REPORT OF THE

RADIOLOGICAL COUNCIL

for the year ended

31 December 2013

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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 ten times in 2013.

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.

The only exception is Council's Chiropractic Advisory Committee which is appointed to supervise the radiation safety examination for chiropractors who wish to apply for licences to operate diagnostic x-ray equipment. The committee, which also advises Council on other chiropractic matters, met once in 2013.

ADMINISTRATIVE SUPPORT

Section 10(4) of the Act provides for the administration of the Act to be paid out of moneys 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 L Dahlskog (Senior Health Physicist) or Mrs M Aerts (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

No amendments were made to the Act or the Radiation Safety (General) Regulations in 2013. Amendments made to the Radiation Safety (Transport of Radioactive Substances) Regulations are listed in attachment 2.

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 and as soon as practicable should any of the abnormal or unplanned radiation exposures specified in that regulation occur.

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 the following reportable incidents during 2013.

Medical Incidents

- A nuclear medicine practice advised that a ^{99m}Tc radiopharmaceutical scan had been mistakenly administered twice. The first scan had been conducted on receipt of the facsimile request with the original request being placed on the patient's notes. The original scan was later discovered and sent to the department for action and was subsequently performed. In investigating the incident a recommendation was made to the department that the original request must be located prior to acting on any facsimile request and that, booking clerks be reminded to check on the currency of request forms.

  Council required that further information was obtained from the practice confirming that the department had acted on the recommendation and also requested information on the practice's standard operating procedures which was subsequently provided and accepted.

- A nuclear medicine practice advised that that a patient had been given a pre-prepared injection intended for another patient. The radiopharmaceutical label on the syringe was not checked against the patient referral details, and instead of the prescribed ^{99m}Tc HDP for a bone scan, a cardiac study injection of ^{99m}Tc tetrofosmin intended for another patient was partially injected. The investigation revealed that the standard procedure of checking the label on the syringe against the patient referral details had not been followed patient.

  Council reviewed the remedial actions taken by the practice to reduce the likelihood of a reoccurrence and agreed that they were satisfactory.

- A nuclear medicine practice advised that on three separate occasions a nuclear medicine scan was conducted when it was not required as the medical team had not cancelled the scan with the nuclear medicine practice. In two of these incidents the medical condition of the patient necessitated the cancellation.

Council advised the practice to review their systems, including information technology systems, in order to minimise the likelihood of a reoccurrence.

- A nuclear medicine practice advised that a quality control error had resulted in eight patients being administered with unlabelled ^{99m}Tc Sodium Pertechnetate instead of the prescribed ^{99m}Tc Sestamibi (Cardiolite). An investigation ascertained that a breakdown of the quality control procedures had occurred. This was exacerbated by the technologist performing the administrations being inadequately trained and also presenting to work whilst unwell.

  As a result of this incident the practice implemented a number of remedial measures, including modifying the laboratory protocol for improved clarity, retraining the technologist and improving supervision.

- A nuclear medicine practice reported that a scan was performed on receipt of a partially completed but unsigned request form which had not in fact been requested nor was needed. The investigation revealed that an *unsigned* form (which was part of a standard package for a trial) was inadvertently sent by staff to the practice; the clerical staff and a medical registrar also processed the form without recognising that it had not been fully completed or signed.

  The process for completing procedures associated with the trial was reviewed and staff were reminded of the correct protocols, in particular that request forms must not be processed unless they are fully completed and signed.

  Council requested that the practice be advised that all partially filled request forms must be removed from the system.

- A nuclear medicine practice reported that on three separate occasions within four weeks, unnecessary nuclear medicine scans had been performed due to the failure, on each occasion, by the patient's medical team to notify the nuclear medicine practice that the scan was no longer required. On investigation it was revealed that medical staff were simultaneously ordering several tests that might possibly be needed rather than doing sequential ordering as assessment progresses.

  The practice was advised and asked to ensure their medical protocols were reviewed to ensure that a nuclear medicine scan not be ordered until assessment of the patient has determined that it is actually required, since otherwise the patient may be subjected to an unnecessary radiation dose if the scan is found to be not needed when the radiopharmaceutical injection has already proceeded.

- A radiotherapy centre reported to Council that the portable monitoring device for a radiotherapy physicist had received a high dose . The dose relates to an incident where the physicist accidentally dropped the device in the radiotherapy

area during quality assurance work and overlooked retrieving it before completing the radiation exposures.

Council was satisfied that the physicist did not receive the dose and that no further action was required.

- A radiotherapy centre reported to Council that an unplanned radiation exposure incident of external beam therapy to the wrong side of a patient had occurred. Investigations continued throughout 2013 and are expected to be finalised in 2014.

Industrial Incidents

- A personal monitoring service provider advised Council that the portable monitoring devices for three personnel working for a company registered for the use of portable density/moisture gauges had been assessed as exceeding the reportable dose levels for the monitoring period. The investigation revealed that the personal monitoring devices had been incorrectly stored above a portable density/moisture gauge and this had resulted in the dose levels being exceeded.

  The company provided the Council with a modified procedure for the use and storage of the personal monitoring devices which was deemed acceptable.

- A personal monitoring service provider advised Council that the portable monitoring device for a person working for a company registered for the use of logging gauges had been assessed as exceeding the reportable dose levels for the monitoring period. The investigation did not reveal any reason for the dose received and it was considered very likely that the dose had resulted from the device being placed in checked baggage during international travel.

  Council required that the company review their procedures to minimise non work related doses to monitoring badges during travel.

- During 2013, five notifications were received regarding logging tools containing radioactive sources becoming stuck down boreholes. In all cases, operations to recover the sources were conducted. When source recovery operations are unsuccessful the sources are classified as abandoned.

  The conditions of registration require that where a source is irretrievably lost in a borehole, written notification is given to the owner and/or operator of the borehole that the source is to be cemented in situ; the location of the source is documented for the owner's records; and that no further drilling is permitted in the immediate vicinity of the source which risks intersecting with its location.

Notification of the abandonment is also provided to the National Offshore Petroleum Safety and Environmental Management Authority and the Petroleum Division of the WA Department of Mines and Petroleum.

A table summarising the notifications is below.

Source Information	Location	Recovered or Abandoned
A 55.5 GBq ^{3}H logging source	Offshore – became stuck at a depth of 5043 m	Abandoned
A 63 GBq ^{137}Cs logging source, and a 55.5 GBq ^{3}H source.	Offshore – became stuck at depths of 3866 m and 3864 m respectively.	Abandoned
A 63 GBq ^{137}Cs logging source, and a 55.5 GBq ^{3}H source.	Offshore – became stuck at depths of 4729 m and 4726 m respectively.	Abandoned
A 63 GBq ^{137}Cs logging source, and a 55.5 GBq ^{3}H source.	Offshore – became stuck at depths of 3762 m and 3759 m respectively.	Abandoned
A ^{60}Co logging source.	North Western Australia	Recovered

PROSECUTIONS

No prosecutions were initiated or finalised in 2013.

MEDICAL AND RELATED RADIATION MATTERS

Compliance Testing

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

No 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.

The number of compliance tests of diagnostic x-ray equipment received by Council in 2013 was 1302. A summary of the statistics for the compliance program per type of diagnostic medical imaging equipment 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 had been operated and run successfully by Western Australian Country Health Services (WACHS).

During 2013 the running of the x-ray operator course was transitioned from WACHS to Curtin University.

On-Line marketing – Offers for Free Dental Examinations

During 2013 several online offers that included x-ray examinations for free or part of a package were brought to the attention of Council. By offering free x-ray examinations the dental practices involved were not adhering to the requirement that all x-ray examinations must be clinically justified.

The practices were advised that the on-line offers were a breach of the Radiation Safety Act as were the on-line companies associated with the offers. The Western Australian Branch of the Australian Dental Association was informed and assisted the Council in ensuring all of its members were aware of the legal requirements.

Electronic Referral Systems

Council discussed the requirements necessary for electronic referral systems given that more enquiries were being received for electronic systems to replace paper based systems.

Council agreed that it would consider each system as it was introduced but that all systems would need to demonstrate that a secure log in was provided and that the system must include the patient's name, date of birth, examinations requested and clinical indication for the referral.

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 2013.

Research Project Title
FOLFOX6m plus SIR-Spheres v FOLFOX6m alone for liver metastases from primary colorectal carcinoma (FOXFIREGlobal)
Cabozantinib vs Prednisone in Metastatic Castration-Resistant Prostate Cancer Patients who have Received Prior Docetaxel and Prior Abiraterone or MDV3100 Patients who have Received Prior Docetaxel and Prior Abiraterone or MDV3100
A Randomised, Multi-Centre, Placebo-Controlled, Parallel Group Study to Determine the Effects of AMG 145 Treatment on Atherosclerotic Disease Burden As Measured By Intravascular Ultrasound in Subjects Undergoing Coronary Catheterisation'
Safety & Performance Study of the ReZolve2 Sirolimus-Eluting Bioresorable Coronary Scaffold – RESTORE II Trial'
A Phase 2, Randomised, Double-Blind, Placebo-Controlled, Multi-Centre Study to Access the Efficacy and Safety of GS-6624 in Subjects with Idiopathic Pulmonary Fibrosis (RAINIER)
Neoadjuvant chemotherapy with nab-paclitaxel in women with HER2-negative high-risk breast cancer – ETNA (Evaluating Treatment with Neoadjuvant Abraxane'
A Phase 3, Randomised, Controlled Study Evaluating the Efficacy and Safety of GS-1101 (CAL-101) in Combination with Ofatumumab for Previously Treated Chronic Lymphocytic Leukemia'
Trastuzamab in HER2 + Breast Cancer Patients (Redfern
International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA).
A Phase III Randomised Study of BBI608 and Best Supportive Care versus Placebo and Best Supportive Care in Patient with Pretreated Advanced Colorectal Carcinoma'
'A Randomised, Open-label, Phase 3 Trial of A+AVD versus ABVD as Frontline Therapy in Patients with Advanced Classical Hodgkin Lymphoma'

Research Project Title
Multicentre open-label study to evaluate efficacy of gabobutrol-enhanced cardiac magnetic resonance imaging (CMRI) for detection of significant coronary artery disease (CAD) in subject with known or suspected CAD by blind image analysis (GADACAD)
'A Phase III Randomized Study of BBI608 and Best Supportive Care Verus Placebo and Best Supportive Care in Patient with Pretreated Advanced Colorectal Carcinoma', Protocol No: CO23
A Phase 3, Randomised, Double Blind, Placebo Controlled Study Evaluating the Efficacy and Safety of Idelalisibb (GS-1101) in Combination with Bendamustine and Rituximab for Previously Treated Indolent Non-Hodgkin Lymphomas'
A Phase 3, Randomized, Double-blind, Controlled Study of Cabozantinib (XL184) vs Placebo in Subjects with Hepatocellular Carcinoma who have received prior Sorafenib'
A Randomized, Double-blind, Placebo-controlled Study of the Burton's Tyrosine Kinase (BTK) Inhibitor, PCI-32765 (Ibrutinib), in Combination with Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone (R-ACHOP) in Subjects with newly diagnosed Non-Germinal Center B-Cell Subtype of Diffuse Large B-Cell Lymphoma'
'A Phase 3, Randomised, Double-blind Study of Tivantinib (ARQ 197) in Subjects with MET Diagnostic-High Inoperable Hepatocellular Carcinoma (HCC) Treated with One Prior Systemic Therapy'
A Phase II/III Randomised, Double-Blind, Placebo-Controlled, Multi-Centre Study of 2 Potential Disease Modifying Therapies in Individuals at Risk for and with Dominantly Inherited 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. The number of compliance tests received by the Council in 2013 was 622. A summary of compliance tests assessed in 2013 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 2013, Council officers marked 597 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 and Petroleum (DMP).

Memorandum of Understanding with the Department of Mines and Petroleum

The Memorandum of Understanding (MoU) that was being developed with the Department of Mines and Petroleum (DMP) was finalised and in 2013.

One of the agreements in the MoU was that a Radiation Liaison Committee (RLC) be

established to provide a framework for liaison between DMP and the Radiological Council.

The decisions and outcomes of the RLC do not limit the statutory obligations and decision making of each agency. At least two representatives of the Radiological Council and the Department of Mines and Petroleum need to be present at each meeting.

Four meetings were held in 2013.

MISCELLANEOUS

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 2013 is in attachment 5.

National Directory for Radiation Protection

At the Australian Health Ministers' Conference (AHMC) 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 2013 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.

Radiological Council Meeting Arrangements

During 2012 Council considered the frequency and format of meetings. Council agreed that due to the increased number of items requiring consideration and the often tight time frames required that it would trial meeting every month instead of every two months. In March the Council reviewed the arrangement and agreed to continue with monthly meetings on a permanent basis.

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), the Commonwealth Government's radiation safety agency in Victoria.

- New Zealand National Radiation Laboratory, the New Zealand national radiation safety organisation
  (Australian agent: Australian Radiation Services Pty Ltd, Victoria).

- Australian Radiation Services Pty Ltd, a company based in Victoria.

- Landauer Inc (USA) for the Luxel based system.

- Global Dosimetry Solutions, a company based in USA.

- Global Medical Solutions Australia, a company based in NSW.

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, transilluminators and sun tanning units used for commercial purposes.

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 2013 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. 51 Temporary Permits were current as at 31 December 2012.

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 2013.

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
Compliance Testing of Diagnostic X-ray Equipment
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 13TH 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	Not appointed
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	Mr J O'Donnell
Prof J McKay	Tertiary Institutions representative	A/Prof Zhongua Sun
Mr G Scott	Medical Radiation Technologist	Mr N Hicks (until June 2013) Mr C Whennan (from June 2013)
Mr C Dillon	Expert in Mining Radiation Hazards	Vacant
Mr G Fee	Expert in Mining Radiation Hazards	Vacant
Mr B Cobb	Co-opted member	not applicable
Mr N Tsurikov	Co-opted member	not applicable

2013 MEETING ATTENDANCE

	12 FEB	12 MAR	9 APR	14 MAY	11 JUN	9 JUL	10 SEP	15 OCT	12 NOV	10 DEC
Dr A Robertson	✓	✓	✓	A	✓	✓	✓	✓	✓	✓
Dr R Fox	✓	✓	✓	✓	✓	D	✓	✓	✓	✓
Dr G Groom	A	✓	✓	✓	D	✓	✓	✓	✓	✓
Dr C Hewavitharana	✓	✓	✓	✓	A	✓	✓	✓	✓	✓
Mr M Ross	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Prof J McKay	✓	✓	✓	✓	✓	✓	✓	✓	A	✓
Mr C Dillon	A	A	A	A	A	✓	A	A	✓	✓
Mr B Cobb	✓	✓	✓	A	A	✓	✓	✓	✓	✓
Mr N Tsurikov	✓	A	✓	A	✓	A	✓	A	A	✓
Mr G Fee	✓	✓	✓	✓	✓	A	✓	✓	✓	✓
Mr G Scott	A	✓	A	✓	A	✓	A	✓	✓	✓
Dr E Thomas (Deputy)					✓					
Dr R Price (Deputy)						✓				

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

Attachment 2: Legislation Amendments

RADIATION SAFETY ACT

None.

