



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



Quarterly Report
of the
Chief Executive Officer of ARPANSA

January to March 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.

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Letter of transmittal

28 May 2021

Senator the Hon Richard Colbeck
Minister for Senior Australians and Aged Care Services
Minister for Sport
Senate
Parliament House
Canberra ACT 2600

Dear Minister

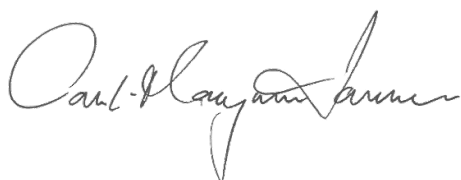
The *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act) requires the Chief Executive Officer (CEO) of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) to submit to the Minister, at the end of each quarter, a report on:

- 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
- 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 January to 31 March 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 4 performance criteria against which ARPANSA seeks to achieve its outcome. These criteria are as follows:

- 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 risk-informed and effective regulation.

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

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

Skin cancer prevention

ARPANSA and the Cancer Council of Victoria commissioned the Queensland University of Technology to study the effectiveness of aerosol sunscreens. The study found that it is extremely difficult to get an effective level of ultraviolet (UV) protection from aerosol products, leaving users at risk of sunburn under Australia's strong UV rays. ARPANSA recommends that users avoid aerosol sunscreens where possible, and instead opt for other sun protection factor products with a more reliable application method, like a cream or a lotion.

The study is available here: <https://www.arpansa.gov.au/news/aerosol-sunscreens-less-reliable-creams-and-lotions>

Enhanced Electromagnetic Energy (EME) Program

In February 2021, ARPANSA published a new safety standard for exposure to radiofrequency EME, *Standard for Limiting Exposure to Radiofrequency Fields – 100 kHz to 300 GHz* (RPS S-1). The updated standard supersedes the previous standard for 'Maximum Exposure Levels to Radiofrequency Field' (RPS 3). The safety standard sets limits for public and occupational exposure across all types of radio waves. The standard is mainly used in the telecommunications industry, but also in various industrial heating processes. The exposure limits in the new standard continue to be set conservatively, meaning they remain

well below the level at which any harm can occur, and will protect the community from all new and existing technologies using EME.

In March 2021, ARPANSA, in collaboration with Swinburne University, published 2 scientific reviews investigating the use of radio waves related to the 5G mobile phone network. The first review assessed studies that examined biological effects and investigated exposure to radar, which uses radio waves similar to 5G. The second review was a statistical analysis of studies investigating the health effects from radiofrequency radiation. Both reviews determined that low-level radio waves, like those used by the 5G network, are not hazardous to human health. The reviews have received global attention and are consistent with national and international radiation health and safety guidelines, which have found low-level 5G radio waves safe for public exposure. The reviews are available at www.nature.com/articles/s41370-021-00297-6 and www.nature.com/articles/s41370-021-00307-7 respectively.

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

International radiological emergency exercise

In March 2021, ARPANSA participated in an International Atomic Energy Agency (IAEA) Convention Exercise (ConvEx), also known as ConvEx-2b. The exercise tested specific parts of the international framework for emergency preparedness and response. ARPANSA was able to verify good practices and identify improvements in the preparation stage. Participation allowed ARPANSA to test the national and international processes for requesting and offering assistance following a nuclear or radiological emergency. Involvement in IAEA exercises is an important element of maintaining effective emergency response systems that protect the Australian community.

Promote patient safety in radiotherapy and diagnostic radiology

Medical imaging

In March 2021, ARPANSA updated and published 3 national diagnostic reference levels (NDRLs) for adult computed tomography (CT) scans. The NDRLs for cervical spine, soft-tissue neck, and kidney-ureter-bladder were updated based on an analysis of data collected through ARPANSA's ongoing National Diagnostic Reference Level Service (NDRLS). The updates were endorsed by professional bodies and the Commonwealth Diagnostic Imaging Accreditation Scheme Advisory Committee in February 2021. The NDRLS provides a point of comparison so that an imaging facility can compare their practice with that of their peers. The aim of DRL comparisons is to encourage imaging facilities to review their practice and thereby ensure an appropriate balance of benefit and risk for patients. This helps to avoid excessive radiation dose to patients from medical imaging.

