



REPORT OF THE

RADIOLOGICAL COUNCIL

for the year ended

31 December 2021



TABLE OF CONTENTS

Statutory Responsibilities of the Council.....	3	Miscellaneous	11
Membership of the Council.....	3	COVID-19.....	11
Advisory Committees	4	Automatic Mutual Recognition	11
Administrative Support	4	Radiation Health Committee.....	11
State Records Act	4	Environmental Health Standing Committee	12
State Electoral Act.....	4	National Directory for Radiation Protection	12
Registrations, Licences and Temporary Permits.....	4	Radiological Council Website	12
Qualifications and Training of Radiation Users	4	X-ray Screening.....	12
Changes to Legislation.....	5	Appendix 1: Registration and Licensing.....	13
2021 in review	6	Attachment 1: Radiological Council.....	15
Radiation Incidents.....	7	Attachment 2: Legislation Amendments	17
Prosecutions	8	Attachment 3: Compliance Testing	18
Medical and Related Radiation Matters	9	Attachment 4: Research Project Applications Assessed	20
Medical Compliance Testing.....	9	Attachment 5: Industrial Radiation Safety Examinations	23
Approvals for Exposure to Radiation for Human Subjects in Medical Research.....	9	Attachment 6: List of Australian Radiation Protection and Nuclear Safety Agency publications for 2021	24
Industrial, Environmental and Mining Radiation.....	10	Attachment 7: Registered Irradiating Apparatus, Electronic Products and sealed Radioactive Substances...25	
Industrial Compliance Testing	10	Attachment 8: Licences and Registrations	27
Standards for Council Examinations.....	10	Abbreviations	33
Mining and Milling of Radioactive Ores.....	10		
Low Level Radioactive Waste Facilities	10		

RADIATION SAFETY ACT 1975

An Act to regulate the keeping and use of radioactive substances, irradiating apparatus and certain electronic products, and for matters incidental thereto.

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 of the Act 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 officially met ten times in 2021, either in person or by video-conference.

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 is 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 (Principal Health Physicist) performing these duties in Ms Upton's absence.

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.

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.

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

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.

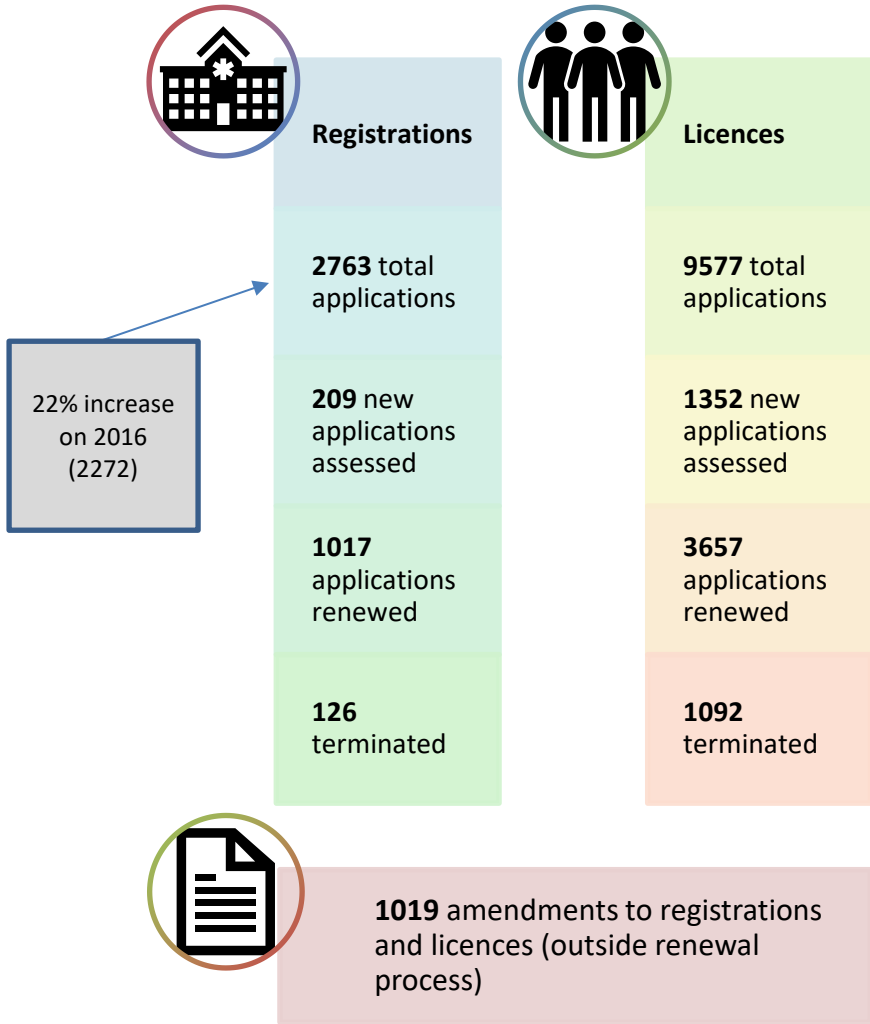
Courses in various aspects of radiation safety are offered by both the government and private sectors.

CHANGES TO LEGISLATION

No amendments were made to the Radiation Safety Act in 2021.