RADIATION SAFETY (GENERAL) REGULATIONS

None

RADIATION SAFETY (TRANSPORT OF RADIOACTIVE SUBSTANCES) REGULATIONS

Radiation Safety (Transport of Radioactive Substances) Amendment Regulations 2013.

Regulations to update and amend the references to the updated Code of Practice Safe Transport of Radioactive Material.

Government Gazette 26 April 2013 pages 1661-3.

RADIATION SAFETY (QUALIFICATIONS) AMENDMENT REGULATIONS

None

Attachment 3: Compliance Testing

Medical

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

Category	A	B	C	Total
CT	51	-	3	54
Dental – intraoral	682	-	13	695
Dental – panoramic and/or cephalometric	130	-	1	131
Fluoroscopic – fixed	33	-	10	43
Fluoroscopic – fixed C or U arm	22	-	11	33
Fluoroscopic – mobile	97	-	9	106
Mammography	62	-	1	63
Radiographic – fixed	95	-	22	117
Radiographic – mobile	57	-	3	60
Total	1229	0	73	1302

Industrial – Fixed Gauges

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

Category	A	B	Total
Density	504	63	567
In-stream analysis	13	4	17
Level	34	4	38
Thickness	-	-	0
Total	551	71	622

[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 55 re-tests conducted during 2013, 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. Of the 16 re-tests conducted during 2013, 100% resulted in the equipment being granted a compliance certificate.

Attachment 4: Industrial Radiation Safety Examinations

Current at 31 December 2013

Category	2013	2012	2011	2010	2009
Borehole Logging	16	37	67	78	41
Fixed Gauges	108	118	138	95	64
Gamma Irradiator	0	0	0	3	3
Industrial Radiography	63	67	24	36	88
Industrial Radiography (Advanced)	31	9	0	0	0
Industrial Radiography (Assistant)	194	121	123	86	146
Portable Gauges	92	233	137	65	50
Portable Gauges (WA Requirements)	8	19	28	19	14
Transport	21	31	17	26	20
Service – Cabinet X-ray	2	1	4	1	4
Service – Industrial Radiography (X-ray)	0	0	0	0	0
Service – X-ray Analysis	0	2	0	3	0
X-ray Analysis – Use	5	11	15	6	8
X-ray Analysis – Use and Restricted Service	57	62	69	47	50
Total	597	711	622	465	488

Attachment 5: List of Australian Radiation Protection and Nuclear Safety Agency publications for 2013

No new documents were published in 2013.

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

Current at 31 December 2013

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

Category	A	B
Bone densitometry	45	-
Cabinet x-ray equipment	140	-
Calibration	2	477
CT	125	-
CT/SPECT	14	-
Dental – intraoral	1954	-
Dental – panoramic and/or cephalometric	345	-
Education and research	17	1012
Fluoroscopic – fixed	98	-
Fluoroscopic – mobile	125	-
Gauges – density/level	4	2706
Gauges – in stream analysis	-	72
Gauges – logging	26	360
Gauges – neutron moisture/density portable	-	445
Gauges – other	-	245
Irradiator	-	48
Isotope Production	1	-
Laser – entertainment	41	-
Laser – industrial	116	-
Laser – medical	247	-
Laser – other medical	175	-
Laser – Podiatry	2	
Laser – research	151	-
Linear accelerator	15	-
Mammography	88	-
Non-destructive testing	104	102
Non-destructive testing – crawler control	-	18
Portable mineral analyser	-	10
Radiographic – fixed	362	-
Radiographic – mobile	412	-
Sealed Sources – other	-	108

[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
Simulator	1	-
Special purpose x-ray	59	-
Static detection/measurement	-	3
Static elimination	-	8
Storage	-	229
Sun Tanning Unit	79[4]	-
Superficial radiotherapy	3	-
Test source	4	-
Therapy	2	22
Therapy – HDR brachytherapy	-	2
Transilluminator	117	-
Tracer Studies	-	27
X-ray analysis	461	-
Total	5335	5894

[4] The number reported in previous years was incorrectly calculated and there has not been an increase in the number of sun-tanning units since regulation of these units was commenced.

Attachment 7: Licences and Registrations

Current at 31 December 2013

Including individual exemptions granted under Section 6 of the Act.

	X-ray and/or Electronic Products		Radioactive Substances		TOTAL	
	2013	2012	2013	2012	2013	2012
Licences	4711	4558	2218	2161	6929	6719
Registrations	1655	1624	384	369	2039	1993
TOTAL	6366	6182	2602	2530	8968	8712
Change from 2012	+ 3.0%		+ 2.8%		+ 2.9%	

Attachment 7 (cont)

Purposes for Licences and Exemptions from Licence

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

A *Granted or renewed in 2013*
B *Total current*

A	B	Purpose
5	9	Bone Densitometry
3	7	Bone Densitometry (Exemption)
23	64	Cabinet X-ray Equipment
0	1	Cobalt Teletherapy Maintenance
17	51	Compliance Testing - Diagnostic X-ray Equipment
40	105	Compliance Testing - Radioactive Gauges
3	5	Cyclotron Operation
3	5	Cyclotron Servicing
1	3	Education (Apparatus)
8	26	Education (Substances)
123	349	Fluoroscopy - Medical
35	141	Fluoroscopy - Medical (Exemption)
19	36	Fluoroscopy - Medical (Non-Specialist Exemption)
0	1	Fluoroscopy - Research
0	1	Fluoroscopy - Veterinary
1	2	Gamma Irradiator - Use
152	403	Gauges - Industrial
0	8	Gauges - Industrial (Installation)
0	2	Gauges - Level (CO2)
82	357	Gauges - Logging
279	639	Gauges - Moisture and/or Density (Portable)
3	5	Gauges - Other (Apparatus)
16	31	Gauges - Other (Substances)
2	12	Installation of X-ray Equipment
1	7	Installation of X-ray Equipment - Dental
3	7	Lasers - Acupuncture
2	8	Lasers - Chiropractic
50	116	Lasers - Dental
2	7	Lasers - Educational
8	20	Lasers - Entertainment
35	72	Lasers - Industrial
71	242	Lasers - Medical
33	86	Lasers - Physiotherapy
9	10	Lasers - Podiatry (Exemption)

A	B	Purpose
14	37	Lasers - Research
25	58	Lasers - Service
1	2	Lasers - Veterinary
1	2	Manufacture of X-ray Equipment
1	3	Medical Physics
7	15	Medical Physics - Radiotherapy (Apparatus)
3	8	Medical Physics - Radiotherapy (Substances)
36	72	Medical Radiation Technology - Diagnostic Nuclear
599	1 032	Medical Radiation Technology - Medical Imaging
84	177	Medical Radiation Technology - Radiation Therapy Irradiating Apparatus
75	231	Medical Radiology
2	3	Non-Medical Irradiation
0	1	Nuclear Medicine - Calibration and QC Sources
14	33	Nuclear Medicine - Diagnostic
14	33	Nuclear Medicine - Therapeutic
0	3	Nuclear Medicine - Veterinary
0	4	Pathology (in vitro) – Sealed Sources
7	12	Pathology Tests
13	32	Portable Mineral Analysers
88	279	Portable Mineral Analysers (X-ray)
3	9	Possession of X-ray Equipment - Diagnostic Medical
1	1	Possession of X-ray Equipment - Diagnostic Medical and Dental
0	3	Quality Assurance Procedures
7	25	Radioactive Ores - Analytical Laboratories
6	9	Radioactive Ores - Exploration
4	17	Radioactive Ores - Mining and/or Processing
3	9	Radioactive Substances - Calibration Sources
1	1	Radioactive Substances - Medical
17	36	Radioactive Substances - Sale
12	29	Radioactive Substances - Service of Devices
1	1	Radioactive Substances - Tracer Studies
8	20	Radioactive Substances - Tracer Studies (Industry)
2	5	Radiography - Chiropractic (Exemption)
18	35	Radiography - Chiropractic (Extended)
58	168	Radiography - Chiropractic (Restricted)
159	394	Radiography - Industrial (Gamma)
159	389	Radiography - Industrial (X-ray)
0	1	Radiography - Medical (Direction and Supervision)
0	1	Radiography - Security
218	609	Radiography - Veterinary
0	2	Radioguidance - Medical (Radioactive Substances)

A	B	Purpose
2	9	Radiology - Veterinary
9	13	Radiopharmaceutical Manufacture and Dispensing
7	19	Radiotherapy - Medical (Apparatus)
7	21	Radiotherapy - Medical (Substances)
2	6	Radiotherapy - Medical Superficial
2	2	Radiotherapy - Veterinary (Apparatus)
2	12	Research
33	69	Research - Unsealed Radioactive Substances
2	3	Research - X-ray
12	37	Sale of Electronic Products
34	90	Sale of X-ray Equipment
4	20	Service of X-ray Equipment - Analytical
10	30	Service of X-ray Equipment - Dental
31	109	Service of X-ray Equipment - Diagnostic
7	11	Service of X-ray Equipment - Diagnostic (Extended)
0	5	Service of X-ray Equipment - Industrial NDT
2	2	Service of X-ray Equipment - Intraoral
8	13	Service of X-ray Equipment - Linear Accelerators
7	30	Service of X-ray Equipment - Other
1	1	Service of X-ray Equipment - Superficial X-ray Therapy
6	14	Special Purpose Enclosed X-ray Equipment
1	1	Static Detection
0	1	Static Electricity Measurement
0	2	Static Elimination
1	1	Storage (Apparatus)
5	11	Storage (Substances)
5	20	Transilluminators
63	125	Transport
0	1	X-ray Analysis
0	1	X-ray Analysis (Research)
19	58	X-ray Analysis - Use
100	263	X-ray Analysis - Use and Service (Restricted)
0	1	X-ray Irradiator

Attachment 7 (cont)

Purposes for Registrations and Exemptions from Registration

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

A *Granted or renewed in 2013*
B *Total current*

A	B	Purpose
7	14	Bone Densitometry
7	22	Bone Densitometry (Exemption)
26	68	Cabinet X-ray Equipment
1	1	Cyclotron Operation
0	1	Disposal of Radioactive Waste – Mt Walton East IWDF
2	4	Education (Apparatus)
4	9	Education (Substances)
2	5	Education - Demonstration Radioactive Sources
1	2	Education - Demonstration Radioactive Sources (Exemption)
3	4	Education - Demonstration Sources
2	3	Fluoroscopy - Medical
1	2	Gamma Irradiator
49	139	Gauges - Industrial
0	4	Gauges - Level (CO2)
10	20	Gauges - Logging
19	44	Gauges - Moisture and/or Density (Portable)
1	7	Gauges - Other (Apparatus)
3	7	Gauges - Other (Substances)
1	6	Lasers - Acupuncture
0	6	Lasers - Chiropractic
31	82	Lasers - Dental
2	2	Lasers - Educational
3	15	Lasers - Entertainment
8	36	Lasers - Industrial
1	1	Lasers - Manufacture
42	96	Lasers - Medical
14	38	Lasers - Physiotherapy
5	5	Lasers - Podiatry
2	5	Lasers - Research
1	6	Lasers - Sale, Service, Maintenance and Testing
0	4	Lasers - Storage
1	2	Lasers - Veterinary
0	2	Manufacture of X-ray Equipment

A	B	Purpose
43	104	Medical Radiology
0	2	Non-Medical Irradiation
7	25	Nuclear Medicine
3	9	Nuclear Medicine - CT (X-ray)/SPECT
0	1	Nuclear Medicine - Veterinary
2	10	Pathology Tests
2	11	Portable Mineral Analysers
44	139	Portable Mineral Analysers (X-ray)
1	11	Radioactive Ores - Analytical Laboratories
4	11	Radioactive Ores - Exploration
11	34	Radioactive Ores - Mining and/or Processing
5	10	Radioactive Substances - Calibration Sources
0	2	Radioactive Substances - Medical
3	7	Radioactive Substances - Sale
0	2	Radioactive Substances - Service of Devices
1	2	Radioactive Substances - Tracer Studies (Industry)
7	14	Radiography - Chest Screening
20	50	Radiography - Chiropractic
0	0	Radiography - Chiropractic (Referrals)
247	643	Radiography - Dental
0	1	Radiography - Forensic
8	22	Radiography - Industrial (Gamma)
8	24	Radiography - Industrial (X-ray)
5	11	Radiography - Mammography Screening
0	0	Radiography - Medical (GP Extended)
26	51	Radiography - Medical (Operator)
11	19	Radiography - Medical (Unrestricted)
30	69	Radiography - Medical Ancillary (Referrals)
1	1	Radiography - Physiotherapy Referrals
0	0	Radiography - Podiatry Referrals
0	1	Radiography - Security
75	211	Radiography - Veterinary
0	1	Radiography - Veterinary (Hospitals)
1	1	Radioguidance - Medical (Radioactive Substances)
0	3	Radiology - Veterinary
0	2	Radiopharmaceutical Manufacture and Dispensing
1	5	Radiotherapy - Medical (Apparatus)
1	9	Radiotherapy - Medical (Substances)
0	1	Radiotherapy - Medical Superficial
0	1	Radiotherapy - Veterinary (Apparatus)
0	2	Regulatory Authority
1	6	Research (Substances)

A	B	Purpose
3	13	Research - Unsealed Radioactive Substances
2	5	Research - X-ray
0	5	Sale of Electronic Products
6	22	Sale of X-ray Equipment
3	5	Secondary Schools - Demonstration Sources
11	28	Secondary Schools - Demonstration Sources (Exemption)
18	44	Security of Radioactive Sources
3	16	Service of X-ray Equipment
1	1	Smoke Detectors - Sale
9	26	Solaria - Possession and Operation
2	6	Special Purpose Enclosed X-ray Equipment
1	1	Static Electricity Measurement
1	3	Static Elimination
6	23	Storage (Apparatus)
9	26	Storage (Substances)
3	14	Transilluminators
6	10	Transport
2	5	X-ray Analysis
34	102	X-ray Analysis - Use
1	1	X-ray Irradiator

ABBREVIATIONS

General Terminology

AHMC	Australian Health Ministers' Conference
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
CBVT	Cone Beam Volumetric Tomography
CT	Computed Tomography
CT/SPECT	Computed Tomography/Single-Photon Emission Computed Tomography
DMP	Western Australian Department of Mines and Petroleum
DSA	Digital Subtraction Angiography
HDR	High Dose Rate
MIT	Medical Imaging Technologist
MoU	Memorandum of Understanding
NDT	Non-Destructive Testing
NMSF	National Mines Safety Framework
PET	Positron Emission Tomography
RHC	Radiation Health Committee
SCER	Standing Council on Energy and Resources
TLD	Thermo-Luminescent Dosimeter
WACHS	Western Australian Country Health Services

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)

REPORT OF THE

RADIOLOGICAL COUNCIL

for the year ended

31 December 2014

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 ten times in 2014.

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.

The only exception is Council's Chiropractic Advisory Committee which is appointed to supervise the radiation safety examination for chiropractors who wish to apply for licences to operate diagnostic x-ray equipment. The committee, which also advises Council on other chiropractic matters, met once in 2014.

