REPORT OF THE

RADIOLOGICAL COUNCIL

for the year ended

31 December 2023

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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 11 times in 2023, 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.

A restructure for the Radiation Health Unit to a new directorate within the Department of Health was announced in December 2022 and was finalised in January 2023. The Unit moved from the Environmental Health Directorate to the Public Health Regulation Directorate.

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

Amendments made in 2023 to the Radiation Safety Act, Radiation Safety (General) Regulations and the Radiation Safety (Qualifications) Regulations are listed in attachment 2.

No amendments were made to the Radiation Safety (Transport of Radioactive Substances) Regulations in 2023.

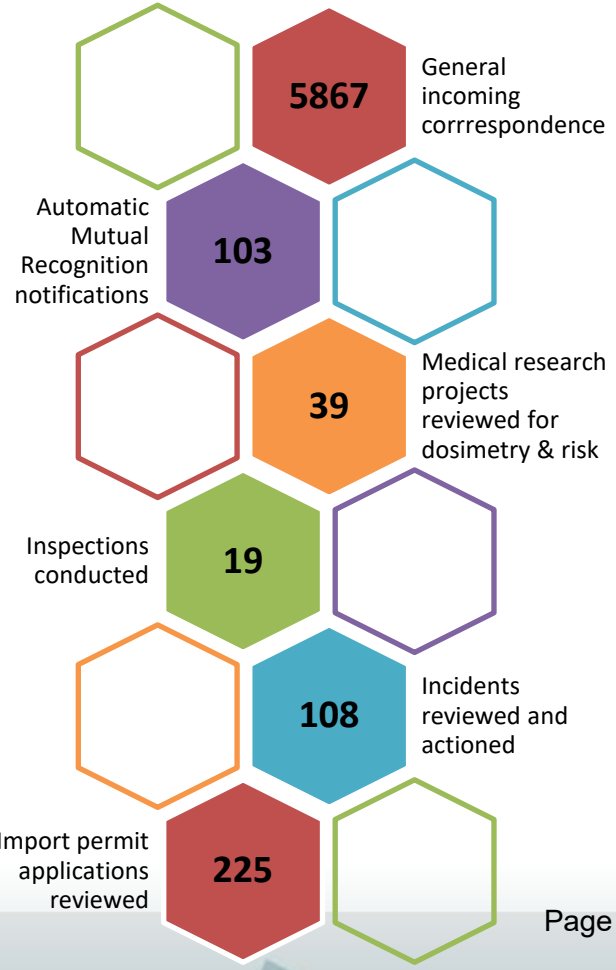
2023 IN REVIEW

Registrations	Licences
3024 total applications	**10723** total applications
183 new applications assessed	**1495** new applications assessed
865 applications renewed	**3789** applications renewed
27 terminated	**1079** terminated

501 amendments to registrations and licences (outside renewal process)

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

4 clerical officers provide administrative support



PROSECUTIONS

No prosecutions were initiated or finalised in 2023.

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 103 incidents during 2023 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.

Missing Source Incident

In addition, an incident occurred in December 2022 and January 2023 concerning the failure of a gauge at a mine site and the subsequent temporary loss of the radioactive source capsule during transport.

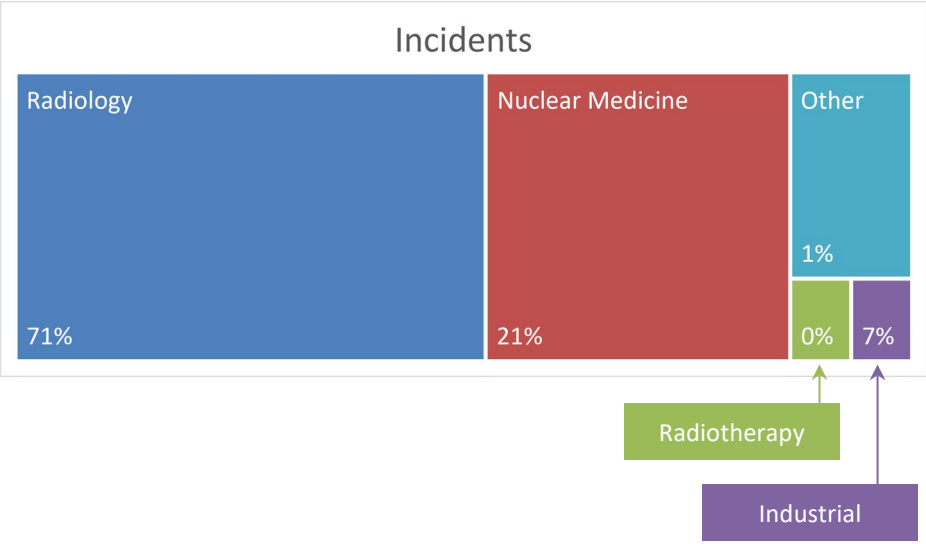
The Council received a report on 25 January 2023 that a Caesium-137 radioactive source capsule was missing while in transit between a mine site north of Newman and Perth between 12-16 January.

The radioactive source capsule was found on 1 February 2023 following a large-scale interagency search for the missing object along the 1400-kilometre stretch of Great Northern Highway, led by the Department of Fire and Emergency Services.

The radioactive source capsule – 8-millimetres high by 6-millimetres round – was located two-metres off the northbound roadside edge of Great Northern Highway. It was found intact and has been safely recovered and placed in secure storage.