Primary Standards Dosimetry Laboratory (PSDL)

This quarter, ARPANSA performed an international comparison of radiation dose to maintain the primary standard for dosimetry of ionising radiation in Australia. In 2020, these comparisons took place for air kerma and absorbed dose to water in Co-60 gamma rays, the primary standards for kilovoltage radiation. The results show the standards maintained by ARPANSA and those of the Bureau International des Poids et

Mesures (BIPM) in France to be in agreement. Through this comparison, Australia's measurement capability can be compared to other standards laboratories around the world, ensuring international consistency of radiation dose measurements.

The dosimetry calibration services continued on schedule with 5 calibrations completed for hospitals, and one on-site calibration conducted for a skin clinic.

Australian Clinical Dosimetry Service (ACDS)

ARPANSA's ACDS audit program assesses the dose of radiation delivered for medical treatments in a range of clinical practices to improve patient safety. The program continued to deliver an above-average number of on-site audits this quarter. The increased audit demand resulted from the COVID-19 disruption to service in 2020. Thirty-five on-site audits were performed, including on 4 new linear accelerators and one Gamma Knife system installation. Additionally, 16 mail-out audits are in progress. All audits scheduled for this quarter were completed despite challenges that recent COVID-19 restrictions imposed.

ACDS staff were key authors for 2 international journal articles regarding corrections for the calculation of dose in bone. Utilising ACDS audit results, these articles add to a growing body of knowledge which may affect radiation oncology dose prescription practices for the treatment of tumours in bony structures.

Ensure risk-informed and effective regulation

Significant regulatory activities

ARPANSA assesses applications for regulatory approvals for certain, otherwise prohibited, activities, including approvals of new or amended licences, changes with significant safety implications, or the construction of items important for safety. In the quarter, the following regulatory approvals were provided:

- A low-dose dealing exemption was granted to the Australian Nuclear Science and Technology Organisation (ANSTO) for soils containing trace monazite residues.
- Approvals for changes with significant safety implications were provided under section 63 of the Australian Radiation Protection and Nuclear Safety Regulations 2018 (ARPANS Regulations) as follows:
 - Approval was granted to ANSTO to revise the Open Pool Australian Lightwater (OPAL) reactor's 'loss of coolant' accident scenario within the safety case.
 - Approval was granted to ANSTO to rectify a defective drain plug located in the coolant boundary of the OPAL reactor.
 - Approval was granted to ANSTO for the removal of Licence Condition 14 from the ANSTO Nuclear Medicine (ANM) licence requiring ANSTO to provide information on a range of issues relating to Intermediate Level Waste (ILW) management.

Significant event reporting

On 11 January 2021, ANSTO informed ARPANSA of an event at the OPAL reactor where an unirradiated rig used in nuclear medicine production inadvertently dropped into the irradiation position within the reactor. The second shutdown system (SSS) activated to shut the reactor down safely. No apparent physical damage

occurred. ANSTO initially attributed the activation of the SSS, rather than the reactor's first shutdown system, to the positioning of the safety instrumentation.

ANSTO informed ARPANSA on 16 March 2021 of an issue with the OPAL reactor's first shutdown system which did not function as designed during the incident on 11 January 2021 (where the independent SSS operated as designed to shut the reactor down safely). ARPANSA instructed ANSTO to demonstrate the full functionality of the reactor's first shutdown system before returning to operation. The reactor remained offline in the quarter whilst ANSTO prepared a safety submission to demonstrate this functionality, which ARPANSA will assess whilst maintaining regular communication with ANSTO.

Inspections

ARPANSA conducted 7 scheduled 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. In addition to the scheduled inspections, ARPANSA undertook one augmented inspection relating to a previous safety incident and an inspection of a new licence holder.

Across all inspections in the quarter, 11 areas for improvement were identified and 3 inspections identified potential non-compliances. Potential non-compliances indicate where the licence holder may not be in compliance with legislation or a condition of licence, such as adherence to a code. Once confirmed, these are considered a breach as described in section '*Details of any breach of licence conditions by a licensee*' of this report. Areas for improvement indicate where licence holder safety performance could be improved such as to meet international best practice.

Inspections play an important part in ARPANSA's compliance and performance monitoring program. A well-implemented and rigorous inspection program, supplemented by monitoring and performance reviews, provides assurances that licence holders are operating safely. The inspection reports can be found on ARPANSA's website at www.arpansa.gov.au/regulation/inspections/reports.

Regulatory guidance development

In January, ARPANSA published the Regulatory Guide *Construction of an item important for safety*. This document sets out the regulatory expectations for identifying and classifying items important to safety and provides guidance for the design and construction of such items in line with the safety analysis. Publishing this guide assists licence holders in achieving and maintaining compliance with ARPANS Act and Regulations.