Amendments made to the Radiation Safety (General) Regulations, the Radiation Safety (Qualifications) Regulations and Radiation Safety (Transport of Radioactive Substances) Regulations are listed in attachment 2.

2021 IN REVIEW



9 officers from the Radiation Health Unit authorised under the Radiation Safety Act to carry out the services of the Radiological Council

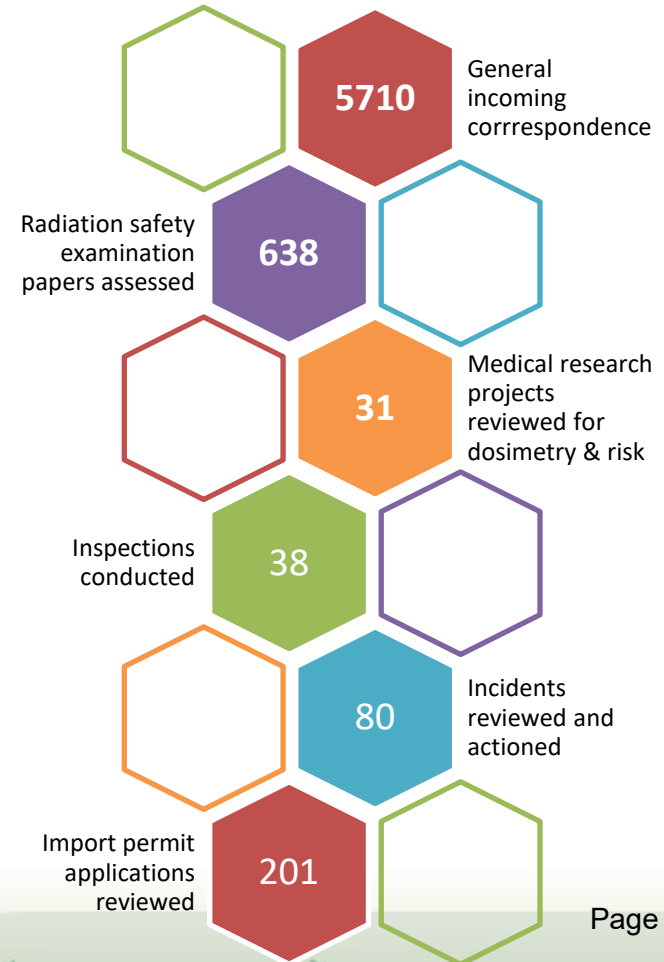
3 clerical officers from the Environmental Health Directorate provide administrative support

36% reduction since 2016 (14)

27% increase on 2016 (7517)

38% increase on 2016 (737)

Indication of 5-year difference

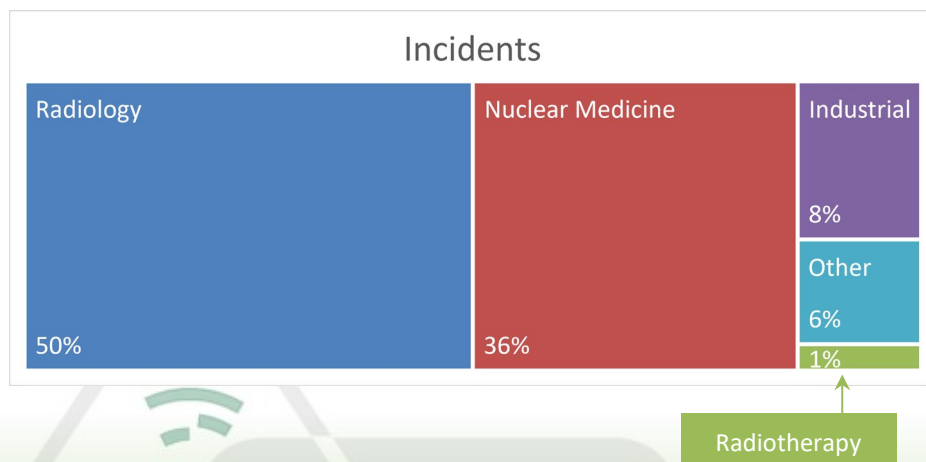


RADIATION INCIDENTS

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 specified medical incidents to be reported to Council as soon as practicable and within 30 days from the date of the incident.

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 80 incidents during 2021 which are presented in the table 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 type	Area	Occurrences
Human Error		
Wrong patient - failure to follow patient ID protocol	Radiology	8
Wrong patient – incorrect patient ID sticker placed on referral	Radiology	4
Incorrect procedure – incorrect information included on request form	Radiology	2
	Nuclear Medicine	1
Incorrect procedure – failure to follow request form	Radiology	18
	Nuclear Medicine	2
Duplication of procedure – due to MRT not following protocol	Radiology	2
	Nuclear Medicine	1
Incorrect activity administered – failure to use automatic dose dispenser correctly	Nuclear Medicine	1
Unintended exposure of fetus – pregnancy check protocols not followed	Nuclear Medicine	1
Intended exposure of fetus – protocol not followed	Radiology	2
Staff protective equipment not worn – failure to follow protocol	Radiology	1

