

**REPORT OF THE** 

## RADIOLOGICAL COUNCIL

for the year ended

**31 December 2024** 



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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 10 times in 2024, 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**

Amendments made in 2024 to the Radiation Safety (General) Regulations and the Radiation Safety (Qualifications) Regulations are listed in attachment 2.

No amendments were made to the Radiation Safety Act or Radiation Safety (Transport of Radioactive Substances) Regulations in 2024.

## **2024 IN REVIEW**



Registrations



Licences

**3075** total applications

**197** new applications assessed

**930** applications renewed

**154** terminated

**11117** total applications

**1384** new applications assessed

**3457** applications renewed

**1026** terminated



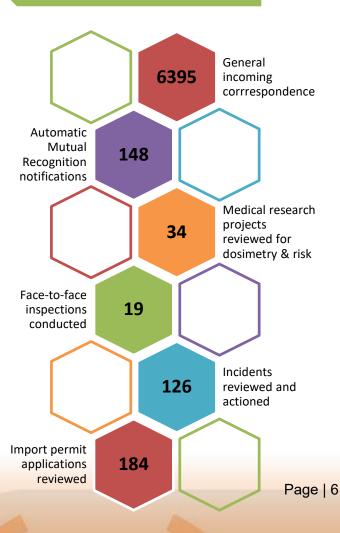
**611** amendments to registrations and licences (outside renewal process)



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



**5 clerical positions** provide administrative support



#### **PROSECUTIONS**

No prosecutions were initiated or finalised in 2024.

#### **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 123 incidents during 2024 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 Update

An incident had occurred over December 2022 and January 2023 concerning the failure of a gauge at a mine site and the subsequent temporary loss of the Caesium-137 radioactive source capsule while

in transit between a mine site north of Newman and Perth.

The radioactive source capsule was found intact and recovered 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.

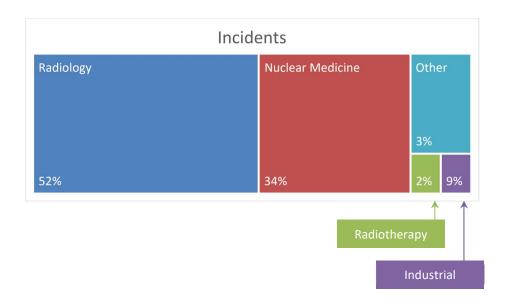
The learnings from the incident were raised nationally with radiation regulators and recommendations were made towards the revision of the Code of Practice for the safe use of fixed radiation gauges. Discussions in the national framework for changes to the equipment standards are continuing.

#### Exceedance of Extremity Dose Limit

An incident occurred on 21 October 2024 at a facility which involved a radiation worker undertaking a manual equipment intervention. The intervention involved the worker's hand being in very close proximity to a high activity radiation source for a short period of time. It is estimated the worker received several Sieverts to their hands. At the end of 2024, no tissue reactions were observed.

The Council issued an immediate direction to cease radiation operations at the facility whilst the Council investigated the incident and until corrective actions are satisfactorily implemented.

The Council also agreed to a Western Australian framework to guide regulatory actions where a tissue equivalent dose limit may have been exceeded.



Incident type	Area	Occurrences
Human Error		
Wrong patient – failure to follow	Radiology	6
patient ID protocol	Nuclear Medicine	1
Unnecessary / repeat exposure -	Radiology	1
not diagnostic quality /scans not cancelled as requested	Nuclear Medicine	6
Wrong patient – incorrect patient ID on referral	Nuclear Medicine	2

Incident type	Area	Occurrences
Incorrect examination undertaken/anatomical site – incorrect clinical information	Radiology	14
Incorrect examination undertaken/anatomical site – failure to follow request form	Radiology	25
Incorrect modality – failure to follow request form	Radiology	3
Duplication of imaging – referral not followed / images saved under another patient's profile	Radiology	4
Incorrect radiopharmaceutical administered – failure to follow protocol	Nuclear Medicine	2
High dose reading on personal monitoring badge – badge scanned through airport scanners /left unattended in exposure bay	Industrial	5
Portal/gate alarms set off – Waste not disposed of as per guidelines	Industrial	2
Human Error		
Unintended release of radioactive substances — spill and contamination in controlled area due to dropped syringe	Nuclear Medicine	1
An additional fraction was delivered to a patient after a system error/patient interruption occurred	Radiation Therapy	3
Unauthorised equipment disposal	Industrial	1

