



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



Quarterly Report
of the
Chief Executive Officer of ARPANSA

October to December 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.

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Letter of transmittal

19 February 2021

Senator the Hon Richard Colbeck
Minister for Aged Care Services and Senior Australians
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, 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 October to 31 December 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 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

During the quarter, the Australian National Radiation Dose Register (ANRDR) Advisory Board met and approved the ANRDR Strategic Directions roadmap to achieve coverage of all workers occupationally exposed to ionising radiation in Australia. The ANRDR team will engage dosimetry service providers in Australia to commence work to submit their dose records to the ANRDR. Pilot programs with each Australian dosimetry service provider are set to commence in early 2021.

ARPANSA's ANRDR helps workers track their personal radiation exposure across different employers and workplaces, which informs workers and employers of the safety risks from radiation exposure. It currently contains dose records for around 46 000 workers, with 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.

Enhanced Electromagnetic Energy (EME) Program

ARPANSA has initiated recruitment activities under the Australian Government's Enhanced Electromagnetic Energy (EME) Program, since additional resourcing became available in July 2020. The Australian Government announced this four-year program in December 2019 to provide clear, reliable and reputable

information accessible to all Australians. The Program included funding for ARPANSA to deliver evidence-based scientific advice, with a clearly informed picture of the problem, associated risks and uncertainty. The ARPANSA components of the Enhanced EME Program include to increase engagement in international forums (such as the World Health Organization and International Commission on Non-Ionizing Radiation Protection), undertake or partner with new EME research, undertake studies to assess EME exposure in the Australian community, and provide expert advice for Australia on EME and health. The activities under the Enhanced EME Program are further outlined in the ARPANSA EME Action Plan available at <https://www.arpansa.gov.au/news/new-electromagnetic-energy-action-plan>.

ARPANSA is also in the final stages of reviewing a new safety standard for exposure to radiofrequency EME – also known as radio waves – previously released for public consultation in August 2020. 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. During public consultation, ARPANSA received 61 submissions and 451 individual comments. ARPANSA has reviewed the submissions and adopted several minor technical changes and clarifications.

Guide for Classification of Radioactive Waste

In October 2020, ARPANSA published an updated Guide for Classification of Radioactive Waste, RPS G-4. The updated guidance supersedes the previous Guide for Classification of Radioactive Waste, RPS 20 (2010). The guide sets out non-prescriptive, best-practice guidance for classifying radioactive waste, with a primary focus on long-term safety after disposal. The classification scheme supports implementation of the safety requirements outlined in the Code for Disposal Facilities for Solid Radioactive Waste, RPS C-3 (2018). The guide was revised to improve clarity, reflect current concepts and the Australian context, and align with international best practice. The guide will be relevant to any proposed radioactive waste management facilities in Australia. The guide is available at <https://www.arpansa.gov.au/guide-classification-radioactive-waste-rps-g-4>.

Advisory on validation of certain packages for transport of radioactive material

In December 2020, ARPANSA published the Advisory Note - *How can I validate the design of Type B(U) and Type C packages for radioactive material, if already approved outside of Australia?* It provides explanations and advice to help ARPANSA licence holders and transporters understand ARPANSA's validation process for certain types of packages (that hold special-form radioactive material) whose design was approved overseas. The publishing of the advisory note is expected to help establish uniformity in Australia of the appropriate use of these packages and align this process with international best practice. The advisory note is available at <https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/codes-and-standards/rpsc-2an>.

Australian Radiation Incident Register Annual Report

ARPANSA published the Australian Radiation Incident Register (ARIR) Annual Report for 2019. This year's feature topic was equipment failures and deficiencies. The ARIR is Australia's national database of incidents and events, where radiation or radioactivity was implicated. Incident reports are collected from Commonwealth, state and territory radiation protection authorities. The ARIR Annual Report is a summary and analysis of data submitted to the ARIR for incidents, primarily in the medical industry. The report raises awareness of the risks associated with common tasks, shares the learnings identified from incidents, and assists in the identification of topical areas where safety efforts may be focused to improve radiation

protection. The report noted a 21 per cent decrease in the number of incidents that regulators reported compared to 2018. This was likely impacted by involvement in COVID-19 response by regulators during the time of data-submission stage in early 2020. The previous upward trend reflected increased awareness and use of the ARIR and the ongoing development of a positive reporting culture which ARPANSA actively promotes. The report is available at <https://www.arpansa.gov.au/regulation-and-licensing/safety-security-transport/australian-radiation-incidents-register/annual-summary-reports>.

