REPORT OF THE

RADIOLOGICAL COUNCIL

for the year ended

31 December 2018

TABLE OF CONTENTS

RADIATION SAFETY ACT 1975

STATUTORY RESPONSIBILITIES OF THE COUNCIL

The Radiological Council is appointed under Section 13 of the Radiation Safety Act to assist the Minister to protect public health and to maintain safe practices in the use of radiation.

In its position as an independent regulatory authority, the Council is required to administer the Act and to —

- implement the scheme of licensing and registration;
- conduct inquiries into alleged contraventions of the Act and, where necessary, to suspend or cancel licences and registrations;
- advise the Minister and make recommendations with respect to the technical aspects of radiation safety requirements, the methods that may be used to prevent or minimise the dangers arising from the use of radioactive substances, irradiating apparatus and electronic products, including the preparation of regulations;
- investigate and prosecute offences.

The Council is also required to keep under review manufactured or assembled devices which emit radiation to determine if control of these devices is necessary under the Act.

Section 10 requires the Minister at all times to have regard to the expressed views of the Council.

MEMBERSHIP OF THE COUNCIL

The Council comprises —

- a medical practitioner appointed by the Governor on the recommendation of the Executive Director Public Health;
- a medical practitioner who is a specialist in radiology or radiotherapy;
- a physician specialising in nuclear medicine;
- a person who possesses relevant qualifications or experience as a physicist;
- a person who possesses relevant qualifications or experience as a radiation

engineer or electronic engineer;

- a representative of the interests of tertiary educational institutions;
- two other persons with special expertise in radiation protection may be nominated by the Minister on the advice of the other members of the Council;
- a medical radiation technologist.

The present members, approved by the Governor, are listed in attachment 1.

The Council met eight times in 2018.

ADVISORY COMMITTEES

The Council may appoint committees under Section 19 of the Act to investigate and advise on any aspect of its functions, or to carry out any function other than those relating to licences and registrations. The present policy is to create, when necessary, short-term working parties which address a specific issue and report back to the Council.

No advisory committees are currently appointed.

ADMINISTRATIVE SUPPORT

Section 10(4) of the Act provides for the administration of the Act to be paid out of monies appropriated by Parliament for the purpose. However, the Council is not funded directly and relies on the Department of Health's Radiation Health Unit for administrative and scientific support. While the greater part of the Unit's duties are directly concerned with supporting the Council's needs, and many of the staff are appointed authorised officers under Section 4(1) of the Act for this purpose, the Unit also provides separate advice to the Department on a range of radiation issues.

The Radiation Health Unit also provides the Secretary of the Council. The position has been held by Ms H Upton (Managing Health Physicist) since February 2002, with Mr D Surin (Health Physicist) performing these duties in Ms Upton's absence.

STATE ELECTORAL ACT

For the purposes of Section 175ZE of the State Electoral Act, the Radiological Council has no expenditure to report. Council's functions are supported from within the budget assigned by the Department of Health to the Radiation Health Unit. The Council does not have a budget in its own right.

STATE RECORDS ACT

The Radiological Council's record keeping systems are managed by the Radiation Health Unit of the Department of Health, and thus the Council's compliance with the State Records Commission Standard 2, Principle 6 is linked to compliance by the Department of Health.

REGISTRATIONS, LICENCES AND TEMPORARY PERMITS

Registration and licensing are the principal means by which the use of radiation is regulated. A summary of the legislative system for registration and licensing in Western Australia is included in appendix 1.

QUALIFICATIONS AND TRAINING OF RADIATION USERS

A summary of the legislative scheme for ensuring the appropriate qualifications and competence of persons applying for licences is included in appendix 2.

CHANGES TO LEGISLATION

Amendments made to the Radiation Safety Act and the Radiation Safety (General) Regulations are listed in attachment 2.

No amendments were made to the Radiation Safety (Transport of Radioactive Substances) Regulations or Radiation Safety (Qualifications) Regulations in 2018.

RADIATION INCIDENTS

Reported incidents involving radiation rarely pose a major health risk to the individuals exposed. Regulation 19A of the Radiation Safety (General) Regulations requires registrants to notify the Council in writing as soon as practicable should any of the abnormal or unplanned radiation exposures specified in that regulation occur. In addition to Regulation 19A, the medical incident reporting condition requires medical incidents specified in that condition to be reported to Council within 7 days. This has resulted in a significant increase in the number of reported incidents.

Although there is no certainty that all incidents are reported, Council encourages reporting and rigorous investigation of the cause as this provides a forum for improving work practices and minimising the risk of recurrence of such incidents.

The Council was notified of 75 incidents during 2018 which are presented in the tables below. The majority of incidents relate to human error and a failure to follow protocols.

Incident	**Occurrences**	**Category**
Radiology		
Error in CT equipment or CT data analysis software requiring repeat imaging	3	Equipment malfunction
Error in mammography equipment resulting in exposures being taken that do not produce a diagnostic image	1	Equipment malfunction
Incorrect patient imaged – failure to correctly identify patient against request form	4	Human error – failure to follow protocol
Incorrect patient imaged due to incorrect patient name being entered on request form	8	Human error – other
Incorrect patient imaged due to error in electronic request system and subsequent failure to check identity of patient	2	Human error – failure to follow protocol
Examination conducted at incorrect time – for example prior to line insertion	2	Human error – failure to follow protocol
Incorrect examination/anatomical site imaged – incorrect code entered into scanner console	1	Human error – failure to follow protocol
Incorrect examination/anatomical site imaged – failure of MIT to check or clarify request form	2	Human error – failure to follow protocol
Incorrect examination/anatomical site imaged – failure to image as per request form	5	Human error – failure to follow protocol
Incorrect examination/anatomical site imaged – failure to refer for correct examination/anatomical site	3	Human error – failure to follow protocol