		I
Incident type	Area	Occurrences
Uncontrolled transport of radioactive pathology samples	Medical	1
Patient Factors Outside of Opera	tor Control	
Extravasation of radiopharmaceutical – following successful cannulation flush	Nuclear Medicine	6
Misadministration of Y-90 microspheres.	Nuclear Medicine	1
Prescribed activity of Y-90 microspheres not administered (outside +/- 10%)	Nuclear Medicine	8
Radiopharmaceutical administered and scan not performed – patient choice not to proceed/clinical status changed	Nuclear Medicine	14
Unintended exposure of fetus – patient advised not pregnant	Radiology	3
Duplication of procedure – due to duplicate referral form	Radiology	4
<b>Equipment Malfunction</b>		
Duplicate imaging required	Radiology	4

Incident type	Area	Occurrences
Radiopharmaceutical administered and scan not successfully performed, or top-up dose required	Nuclear Medicine	1
Unintended x-ray exposure of XRF equipment operator	Industrial	1
Fixed gauge – source shutter unable to be turned to off position.	Industrial	1
Logging source stuck in hole – protocol followed; source recovered	Industrial	2
Other		
Radiation worker undertook manual equipment intervention with high activity radiation source	Other	1
Fixed gauge – blockage on a continuous belt caused lid (only) of analyser housing to be displaced	Industrial	1
Images lost after a barium study was performed / equipment was not checked prior to use	Radiology	1
Unauthorised release of medical radioactive waste to general waste stream	Other	1



#### MEDICAL AND RELATED RADIATION MATTERS

## **Medical Compliance Testing**

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

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

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

The Council's Compliance Testing Working Group met several times in 2024 to review existing compliance testing workbooks and the examination to be undertaken by persons wishing to obtain a licence for compliance testing.

A summary of the compliance tests entered into the database in 2024 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 2024, 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 2024 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.

The assessment of Council examinations is now conducted by the training 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. The memorandum was endorsed by the Council in September 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.

#### 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.

#### 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. A disposal campaign for low-level radioactive waste did not occur in 2024.

## X-ray Screening

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 and expanded in 2024.

#### 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 2024 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. 33 Temporary Permits were current as at 31 December 2024.

#### 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 2024.

#### **Automatic Mutual Recognition**

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

In 2024, 148 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 IN 2024

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
Dr E Thomas	Dr R Troedson	Nuclear Medicine Physician
Mr C Storm	Ms M McGibbons	Physicist
Mr J Pereira	Dr W Green	Electronic Engineer
A/Prof R Francis (until 30 April 2024)		Tertiary Institutions representative
Assoc Prof Nigel Marks (from 1 May 2024)	Adj Prof Martin Ebert (from 21 January 2024)	Tertiary Institutions representative
A/Prof S Maresse (until 13 September 2024)	Dr C Ng	Medical Radiation Technologist
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



