Part 1: CEO's Review



I'm pleased to present to you the seventeenth Annual Report of the CEO of ARPANSA, the sixth under my stewardship of the Agency. In this review, I highlight some of the major developments during the year, summarise the financial results and look ahead at challenges for the next financial year.

The Annual Report also gives me an opportunity to thank ARPANSA's competent and dedicated staff who have continued to deliver radiation protection and nuclear safety outcomes to the Australian community against a background of fiscal challenges within the Australian Public Service. Over all, we have been able to meet the targets outlined in the *Portfolio Budget Statements* and remain well positioned to meet the challenges over the years to come.

Significant issues and developments

Regulatory environment and performance

Details on inspections, licensing activities, breaches and other aspects of ARPANSA's regulatory work are provided in Part 3: Report on Performance, of this Annual Report. A number of more general observations are made below.

ARPANS Act and Regulations

The Australian Radiation Protection and Nuclear Safety Amendment Bill was introduced in the House of Representatives during the 2015 winter sitting. The Bill subsequently passed both Houses of Parliament without amendment, and makes changes to the *Australian Radiation Protection and Nuclear Safety Act 1998* (ARPANS Act) to, among other things, provide for the regulation of legacy sites with radioactive material, and provide greater capacity for ARPANSA to act in the event of an emergency or non-compliance with the legislation.

During the period, the Federal Executive Council also approved certain changes to the Australian Radiation Protection and Nuclear Safety Regulations 1999 (the Regulations) and Australian Radiation Protection and Nuclear Safety (Licence Charges) Regulations 2000. In addition to indexing the licence application fees and annual licence charges in line with the Wage Price Index, the changes also included certain amendments to cut red tape and reduce regulatory burden and bring the regulations in line with the latest drafting convention of the Office of Parliamentary Counsel.



Regulator Performance Framework

Consistent with the Australian Government Regulator Performance Framework, ARPANSA Regulatory Services Branch implemented a new 'regulatory delivery model' effective January 2015. The delivery model provides improvements in regulatory effectiveness and efficiency, including the use of risk-based oversight and risk-informed decision-making. The main objectives of the delivery model are aligned with the Regulator Performance Framework, as follows:

- avoid unnecessary intervention in the operations of regulated activities
- communicate with regulated entities clearly and effectively
- take action proportionate to the regulatory risks being managed
- choose an approach to compliance and monitoring that is streamlined and coordinated
- remain open and transparent in dealings with regulated entities and the public
- perform frequent self-assessments in order to improve the delivery model.

Performance indicators were developed and trialled in recent months, prior to their required implementation in 2015-16.

Trusted international standards

In late 2014, and as part of the *Industry Innovation* and *Competitiveness Agenda*, the Government adopted the principle that, if a system, service or product has been approved under a trusted international standard or risk assessment, then regulators should not impose any additional

requirements for approval in Australia, unless it can be demonstrated that there is a good reason to do so.

The term international best practice is generally accepted to be the principles underlying the world's best safety and security policies and practices across radiation and nuclear industries (see www.arpansa. gov.au/Regulation/ibp). ARPANSA participates in risk assessments carried out in international scientific fora, and in the setting of international standards, through participation in the Safety Standards Committees (on radiation, transport, waste and nuclear safety) and the Nuclear Security Guidance Committee of the International Atomic Energy Agency (IAEA). ARPANSA also participates in the work of the World Health Organization (WHO), the International Commissions on Radiological Protection (ICRP) and Non-Ionizing Radiation Protection (ICNIRP), and other fora.

ARPANSA has a high level of confidence in the adequacy of the international framework for protection and is applying it in its own licensing activities. This is consistent with subsections 32(3) and 33(3) of the ARPANS Act requiring the CEO to take into account international best practice in relation to radiation protection and nuclear safety when making a decision on whether to issue a licence.

Australian jurisdictions, through the work of the Radiation Health Committee established under the ARPANS Act, have agreed to use these international standards as a basis for nationally uniform radiation regulation. In light of its ongoing work in assisting with the development of international standards, and in line with the Industry Innovation and Competitiveness Agenda, ARPANSA has embarked on a systematic update of the suite of radiation protection and nuclear safety guidance documents used in Australia, to ensure they continue to reflect current international best practice, in collaboration with state and territory regulators.