Incident type	Area	Occurrences
Unintended release of radioactive substances – spill and contamination due to failure to follow protocol	Other	2
Accidental laser exposure - failure to turn off cosmetic device following use	Other	1
Accidental exposure of person during medical x-ray training	Other	1
Unnecessary CT imaging required – due to trainee error in placement of I-125 seed	Radiology	1
Transport incident – unauthorised release of Naturally Occurring Radioactive Material	Industrial	1
Equipment Malfunction		
Duplicate imaging required	Radiology	1
Radiopharmaceutical administered and scan not able to be performed	Nuclear Medicine	1
Radiopharmaceutical administration suspended during therapy due to rapid dissociation of I-131 – pre-administration QC protocol followed	Nuclear Medicine	1
Radiopharmaceutical administration duplicated – failure of glomerular filtration rate sample counting equipment	Nuclear Medicine	1

Incident type	Area	Occurrences
Logging source stuck in hole – protocol followed and source subsequently recovered	Industrial	1
Operator high dose recorded – monitoring batch detached from holder in exposure area	Radiotherapy	1
	Industrial Radiography	2
Patient Factors Outside of Operator Control		
Extravasation of radiopharmaceutical – following successful cannulation flush	Nuclear Medicine	6
Radiopharmaceutical administered and scan not performed – patient choice not to proceed	Nuclear Medicine	9
Radiopharmaceutical administered and scan not performed – patient's clinical status changed	Nuclear Medicine	6
Unintended exposure of fetus – patient advised not pregnant	Radiology	1
Other		
Operator high dose recorded – unknown cause	Industrial	2

PROSECUTIONS

No prosecutions were initiated or finalised in 2021.

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 2021 is included in attachment 3.

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 Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes* (Radiation Protection Series 8), 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 exceeds Council's dose threshold.

In 2021, Council assessed and approved the radiation component of the research applications listed in attachment 4.

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 2021 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 2021, Council officers marked 554 industrial examination papers. The number of examinations marked in each category is listed in attachment 5.

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 (MSI) Regulations under the MSI Act. These regulations are administered through the Department of Mines, Industry Regulation and Safety (DMIRS).

The Work Health and Safety (WHS) Act 2020 is due to commence when the WHS regulations are finalised, which is expected to be in March 2022. These will replace the MSI Act and Regulations. It is understood that this will require consequential amendments to the Radiation Safety Act.

Low Level Radioactive Waste Facilities

Council has been continuing to liaise with the proponent and review of documentation associated with a proposal for a privately owned and commercially operated low-level radioactive waste facility in Western Australia. The assessment process is continuing and is now expected to be completed in 2022. Independent technical advice has been sought to determine the proposed facility's compliance with the applicable safety standards. As at the end of 2021, the site is authorised only for the storage of radioactive material.

The existing State owned and operated low level Intractable Waste Disposal Facility has remained in contact with Council with regards to proposals for a disposal operation. However, the planned disposal campaign for low-level radioactive waste did not occur in 2021.

MISCELLANEOUS

COVID-19

The Radiological Council has been cognisant of the difficulties individuals and operations have faced during the COVID-19 pandemic. However, as the situation evolved in Western Australia, the Council undertook initiatives to ensure that radiation safety was not compromised. The initiatives were both industry-wide or as needed on a case by case basis. Individuals and organisations regulated under the Radiation Safety Act were recommended to consider business continuity planning, noting that radiation safety and the security and oversight of radioactive sources, irradiating apparatus and electronic products was to remain paramount.

Automatic Mutual Recognition

In 2020 the Council was advised of the proposal to establish a scheme for automatic mutual recognition (AMR) for the purposes of streamlining occupational registration processes for applicants working in more than one jurisdiction.

The Mutual Recognition Amendment Bill 2021 (Commonwealth) (the Commonwealth Amendment Bill) amends the Mutual Recognition Act 1992 (Commonwealth) to introduce AMR of occupations. The Commonwealth Amendment Bill allows a person who is licensed, registered or approved in one State to be considered registered, licensed or approved to perform the same activities in another jurisdiction without the need to go through application processes or pay additional registration fees. The Commonwealth Amendment Bill passed the House of Representatives on 23 June 2021 and commenced 1 July 2021

The AMR scheme has been developed through an Intergovernmental

Agreement between the Commonwealth, State and Territory Governments. States and Territories agreed to introduce legislation to facilitate the scheme and provided a five-year timeline (to 2026) to establish governance, monitoring, and review mechanisms as part of the scheme's implementation. When introduced, the scheme will require sharing of information (such as disciplinary actions and other data) between jurisdictions.

Some jurisdictions have already commenced the AMR scheme. In November 2021, the Western Australian Government introduced the Mutual Recognition Amendment Bill 2021 into Parliament to allow Western Australia to participate in the scheme. The Western Australian Government is working towards commencing the scheme from 1 July 2022. The Council is continuing to work through the licence purposes that may be affected by the application of AMR.

Until the AMR scheme commences in Western Australia, people can still apply to work here under existing mutual recognition arrangements.

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 2021 is in attachment 6.

Environmental Health Standing Committee

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).

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.

The *National Directory for Radiation Protection (2nd Edition, 2021)* (NDRP 2nd edition, 2021) was published in October 2021, having received endorsement from all State and Territory Health Ministers between July and October 2021.

Council will continue its participation and further development of the NDRP through the national Radiation Health Committee and the Radiation Health Expert Review Panel under enHealth.