## **2024 MEETING ATTENDANCE**

	13 ГЕВ	12 Mar	9 Apr	14 May	9 Jul	13 Aug	10 SEP	8 Ост	12 Nov	12 DEC
Dr A Robertson	✓	✓	✓	✓	Α	✓	✓	✓	✓	✓
Dr R Bangor-Jones	✓	✓	$\checkmark$	✓	√D	✓	✓	✓	✓	✓
Dr M Morris	✓	Α	Α	Α	✓	Α	Α	Α	Α	Α
Dr V Vaidya	-	√D	√D	-	<b>√</b> 0	-	√D	√D	√D	√D
Dr E Thomas	Α	✓	$\checkmark$	$\checkmark$	$\checkmark$	Α	✓	✓	Α	✓
Mr C Storm	✓	✓	$\checkmark$	Α	✓	✓	✓	✓	✓	✓
Ms M McGibbons	<b>√</b> 0	-	<b>√</b> O	√D	<b>√</b> O	<b>√</b> O	<b>√</b> 0	<b>√</b> 0	<b>√</b> 0	<b>√</b> 0
Mr J Pereira	Α	✓	Α	$\checkmark$	✓	✓	✓	✓	✓	✓
A/Prof R Francis	Α	Α	-	NA	NA	NA	NA	NA	NA	NA
A/Prof S Maresse	$\checkmark$	✓	$\checkmark$	Α	✓	✓	✓	-	-	-
Dr C Ng	-	-	-	√D	-	-	-	√D	√D	√D
Mr N Tsurikov	Α	$\checkmark$	Α	✓	$\checkmark$	✓	✓	✓	✓	✓
Mr F Harris	✓	Α	$\checkmark$	Α	✓	✓	✓	Α	✓	✓
Dr J Burrage	$\checkmark$	✓	$\checkmark$	$\checkmark$	✓	✓	✓	✓	✓	✓
A/Prof N Marks	NA	NA	NA	✓	Α	✓	✓	✓	Α	Α
Dr M Ebert	NA	NA	NA	-	✓D	-	<b>√</b> O	<b>√</b> 0	√D	Α

<sup>✓</sup> attended D deputy A apology O observer NA not appointed at the time

#### **ATTACHMENT 2: LEGISLATION AMENDMENTS**

#### **RADIATION SAFETY ACT**

None

## **RADIATION SAFETY (GENERAL) REGULATIONS**

Health Regulations Amendment (Fees and Charges) Regulations 2024 Pt.9

Amendment to fees (Schedule 15).

Government Gazette 12 June 2024 SL 2024/91

## **RADIATION SAFETY (QUALIFICATIONS) REGULATIONS**

Health Regulations Amendment (Fees and Charges) Regulations 2024 Pt.10

Amendment to fees for examinations (Schedule 2).

Government Gazette 12 June 2024 SL 2024/91

# RADIATION SAFETY (TRANSPORT OF RADIOACTIVE SUBSTANCES) REGULATIONS

None



#### **ATTACHMENT 3: COMPLIANCE TESTING**

#### Medical

**A** Compliant

**B** Conditionally compliant

**C** Non-compliant<sup>1</sup>

Category	Α	В	С	Total
СТ	103	-		103
Dental – cone beam CT	87	-		87
Dental – intraoral	1191	-	9	1200
Dental – panoramic and/or cephalometric	236	-		236
Fluoroscopic – fixed	34	-	1	35
Fluoroscopic – fixed C or U arm	31	-	2	33
Fluoroscopic – mobile	153	-	5	158
Mammography	91	-	1	92
Radiographic – fixed	130	-	2	132
Radiographic – mobile	63	-	4	67
Total	2119	0	24	2143

<sup>&</sup>lt;sup>1</sup> 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 33 re-tests conducted during 2024, 100% resulted in the equipment being granted either a compliance or conditional compliance certificate.

## Industrial – Fixed Gauges

A CompliantB Non-compliant<sup>2</sup>

Category	Α	В	Total
Density	281	22	303
In-stream analysis	3	1	4
Level	20	7	27
Other	7		7
Total	311	30	341

<sup>&</sup>lt;sup>2</sup> 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 2/3, Randomized, Double-blind, Controlled Study of Zanzalintinib (XL092) in Combination with Pembrolizumab vs Pembrolizumab in the First-line Treatment of Subjects with PD-L1 Positive Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma

VANISH: The evolution of pulmonary lesions on high resolution computed tomography scans in immunocompromised children with a suspected invasive fungal disease

A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy, Safety, and Tolerability of BMS-986278 in Participants with Idiopathic Pulmonary Fibrosis International clinical research programme to improve outcomes in newly diagnosed Ewing Sarcoma – Trial 1 (INTER-EWING-1)

A Phase 2a, double-blind, placebo-controlled, multi-center, randomized study evaluating LSTA1 when added to standard of care (SoC) versus standard of care alone in subjects with advanced solid tumors