ADMINISTRATIVE SUPPORT

Section 10(4) of the Act provides for the administration of the Act to be paid out of moneys 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 L Dahlskog (Senior Health Physicist) or Mrs M Aerts (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, 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 (Transport of Radioactive Substances) Regulations.

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 74 incidents during 2014 which are presented in the tables below. The majority of incidents were caused by human error and the failure to follow protocol.

Incident	**Occurrences**	**Category**
Radiology		
Incorrect patient imaged due to incorrect patient name being entered on request form	4	Human error - other
Incorrect patient imaged	3	Human error - failure to follow protocol
Incorrect anatomical site imaged – failure to check request form	11	Human error - failure to follow protocol
Incorrect anatomical site imaged	1	Protocol followed – referral form incorrect
Patient found to be pregnant following imaging.	6	Protocol followed – patient identified as not being pregnant
Duplicate procedure required – incorrect image receptor used	1	Human error - failure to follow protocol
Duplicate procedure – multiple request forms provided	3	Human error - other
CT examination conducted on staff member without referral and by radiotherapist	1	Human error - failure to follow protocol
Industrial		
Industrial radiography equipment left unattended	1	Human error - failure to follow protocol
Stolen x-ray equipment	1	Theft

Incident	Occurrences	Category
Borehole logging source stuck in borehole	4	Equipment malfunction/unavoidable – source retrieved
Fixed gauge not isolated properly before relocation	1	Human error – failure to follow protocol
Portable gauge struck by slow moving vehicle	1	Human error – failure to follow protocol
Nuclear Medicine		
Incorrect radiopharmaceutical administered	3	Human error - failure to follow protocol
Incorrect activity of radiopharmaceutical administered	1	Human error in calculating dose correctly
Incorrect patient	1	Human error - failure to follow protocol
Accumulation of radiopharmaceutical at incorrect site	1	Protocol followed – occurred due to unforeseen clinical reason
Patient found to be pregnant following procedure	2	Protocol followed – patient advised not pregnant
Radiopharmaceutical administered but scan not performed	2	Protocol followed – patient did not proceed with procedure.
Radiopharmaceutical administered but scan not performed	2	Protocol followed – study abandoned as patient unable to stay still
Radiopharmaceutical administered but scan not performed	5	Late cancellation of procedures/ inadequate communication with nuclear medicine
Extravasation of radiopharmaceutical	3	Protocol followed – IV administration failed after successful cannulation flush
Incorrectly labelled pharmaceutical provided	3	Human error - failure to follow protocol. 3 patients affected before recall of pharmaceutical.
Other		
Abnormal and unplanned exposure – dose rate in excess of dose constraint	2	Human error - failure to follow protocol

Incident	Occurrences	Category
Dose received by personal monitoring device but not by wearer	10	Failure to adequately secure or appropriately store monitoring device
High extremity dose received in preparation of radiopharmaceuticals	1	Protocol followed – action to be taken to reduce doses

PROSECUTIONS

No prosecutions were initiated or finalised in 2014.

MEDICAL AND RELATED RADIATION MATTERS

Compliance Testing

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

No 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.

The number of compliance tests of diagnostic x-ray equipment received by Council in 2014 was 1301. A summary of the statistics for the compliance program per type of diagnostic medical imaging equipment 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.

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 2014.

Research Project Title
Outcomes and predictors of efficacy of palliative radiotherapy in patients with malignant pleural mesothelioma.
Determining prognosis and treatment response: novel imaging modalities for Glioblastoma
A double blind randomised placebo controlled 2x2 factorial trial of the effect of Vitamin K and Colchicine on Vascular Calcification Activity in subjects with Diabetes Mellitus: The ViKCoVaC Diabetes Study: The ViKCoVac Diabetes Study
A double blind, randomised, placebo controlled phase III study of nintedanib plus best supportive care (BSC) versus placebo plus BSC inpatients with colorectal cancer refractory to standard therapies. (LUME-Colon 1)
A Phase 3, Randomised, Open-Label Study of Nivolumab Combined with Ipilimumab versus Sunitinib Monotherapy in Subjects with Previously Untreated, Advanced or Metastatic Renal Cell Carcinoma.

Commissioning of first CyberKnife System in Australia

In 2014, the first CyberKnife System was commissioned in Australia in a medical facility in Western Australia. CyberKnife is a fully robotic linear accelerator system used for radiation therapy in treating both cancerous and non-cancerous tumours and other conditions.

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. The number of compliance tests *received* by the Council in 2014 was 586. A summary of compliance tests *assessed* in 2014 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 2014, Council officers marked 632 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 and Petroleum (DMP).

During 2014 a brochure, *Transporting Uranium Oxide in WA*, was jointly produced by Council and DMP. This is available on the DMP website at – www.dmp.wa.gov.au/documents/Transporting_Uranium_Oxide_in_WA.pdf.

Memorandum of Understanding with the Department of Mines and Petroleum

The Memorandum of Understanding (MoU) that was being developed with the Department of Mines and Petroleum (DMP) was finalised and in 2013.

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

The decisions and outcomes of the RLC do not limit the statutory obligations and decision making of each agency. At least two representatives of the Radiological Council and the Department of Mines and Petroleum need to be present at each meeting.

Four meetings were held in 2014.

MISCELLANEOUS

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 2014 is in attachment 5.

National Directory for Radiation Protection

At the Australian Health Ministers' Conference (AHMC) 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 2014 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), the Commonwealth Government's radiation safety agency in Victoria.

- New Zealand National Radiation Laboratory, the New Zealand national radiation safety organisation
  (Australian agent: Australian Radiation Services Pty Ltd, Victoria).

- Australian Radiation Services Pty Ltd, a company based in Victoria.

- Landauer Inc (USA) for the Luxel based system.

- Global Dosimetry Solutions, a company based in USA.

- Global Medical Solutions Australia, a company based in NSW.

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, transilluminators and sun tanning units used for commercial purposes.

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 2014 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. 37 Temporary Permits were current as at 31 December 2014.

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 2014.

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
Compliance Testing of Diagnostic X-ray Equipment
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 13TH 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	Mr J O'Donnell
Prof J McKay	Tertiary Institutions representative	A/Prof Z Sun
Mr G Scott	Medical Radiation Technologist	Mr C Whennan
Mr G Fee	Expert in Mining Radiation Hazards	
Mr C Dillon (resigned during 2014)	Expert in Mining Radiation Hazards	
Mr B Cobb	Co-opted member	not applicable
Mr N Tsurikov	Co-opted member	not applicable

2014 MEETING ATTENDANCE

	18 FEB	11 MAR	8 APR	20 MAY	8 JUL	12 AUG	9 SEP	14 OCT	11 NOV	11 DEC
Dr A Robertson	✓	✓	✓	✓	✓	✓	A	✓	✓	✓
Dr R Fox	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Dr G Groom	✓	✓	✓	✓	✓	✓	✓	✓	D	✓
Dr C Hewavitharana	A	✓	✓	A	✓	✓	A	✓	✓	A
Mr M Ross	✓	✓	A	✓	A	✓	✓	✓	✓	✓
Prof J McKay	✓	✓	✓	✓	A	A	✓	✓	D	✓
Mr B Cobb	✓	✓	✓	A	✓	✓	✓	✓	✓	✓
Mr N Tsurikov	A	✓	✓	A	✓	A	A	✓	A	✓
Mr G Fee	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mr C Dillon	A	A	A	A	A	R	R	R	R	R
Mr G Scott	A	✓	A	✓	A	✓	A	✓	✓	A

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

Attachment 2: Legislation Amendments

RADIATION SAFETY ACT

Statutes (Repeals and Minor Amendments) Act 2014 s. 33

Amendments to definitions (Section 4).

Government Gazette 5 September 2014 pages 3213.

RADIATION SAFETY (GENERAL) REGULATIONS

Radiation Safety (General) Amendment Regulations 2014

Amendment to fees (Schedule XV).

Government Gazette 30 December 2014 pages 5501-3.

RADIATION SAFETY (TRANSPORT OF RADIOACTIVE SUBSTANCES) REGULATIONS

None

RADIATION SAFETY (QUALIFICATIONS) AMENDMENT REGULATIONS

Radiation Safety (Qualifications) Amendment Regulations 2014

Amendment to fees (Schedule 2).

Government Gazette 30 December 2014 pages 5503-4.

Attachment 3: Compliance Testing

Medical

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

Category	A	B	C	Total
CT	49	-	1	50
Dental – intraoral	620	-	8	628
Dental – panoramic and/or cephalometric	136	-	-	136
Fluoroscopic – fixed	36	-	11	47
Fluoroscopic – fixed C or U arm	24	-	4	28
Fluoroscopic – mobile	117	-	8	125
Mammography	63	-	1	64
Radiographic – fixed	120	1	16	137
Radiographic – mobile	83	-	3	86
Total	1248	1	82	1301

Industrial – Fixed Gauges

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

Category	A	B	Total
Density	268	185	453
In-stream analysis	12	0	12
Level	46	94	140
Total	326	279	605

[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 63 re-tests conducted during 2014, 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. Of the 12 re-tests conducted during 2014, 100% resulted in the equipment being granted a compliance certificate.

Attachment 4: Industrial Radiation Safety Examinations

Current at 31 December 2014

Category	2014	2013	2012	2011	2010
Borehole Logging	29	16	37	67	78
Fixed Gauges	153	108	118	138	95
Gamma Irradiator	0	0	0	0	3
Industrial Radiography	73	63	67	24	36
Industrial Radiography (Advanced)	16	31	9	0	0
Industrial Radiography (Assistant)	237	194	121	123	86
Portable Gauges	46	92	233	137	65
Portable Gauges (WA Requirements)	14	8	19	28	19
Transport	17	21	31	17	26
Service – Cabinet X-ray	5	2	1	4	1
Service – Industrial Radiography (X-ray)	0	0	0	0	0
Service – X-ray Analysis	0	0	2	0	3
X-ray Analysis – Use	0	5	11	15	6
X-ray Analysis – Use and Restricted Service	42	57	62	69	47
Total	632	597	711	622	465

Attachment 5: List of Australian Radiation Protection and Nuclear Safety Agency publications for 2014

	Title
RPS F-1	Fundamentals for Protection Against Ionising Radiation (2014)
RPS C-2	Code for the Safe Transport of Radioactive Material (2014)

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

Current at 31 December 2014

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

Category	A	B
Bone densitometry	50	-
Cabinet x-ray equipment	148	-
Calibration	2	479
CT	127	-
CT/SPECT	15	-
Dental – cone beam CT	8	-
Dental – intraoral	2070	-
Dental – panoramic and/or cephalometric	394	-
Education and research	19	1040
Fluoroscopic – fixed	92	-
Fluoroscopic – mobile	140	-
Gauges – density/level	4	2913
Gauges – in stream analysis	1	77
Gauges – logging	22	406
Gauges – neutron moisture/density portable	-	463
Gauges – other	-	246
Irradiator	-	48
Isotope Production	1	-
Laser – entertainment	92	-
Laser – industrial	115	-
Laser – medical	269	-
Laser – other medical	190	-
Laser – Podiatry	7	
Laser – research	163	-
Linear accelerator	20	-
Mammography	84	-
Non-destructive testing	151	113
Non-destructive testing – crawler control	-	17
Portable mineral analyser	-	10
Radiographic – fixed	352	-
Radiographic – mobile	408	-

[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	-	113
Simulator	2	-
Special purpose x-ray	44	-
Static detection/measurement	-	3
Static elimination	-	8
Storage	-	259
Sun Tanning Unit	71	-
Superficial radiotherapy	3	-
Test source	3	1
Therapy	2	26
Therapy – HDR brachytherapy	-	2
Transilluminator	115	-
Tracer Studies	-	27
X-ray analysis	497	-
Total	5681	6251

Attachment 7: Licences and Registrations

Current at 31 December 2014

Including individual exemptions granted under Section 6 of the Act.

	X-ray and/or Electronic Products		Radioactive Substances		TOTAL	
	2014	2013	2014	2013	2014	2013
Licences	5000	4711	2315	2218	7315	6929
Registrations	1753	1655	404	384	2157	2039
TOTAL	6753	6366	2719	2602	9472	8968
Change from 2013	+ 6.1%		+ 4.5%		+ 5.6%	

Attachment 7 (cont)

Purposes for Licences and Exemptions from Licence

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

A *Granted or renewed in 2014*
B *Total current*

A	B	Purpose
10	16	Bone Densitometry
0	7	Bone Densitometry (Exemption)
24	69	Cabinet X-ray Equipment
1	1	Cobalt Teletherapy Maintenance
23	51	Compliance Testing - Diagnostic X-ray Equipment
24	105	Compliance Testing - Radioactive Gauges
1	5	Cyclotron Operation
1	4	Cyclotron Servicing
1	3	Education (Apparatus)
13	28	Education (Substances)
139	373	Fluoroscopy - Medical
53	130	Fluoroscopy - Medical (Exemption)
8	27	Fluoroscopy - Medical (Non-Specialist Exemption)
11	11	Fluoroscopy - Podiatry
1	1	Fluoroscopy - Research
0	1	Fluoroscopy - Veterinary
1	2	Gamma Irradiator - Use
165	435	Gauges - Industrial
3	8	Gauges - Industrial (Installation)
1	2	Gauges - Level (CO2)
169	393	Gauges - Logging
216	627	Gauges - Moisture and/or Density (Portable)
2	6	Gauges - Other (Apparatus)
11	27	Gauges - Other (Substances)
0	4	Installation of X-ray Equipment
4	7	Installation of X-ray Equipment - Dental
3	5	Lasers - Acupuncture
0	8	Lasers - Chiropractic
58	137	Lasers - Dental
2	7	Lasers - Educational
8	22	Lasers - Entertainment
21	70	Lasers - Industrial
100	254	Lasers - Medical
50	98	Lasers - Physiotherapy

A	B	Purpose
13	22	Lasers - Podiatry (Exemption)
17	42	Lasers - Research
17	60	Lasers - Service
0	3	Lasers - Veterinary
1	2	Manufacture of X-ray Equipment
2	2	Medical Physics
4	12	Medical Physics - Radiotherapy (Apparatus)
1	7	Medical Physics - Radiotherapy (Substances)
21	68	Medical Radiation Technology - Diagnostic Nuclear
402	1 106	Medical Radiation Technology - Medical Imaging
56	173	Medical Radiation Technology - Radiation Therapy Irradiating Apparatus
104	261	Medical Radiology
2	3	Non-Medical Irradiation
0	0	Nuclear Medicine - Calibration and QC Sources
5	31	Nuclear Medicine - Diagnostic
5	31	Nuclear Medicine - Therapeutic
1	3	Nuclear Medicine - Veterinary
0	5	Pathology (in vitro) – Sealed Sources
2	10	Pathology Tests
9	31	Portable Mineral Analysers
106	289	Portable Mineral Analysers (X-ray)
3	9	Possession of X-ray Equipment - Diagnostic Medical
2	4	Possession of X-ray Equipment - Diagnostic Medical and Dental
1	1	Quality Assurance Procedures
8	29	Radioactive Ores - Analytical Laboratories
7	12	Radioactive Ores - Exploration
6	17	Radioactive Ores - Mining and/or Processing
2	8	Radioactive Substances - Calibration Sources
0	1	Radioactive Substances - Medical
14	38	Radioactive Substances - Sale
9	32	Radioactive Substances - Service of Devices
0	1	Radioactive Substances - Tracer Studies
8	15	Radioactive Substances - Tracer Studies (Industry)
0	0	Radiography - Chiropractic (Exemption)
6	34	Radiography - Chiropractic (Extended)
69	178	Radiography - Chiropractic (Restricted)
159	441	Radiography - Industrial (Gamma)
163	438	Radiography - Industrial (X-ray)
0	1	Radiography - Medical (Direction and Supervision)
2	2	Radiography - Security
231	632	Radiography - Veterinary