Incident	Occurrences	Category
Patient found to be pregnant following imaging.	2	Protocol followed – patient identified as not being pregnant
Incorrect modality – incorrect modality entered into system	1	Human error – failure to follow protocol
Duplication of imaging due to different request forms being completed	1	Human error – failure to follow protocol
Duplication of imaging due to not checking that the examination had already been performed as noted on the request form.	1	Human error – failure to follow protocol
Duplication of imaging due to the request form being kept on the work list and the images not being sent for reporting.	1	Human error – failure to follow protocol
Unintended exposure of radiation worker	1	Human error – failure to follow protocol
Dose to radiation worker recorded but not received	3	Human Error – failure to wear personal dosimeters appropriately
Unauthorised operation of x-ray equipment	1	Unauthorised use of equipment
Radiotherapy		
Unintended exposure of staff member	1	Human error – failure to follow protocol
Exposure of personal monitoring device whilst not being worn by staff member	2	Human Error – failure of personal monitoring device to be appropriately secured
Nuclear Medicine		
Incorrect radiopharmaceutical administered	3	Human error - failure to follow protocol
Incorrect patient imaged due to incorrect patient name being entered on request form	1	Human error – other
Extravasation of radiopharmaceutical	2	Protocol followed – IV administration failed after successful cannulation flush.
Radiopharmaceutical administered but scan not performed	1	Protocol followed – patient did not proceed with procedure.
Radiopharmaceutical had already been administered before team requested a different diagnostic test or cancelled the original test.	2	Human error – communication between treating teams needed improvement

Incident	Occurrences	Category
Radiopharmaceutical administered but scan not performed	2	Protocol followed – patient's status changed rapidly and the diagnostic test was no longer required.
Radiopharmaceutical administered but scan not performed	7	Protocol followed – patient could not tolerate procedure/refused procedure or did not return for procedure.
Radiopharmaceutical administered but image not useable	1	Protocol followed – patient moved during scan rendering the image non diagnostic
Contamination of equipment – incorrect centrifuge container was used within equipment.	1	Human error - failure to follow protocol
Industrial		
Stolen x-ray equipment	1	Equipment was not operational.
Unauthorised disposal of irradiating apparatus	2	Human error - failure to follow protocol
Vehicle incident whilst radioactive source on board	1	Protocol followed – vehicle rolled over after slipping down steep incline.
Borehole logging source stuck in borehole	2	Equipment malfunction/unavoidable – source retrieved
Equipment damaged	1	Protocols followed – no dose received or damage to the containment of the radioactive source
Other		
Disposal of radioactive waste to sewer in excess of disposal limits	2	Human error - failure to follow protocol
Contamination of laboratory surfaces with radioactive material	1	Human error - failure to follow protocol

PROSECUTIONS

No prosecutions were initiated or finalised in 2018.

However, in one matter advice on prosecution was sought from the State Solicitor's Office. Due to circumstances beyond the Council's control the conclusions provided by the State Solicitor's Office that a company may have committed an offence contrary to section 28(4) of the Radiation Safety Act by possessing equipment beyond the expiry dates of the registration certificates, could not be commenced as the limitation period for prosecuting the company in respect of the possible offending had already expired.

MEDICAL AND RELATED RADIATION MATTERS

Medical Compliance Testing

Council's compliance testing program, which commenced in 1997, applies to diagnostic x-ray equipment used on living humans for medical radiography, fluoroscopy, chiropractic radiography, dental radiography and computed tomography.

No such x-ray equipment may be used for human diagnostic purposes unless it has a current certificate of compliance, a certificate of conditional compliance or an exemption from compliance.

Through conditions imposed on registrations under Section 36 of the Act, registrants are legally responsible for satisfying the requirements of the compliance testing program.

A summary of the compliance tests assessed in 2018 is included in attachment 3

X-Ray Operator Course

X-ray operators are approved by the Radiological Council to perform basic radiography of the chest and extremities in remote and rural areas where radiology services are otherwise not available. A Radiological Council approved training course suitable as a prerequisite for approval of an x-ray operator has been run successfully by Curtin University of Technology since 2013.

Changes to Laser Regulations

During 2018 the Radiological Council amended the training and qualification requirements for using lasers on people for the purposes of hair removal and for superficial cosmetic procedures.

Council sought comment from the appropriate professional medical colleges and also reviewed the protocols used in Queensland and Tasmania (as the other jurisdictions in Australia that regulate lasers used for cosmetic purposes) for the licensing of users of cosmetic lasers.

Council agreed that the following requirements would be introduced;

> Non-medical practitioners wishing to obtain a licence (exemption) to use lasers for hair removal must –
>
> - Be an Enrolled Nurse or Registered Nurse, or at least hold a Diploma or Certificate IV in beauty therapy;

- Have attended a recognised laser safety course;
- Have undertaken 25 hrs practical training under the immediate personal supervision of a person licensed in WA for the use of lasers for hair removal.

Non-medical practitioners wishing to obtain a licence (exemption) to use lasers for superficial cosmetic procedures must –

- Be an Enrolled Nurse or Registered Nurse, or at least hold a Diploma or Certificate IV in beauty therapy;
- Have attended a recognised laser safety course;
- Have undertaken 50 hrs practical training in the use of lasers for pigment treatment under the immediate personal supervision of a person licensed in WA for this purpose;
- Have undertaken 50 hrs practical training in the use of lasers for vascular treatment under the immediate personal supervision of a person licensed in WA for this purpose.

The number of persons who currently hold these types of licences (exemptions) are listed in attachment 7.

Changes to Podiatrist Requirements

At the end of 2017 the Council considered a request from the Australian Association of Podiatric Surgeons Council to extend the permitted range of x-ray examinations for which registered podiatrists are permitted to refer. After consulting with the Podiatry Board of Australia and referring to the range of examinations for which Medicare allows podiatrists to refer Council agreed to extend the permitted range to include plain radiography of the lower leg, knee and femur.