Given the remote location, the risk of radiation exposure was assessed as negligible.

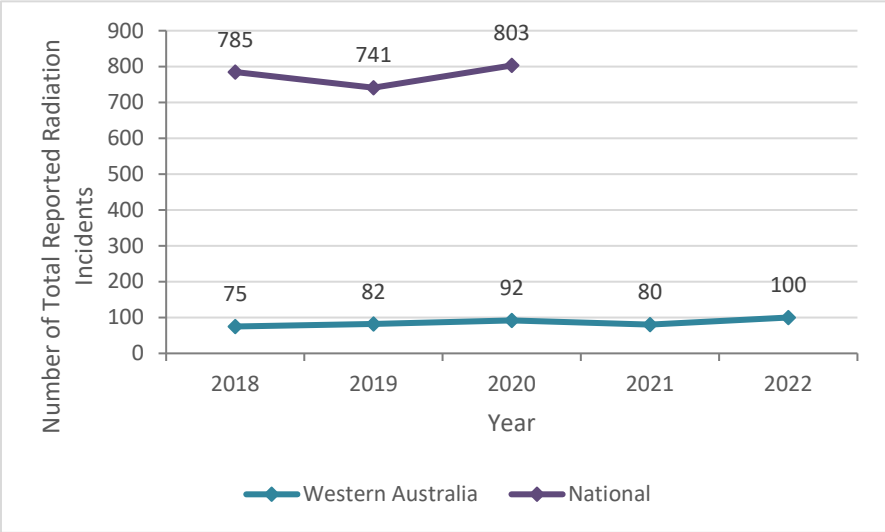
The Council acknowledges the efforts of all State and Commonwealth agencies involved in the recovery operation.



Incident type	Area	Occurrences
Human Error		
Wrong patient - failure to follow patient ID protocol	Radiology	13
Wrong patient – incorrect patient ID on referral	Radiology	8
	Nuclear Medicine	1
Incorrect procedure – incorrect information included on request form	Radiology	2
Incorrect procedure – failure to follow request form	Radiology	20
Incorrect modality – failure to follow request form	Radiology	9
Duplication of procedure – due to incorrect recording of images in PACS	Radiology	3
Incorrect radiopharmaceutical administered – failure to follow protocol	Nuclear Medicine	6
Unintended release of radioactive substances – spill and contamination in controlled area due to dropped syringe	Nuclear Medicine	1
Unauthorised access to controlled area during research laser use	Other	1
Unnecessary staff exposure due to failure of operator to verify room empty during testing	Radiology	1
Equipment Malfunction		
Duplicate imaging required	Radiology	5
Radiopharmaceutical administered and scan not successfully performed or top-up dose required	Nuclear Medicine	3

Incident type	Area	Occurrences
Logging source stuck in hole – protocol followed, source recovered	Industrial	4
Patient Factors Outside of Operator Control		
Extravasation of radiopharmaceutical – following successful cannulation flush	Nuclear Medicine	3
Radiopharmaceutical administered and scan not performed – patient choice not to proceed	Nuclear Medicine	6
Radiopharmaceutical administered and scan not performed – patient's clinical status changed	Nuclear Medicine	3
Unintended exposure of fetus – patient advised not pregnant	Radiology	1
Duplication of procedure – due to duplicate referral form	Radiology	11
Duplication of procedure – due to incorrect PICC line insertion	Radiology	1
Other		
Unauthorised disabling of fluoroscopic equipment in theatre	Radiology	1
Missing source incident	Industrial	1
Portable gauge run over by truck	Industrial	1
During attempted recovery of borehole logging tool, the radioactive source was drilled through	Industrial	1

The graph below illustrates the number of incidents in Western Australia compared to data available from the Australian Radiation Incident Register[1]. ARIR data is currently only available up to 2020.



[1] www.arpansa.gov.au/regulation-and-licensing/safety-security-transport/australian-radiation-incidents-register

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 entered into the database in 2023 is included in attachment 3. There are a number of tests conducted in 2023 that are awaiting entry into the database.

Whilst Western Australia has for many decades had an established and well-regarded diagnostic x-ray equipment compliance testing program, this is not the case across all Australian jurisdictions. In 2022 the Council was represented on a national compliance testing working group, which was formed to compile a reference document of compliance testing requirements that should be mandated by radiation regulators. The group met numerous times during 2023 and drafted a document of testing requirements which was provided to the Radiation Health Committee at its November meeting.

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 2023, Council assessed and approved the radiation component of the research applications listed in attachment 4.

Medical Imaging at Urgent Care Clinics

Council was requested to review the limitation applied to x-ray operators (XRO) prohibiting their operation within the metropolitan area, such that new metropolitan urgent care clinics may utilise x-ray operators in lieu of qualified medical imaging technologists (MIT). Existing urgent care clinics utilise MITs to provide their medical imaging service.

The WA XRO program is intended to provide limited medical imaging services in rural and remote areas where a medical imaging service would otherwise not be available. The limitation on the operation of XROs has been in place since 2001.

The Council reviewed the matter, including the medical imaging

services provided more broadly in WA Urgent Care Clinics, the applicability of the WA XRO program and the situation in other Australian jurisdictions, and noted that the review does not support a change to the current requirement for a licensed MIT.

The Council reaffirmed its decision to restrict XROs to services outside the metropolitan area.

