

REPORT OF THE

RADIOLOGICAL COUNCIL

for the year ended

31 December 2017

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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 nine times in 2017.

Vale Dr Jim McNulty

Council formally acknowledged the passing of Dr Jim McNulty AO and his significant contribution to the Council. Dr McNulty had chaired the Council since its inception in 1976 until 2000 but also chaired its predecessor, the Radiological Advisory Council, from 1973. His long experience in occupational health but particularly in radiation safety will be missed.

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 (General) Regulations and the Radiation Safety (Qualifications) Regulations in 2017 are listed in attachment 2.

No amendments were made to the Radiation Safety Act and the Radiation Safety (Transport of Radioactive Substances) Regulations.

MUTUAL RECOGNITION ACT

The Mutual Recognition Act (MRA) was established to provide for the recognition of regulatory standards adopted by other Australian State and Territory jurisdictions regarding goods and occupations. Under the Radiation Safety Act, mutual recognition applies to licence categories which are considered to be an "occupation, trade, profession or calling" and not licences issued for activities.

Council considered and agreed to implement legal advice which required the application of the MRA to industrial radiography and service of radiation sources (including irradiating apparatus, electronic products and devices containing radioactive substances) as such occupations for which the MRA applies. Licence applicants in these occupations who hold a valid licence in another Australian State or Territory may apply for the equivalent licence in Western Australia under the MRA.

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 48 incidents during 2017 which are presented in the tables below. The majority of incidents were in medical imaging and were due to a failure to follow protocol.

| Incident | Occurrences | Category |
|------------------------------------------------------------------------------------------------------------------------|-------------|------------------------------------------------------------------|
| Radiology | | |
| Error in CT equipment or CT data analysis software requiring repeat imaging | 2 | Equipment Malfunction |
| Incorrect patient imaged - failure to correctly identify patient against request form | 1 | Human error - failure to follow protocol |
| Incorrect patient imaged due to incorrect patient name being entered on request form | 4 | Human error - other |
| Incorrect patient imaged due to error in electronic request system and subsequent failure to check identity of patient | 3 | Equipment Malfunction & human error - failure to follow protocol |
| Incorrect examination/anatomical site imaged – failure of MIT to check request form | 6 | Human error - failure to follow protocol |
| Incorrect examination/anatomical site imaged – failure to refer for correct examination/anatomical site | 2 | Human error - failure to follow protocol |
| Patient found to be pregnant following imaging. | 2 | Protocol followed – patient identified as not being pregnant |
| Incorrect modality - failure to check request form | 2 | Human error - failure to follow protocol |
| Duplication of imaging due to different request forms being completed | 1 | Human error - failure to follow protocol |
| Unintended exposure of radiation worker | 1 | Human error - failure to follow protocol |

| Incident | Occurrences | Catagory |
|--------------------------------------------------------------------------|-------------|----------------------------------------------------------------------------------|
| incident | Occurrences | Category |
| Unauthorised operation of x-ray equipment | 4 | Unauthorised use of equipment |
| Radiotherapy | | |
| Patient determined to be pregnant during course of radiotherapy | 1 | Protocol followed |
| Nuclear Medicine | | |
| Incorrect radiopharmaceutical administered | 1 | Human error - failure to follow protocol |
| Incorrect dose of radiopharmaceutical administered | 2 | Human error - failure to follow protocol |
| Extravasation of radiopharmaceutical | 3 | Protocol followed – IV administration failed after successful cannulation flush. |
| Radiopharmaceutical administered but scan not performed | 5 | Protocol followed – patient did not proceed with procedure. |
| Industrial | | |
| Unauthorised disposal of radioactive contaminated material | 1 | Human error - failure to follow protocol |
| Stolen x-ray equipment | 1 | Theft |
| Borehole logging source stuck in borehole | 2 | Equipment malfunction/unavoidable – source retrieved |
| 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 |
| Abnormal and unplanned exposure – dose rate in excess of dose constraint | 1 | Unintended exposure of monitoring device |

PROSECUTIONS

No prosecutions were initiated or finalised in 2017.

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 2017 is included in attachment 3

Cone beam CT

During 2017, the Radiological Council conducted a review of the requirements for the use of dental cone beam CT equipment in Western Australia and sought comment from the appropriate professional association. Following the review, Council agreed that eligibility for a licence to use dental cone beam CT equipment would be extended to registered dentists who have undertaken adequate training in radiation safety, justification and optimisation of examinations. Cone Beam CT images are still required to be reported on by a registered medical radiologist or dento-maxillofacial radiologist.