A	B	Purpose
0	2	Radioguidance - Medical (Radioactive Substances)
3	9	Radiology - Veterinary
4	13	Radiopharmaceutical Manufacture and Dispensing
5	19	Radiotherapy - Medical (Apparatus)
4	20	Radiotherapy - Medical (Substances)
1	5	Radiotherapy - Medical Superficial
0	2	Radiotherapy - Veterinary (Apparatus)
5	11	Research
23	67	Research - Unsealed Radioactive Substances
1	3	Research - X-ray
14	35	Sale of Electronic Products
31	85	Sale of X-ray Equipment
10	22	Service of X-ray Equipment - Analytical
13	31	Service of X-ray Equipment - Dental
38	101	Service of X-ray Equipment - Diagnostic
2	11	Service of X-ray Equipment - Diagnostic (Extended)
1	5	Service of X-ray Equipment - Industrial NDT
0	1	Service of X-ray Equipment - Intraoral
4	14	Service of X-ray Equipment - Linear Accelerators
19	22	Service of X-ray Equipment - Other
0	1	Service of X-ray Equipment - Superficial X-ray Therapy
6	16	Special Purpose Enclosed X-ray Equipment
0	1	Static Detection
1	1	Static Electricity Measurement
1	2	Static Elimination
0	1	Storage (Apparatus)
1	12	Storage (Substances)
12	24	Transilluminators
33	130	Transport
0	1	X-ray Analysis
1	1	X-ray Analysis (Research)
23	61	X-ray Analysis - Use
98	279	X-ray Analysis - Use and Service (Restricted)
0	1	X-ray Irradiator

Attachment 7 (cont)

Purposes for Registrations and Exemptions from Registration

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

A *Granted or renewed in 2014*
B *Total current*

A	B	Purpose
10	18	Bone Densitometry
8	21	Bone Densitometry (Exemption)
29	73	Cabinet X-ray Equipment
0	1	Cyclotron Operation
1	1	Disposal of Radioactive Waste – Mt Walton East IWDF
1	4	Education (Apparatus)
2	9	Education (Substances)
1	5	Education - Demonstration Radioactive Sources
1	2	Education - Demonstration Radioactive Sources (Exemption)
0	9	Education - Demonstration Sources
1	3	Fluoroscopy - Medical
1	2	Gamma Irradiator
44	140	Gauges - Industrial
0	4	Gauges - Level (CO2)
8	21	Gauges - Logging
16	51	Gauges - Moisture and/or Density (Portable)
4	9	Gauges - Other (Apparatus)
1	7	Gauges - Other (Substances)
2	5	Lasers - Acupuncture
1	6	Lasers - Chiropractic
28	92	Lasers - Dental
0	2	Lasers - Educational
9	22	Lasers - Entertainment
10	35	Lasers - Industrial
0	1	Lasers - Manufacture
34	106	Lasers - Medical
1	2	Lasers - Other
12	40	Lasers - Physiotherapy
4	8	Lasers - Podiatry
0	5	Lasers - Research
3	6	Lasers - Sale, Service, Maintenance and Testing
1	5	Lasers - Storage
0	4	Lasers - Veterinary

A	B	Purpose
1	2	Manufacture of X-ray Equipment
40	111	Medical Radiology
1	2	Non-Medical Irradiation
9	26	Nuclear Medicine
5	14	Nuclear Medicine - CT (X-ray)/SPECT
1	1	Nuclear Medicine - Veterinary
3	9	Pathology Tests
1	9	Portable Mineral Analysers
57	159	Portable Mineral Analysers (X-ray)
4	11	Radioactive Ores - Analytical Laboratories
4	11	Radioactive Ores - Exploration
8	34	Radioactive Ores - Mining and/or Processing
6	10	Radioactive Substances - Calibration Sources
0	2	Radioactive Substances - Medical
4	8	Radioactive Substances - Sale
2	2	Radioactive Substances - Service of Devices
0	2	Radioactive Substances - Tracer Studies (Industry)
6	14	Radiography - Chest Screening
17	49	Radiography - Chiropractic
0	0	Radiography - Chiropractic (Referrals)
258	688	Radiography - Dental
0	1	Radiography - Forensic
7	22	Radiography - Industrial (Gamma)
10	23	Radiography - Industrial (X-ray)
2	13	Radiography - Mammography Screening
0	0	Radiography - Medical (GP Extended)
18	52	Radiography - Medical (Operator)
8	22	Radiography - Medical (Unrestricted)
26	70	Radiography - Medical Ancillary (Referrals)
0	1	Radiography - Physiotherapy Referrals
0	0	Radiography - Podiatry Referrals
1	1	Radiography - Security
68	214	Radiography - Veterinary
1	1	Radiography - Veterinary (Hospitals)
1	1	Radioguidance - Medical (Radioactive Substances)
2	3	Radiology - Veterinary
1	2	Radiopharmaceutical Manufacture and Dispensing
1	1	Radiotherapy - Medical (Apparatus)
4	10	Radiotherapy - Medical (Substances)
3	6	Radiotherapy - Medical (X-rays)
1	1	Radiotherapy - Medical Superficial
0	1	Radiotherapy - Veterinary (Apparatus)

A	B	Purpose
2	2	Regulatory Authority
2	6	Research (Substances)
5	12	Research - Unsealed Radioactive Substances
0	5	Research - X-ray
2	5	Sale of Electronic Products
8	21	Sale of X-ray Equipment
3	7	Secondary Schools - Demonstration Sources
8	27	Secondary Schools - Demonstration Sources (Exemption)
18	45	Security of Radioactive Sources
10	17	Service of X-ray Equipment
0	1	Smoke Detectors - Sale
13	26	Solaria - Possession and Operation
2	7	Special Purpose Enclosed X-ray Equipment
0	1	Static Electricity Measurement
1	2	Static Elimination
9	27	Storage (Apparatus)
9	28	Storage (Substances)
6	14	Transilluminators
1	10	Transport
2	7	X-ray Analysis
36	105	X-ray Analysis - Use
0	1	X-ray Irradiator

ABBREVIATIONS

General Terminology

AHMC	Australian Health Ministers' Conference
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
CBVT	Cone Beam Volumetric Tomography
CT	Computed Tomography
CT/SPECT	Computed Tomography/Single-Photon Emission Computed Tomography
DMP	Western Australian Department of Mines and Petroleum
DSA	Digital Subtraction Angiography
HDR	High Dose Rate
MIT	Medical Imaging Technologist
MoU	Memorandum of Understanding
NDT	Non-Destructive Testing
NMSF	National Mines Safety Framework
PET	Positron Emission Tomography
RHC	Radiation Health Committee
SCER	Standing Council on Energy and Resources
TLD	Thermo-Luminescent Dosimeter
WACHS	Western Australian Country Health Services

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)

REPORT OF THE

RADIOLOGICAL COUNCIL

for the year ended

31 December 2015

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 2015.

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.

The only exception is Council's Chiropractic Advisory Committee which is appointed to supervise the radiation safety examination for chiropractors who wish to apply for licences to operate diagnostic x-ray equipment. The committee, which also advises Council on other chiropractic matters, met once in 2015.

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 L Dahlskog (Senior Health Physicist) or Mrs M Aerts (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 2015 are listed in attachment 2.

No amendments were made to the Radiation Safety Act and the Radiation Safety (Transport of Radioactive Substances) Regulations in 2015.

PROSECUTIONS

No prosecutions were initiated or finalised in 2015.

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 34 incidents during 2015 which are presented in the tables below. The majority of incidents were caused by human error and the failure to follow protocol.

Incident	**Occurrences**	**Category**
Radiology		
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	3	Human error – other
Incorrect anatomical site imaged – failure to check request form	3	Human error – failure to follow protocol
Patient found to be pregnant following imaging.	2	Protocol followed – patient identified as not being pregnant
Dose received by staff members	1	Human Error – failure to heed warning signs
Radiotherapy		
An overdose to the site greater than 2% higher than planned.	1	Human error – fault identified after the first 3 of a total of 4 treatments.
Unauthorised diagnostic x-ray procedure of a staff member by another staff member	1	Human error – failure to follow protocol

Industrial		
Borehole logging source stuck in borehole	1	Equipment malfunction/unavoidable – source retrieved
Temporary loss of control of a radioactive source	1	Human error – failure to follow protocol. Source recovered.
Nuclear Medicine		
Incorrect radiopharmaceutical administered	2	Human error – failure to follow protocol
Incorrect activity of radiopharmaceutical administered	3	Human error – failure to follow protocol
Incorrect activity of radiopharmaceutical administered	5	Human error – equipment malfunction
Incorrect activity of radiopharmaceutical administered	1	Human error in setting up equipment calibration.
Radiopharmaceutical administered but scan not performed	1	Protocol followed – patient did not proceed with procedure.
Radiopharmaceutical administered but scan not performed	1	Protocol followed – patient's status changed rapidly and the diagnostic test was no longer required.
Extravasation of radiopharmaceutical	1	Protocol followed – IV administration failed after successful cannulation flush
Delay in intended imaging associated with the need to take the patient to surgery	1	Human error – inadequate communication between teams
Loss of small radioactive source in human tissue	1	Human error – the small source was misidentified
Other		
Excessive discharge of radioactive effluent	1	Equipment malfunction
Dose received by personal monitoring device but not by wearer	2	Failure to adequately secure or appropriately store monitoring device
Transport incident – transport package damaged at warehouse	1	Human error – radioactive source undamaged and able to be used by consignee.

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 2015 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.

Laser Regulatory Options

During 2015 Council was requested to consider whether it wishes its officers to conduct a review of the training and qualification prerequisites for the use of lasers for cosmetic purposes. Council asked its officers to conduct the review which was not finalised in 2015

Ban on the Use of Solaria for Commercial Sun tanning

In 2015, the Minister announced that a ban on commercial sun tanning units will take effect on 1 January 2016. Following this announcement, the Council liaised with the Department of Health and progressed the development of an implementation plan for the ban, consideration of compensation options, disposal issues and consideration of a business assistance package.

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 2015.

Research Project Title
68Ga-PSMA PET-CT in biochemical relapse following primary treatment of Prostate Carcinoma (PCa)
A Multicentre Randomized Phase II Trial Comparing NAB Paclitaxel v Paclitaxel in Patients with Advanced Urothelial Cancer Progressing on or after a Platinum Containing Regimen.
A 24-month, Multicentre, Randomized, Double-blind, Placebo-controlled, Parallel group, Efficacy, Safety, Tolerability, Biomarker, and Pharmacokinetic Study of AZD3293 in Early Alzheimer's Disease (AMARANTH Study)
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 B-Cell Lymphoid Malignancies
A randomised, multi-centre, open-label, phase III study of adjuvant Lapatanib, Trastuzumab, their sequence and their combination in patients with HER2/ErbB2 positive primary breast cancer.
A phase III, randomised, double-blind, placebo-controlled, parallel-group, multicentre efficacy and safety study of gantenerumab in participants with mild Alzheimer's disease

Research Project Title
A Phase 3 Randomised, Double-blind, Placebo-controlled Study to Assess the Safety and Efficacy of S-888711 (Lusutrombopag) for the Treatment of Thrombocytopenia in Patients with Chronic Liver Disease Undergoing Elective Invasive Procedures.
Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of Ramucirumab and Best Supportive Care (BSC) Versus Placebo and BSC as Second-Line Treatment in Patients with Hepatocellular Carcinoma and Elevated Baseline Alpha-Fetoprotein (AFP) Following First-Line Therapy with Sorafenib.
Adaptive Radiotherapy for Head and Neck Cancer, Feasibility and Clinical Implications
A Phase 3, Randomized, Efficacy and Safety Study of Enzalutamide Plus Leuprolide, Enzalutamide Monotherapy, and Placebo Plus Leuprolide in Men with High Risk Non-metastatic Prostate Cancer Progressing after Definitive Therapy.
Multi-modality imaging and biomarkers to improve risk stratification for secondary prevention after acute coronary syndrome.
Comparison of HBED and DOTAGA conjugated 68Ga PSMA ligands: diagnostic efficacy and biodistribution in prostate cancer (PCa).
An Open-label, Randomized, Phase 3 Study of Nivolumab or Chemotherapy in Subjects with Relapsed Small-Cell Lung Cancer after Platinum-base First Line Chemotherapy (CheckMate 331).
A Phase 3, Randomised, Open-Label Study of Nivolumab Combined with Ipilimumab versus Sunitinib Monotherapy in Subjects with Previously Untreated, Advanced or Metastatic Renal Cell Carcinoma.
A Phase III Double Blind Placebo Controlled Randomized Study of Adjuvant MED14736in Completely Resected Non-Small Cell Lung Cancer. Protocol Number: BR.31/CTC0154/ALTG14/001
A Clinical Evaluation of the Medtronic Polymer-Free Drug-Eluting Coronary Stent System in De Novo Native Coronary Artery Lesions.
An Open-label, Randomised, Phase 3 Study of Nivolumab or Nivlumab plus Ipilimumab, versus platinum doublet chemotherapy in Subjects with Chemotherapy-Naïve Stage IV or Recurrent Non-Small Cell Lung Cancer (NSCLC) (CheckMate 227).

Research Project Title
A Phase II/III Randomised, Double-Blind, Placebo-Controlled Multi-Centre Study of 2 Potential Disease Modifying Therapies in Individuals at Risk for and with Dominantly Inherited Alzheimer's Disease.
A Phase 3 Multicenter, Randomised, Double Blind, Placebo Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Aducanumab (BIIB037) in subjects with Early Alzheimer's Disease.
A Phase III, randomized, double-blind, controlled, multicentre study of intravenous PI3K inhibitor copanlisib in combination with standard immunochemotherapy versus standard immunochemotherapy in patients with relapsed indolent non-Hodgkin's lymphoma (iNHL).
Multi-modality imaging and biomarkers to improve risk stratification for secondary prevention after acute coronary syndrome.
A double blind randomised placebo controlled 2x2 factorial trial of the effect of Vitamin K and Colchicine on Vascular Calcification Activity in subjects with Diabetes Mellitus: The ViKCoVac Diabetes Study
A Randomised, Multi-centre Phase III Study of Nivolumab versus Sorafenib as First –line Treatment in Patients with Advanced Hepatocellular Carcinoma.
A Phase 3 Multicenter, Randomised, Double Blind, Placebo Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Aducanumab (BIIB037) in subjects with Early Alzheimer's Disease.
Dose Optimization Study of Idelalisib in Follicular Lymphoma and Small Lymphocytic Lymphoma (Gilead GS-US-313-1580)
The Australian SHAM controlled clinical trial of Renal DeNervation in patients with resistant hypertension (AUSHAM-RDN)

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 compliance tests assessed in 2015 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 2015, Council officers marked 459 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 and Petroleum (DMP).

