSA's updated Compliance Manual. The current compliance manual is available on the ARPANSA website at www.arpansa.gov.au/regulation-and-licensing/regulation/our-regulatory-services/how-we-regulate.

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. There has been one breach with significant implications for safety during the quarter:

- ANSTO failed to comply with subsection 60(1) of the Regulations in that its Health Products Division has not effectively managed or stayed within their safety plans in relation to lutetium-177 (Lu-177) production, where Lu-177 is a radiopharmaceutical used for treatment of prostate cancer. The processing of Lu-177 into a radiopharmaceutical has risks to workers that must be managed. This breach was identified during a reactive inspection undertaken after a safety incident at Health Products. Compliance with section 60 of the Regulations is a licence condition that requires all reasonably practical steps to manage safety to be taken.

There were four breaches issued this quarter that were considered to have minor or no safety implications:

- During an inspection of a facility, it was determined that the licence holder had failed to comply with a relevant code or standard, as stated in their licence, including requirements of Radiation Health Series 24 *Code of Practice for the Design and Safe Operation of Non-medical Irradiation Facilities (1988)*, and requirements of the Australian Standard *AS/NZS 2243.4:2018 Safety in Laboratories: Ionizing radiations*.
- A licence holder failed to comply with the requirement to ensure that any person who enters the facility authorised by the licence, including for repair, maintenance or monitoring activities, has received appropriate training in radiation safety and training with respect to the facility which is a condition of licence.
- A licence holder failed to conduct a review each year of its disposal facility performance against the dose constraint of 30 micro sieverts (μSv) effective dose per annum for both workers and members of the public and provide the results to ARPANSA in the annual report which is a condition of licence.

- A licence holder failed to report on the airborne radionuclide discharges for several facilities within the prescribed timeframe, as required by licence conditions. The outstanding reports were subsequently provided, demonstrating compliance with the discharge levels. After consulting with the licence holder, the licence conditions were amended to provide for more reasonable timeframes for reporting.

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 met virtually on the 19 and 20 April 2021.

The main topics were radiation safety in relation to laser technology and medical imaging. ARPANSA's regulatory function was also discussed, and the Council heard a presentation on the Northern Territory Government's final report into the Gunbalanya-Kakadu Cancer Cluster which found no evidence that environmental ionising radiation was a contributing factor to cancer rates in nearby communities.

The working groups established in 2020 to focus on medical imaging and safety concerns relating to laser technology also convened virtually in June 2021. The working groups are looking at methods of obtaining relevant data and information to inform future considerations on their respective topics, to ensure the optimisation of the use of medical imaging and improve the safety around the use of lasers.

The meeting summaries are available at www.arpansa.gov.au/rhsac. The next meeting is scheduled for 4 and 5 August 2021 and will also be held virtually due to COVID-19 restrictions.

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) meeting scheduled for June 2021 was postponed to a later date in October 2021 to provide additional time for work relevant to the proposed transitioning of the Radiation Protection Series document framework to a new model.

Nuclear Safety Committee

The Nuclear Safety Committee (NSC) met virtually on 11 June 2021. The NSC discussed regulatory performance of significant facilities including the ANSTO OPAL reactor.

The NSC provided formal advice to the CEO of ARPANSA under section 26(1)(a) of the Act. The subject of the advice concerned defects identified in the ANSTO OPAL reactor riser, and ANSTO's associated rectification plan.

The minutes of meetings and NSC advice are available at www.arpansa.gov.au/nsc.

The next meeting of the NSC is scheduled for 12 November 2021.