



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



Quarterly Report
of the
Chief Executive Officer of ARPANSA

April to June 2020



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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

Table of contents

Letter of transmittal	1
The operations of the CEO and ARPANSA	2
Provide high quality advice to government and the community on health, safety and environmental risks from radiation	2
Provide emergency preparedness and response systems for a radiological or nuclear incident	4
Promote patient safety in radiotherapy and diagnostic radiology	4
Ensure risk-informed and effective regulation	5
International engagement	8
Details of directions given by the Minister	9
Details of directions given by the CEO	9
Details of improvement notices given by inspectors	9
Details of any breach of licence conditions by a licensee	9
Facilities licensed under Part 5 of the ARPANS Act	9
The operations of the Council and committees	9
Radiation Health and Safety Advisory Council	9
Radiation Health Committee.....	10
Nuclear Safety Committee	10

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Letter of transmittal

3 September 2020

Senator the Hon Richard Colbeck
Minister for Aged Care and Senior Australians
Minister for Youth and 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 (RHC)
- 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 2020.

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 2019-20 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 2019-20 PBS, describes four performance criteria, against which ARPANSA seeks to achieve its outcome. These criteria 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 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

Occupational exposure to radiation

The Australian National Radiation Dose Register (ANRDR) holds dose records for around 46 000 workers. This includes full coverage of workers from all state and territory-licensed uranium mining and milling operations, and partial coverage of workers from Commonwealth licence holders, state and territory regulatory bodies, the mineral sands mining and processing industry, as well as the medical and veterinary sectors. The aim of the ANRDR is to cover all occupationally exposed workers in Australia, and work to ensure that this can be achieved across all jurisdictions is in progress.

A pilot program for dosimetry service providers to submit dose records to the ANRDR was put on hold during the COVID-19 pandemic response. A schedule of works for the ANRDR to identify a pathway to achieve its vision has been developed and is pending submission to the ANRDR Advisory Board for their review. ARPANSA coordinates the ANRDR Advisory Board, which consists of members from most jurisdictional regulators (including an ARPANSA representative). The board's primary purpose is to be a place for jurisdictional radiation regulators to represent their views with regard to ANRDR matters, and to provide advice and guidance to ARPANSA on the approach to development and national expansion of the ANRDR.

Radiation at work explained

ARPANSA developed a suite of factsheets about exposure to radiation in workplaces (occupational exposure). These have been designed to keep workers informed about the type of radiation they may be exposed to, any possible health effects and how to adequately protect themselves. The use of radiation in the workplace is a normal and required part of many occupations. For example, radiation is used (or produced) widely in the health sector to diagnose or treat patients, the mining industry in the processing of minerals and ores and in technology used in our homes and devices. More information can be found at www.arpansa.gov.au/news/radiation-work-explained.

Funding for an Enhanced EME Program

ARPANSA completed plans to implement activities under the Australian Government's Enhanced Electromagnetic Energy (EME) Program, with additional resources to be obtained from July 2020. The Australian Government announced this four-year program to provide clear, reliable and reputable information accessible to all Australians, and included funding for ARPANSA to deliver evidence-based scientific advice with a clearly informed picture of the problem and associated risks and uncertainty. The ARPANSA components of the Enhanced EME program include new forms of engagement into international forums (such as the World Health Organization and International Commission on Non-Ionizing Radiation Protection), undertaking or partnering on new EME research, undertaking studies to assess EME exposure in the Australian community, offering EME equipment calibration services and providing expert advice for Australia on EME and health.

Statement on 5G and COVID-19

The COVID-19 pandemic has seen some members of the public express concern about the human immune system and whether it can be compromised by wireless telecommunications sources such as 5G. ARPANSA reviewed the scientific evidence and issued a statement that there is no established evidence that low level radio wave exposure from 5G and other wireless telecommunications can affect the immune system or cause any other long term or short term health effects. The statement can be found at www.arpansa.gov.au/news/5g-and-other-telecommunications-do-not-affect-immune-system.

Product warning for UVC lamps and COVID-19

ARPANSA issued a product warning to advise consumers of the dangers of portable devices that emit ultraviolet (UV) radiation (www.arpansa.gov.au/understanding-radiation/sources-radiation/more-radiation-sources/UVC-germicidal-lamps-personal). In light of the COVID-19 pandemic, some companies and individuals are promoting UV radiation devices to treat or prevent the spread of coronavirus. These devices emit short-wave UV radiation known as UVC and have been marketed for use in personal or home sterilisation as a means of killing the virus responsible for COVID-19. ARPANSA's advice is that the use of these lamps on the body exposes people to harmful ultraviolet radiation which may cause injury and increase the risk of skin cancer and permanent eye damage.