Regulatory guides are available at www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides.

Stakeholder engagement

ARPANSA met with the Department of Defence to coordinate and discuss outcomes of the Defence-ARPANSA Liaison Forum meeting held in 2020. The meeting highlighted challenges due to COVID-19 travel restriction and discussions were held in relation to planning emergency exercise activities. Both agencies committed to conducting campaign-style inspection programs, particularly where new border openings identified an opportunity.

ARPANSA also met with Defence Radiation Safety and Assurance to clarify several source-related matters, the timeline for inspections, and to discuss expectations regarding changes with significant safety implications.

ARPANSA hosted the Transport Competent Authorities Forum involving members from ARPANSA, Australian Maritime Safety Authority, Civil Aviation Safety Authority, state and territory radiation regulators, and industry observers. The meeting focussed on the harmonisation of transport packaging approvals which is a recommendation from the 2018 Integrated Regulatory Review Service mission.

ARPANSA met with ANSTO Health Products to discuss the independent safety review implementation plan. The meeting also clarified regulatory expectations regarding the periodic safety and security review (PSSR). Delivery timeframes for the PSSR plans and other basis documents were discussed.

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, the Minister for Health has authorised ARPANSA officers 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 | 31 | 56 | 88 |
| Import of medical radioisotope | 0 | 94 | 3 |
| Export of high activity source | 0 | 8 | 0 |

Transport of radioactive material

ARPANSA endorsed 3 transport security plans during the quarter. 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.

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 for taking 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 global travel restrictions relating to COVID-19. However, ARPANSA maintained international relations remotely wherever possible through a range of virtual means. A sample of these engagement activities is outlined below.

In the quarter, ARPANSA nominated a number of staff members to be the Australian representatives to the 5 IAEA Safety Standards Committees for the next 3-year terms and support the Australian Safeguards and Non-proliferation Office as the alternate member for the Nuclear Security Guidance Committee. These committees provide feedback to the IAEA on its emergency preparedness and response, nuclear, radiation, transport and waste safety programs, and our involvement ensures that Australia can influence the development of IAEA guidance that is adopted as part of the ARPANSA Radiation Protection Series.

ARPANSA's CEO and another staff member participated virtually in the Convention on Nuclear Safety (CNS) Officers' Meeting in their capacity as Vice-President and a Rapporteur, respectively, for the Eighth Organizational Meeting of Contracting Parties. After initially being postponed in 2020, due to the COVID-19 pandemic, it was announced that the Eighth Review Meeting would be merged with the ninth Review Meeting scheduled for 2023. A proposal was supported that would establish a working group to develop ground rules for actions to safeguard the continuation, integrity and utility of the CNS process should any future disruptive events occur.

An ARPANSA representative attended the 54th session of the Nuclear Energy Agency (NEA) Radioactive Waste Management Committee. The meeting discussed the challenges of extended storage, transportation and impacts on disposal, the development and improvement of radioactive waste matrices and a methodology to address all hazards in radioactive waste. The NEA which is organised under the Organisation for Economic Co-operation and Development (OECD) is an intergovernmental agency that facilitates cooperation among countries with advanced nuclear technology infrastructures to seek excellence in nuclear safety, technology, science, environment and law.

ARPANSA participated in the third session of the NEA Committee on Decommissioning of Nuclear Installations and Legacy Management. The meeting discussed the management of materials from decommissioning, the management of legacy sites, and the application of new/modified materials as a factor of optimisation of radioactive waste management programs. Feedback mechanisms for lessons learned, particularly as it related to challenges faced during COVID-19, were also considered.

An ARPANSA staff member, in their capacity as Chair of the Expert Group on Medical Exposure within the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), participated virtually in the third International Conference on Advances in Radiation Oncology and the European Congress of Radiology, where summary overviews of the UNSCEAR assessment of global medical exposures of patients were presented. The UNSCEAR Medical Exposure Survey commenced in 2014 and sought data from all United Nations Member States on annual numbers of medical procedures involving the use of ionising radiation and on the associated doses to patients.

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 the Australian Nuclear Science and Technology Organisation (ANSTO) under section 80A of the Act. ARPANSA found 2 high-activity sealed radiation sources being stored without being covered by an approved security plan. These plans are required under the *Code of Practice for the Security of Radioactive Sources* (RPS 11). On this basis, ARPANSA informed ANSTO that they must take appropriate action to remedy the contravention and ensure a return to compliance.