A Phase 2/3, adaptive, randomized, open-label, clinical study to evaluate neoadjuvant and adjuvant V940 (mRNA-4157) in combination with pembrolizumab (MK- 3475) versus standard of care, and pembrolizumab monotherapy in participants with resectable locally advanced cutaneous squamous cell carcinoma (LA cSCC) (INTerpath-007)

A Phase III, Multicentre, Randomised, Open-label Study to Compare the Efficacy and Safety of AZD0486 plus Rituximab versus Chemotherapy plus Rituximab in Previously Untreated Participants with Follicular Lymphoma

#### **Research Project Title**

A Phase II, Open-label, Multi-centre Study to Evaluate Safety, Tolerability, Efficacy, PK, and Immunogenicity of AZD0901 as Monotherapy and in Combination with Anti-cancer Agents in Participants with Advanced Solid Tumours Expressing Claudin 18.2 (Clarity-PT01)

A Global Multicenter, Open Label, Randomized Phase 3 Registrational Study of Lisaftoclax (APG-2575) in Previously Treated Patients with Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma (GLORA Study)

A Phase 3, Randomized, Double-blind, Multicenter Study of MK-1084 in Combination With Pembrolizumab Compared With Pembrolizumab Plus Placebo as First line Treatment of Participants With KRAS G12C-Mutant, Metastatic NSCLC With PD-L1 TPS ≥50%

A Phase 3, multicenter, double-blind, randomized, placebocontrolled study of ivosidenib in participants ≥18 years of age with locally advanced or metastatic conventional chondrosarcoma with an IDH1 mutation, untreated or previously treated with 1 systemic treatment regimen (CHONQUER study)

A Phase 3, Randomized, Double-blind, Add-on Study Evaluating the Safety and Efficacy of Navtemadlin Plus Ruxolitnib vs Placebo Plus Ruxolitnib in JAL Inhibitor-Naïve Patients with Myselofibrosis Who Have Suboptimal Response to Ruxolitnib

A Randomized, double-blind, placebo-controlled, global study to evaluate the efficacy, safety, and tolerability of BMS-986446, an Anti-MTBR Tau Monoclonal Antibody, in participants with early Alzheimer's Disease (TargetTau-1)

## **Research Project Title**

Open Label Pilot Study Evaluating Diagnostic Efficacy and Dosimetry of MNPR-101-DFO\*-89Zr in Patients with Solid Tumours.

A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy, Safety, and Tolerability of BMS-986278 in Participants with Progressive Pulmonary Fibrosis

EpLCART: 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 2/3 Multicentre, Open-label, Randomized, Active-Control Study of Zilovertamab Vedotin (MK-2140) in Combination with Standard of Care in Participants With Relapsed or Refractory Diffuse Large B-Cell Lymphoma (waveLINE-003)

A Modular Phase II, Single-arm, Multicenter, Open-label Study to Evaluate the Efficacy and Safety of AZD0486 in Participants with Relapsed or Refractory B-cell Non-Hodgkin Lymphoma

VELOCITY-HNSCC Substudy-01: A Phase 2 Study of Novel Combination Therapies in Participants with Previously Untreated Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma Regardless of PD-L1 Expression Status

KT-US-484-0136: An Adaptive Phase 3, Randomized, Open-Label, Multicenter Study to Compare the Efficacy and Safety of Axicabtagene Ciloleucel versus Standard of Care Therapy as First-Line Therapy in Subjects with High-Risk Large B-Cell Lymphoma (ZUMA-23)

An Open Labelled Extension Phase II Trial of Probucol in Alzheimer's Disease: The Impact on Cognition

## **Research Project Title**

Subdue-3: A Phase 0 study of SUB-urothelial Durvalumab-Zirconium to investigate local and systemic distribution of Durvalumab when injected in the sub-urothelium.