Radiological Council Website

The transition of the Radiological Council website to a new platform under a content management system commenced late in 2021. The website architecture will be based on that used for other entities within the Department of Health, and so already meets the website standards set by the Office of Digital Government, Department of Premier and Cabinet.

Authorised officers under the Radiation Safety Act were trained in the use of the new content management system. The new website is expected to be launched in the first quarter of 2022.

X-ray Screening

In April 2021, Council was advised that a tender was in progress for x-ray equipment to be used in Western Australia for the purpose of security screening of individuals. The use of x-ray equipment for this purpose is not currently approved in Western Australia.

Council has been liaising with representatives of the agency that is managing the tender. The agency engaged a consultant to assist with the justification, submission and application to utilise the radiation technology.

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 2021 are included in attachment 7.

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. 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. 31 Temporary Permits were current as at 31 December 2021.

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 8 shows the types and numbers of licences and

registrations (or individual exemptions) granted or renewed in 2021.

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.

ATTACHMENT 1: RADIOLOGICAL COUNCIL**MEMBERS OF THE RADIOLOGICAL COUNCIL**

Members	Qualification or Designation	Deputy
<i>Appointment under Sections 13(2)(a) and 13(3) of the Act</i>		
Dr A Robertson (Chairman)	Medical Practitioner	Dr R Bangor Jones
<i>Appointment under Sections 13(2)(b), 15(1) and 17 (1) of the Act</i>		
Dr C Hewavitharana	Radiologist	Dr D Dissanayake
Dr E Thomas	Nuclear Medicine Physician	Dr R Troedson
Dr R Price	Physicist	Mr C Storm
Mr D Kwiatkowski	Electronic Engineer	Vacant
A/Prof R Francis	Tertiary Institutions representative	Prof P Parizel
Vacant	Medical Radiation Technologist	Ms H Parry
Mr N Tsurikov	Expert in Mining Radiation Hazards	N/a
Mr F Harris	Expert in Mining Radiation Hazards	N/a

2021 MEETING ATTENDANCE

	9 FEB	9 MAR	13 APR	11 MAY	8 JUN	13 JUL	14 SEP	12 OCT	9 NOV	14 DEC
Dr A Robertson	D	D	D	D	✓	✓	✓	✓	✓	D
Dr R Bangor-Jones	✓	✓	✓	✓	A	O	O	A	A	✓
Dr R Price	✓	✓	D	✓	✓	✓	✓	✓	✓	D
A/Prof R Francis	✓	A	A	✓	✓	A	✓	✓	✓	✓
Dr E Thomas	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Dr C Hewavitharana	✓	✓	✓	✓	✓	✓	✓	✓	A	✓
Mr D Kwiatkowski	✓	✓	✓	✓	✓	✓	A	A	A	A
Ms H Parry	✓	✓	✓	A	✓	✓	A	✓	✓	A
Mr N Tsurikov	✓	✓	A	✓	✓	✓	✓	✓	✓	✓
Mr F Harris	✓	✓	✓	✓	✓	A	✓	A	A	✓
Mr C Storm	O	O	✓	O	O	O	O	O	O	✓

✓ attended D deputy A apology O observer R retired

ATTACHMENT 2: LEGISLATION AMENDMENTS**RADIATION SAFETY ACT**

None

RADIATION SAFETY (GENERAL) REGULATIONS

Health Regulations Amendment (Fees and Charges) Regulations 2021 Pt.6

Amendment to fees (Schedule XV).

Government Gazette 29 June 2021 SL 2021/108

RADIATION SAFETY (QUALIFICATIONS) REGULATIONS

Health Regulations Amendment (Fees and Charges) Regulations 2021 Pt.7

Amendment to fees for examinations (Schedule 2).

Government Gazette 29 June 2021 SL 2021/108

RADIATION SAFETY (TRANSPORT OF RADIOACTIVE SUBSTANCES) REGULATIONS

Radiation Safety (Transport of Radioactive Substances) Amendment Regulations 2021

Amendments to the definitions and terms so as to adopt the *Code for the Safe Transport of Radioactive Material (2019)*, RPS C-2 published by the Australian Radiation Protection and Nuclear Safety Agency and the International Atomic Energy Agency *Regulations for the Safe Transport of Radioactive Material 2018 Edition*, SSR-6 (Rev. 1).

Government Gazette 10 September 2021 SL 2021/160

ATTACHMENT 3: COMPLIANCE TESTING

Medical

- A** *Compliant*
- B** *Conditionally compliant*
- C** *Non-compliant¹*

Category	A	B	C	Total
CT	84	-	-	84
Dental – cone beam CT	37	-	-	37
Dental – intraoral	694	-	2	696
Dental – panoramic and/or cephalometric	158	-	1	159
Fluoroscopic – fixed	39	-	6	45
Fluoroscopic – fixed C or U arm	27	-	3	30
Fluoroscopic – mobile	123	-	1	124
Mammography	59	-	-	59
Radiographic – fixed	96	-	4	100
Radiographic – mobile	52	-	3	55
Total	1369	0	20	1389

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 24 re-tests conducted during 2021, 100% resulted in the equipment being granted either a compliance or conditional compliance certificate.