Lasers for Tattoo Removal

During 2017, the Radiological Council considered and agreed to changes to the training and qualification requirements for the use of lasers for tattoo removal following the commencement of a review into the use of lasers for cosmetic purposes. Council agreed that suitably trained Registered Nurses would be eligible for a licence (exemption) to use lasers for tattoo removal.

Council will be considering the requirements for additional cosmetic procedures in 2018.

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.

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 2017.

Research Project Title

A Randomized Phase 3 Study of Vincristine, Dactinomycin, Cyclophosphamide (VAC) Alternating with Vincristine and Irinotecan (VI) Versus VAC/VI Plus Temsirolimus (TORI, Torisel, NSC# 683864, IND# 122782) in Patients with Intermediate Risk (IR) Rhabdomyosarcoma (RMS)

A Phase 3, Randomized, Double blind, Placebo controlled, Multicentre Study of Bendamustine and Rituximab (BR) Alone Versus in Combination with Acalabrutinib (ACP 196) in Subjects with Previously Untreated Mantle Cell Lymphoma (WA)

Applications received from multiple facilities.

Randomised Blinded Phase 3 Assessment of Second or Third Line Chemotherapy with Docetaxel + Plinabulin Compared to Docetaxel + Placebo in Patients with Advanced Non-Small Cell Lung Cancer and with at Least One Measurable Lung Lesion.

Research Project Title

A Phase III, Randomized, Double- Blind, Placebo-Controlled Clinical Trial of Pembrolizumab (MK-3475) as Monotherapy in the Adjuvant Treatment of Renal Cell Carcinoma Post Nephrectomy.

A Phase 2 Multiple Dose, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ABBV-8E12 in Subjects with Early Alzheimer's Disease.

A Phase 2 Multiple Dose, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ABBV-8E12 in Subjects with Early Alzheimer's Disease.

A Randomized, Multicenter, open-Label, Phase 3 Study of Acalabrutinib (ACP-196) Versus Investigator's Choice of Either Idelalisib Plus Rituximab or Bendamustine Plus Rituximab in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia.

A Randomised, Double-Blind, placebo Controlled Study of Venetoclax Co-Administered with Low Dose Cytarabine Versus Low Dose Cytarabine in Treatment Naïve Patients with Acute Myeloid Leukemia Who Are Ineligible for Intensive Chemotherapy.

A Multicenter, Randomized, Double-blind, Placebo-controlled Phase 3 Study of the Bruton's Tyrosine Kinase (BTK) Inhibitor, Ibrutinib, in Combination with Rituximab versus Placebo in Combination with Rituximab in Treatment Naïve Subjects with Follicular Lymphoma

A Phase 1b/3 Randomized Open Label Study Investigating the Safety and Efficacy of Blinatumomab in Combination with Pembrolizumab Versus Standard of Care Chemotherapy in Adult Subjects with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)

A Multicentre, Open-Label, Phase 3 Trial of Allogenic Epstein-Barr Virus Cytotoxic T Lymphocytes (EBV-CTLs) for Allogenic Hematopoietic Cell Transplant (alloHCT) Patients with EBV-Associated Post-Transplant Lymphoproliferative Disease (EBV-PTLD) after Failure of Rituximab

A Multicentre, Open-Label, Phase 3 Trial of Allogenic Epstein-Barr Virus Cytotoxic T Lymphocytes (EBV-CTLs) for Solid Organ Transplant (SOT) Patients with EBV-Associated Post Transplant Lymphoproliferative Disease (EBV-PTLD) after Failure of Rituximab or Rituximab and Chemotherapy

Research Project Title

A randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Rovalpitzumab Tesirine (Rova-T) as Maintenance Therapy Following First-Line Platinum-Based Chemotherapy in Subjects with Extensive Stage Small Cell Lung Cancer (MERU)

A Randomized, Double-Blind, Delayed-Start Study of LY3314814 (AZD3293) in Early Alzheimer's Disease Dementia (Extension of Study AZES, The AMARANTH study).

A Phase II/III, Randomised, Multicentre Study of MOR00208 with Bendamustine versus Rituximab with Bendamustine in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma Who Are Not Eligible for High-Dose Chemotherapy and Autologous Stem-Cell Transplantation.

A Placebo-controlled, Double-Blind, Parallel-Group, 24 Month Study to Evaluate the Efficacy and Safety of E2609 in Subjects with Early Alzheimer's Disease (EAD)

A Randomized, Double-blind, Phase 2 Trial to Assess Safety and Efficacy of Lenvatinib in at Two Different Starting Doses (18 mg vs. 14 mg QD) in Combination with Everolimus (5 mg QD) in Renal Cell Carcinoma Following One Prior VEGF-Targeted Treatment.