A randomised phase II study of Pembrolizumab and Brentuximab vedotin versus GDP, followed by high dose chemotherapy and autologous stem cell transplantation for relapsed/refractory Classical Hodgkin Lymphoma – HD11

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 - NLG-LBC7 (POLAR BEAR)

A Phase 1 First-In-Human Study Evaluating Safety, Pharmacokinetics, and Efficacy of ABBV-291 in Non-Hodgkin's Lymphoma

A Phase I/II Open-Label Multi-Centre Master Protocol to Evaluate Safety and Efficacy of ADZ0486 Monotherapy in Combination with Other Anticancer Agents in Participants with Mature B-Cell Malignancies

A Randomized, Open-Label, Multicenter, Phase 3 Study of Zilovertamab Vedotin (MK-2140) in Combination With R-CHP Versus R-CHOP in Participants with Previously Untreated Diffuse Large B-Cell Lymphoma (DLBCL) – MKD-2140-010-00/ waveLINE-010

A Study to Investigate the Efficacy and Safety of Sonrotoclax Plus Zanubrutinib Compared With Placebo Plus Zanubrutinib in Adult Patients With Relapsed/Refractory Mantle Cell Lymphoma.

## **Research Project Title**

A Multicenter, Randomized, Double-blind, Phase 2/3 Study of Ficerafusp Alfa (BCA101) or Placebo in Combination with Pembrolizumab for First-Line Treatment of PD-L1-positive, Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma.

ANHL2121 A Phase 2 Study of Tovorafenib (DAY101) in Relapsed and Refractory Langerhans Cell Histiocytosis

A Phase 3, Open-Label Study of Elranatamab Monotherapy Versus Elotuzumab, Pomalidomide, Dexamethasone (EPd) or Pomalidomide, Bortezomib, Dexamethasone (PVd) or Carfilzomib, Dexamethasone (Kd) in Participants with Relapsed/Refractory Multiple Myeloma Who Received Prior Anti-CD38 Directed Therapy.

## **Research Project Title**

A Phase 3, Randomized, Open-Label, Multicentre Study to Compare the Efficacy and Safety of BMS-986393, a GPRC5D-directed CAR-T Cell Therapy, Versus Standard Regimens in Adult Participants with Relapsed or Refractory and Lenalidomide-refractory Multiple Myeloma

A Phase 3, Randomized, open-label Study of Nivolumab + Relatlimab Fixed-dose Combination with Chemotherapy Versus Pembrolizumab with Chemotherapy as First-line Treatment for Participants with Non-squamous, Stage IV or Recurrent Non-small Cell Lung Cancer with Tumor Cell PD-L1 expression of 1% to 49%.



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

#### Current at 31 December 2024

A Irradiating apparatus and electronic products<sup>3</sup>

B Radioactive substances (sealed sources only)

Category	Α	В
Bone densitometry	76	-
Cabinet x-ray equipment	242	-
Calibration	1	711
Contraband detection – portable x-ray	4	-
CT	162	-
SPECT-CT and PET-CT	40	-
Dental – cone beam CT	150	-
Dental – intraoral	2864	-
Dental – panoramic and/or cephalometric	553	-
Education and research	32	791
Fluoroscopic – fixed	80	-
Fluoroscopic – mobile	159	-
Gauges – density/level	10	4035
Gauges – in stream analysis	2	88
Gauges – logging	66	489
Gauges – neutron moisture/density portable	-	605
Gauges – other	-	361
Irradiator	-	48
Isotope Production	3	-
Laser – entertainment	225	-

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

Category	Α	В
Laser – industrial	282	-
Laser – medical	459	-
Laser – other medical	513	-
Laser – podiatry	30	
Laser – research	238	-
Linear accelerator	28	-
Mammography	72	-
Non-destructive testing	243	163
Non-destructive testing – crawler control	-	19
Portable mineral analyser	-	7
Radiographic – fixed	388	-
Radiographic – mobile	421	-
Radiographic – Screening	2	-
Sealed Sources – other	-	296
Simulator	8	-
Special purpose x-ray	44	-
Static detection/measurement	-	2
Static elimination	-	18
Storage	-	325
Superficial radiotherapy	2	-
Test source	3	-
Therapy	4	32
Therapy – HDR brachytherapy	-	2
Transilluminator	124	-
Tracer Studies	-	131
X-ray analysis	922	-
X-ray – industrial	2	-
Total	8454	8123

## ATTACHMENT 6: LICENCES AND REGISTRATIONS

Current at 31 December 2024

Including individual exemptions granted under Section 6 of the Act.