Approvals for Exposure to Radiation for Human Subjects in Medical Research

In Western Australia, all research projects involving exposure of human participants to ionising radiation must be evaluated by the Radiation Safety Officer. When the estimated radiation dose exceeds prescribed levels, Council approval must be obtained in addition to the approval by an Ethics Committee.

In keeping with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Radiation Protection Series # 8 (2005) *Exposure of Humans to Ionizing Radiation for Research Purposes*, the Council assesses research projects which involve exposing humans to ionising radiation without proven benefits to the irradiated subjects and where the dose to any individual adult subject exceeds 5 mSv in any year.

Council assessed and approved the radiation component of the following research applications or amendments in 2018.

Research Project Title
A randomized, double-blind, placebo-controlled, two cohort parallel group study to evaluate the efficacy of CAD106 and CNP520 in participants at risk for the onset of clinical symptoms of Alzheimer's disease.
A Phase IA, Open-Label, Multiple-Dose, Dose Escalation Study to investigate the Safety and Pharmacokinetics of the BTK Inhibitor BGB-311 in Subjects with Indolent BCell Lymphoid Malignancies
A Randomized, Open-Label, Phase 3 Study to Evaluate Efficacy and Safety of Pembrolizumab (MK-3475) plus Epacadostat vs Standard of Care (Sunitinib or Pazopanib) as First-Line Treatment for Locally Advanced or Metastatic Renal Cell Carcinoma (mRcc)(KEYNOTE-679/ECHO-302)
A phase 1, open-label, dose-escalation study of the safety and pharmacokinetics of HMPL-523 in patients with relapsed hematologic malignancies
A Multinational, Multicentre, Randomized, Phase 3 Study of Tesetaxel plus a Reduced Dose of Capecitabine verus Capecitabine Alone in Patients with HER2 Negative, Hormone Receptor Positive, Locally Advanced or Metastatic Breast Cancer Previously Treated with a Taxane.
A phase 2b open-label study of Selinexor (KPT-330) in patients with relapsed/refractory diffuse large B-Cell lymphoma (DLBCL)

Research Project Title
Potential of ^{68}Gallium DOTATATE PET for detecting high risk atherosclerosis in humans.
A Phase 1b, Open Label, Multiple Dose, Dose Escalation and Expansion Study to Assess Safety, Tolerability and Antitumor Activities of the Combination of BGB-3111 with BGB-A317 in Subjects with B-Cell Lymphoid Malignancies. (Previously approved in 2016 but modification to duration of treatment was requested).
A Phase III, Multicentre, Randomized, Double-Blind, Placebo-Controlled Study of Atezolizumab (Anti-PD-L1 Antibody) as Adjuvant Therapy and Definitive Local Therapy in Patients with High-Risk Locally Advanced Squamous Cell Carcinoma of the Head and Neck.
A Phase 3, randomised, double blind study of adjuvant Nivolumab versus placebo for participants with Hepatocellular carcinoma who are at high risk of recurrence after curative hepatic resection or ablation.
A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study Comparing CB-839 in Combination with Cabozantinib (CB-Cab) vs. Placebo with Cabozantinib (Pbo-Cabo) in Patient with Advanced or Metastatic Renal Cell Carcinoma (RCC).
Randomized, open label, multicentre study assessing the clinical benefit of isatuximab combined with carfilzomib (Kyprolis) and dexamethasone versus carfilzomib with dexamethasone in patients with relapsed and/or refractory multiple myeloma previously treated with 1 to 3 prior lines.
A randomised phase 2 trial of ^{177}Lu-PSMA617 theranostic versus cabazitaxel in men with progressive metastatic castration resistant prostate cancer.
A Randomized, Double Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of BG00011 in Patients with Idiopathic Pulmonary Fibrosis.
A Phase 3 randomized, open-label, multicentre study assessing the clinical benefit of isatuximab in combination with bortezomib, lenalidomide and dexamethasone versus bortezomib, lenalidomide and dexamethasone in patients with newly diagnosed multiple myeloma not eligible for transplant.
A randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of CNP520 in participants at risk for the onset of clinical symptoms of Alzheimer's disease.

Research Project Title
A randomized, double blind, placebo-controlled, parallel group, phase 2 study to evaluate the safety and efficacy of CT1812 in subjects with mild to moderate Alzheimer's Disease.
A Phase III, Randomized, Double-blind, Placebo-Controlled Study of Adagloxad Simolenin (OBI-822)/OBI-821 Treatment for High Risk Early Stage Triple Negative Breast Cancer Patients, defined as Residual Invasive Disease following Neoadjuvant Chemotherapy OR ≥ 4 Positive Axillary Nodes.
A Phase 1B/2 study to evaluate safety and anti-tumour activity of Avelumab in combination with the poly (adenosine diphosphate [ADP]-ribose) polymerase (PARP) inhibitor Talazoparib in patients with locally advanced or metastatic solid tumors.
A Phase 2 Efficacy and Safety Study of Niraparib in Men with Metastatic Castration-Resistant Prostate Cancer and DNA-Repair Anomalies.
Oestradiol PET scans in metastatic lobular breast cancer: investigation of utility in assessing disease burden and treatment response.
Adjuvant therapy with Pembrolizumab versus placebo in resected highrisk stage II melanoma: A randomized, double-blind Phase 3 study.
A Phase III, Randomized, Open-Label, Multi-Center, Global Study to Determine the Efficacy and Safety of Durvalumab in Combination with Gemcitabine+Cisplatin for Neoadjuvant Treatment Followed by Durvalumab Alone for Adjuvant Treatment in Patients with Muscle-Invasive Cancer.
A phase 3, multicenter, randomized, open-label, active-controlled study of DS-8201A, an anti-HER2-antibody drug conjugate, versus ado-trastuzumab emtansine (T-DM1) for HER2-positive,unresectable and/or metastatic breast cancer subjects previously treated with trastuzumab and taxane.
A Phase 3, Multicenter, Randomized, Open-Label, Active-Controlled Study Of DS-8201a, An Anti-HER2-Antibody Drug Conjugate, Versus Treatment Of Investigator's Choice For HER2-Positive, Unresectable And/Or Metastatic Breast Cancer Subjects Pretreated With Prior Standard Of Care HER2 Therapies, Including T-DM1
A Phase 2b Randomized Study to Assess the Efficacy and Safety of the Combination of Ublituximab + TGR-1202 with or without Bendamustine and TGR-1202 alone in Patients with Previously Treated Non-Hodgkin's Lymphoma
A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of BG00011 in Patients with Idiopathic Pulmonary Fibrosis