Industrial – Fixed Gauges

- A** *Compliant*
B *Non-compliant²*

Category	A	B	Total
Density	792	79	871
In-stream analysis	6	-	6
Level	94	-	94
Other	10	-	10
Total	902	79	981

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: RESEARCH PROJECT APPLICATIONS ASSESSED

Research Project Title
A phase 3, multicentre, randomized, open-label, active-controlled study of Trastuzumab Deruxtecan (T-DXd) versus Trastuzumab Emansine (TDM1) in subjects with high-risk HER2-positive primary breast cancer who have residual invasive disease in breast or axillary lymph nodes following neoadjuvant therapy.
A phase 3, randomized, multi-center, open-label study of Trastuzumab Deruxtecan (T-DXd) versus investigator's choice chemotherapy in HER2-low, hormone receptor positive breast cancer patients whose disease has progressed on endocrine therapy in the metastatic setting.
An open-label, multicenter, rollover study to evaluate the safety, tolerability and efficacy of long-term gantenerumab administration in participants with Alzheimer's disease.
A phase 3, multicenter, randomized, double-blind, placebo-controlled trial comparing the efficacy and safety of tafasitamab plus lenalidomide in addition to R-CHOP versus R-CHOP in previously untreated, high-intermediate and high-risk patients with newly-diagnosed diffuse large B-cell lymphoma (DLBCL).
AHEAD 3-45 Study: A Placebo-Controlled, Double-Blind, Parallel-Treatment Arm, 216 Week Study to Evaluate Efficacy and Safety of Treatment with BAN2401 in Subjects with Preclinical Alzheimer's Disease and Elevated Amyloid (A45 Trial) and in Subjects with Early Preclinical Alzheimer's Disease and Intermediate Amyloid (A3 Trial).
The NIPU Study – Nivolumab and ipilimumab +/- UV1 vaccination as second line treatment in patients with malignant mesothelioma.

Research Project Title
A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Assess the Efficacy and Safety of JNJ-63733657, an Anti-tau Monoclonal Antibody, in Participants with Early Alzheimer's Disease.
A phase III randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of PRM-151 in patients with idiopathic pulmonary fibrosis.
A Phase 3, Randomized Study to Evaluate the Efficacy and Safety of Pembrolizumab (MK-3475) plus Lenvatinib (E7080/MK-7902) plus Chemotherapy Compared with Standard of Care Therapy as First-line Intervention in Participants with Advanced/Metastatic HER2 Negative Gastric/Gastroesophageal Junction Adenocarcinoma (LEAP-015)
Dulaglutide or semaglutide and vascular inflammation in coronary ischaemia: A positron emission tomography study.
Tracking the natural history of Dutch-type Hereditary Cerebral Amyloid Angiopathy - A trial run in study (TRACK D-CAA)
Towards Non-Invasive Patient-Specific Biomechanical Growth Rate Predication of Abdominal Aortic Aneurysms
A Phase 2 Randomized Double-blind Study of Relatlimab plus Nivolumab in Combination with Chemotherapy vs. Nivolumab in Combination with Chemotherapy as First Line Treatment for Participants with Stage IV or Recurrent Non-small Cell Lung Cancer (NSCLC)

Research Project Title

Multicentre, Open Label, Phase 3 study of Tabelecleucel for Solid Organ or Allogeneic Hematopoietic Cell Transplant Subjects with Epstein-Barr Virus-Associated Post-Transplant Lymphoproliferative Disease after Failure of Rituximab or Rituximab and Chemotherapy.

A Phase Ia/b Clinical Study on Safety, Tolerability, and Pharmacokinetics/Pharmacodynamics of BTK Protein Degradation Agent HSK29116 in Subjects with Relapsed or Refractory B-Cell Malignancy

A Phase Ia/Ib Dose-Escalation And Dose-Expansion Study Evaluating The Safety, Pharmacokinetics, And Activity Of Gdc 6036 As A Single Agent And In Combination With Other Anti-Cancer Therapies In Patients With Advanced Or Metastatic Solid Tumors With A KRAS G12c Mutation.

AL002-2 - A phase 2 randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of AL002 in participants with Early Alzheimer's disease

A Phase 3, Randomised, Double Blind, Placebo Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Tafasitamab Plus Lenalidomide in Addition to Rituximab Versus Lenalidomide in Addition to Rituximab in Patients with Relapsed/Refractory (R/R) Follicular Lymphoma Grade 1 to 3a or R/R Marginal Zone Lymphoma.

A Global, Phase 2 Study of ARX788 in HER2-Positive Metastatic Breast Cancer Patients Whose Disease is Resistant or Refractory to T-DM1, and/or T-DXd, and/or Tucatinib-Containing Regimens ACE-Breast-03

Phase ½ Study of Bempegaldesleukin in Combination with Nivolumab in Children, Adolescents, and Young Adults with Recurrent or Refractory Malignancies.

Research Project Title

A Phase 1, Open-Label, Dose-Escalation and Expansion Study of the Bruton Tyrosine Kinase-Targeted Protein-Degrader BGB-16673 in Patients With B-Cell Malignancies.

A double-blind placebo controlled randomized phase III trial of Fulvestrant and Ipatasertib as treatment for advanced/metastatic HER-2 negative and estrogen receptor positive (ER+) breast cancer following progression on first line CDK 4/6 inhibitor and aromatase inhibitor.