A Phase III Randomized, Open-label, Clinical Trial to Compare Pembrolizumab with Brentuximab Vedotin in Subjects with Relapsed or Refactory Classical Hodgkin Lymphoma.

A placebo-controlled, double-blind, parallel-group, 24-month study to evaluate the efficacy and Safety of E2609 in subjects with early Alzheimer's Disease.

Phase 3, Randomised, Open-Label Study of Nivolumab Combined with Cabozantinib or Nivolumab and Ipilimumab Combined with Cabzozantinib versus Sunitinib in Participants with Previously Untreated, Advanced or Metastatic Renal Cell Carcinoma.

A 56 week, Double-Blind, Randomised Study to Evaluate the Efficacy of Testosterone, With and Without DHA Supplementation on Cerebral Amyloid Load in Known Brain Amyloid-PET Positive Men with Subjective Memory Complaints.

Stimulation of the Left Ventricular Endocardium for Cardiac Resynchronization Therapy in non-responders and previously untreatable patients (SOLVE CRT)

Phase 3 Study of Ibrutinib in Combination with Venetoclax in Subjects with Mantle Cell Lymphoma

Research Project Title

A Randomized Phase 3 Comparison of IMO-2125 with Ipilimumab versus Ipilimumab Alone in Subjects with Anti-PD-1 Refractory Melanoma.

A Phase III multicentre randomised double-blind placebo-controlled parallel-group efficacy and safety study of Gantenerumab in patients with prodromal to mild Alzheimer's Disease

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 2017 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 2017, Council officers marked 392 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 and Petroleum

A Memorandum of Understanding (MoU) has existed with the Department of Mines, Industry Regulation and Safety (DMIRS) 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 2017 as both agencies decided that the MoU should be reviewed and reassessed to streamline the RLC functionality.

Allegation of Examination Misconduct

The Council investigated an allegation of misconduct in the supervision and invigilation of examinations by a private consultancy. The consultancy cooperated fully with the investigation.

Council regarded the matter seriously and all course and examination providers were reminded of their obligations with respect to conducting examinations.

Low Level Radioactive Waste Facility

Western Australia is currently the only State in Australia with a low-level radioactive waste facility. Council has been liaising with the proponent and other State Government agencies with respect to a proposal for a second facility, which is to be privately owned and operated.

As the proposal documentation includes the acceptance of waste generated within Australia, Council queried the State Government's policy regarding the acceptance of waste that has been generated outside of Western Australia.

The review and assessment process is expected to continue in 2018.

MISCELLANEOUS

Integrated Regulatory Review Service (IRRS) Mission to Australia

The Radiological Council has been invited to participate 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 an IRRS mission is to perform a peer review of Australia's regulatory frameworks for nuclear and radiation safety.

In 2017, Council undertook the initial phase of the review, a self-assessment process which provides for internal analysis and benchmarking of the regulatory framework for radiation against international best practice IAEA safety standards. The IRRS team of international radiation safety experts is planned to visit Australia in 2018 to complete the mission.

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 2017 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 2017 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.

Reduction in Administrative Support

To carry out its responsibilities and functions the Council relies on the resourcing of administrative and scientific technical staff from the Department of Health's Radiation Health Unit. The Department of Health's voluntary severance scheme from 2016 - 2017 resulted in considerable reductions in staff, with the majority being senior level staff with substantial experience and expertise. This continued a trend from the last 20 years, where the Radiation Health Unit itself has seen its scientific and technical staff numbers halved, with a concomitant increase in the number of facilities and individuals requiring authorisation (approximately 2.5 times).

The need to allocate the limited resources to major projects in mining and medicine, where significant investigation and research is essential to identify any potential radiation risks and to ensure the proper protection of the public, occupationally exposed workers and the environment, has resulted in significant delays.

Council has alerted the Minister for Health that it might not be unable to maintain the high standards of radiation safety to the people of Western Australia required of both the Council and the Minister by the Radiation Safety Act. Council has raised its concerns with the Minister for Health and Department of Health, with a view to retaining high standards of radiation safety.

Resolution of Regulation Amendments for Lasers

In 2016, the Council was advised that amendments were made to the Radiation Safety (General) Regulations which deleted Schedule XIV(10) of the regulations, without consultation with the Council for approval. Schedule XIV imposes requirements for all Class 4 lasers and requires that surfaces within the controlled area are rendered non-reflective to reduce the possibility of hazardous diffuse reflections.

The reinstatement of Schedule XIV(10) was gazetted in March 2017.

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 2017 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. 76 Temporary Permits were current as at 31 December 2017.

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 total numbers of licences and registrations.