Details of any breach of licence conditions by a licensee

ARPANSA categorises breaches of licence conditions based on whether the implications for safety (or the potential risks to safety) were either minor or significant.

Breaches with minor or no significant safety implications are typically administrative failures to meet regulatory requirements. For example, failure to label equipment properly, submit paperwork on time, complete scheduled training, keep up-to-date inventories, or conduct scheduled reviews of planning documents. As a matter of policy, ARPANSA does not publicly name entities for minor breaches.

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 were 3 breaches issued this quarter. Two were considered to have minor or no safety implications. These were:

- During an inspection of sources of radiation, it was determined that the licence holder had failed to review and update their plans and arrangements for managing safety at least once every 3 years, as required under subsection 61(1) of the ARPANS Regulations.
- A licence holder failed to notify the CEO within 7 days of the transfer of 2 molybdenum-99 (Mo-99) sources to another licence holder, as required under subsection 65(3) of the ARPANS Regulations.

One breach had significant safety implications:

- During an inspection of sources of radiation, the review and update of ANSTO's security plan for radioactive sources was found to be significantly out of date according to their arrangements for managing safety. ARPANSA determined that ANSTO was in contravention of subsection 81(b) of the ARPANS Regulations for failing to implement the *Code of Practice for the Security of Radioactive Sources*), as well as update their internal plans and procedures.

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 twice during the quarter for working group meetings on 22 and 23 March 2021. The meetings took place virtually and continued to explore the topics of radiation safety in relation to laser technology and medical imaging. The discussion on laser safety covered the clinical and patient safety and public exposure perspectives, outlining issues around promoting uniformity of regulation and concerns about the oversight of various uses of laser technology.

The medical imaging working group focused on reducing the cumulative and individual population dose, discussing the areas of potential concern, and agreeing on the need for further data and evidence.

The minutes of meetings are available at www.arpansa.gov.au/rhsac. The next meeting is scheduled for 19 and 20 April 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) met on 2 occasions during the quarter. A single-issue meeting of the RHC was held virtually on 10 February 2021 and focussed on a potential review of the Radiation Protection Series (RPS) framework and a new type of RPS document regarding regulatory expectations.

The RHC also met virtually on 24 and 25 March 2021. The RHC discussed a letter from the CEO of ARPANSA to the Chair of the Environmental Health Standing Committee (enHealth) on the recent developments in the regulation of non-ionising radiation (NIR). The RHC acknowledged the letter would be useful to establish a risk-informed strategy for the regulation of NIR.

The RHC approved a multi-jurisdictional program to collect radiation monitoring data on cabinet X-ray equipment. The program will be used to justify the exemption whereby operators of cabinet X-ray equipment are not required to hold a user licence.

The RHC also endorsed the draft Statement on 'Wearable personal dosimeter and airport CT-security scanners' with jurisdictions to include radiation monitoring data to finalise the statement. Prior to finalisation, the Statement will be communicated with the Department of Home Affairs (DHA) for feedback. The aim of this statement is to prevent a potential false, high dose from being recorded, as radiation workers have their wearable personal dosimeters scanned with carry-on baggage as part of the airport security screening process. This statement will help DHA consider the development of a policy and guidance regarding an exemption of wearable personal dosimeters from being subject to airport CT-baggage scanners.

The RHC discussed the process of implementing the RPS framework to provide a more effective and efficient approach that protects human health and the environment from the harmful effects of radiation. The RPS associates requirements with regulatory expectations, providing clarity for those responsible for safety. The framework will introduce a new type of document 'Regulatory Expectations', which will

promote nationally consistent regulatory expectations and establish a 'baseline' for compliance against applicable Codes. The RHC agreed to adopt this framework and incorporate Regulatory Expectation documents into the RPS series.

The minutes of this RHC meeting are provided online at www.arpansa.gov.au/rhc. The next RHC meeting is scheduled to take place on 16–17 June 2021.

Nuclear Safety Committee

The Nuclear Safety Committee (NSC) met on 5 March 2021 via video conference. This was the first meeting of the new triennium with 2 new committee members.

The committee provided comments on the early stages of a revision to ARPANSA's Waste Facility Guidance that will be used to develop and assess applications for the National Radioactive Waste Management Facility and any other waste facilities. The committee also discussed matters relating to ARPANSA's regulatory oversight activities, including the ANSTO OPAL Reactor Riser structural defects.

The minutes of meetings are available at www.arpansa.gov.au/nsc. The next meeting of the NSC is scheduled for 11 June 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.