Memorandum of Understanding with the Department of Mines and Petroleum

A Memorandum of Understanding (MoU) has existed with the Department of Mines and Petroleum (DMP) 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 DMP and the Radiological Council.

The decisions and outcomes of the RLC do not limit the statutory obligations and decision making of each agency. At least two representatives of the Radiological Council and the Department of Mines and Petroleum need to be present at each meeting. DMP advised that it would like to amend the functions and composition of the RLC in order to streamline its functionality.

Two meetings were held in 2015.

MISCELLANEOUS

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 2015 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 2015 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), the Commonwealth Government's radiation safety agency in Victoria.
- New Zealand National Radiation Laboratory, the New Zealand national radiation safety organisation
  (Australian agent: Australian Radiation Services Pty Ltd, Victoria).
- Australian Radiation Services Pty Ltd, a company based in Victoria.
- Landauer Inc (USA) for the Luxel based system.
- Global Dosimetry Solutions, a company based in USA.
- Global Medical Solutions Australia, a company based in NSW.

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, transilluminators and sun tanning units used for commercial purposes.

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 2015 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. 53 Temporary Permits were current as at 31 December 2015.

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 2015.[1]

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.

[1] A list of the purposes for both licences and registrations (and exemptions) are normally included in this attachment but could not be generated due to a technical error.

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	Mr J O'Donnell
Prof J McKay	Tertiary Institutions representative	A/Prof Z Sun
Mr G Scott	Medical Radiation Technologist	Mr C Whennan
Mr G Fee	Expert in Mining Radiation Hazards	Vacant
Mr B Cobb	Co-opted member	not applicable
Mr N Tsurikov	Co-opted member	not applicable
Vacant	Expert in Mining Radiation Hazards	Vacant

2015 MEETING ATTENDANCE

	10 FEB	17 MAR	12 MAY	9 JUN	18 AUG	20 OCT	10 NOV	8 DEC
Dr A Robertson	✓	✓	✓	A	✓	✓	✓	✓
Dr R Fox	✓	✓	✓	✓	✓	✓	✓	✓
Dr G Groom	✓	✓	✓	✓	✓	✓	✓	A
Dr C Hewavitharana	✓	✓	A	A	A	✓	✓	✓
Mr M Ross	✓	✓	✓	✓	✓	✓	✓	✓
Prof J McKay	✓	✓	✓	A	✓	✓	A	✓
Mr B Cobb	A	✓	✓	✓	✓	✓	✓	✓
Mr N Tsurikov	✓	A	✓	✓	A	✓	✓	✓
Mr G Fee	✓	✓	✓	✓	✓	A	A	✓
Mr G Scott	✓	✓	✓	✓	✓	✓	✓	A
Dr E Thomas (deputy for Dr Groom)								✓

✓ attended A apology NA not appointed at the time

Attachment 2: Legislation Amendments

RADIATION SAFETY ACT

None

RADIATION SAFETY (GENERAL) REGULATIONS

Radiation Safety (General) Amendment Regulations 2015

Amendment to fees (Schedule XV).

Government Gazette 19 May 2015 pages 1754-7.

Radiation Safety (General) Amendment Regulations (No. 2) 2015

Delete definitions and regulations associated with the commercial use of solariums.

Government Gazette 9 October 2015 pages 3982.

RADIATION SAFETY (QUALIFICATIONS) REGULATIONS

Radiation Safety (Qualifications) Amendment Regulations 2015

Amendment to fees (Schedule 2).

Government Gazette 19 May 2015 pages 1753-4.

RADIATION SAFETY (TRANSPORT OF RADIOACTIVE SUBSTANCES) REGULATIONS

None

Attachment 3: Compliance Testing

Medical

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

Category	A	B	C	Total
CT	68	-	2	70
Dental – intraoral	639	-	5	644
Dental – panoramic and/or cephalometric	148	-	-	148
Dental – cone beam CT	5	-	-	5
Fluoroscopic – fixed	31	-	7	38
Fluoroscopic – fixed C or U arm	23	-	1	24
Fluoroscopic – mobile	104	-	5	109
Radiographic – fixed	103	-	23	126
Radiographic – mobile	68	-	3	71
Mammography	44	-	1	45
Total	1233	0	47	1280

Industrial – Fixed Gauges

- **A** *Compliant*
- **B** *Non-compliant*[3]

Category	A	B	Total
Density	502	40	542
In-stream analysis	4	-	4
Level	51	12	63
Total	557	52	609

[2] 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 40 re-tests conducted during 2015, 98% resulted in the equipment being granted either a compliance or conditional compliance certificate.

[3] 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 2 re-tests conducted during 2015, 100% resulted in the equipment being granted a compliance certificate.

Attachment 4: Industrial Radiation Safety Examinations

Current at 31 December 2015

Category	2015	2014	2013	2012	2011
Borehole Logging	13	29	16	37	67
Fixed Gauges	125	153	108	118	138
Industrial Radiography	63	73	63	67	24
Industrial Radiography (Advanced)	19	16	31	9	0
Industrial Radiography (Assistant)	129	237	194	121	123
Portable Gauges	23	46	92	233	137
Portable Gauges (WA Requirements)	1	14	8	19	28
Transport	32	17	21	31	17
Service – Cabinet X-ray	4	5	2	1	4
Service – Industrial Radiography (X-ray)	0	0	0	0	0
Service – X-ray Analysis	3	0	0	2	0
X-ray Analysis – Use	0	0	5	11	15
X-ray Analysis – Use and Restricted Service	47	42	57	62	69
Total	459	632	597	711	622

Attachment 5: List of Australian Radiation Protection and Nuclear Safety Agency publications for 2015

Title
RPS G-1 Guide for Radiation Protection of the Environment (2015)

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

Current at 31 December 2015

A *Irradiating apparatus and electronic products*[4]
B *Radioactive substances (sealed sources only)*

Category	A	B
Bone densitometry	55	-
Cabinet x-ray equipment	162	-
Calibration	2	550
CT	132	-
CT/SPECT	15	-
Dental – cone beam CT	10	-
Dental – intraoral	2133	-
Dental – panoramic and/or cephalometric	412	-
Education and research	19	1053
Fluoroscopic – fixed	93	-
Fluoroscopic – mobile	142	-
Gauges – density/level	4	3196
Gauges – in stream analysis	-	81
Gauges – logging	31	432
Gauges – neutron moisture/density portable	-	469
Gauges – other	-	273
Irradiator	-	48
Isotope Production	1	-
Laser – entertainment	132	-
Laser – industrial	128	-
Laser – medical	273	-
Laser – other medical	201	-
Laser – Podiatry	9	
Laser – research	171	-
Linear accelerator	20	-
Mammography	81	-
Non-destructive testing	164	123
Non-destructive testing – crawler control	-	18
Portable mineral analyser	-	10
Radiographic – fixed	352	-
Radiographic – mobile	409	-

[4] 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	-	114
Simulator	3	-
Special purpose x-ray	46	-
Static detection/measurement	-	3
Static elimination	-	8
Storage	-	273
Sun Tanning Unit	0	-
Superficial radiotherapy	3	-
Test source	4	-
Therapy	2	25
Therapy – HDR brachytherapy	-	1
Transilluminator	119	-
Tracer Studies	-	27
X-ray analysis	535	-
Total	5863	6704

Attachment 7: Licences and Registrations

Current at 31 December 2015

Including individual exemptions granted under Section 6 of the Act.

	X-ray and/or Electronic Products		Radioactive Substances		TOTAL	
	2015	2014	2015	2014	2015	2014
Licences	5219	5000	2316	2315	7535	7315
Registrations	1800	1753	403	404	2203	2157
TOTAL	7019	6753	2719	2719	9738	9472
Change from 2014	+ 3.9%		-		+ 2.8%	

ABBREVIATIONS

General Terminology

ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
CT	Computed Tomography
CT/SPECT	Computed Tomography/Single-Photon Emission Computed Tomography
DMP	Western Australian Department of Mines and Petroleum
HDR	High Dose Rate
MIT	Medical Imaging Technologist
MoU	Memorandum of Understanding
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)

REPORT OF THE

RADIOLOGICAL COUNCIL

for the year ended

31 December 2016

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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 2016.

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.

The only exception is Council's Chiropractic Advisory Committee which is appointed to supervise the radiation safety examination for chiropractors who wish to apply for licences to operate diagnostic x-ray equipment. The committee, which also advises Council on other chiropractic matters, met once in 2016.

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. Mr L Dahlskog (Senior Health Physicist) and Mrs M Aerts (Health Physicist) performed these duties in Ms Upton's absence until their resignation on 30 June 2016.

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, the Radiation Safety (General) Regulations and the Radiation Safety (Qualifications) Regulations in 2016 are listed in attachment 2.

No amendments were made to the Radiation Safety (Transport of Radioactive Substances) Regulations in 2016.

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 47 incidents during 2016 which are presented in the tables below. The majority of incidents were in medical imaging due to a failure to follow protocol. A more detailed description of three of the more significant incidents of 2016 is provided below.

Incident	**Occurrences**	**Category**
Radiology		
Error in CT equipment or CT data analysis software requiring repeat imaging	2	Equipment Malfunction
Wrong patient imaged - failure to correctly identify patient against request form	7	Human error - failure to follow protocol
Wrong patient imaged due to incorrect patient name being entered on request form	2	Human error - other
Wrong patient imaged due to error in electronic request system and subsequent failure to check identity of patient	1	Equipment Malfunction & human error - failure to follow protocol
Wrong anatomical site imaged – failure to check request form	5	Human error - failure to follow protocol
Failure to confirm pregnancy status	2	Human error - failure to follow protocol
Wrong modality - failure to check request form	4	Human error - failure to follow protocol
Incorrect positioning of patient requiring repeat imaging	1	Human error - failure to follow protocol
Unauthorised operation of fluoroscopic x-ray equipment by nurse	1	Unauthorised use of equipment
Duplication of imaging due to operator administrative error	1	Human error - failure to follow protocol

Incident	Occurrences	Category
Triplication of imaging due to 3 different request forms being completed	1	Human error - failure to follow protocol
Failure to cancel imaging associated with cancelled surgery	1	Human error - other
Unauthorised operation of fluoroscopic x-ray equipment by surgeon	1	Unauthorised use of equipment
Radiotherapy		
Systemic error introduced in modelling electron beam of linear accelerator & not detected by quality assurance process. Affected 37 patients treatment plans over a period of ten years	1	Human error - failure to follow protocol & near miss
Failure to communicate temporary halt of treatment	1	Human error - failure to follow protocol
Use of new model of high dose rate brachytherapy unit resulted in delivery of radiation partially to wrong anatomical site	1	Human error - failure to follow protocol
Lasers		
Surgeon misjudged laser positioning and directed it on own finger	1	User injury
Activation of medical laser without others wearing personal protective equipment	1	Human error - failure to follow protocol
Industrial		
Industrial Radiographer failed to clear controlled area before exposure was performed	1	Human error - failure to follow protocol
Abandonment of logging source which was stuck in borehole	1	Equipment malfunction/unavoidable
Nuclear Medicine		
Wrong radiopharmaceutical administered	1	Human error - failure to follow protocol
Patient discharged before scan completed	2	Human error - failure to follow protocol
Out of date request form actioned – failure to notice date by administrative and imaging staff	1	Human error - failure to follow protocol
Failure of radiopharmaceutical dose dispenser infusion sets requiring repeat imaging	2	Equipment malfunction
Failure of laboratory to perform complete testing of sample resulting in patient dose for no benefit	1	Human error - failure to follow protocol

Incident	Occurrences	Category
Radiolabelling error by Radiochemist	3	Human error - failure to follow protocol
Other		
Abnormal and unplanned exposure – dose rate in excess of dose constraint	1	-

PROSECUTIONS

No prosecutions were initiated or finalised in 2016.

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.

The number of compliance tests of diagnostic x-ray equipment received by Council in 2016 was 1337. A summary of the statistics for the compliance program per type of diagnostic medical imaging equipment 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.

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 2016.

Research Project Title
A Phase 3, Randomised, Open-Label Study Evaluating the Efficacy and Safety of Idelalisib in Combination with Obinutuzumab Compared to Chlorambucil in Combination with Obinutuzumab for Previously Untreated Chronic Lymphocytic Leukaemia.
A Phase II, Study of Ibrutunib, Rituximaband mini-CHOP therapy in very elderly patients with newly diagnosed Diffuse Large B-Cell Lymphoma (DLBCL) – NHL29.
A Phase III open-label, multicentre trial of avelumab (MSB0010718C) as a third line treatment of unresectable, recurrent, or metastatic gastric or gastroesophageal junction adenocarcinoma.
A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Study of Crenezumab in Patients with Prodromal to Mild Alzheimer's Disease.
Protocol 54861911 ALZ2003: A phase 2b/3 Randomised, Double-blind, Placebo-Controlled, Parallel group, Multicenter Study Investigation the Efficacy and Safety of JNJ-54861911 in Subjects who are Asymptomatic at Risk for Developing Alzheimer's Dementia.
A Non-Randomised Study to Evaluate the Safety and Performance of the ARIATTM Emphysema Treatment System in Patients with Severe Emphysema with Hyperinflation of the Lung.

Research Project Title
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.
A Phase III open-label, multicentre trial of avelumab (MSB0010718C) versus continuation of first line treatment of unresectable, recurrent, or metastatic gastric or gastro-esophageal junction adenocarcinoma.
A Phase 3, Multicenter, Randomised, Double Blind Study of Bortezomib and Dexamthasone in combination with either Venetoclax or Placebo in subjects with Relapsed or Refractory Multiple Myeloma who are sensitive or naïve to Proteasome Inhibitors.
A Phase III open-label, multicentre trial of avelumab (MSB0010718C) versus platinum-base doublet as a first-line treatment of recurrent or Stage IV PD-L1+ non-small cell lung cancer.
A Phase 3 Open-Label, Randomised, Parallel, 2-Arm, Multi Centre Study of Talazoparib (BMN 673) versus Physician's Choice in Germline BRCA Mutation Subjects with Locally Advanced and/or Metastatic Breast Cancer, Who Have Received Prior Chemotherapy Regimens for Metastatic Disease.
A Phase I, open-label, multiple-ascending dose trial to investigate the safety, tolerability, pharmacokinetics, biological and clinical activity of MSB0011359C in subjects with metastatic or locally advanced solid tumors and expansion to selected indications.
A Phase 3, multinational, Randomized, Open-label, Parallel-Arm Study of Avelumab (MSB0010718C) in Combination with Axitinib (Inlyta®) versus Sunitinib (Sutent®)Monotherapy in the First-Line Treatment of Patients with Advanced Renal Cell Carcinoma.
Augmented CeRebral Oximetry and Near-Infrared SpectroscopY Measurements in subarachnoid haemorrhage – ACRONYM.
A Two-arm, Open-label, Randomized Phase II Study of Pembrolizumab (MK-3475) Monotherapy versus Standard Chemotherapy in platinum Pre-treated, Recurrent or Metastatic Nasopharyngeal Cancer.
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.