New Cyclotron Radiopharmaceutical Production Facility

Previously, only one cyclotron radiopharmaceutical manufacture and dispensing facility has existed in Western Australia.

In 2020, a private company commenced discussions with the Council regarding their intent to build and operate a privately owned cyclotron radiopharmaceutical manufacture and dispensing facility in Perth. Over 2021 and 2022 the Council liaised with the proponent and reviewed documentation associated with the proposal. In 2022 the Council provided approvals under the Radiation Safety Act for the facility design (radiation shielding and other design safety features), operator training, cyclotron and hot cell installation and associated commissioning activities.

The Council continued the assessment process for the operational aspects of the facility. This was completed in 2023 and the Council provided approval for the facility to commence operations.

Review of I-131 Discharge to Sewer

In 2020 the Council received a request from two Western Australian nuclear medicine physicians to amend the patient administration and discharge requirements relating to inpatient I-131 therapies. To adequately address this request, the Council needed to undertake a review relating to I-131 requirements, and particularly the discharge of I-131 contaminated effluent to sewer and associated implications for the Western Australian community.

The commencement of the review was delayed at the time due to the Council needing to complete pre-existing reviews. The review commenced in 2021 and was further prioritised in 2022 with the Council reconsidering its operational resources. The review was finalised mid-2023 and established that direct discharge of I-131 from nuclear medicine patient waste at treating facilities in WA is not of concern.

Council has agreed to progress consultation on the review outcomes with Water Corporation, with a view to conducting a trial to further support amendment of the Radiation Safety (General) Regulations.

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 2023 is included in attachment 3.

Standards for Council Examinations

Successful completion of the relevant Radiological Council radiation safety examination is a prerequisite for many types of licences issued under the Radiation Safety Act, often along with attendance at a recognised radiation safety course and/or practical experience or competency sign-off.

Prior to 2002, recognised training providers assessed the Council examinations that they invigilated. In 2002 a review was conducted of the examination marking and following significant issues with inconsistent marking the Council agreed that greater control would be exercised with all examinations being returned to Council's officers for marking.

In February 2023, the Council considered that the examinations have largely been re-written to minimise the need for subjective marking. Council agreed that the assessment of its examination papers would be returned to the training providers and a quality control system be introduced to provide the necessary oversight to ensure validity and consistency across providers. All original examination papers are required to be submitted to the Council for review by Council officers as and when directed.

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 regulation administered by the Mines Safety Directorate of the Department of Energy, Mines, Industry Regulation and Safety (DEMIRS).

Memorandum of Understanding

Following the Work Health and Safety (WHS) Act 2020 coming into effect in March 2022, DEMIRS and Council agreed to progress and reinstitute a Memorandum of Understanding (MoU) for radiation on mining operations.

Drafting of the MoU commenced in 2022 and was largely finalised in 2023. It is expected that the final version will be signed off by both organisations early in 2024.

MISCELLANEOUS

Radiation Health Committee

The Radiation Health Committee (RHC) is a body established to advise the Chief Executive Officer of the Australian Radiation Protection and Nuclear Safety Agency (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.

Radiation Health Expert Reference Panel

The Radiation Health Expert Reference Panel (RHERP) is comprised of representatives from each Australian jurisdiction's radiation safety regulator and is established under the Environmental Health Standing Committee (enHealth) to provide expert advice on radiation specific issues.

EnHealth is a standing committee of the Australian Health Protection Principal Committee and 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.

Integrated Regulatory Review Service – Follow-Up Mission to Australia

In 2018 Australia hosted the International Atomic Energy Agency Integrated Regulatory Review Service (IRRS) mission. The principal recommendation of the IRRS was that the Commonwealth Government, in conjunction with State and Territory Governments, ensure a consistent level of protection of people and the environment through effective coordination and harmonized implementation of codes and guides by the Commonwealth, States and Territory regulatory bodies.

A national action plan was developed to help address the recommendations and suggestions of the 2018 mission.

The IAEA conducted a follow-up IRRS mission in 2023 to peer review the findings and consider whether sufficient action had been taken to give confidence of resolution for the items closed, and to provide any additional findings. Interviews were conducted with representatives from the jurisdictions and questions were asked on the reference material that had been provided to the IRRS mission team.

The IRRS team noted that in the intervening years since the 2018 report there had been significant changes in the radiation protection landscape including the announcement of AUKUS partnership, the establishment of the Australian Radioactive Waste Agency (ARWA) with the mission of handling the nation's radioactive waste and the COVID pandemic, which affected the resources of various regulatory bodies. The IRRS team noted that these developments had an impact on the implementation on the action plan developed after the 2018 mission but that Australia has made considerable progress in addressing the recommendations and suggestions.

The IRRS team reiterated the challenges and importance of the establishment of a national framework for radiation safety that

ensures a consistent level of safety and protection for individuals and the environment across all jurisdictions and emphasised the following –

- Finalising and implementing a national strategy on radiation safety.
- Encouraging and facilitating effective and efficient inter-jurisdictional collaboration in the development of regulatory activities.
- Considering binding mechanisms to guarantee consistent and timely implementation of the National Directory of Radiation Protection 2 (NDRP2).

The IRRS team recognised the strong commitment of the Australian Government, ARPANSA, the Commonwealth Department of Health and Aged Care, ARWA and the State and Territory regulatory bodies to radiation safety.