First-in-human (FIH), Open-Label, Phase I Dose Escalation Study of ADG126 in Patients with Advanced Malignancies.

A First-in-human, Open-label, Multiple center Phase 1 Dose-Escalation Study to Evaluate Safety, Tolerability, Pharmacokinetic, Immunogenicity, and Preliminary Efficacy of SG301 in Subjects with Relapsed or Refractory Multiple Myeloma and other Haematological Malignancies.

A Phase 3 Open-Label, Randomized Study of LOXO-305 versus Investigator's Choice of Idelalisib plus Rituximab or Bendamustine plus Rituximab in BTK Inhibitor Pretreated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (BRUIN CLL-321).

A Phase 3, Randomized, Multicenter, Open-Label Study Comparing Iberdomide, Daratumumab and Dexamethasone (IberDd) Versus Daratumumab, Bortezomib, and Dexamethasone (DVd) in Subjects with Relapsed or Refractory Multiple Myeloma (RRMM) (EXCALIBER-RRMM).

A Phase 3 Open-Label, Randomized Study of LOXO-305 versus Investigator Choice of BTK Inhibitor in Patients with previously treated BTK Inhibitor Naïve Mantle Cell Lymphoma (BRUIN-MCL-321).

Research Project Title

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 3 Open-Label, Randomized Study of Fixed Duration Pirtobrutinib (LOXO-305) plus Venetoclax and Rituximab versus Venetoclax and Rituximab in Previously Treated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (BRUIN-CLL-322)" – LOXO-BTK-20022

A confirmatory, prospective, open-label, multi-centre phase 3 study to evaluate diagnostic performance of 89Zirconium-labelled girentuximab (89Zr-TLX250) to non-invasively detect clear cell renal cell carcinoma (ccRCC) by positron emission tomography/CT (PET/CT) imaging in patients with indeterminate renal masses.

A Phase 1 Clinical Study to Evaluate the Tolerability, Safety, Immunogenicity and Efficacy of the Neoantigen mRNA Personalised Cancer Vaccine SW1115C3 in Patients with Advanced Malignant Solid Tumours

Research Project Title

A Randomized, Multicenter, Phase 3 Study of Zanidatamab in Combination with Chemotherapy with or without Tislelizumab in Subjects with HER2-positive Unresectable Locally Advanced or Metastatic Gastroesophageal Adenocarcinoma (GEA).

A Phase 3 Open-Label, Randomized Study of Fixed Duration Pirtobrutinib (LOXO-305) plus Venetoclax and Rituximab versus Venetoclax and Rituximab in Previously Treated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma.

A Phase I/II, First-in-Human (FIH), Open-Label, Dose Escalation and Expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of LM-108 (an Anti-CCR8 mAb) as a Single Agent or in Combination with Anti-PD-1 Antibody in Subjects with Advanced Solid Tumours

A Phase Ib/II, Open-Label, Multicenter, Randomized Umbrella Study Evaluating the Efficacy and Safety of Multiple Immunotherapy-Based Treatment Combinations in Patients with Metastatic Triple-Negative Breast Cancer (TNBC)

ATTACHMENT 5: INDUSTRIAL RADIATION SAFETY EXAMINATIONS*Current at 31 December 2021*

Category	2021	2020	2019	2018	2017
Borehole Logging	115	87	46	24	29
Fixed Gauges	134	85	119	83	109
Industrial Radiography	22	15	33	30	49
Industrial Radiography (Advanced)	-	-	1	0	0
Industrial Radiography (Assistant)	86	83	97	109	57
Portable Gauges	102	78	80	61	50
Portable Gauges (WA Requirements)	-	3	14	8	3
Transport	25	22	54	25	42
Service – Cabinet X-ray	2	3	16	2	5
Service – Industrial Radiography (X-ray)	0	0	1	0	0
Service – X-ray Analysis	0	0	2	0	0
X-ray Analysis – Use	0	1	0	0	0
X-ray Analysis – Use and Restricted Service	68	44	47	111	48
Total	554	421	510	453	392

ATTACHMENT 6: LIST OF AUSTRALIAN RADIATION PROTECTION AND NUCLEAR SAFETY AGENCY PUBLICATIONS FOR 2021

Title
NDRP 2nd edition, 2021 <i>National Directory for Radiation Protection (2nd Edition, 2021)</i>
RPS S-1 (Rev. 1) <i>Standard for Limiting Exposure to Radiofrequency Fields – 100 kHz to 300 GHz (2021)</i>

ATTACHMENT 7: REGISTERED IRRADIATING APPARATUS, ELECTRONIC PRODUCTS AND SEALED RADIOACTIVE SUBSTANCES

Current at 31 December 2021

- A** *Irradiating apparatus and electronic products³*
- B** *Radioactive substances (sealed sources only)*

Category	A	B
Bone densitometry	70	-
Cabinet x-ray equipment	210	-
Calibration	1	791
CT	142	-
SPECT-CT and PET-CT	39	-
Dental – cone beam CT	82	-
Dental – intraoral	2628	-
Dental – panoramic and/or cephalometric	520	-
Education and research	24	970
Fluoroscopic – fixed	86	-
Fluoroscopic – mobile	154	-
Gauges – density/level	10	3607
Gauges – in stream analysis	2	89
Gauges – logging	60	422
Gauges – neutron moisture/density portable	-	471
Gauges – other	-	341
Irradiator	-	48
Isotope Production	1	-
Laser – entertainment	55	-