Research Project Title
Randomized 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.
A Phase 3 Randomized, Open-Label Study Comparing Pexa-Vec (Vaccinia GM-CSF/Thymidine Kinase – Deactivated Virus) Followed by Sorafenib Versus Sorafenib in Patients with Advanced Hepatocellular Carcinoma (HCC) Without Prior Systemic Therapy.
A Phase 3, Multicentre, Multinational, Randomised, Open-Label, Parallel-Arm Study of Avelumab (MSB0010718C) Plus Best Supportive Care Versus Best Supportive Care Alone as a Maintenance Treatment in Patients with Locally Advanced or Metastatic Urothelial Cancer whose Disease did not progress after completion of First-Line Platinum-Containing Chemotherapy.
A Phase 3 Multicenter, Randomised, Double Blind, Placebo Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Aducanumab (BIIB037) in subjects with Early Alzheimer's Disease.
Effect of LY3202626 on Alzheimer's Disease Progression as Measured by Cerebral 18F-AV-1451 Tau-PET in Mild Alzheimer's Disease Dementia.
A Randomised Phase II Study of nab-paclitaxel Combination with Carboplatin as First Line Treatment of Gastrointestinal Neuroendocrine Carcinomas.
A randomised, multicentre, double-blind, placebo-controlled phase II study of the efficacy and safety of trastuzumab emtansine in combination with atezolizumab or atezolizumab-placebo in patients with HER2-positive locally advanced or metastatic breast cancer who have received prior trastuzumab and taxane based therapy.
A prospective randomised multi-centre study of the impact of Ga-68 PSMA-PET/CT imaging for staging high risk prostate cancer prior to curative-intent surgery or radiotherapy.
A Phase3 Placebo-Controlled Study of Carboplatin/ Paclitaxel With or Without Concurrent and Continuation Maintenance Veliparib (PARP inhibitor) in Subjects with Previously Untreated Stages III or IV High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.
A Phase 3, Randomized, Open-Label, Multicentre Study Comparing the Efficacy and Safety of the Bruton's Tyrosine (BTK) Inhibitors BGB-3111 and Ibrutinib in Subjects with Waldenstrom's Macroglobulinemia (WM).

Research Project Title
Outcomes and predictors of efficacy of palliative radiotherapy in patients with malignant pleural mesothelioma.
A Phase III, Double-Blinded, Randomized, Placebo-Controlled Study of Atezolizumab Plus Cobimetinib and Vemurafenib Versus Placebo Plus Cobimetinib and Vemurafenib in Previously Untreated BRAFV600 Mutation-Positive Patients with Unresectable Locally Advanced or Metastatic Melanoma.

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. The number of compliance tests received by the Council in 2016 was 685. A summary of compliance tests assessed in 2016 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 2016, Council officers marked 290 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 and Petroleum (DMP).

Memorandum of Understanding with the Department of Mines and Petroleum

A Memorandum of Understanding (MoU) has existed with the Department of Mines and Petroleum (DMP) 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 DMP and the Radiological Council.

The decisions and outcomes of the RLC do not limit the statutory obligations and decision making of each agency. At least two representatives of the Radiological Council and the Department of Mines and Petroleum need to be present at each meeting. DMP advised that it would like to amend the functions and composition of the RLC in order to streamline its functionality.

Two meetings were held in 2016.

MISCELLANEOUS

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 2016 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 2016 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 – Voluntary Severance Scheme

Major staff redundancies imposed by the Department of Health in 2016 have left the Council's support arm, the Radiation Health Unit of the Environmental Health Directorate, inadequately resourced.

Staff reductions of almost 30% (the majority of voluntary severances occurred at the senior level – senior positions were reduced by 60%) are already impacting applications for registration and licences by delaying the approvals process. 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 which is affecting small business and individuals.

The Radiological Council alerted the Minister for Health that it might 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.

Regulation Amendments for Lasers

The Council was advised that amendments were made to the Radiation Safety (General) Regulations, which deleted Schedule XIV(10) of the regulations. 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 Council had not been consulted and had therefore not approved the amendments. Schedule XIV applies to all medical and industrial facilities that use Class 4 lasers, and the Council considered clause 10 to be essential. The deletion also created a disparity between the requirements for Class 3B lasers which were still required to meet the same requirement.

Council liaised with the Department of Health for the reinstatement of the clause.

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, transilluminators and sun tanning units used for commercial purposes.

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 2016 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. 44 Temporary Permits were current as at 31 December 2016.

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 2016.

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	Mr J O'Donnell
Prof J McKay	Tertiary Institutions representative	A/Prof Z Sun
Mr G Scott (until June 2016)	Medical Radiation Technologist	
Mr C Whennan (from August 2016)	Medical Radiation Technologist	Mr R Hart
Mr G Fee	Expert in Mining Radiation Hazards	Vacant
Mr B Cobb	Co-opted member	not applicable
Mr N Tsurikov	Co-opted member	not applicable
Vacant	Expert in Mining Radiation Hazards	Vacant

2016 MEETING ATTENDANCE

	9 FEB	8 MAR	12 APR	10 MAY	14 JUN	9 AUG	13 SEP	8 NOV	20 DEC
Dr A Robertson	✓	✓	A	A	✓	A	✓	A	✓
Dr R Fox	✓	✓	✓	✓	✓	✓	✓	✓	✓
Dr G Groom	✓	A	✓	✓	A	✓	✓	✓	✓
Dr C Hewavitharana	A	✓	✓	✓	✓	✓	✓	✓	A
Mr M Ross	✓	✓	A	✓	✓	A	✓	✓	✓
Prof J McKay	✓	✓	✓	✓	✓	✓	✓	✓	A
Mr B Cobb	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mr N Tsurikov	✓	✓	✓	✓	A	A	✓	✓	A
Mr G Fee	A	A	R	R	R	R	R	R	R
Mr G Scott	✓	✓	✓	A	✓	R	R	R	R
Mr C Whennan	NA	NA	NA	NA	NA	NA	✓	A	A

✓ attended A apology NA not appointed at the time R resigned

Attachment 2: Legislation Amendments

RADIATION SAFETY ACT

Public Health (Consequential Provisions) Act 2016 s.102

Consequential amendments to replace references to Executive Director with Chief Health Officer.

Date of assent 25 July 2016. Government Gazette 10 January 2017 page 165 with commencement on 24 January 2017.

RADIATION SAFETY (GENERAL) REGULATIONS

Health Regulations Amendment (Fees and Charges) Regulations 2016 Pt.6

Amendment to fees (Schedule XV).

Government Gazette 17 June 2016 pages 2101-5.

Radiation Safety (General) Amendment Regulations 2016

Regulations to update references to the Mines Safety and Inspection Act 1994, Planning and Developments Act 2005 and Health Act 1911, and to update the definition to the National Health and Medical Research Council. Schedule XIV item 10 of the requirements to be complied with in respect of premises in which class 4 lasers are operated or used was also deleted.

Government Gazette 20 September 2016 pages 3967-8.

RADIATION SAFETY (QUALIFICATIONS) AMENDMENT REGULATIONS

Health Regulations Amendment (Fees and Charges) Regulations 2016 Pt.7

Amendment to fees (Schedule 2).

Government Gazette 17 June 2016 pages 2101-5.

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	54	-	-	57
Dental – intraoral	714	-	13	727
Dental – panoramic and/or cephalometric	134	-	1	135
Dental – cone beam CT	6	-	-	6
Fluoroscopic – fixed	30	-	1	31
Fluoroscopic – fixed C or U arm	29	-	5	34
Fluoroscopic – mobile	108	-	6	114
Radiographic – fixed	115	-	20	135
Radiographic – mobile	47	-	1	48
Mammography	50	-	3	53
Total	1287	0	50	1337

Industrial – Fixed Gauges

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

Category	A	B	Total
Density	468	114	582
In-stream analysis	7	-	7
Level	69	27	96
Total	544	141	685

[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 40 re-tests conducted during 2016, 90% 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. Of the 2 re-tests conducted during 2016, 100% resulted in the equipment being granted a compliance certificate.

Attachment 4: Industrial Radiation Safety Examinations

Current at 31 December 2016

Category	2016	2015	2014	2013	2012
Borehole Logging	20	13	29	16	37
Fixed Gauges	68	125	153	108	118
Industrial Radiography	46	63	73	63	67
Industrial Radiography (Advanced)	4	19	16	31	9
Industrial Radiography (Assistant)	78	129	237	194	121
Portable Gauges	18	23	46	92	233
Portable Gauges (WA Requirements)	2	1	14	8	19
Transport	22	32	17	21	31
Service – Cabinet X-ray	1	4	5	2	1
Service – Industrial Radiography (X-ray)	0	0	0	0	0
Service – X-ray Analysis	1	3	0	0	2
X-ray Analysis – Use	0	0	0	5	11
X-ray Analysis – Use and Restricted Service	30	47	42	57	62
Total	290	459	632	597	711

Attachment 5: List of Australian Radiation Protection and Nuclear Safety Agency publications for 2016

Title
RPS C-1 Code for Radiation Protection in Planned Exposure Situations (2016)

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

Current at 31 December 2016

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

Category	A	B
Bone densitometry	57	-
Cabinet x-ray equipment	168	-
Calibration	2	573
CT	137	-
CT/SPECT	20	-
Dental – cone beam CT	10	-
Dental – intraoral	2202	-
Dental – panoramic and/or cephalometric	435	-
Education and research	20	1080
Fluoroscopic – fixed	90	-
Fluoroscopic – mobile	145	-
Gauges – density/level	4	3472
Gauges – in stream analysis	-	86
Gauges – logging	32	425
Gauges – neutron moisture/density portable	-	457
Gauges – other	-	279
Irradiator	-	48
Isotope Production	1	-
Laser – entertainment	149	-
Laser – industrial	164	-
Laser – medical	312	-
Laser – other medical	235	-
Laser – Podiatry	9	
Laser – research	193	-
Linear accelerator	20	-
Mammography	80	-
Non-destructive testing	179	125
Non-destructive testing – crawler control	-	15
Portable mineral analyser	-	10
Radiographic – fixed	353	-
Radiographic – mobile	415	-

[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	-	121
Simulator	4	-
Special purpose x-ray	47	-
Static detection/measurement	-	3
Static elimination	-	8
Storage	-	296
Sun Tanning Unit	-	-
Superficial radiotherapy	3	-
Test source	2	-
Therapy	4	24
Therapy – HDR brachytherapy	-	1
Transilluminator	121	-
Tracer Studies	-	27
X-ray analysis	565	-
Total	6178	7052

Attachment 7: Licences and Registrations

Current at 31 December 2016

Including individual exemptions granted under Section 6 of the Act.

	X-ray and/or Electronic Products		Radioactive Substances		TOTAL	
	2016	2015	2016	2015	2016	2015
Licences	5287	5219	2230	2316	7517	7535
Registrations	1859	1800	413	403	2272	2203
TOTAL	7146	7019	2643	2719	9789	9738
Change from 2015	+ 1.8%		- 2.8%		+ 0.5%	

Attachment 7 (cont)

Purposes for Licences and Exemptions from Licence

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

A *Granted or renewed in 2016*
B *Total current*

A	B	Purpose
8	27	Bone Densitometry
2	4	Bone Densitometry (Exemption)
29	92	Cabinet X-ray Equipment
0	1	Cobalt Teletherapy Maintenance
20	57	Compliance Testing - Diagnostic X-ray Equipment
127	224	Compliance Testing - Radioactive Gauges
8	10	Cyclotron Operation
3	4	Cyclotron Servicing
1	3	Education (Apparatus)
12	31	Education (Substances)
135	414	Fluoroscopy - Medical
31	115	Fluoroscopy - Medical (Exemption)
11	21	Fluoroscopy - Medical (Non-Specialist Exemption)
0	1	Fluoroscopy - Research
0	1	Fluoroscopy - Veterinary
1	3	Gamma Irradiator - Use
165	510	Gauges - Industrial
1	9	Gauges - Industrial (Installation)
0	1	Gauges - Level (CO2)
82	315	Gauges - Logging
171	436	Gauges - Moisture and/or Density (Portable)
2	4	Gauges - Other (Apparatus)
17	40	Gauges - Other (Substances)
3	3	Installation of X-ray Equipment
1	4	Installation of X-ray Equipment - Dental
2	5	Lasers - Acupuncture
1	11	Lasers - Chiropractic
65	174	Lasers - Dental
3	7	Lasers - Educational
9	30	Lasers - Entertainment
32	65	Lasers - Industrial
93	292	Lasers - Medical
31	97	Lasers - Physiotherapy
13	28	Lasers - Podiatry (Exemption)

A	B	Purpose
13	49	Lasers - Research
27	71	Lasers - Service
4	10	Lasers - Veterinary
1	2	Manufacture of X-ray Equipment
1	3	Medical Physics
4	14	Medical Physics - Radiotherapy (Apparatus)
4	12	Medical Physics - Radiotherapy (Substances)
35	70	Medical Radiation Technology - Diagnostic Nuclear
575	1134	Medical Radiation Technology - Medical Imaging
7	12	Medical Radiation Technology - Nuclear Medicine - Diagnostic CT
79	179	Medical Radiation Technology - Radiation Therapy Irradiating Apparatus
92	179	Medical Radiology
3	5	Non-Medical Irradiation
0	2	Nuclear Medicine - Calibration and QC Sources
15	38	Nuclear Medicine - Diagnostic
12	32	Nuclear Medicine - Therapeutic
1	3	Nuclear Medicine - Veterinary
0	3	Pathology (in vitro) – Sealed Sources
3	6	Pathology Tests
16	30	Portable Mineral Analysers
83	268	Portable Mineral Analysers (X-ray)
1	8	Possession of X-ray Equipment - Diagnostic Medical
1	6	Possession of X-ray Equipment - Diagnostic Medical and Dental
0	3	Quality Assurance Procedures
5	30	Radioactive Ores - Analytical Laboratories
3	11	Radioactive Ores - Exploration
4	17	Radioactive Ores - Mining and/or Processing
5	11	Radioactive Substances - Calibration Sources
1	1	Radioactive Substances - Medical
18	40	Radioactive Substances - Sale
13	39	Radioactive Substances - Service of Devices
6	18	Radioactive Substances - Tracer Studies (Industry)
0	1	Radiography - Chiropractic (Exemption)
12	27	Radiography - Chiropractic (Extended)
56	186	Radiography - Chiropractic (Restricted)
138	462	Radiography - Industrial (Gamma)
139	467	Radiography - Industrial (X-ray)
0	1	Radiography - Medical (Direction and Supervision)
0	3	Radiography - Security
244	729	Radiography - Veterinary