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

Comprehensive Nuclear-Test-Ban Treaty (CTBT) monitoring stations

Due to the COVID-19 pandemic, ARPANSA staff have not been able to travel to undertake scheduled annual maintenance on part of its radionuclide monitoring system. Contingencies are in place to remotely support local operators with more limited maintenance, and further contingencies are being considered. This work forms part of Australia's involvement in the Comprehensive Nuclear-Test-Ban Treaty (CTBT), which bans nuclear explosions and testing and includes a monitoring network to detect nuclear activity. The CTBT international monitoring system aims to ensure that no nuclear explosion goes undetected. ARPANSA is responsible for a total of eleven radionuclide monitoring stations (including two noble gas stations) in nine locations; seven in Australian territories including Cocos Island, Antarctica and Macquarie Island; and two in the Pacific region.

Emergency exercising

ARPANSA participated in an International Atomic Energy Agency (IAEA) Convention Exercise (ConvEx) known as ConvEx-2a on 12 May 2020. ConvEx-2 exercises are designed to test specific parts of the international framework for emergency preparedness and response. This emergency exercise followed a hypothetical scenario of an explosion in central Melbourne with suspected (and later confirmed) radiological material present. Due to COVID-19 restrictions, the exercise was undertaken using a 'Virtual Operations Centre', enabling activation and exercising of ARPANSA's Incident Management Plan and testing of established communication protocols with the IAEA Incident and Emergency Centre in Vienna. The exercise demonstrated that ARPANSA could effectively coordinate core elements of our response to an emergency while working remotely from the office, including development of technical advice and provision of this information via established platforms for communication with the IAEA.

Promote patient safety in radiotherapy and diagnostic radiology

Medical imaging

ARPANSA has released national diagnostic reference levels (DRLs) for X-ray diagnostic coronary angiography procedures. The release follows several years of survey data collection from imaging facilities around Australia and a consultation and review process through a liaison panel comprising representatives of relevant professional bodies. The panel made recommendations for DRLs that the participating professions endorsed before the DRLs were published on ARPANSA's web pages. DRLs support the safe use of medical imaging by giving imaging facilities a benchmark against which to assess the level of radiation they use when performing a particular imaging task. Publishing a national DRL triggers regulatory requirements for imaging facilities that perform these procedures to conduct periodic comparisons of their radiation levels with the national benchmark. The aim of the process is to encourage all imaging facilities to periodically review their practice and for those facilities above the benchmark to consider whether they can reduce radiation dose levels while still maintaining the necessary image quality to perform the diagnostic task. This optimisation process supports the ongoing safe and effective use of radiation in medicine.

Primary Standards Dosimetry Laboratory (PSDL)

The PSDL completed planning for the relocation of the control room for one of the laboratory's linear accelerators (linacs). This will make space available for a new facility for high frequency non-ionising radiation measurements (such as radio waves used in 5G technology), and improve efficiency by consolidating workspace in the existing laboratories.

The PSDL calibrates equipment that is used in hospitals to make sure the correct dose is delivered during radiotherapy. Calibration services continued during the COVID-19 restrictions, although at a reduced rate.

PSDL maintains the High Energy Primary Standard, which is the ultimate reference for the dose that is delivered in nearly all radiotherapy treatments in Australia. The existing standard is aging and a study regarding the technology that could be used to replace it was completed. International laboratories were consulted and four options, with cost estimates, were identified. This work will culminate with the design, construction and delivery of a new High Energy Primary Standard for Australia.

Australian Clinical Dosimetry Service (ACDS)

The ACDS audit program assesses the dose of radiation delivered for medical treatments in a range of clinical practices in order to improve patient safety. It includes remote and onsite measurements of the radiation delivered for treatments. COVID-19 resulted in a pause of the ACDS audit schedule from 22 March to 10 April 2020, after which a skeleton service was provided to ensure that four new linear accelerator installations were licenced on time and treatments were not delayed. The ACDS recommenced full service on 17 May and 19 onsite audits were performed over seven weeks, with interstate travel to New South Wales, Queensland, Tasmania and South Australia despite border closures and reduced flights.

Ensure risk-informed and effective regulation

Significant regulatory activities

ARPANSA issues regulatory approvals that are required prior to commencing certain activities; these can include the issue 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:

- construction of an item important for safety, namely, the Waste Transfer System at the Australian Nuclear Science and Technology Organisation's (ANSTO) SyMo facility, under section 66 of the Regulations. The SyMo facility is a new purpose-built facility at ANSTO that will apply ANSTO Synroc technology for the immobilisation of intermediate level liquid waste arising from molybdenum-99 production for nuclear medicine.
- relocation of the ARPANSA Medical Radiation Services Branch Synergy Linac Control Room
- approval to undertake routine verification measurements of the spent uranium filter cups, using the IAEA's verification method, in ANSTO's Waste Operations hot-cells.