Research Project Title
A Multinational, Multicenter, Randomized, Phase 3 Study pf Tesetaxel plus Reduced Dose of Capecitabine versus Capecitabine Aline in Patients with HER2 Negative, Hormone Receptor Positive, Locally Advanced or Metastatic Breast Cancer Previously Treated with Taxane
Randomised Trial of Genetic Testing and Targeted Zoledronic acid Therapy to Prevent SQSTM1 Mediated Paget's Disease (Zoledronate) in the Prevention of Paget's. (The study was previously approved but due to the slow recruitment of patients, an extension was requested and approved.)
A Phase III, Randomised, Open-Label, Controlled, Multi-Centre, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer.
Tisagenlecleucel versus standard of care in adult patients with relapsed or refractory aggressive B-cell non-Hodgkin lymphoma: A randomized, open label, phase III trial.
An investigator-initiated, non-randomised, phase II study of combination CTLA-4 and PD-L1 blockade in combination with HER2 blockade in advanced HER2-positive breast cancers that have progressed on prior trastuzumab-based therapy.
A Phase 2, Multicenter, Randomized, Parallel-Group, Double-Blind, Controlled Study of Aducanumab (BIIB037) in Subjects With Mild Cognitive Impairment due to Alzheimer's Disease or With Mild Alzheimer's Disease Dementia to Evaluate the Safety of Continued Dosing in Subjects with Asymptomatic Amyloid-Related Imaging Abnormalities

INDUSTRIAL, ENVIRONMENTAL and MINING RADIATION

Industrial Compliance Testing

The Council's compliance testing program for fixed radiation gauges commenced in 1999. Gauges are not approved for use without a current certificate of compliance. A summary of the compliance tests assessed in 2018 is included in attachment 3.

Standards for Council Examinations

In 2002, the Council agreed that greater control should be exercised over industrial radiation safety examinations and decided that while course providers may continue to invigilate examinations, all industrial papers would be returned to Council's officers for marking. In 2018, Council officers marked 453 industrial examination papers. The number of examinations marked in each category is listed in attachment 4.

Mining and Milling of Radioactive Ores

The mining, milling, processing, certain exploration activities and the transport of radioactive ores are subject to the Radiation Safety Act and subsidiary legislation.

The Council has an independent role to ensure the appropriate oversight of the radiation safety aspects of the mining and milling of radioactive ores and this includes –

- the review of radiation management plans.
- approvals of Radiation Safety Officers.
- the review of occupational and environmental reports.
- conducting independent monitoring and surveillance.
- conducting inspections and audits.

The mining and milling of radioactive ores are also subject to Part 16 of the Mines Safety and Inspection Regulations under the Mines Safety and Inspection Act. These regulations are administered through the Department of Mines, Industry Regulation and Safety (DMIRS).

Memorandum of Understanding with the Department of Mines, Industry Regulation and Safety

A Memorandum of Understanding (MoU) has existed with the Department of Mines, Industry Regulation and Safety (DMIRS) and its predecessor department since 2013.

One of the agreements in the MoU was that a Radiation Liaison Committee (RLC) be established to provide a framework for liaison between DMIRS and the Radiological Council.

No meetings were held in 2018 as both agencies decided that the MoU should be reviewed and reassessed. The review will be ongoing during 2019.

Low Level Radioactive Waste Facility

Council has been continuing to liaise and review documentation associated with a proposal for a low level radioactive waste facility in Western Australia. A formal application for the registration of the premises was not received in 2018, but the formal assessment of the process is expected to be completed in 2019.

MISCELLANEOUS

Integrated Regulatory Review Service (IRRS) Mission to Australia

The Radiological Council in Western Australia participated in the International Regulatory Review Service (IRRS) offered by the International Atomic Energy Agency (IAEA) through the Commonwealth's Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). The purpose of the IRRS mission was to perform a peer review of Australia's regulatory frameworks for nuclear and radiation safety. The scope of the review included all facilities and activities regulated in Australia, with the exception of the uranium mining industry and the management of waste containing naturally occurring radioactive material (NORM).

In the initial phase of the review, prior to the visit from the IRRS team of international radiation safety experts, a self-assessment was conducted in 2017-2018. The self-assessment process allowed for an internal analysis, benchmarking the regulatory framework for radiation against international best practice IAEA safety standards.

The main deficiencies identified in the self-assessment were associated with the resources available to the Radiological Council in carrying out the responsibilities and functions of the regulatory body. The loss of support staff and expertise has had a severe impact on the implementation of the regulatory framework in Western Australia and this has been raised as a key concern in communications with both the Department and the Minister for Health since 2016.

The full report from the IRRS team can be accessed through the following link – www.arpansa.gov.au/sites/default/files/irrs_australia_report_2018.pdf

The IRRS team recognised that many of its recommendations and suggestions confirmed or elaborated on the actions identified by Australia's jurisdictions as a result of their self-assessments.