Security of Radioactive Sources

The Council requires compliance with the Australian *Code of Practice for the Security of Radioactive Sources* (Radiation Protection Series 11). The Code specifies security requirements to be implemented by persons responsible for sealed radioactive sources in order to decrease the likelihood of unauthorised access to a radioactive source.

The Code imposes additional obligations on registrants of security enhanced sources (Categories 1, 2 and 3). Persons responsible for security enhanced sources must ensure a source security plan is developed which demonstrates how they will satisfy the requirements of the Code by implementing risk-based security measures appropriate to the category of the source. Persons responsible for security enhanced sources must ensure that the source security plan is assessed and endorsed by an accredited assessor.

The program is ongoing.

Low Level Radioactive Waste Facilities

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. The planned disposal campaign for low-level radioactive waste did not occur in 2023.

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.

In April 2022, Council provided in-principle approval for x-ray equipment to be used in Western Australia for screening of prisoners in custodial facilities for contraband detection. The x-ray screening program commenced in 2023.

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 2023 are included in attachment 5.

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. 43 Temporary Permits were current as at 31 December 2023.

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 6 shows the types and numbers of licences and registrations (or individual exemptions) granted or renewed in 2023.

Automatic Mutual Recognition

Automatic Mutual Recognition may apply if a person is entering Western Australia from a participating jurisdiction to undertake temporary work.

In 2023, 103 notifications were received by the Council.

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	Deputy	Qualification or Designation	
Appointment under Sections 13(2)(a) and 13(3) of the Act			
Dr A Robertson (Chair)	Dr R Bangor-Jones	Medical Practitioner	
Appointment under Sections 13(2)(b), 15(1) and 17 (1) of the Act			
Dr M Morris	Dr V Vaidya	Radiologist	until 19 February 2025
Dr E Thomas	Dr R Troedson	Nuclear Medicine Physician	until 13 June 2025
Mr C Storm	Ms M McGibbons	Physicist	until 18 October 2025
Mr J Pereira	Dr W Green	Electronic Engineer	until 19 February 2025
A/Prof R Francis	Prof P Parizel	Tertiary Institutions representative	until 30 April 2024
A/Prof S Maresse	Dr C Ng	Medical Radiation Technologist	until 18 October 2025
Mr N Tsurikov	N/a	Expert in Mining Radiation Hazards	
Mr F Harris	N/a	Expert in Mining Radiation Hazards	
Dr J Burrage	N/a	Expert in Medical Physics	

2023 MEETING ATTENDANCE

	14 Feb	14 Mar	11 Apr	9 May	13 Jun	10 Jul	8 Aug	12 Sep	10 Oct	14 Nov	12 Dec
Dr A Robertson	✓	✓	✓	A	A	A	A	✓	✓	✓	✓
Dr R Bangor-Jones	✓	✓	✓	✓D	✓D	✓D	✓D	✓	✓	✓	✓
Dr M Morris	✓	✓	✓	✓	✓	A	A	✓	✓	A	✓
Dr V Vaidya	✓O	A	✓O	✓O	✓O	✓D	✓D	✓O	✓O	✓D	✓O
Dr E Thomas	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	A
Mr C Storm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ms M McGibbons	✓O	✓O	✓O	✓O	✓O	✓O	✓O	✓O	✓O	✓O	✓O
Mr J Pereira	✓	✓	✓	✓	✓	A	✓	✓	A	✓	✓
A/Prof R Francis	✓	A	✓	✓	✓	✓	✓	✓	✓	✓	A
Prof P Parizel											✓D
A/Prof S Maresse	✓	✓	✓	✓	✓	✓	✓	A	✓	✓	✓
Dr C Ng			A					✓D			
Mr N Tsurikov	✓	A	✓	✓	✓	✓	✓	A	A	A	A
Mr F Harris	✓	✓	✓	✓	A	✓	A	✓	✓	✓	✓
Dr J Burrage	✓	✓	✓	✓	✓	✓	✓	✓	A	✓	✓

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

ATTACHMENT 2: LEGISLATION AMENDMENTS

RADIATION SAFETY ACT

Directors' Liability Reform Act 2023 Pt. 3 Div.52

Consequential amendments in relation to the criminal liability of directors and other persons involved in the management of bodies corporate, and for related purposes.

Date of assent 4 April 2023; commencement 5 April 2023.

RADIATION SAFETY (GENERAL) REGULATIONS

Health Regulations Amendment (Fees and Charges) Regulations 2023 Pt.9

Amendment to fees (Schedule 15).

Government Gazette 30 June 2023 SL 2023/96

RADIATION SAFETY (QUALIFICATIONS) REGULATIONS

Health Regulations Amendment (Fees and Charges) Regulations 2023 Pt.10

Amendment to fees for examinations (Schedule 2).

Government Gazette 30 June 2023 SL 2023/96

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	44	-	1	44
Dental – cone beam CT	46	-	1	47
Dental – intraoral	455	-	2	457
Dental – panoramic and/or cephalometric	95	-	1	95
Fluoroscopic – fixed	20	-	1	21
Fluoroscopic – fixed C or U arm	16	-	1	17
Fluoroscopic – mobile	49	-	5	54
Mammography	21	-	-	21
Radiographic – fixed	70	-	3	73
Radiographic – mobile	43	-	1	44
Total	859	0	14	873

[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 4 re-tests conducted during 2023, 100% resulted in the equipment being granted either a compliance or conditional compliance certificate.