Implementation of ANAO Recommendations

In early 2014, the Australian National Audit Office (ANAO) released its report on ARPANSA's regulation of Commonwealth licence holders concluding that ARPANSA had been "generally effective in managing key aspects of the regulatory framework applying to the possession and use of radiation and nuclear sources and facilities by Australian

Government entities". Since that time, ARPANSA has implemented a new regulatory delivery model that promotes regulatory effectiveness and the use of risk-informed decision-making. ARPANSA has recently concluded that all ANAO recommendations have been satisfactorily addressed, including the long-term initiative to develop a more robust cost recovery model (which requires several years of monitoring before it culminates with changes that coincide with the 'sunsetting' of the Regulations in 2019).

Medical radiation protection

A web-based Appropriate Referral Training Module has been completed in collaboration with Department of Health and the Australian Commission on Safety and Quality in Health Care (ACSQHC) to provide radiation dosimetry information to referrers, including general practitioners and other health professionals, to improve referral quality and patient communication of risk and benefit. ARPANSA has consulted widely with stakeholders, including referrers, radiologists, radiographers and medical physicists, regional and metropolitan hospitals and other key stakeholders including WA Health, the Royal Australian College of General Practitioners, the Australian College of Rural and Remote Medicine, the Australian Institute of Radiography, the Australian Diagnostic Imaging Association and NPS MedicineWise. Feedback has also been received from a number of the State Radiation Advisory Councils.

Many of these other stakeholders are represented by the Project Reference Group run under the auspices of the ACSQHC.

In December 2014, I signed an arrangement with the Department of Health for a duration of two years to consolidate the Australian Clinical Dosimetry Service, which audits the dosimetry of linear accelerators used in radiation therapy in Australia. The audits are aimed at reducing the risks of dosimetric errors in the treatment of cancer patients and are carried out at different levels of complexity, with the less complex audits carried out at higher frequency. ARPANSA is also tasked with developing a cost recovery model for this service and maintains close interactions with a variety of stakeholders, such as state and territory regulators, professional colleges, the medical profession, and patient safety advocacy groups.

Ultraviolet and electromagnetic radiation

ARPANSA's involvement with the World Health Organization (WHO) is formally recognised through ARPANSA's status as a Collaborating Centre for Radiation Protection. WHO and the International Commission for Non-Ionizing Radiation Protection (ICNIRP) are key fora for development of protective approaches to non-ionising radiation, in particular, ultraviolet radiation (prevention of skin cancer) and electromagnetic radiation such as radiofrequency radiation used in mobile and fixed communication (an area where perceptions of health effects and risks are widely divergent, both among experts and among the general public).

ARPANSA continues to maintain an ultraviolet radiation (UVR) monitoring network with real time information on exposure levels accessible from ARPANSA's website and via multiple platforms (see www.arpansa.gov.au/uvindex). We continue to maintain a dialogue with stakeholders regarding electromagnetic radiation, including community groups, via the Electromagnetic Energy Reference Group (see www.arpansa.gov.au/AboutUs/Collaboration/emerg.cfm), which was re-established with amended Terms of Reference and new membership during the year.

Radiation incidents

ARPANSA maintains a nationwide incident register, called the Australian Radiation Incident Register (ARIR)¹. Analysis of the incidents is conducted annually and published on the ARPANSA website. For this financial year, ARPANSA reported four incidents to the register. In total, over the 2014 calendar year (reporting to the ARIR takes place on a calendar year basis), 286 incidents have been reported to the register. The majority of these concern medical uses of radiation, which reflects the fact that millions of medical procedures involving radiation are carried out every year across Australia.

The number of incidents reported for 2014 is an increase from 201 in 2013 and from a fairly stable figure of 100-120 reports in previous years. Analysis of 2014 data is yet to be carried out; however, as a preliminary view I offer the hypothesis, as last year, that the increase in reporting levels is at least partly

due to proactive awareness-raising by ARPANSA which has resulted in an increased *reporting* of incidents to ARIR. Thus, the upward trend may be an illustration of improved safety culture rather than deterioration of safety *per se*. Through the Radiation Health Committee, ARPANSA will continue to raise awareness of the value of reporting and the need to improve consistency and quality of reporting across Australia to add value to information obtained from the register.