The key issues that are relevant to the regulation of radiation safety in Western Australia as taken directly from the report are listed below;

- *The Commonwealth Government, in conjunction with State and Territory Governments, should ensure full implementation of the Code of Conduct on the Safety and Security of Radioactive Sources, continuing to promote the safe and secure use of radioactive sources. This will contribute to the safety and security of the domestic and international communities and fulfil Australia's commitment to this important international instrument.*
- *The Commonwealth, State and Territory governments should ensure that all parties having responsibilities for safety of facilities and regulatory activities have the necessary competence and resources to carry out their responsibilities.*
- *State and Territory regulatory bodies should establish a strategy and allocate*

resources to ensure that inspections of facilities and activities are conducted consistently and in accordance with a graded approach.

- *Regulatory bodies in all jurisdictions should assess domestic and international experience related to nuclear and radiation safety and evaluate the need for updating their processes for authorization, review and assessment, inspections and regulations*.

As part of the IRRS, the Council identified that the Western Australian regulatory framework generally conforms to the requirements outlined under the IRRS modules undertaken. The key findings against each module will be used for the development of an action plan.

Radiation Health Committee

The Radiation Health Committee (RHC) is a body established to advise the Chief Executive Officer of ARPANSA and its Radiation Health & Safety Advisory Council on matters relating to radiation protection, formulating draft national policies, codes and standards for consideration by the Commonwealth, States and Territories.

Western Australia has representation on the RHC through the Secretary of the Radiological Council who attends the committee meetings tri-monthly.

A list of publications approved by the RHC and published by ARPANSA in 2018 is in attachment 5.

National Directory for Radiation Protection

At the Australian Health Ministers' Conference held in June 2004, the Ministers endorsed the adoption of the National Directory for Radiation Protection, Edition 1, as the Framework for National Uniformity in Radiation Protection.

Further development of the National Directory continued in 2018 through the national Radiation Health Committee.

Council continued its participation in the development of the National Directory and provided comment to the Radiation Health Committee.

Personal Radiation Monitoring Services

Council currently recognises six organisations for the provision of a personal radiation monitoring service in accordance with the Regulations –

- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)
- Global Dosimetry Solutions
- Global Medical Solutions Australia
- Landauer Australasia
- National Radiation Laboratory, New Zealand
- SGS Radiation Services Pty Ltd

Appendix 1: Registration and Licensing

Registrations

Section 28 of the Act requires prescribed radioactive substances, x-ray equipment and electronic products, together with the associated premises, to be registered. Registrants may include individuals, companies, organisations or institutions.

All x-ray equipment is prescribed while prescribed electronic products include lasers and transilluminators.

Radioactive substances that exceed the exempt quantities prescribed in the regulations are subject to registration. A small number of devices containing radioactive substances in excess of the exempt limits, but which pose a minimal hazard to users, have been exempted by regulation from control under the Act.

The numbers of devices and sealed radiation sources registered as at 31 December 2018 are included in attachment 6.

Licences

Section 25 of the Act requires persons who manufacture, store, transport, sell, possess, install, service, maintain, repair, use, operate or otherwise deal with prescribed radioactive substances, x-ray equipment or electronic products to be licensed or, where permitted, work under the direction and supervision of a licensee.

Section 29 of the Act also creates an offence for a person to sell any prescribed substances or devices unless they require the purchaser to produce evidence that they hold a relevant licence or are otherwise exempted by the Act or regulations. Sales also must be notified in writing to the Council, without delay, identifying the purchaser and the particulars of the relevant licence or exemption.

Exemptions from Licence

A licence is not required where a general exemption is provided by the regulations or where a person has been granted an individual exemption from licence. Although exempt from licensing, the regulations nevertheless specify the minimum qualifications or training required for these radiation workers.

Temporary Permits

The shortest period for which a licence or registration can be granted is 12 months. However, for shorter periods an application may be made for a Temporary Permit. Permits cannot exceed a duration of 3 months. 29 Temporary Permits were current as at 31 December 2018.

Conditions, Restrictions and Limitations

A range of performance and safety requirements for radioactive substances, x-ray equipment and the prescribed electronic products are specified in the regulations. However, additional safety measures may be applied by the Council under Section 36 of the Act through conditions, restrictions and limitations applied to registrations, licences, temporary permits and exemptions.

Failure to comply with a condition is an offence.

Attachment 7 shows the types and numbers of licences and registrations (or individual exemptions) granted or renewed in 2018.

Commonwealth Government Agencies and Contractors

The Radiation Safety Act does not apply to Commonwealth agencies or to their employees (or contractors) who might use radiation in Western Australia. Those agencies are regulated by ARPANSA under the Commonwealth Government's Australian Radiation Protection and Nuclear Safety Act 1999.

Appendix 2: Licence Prerequisites

Before a licence may be granted, the Council has an obligation to ensure that an applicant has appropriate qualifications, competence and experience (Section 33).

Protocols have been developed which prescribe the prerequisite qualifications and experience necessary for a wide range of radiation uses. Some qualifications are recognised by the Council because an appropriate degree of radiation safety training is inherent in gaining those qualifications. However, other applicants may be required to attend a recognised radiation safety course and pass an examination. The Council has authority to impose examinations under the Radiation Safety (Qualifications) Regulations.

Persons who are not required to hold a licence themselves but who must work under the direction and supervision of a licensee may also be required to hold certain qualifications or to have undergone additional radiation safety training. These requirements may be imposed by regulation or through conditions, restrictions and limitations imposed under Section 36. The registrant for the premises where the individual works is primarily responsible for ensuring compliance with these criteria.