	X-ray and/or Electronic Products		Radioactive Substances		TOTAL	
	2024	2023	2024	2023	2024	2023
Licences	8476	8155	2641	2568	11117	10723
Registrations	2638	2569	437	455	3075	3024
TOTAL	11114	10724	3078	3023	14192	13747
Change from 2023	+ 3	3.6%	+ 1	.8%	+ 3.	2%

## Attachment 6 (cont)

## Purposes for Licences and Exemptions from Licence – total current as at 31 December 2024

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

Total	Purpose
14	Bone Densitometry
3	Bone Densitometry (Exemption)
98	Cabinet X-ray Equipment
54	Compliance Testing – Diagnostic X-ray Equipment
660	Compliance Testing – Radioactive Gauges
131	Contraband Detection – Custodial Facilities
16	Contraband Detection – Portable X-ray
32	Cyclotron Operation
6	Cyclotron Servicing
4	Education (Apparatus)
27	Education (Substances)
549	Fluoroscopy – Medical
47	Fluoroscopy – Medical (Exemption)
21	Fluoroscopy – Medical (Non-Specialist Exemption)
17	Fluoroscopy – Podiatry (Exemption)
5	Fluoroscopy – Veterinary
656	Gauges – Industrial
4	Gauges – Industrial (Installation)
1	Gauges – Level (CO2)
382	Gauges – Logging
640	Gauges – Moisture and/or Density (Portable)

Total	Purpose
18	Gauges – Other (Apparatus)
115	Gauges – Other (Substances)
2	Installation of X-ray Equipment
2	Installation of X-ray Equipment – Dental
8	Irradiator – Gamma
3	Irradiator – X-ray
2	Lasers – Acupuncture
139	Lasers – Allied Health <sup>4</sup>
71	Lasers – Allied Health <sup>4</sup> (Exemption)
1	Lasers – Astronomy
217	Lasers – Dental
5	Lasers – Educational
42	Lasers – Entertainment
615	Lasers – Hair Removal (Exemption)
146	Lasers – Industrial
350	Lasers – Medical
110	Lasers – Medical (Exemption)
4	Lasers – Other
71	Lasers – Research
105	Lasers – Service
176	Lasers – Superficial Cosmetic (Exemption)

<sup>&</sup>lt;sup>4</sup> Lasers – allied health includes licences previously issued for chiropractic, osteopathy, physiotherapy and podiatry.

Total	Purpose
58	Lasers – Tattoo Removal (Exemption)
28	Lasers – Veterinary
1	Manufacture of X-ray Equipment
4	Medical Physics
36	Medical Physics – Radiotherapy (Apparatus)
29	Medical Physics – Radiotherapy (Substances)
102	Medical Radiation Technology – Diagnostic Nuclear
1529	Medical Radiation Technology – Medical Imaging
53	Medical Radiation Technology – Nuclear Medicine – Diagnostic CT
260	Medical Radiation Technology – Radiation Therapy Irradiating Apparatus
350	Medical Radiology
13	Nuclear Medicine – Calibration and QC Sources
38	Nuclear Medicine – Diagnostic
38	Nuclear Medicine – Therapeutic
2	Nuclear Medicine – Therapy (Endocrinology)
5	Nuclear Medicine – Veterinary
1	Pathology (In Vitro) – Sealed Sources
6	Pathology Tests
14	Portable Mineral Analysers
642	Portable Mineral Analysers (X-ray)
2	Possession of X-ray Equipment - Diagnostic Medical
1	Quality Assurance Procedures
45	Radioactive Ores – Analytical Laboratories
22	Radioactive Ores – Exploration
23	Radioactive Ores – Mining and/or Processing
11	Radioactive Substances – Calibration Sources
1	Radioactive Substances – Medical