Industrial – Fixed Gauges

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

Category	A	B	Total
Density	299	-	299
In-stream analysis	3	-	3
Level	70	-	70
Other	1	-	1
Total	373	-	373

[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.

ATTACHMENT 4: RESEARCH PROJECT APPLICATIONS ASSESSED

Research Project Title
A Phase 3, Randomized, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Combination with R-CHOP Compared to R-CHOP in Subjects with Newly Diagnosed Diffuse Large B-Cell Lymphoma (DLBCL).
Colchicine Atherosclerotic Plaque (CAP) – Biomarker and Imaging Sub-study
Phase Ib Multicenter, Open-label Study to Evaluate the Safety and Tolerability of Trastuzumab Deruxtecan (T-DXd) and Immunotherapy Agents With and Without Chemotherapy Agents in First-line Treatment of Patients with Advanced or Metastatic Non-squamous Non-small Cell Lung Cancer (NSCLC) and Human Epidermal Growth Factor Receptor 2 (HER2) Overexpression (OE) (DESTINY-Lung03)
A Phase 1b/2 Study of BMS-986442 in Combination with Nivolumab or Nivolumab and Chemotherapies in Participants with Advanced Solid Tumors and Non-small Cell Lung Cancer
A Phase 1, Randomized, Double-Blind, Placebo Controlled, Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, Immunogenicity, Pharmacokinetics, and Pharmacodynamics of PRX012 in Subjects with Alzheimer's Disease.
A randomized, double-blind, placebo-controlled, phase III study evaluating the efficacy and safety of ociperlimab (WCD118/BGB-A1217) combined with tislelizumab (VDT482/BGB-A317) plus platinum-based doublet chemotherapy versus placebo combined with pembrolizumab plus platinum-based doublet chemotherapy as first-line therapy for participants with locally advanced or metastatic non-small cell lung cancer (NSCLC).

Research Project Title
A Phase III, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Combination with Rituximab and Lenalidomide (R2) compared to R2 in Subjects with Relapsed or Refractory Follicular Lymphoma (EPCORETM FL-1)
A Phase 3 Randomized Clinical Study of MK-4280A (coformulated favezelimab [MK-4280] plus pembrolizumab [MK-3475]) Versus Physician's Choice Chemotherapy in PD-(L) 1-refractory, Relapsed or Refractory Classical Hodgkin Lymphoma
A Phase 3, Open-Label, Multi-Center, Randomized Study Evaluating the Efficacy and Safety of TAR-200 in Combination with Cetrelimab or TAR-200 Alone Versus Intravesical Bacillus Calmette-Guérin (BCG) in Participants with BCG-naïve High-Risk Non-Muscle Invasive Bladder Cancer (HR-NMIBC).
A Phase II, Multicenter, Randomized, Double-Blind Study of RO7247669 combined with NAB-PACLITAXEL compared with PEMBROLIZUMAB combined with NAB-PACLITAXEL in participants with previously untreated, PD-L1−POSITIVE, locally-advanced unresectable or metastatic triple-negative breast cancer.
A Phase 1, Multicenter, Open-Label Study of CB-010, a CRISPR-Edited Allogeneic Anti-CD19 CAR-T Cell Therapy in Patients with Relapsed/Refractory B Cell Non-Hodgkin Lymphoma (ANTLER)
A Randomized, Open-Label, Phase 3 Trial to Compare the Efficacy and Safety of Idecabtagene Vicleucel with Lenalidomide Maintenance versus Lenalidomide Maintenance Therapy Alone in Adult Participants with Newly Diagnosed Multiple Myeloma Who Have Suboptimal Response After Autologous Stem Cell Transplantation

Research Project Title
A Phase 1/2, Open-Label, Multicenter, Dose Escalation and Cohort Expansion Study of the Safety and Efficacy of Anti-CD19 Allogeneic CRISPR-Cas9–Engineered T Cells (CTX112) in Subjects With Relapsed or Refractory B Cell Malignancies.
A Phase 1 Cohort Dose Escalation and Expansion Trial to Determine the Safety, Tolerance, Maximum Tolerated Dose, and Preliminary Antineoplastic Activity of IKS03, a CD19-Targeting Antibody Drug Conjugate (ADC), in Patients with Advanced B cell Non-Hodgkin Lymphomas (NHL)
A Phase 1b Study to Evaluate HMBD-001 in Combination with Docetaxel with or without Cetuximab in Participants with Advanced Squamous Non-Small Cell Lung Cancers
IMaging of cancer imMUNOtherapy targets with Positron Emission Tomography: Characterising PD-L1 with 89Zr-Durvalumab (MEDI4736) – ImmunoPET Phase 1 Study
Randomized, open-label, multi-center phase III trial comparing tisagenlecleucel to standard of care in adult participants with relapsed or refractory follicular lymphoma (CCTL019E2301).
In children with chronic wet-sounding cough (CWC) suspected of having protracted bacterial bronchitis (PBB) for those with high risk traits (recurrent antibiotics for CWC, airway Hi infection or cough duration >6 months), does 9 months of regular azithro (vs. controls), reduce future recPBB and bronchiectasis (BE) risk at 12 months and 24 months.