ARPANSA also received documents from licence holders that were requested or required to be provided under licence conditions that ARPANSA imposed. This allows ARPANSA to maintain oversight of activities occurring at licence holders.

The following documents were received during the quarter:

- advice on plans to remove waste stored in the ANSTO Interim Waste Store.
- evidence of training of senior managers at the ANSTO Nuclear Medicine (ANM) facility on the management of conflicting production and safety priorities, advice on intermediate level waste management, including current holdings, future generation, treatment, storage and disposal, and the provision of an updated ANM facility risk assessment.
- a current Safety Analysis Report for ANSTO's Camperdown facility.
- a schematic depicting its 10 Year Major Waste Stream Strategy, as requested at the ANSTO-ARPANSA Liaison Forum meeting in March 2020.
- following a request from the ARPANSA Chief Regulatory Officer, advice was provided by licence holders regarding arrangements at facilities impacted by the COVID-19 pandemic.

Inspections

ARPANSA conducted six scheduled 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 Australian Radiation Protection and Nuclear Safety Regulations 2018 (ARPANS Regulations). The scope and frequency of inspections are determined from an assessment of the risk presented from the controlled activity and a range of factors including licence holder safety performance. Effects of changed working circumstances during the COVID-19 pandemic have resulted in some changes to the scheduled inspections and oversight measures. While these measures have impacted ARPANSA and our licence holders, inspections continue to be carried out by physical and digital means, as applicable.

This quarter's inspections identified zero potential non-compliances. Twelve areas for improvement were identified. Potential non-compliances indicate an area where the licence holder may not have complied with legislation or a condition of licence, such as adherence to a code. Once confirmed, these are considered a breach as described in the 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, rigorous inspection program supplemented by monitoring and performance reviews provides confidence that licence holders are operating safely. The inspection reports can be found on ARPANSA's website at www.arpansa.gov.au/regulation/inspections/reports.

Stakeholder engagement

A draft ARPANSA 'Regulatory Guide: Safety Analysis Report for Controlled Facilities' has been developed and circulated for stakeholder comment. This guide provides information on preparing a safety analysis at each stage of the life for facilities that ARPANSA might regulate, such as preparing a site, construction, and operation of a facility. It aims to help ensure that the safety analysis of non-reactor facilities is prepared in accordance with best international practice. ARPANSA uses this document to assess licence applications for facilities that it must regulate. This guidance was developed as part of the ARPANSA Integrated Regulatory Review Service (IRRS) Action Plan. Stakeholder comments are due on 24 July 2020.

A meeting was held with the South Australian Environment Protection Authority on 22 May 2020, with representation from the ARPANSA Regulatory Services Branch and ARPANSA Medical Radiation Services Branch, concerning their draft guide for Radiation Facilities Licence Application (Category IV). Feedback was provided on the draft document, which will be applied for the proposed proton therapy unit in Adelaide.

ARPANSA has been in discussion with the Western Australian Department of Finance regarding ARPANSA's potential review of a 2017 safety assessment for the Mount Walton Intractable Waste Disposal Facility. Following discussion with the Radiation Health Unit of the Western Australian Department of Health, it is considered that ARPANSA's recommendation, from its 2018 compliance audit of the facility, to update the assessment to bring into line with international best practice, should be completed prior to ARPANSA performing the review.

Standards development

Work on revision of the Radiation Protection Standard for Maximum Exposure Levels to Radiofrequency Fields — 3 kHz to 300 GHz (Radiation Protection Series No. 3) continued during the quarter. It is anticipated that the revised standard, 'Standard for Limiting Exposure to Radiofrequency Fields – 100 KHz to 300 GHz (RPS S-1)', can be released for public consultation in the July to September quarter of 2020. RPS S-1 is based on the 2020 guidelines of the International Commission for Non-Ionizing Radiation Protection (ICNIRP) for high frequency fields. It covers all radiofrequency (RF) (EME) frequencies including those used by 5G and future telecommunications technologies.