In addition to the ARIR, ARPANSA is also responsible for reporting incidents to the IAEA International Nuclear Events Scale reporting system on behalf of Australia. One event involved worker exposure to a displaced borehole logging source at a mine site, where two workers received doses above the statutory dose limit, was reported.

Status of protection of the Australian community against the harmful effects of radiation

The exposure to radiation from different sources is summarised in Figure 1. This diagram outlines radiation doses to the *average Australian* in one year. The general level of exposure is low in international comparison, mainly due to the fact that average background radiation levels in Australia are low. The radiation exposure from medical procedures is an increasing source of exposure. While these procedures are ordered for the purpose of managing the health of patients, there is a need to be vigilant in optimising protection of patients and the previously mentioned development of support modules for referrals is a step in this direction.

Based on data in the ARIR and other information sources, I consider radiation safety in regulated activities in Australia is generally well managed and the Australian community is being afforded a high level of safety. There is, however, no room for complacency and the incidents and breaches should be appropriately addressed and safety and security systems improved as appropriate. Importantly, the culture of safety and security in dealing with sources and facilities should be promoted within a system of continuous improvement.

^{1.} The definition of incident for the purpose of the ARIR is outlined in Schedule 13 of the *National Directory for Radiation Protection*, Radiation Protections Series No. 6, and can be found at www.arpansa.gov.au/RadiationProtection/arir.

ARPANSA also strives at providing unbiased information and advice to the public as well as to professionals. While this is done for the purpose of public information, it also allows people to take their own informed decisions in relation to radiation risks.

Finances and efficiencies

For the financial year ending 30 June 2015, ARPANSA reported an operating deficit of \$1.64m. This deficit is attributed to depreciation and amortisation expense not requiring appropriation.

Revenue for the year totalled \$24.1m, of which 55% was appropriated by government. The remaining amounts related to regulatory licence fees and charges and from the sale of goods and services. ARPANSA's expenses totalled \$25.8m. Approximately 61% of these expenses are attributed to employee benefits.

In the Annual Report for 2013-14, I indicated that we would continue to strive to become a leaner and more efficient Agency. Through the implementation of various programs, based on thorough reviews of parts of the Agency's services or more broad ranging assessments, we have established targets

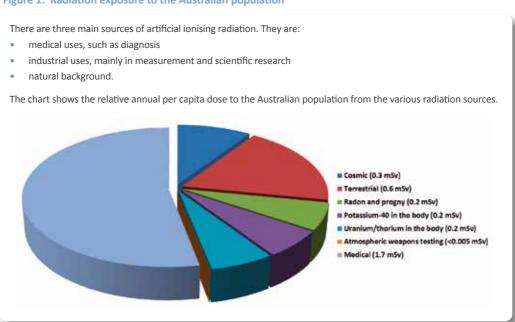
for staffing that would sustain satisfactory delivery of the Agency's outcome. The implementation of these programs has resulted in a reduction in staffing levels, which now should stabilise at about 130. I also consider that the Agency's delivery of radiation protection and nuclear safety to the Australian community is of sustained high quality, and it is continually monitored to promote and support continuous improvement.

My Executive Group is committed to reviewing and improving the efficiency and effectiveness by which ARPANSA delivers its program, to ensure that the agency can deliver its outcomes within available resources.

Outlook

In accordance with the Public Governance. Performance and Accountability Act 2013, ARPANSA has published its Corporate Plan on the website (see www.arpansa.gov.au/AboutUs/Corporate/ corplan2015-19.cfm). It describes our operating environment as well as the performance indicators, looking four years into the future. Below, I highlight some issues that will be of importance during 2015-16.