Research Project Title
A Phase 3, multicenter, randomized, open-label, parallel group, treatment study to assess the efficacy and safety of the lifileucel (LN-144, autologous tumor-infiltrating lymphocytes [TIL]) regimen in combination with pembrolizumab compared with pembrolizumab monotherapy in participants with untreated, unresectable, or metastatic melanoma.
A Randomized, Controlled, Open-Label, Phase 2 Study of Cemiplimab as a Single Agent and in Combination with RP1 in Patients with Advanced Cutaneous Squamous Cell Carcinoma
Biomechanics Meets Phenomics: Towards Understanding and Predicting Abdominal Aortic Aneurysm (AAA) Disease Progression
Phase 1, First-in-human study of JNJ-87801493 in combination with CD3 T-Cell Engagers in Participants with Relapsed/Refractory B-cell Non-Hodgkin Lymphoid Malignancies (NHL)
A Phase 3, Open-Label, Randomized Study of Sonrotoclax (BGB-11417) Plus Zanubrutinib (BGB-3111) Compared with Venetoclax Plus Obinutuzumab in Patients with previously untreated Chronic Lymphocytic Leukemia
A randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of PLN-74809 (bexotegrast) for the treatment of idiopathic pulmonary fibrosis (BEACON-IPF)
A Phase 3, Open-label, Multicenter, Randomized Study to Evaluate the Efficacy and Safety of Romosozumab Compared with Bisphosphonates in Children and Adolescents With Osteogenesis Imperfecta (Protocol No. 20200105)

Research Project Title
A phase III, multicenter, randomized, open-label study comparing the efficacy and safety of Glofitamab (RO7082859) in combination with Polatuzumab Vedotin Rituximab, Cyclophosphamide, Doxorubicin, and Prednisone (Pola-R-CHP) versus Pola-R-CHP in previously untreated patients with large B-cell lymphoma
POLAR BEAR (NLG LBC7 / ALLG NHL39): R-MINI-CHOP versus R-MINI-CHP in combination with polatuzumab-vedotin, as primary treatment for patients with diffuse large B-cell lymphoma, ≥80 years, or frail ≥75 years – an open label randomized Nordic Lymphoma Group phase III trial.
A randomised, open-label, Phase 2 study evaluating lymphodepletion with fludarabine, cyclophosphamide and ALLO-647, vs. fludarabine and cyclophosphamide alone, in subjects with relapsed/refractory Large B-Cell Lymphoma (LBCL) receiving ALLO-501A allogeneic CAR T cell therapy
A phase II open-label, multi-centre study of minimal residual disease-directed consolidation with epcoritamab or epcoritamab-lenalidomide-rituximab post anti-CD19 CAR T-cell therapy for large B-cell lymphoma
A Phase 1-2, Open-Label Study of the Safety, Pharmacokinetics, Pharmacodynamics, and Preliminary Activity of Tolinapant in Combination with Oral Decitabine/Cedazuridine and Oral Decitabine/Cedazuridine Alone in Subjects with Relapsed/Refractory Peripheral T cell Lymphoma
A Phase 3, Open-Label, Randomized Study of Sonrotoclax (BGB-11417) Plus Zanubrutinib (BGB-3111) Compared with Venetoclax Plus Obinutuzumab in Patients with Previously Untreated Chronic Lymphocytic Leukemia

Research Project Title
A Multicentre, Phase II, Randomised, Ppen-label Study to Evaluate the Efficacy of Acalabrutinib in Combination with Venetoclax and Rituximab in Participants with Treatment Naïve Mantle Cell Lymphoma
An Open-Label, Phase 2b, Global Multicenter Cohort Trial to Assess the Safety and Efficacy of Zipalertinib in Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer with Exon 20 Insertion and Uncommon/Single or Compound Epidermal Growth Factor Receptor Mutations
A Phase 3, Multicenter, Randomized, Open-Label Trial to Evaluate the Safety and Efficacy of Epcoritamab + Rituximab and Lenalidomide (R2) Compared to Chemoimmunotherapy in Previously Untreated Follicular Lymphoma (EPCORE™FL-2)
A Phase 1b Multicenter, Open-label, Study of JNJ-90014496, an Autologous CD19/CD20 Bi-specific CAR-T Cell Therapy in Adult Participants with Relapsed or Refractory B-cell Non-Hodgkin Lymphoma
A Phase 1 Open-Label Dose-Escalation Study of Bcl-2 Inhibitor BGB-21447 in Patients with Mature B-Cell Malignancies
A Phase I study to evaluate the safety and preliminary efficacy of ATA3219, allogeneic anti_CD19 chimeric antigen receptor T-cell therapy, in subjects with relapsed/refractory B-cell non-Hodgkin lymphoma.
A Phase 3 Randomized, Open-Label, Multicenter Study of Zanubrutinib (BGB-3111) Plus Anti-CD20 Antibodies Versus Lenalidomide Plus Rituximab in Patients With Relapsed/Refractory Follicular or Marginal Zone Lymphoma

Research Project Title
Phase I/II, Open-Label, Multiple Centre Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity and Preliminary Efficacy of AZD0305 in Patients with Relapsed or Refractory Multiple Myeloma

ATTACHMENT 5: REGISTERED IRRADIATING APPARATUS, ELECTRONIC PRODUCTS AND SEALED RADIOACTIVE SUBSTANCES

Current at 31 December 2023

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

Category	A	B
Bone densitometry	72	-
Cabinet x-ray equipment	238	-
Calibration	1	710
CT	146	-
SPECT-CT and PET-CT	39	-
Dental – cone beam CT	126	-
Dental – intraoral	2728	-
Dental – panoramic and/or cephalometric	539	-
Education and research	24	793
Fluoroscopic – fixed	78	-
Fluoroscopic – mobile	154	-
Gauges – density/level	10	3948
Gauges – in stream analysis	2	89
Gauges – logging	72	484
Gauges – neutron moisture/density portable	-	539
Gauges – other	-	357
Irradiator	-	48
Isotope Production	2	-
Laser – entertainment	175	-
Laser – industrial	257	-