Regulatory Advice to Other Jurisdictions

ARPANSA reviewed the Safety Analysis Report for the proposed proton therapy unit of the Australian Bragg Centre for Proton Therapy and Research, at the request of the South Australian Environment Protection Authority. Proton therapy offers greater precision in targeting cancerous tissues, largely avoiding surrounding healthy tissue and lowering the risk of side effects when treating tumours close to vital organs or in children. ARPANSA's review took account of advice received from the Dutch radiation protection regulator (Autoriteit Nucleaire Veiligheid en Stralingsbescherming (ANVS)) regarding its assessment and licensing of Dutch proton therapy units.

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

Nuclear powered warship visit

ARPANSA conducted environmental and emergency radiation monitoring while a French naval vessel visited Western Australia this quarter. Air, water and personal monitoring services were carried out to ensure no radioactive discharges to the environment were made during the visit. Visits are arranged through the Visiting Ships Panel (Nuclear), of which ARPANSA is a member. Port visits by warships of friendly nations are an aspect of Australia's defence cooperation in peacetime.

Promote patient safety in radiotherapy and diagnostic radiology

Medical imaging

ARPANSA concluded a procurement process and commenced work on important changes to the data portal and associated administration interface that support the computed tomography (CT) component of the National Diagnostic Reference Level Service (NDRLS). The changes will improve the efficiency of the service through correction of software issues, the inclusion of additional management tools and improved functionality of the client portal. NDRLS surveys, completed by participating imaging facilities, collect data on metrics for patient dose from ionising radiation in diagnostic imaging, particularly for CT. ARPANSA uses this data to calculate Australian diagnostic reference levels (DRLs) for common types of CT scans. The DRLs provide a point of comparison so a given 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 in Australia.

Primary Standards Dosimetry Laboratory (PSDL)

ARPANSA's PSDL relocated the control room for one of the laboratory's linear accelerators (linacs) to make space available for a new facility for high frequency non-ionising radiation measurements (including radio waves used in 5G technology). The move also consolidates existing workspace to improve linac efficiency.

ARPANSA completed calibrations for 17 radiotherapy facilities, calibrated equipment for two commercial providers of radiation calibration services and calibrated two neutron monitors. ARPANSA's PSDL calibrates equipment that is used in hospitals to make sure the correct dose is delivered during radiotherapy. An increased rate of service calibrations in December helped counter a reduced rate of services during Victoria's COVID-19 restrictions.

Planning continued for a new primary standard for radiation dose, to underpin Australia's existing and new radiotherapy dosimetry requirements, and to replace the existing instrument which has exceeded its nominal lifespan. A three-year project to procure and commission a new standard is at the proposal stage.

Australian Clinical Dosimetry Service (ACDS)

ARPANSA's ACDS audit program resumed full-service delivery this quarter. This program assesses the dose of radiation delivered for medical treatments in a range of clinical practices in order to improve patient safety. Full service was achieved through continued use of alternative measures (including the temporary relocation of staff) introduced to overcome the challenges that COVID-19 border restrictions imposed.

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 licence for a radiation source was granted to the Australian Signals Directorate to deal with an x-ray for baggage inspections and other security purposes.
- The radiation source licence held by National Archives of Australia was surrendered due to a device being disposed.
- Approvals for changes with significant safety implications under section 63 of the Australian Radiation Protection and Nuclear Safety (ARPANS) Regulations 2018 were:
 - Approval was granted to the Australian Nuclear Science and Technology Organisation (ANSTO) Nuclear Medicine (ANM) Facility to perform hot commissioning, qualification and validation of a second dissolution hot cell, known as DCEL2. When fully commissioned, this hot cell will improve reliability of the supply of nuclear medicine to the community.
 - Removal of a licence condition on the ANSTO SyMo Facility that restricted certain commissioning tests. These non-radiological performance tests may now be carried out on plant and equipment to provide data needed to support ANSTO's application for an operating licence.

- ARPANSA amended a licence for the ANSTO Interim Waste Facility (IWS). A licence condition that related to plans for the removal of waste holding was met and subsequently removed. A new licence condition was added, that requires detailed information about the isotopic content of waste packages be submitted to the CEO of ARPANSA, before materials from overseas processing facilities are sent to the IWS. This will allow greater regulatory oversight of the returned reprocessed waste.

Significant Event Reporting

ANSTO Open-Pool Australian Lightwater (OPAL) Reactor Riser Structural Defects

ANSTO informed ARPANSA on 11 November 2020 that structural defects had been observed in the OPAL Riser during a planned inspection of the OPAL reactor pool. The inspection took place during a planned shutdown of the reactor.

The OPAL Riser, also known as the 'Upper Chimney', forms part of the reactor primary cooling system (PCS) and performs various safety functions during normal operation and accident conditions.

As a result of the defects, the OPAL reactor did not return to operation when originally planned. ANSTO assessed the situation, conducted further inspections, and prepared a submission to ARPANSA providing justification to return to operation.