A	B	Purpose
0	2	Radioguidance - Medical (Radioactive Substances)
1	4	Radiology - Dental
2	11	Radiology - Veterinary
8	13	Radiopharmaceutical Manufacture and Dispensing
6	20	Radiotherapy - Medical (Apparatus)
6	20	Radiotherapy - Medical (Substances)
1	2	Radiotherapy - Medical Superficial
0	1	Radiotherapy - Veterinary (Apparatus)
4	11	Research
17	48	Research - Unsealed Radioactive Substances
3	7	Research - X-ray
14	38	Sale of Electronic Products
31	85	Sale of X-ray Equipment
5	22	Service of X-ray Equipment - Analytical
4	28	Service of X-ray Equipment - Cabinet
8	29	Service of X-ray Equipment - Dental
47	126	Service of X-ray Equipment - Diagnostic
1	4	Service of X-ray Equipment - Diagnostic (Extended)
0	4	Service of X-ray Equipment - Industrial NDT
8	15	Service of X-ray Equipment - Linear Accelerators
2	8	Service of X-ray Equipment - Other
4	6	Service of X-ray Equipment - Superficial X-ray Therapy
6	15	Special Purpose Enclosed X-ray Equipment
1	1	Static Detection
0	1	Static Electricity Measurement
1	2	Static Elimination
4	7	Storage (Substances)
2	19	Transilluminators
51	140	Transport
0	1	X-ray Analysis (Research)
20	85	X-ray Analysis - Use
82	276	X-ray Analysis - Use and Service (Restricted)
0	1	X-ray Irradiator

Attachment 7 (cont)

Purposes for Registrations and Exemptions from Registration

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

A *Granted or renewed in 2016*
B *Total current*

A	B	Purpose
5	21	Bone Densitometry
7	18	Bone Densitometry (Exemption)
24	76	Cabinet X-ray Equipment
0	2	Cyclotron Operation
0	1	Disposal of Radioactive Waste – Mt Walton East IWDF
1	10	Education (Apparatus)
6	18	Education (Substances)
9	28	Education - Demonstration Radioactive Sources (Exemption)
2	5	Fluoroscopy - Medical
1	2	Gamma Irradiator
41	150	Gauges - Industrial
0	4	Gauges - Level (CO2)
5	23	Gauges - Logging
15	54	Gauges - Moisture and/or Density (Portable)
3	14	Gauges - Other (Apparatus)
3	7	Gauges - Other (Substances)
2	4	Lasers - Acupuncture
2	9	Lasers - Chiropractic
47	113	Lasers - Dental
1	2	Lasers - Educational
8	30	Lasers - Entertainment
11	37	Lasers - Industrial
1	1	Lasers - Manufacture
49	124	Lasers - Medical
16	46	Lasers - Physiotherapy
6	10	Lasers - Podiatry
3	6	Lasers - Research
0	6	Lasers - Sale, Service, Maintenance and Testing
2	7	Lasers - Storage
2	7	Lasers - Veterinary
0	2	Manufacture of X-ray Equipment
41	115	Medical Radiology
1	2	Non-Medical Irradiation

A	B	Purpose
5	22	Nuclear Medicine
5	15	Nuclear Medicine - CT (X-ray)/SPECT
1	10	Nuclear Medicine - Therapeutic
0	2	Nuclear Medicine - Veterinary
2	7	Pathology Tests
1	9	Portable Mineral Analysers
41	166	Portable Mineral Analysers (X-ray)
1	11	Radioactive Ores - Analytical Laboratories
3	12	Radioactive Ores - Exploration
12	35	Radioactive Ores - Mining and/or Processing
3	7	Radioactive Substances - Calibration Sources
0	1	Radioactive Substances - Medical
4	9	Radioactive Substances - Sale
1	3	Radioactive Substances - Service of Devices
1	2	Radioactive Substances - Tracer Studies (Industry)
5	14	Radiography - Chest Screening
13	43	Radiography - Chiropractic
254	737	Radiography - Dental
1	1	Radiography - Forensic
8	25	Radiography - Industrial (Gamma)
8	31	Radiography - Industrial (X-ray)
6	13	Radiography - Mammography Screening
25	45	Radiography - Medical (Operator)
7	18	Radiography - Medical (Unrestricted)
31	82	Radiography - Medical Ancillary (Referrals)
0	1	Radiography - Physiotherapy Referrals
0	1	Radiography - Security
78	247	Radiography - Veterinary
0	3	Radioguidance - Medical (Radioactive Substances)
1	3	Radiology - Veterinary
0	2	Radiopharmaceutical Manufacture and Dispensing
0	7	Radiotherapy - Medical (Apparatus)
0	8	Radiotherapy - Medical (Substances)
0	1	Radiotherapy - Veterinary (Apparatus)
0	2	Regulatory Authority
1	5	Research
0	5	Research (Substances)
4	12	Research - Unsealed Radioactive Substances
3	7	Research - X-ray
0	5	Sale of Electronic Products
7	22	Sale of X-ray Equipment
14	47	Security of Radioactive Sources

A	B	Purpose
2	16	Service of X-ray Equipment
2	8	Special Purpose Enclosed X-ray Equipment
1	1	Static Electricity Measurement
0	2	Static Elimination
7	35	Storage (Apparatus)
11	39	Storage (Substances)
3	14	Transilluminators
5	12	Transport
0	6	X-ray Analysis
23	115	X-ray Analysis - Use
1	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
DMP	Western Australian Department of Mines and Petroleum
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)

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	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

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	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 MEETING ATTENDANCE

	14 FEB	11 APR	9 MAY	13 JUN	11 JUL	8 AUG	10 OCT	14 NOV	20 DEC
Dr A Robertson	✓	✓	✓	✓	✓	✓	✓	✓	✓
Dr R Fox	✓	✓	✓	D	D	✓	✓	✓	✓
Dr G Groom	✓	✓	✓	D	✓	✓	✓	✓	✓
Dr C Hewavitharana	✓	✓	✓	✓	✓	A	✓	✓	A
Mr M Ross	✓	A	✓	A	✓	✓	✓	✓	A
Prof J McKay	✓	✓	✓	✓	✓	D	✓	✓	A
Mr B Cobb	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mr N Tsurikov	✓	✓	✓	✓	A	✓	✓	A	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

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-compliant*[1]

Category	A	B	C	Total
CT	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-compliant*[2]

Category	A	B	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 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 products*[3]
B *Radioactive substances (sealed sources only)*

Category	A	B
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	A	B
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)

REPORT OF THE

RADIOLOGICAL COUNCIL

for the year ended

31 December 2018

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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 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)

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)

REPORT OF THE

RADIOLOGICAL COUNCIL

for the year ended

31 December 2019

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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 2019.

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

No amendments were made to the Radiation Safety Act or the Radiation Safety (Transport of Radioactive Substances) Regulations in 2019.

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

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 an 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 82 incidents during 2019 which are presented in the tables below. The majority of incidents relate to human error and a failure to follow protocols. All reported incidents are followed up by Council and its officers and attention is given to analysing the root cause and ensuring procedures and protocols are amended where necessary in order to minimise the chance of reoccurrence.

Incident	**Occurrences**	**Category**
Radiology		
Error in CT equipment requiring repeat imaging	1	Equipment malfunction
Patient injury – observable acute radiation effect	1	Interventional fluoroscopy procedure
Incorrect patient imaged – failure to correctly identify patient against request form	19	Human error – failure to follow protocol
Incorrect patient imaged due to incorrect patient name being entered on request form	5	Human error – other
Incorrect examination/anatomical site imaged – failure to image as per request form	16	Human error – failure to follow protocol
Incorrect examination/anatomical site imaged – failure to refer for correct examination/anatomical site	1	Human error – failure to follow protocol
Incorrect modality selected by MIT	1	Human error – failure to follow protocol
Duplication of imaging due to duplication of request form for inpatient and outpatient systems	1	Human error – failure to follow protocol
Exposure whilst persons other than patient unintentionally in the room	2	Human error – failure to follow protocol

Incident	Occurrences	Category
Radiotherapy		
Incorrect treatment site for superficial radiotherapy	1	Human error
Nuclear Medicine		
Incorrect activity of radiopharmaceutical administered	2	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	8	Protocol followed – IV administration failed after successful cannulation flush.
Radiopharmaceutical administered but scan not performed	5	Protocol followed – patient did not proceed with procedure.
Radiopharmaceutical administered but scan not performed - team requested a different diagnostic test or cancelled the original test.	2	Human error – communication between treating teams needed improvement
Radiopharmaceutical administered but scan not performed – patient's status changed and the diagnostic test was no longer required.	4	Protocol followed
Duplicate scan required - failure to image as per request form	3	Human error – failure to follow protocol
Malfunction of equipment – poor efficacy of radiopharmaceutical dispensing kit	1	Product recalled. 9 patients across 3 sites affected.
Industrial		
Potential for exposure of persons during industrial radiography	1	Failure to follow protocol and check exclusion zone was vacant before exposures.
Potential for exposure of persons – industrial radiography source disconnect	1	Human error – use of incompatible radiography accessory and parts with excessive wear.
Vehicle incident whilst mineral sands on board	1	Protocol followed – unintentional collision and spill cleaned up.
Vehicle incident whilst radioactive source on board	1	Protocol followed – vehicle rolled after accident.
Unintentional exposure of persons – fixed gauge not isolated	1	Human error - failure to follow protocol

Incident	**Occurrences**	**Category**
Unintentional x-ray exposure of persons	1	Child passed through baggage cabinet x-ray equipment.
Other		
Disposal of radioactive source to scrap metal yard	1	Human error - other
Unintended release of radioactive substances – radiopharmaceutical manufacturing	1	Equipment malfunction

PROSECUTIONS

No prosecutions were initiated or finalised in 2019.

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 2019 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.

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 2019.

Research Project Title
A randomized, Multicenter, Open-Label, Phase 3 Study to Comapre the Efficacy and Safety of Acalabrutinib (ACP-196) in Combination with Venetoclax with and without Obinutuzumab Compared to Investigator's Choice of Chemoimmunotherapy in Subjects with Previously Untreated Chronic Lymphocytic Leukemia Without del(17p) or TP53 Mutation.
Effect of high-dose fish oil supplementation on arterial inflammation in patients with elevated lipoprotein (a).
Towards visualising and understanding patient-specific biomechanics of abdominal aortic aneurysms (AAA).
A randomized, double-blind, placebo-controlled, phase III study evaluating the efficacy and safety of pembrolizumab plus platinum-based doublet chemotherapy with or without canakinumab as first line therapy for locally advanced or metastatic non-squamous and squamous non-small cell lung cancer subjects.
A Phase 3 Randomised, Placebo-controlled, Double-blind Study of Niraparib in Combination with Abiraterone Acetate and Predisone Versus Abiraterone Acetate and Prednisone for Treatment of Subjects with Metastatic Prostate Cancer.
A multicenter, randomized, double-blind, placebo controlled, two-arm, phase 2 study of ME-401 in subjects with follicular lymphoma after failure of two or more prior systemic therapies.
A Randomised Open-Label, Phase 1b Study of the Safety of Pirfenidone Solution for Inhalation (AP01) in Patients with Idiopathic Pulmonary Fibrosis
A Randomised, Controlled Phase 3 Study of Cabozantinib (XL184) in Combination with Atezolizumab verus Sorafenib in Sorafenib in Subjects with Advanced Hepatocellular Carcinoma Who Have Not Received Previous Systemic Anticancer Therapy
A Phase 3, Randomised, Double-blind Trial of Pembrolizumab (MK-3475) Plus Enzalutamide Versus Placebo Plus Enzalutamide in Participants with Metastatic Castration-Resistant Prostate Cancer (mCRPC)
A Phase 2, Open-Label, Single-Arm Study of Pamiparib (BGB-290) for the Treatment of Patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC) with Homologous Recombination Deficiency (HRD)
A Phase III Prospective Double Blind Placebo Controlled Randomised Study of Adjuvant MEDI4736 in Completely Resected Non-Small Cell Lung Cancer
Effectiveness of a Fast Track Giant Cell Arteritis Clinic in Western Australia
Exploring the role of androgen receptor blockade in increasing the expression of prostate specific membrane antigen (PSMA) and enhancing 68Ga-PSMA-11-PET/CT imaging in patients with metastatic prostate cancer.
A Phase 3, Randomised, Double –blind study of Pembrolizumab (MK-3475) Plus Docetaxel Plus Prednisone verus Placebo Plus Docetaxel Plus Prednisone in Participants with Chemotherapy-naïve Metastatic Castration –Resistant Prostate Cancer (mCRPC) who have progressed on a Next Generation Hormonal Agent (NHA) (KEYNOTE-921)

Research Project Title
A Phase 2, 24-Week Randomised, Double-blind, Placebo-Controlled Multicenter Study, with an 80-Week Active Treatment Extension, to evaluate the Efficacy and Safety of CC-90001 in Subjects with Idiopathic Pulmonary Fibrosis
NHL 31 TREB-L - An Open label, Multicentre, Phase I study of Ibrutinib, Rituximab, Valaciclovir and 3rd Party EBV specific T cells in Patients with immunosuppression related EBV-positive Brain and/or Systemic B cell lymphomas, that are relapsed/refractory or unsuitable for standard first-line treatments
A Phase III Open-Label, Multi-Centre, randomised Study Comparing NUC-1031 plus Cisplatin to Gemcitabine plus Cisplatin in Patients with Previously Untreated Locally Advanced or Metastatic Biliary Tract Cancer.
A Phase II, Open-Label, Multicenter, Randomized Study Of The Efficacy And Safety Of RO7198457 In Combination With Pembrolizumab Versus Pembrolizumab In Patients With Previously Untreated Advanced Melanoma.
A Phase 2, Open-Label, Randomized, Multicenter Trial of Encorafenib + Binimetinib Evaluating a Standard-dose and a High-dose Regimen in Patients With BRAFV600-Mutant Melanoma Brain Metastasis
A Phase 3, Randomized Open-label Study of Pembrolizumab (MK-3475) Plus Olaparib Versus Abiraterone Acetate or Enzalutamide in Participants with Metastatic Castration-resistant Prostate Cancer (mCRPC) Who are Unselected for Homologous Recombination Repair Defects and Have Failed Prior Treatment with One Next-generation Hormonal Agent (NHA) and Chemotherapy (KEYLYNK-010)
REGENERON 1788: A Randomized, Placebo-Controlled, Double-Blind Study of Adjuvant Cemiplimab Versus Placebo after Surgery and Radiation Therapy in Patients with High Risk Cutaneous Squamous Cell Carcinoma
A phase I/II, open-label, dose escalation and expansion study to evaluate safety, tolerability, and clinical activity of the antibody-drug conjugate GSK2857916 administered in combination with Lenalidomide plus dexamethasone (Arm A), or Bortezomib plus Dexamethasone (Arm B) in participants with relapsed/refractory multiple myeloma.
A Phase 1, Open-Label, Dose-Escalation and Cohort Expansion First-in-Human Study of the Safety, Tolerability, Activity and Pharmacokinetics of REGN3767 (anti-LAG-3 mAb) Administered Alone or in Combination with REGN2810 (anti-PD-1 mAb) in Patients with Advanced Malignancies.
Differentiating Renal Oncocytoma from Renal Cell Carcinoma Using Sestamibi Imaging
An open-label randomized phase 2 trial of SAR439859, versus endocrine monotherapy as per physician’s choice in premenopausal and post-menopausal patients with estrogen receptor-positive, HER2-negative locally advanced or metastatic breast cancer with prior exposure to hormonal therapies
A randomized, multi-arm study platform to compare the efficacy of experimental therapies versus standard of care in patients with acute myeloid leukaemia in first remission

Research Project Title
A Phase 2 Study of Erdafitinib in Subjects with Advanced Solid Tumors and Fibroblast Growth Factor Receptor Gene Alterations
Global clinical study of renal denervation with Symplicity SpyralTM multi-electrode renal denervation system in patients with uncontrolled hypertension on standard medical therapy.
A Phase II/III Randomised, Double-Blind, Placebo-Controlled, Cognitive Endpoint, Multicenter Study of Potential Disease Modifying Therapies in Individuals at Risk for and with Dominantly Inherited Alzheimer's Disease
FASTRACK II: Focal Ablative Stereotactic Radiosurgery for Cancers of the Kidney – A Phase II Trial
Colchicine for Coronary Plaque Modification in Acute Coronary Syndrome Study
Investigation into the Influence of Patient Ambulation and Components Alignment on Medium – Term Patient Outcomes after Total Knee Arthroplasty

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 2019 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 2019, Council officers marked 510 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).