[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
Laser – medical	432	-
Laser – other medical	471	-
Laser – podiatry	27	
Laser – research	235	-
Linear accelerator	28	-
Mammography	68	-
Non-destructive testing	253	161
Non-destructive testing – crawler control	-	17
Portable mineral analyser	-	7
Radiographic – fixed	373	-
Radiographic – mobile	416	-
Radiographic – Screening	2	-
Sealed Sources – other	-	252
Simulator	8	-
Special purpose x-ray	44	-
Static detection/measurement	-	2
Static elimination	-	18
Storage	-	268
Superficial radiotherapy	2	-
Test source	3	-
Therapy	4	30
Therapy – HDR brachytherapy	-	2
Transilluminator	122	-
Tracer Studies	-	131
X-ray analysis	885	-
Total	8036	7856

ATTACHMENT 6: LICENCES AND REGISTRATIONS

Current at 31 December 2023

Including individual exemptions granted under Section 6 of the Act.

	X-ray and/or Electronic Products		Radioactive Substances		TOTAL	
	2023	2022	2023	2022	2023	2022
Licences	8155	7612	2568	2439	10723	10051
Registrations	2569	2423	455	441	3024	2864
TOTAL	10724	10035	3023	2880	13747	12915
Change from 2022	+ 6.9%		+ 5.0%		+ 6.4%	

Attachment 6 (cont)

Purposes for Licences and Exemptions from Licence – total current as at 31 December 2023

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

Total	Purpose
14	Bone Densitometry
3	Bone Densitometry (Exemption)
104	Cabinet X-ray Equipment
54	Compliance Testing - Diagnostic X-ray Equipment
615	Compliance Testing - Radioactive Gauges
103	Contraband Detection - Custodial Facilities
30	Cyclotron Operation
6	Cyclotron Servicing
5	Education (Apparatus)
30	Education (Substances)
559	Fluoroscopy - Medical
54	Fluoroscopy - Medical (Exemption)
33	Fluoroscopy - Medical (Non-Specialist Exemption)
16	Fluoroscopy - Podiatry (Exemption)
5	Fluoroscopy - Veterinary
607	Gauges - Industrial
7	Gauges - Industrial (Installation)
1	Gauges - Level (CO_2)
371	Gauges - Logging
609	Gauges - Moisture and/or Density (Portable)
9	Gauges - Other (Apparatus)

Total	Purpose
113	Gauges - Other (Substances)
2	Installation of X-ray Equipment
2	Installation of X-ray Equipment - Dental
6	Irradiator - Gamma
3	Irradiator - X-ray
2	Lasers - Acupuncture
141	Lasers - Allied Health[5]
62	Lasers - Allied Health (Exemption)[5]
1	Lasers - Astronomy
198	Lasers - Dental
5	Lasers - Educational
40	Lasers - Entertainment
658	Lasers - Hair Removal (Exemption)
118	Lasers - Industrial
362	Lasers - Medical
91	Lasers - Medical (Exemption)
7	Lasers - Other
68	Lasers - Research
95	Lasers - Service
144	Lasers - Superficial Cosmetic (Exemption)
39	Lasers - Tattoo Removal (Exemption)

[5] Lasers – allied health includes licences previously issued for chiropractic, osteopathy, physiotherapy and podiatry.

Total	Purpose
27	Lasers - Veterinary
1	Manufacture of X-ray Equipment
4	Medical Physics
34	Medical Physics - Radiotherapy (Apparatus)
26	Medical Physics - Radiotherapy (Substances)
101	Medical Radiation Technology - Diagnostic Nuclear
1460	Medical Radiation Technology - Medical Imaging
46	Medical Radiation Technology - Nuclear Medicine - Diagnostic CT
256	Medical Radiation Technology - Radiation Therapy Irradiating Apparatus
339	Medical Radiology
10	Nuclear Medicine - Calibration and QC Sources
41	Nuclear Medicine - Diagnostic
40	Nuclear Medicine - Therapeutic
7	Nuclear Medicine - Veterinary
2	Pathology (In Vitro) - Sealed Sources
6	Pathology Tests
12	Portable Mineral Analysers
642	Portable Mineral Analysers (X-ray)
2	Possession of X-ray Equipment - Diagnostic Medical
2	Quality Assurance Procedures
37	Radioactive Ores - Analytical Laboratories
15	Radioactive Ores - Exploration
21	Radioactive Ores - Mining and/or Processing
14	Radioactive Substances - Calibration Sources
1	Radioactive Substances - Medical
37	Radioactive Substances - Sale
41	Radioactive Substances - Service of Devices