Figure 1: Radiation exposure to the Australian population



Source: ARPANSA website at www.arpansa.gov.au/RadiationProtection/basics/understand.cfm

- The Little Forest Legacy Site (LFLS) at Lucas Heights was taken into operation in the 1960s as a disposal facility for radioactive, chemical and other waste, generated during operations supervised by the Australian Atomic Energy Commission. While LFLS has been continuously maintained by the Australian Nuclear Science and Technology Organisation (ANSTO), it has formally not been licensed. ARPANSA is currently reviewing ANSTO's application for a licence to possess or control the LFLS as a storage facility. This licence will bring the site under regulatory control, enabling ARPANSA to issue conditions governing the short and long-term management of both the waste and the site².
- During 2015-16, ANSTO will receive intermediate level waste resulting from the reprocessing of fuel from the permanently shut down High Flux Australian Reactor (HIFAR). The fuel has been reprocessed in France under an agreement which stipulates that all primary waste (including fission products with the fissile material removed) will be returned to Australia. A purpose-built facility, the *Interim Waste Store*³, will house the waste until such time it can be transported to a *National Radioactive Waste Management Facility* (NRWMF), the licensing of which is a number of years away.
- The Department of Industry and Science (DoIS) is currently in the process of identifying potential sites for the NRWMF referred to above. ARPANSA, as the regulator, is responsible for reviewing any application and eventually making a decision on a licence to prepare a site for the NRWMF. While this process is entirely driven by DoIS, ARPANSA expects increased involvement with stakeholders as the process identifies preferred site(s) for the facility, in order to explain ARPANSA's role. Formal consultation under the provisions of the ARPANS Act will commence once ARPANSA has received a reviewable application. ARPANSA has established an internal project for regulatory oversight of the establishment of the NRWMF and is liaising internationally to secure necessary expertise for the review.
- ARPANSA will monitor and as necessary interact with ongoing reviews in the nuclear field. These include a scoping study on nuclear

- regulation driven by DoIS and stemming from the *Energy White Paper*; and the South Australian Nuclear Fuel Cycle Royal Commission which looks into expanded nuclear fuel cycle facilities, such as expanded uranium mining, uranium enrichment, reactor fuel fabrication, reprocessing of used fuel, waste storage and disposal, and power reactors.
- ARPANSA will continue to play a significant role in protection from non-ionising radiation.
 In particular, this involves supporting WHO in developing fundamental principles and basic safety standards for protection from the harmful effects of non-ionising radiation.
 ARPANSA will also continue to monitor levels of non-ionising radiation in the environment, such as electromagnetic fields in work environments, and solar UVR.
- As noted earlier in this review, the exposure of the Australian population from medical imaging procedures that involve ionising radiation is increasing and while it is higher in some other countries with well-developed health care systems, it is higher in Australia than in some comparable European countries. ARPANSA will therefore continue to work with the Department of Health, and within established networks that involve colleges, practitioners, patient safety advocacy groups and epidemiologists; to characterise risks and promote good radiation protection practices in health care, while fully respecting the expertise of the medical profession in making the necessary judgements with regard to the justification of such procedures.
- ARPANSA will continue to expand and improve its services to the Australian community in a variety of areas. This includes:
 - » further consolidating and expanding the Australian National Radiation Dose Register
 - » developing a sustainable funding model for the Australian Clinical Dosimetry Service
 - » consolidating the interaction with relevant bodies (nationally and internationally) in emergency preparedness and response, and in nuclear security
 - » upgrading and consolidating the Personal Radiation Monitoring Service

^{2.} ANSTO was issued with a licence on 9 July 2015.

^{3.} ANSTO was issued with a licence to operate the Interim Waste Store on 8 May 2015.

- » consolidating and expanding the services related to protection from UVR
- » improving the Australian Radiation Incident Register, and finally
- » by further improving the timeliness and quality of advice to the Australian Government and community. This also includes evaluating and as necessary improving the 'talk to a scientist' program, where ARPANSA scientists are available to questions from the public twice a week (see www.arpansa.gov.au/Public/talk).

While the above are challenges that ARPANSA faces in relation to radiation protection and nuclear safety, it is also clear that there are challenges associated with sustaining the delivery of these outcomes. These challenges are related to retirements among a workforce with many

long-serving, highly skilled and experienced staff members, and to the need to find further efficiencies in the Agency's delivery of services. During the year, succession planning was completed in all major areas and a long-term recruitment program has already started and will continue during 2015-16, while bearing in mind the need to stay within a sustainable staffing level.

I will continue to work with the Agency's staff to reach the goals as laid out in the Corporate Plan, while also paying attention to the needs of staff and the necessary competence structure; with the aim of maintaining the Agency's national and international status and improving the working environments and interactivity. I am confident the Agency remains well placed to meet these challenges.