Total	Purpose
33	Radioactive Substances – Sale
33	Radioactive Substances – Service of Devices
11	Radioactive Substances – Tracer Studies (Industry)
21	Radiography – Chiropractic (Extended)
190	Radiography – Chiropractic (Restricted)
5	Radiography – Dental (Exemption)
418	Radiography – Industrial (Gamma)
402	Radiography – Industrial (X-ray)
3	Radiography – Mammography Screening (Exemption)
4	Radiography – Security
1105	Radiography – Veterinary
1	Radioguidance – Medical (Radioactive Substances)
248	Radiology – Dental
16	Radiology – Veterinary
32	Radiopharmaceutical Manufacture and Dispensing
34	Radiotherapy – Medical (Apparatus)
17	Radiotherapy – Medical (Substances)
5	Research
36	Research – Unsealed Radioactive Substances
20	Research – X-ray
36	Sale of Electronic Products
80	Sale of X-ray Equipment
38	Service of X-ray Equipment – Analytical
38	Service of X-ray Equipment – Cabinet
31	Service of X-ray Equipment – Dental
145	Service of X-ray Equipment – Diagnostic
1	Service of X-ray Equipment – Diagnostic (Extended)
2	Service of X-ray Equipment – Industrial NDT
55	Service of X-ray Equipment – Linear Accelerators

Total	Purpose
5	Service of X-ray Equipment – Other
4	Service of X-ray Equipment – Superficial X-ray Therapy
20	Special Purpose Enclosed X-ray Equipment
3	Static Detection
1	Static Electricity Measurement
1	Static Elimination
7	Storage (Apparatus)

Total	Purpose
20	Storage (Substances)
19	Transilluminators
153	Transport
178	X-ray Analysis – Use
378	X-ray Analysis – Use and Service (Restricted)
10	X-ray – Industrial

## Attachment 6 (cont)

## Purposes for Registrations and Exemptions from Registration – total current as at 31 December 2024

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

Total	Purpose
26	Bone Densitometry
11	Bone Densitometry (Exemption)
95	Cabinet X-ray Equipment
1	Contraband Detection – Custodial Facilities
1	Contraband Detection – Portable X-ray
4	Cyclotron Operation
3	Disposal of Radioactive Waste
10	Education (Apparatus)
16	Education (Substances)
25	Education – Demonstration Radioactive Sources (Exemption)
5	Fluoroscopy – Medical
2	Fluoroscopy – Podiatry
3	Gamma Irradiator
147	Gauges – Industrial
2	Gauges – Level (CO2)
18	Gauges – Logging
51	Gauges – Moisture and/or Density (Portable)
18	Gauges – Other (Apparatus)
6	Gauges – Other (Substances)
1	Lasers – Acupuncture
12	Lasers – Analyser
1	Lasers – Astronomy
11	Lasers – Chiropractic

Total	Purpose
159	Lasers – Dental
2	Lasers – Educational
21	Lasers – Entertainment
75	Lasers – Hair Removal
54	Lasers – Industrial
2	Lasers – Manufacture
205	Lasers – Medical
1	Lasers – Osteopathy
6	Lasers – Other
58	Lasers – Physiotherapy
31	Lasers – Podiatry
8	Lasers – Research
8	Lasers – Sale, Service, Maintenance and Testing
43	Lasers – Storage
50	Lasers – Superficial Cosmetic
17	Lasers – Tattoo Removal
18	Lasers – Veterinary
2	Manufacture of X-ray Equipment
159	Medical Radiology
21	Nuclear Medicine – Computed Tomography
26	Nuclear Medicine – Diagnostic
11	Nuclear Medicine – Therapeutic
4	Nuclear Medicine – Veterinary

Total	Purpose
6	Pathology Tests
4	Portable Mineral Analysers
330	Portable Mineral Analysers (X-ray)
15	Radioactive Ores – Analytical Laboratories
12	Radioactive Ores – Exploration
38	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)
13	Radiography – Chest Screening
47	Radiography – Chiropractic
877	Radiography – Dental
1	Radiography – Forensic
25	Radiography – Industrial (Gamma)
37	Radiography – Industrial (X-ray)
15	Radiography – Mammography Screening
41	Radiography – Medical (Operator)
10	Radiography – Medical (Unrestricted)
1	Radiography – Security
301	Radiography – Veterinary
4	Radioguidance – Medical (Radioactive Substances)
130	Radiology – Dental

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

DEMIRS Western Australian Department of Energy 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

XRF X-ray Fluorescence

## **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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