Total	Purpose
12	Radioactive Substances - Tracer Studies (Industry)
18	Radiography - Chiropractic (Extended)
181	Radiography - Chiropractic (Restricted)
1	Radiography - Forensic
417	Radiography - Industrial (Gamma)
430	Radiography - Industrial (X-ray)
3	Radiography - Mammography Screening (Exemption)
5	Radiography - Security
1043	Radiography - Veterinary
1	Radioguidance - Medical (Radioactive Substances)
193	Radiology - Dental
14	Radiology - Veterinary
31	Radiopharmaceutical Manufacture and Dispensing
30	Radiotherapy - Medical (Apparatus)
18	Radiotherapy - Medical (Substances)
9	Research
38	Research - Unsealed Radioactive Substances
19	Research - X-ray
35	Sale of Electronic Products
81	Sale of X-ray Equipment
35	Service of X-ray Equipment - Analytical
38	Service of X-ray Equipment - Cabinet
34	Service of X-ray Equipment - Dental
152	Service of X-ray Equipment - Diagnostic
3	Service of X-ray Equipment - Diagnostic (Extended)
3	Service of X-ray Equipment - Industrial NDT
47	Service of X-ray Equipment - Linear Accelerators
6	Service of X-ray Equipment - Other
4	Service of X-ray Equipment - Superficial X-ray Therapy

Total	Purpose
21	Special Purpose Enclosed X-ray Equipment
2	Static Detection
1	Static Electricity Measurement
1	Static Elimination
5	Storage (Apparatus)
16	Storage (Substances)

Total	Purpose
22	Transilluminators
163	Transport
175	X-ray Analysis - Use
350	X-ray Analysis - Use and Service (Restricted)
3	X-ray - Industrial

Attachment 6 (cont)

Purposes for Registrations and Exemptions from Registration – total current as at 31 December 2023

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

Total	Purpose
26	Bone Densitometry
11	Bone Densitometry (Exemption)
99	Cabinet X-ray Equipment
1	Contraband Detection – Custodial
4	Cyclotron Operation
3	Disposal of Radioactive Waste
9	Education (Apparatus)
16	Education (Substances)
28	Education – Demonstration Radioactive Sources (Exemption)
6	Fluoroscopy – Medical
1	Fluoroscopy – Podiatry
3	Gamma Irradiator
150	Gauges – Industrial
3	Gauges – Level (CO2)
19	Gauges – Logging
49	Gauges – Moisture and/or Density (Portable)
17	Gauges – Other (Apparatus)
5	Gauges – Other (Substances)
1	Lasers – Acupuncture
6	Lasers – Analyser
1	Lasers – Astronomy
9	Lasers – Chiropractic
149	Lasers – Dental

Total	Purpose
3	Lasers – Educational
26	Lasers – Entertainment
77	Lasers – Hair Removal
59	Lasers – Industrial
2	Lasers – Manufacture
199	Lasers – Medical
1	Lasers – Osteopathy
3	Lasers – Other
56	Lasers – Physiotherapy
27	Lasers – Podiatry
8	Lasers – Research
9	Lasers – Sale, Service, Maintenance and Testing
32	Lasers – Storage
39	Lasers – Superficial Cosmetic
7	Lasers – Tattoo Removal
16	Lasers – Veterinary
2	Manufacture of X-ray Equipment
154	Medical Radiology
22	Nuclear Medicine – Computed Tomography
26	Nuclear Medicine – Diagnostic
12	Nuclear Medicine – Therapeutic
5	Nuclear Medicine – Veterinary
6	Pathology Tests

Total	Purpose
4	Portable Mineral Analysers
329	Portable Mineral Analysers (X-ray)
15	Radioactive Ores – Analytical Laboratories
11	Radioactive Ores – Exploration
41	Radioactive Ores – Mining and/or Processing
16	Radioactive Substances – Calibration Sources
1	Radioactive Substances – Medical
8	Radioactive Substances – Sale
3	Radioactive Substances – Service of Devices
2	Radioactive Substances – Tracer Studies (Industry)
14	Radiography – Chest Screening
47	Radiography – Chiropractic
856	Radiography – Dental
1	Radiography – Forensic
26	Radiography – Industrial (Gamma)
37	Radiography – Industrial (X-ray)
15	Radiography – Mammography Screening
41	Radiography – Medical (Operator)
10	Radiography – Medical (Unrestricted)
1	Radiography – Security
295	Radiography – Veterinary
4	Radioguidance – Medical (Radioactive Substances)
99	Radiology – Dental

Total	Purpose
7	Radiology – Veterinary
3	Radiopharmaceutical Manufacture and Dispensing
14	Radiotherapy – Medical (Apparatus)
6	Radiotherapy – Medical (Substances)
1	Radiotherapy – Veterinary (Apparatus)
2	Regulatory Authority
5	Research (Substances)
9	Research – Unsealed Radioactive Substances
8	Research – X-ray
9	Sale of Electronic Products
24	Sale of X-ray Equipment
53	Security of Radioactive Sources
16	Service of X-ray Equipment
16	Special Purpose Enclosed X-ray Equipment
1	Static Electricity Measurement
2	Static Elimination
69	Storage (Apparatus)
62	Storage (Substances)
13	Transilluminators
15	Transport
158	X-ray Analysis
2	X-ray Irradiator
4	X-ray - Industrial

ABBREVIATIONS

General Terminology

AMR	Automatic Mutual Recognition
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
CT	Computed Tomography
CT/SPECT	Computed Tomography/Single-Photon Emission Computed Tomography
DEMIRS	Western Australian Department of Energy Mines, Industry Regulation and Safety (formerly Department of Mines, Industry Regulation and Safety)
enHealth	Environmental Health Standing Committee
HDR	High Dose Rate
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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