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
Laser – industrial	221	-
Laser – medical	396	-
Laser – other medical	429	-
Laser – podiatry	18	-
Laser – research	217	-
Linear accelerator	27	-
Mammography	73	-
Non-destructive testing	228	129
Non-destructive testing – crawler control	-	16
Portable mineral analyser	-	8
Radiographic – fixed	372	-
Radiographic – mobile	406	-
Sealed Sources – other	-	205
Simulator	7	-
Special purpose x-ray	50	-
Static detection/measurement	-	3
Static elimination	-	14
Storage	-	358
Superficial radiotherapy	2	-
Test source	3	-
Therapy	4	28
Therapy – HDR brachytherapy	-	2
Transilluminator	129	-
Tracer Studies	-	131
X-ray analysis	808	-
Total	7474	7633

ATTACHMENT 8: LICENCES AND REGISTRATIONS

Current at 31 December 2021

Including individual exemptions granted under Section 6 of the Act.

	X-ray and/or Electronic Products		Radioactive Substances		TOTAL	
	2021	2020	2021	2020	2021	2020
Licences	7153	6750	2424	2349	9577	9099
Registrations	2334	2242	429	421	2763	2663
TOTAL	9487	8992	2853	2770	12340	11762
Change from 2020	+ 5.5%		+ 3.0%		+ 4.9%	



Attachment 8 (cont)

Purposes for Licences and Exemptions from Licence – total current as at 31 December 2021

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

Total	Purpose
19	Bone Densitometry
3	Bone Densitometry (Exemption)
112	Cabinet X-ray Equipment
60	Compliance Testing - Diagnostic X-ray Equipment
555	Compliance Testing - Radioactive Gauges
13	Cyclotron Operation
4	Cyclotron Servicing
5	Education (Apparatus)
27	Education (Substances)
509	Fluoroscopy - Medical
72	Fluoroscopy - Medical (Exemption)
32	Fluoroscopy - Medical (Non-Specialist Exemption)
16	Fluoroscopy - Podiatry (Exemption)
2	Fluoroscopy - Veterinary
5	Gamma Irradiator - Use
549	Gauges - Industrial
7	Gauges - Industrial (Installation)
1	Gauges - Level (CO2)
344	Gauges - Logging
580	Gauges - Moisture and/or Density (Portable)
4	Gauges - Other (Apparatus)
97	Gauges - Other (Substances)
1	Installation of X-ray Equipment

Total	Purpose
3	Installation of X-ray Equipment - Dental
4	Lasers - Acupuncture
2	Lasers - Allied Health
3	Lasers - Allied Health (Exemption)
0	Lasers - Astronomy
11	Lasers - Chiropractic
201	Lasers - Dental
8	Lasers - Educational
34	Lasers - Entertainment
512	Lasers - Hair Removal (Exemption)
83	Lasers - Industrial
345	Lasers - Medical
23	Lasers - Medical (Exemption)
1	Lasers - Osteopathy (Exemption)
8	Lasers - Other
120	Lasers - Physiotherapy
46	Lasers - Podiatry (Exemption)
66	Lasers - Research
91	Lasers - Service
92	Lasers - Superficial Cosmetic (Exemption)
19	Lasers - Tattoo Removal (Exemption)
23	Lasers - Veterinary
1	Manufacture of X-ray Equipment

Total	Purpose
2	Medical Physics
32	Medical Physics - Radiotherapy (Apparatus)
21	Medical Physics - Radiotherapy (Substances)
96	Medical Radiation Technology - Diagnostic Nuclear
1334	Medical Radiation Technology - Medical Imaging
35	Medical Radiation Technology - Nuclear Medicine - Diagnostic CT
240	Medical Radiation Technology - Radiation Therapy Irradiating Apparatus
321	Medical Radiology
4	Nuclear Medicine - Calibration and QC Sources
45	Nuclear Medicine - Diagnostic
39	Nuclear Medicine - Therapeutic
1	Nuclear Medicine - Therapy (Endocrinology)
6	Nuclear Medicine - Veterinary
7	Pathology Tests
16	Portable Mineral Analysers
508	Portable Mineral Analysers (X-ray)
3	Possession of X-ray Equipment - Diagnostic Medical
1	Possession of X-ray Equipment - Diagnostic Medical and Dental
3	Quality Assurance Procedures
30	Radioactive Ores - Analytical Laboratories
13	Radioactive Ores - Exploration
18	Radioactive Ores - Mining and/or Processing
15	Radioactive Substances - Calibration Sources
1	Radioactive Substances - Medical
38	Radioactive Substances - Sale
41	Radioactive Substances - Service of Devices