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 for storage (only) of naturally occurring radioactive material was received and granted in 2019. The assessment process is continuing with assessment of the first stage of disposal expected to be completed in 2020.

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 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.

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 are being used in the ongoing 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 2019 is in attachment 5.

Environmental Health Standing Committee (enHealth)

The Environmental Health Standing Committee (enHealth) is a standing committee of the Australian Health Protection Principal Committee (AHPPC).

Under its Terms of Reference, enHealth is responsible for providing agreed environmental health policy advice, implementation of the *National Environmental Health Strategy*, consultation with key stakeholders, and the development and coordination of research, information and practical resources on environmental health matters at a national level. The development of national advice by enHealth is based on significant collaboration and consultation with federal and state and territory agencies, departments and organisations that deal with environmental health matters.

Consequently a Radiation Health Expert Reference Panel (RHERP) has been established under enHealth to provide expert advice on specific issues as directed by the Environmental Health Standing Committee (enHealth). This will include the development of a National Strategy for Uniformity of Radiation Protection and Nuclear Safety Regulation in Australia.

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 2019 through the national Radiation Health Committee and the Radiation Health Expert Review Panel under enHealth.

Council continued its participation in the development of the National Directory and provided comment to both committees.

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 2019 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. 106 Temporary Permits were current as at 31 December 2019.

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 2019.

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 (until 28/02/2019) Dr R Bangor Jones (from 28/5/2019…)
Appointment under Sections 13(2)(b), 15(1) and 17 (1) of the Act		
Dr C Hewavitharana	Radiologist	Dr D Dissanayake
Dr G Groom (until 28/02/2019)	Nuclear Medicine Physician	Dr E Thomas
Dr E Thomas (from 28/05/2019)	Nuclear Medicine Physician	Vacant
Dr R Fox (until 14/06/2019)	Physicist	Dr R Price
Dr R Price (from 20/09/2019)	Physicist	Mr C Storm
Mr D Kwiatkowski	Electronic Engineer	Not appointed
A/Prof R Francis	Tertiary Institutions representative	Not appointed
Mr C Whennan	Medical Radiation Technologist	Ms H Parry
Mr N Tsurikov	Co-opted member	Not applicable
Vacant	Expert in Mining Radiation Hazards	Vacant

2019 MEETING ATTENDANCE

	12 FEB	9 APR	14 MAY	9 JUL	13 AUG	10 SEP	8 OCT	12 NOV	10 DEC
Dr A Robertson	✓	✓	✓	✓	A	✓	✓	✓	✓
Dr R Bangor-Jones	NA	NA	NA	O	D	D/O	A	O	O
Dr R Fox	✓	✓	A	NA	NA	NA	NA	NA	NA
A/Prof R Francis	NA	✓	✓	✓	✓	✓	A	✓	A
Dr G Groom	✓	NA	NA	NA	NA	NA	NA	NA	NA
Dr C Hewavitharana	A	✓	✓	NA	✓	✓	✓	✓	A
Mr D Kwiatkowski	NA	✓	✓	✓	✓	✓	✓	A	A
Ms H Parry	NA	NA	NA	NA	NA	NA	NA	O	NA
Dr R Price	NA	NA	NA	NA	NA	NA	NA	✓	✓
Mr C Storm	NA	NA	NA	NA	NA	NA	NA	NA	O
Dr E Thomas	NA	NA	NA	✓	✓	✓	✓	✓	✓
Mr N Tsurikov	NA	✓	✓	✓	A	A	✓	✓	✓
Mr C Whennan	A	✓	✓	NA	NA	NA	NA	✓	✓

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

Attachment 2: Legislation Amendments

RADIATION SAFETY ACT

None

RADIATION SAFETY (GENERAL) REGULATIONS

Health Regulations Amendment (Fees and Charges) Regulations 2019 Pt.9

Amendment to fees (Schedule XV).

Government Gazette 14 June 2019 pages 1883-94.

RADIATION SAFETY (QUALIFICATIONS) REGULATIONS

Health Regulations Amendment (Fees and Charges) Regulations 2019 Pt.9

Amendment to fees for examinations (Schedule 2).

Government Gazette 14 June 2019 pages 1883-94

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	107	1	-	108
Dental – cone beam CT	31	-	-	31
Dental – intraoral	985	2	10	997
Dental – panoramic and/or cephalometric	227	1	1	229
Fluoroscopic – fixed	45	-	3	48
Fluoroscopic – fixed C or U arm	37	-	3	40
Fluoroscopic – mobile	126	-	10	136
Mammography	76	-	3	79
Radiographic – fixed	137	-	16	153
Radiographic – mobile	69	-	1	70
Total	1840	4	47	1891

Industrial – Fixed Gauges

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

Category	A	B	Total
Density	509	7	516
In-stream analysis	21	-	21
Level	38	-	38
Total	568	7	575

[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 55 re-tests conducted during 2019, 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 2019

Category	2019	2018	2017	2016	2015
Borehole Logging	46	24	29	20	13
Fixed Gauges	119	83	109	68	125
Industrial Radiography	33	30	49	46	63
Industrial Radiography (Advanced)	1	0	0	4	19
Industrial Radiography (Assistant)	97	109	57	78	129
Portable Gauges	80	61	50	18	23
Portable Gauges (WA Requirements)	14	8	3	2	1
Transport	54	25	42	22	32
Service – Cabinet X-ray	16	2	5	1	4
Service – Industrial Radiography (X-ray)	1	0	0	0	0
Service – X-ray Analysis	2	0	0	1	3
X-ray Analysis – Use	0	0	0	0	0
X-ray Analysis – Use and Restricted Service	47	111	48	30	47
Total	510	453	392	290	459

Attachment 5: List of Australian Radiation Protection and Nuclear Safety Agency publications for 2019

	Title
RPS C-2	Code for the Safe Transport of Radioactive Material (2019)
RPS C-5	Code for Radiation protection in Medical Exposure (2019)
RPS 11	Code of Practice for the Security of Radioactive Sources (2019)
RPS G-3	Guide for Radiation Protection in Emergency Exposure Situations

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

Current at 31 December 2019

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

Category	A	B
Bone densitometry	64	-
Cabinet x-ray equipment	190	-
Calibration	2	694
CT	130	-
CT/SPECT	35	-
Dental – intraoral	2391	-
Dental – panoramic and/or cephalometric	492	-
Dental – cone beam CT	41	-
Education and research	20	1166
Fluoroscopic – fixed	81	-
Fluoroscopic – mobile	135	-
Gauges – density/level	7	3634
Gauges – in stream analysis	2	78
Gauges – logging	34	408
Gauges – neutron moisture/density portable	-	420
Gauges – other	-	321
Irradiator	-	48
Isotope Production	1	-
Laser – entertainment	228	-
Laser – industrial	205	-
Laser – medical	363	-
Laser – other medical	341	-
Laser – podiatry	14	
Laser – research	183	-
Linear accelerator	22	-
Mammography	70	-
Non-destructive testing	212	126
Non-destructive testing – crawler control	-	17
Portable mineral analyser	-	8
Radiographic – fixed	356	-
Radiographic – mobile	399	-

[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	-	135
Simulator	7	-
Special purpose x-ray	46	-
Static detection/measurement	-	3
Static elimination	-	16
Storage	-	314
Superficial radiotherapy	2	-
Test source	2	-
Therapy	5	26
Therapy – HDR brachytherapy	-	2
Transilluminator	127	-
Tracer Studies	-	131
X-ray analysis	648	-
Total	6856	7548

Attachment 7: Licences and Registrations

Current at 31 December 2019

Including individual exemptions granted under Section 6 of the Act.

	X-ray and/or Electronic Products		Radioactive Substances		TOTAL	
	2019	2018	2019	2018	2019	2018
Licences	6195	5819	2228	2137	8423	7956
Registrations	2127	2057	432	445	2559	2502
TOTAL	8322	7876	2660	2582	10982	10458
Change from 2018	+ 5.7%		+ 3.0%		+ 5.0%	

Attachment 7 (cont)

Purposes for Licences and Exemptions from Licence – total current as at 31 December 2019

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

Total	Purpose
20	Bone Densitometry
3	Bone Densitometry (Exemption)
105	Cabinet X-ray Equipment
1	Cobalt Teletherapy Maintenance
60	Compliance Testing - Diagnostic X-ray Equipment
540	Compliance Testing - Radioactive Gauges
12	Cyclotron Operation
5	Cyclotron Servicing
4	Education (Apparatus)
29	Education (Substances)
469	Fluoroscopy - Medical
92	Fluoroscopy - Medical (Exemption)
37	Fluoroscopy - Medical (Non-Specialist Exemption)
17	Fluoroscopy - Podiatry (Exemption)
2	Fluoroscopy - Veterinary
5	Gamma Irradiator - Use
539	Gauges - Industrial
7	Gauges - Industrial (Installation)
1	Gauges - Level (CO2)
289	Gauges - Logging
469	Gauges - Moisture and/or Density (Portable)
5	Gauges - Other (Apparatus)
44	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
206	Lasers - Dental
5	Lasers - Educational
28	Lasers - Entertainment
253	Lasers - Hair Removal (Exemption)
68	Lasers - Industrial
324	Lasers - Medical
11	Lasers - Other
126	Lasers - Physiotherapy

Total	Purpose
38	Lasers - Podiatry (Exemption)
60	Lasers - Research
82	Lasers - Service
60	Lasers - Superficial Cosmetic (Exemption)
19	Lasers - Tattoo Removal (Exemption)
21	Lasers - Veterinary
2	Manufacture of X-ray Equipment
3	Medical Physics
23	Medical Physics - Radiotherapy (Apparatus)
13	Medical Physics - Radiotherapy (Substances)
85	Medical Radiation Technology - Diagnostic Nuclear
1209	Medical Radiation Technology - Medical Imaging
23	Medical Radiation Technology - Nuclear Medicine - Diagnostic CT
219	Medical Radiation Technology - Radiation Therapy Irradiating Apparatus
287	Medical Radiology
5	Non-Medical Irradiation
5	Nuclear Medicine - Calibration and QC Sources
41	Nuclear Medicine - Diagnostic
34	Nuclear Medicine - Therapeutic
1	Nuclear Medicine - Therapy (Endocrinology)
4	Nuclear Medicine - Veterinary
6	Pathology Tests
23	Portable Mineral Analysers
379	Portable Mineral Analysers (X-ray)
5	Possession of X-ray Equipment - Diagnostic Medical
5	Possession of X-ray Equipment - Diagnostic Medical and Dental
3	Quality Assurance Procedures
31	Radioactive Ores - Analytical Laboratories
12	Radioactive Ores - Exploration
18	Radioactive Ores - Mining and/or Processing
13	Radioactive Substances - Calibration Sources
1	Radioactive Substances - Medical
40	Radioactive Substances - Sale
42	Radioactive Substances - Service of Devices
19	Radioactive Substances - Tracer Studies (Industry)
27	Radiography - Chiropractic (Extended)
165	Radiography - Chiropractic (Restricted)
429	Radiography - Industrial (Gamma)
444	Radiography - Industrial (X-ray)
1	Radiography - Mammography Screening (Exemption)

Total	Purpose
1	Radiography - Medical (Direction and Supervision)
3	Radiography - Security
838	Radiography - Veterinary
3	Radioguidance - Medical (Radioactive Substances)
92	Radiology - Dental
13	Radiology - Veterinary
20	Radiopharmaceutical Manufacture and Dispensing
27	Radiotherapy - Medical (Apparatus)
23	Radiotherapy - Medical (Substances)
1	Radiotherapy - Medical Superficial
12	Research
43	Research - Unsealed Radioactive Substances
12	Research - X-ray
42	Sale of Electronic Products
101	Sale of X-ray Equipment
32	Service of X-ray Equipment - Analytical
42	Service of X-ray Equipment - Cabinet
29	Service of X-ray Equipment - Dental
136	Service of X-ray Equipment - Diagnostic
3	Service of X-ray Equipment - Diagnostic (Extended)
3	Service of X-ray Equipment - Industrial NDT
28	Service of X-ray Equipment - Linear Accelerators
6	Service of X-ray Equipment - Other
6	Service of X-ray Equipment - Superficial X-ray Therapy
16	Special Purpose Enclosed X-ray Equipment
1	Static Detection
1	Static Electricity Measurement
1	Static Elimination
5	Storage (Apparatus)
26	Storage (Substances)
20	Transilluminators
173	Transport
95	X-ray Analysis - Use
296	X-ray Analysis - Use and Service (Restricted)
3	X-ray Irradiator
5	X-ray - Industrial

Attachment 7 (cont)

Purposes for Registrations and Exemptions from Registration – total current as at 31 December 2019

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

Total	Purpose
25	Bone Densitometry
13	Bone Densitometry (Exemption)
85	Cabinet X-ray Equipment
2	Cyclotron Operation
2	Disposal of Radioactive Waste
9	Education (Apparatus)
18	Education (Substances)
27	Education – Demonstration Radioactive Sources (Exemption)
6	Fluoroscopy – Medical
1	Fluoroscopy – Podiatry
2	Gamma Irradiator
146	Gauges – Industrial
3	Gauges – Level (CO2)
21	Gauges – Logging
48	Gauges – Moisture and/or Density (Portable)
16	Gauges – Other (Apparatus)
9	Gauges – Other (Substances)
3	Lasers – Acupuncture
10	Lasers – Chiropractic
126	Lasers – Dental
2	Lasers – Educational
44	Lasers – Entertainment
53	Lasers – Hair Removal
37	Lasers – Industrial
1	Lasers – Manufacture
154	Lasers – Medical
1	Lasers – Osteopathy
5	Lasers – Other
43	Lasers – Physiotherapy
12	Lasers – Podiatry
7	Lasers – Research
6	Lasers – Sale, Service, Maintenance and Testing
8	Lasers – Storage
27	Lasers – Superficial Cosmetic
3	Lasers – Tattoo Removal

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

Total	Purpose
5	Sale of Electronic Products
25	Sale of X-ray Equipment
53	Security of Radioactive Sources
16	Service of X-ray Equipment
12	Special Purpose Enclosed X-ray Equipment
1	Static Electricity Measurement
2	Static Elimination
50	Storage (Apparatus)
44	Storage (Substances)
13	Transilluminators
15	Transport
120	X-ray Analysis
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
enHealth	Environmental Health Standing Committee
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
RHERP	Radiation Health Expert Reference Panel

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)