Courses in various aspects of radiation safety are offered by both the government and private sectors, for example –

Bone Densitometry
Fluoroscopy – Medical
Fixed Radioactive Gauges
Industrial Radiography
Lasers – Medical and Industrial
Portable Radioactive Gauges
Transport of Radioactive Substances
Unsealed Radioisotope Handling
Well (Borehole) Logging
X-ray Operator

Attachment 1: Radiological Council

MEMBERS OF THE RADIOLOGICAL COUNCIL

Members	Qualification or Designation	Deputy
Appointment under Sections 13(2)(a) and 13(3) of the Act		
Dr A Robertson (Chairman)	Medical Practitioner	Dr G Groom
Appointment under Sections 13(2)(b), 15(1) and 17 (1) of the Act		
Dr C Hewavitharana	Radiologist	Dr D Dissanayake
Dr G Groom	Nuclear Medicine Physician	Dr E Thomas
Dr R Fox	Physicist	Dr R Price
Mr M Ross	Electronic Engineer	Not appointed
A/Prof R Francis	Tertiary Institutions representative	Not appointed
Mr C Whennan	Medical Radiation Technologist	Dr Robin Hart
Mr B Cobb	Co-opted member	not applicable
Mr N Tsurikov	Co-opted member	not applicable
Vacant	Expert in Mining Radiation Hazards	Vacant

2018 MEETING ATTENDANCE

	13 FEB	13 MAR	10 APR	11 MAY	12 JUN	14 AUG	13 NOV	11 DEC
Dr A Robertson	✓	✓	✓	✓	✓	✓	✓	✓
Mr B Cobb	✓	✓	✓	✓	✓	✓	✓	✓
Dr R Fox	✓	✓	✓	✓	✓	✓	✓	✓
A/Prof R Francis	NA	NA	NA	✓	✓	✓	✓	✓
Dr G Groom	✓	✓	D	✓	✓	D	✓	✓
Dr C Hewavitharana	A	✓	✓	A	✓	✓	NA	NA
Mr M Ross	A	✓	A	A	✓	✓	NA	NA
Mr N Tsurikov	✓	✓	✓	A	✓	✓	✓	✓
Mr C Whennan	A	✓	A	A	A	✓	A	A

✓ attended D deputy A apology NA not appointed at the time

Attachment 2: Legislation Amendments

RADIATION SAFETY ACT

Health Practitioner Regulation National Law (WA) Amendment Act 2018 s.118

Consequential amendments to amend the definition of a nurse practitioner.

Date of assent 19 April 2018. Government Gazette 13 November 2018 page 4427-8 with commencement on 1 December 2018.

RADIATION SAFETY (GENERAL) REGULATIONS

Health Regulations Amendment (Fees and Charges) Regulations 2018 Pt.9

Amendment to fees (Schedule XV).

Government Gazette 25 May 2018 pages 1632-9.

Radiation Safety (General) Amendment Regulations 2018

Regulations to delete fees for the registration and or renewal of registration of premises associated with obsolete equipment.

Government Gazette 16 October 2018 pages 4094.

RADIATION SAFETY (QUALIFICATIONS) AMENDMENT REGULATIONS

None

RADIATION SAFETY (TRANSPORT OF RADIOACTIVE SUBSTANCES) REGULATIONS

None

Attachment 3: Compliance Testing

Medical

- **A** *Compliant*
- **B** *Conditionally compliant*
- **C** *Non-compliant*[1]

Category	A	B	C	Total
CT	45	-	-	45
Dental – cone beam CT	10	-	-	10
Dental – intraoral	590	-	3	593
Dental – panoramic and/or cephalometric	126	-	1	127
Fluoroscopic – fixed	24	-	1	25
Fluoroscopic – fixed C or U arm	22	-	-	22
Fluoroscopic – mobile	98	-	-	98
Mammography	37	-	-	37
Radiographic – fixed	93	-	1	94
Radiographic – mobile	54	-	-	54
Total	1099	0	6	1105

Industrial – Fixed Gauges

- **A** *Compliant*
- **B** *Non-compliant*[2]

Category	A	B	Total
Density	198	4	202
In-stream analysis	8	-	8
Level	52	13	65
Total	258	17	275

[1] Equipment deemed to be non-compliant may continue to be used for a further three months while the problem is being addressed provided that the reason for non-compliance does not significantly increase the radiation dose to the patient. A re-test is then required. Of the 16 re-tests conducted during 2018, 100% resulted in the equipment being granted either a compliance or conditional compliance certificate.

[2] Equipment that has been assessed as non-compliant cannot be used until it has been re-tested and issued with a certificate of compliance.

Attachment 4: Industrial Radiation Safety Examinations

Current at 31 December 2018

Category	2018	2017	2016	2015	2014
Borehole Logging	24	29	20	13	29
Fixed Gauges	83	109	68	125	153
Industrial Radiography	30	49	46	63	73
Industrial Radiography (Advanced)	0	0	4	19	16
Industrial Radiography (Assistant)	109	57	78	129	237
Portable Gauges	61	50	18	23	46
Portable Gauges (WA Requirements)	8	3	2	1	14
Transport	25	42	22	32	17
Service – Cabinet X-ray	2	5	1	4	5
Service – Industrial Radiography (X-ray)	0	0	0	0	0
Service – X-ray Analysis	0	0	1	3	0
X-ray Analysis – Use	0	0	0	0	0
X-ray Analysis – Use and Restricted Service	111	48	30	47	42
Total	453	392	290	459	632

Attachment 5: List of Australian Radiation Protection and Nuclear Safety Agency publications for 2018

	Title
RPS C-3	Code for Disposal Facilities for Solid Radioactive Waste (2018)
RPS C-4	Code of Radiation Protection Requirements for Industrial Radiography (2018)
RPS C-6	Code for Disposal of Radioactive Waste by the User (2018)

Attachment 6: Registered Irradiating Apparatus, Electronic Products and Radioactive Substances (sealed sources)

Current at 31 December 2018

A *Irradiating apparatus and electronic products*[3]
B *Radioactive substances (sealed sources only)*