National uniformity

ARPANSA is a member of the Radiation Health Expert Reference Panel (RHERP), which met on 15 April, 13 May and 16 June 2020. RHERP is a network of experts including nominated representatives from Australian jurisdictional radiation regulators as well as other experts. It works under the guidance of the Environmental Health Standing Committee (enHealth), part of the Commonwealth of Australian Governments (COAG) structure. RHERP was established to develop a national strategy for uniformity of radiation protection and nuclear safety regulation in Australia, and to provide expert advice on radiation protection and nuclear safety matters to enHealth. In accordance with ARPANSA's action plan in response to recommendations from the 2018 IRRS mission, leaders from ARPANSA and state and territory jurisdictions have now been assigned to various actions through enHealth.

Project updates

ARPANSA is monitoring the progress of the ANSTO Health Safety Review Implementation Plan. ANSTO's next status update report is due by the end of July 2020. ARPANSA completed an inspection of ANSTO Health Products in May 2020 that covered some of the improvements ANSTO indicated had been completed but, due to COVID-19 restrictions, the majority of the inspection was conducted remotely with a limited scope. As a result, not all of ANSTO's actions could be verified.

ARPANSA provided evidence at a hearing for the Commonwealth Senate Economics Legislation Committee's Inquiry into the National Radioactive Waste Management Amendment (Site Specification, Community Fund and Other Measures) Bill 2020. This Bill relates to the Department of Industry Innovation and Science's proposed National Radioactive Waste Management Facility (NRWMF) at Kimba, South Australia. ARPANSA is responsible for the licensing and regulation of any future NRWMF if it proceeds and

continues to provide advice on regulatory matters to relevant government stakeholders and the Parliament as required.

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 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 month
Import of non-medical radioisotope	59	33	6
Import of medical radioisotope	-	74	7
Export of high activity source	-	5	-

Transport of radioactive material

ARPANSA approves certain plans and packages for the transport of significant quantities of radioactive material by licence holders.

ARPANSA endorsed six transport security plans this quarter. 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.

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 impact of global travel restrictions relating to COVID-19. ARPANSA maintained international relations remotely wherever possible.

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

There were three breaches determined in this quarter that were considered to have minor or no significant safety implications. The breaches were for failing to comply with licence conditions, including those in the Australian Radiation Protection and Nuclear Safety Regulations 2018. These breaches were:

- One for failing to take reasonably practicable steps to ensure the licence holder plans and arrangements for managing safety were implemented under section 60 of the regulations. Instances where these were not fully implemented included routine checks and calibrations.
- One for failing to ensure that the requirements of the Code of Practice for the Security of Radioactive Sources (2019) (RPS 11) were met, including having appropriate physical detection measures in place and having an endorsed security plan, which is required under section 59 (1) of the regulations.
- One for failing to seek prior approval for the transfer of a radiation source as required under section 65(2) of the Regulations. The source was a low risk source that was transferred without prior approval to a recipient that was found not to be licenced for this type of equipment. This breach was self-reported.

There were no breaches with significant safety implications this quarter.

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) did not meet during the quarter.

The minutes of past meetings are on ARPANSA's website at www.arpansa.gov.au/rhsac. The next meeting is scheduled for 27-28 July 2020 via videoconference.

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 minutes of RHC meetings are provided online at www.arpansa.gov.au/rhc.

The following RHC Statements have been published on ARPANSA's website:

- *Statement on Safe Handling of Deceased Persons Recently Treated with Radioactive Material*

This Statement intends to provide information to persons such as cemetery and crematorium workers, funeral parlour staff and directors, embalmers and coroners, who in the course of their work may be required to deal with deceased persons who had recently undergone medical procedures involving radioactive material, such as nuclear medicine for cancer treatment. It sets out information to assist in achieving the levels of protection specified in the Code for Radiation Protection in Medical Exposure (RPS C-5) which contains the requirements that govern radiation protection in radiotherapy and nuclear medicine.

- *Statement on Ethical Review for Multi-Centre Trials*

The RHC notes that there have been some issues in consistently applying the requirements of the Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (RPS 8). The Committee is considering revising the Code but, in the interim, has issued this statement in relation to multi-centre research trials. The statement provides information how the code should apply under the National Mutual Acceptance (NMA) arrangements for multi-centre trials where a single central Human Research Ethics Committee (HREC) undertakes review.

The next RHC meeting will take place via video conference on 22 July 2020.

The nomination for new members on the RHC for the next 2021-2023 triennium has been advertised in the media and on ARPANSA's website. The nominations close on 31 August 2020.

Nuclear Safety Committee

The Nuclear Safety Committee (NSC) did not meet during this quarter due to the requirement for the regional and interstate travel by members under the COVID-19 pandemic restrictions. The NSC was postponed from June to August 2020 and will include video conference attendance options.

The call for nominations of new members on the NSC for the next triennium (2021-2023) has been advertised in the media and on ARPANSA's website. Nominations close on 31 August 2020.

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.