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

Radiological Council

2017 Annual Report

Attachment 1: Radiological Council

MEMBERS OF THE RADIOLOGICAL COUNCIL

| Members | Qualification or Designation | Deputy |
|------------------------------|------------------------------------------|------------------|
| Appointment under Sectio | ns 13(2)(a) and 13(3) of the Act | |
| Dr A Robertson (Chairman) | Medical Practitioner | Dr G Groom |
| Appointment under Section | ns 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 | Mr J O'Donnell |
| Prof J McKay | Tertiary Institutions representative | A/Prof Z Sun |
| Mr C Whennan | Medical Radiation Technologist | Mr R Hart |
| Mr B Cobb | Co-opted member | not applicable |
| Mr N Tsurikov | Co-opted member | not applicable |
| Vacant | Expert in Mining Radiation Hazards | Vacant |

2017 Annual Report

2017 MEETING ATTENDANCE

| | 14 FEB | 11 Apr | 9 May | 13 JUN | 11 JUL | 8 Aug | 10 Ост | 14 Nov | 20 DEC |
|--------------------|--------|--------|-------|--------|--------|-------|--------|--------|--------|
| Dr A Robertson | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Dr R Fox | ✓ | ✓ | ✓ | D | D | ✓ | ✓ | ✓ | ✓ |
| Dr G Groom | ✓ | ✓ | ✓ | D | ✓ | ✓ | ✓ | ✓ | ✓ |
| Dr C Hewavitharana | ✓ | ✓ | ✓ | ✓ | ✓ | Α | ✓ | ✓ | Α |
| Mr M Ross | ✓ | Α | ✓ | Α | ✓ | ✓ | ✓ | ✓ | Α |
| Prof J McKay | ✓ | ✓ | ✓ | ✓ | ✓ | D | ✓ | ✓ | Α |
| Mr B Cobb | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Mr N Tsurikov | ✓ | ✓ | ✓ | ✓ | Α | ✓ | ✓ | Α | Α |
| Mr C Whennan | Α | ✓ | Α | Α | Α | Α | ✓ | ✓ | Α |

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

Attachment 2: Legislation Amendments

RADIATION SAFETY ACT

None

RADIATION SAFETY (GENERAL) REGULATIONS

Health Regulations Amendment (Public Health) Regulations 2016 Pt.31

Amendment to Regulation 58(5)(a) to update reference to the Public Health Act 2016.

Government Gazette 10 January 2017 pages 237-308.

Radiation Safety (General) Amendment Regulations 2017

Amendment to Schedule XIV to reinstate clause 10 with respect to the control of surfaces in the use of Class 4 lasers.

Government Gazette 7 March 2017 pages 1526-7.

Health Regulations Amendment (Fees and Charges) Regulations 2017 Pt.9

Amendment to fees (Schedule XV).

Government Gazette 30 June 2017 pages 3568-74.

RADIATION SAFETY (QUALIFICATIONS) AMENDMENT REGULATIONS

Health Regulations Amendment (Fees and Charges) Regulations 2017 Pt.10

Amendment to fees (Schedule 2).

Government Gazette 30 June 2017 pages 3568-74.

RADIATION SAFETY (TRANSPORT OF RADIOACTIVE SUBSTANCES) REGULATIONS

None

Attachment 3: Compliance Testing

Medical

A Compliant

B Conditionally compliant

C Non-compliant¹

| Category | Α | В | С | Total |
|-----------------------------------------|------|---|----|-------|
| СТ | 64 | - | - | 64 |
| Dental – intraoral | 592 | 1 | 1 | 594 |
| Dental – panoramic and/or cephalometric | 129 | - | - | 129 |
| Dental – cone beam CT | 3 | - | - | 3 |
| Fluoroscopic – fixed | 41 | - | 4 | 45 |
| Fluoroscopic – fixed C or U arm | 26 | - | - | 26 |
| Fluoroscopic – mobile | 107 | - | 2 | 109 |
| Radiographic – fixed | 94 | - | 6 | 100 |
| Radiographic – mobile | 66 | - | - | 66 |
| Mammography | 56 | - | - | 56 |
| Total | 1178 | 1 | 13 | 1192 |

Industrial - Fixed Gauges

A Compliant

B Non-compliant²

| Category | Α | В | Total |
|--------------------|-----|----|-------|
| Density | 178 | 8 | 186 |
| In-stream analysis | 1 | - | 1 |
| Level | 40 | 2 | 42 |
| Total | 219 | 10 | 229 |

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 17 re-tests conducted during 2017, 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

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. Of the 15 re-tests conducted during 2017, 100% resulted in the equipment being granted a compliance certificate.