Category	A	B
Bone densitometry	62	-
Cabinet x-ray equipment	180	-
Calibration	2	650
CT	142	-
CT/SPECT	22	-
Dental – intraoral	2284	-
Dental – panoramic and/or cephalometric	472	-
Dental – cone beam CT	26	-
Education and research	21	1164
Fluoroscopic – fixed	89	-
Fluoroscopic – mobile	138	-
Gauges – density/level	8	3724
Gauges – in stream analysis	2	86
Gauges – logging	35	435
Gauges – neutron moisture/density portable	-	426
Gauges – other	-	317
Irradiator	-	48
Isotope Production	1	-
Laser – entertainment	202	-
Laser – industrial	203	-
Laser – medical	341	-
Laser – other medical	304	-
Laser – Podiatry	13	
Laser – research	201	-
Linear accelerator	20	-
Mammography	75	-
Non-destructive testing	217	151
Non-destructive testing – crawler control	-	17
Portable mineral analyser	-	8
Radiographic – fixed	358	-
Radiographic – mobile	420	-

[3] This data column specifically excludes x-ray equipment that is no longer operable but for which compliance testing data is held.

Category	A	B
Sealed Sources – other	-	129
Simulator	6	-
Special purpose x-ray	47	-
Static detection/measurement	-	3
Static elimination	-	13
Storage	-	322
Superficial radiotherapy	2	-
Test source	2	-
Therapy	5	26
Therapy – HDR brachytherapy	-	2
Transilluminator	121	-
Tracer Studies	-	117
X-ray analysis	619	-
Total	6640	7638

Attachment 7: Licences and Registrations

Current at 31 December 2018

Including individual exemptions granted under Section 6 of the Act.

	X-ray and/or Electronic Products		Radioactive Substances		TOTAL	
	2018	2017	2018	2017	2018	2017
Licences	5819	5416	2137	2129	7956	7545
Registrations	2057	1929	445	428	2502	2357
TOTAL	7876	7345	2582	2557	10458	9902
Change from 2017	+ 7.2%		+ 1.0%		+ 5.6%	

Attachment 7 (cont)

Purposes for Licences and Exemptions from Licence – total current as at 31 December 2018

Note: A *single licence may be granted for one or more purposes.*

Total	Purpose
20	Bone Densitometry
3	Bone Densitometry (Exemption)
96	Cabinet X-ray Equipment
1	Cobalt Teletherapy Maintenance
58	Compliance Testing - Diagnostic X-ray Equipment
485	Compliance Testing - Radioactive Gauges
12	Cyclotron Operation
5	Cyclotron Servicing
4	Education (Apparatus)
32	Education (Substances)
450	Fluoroscopy - Medical
99	Fluoroscopy - Medical (Exemption)
36	Fluoroscopy - Medical (Non-Specialist Exemption)
14	Fluoroscopy - Podiatry (Exemption)
2	Fluoroscopy - Veterinary
5	Gamma Irradiator - Use
503	Gauges - Industrial
7	Gauges - Industrial (Installation)
1	Gauges - Level (CO2)
262	Gauges - Logging
451	Gauges - Moisture and/or Density (Portable)
5	Gauges - Other (Apparatus)
45	Gauges - Other (Substances)
2	Installation of X-ray Equipment
2	Installation of X-ray Equipment - Dental
5	Lasers - Acupuncture
1	Lasers - Astronomy
12	Lasers - Chiropractic
190	Lasers - Dental
6	Lasers - Educational
28	Lasers - Entertainment
135	Lasers - Hair Removal (Exemption)
69	Lasers - Industrial
321	Lasers - Medical
8	Lasers - Other
110	Lasers - Physiotherapy

Total	Purpose
39	Lasers - Podiatry (Exemption)
57	Lasers - Research
76	Lasers - Service
34	Lasers - Superficial Cosmetic (Exemption)
11	Lasers - Tattoo Removal (Exemption)
16	Lasers - Veterinary
2	Manufacture of X-ray Equipment
3	Medical Physics
24	Medical Physics - Radiotherapy (Apparatus)
15	Medical Physics - Radiotherapy (Substances)
82	Medical Radiation Technology - Diagnostic Nuclear
1187	Medical Radiation Technology - Medical Imaging
20	Medical Radiation Technology - Nuclear Medicine - Diagnostic CT
204	Medical Radiation Technology - Radiation Therapy Irradiating Apparatus
188	Medical Radiology
5	Non-Medical Irradiation
5	Nuclear Medicine - Calibration and QC Sources
41	Nuclear Medicine - Diagnostic
32	Nuclear Medicine - Therapeutic
1	Nuclear Medicine - Therapy (Endocrinology)
4	Nuclear Medicine - Veterinary
8	Pathology Tests
24	Portable Mineral Analysers
328	Portable Mineral Analysers (X-ray)
5	Possession of X-ray Equipment - Diagnostic Medical
6	Possession of X-ray Equipment - Diagnostic Medical and Dental
3	Quality Assurance Procedures
29	Radioactive Ores - Analytical Laboratories
12	Radioactive Ores - Exploration
18	Radioactive Ores - Mining and/or Processing
11	Radioactive Substances - Calibration Sources
1	Radioactive Substances - Medical
41	Radioactive Substances - Sale
40	Radioactive Substances - Service of Devices
19	Radioactive Substances - Tracer Studies (Industry)
25	Radiography - Chiropractic (Extended)
167	Radiography - Chiropractic (Restricted)
419	Radiography - Industrial (Gamma)
441	Radiography - Industrial (X-ray)
1	Radiography - Mammography Screening (Exemption)