Total	Purpose
16	Radioactive Substances - Tracer Studies (Industry)
26	Radiography - Chiropractic (Extended)
169	Radiography - Chiropractic (Restricted)
1	Radiography - Forensic
418	Radiography - Industrial (Gamma)
420	Radiography - Industrial (X-ray)
3	Radiography - Mammography Screening (Exemption)
-	Radiography - Medical (Direction and Supervision)
3	Radiography - Security
947	Radiography - Veterinary
3	Radioguidance - Medical (Radioactive Substances)
153	Radiology - Dental
11	Radiology - Veterinary
25	Radiopharmaceutical Manufacture and Dispensing
29	Radiotherapy - Medical (Apparatus)
20	Radiotherapy - Medical (Substances)
11	Research
37	Research - Unsealed Radioactive Substances
16	Research - X-ray
35	Sale of Electronic Products
92	Sale of X-ray Equipment
33	Service of X-ray Equipment - Analytical
37	Service of X-ray Equipment - Cabinet
34	Service of X-ray Equipment - Dental
142	Service of X-ray Equipment - Diagnostic
5	Service of X-ray Equipment - Diagnostic (Extended)
3	Service of X-ray Equipment - Industrial NDT
42	Service of X-ray Equipment - Linear Accelerators
4	Service of X-ray Equipment - Other

Total	Purpose
5	Service of X-ray Equipment - Superficial X-ray Therapy
18	Special Purpose Enclosed X-ray Equipment
1	Static Detection
1	Static Electricity Measurement
1	Static Elimination
4	Storage (Apparatus)
17	Storage (Substances)

Total	Purpose
21	Transilluminators
148	Transport
128	X-ray Analysis - Use
306	X-ray Analysis - Use and Service (Restricted)
3	X-ray Irradiator
5	X-ray - Industrial

Attachment 8 (cont)

Purposes for Registrations and Exemptions from Registration – total current as at 31 December 2021

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

Total	Purpose
26	Bone Densitometry
13	Bone Densitometry (Exemption)
93	Cabinet X-ray Equipment
2	Cyclotron Operation
2	Disposal of Radioactive Waste
9	Education (Apparatus)
15	Education (Substances)
28	Education – Demonstration Radioactive Sources (Exemption)
6	Fluoroscopy – Medical
1	Fluoroscopy – Podiatry
4	Gamma Irradiator
134	Gauges – Industrial
3	Gauges – Level (CO2)
19	Gauges – Logging
46	Gauges – Moisture and/or Density (Portable)
16	Gauges – Other (Apparatus)
7	Gauges – Other (Substances)
2	Lasers – Acupuncture
2	Lasers – Analyser
1	Lasers – Astronomy
9	Lasers – Chiropractic
140	Lasers – Dental
2	Lasers – Educational

Total	Purpose
15	Lasers – Entertainment
70	Lasers – Hair Removal
45	Lasers – Industrial
2	Lasers – Manufacture
182	Lasers – Medical
1	Lasers – Osteopathy
3	Lasers – Other
53	Lasers – Physiotherapy
19	Lasers – Podiatry
8	Lasers – Research
10	Lasers – Sale, Service, Maintenance and Testing
20	Lasers – Storage
35	Lasers – Superficial Cosmetic
3	Lasers – Tattoo Removal
15	Lasers – Veterinary
2	Manufacture of X-ray Equipment
146	Medical Radiology
24	Nuclear Medicine – Diagnostic
21	Nuclear Medicine – Computed Tomography
11	Nuclear Medicine – Therapeutic
4	Nuclear Medicine – Veterinary
6	Pathology Tests
5	Portable Mineral Analysers

Total	Purpose
271	Portable Mineral Analysers (X-ray)
13	Radioactive Ores – Analytical Laboratories
10	Radioactive Ores – Exploration
37	Radioactive Ores – Mining and/or Processing
14	Radioactive Substances – Calibration Sources
1	Radioactive Substances – Medical
7	Radioactive Substances – Sale
3	Radioactive Substances – Service of Devices
2	Radioactive Substances – Tracer Studies (Industry)
14	Radiography – Chest Screening
44	Radiography – Chiropractic
824	Radiography – Dental
1	Radiography – Forensic
26	Radiography – Industrial (Gamma)
34	Radiography – Industrial (X-ray)
14	Radiography – Mammography Screening
44	Radiography – Medical (Operator)
10	Radiography – Medical (Unrestricted)
1	Radiography – Security
282	Radiography – Veterinary
4	Radioguidance – Medical (Radioactive Substances)
63	Radiology – Dental
4	Radiology – Veterinary

Total	Purpose
2	Radiopharmaceutical Manufacture and Dispensing
12	Radiotherapy – Medical (Apparatus)
6	Radiotherapy – Medical (Substances)
1	Radiotherapy – Veterinary (Apparatus)
1	Radiotherapy – Veterinary (Substances)
2	Regulatory Authority
5	Research (Substances)
11	Research – Unsealed Radioactive Substances
9	Research – X-ray
6	Sale of Electronic Products
22	Sale of X-ray Equipment
52	Security of Radioactive Sources
16	Service of X-ray Equipment
12	Special Purpose Enclosed X-ray Equipment
1	Static Electricity Measurement
2	Static Elimination
67	Storage (Apparatus)
56	Storage (Substances)
13	Transilluminators
17	Transport
132	X-ray Analysis
2	X-ray Irradiator
1	X-ray - Industrial

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
MIT	Medical Imaging Technologist
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)

The Government of Western Australia acknowledges the traditional custodians throughout Western Australia and their continuing connection to the land, waters and community. We pay our respects to all members of the Aboriginal communities and their cultures; and to Elders both past and present.

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