Attachment 4: Industrial Radiation Safety Examinations

Current at 31 December 2017

| Category | 2017 | 2016 | 2015 | 2014 | 2013 |
|---------------------------------------------|------|------|------|------|------|
| Borehole Logging | 29 | 20 | 13 | 29 | 16 |
| Fixed Gauges | 109 | 68 | 125 | 153 | 108 |
| Industrial Radiography | 49 | 46 | 63 | 73 | 63 |
| Industrial Radiography (Advanced) | 0 | 4 | 19 | 16 | 31 |
| Industrial Radiography (Assistant) | 57 | 78 | 129 | 237 | 194 |
| Portable Gauges | 50 | 18 | 23 | 46 | 92 |
| Portable Gauges (WA Requirements) | 3 | 2 | 1 | 14 | 8 |
| Transport | 42 | 22 | 32 | 17 | 21 |
| Service – Cabinet X-ray | 5 | 1 | 4 | 5 | 2 |
| Service – Industrial Radiography (X-ray) | 0 | 0 | 0 | 0 | 0 |
| Service – X-ray Analysis | 0 | 1 | 3 | 0 | 0 |
| X-ray Analysis – Use | 0 | 0 | 0 | 0 | 5 |
| X-ray Analysis – Use and Restricted Service | 48 | 30 | 47 | 42 | 57 |
| Total | 392 | 290 | 459 | 632 | 597 |

Attachment 5: List of Australian Radiation Protection and Nuclear Safety Agency publications for 2017

Title

RPS G-2 Guide for Radiation Protection in Existing Exposure Situations (2017)

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

Current at 31 December 2017

A Irradiating apparatus and electronic products³

B Radioactive substances (sealed sources only)

| Category | Α | В |
|--------------------------------------------|------|------|
| Bone densitometry | 60 | - |
| Cabinet x-ray equipment | 175 | - |
| Calibration | 2 | 639 |
| CT | 140 | - |
| CT/SPECT | 21 | - |
| Dental – intraoral | 2278 | - |
| Dental – panoramic and/or cephalometric | 457 | - |
| Dental – cone beam CT | 18 | - |
| Education and research | 20 | 1120 |
| Fluoroscopic – fixed | 89 | - |
| Fluoroscopic – mobile | 140 | - |
| Gauges – density/level | 7 | 3669 |
| Gauges – in stream analysis | 2 | 87 |
| Gauges – logging | 38 | 428 |
| Gauges – neutron moisture/density portable | - | 452 |
| Gauges – other | - | 308 |
| Irradiator | - | 48 |
| Isotope Production | 1 | - |
| Laser – entertainment | 152 | - |
| Laser – industrial | 196 | - |
| Laser – medical | 324 | - |
| Laser – other medical | 256 | - |
| Laser – Podiatry | 12 | |
| Laser – research | 208 | - |
| Linear accelerator | 20 | - |
| Mammography | 75 | - |
| Non-destructive testing | 210 | 131 |
| Non-destructive testing – crawler control | - | 13 |
| Portable mineral analyser | - | 9 |
| Radiographic – fixed | 353 | - |
| Radiographic – mobile | 414 | - |

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

| Category | Α | В |
|------------------------------|------|------|
| Sealed Sources – other | - | 126 |
| Simulator | 6 | - |
| Special purpose x-ray | 48 | - |
| Static detection/measurement | - | 3 |
| Static elimination | - | 11 |
| Storage | - | 317 |
| Superficial radiotherapy | 2 | - |
| Test source | 2 | - |
| Therapy | 5 | 25 |
| Therapy – HDR brachytherapy | - | 1 |
| Transilluminator | 121 | - |
| Tracer Studies | - | 111 |
| X-ray analysis | 574 | - |
| Total | 6426 | 7498 |

Attachment 7: Licences and Registrations

Current at 31 December 2017

Including individual exemptions granted under Section 6 of the Act.

| | X-ray and/or Electronic Products | | Radioactive Substances | | TOTAL | |
|------------------|----------------------------------------|------|---------------------------|------|--------|------|
| | 2017 | 2016 | 2017 | 2016 | 2017 | 2016 |
| Licences | 5416 | 5287 | 2129 | 2230 | 7545 | 7517 |
| Registrations | 1929 | 1859 | 428 | 413 | 2357 | 2272 |
| TOTAL | 7345 | 7146 | 2557 | 2643 | 9902 | 9789 |
| Change from 2016 | + 2.8% | | - 3.3% | | + 1.2% | |

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

MIT Medical Imaging Technologist
MoU Memorandum of Understanding
MRT Medical Radiation Technologist

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)