ARPANSA received the submission on 27 November 2020. After reviewing the submission, ARPANSA concluded that ANSTO had provided satisfactory evidence regarding the safety of continued operation of the reactor, subject to further assessment and monitoring. The OPAL reactor then returned to power on 30 November 2020.

On 7 December 2020, ARPANSA and ANSTO representatives met to discuss the safety management of the structural defects, including regular surveillance, mitigating measures and rectification options for the future. On 24 December 2020, ANSTO provided ARPANSA with a plan with timelines to rectify the defects in the OPAL Riser. ARPANSA will consider this plan whilst continuing to conduct site visits, inspections and meet with ANSTO to review their progress against the plan.

ANSTO Health Products Exposure Incident

On 23 December 2020, ANSTO informed ARPANSA about an exposure to the hands of two staff members at their Health Products facility while they were investigating a leaking flange on a process waste container. The exposure was from lutetium-177, which is used in the treatment of a variety of cancers. The staff used protective equipment providing limited protection during the collection of a sample of liquid and crystalline material coming from the flange.

On 4 January 2021, ANSTO provided ARPANSA with a detailed assessment with calculations of estimated radiation doses to the staff. The assessment indicated that the best estimate extremity dose to the most exposed individual was 160 millisieverts (mSv) which is less than the annual statutory dose limit to the body extremities of 500 mSv. ARPANSA has sought further information about the incident from ANSTO. ARPANSA will perform an independent assessment of the extremity doses based on information already provided. ARPANSA will undertake an augmented inspection to better understand the sequence of events that led to the exposure, including an assessment of the associated human factors. A preliminary assessment of the incident has identified this as a Level 1 event on the International Nuclear and

Radiological Event Scale (INES), which has been reported to the International Atomic Energy Agency. Level 1 is the lowest category of event on a scale of 1 to 7 in the INES reporting system.

Inspections

ARPANSA conducted eight scheduled inspections, and one site visit, during the quarter. Five additional inspections were conducted including low-risk inspections deferred from previous quarters due to COVID-19 restrictions, and an inspection to independently confirm no elevated radiation levels as part of a request from a licence holder to surrender a facility licence. ARPANSA undertakes a scheduled inspection program of licence holders to monitor compliance with the *Australian Radiation Protection and Nuclear Safety Act 1998* (ARPANS Act) and ARPANS Regulations. The scope and frequency of inspections are determined based on an assessment of the risk presented from the controlled activity and a range of factors including licence holder safety performance. One inspection was not carried out as the source of radiation to be inspected was no longer at the site.

This quarter's inspections did not identify any potential regulatory non-compliances. However, 30 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

ARPANSA published the performance objectives and criteria (POC) applying to radiation sources. The POC provides a comprehensive list of features, controls and behaviours that contribute to safety and are used to assess compliance together with legal requirements including codes and standards. They help to establish the scope and detail of inspections and support the delivery of a consistent, transparent and rigorous regulatory service. The new POC is closely aligned with ARPANSA's *Regulatory Guide: Plans and arrangements for managing safety*. The revised source POC will come into effect on 1 January 2021.

ARPANSA concluded consultation on a draft *Compliance Manual* in December 2020. Stakeholders' comments are currently being addressed. This manual lays out how ARPANSA encourages regulatory compliance and deals with areas of non-compliance. This includes a graded approach to managing non-compliances and how ARPANSA reports on these publicly. Publishing this manual on ARPANSA's website provides transparency to licence holders and the community on how regulatory compliance is managed.

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 months
Import of non-medical radioisotope	42	57	3
Import of medical radioisotope	0	98	4
Export of high activity source	-	10	-

Transport of radioactive material

Safety

ARPANSA issued one validation certificate to ANSTO for special form radioactive material. The special form materials are sealed capsules that will be used for managing disused radioactive sources.

Security

ARPANSA endorsed three transport security plans this 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 security arrangements, 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. However, ARPANSA maintained international relations remotely wherever possible through a range of virtual means.

An ARPANSA staff member, Dr Ken Karipidis, was appointed as a member of the International Commission on Occupational Health, Scientific Committee on Radiation and Work. The Committee provides expert advice on safety of radiation exposure in occupational settings including ionising and non-ionising radiation,

electromagnetic fields and optical radiation. It also facilitates a multidisciplinary network of experts for sharing knowledge on adverse health effects and regulation in the protection of workers from radiation.

ARPANSA participated in several virtual events for the International Atomic Energy Agency (IAEA) safety standards committees, on the topics of radioactive waste safety, radiation use safety, and emergency preparedness and response for radiological events. Participating in these committees enables ARPANSA to contribute to the global nuclear safety regime through the international standards that these committees develop, which are the international best practice basis for Australia's domestic guidance and standards.