Total	Purpose
1	Radiography - Medical (Direction and Supervision)
3	Radiography - Security
791	Radiography - Veterinary
2	Radioguidance - Medical (Radioactive Substances)
33	Radiology - Dental
12	Radiology - Veterinary
20	Radiopharmaceutical Manufacture and Dispensing
26	Radiotherapy - Medical (Apparatus)
23	Radiotherapy - Medical (Substances)
2	Radiotherapy - Medical Superficial
12	Research
45	Research - Unsealed Radioactive Substances
8	Research - X-ray
40	Sale of Electronic Products
95	Sale of X-ray Equipment
1	Service of Devices - HDR Brachytherapy
29	Service of X-ray Equipment - Analytical
42	Service of X-ray Equipment - Cabinet
29	Service of X-ray Equipment - Dental
134	Service of X-ray Equipment - Diagnostic
3	Service of X-ray Equipment - Diagnostic (Extended)
3	Service of X-ray Equipment - Industrial NDT
29	Service of X-ray Equipment - Linear Accelerators
10	Service of X-ray Equipment - Other
7	Service of X-ray Equipment - Superficial X-ray Therapy
17	Special Purpose Enclosed X-ray Equipment
1	Static Detection
1	Static Electricity Measurement
1	Static Elimination
17	Storage (Substances)
20	Transilluminators
156	Transport
82	X-ray Analysis - Use
292	X-ray Analysis - Use and Service (Restricted)
3	X-ray Irradiator

Attachment 7 (cont)

Purposes for Registrations and Exemptions from Registration – total current as at 31 December 2018

Note: A *single registration may be granted for one or more purposes.*

Total	Purpose
25	Bone Densitometry
16	Bone Densitometry (Exemption)
82	Cabinet X-ray Equipment
2	Cyclotron Operation
3	Disposal of Radioactive Waste
10	Education (Apparatus)
18	Education (Substances)
27	Education – Demonstration Radioactive Sources (Exemption)
6	Fluoroscopy – Medical
1	Fluoroscopy – Podiatry
2	Gamma Irradiator
157	Gauges – Industrial
1	Gauges – Industrial (X-ray)
4	Gauges – Level (CO2)
22	Gauges – Logging
51	Gauges – Moisture and/or Density (Portable)
15	Gauges – Other (Apparatus)
9	Gauges – Other (Substances)
3	Lasers – Acupuncture
1	Lasers – Chiropractic
127	Lasers – Dental
2	Lasers – Educational
39	Lasers – Entertainment
37	Lasers – Hair Removal
37	Lasers – Industrial
1	Lasers – Manufacture
143	Lasers – Medical
1	Lasers – Other
42	Lasers – Physiotherapy
13	Lasers – Podiatry
6	Lasers – Research
6	Lasers – Sale, Service, Maintenance and Testing
8	Lasers – Storage
19	Lasers – Superficial Cosmetic
2	Lasers – Tattoo Removal

Total	Purpose
10	Lasers – Veterinary
2	Manufacture of X-ray Equipment
466	Medical Radiology
2	Non-Medical Irradiation
2	Nuclear Medicine – Diagnostic
18	Nuclear Medicine – Non-diagnostic CT X-ray
10	Nuclear Medicine – Therapeutic
6	Nuclear Medicine – Veterinary
9	Pathology Tests
8	Portable Mineral Analysers
197	Portable Mineral Analysers (X-ray)
11	Radioactive Ores – Analytical Laboratories
9	Radioactive Ores – Exploration
39	Radioactive Ores – Mining and/or Processing
10	Radioactive Substances – Calibration Sources
1	Radioactive Substances – Medical
9	Radioactive Substances – Sale
2	Radioactive Substances – Service of Devices
2	Radioactive Substances – Tracer Studies (Industry)
14	Radiography – Chest Screening
45	Radiography – Chiropractic
782	Radiography – Dental
1	Radiography – Forensic
30	Radiography – Industrial (Gamma)
35	Radiography – Industrial (X-ray)
13	Radiography – Mammography Screening
45	Radiography – Medical (Operator)
18	Radiography – Medical (Unrestricted)
93	Radiography – Medical Ancillary (Referrals)
1	Radiography – Physiotherapy Referrals
1	Radiography – Security
264	Radiography – Veterinary
3	Radioguidance – Medical (Radioactive Substances)
10	Radiology – Dental
3	Radiology – Veterinary
2	Radiopharmaceutical Manufacture and Dispensing
8	Radiotherapy – Medical (Apparatus)
7	Radiotherapy – Medical (Substances)
2	Radiotherapy – Veterinary (Apparatus)
2	Regulatory Authority
5	Research (Substances)
12	Research – Unsealed Radioactive Substances

Total	Purpose
7	Research – X-ray
5	Sale of Electronic Products
23	Sale of X-ray Equipment
54	Security of Radioactive Sources
16	Service of X-ray Equipment
10	Special Purpose Enclosed X-ray Equipment
1	Static Electricity Measurement
2	Static Elimination
50	Storage (Apparatus)
45	Storage (Substances)
13	Transilluminators
16	Transport
4	X-ray Analysis
113	X-ray Analysis – Use
1	X-ray Irradiator

ABBREVIATIONS

General Terminology

ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
CT	Computed Tomography
CT/SPECT	Computed Tomography/Single-Photon Emission Computed Tomography
DMIRS	Western Australian Department of Mines, Industry Regulation and Safety
HDR	High Dose Rate
IRRS	International Regulatory Review Service
MIT	Medical Imaging Technologist
MRT	Medical Radiation Technologist
MoU	Memorandum of Understanding
NDT	Non-Destructive Testing
PET	Positron Emission Tomography
RHC	Radiation Health Committee

Units of Activity

Bq	Becquerel (1 disintegration per second)
MBq	megabecquerel (1,000,000 Becquerels)
GBq	gigabecquerel (1,000,000,000 Becquerels)

Units of Effective Dose

Sv	Sievert (1 joule per kilogram multiplied by a modifying factor for the type of radiation and the radiological sensitivities of the organs and tissues being irradiated)
mSv	millisievert (one thousandth of a Sievert)
µSv	microsievert (one millionth of a Sievert)