ARPANSA also participated virtually in a Working Party on Nuclear Emergency Matters (WPNEM), which discussed the work of expert groups associated with the Nuclear Energy Agency (NEA) Committee on Radiological Protection and Public Health (CRPPH). The emphasis was on mental health and psycho-social support in nuclear and radiological emergencies.

ARPANSA participated in an IAEA virtual workshop on 'Periodic Safety Reviews for Research Reactors'. The workshop emphasised the importance of such reviews, which have historically been mainly carried out for nuclear power plants only. However, some research reactor operators have undertaken such assessments, including the ANSTO OPAL Reactor. ANSTO presented their experience from a 2011 review and preparation phase for a review scheduled for November 2021. Australia has mature guidance and reasonable experience relative to other research reactor operating countries. The workshop still provided an opportunity for ARPANSA to improve its planning, assessment and requirements for future reviews.

ARPANSA attended a virtual meeting of the of the Joint IAEA-OECD/NEA Fuel Incident Notification and Analysis System (FINAS), which focussed on the operating experience from safety events reported in FINAS. The IAEA is publishing a technical document on this topic which will be very instructive for developing and reviewing ARPANSA's regulatory guides for nuclear fuel cycle facilities in Australia.

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 an Improvement Notice under section 80A of the Act to ANSTO's Camperdown Facility regarding fluorine-18 (F-18) manual handling processes in the radiochemistry laboratory fume cupboard. The routine quantity of radioisotope used in these processes was greater than that identified in the safety assessment and Safety Analysis Report (SAR). ANSTO responded to the Improvement Notice by its due date, justifying the acceptability of current manual handling operations using an activity concentration of 1 Gigabecquerel per millilitre (GBq/ml), and using radiation attenuating gloves. ARPANSA accepted this interim measure pending the development of a long-term solution.

Details of any breach of licence conditions by a licensee

There were two breaches with no or minor safety implications this quarter. These were:

- A licence holder failed to comply with a condition of their licence when a required annual calibration of a piece of radiation monitoring equipment was not carried out. This equipment is part of an interlock that prevents access to a hot cell when high levels of radiation are detected. A subsequent check of the equipment indicated it had been functioning correctly.
- A licence holder failed to seek approval to dispose of a source of radiation (an ultraviolet (UV) germicidal lamp housed in a biological safety cabinet). This is required under section 65 of the Regulations. The licence holder self-reported the oversight and there were no other issues with the disposal.

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 (the Council) met twice during the quarter on 21 October 2020 and 9 December 2020.

The first meeting discussed radiation safety in the field of medical imaging, with a focus on procedures that may present risks of any concern based on the age and treatment patterns of patient cohorts. Future discussions will invite input from jurisdictional radiological councils.

The second meeting discussed a range of potential radiation safety issues in relation to laser technology. Laser technology has proliferated in Australia through commercial availability. The Council discussed the potential health impacts of new laser technologies, and independent regulatory oversight issues.

The Council also finalised advice to the CEO of ARPANSA on naturally occurring radioactive material (NORM) in Australia, focussing on the developing approach to the management of NORM both internationally and in Australia. The Council's recommendations aim to improve national uniformity within Australia and increase Australia's influence, through ARPANSA, on international policy setting for NORM.

The minutes of meetings are available at www.arpansa.gov.au/rhsac. The next meeting is scheduled for 22-23 March 2020.

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 virtually on 18 and 19 November 2020.

The committee discussed various issues related to national uniformity and RHC projects. This includes formal documents describing how RHC and the Environmental Health Standing Committee (enHealth) should interface, the end-state of Radiation Protection Series (RPS) documents codes, standards, guides and regulatory expectations. The RHC agreed that the regulatory expectations documents would be RHC documents which will be the topic of an upcoming single-issue meeting. The RHC endorsed the guidance for implementation of the Medical Exposure Code (RPS C-5) in terms of approach and content, subject to review, 12 months after implementation of this Code.

The minutes of meetings are available at www.arpansa.gov.au/rhc. The RHC's next online single-issue meeting will be held on 10 February 2021. The next full RHC meeting will be held on 24-25 March 2021.

The appointment of the RHC for 2021-2023 was finalised.

Nuclear Safety Committee

The Nuclear Safety Committee (NSC) met on 13 November 2020.

At this meeting the NSC validated the Regulatory Performance Framework annual report, reviewed guidance and part of a submission related to the ANM Facility and was provided with an overview of other relevant regulatory activities.

The minutes of meetings are available at www.arpansa.gov.au/nsc. The next meeting of the NSC is scheduled for 5 March 2021.

The appointment of NSC members for 2021-2023 was finalised.

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.