REPORT OF THE

RADIOLOGICAL COUNCIL

for the year ended

31 December 2020

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RADIATION SAFETY ACT 1975

STATUTORY RESPONSIBILITIES OF THE COUNCIL

The Radiological Council is appointed under Section 13 of the Radiation Safety Act to assist the Minister to protect public health and to maintain safe practices in the use of radiation.

In its position as an independent regulatory authority, the Council is required to administer the Act and to —

- implement the scheme of licensing and registration;
- conduct inquiries into alleged contraventions of the Act and, where necessary, to suspend or cancel licences and registrations;
- advise the Minister and make recommendations with respect to the technical aspects of radiation safety requirements, the methods that may be used to prevent or minimise the dangers arising from the use of radioactive substances, irradiating apparatus and electronic products, including the preparation of regulations;
- investigate and prosecute offences.

The Council is also required to keep under review manufactured or assembled devices which emit radiation to determine if control of these devices is necessary under the Act.

Section 10 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 eight times in 2020. In April, owing to restrictions resulting from COVID-19, it was agreed to have an informal meeting with available Council members to discuss certain matters; members did not attend in person. The outcomes of the April discussion were taken to the next meeting for formal consideration.

ADVISORY COMMITTEES

The Council may appoint committees under Section 19 of the Act to investigate and advise on any aspect of its functions, or to carry out any function other than those relating to licences and registrations. The present policy is to create, when necessary, short-term working parties which address a specific issue and report back to the Council.

No advisory committees are currently appointed.

ADMINISTRATIVE SUPPORT

Section 10(4) of the Act provides for the administration of the Act to be paid out of monies appropriated by Parliament for the purpose. However, the Council is not funded directly and relies on the Department of Health's Radiation Health Unit for administrative and scientific support. While the greater part of the Unit's duties are directly concerned with supporting the Council's needs, and many of the staff are appointed authorised officers under Section 4(1) of the Act for this purpose, the Unit also provides separate advice to the Department on a range of radiation issues.

The Radiation Health Unit also provides the Secretary of the Council. The position has been held by Ms H Upton (Managing Health Physicist) since February 2002, with Mr D Surin (Principal Health Physicist) performing these duties in Ms Upton's absence.

STATE ELECTORAL ACT

For the purposes of Section 175ZE of the State Electoral Act, the Radiological Council has no expenditure to report. Council's functions are supported from within the budget assigned by the Department of Health to the Radiation Health Unit. The Council does not have a budget in its own right.

STATE RECORDS ACT

The Radiological Council's record keeping systems are managed by the Radiation Health Unit of the Department of Health, and thus the Council's compliance with the State Records Commission Standard 2, Principle 6 is linked to compliance by the Department of Health.

REGISTRATIONS, LICENCES AND TEMPORARY PERMITS

Registration and licensing are the principal means by which the use of radiation is regulated. A summary of the legislative system for registration and licensing in Western Australia is included in appendix 1.

QUALIFICATIONS AND TRAINING OF RADIATION USERS

A summary of the legislative scheme for ensuring the appropriate qualifications and competence of persons applying for licences is included in appendix 2.

CHANGES TO LEGISLATION

No amendments were made to the Radiation Safety Act or the Radiation Safety (Transport of Radioactive Substances) Regulations in 2020.

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

RADIATION INCIDENTS

Reported incidents involving radiation rarely pose a major health risk to the individuals exposed. Regulation 19A of the Radiation Safety (General) Regulations requires registrants to notify the Council in writing as soon as practicable should any of the abnormal or unplanned radiation exposures specified in that regulation occur. In addition to Regulation 19A, the medical incident reporting condition requires medical incidents specified in that condition to be reported to Council 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 92 incidents during 2020 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.

The first incident in the Radiology section of the table relates to a patient that received a radiation injury due to a high skin dose from an interventional fluoroscopy procedure. The nature of interventional fluoroscopy is such that the benefits of the imaging required for the procedure far outweigh the risks from radiation exposure. In this case, the life-saving procedure required extensive use of fluoroscopic imaging.

The last incident in the table relates to the unintended release to sewer of radioactive iodine due to a malfunction in the pump control of a hospital radioactive waste holding tank. Radioactive waste from nuclear medicine patients is routinely released into sewer, both from private residences and nuclear medicine practices. The Radiation Safety Act permits release to sewer within specified limits, which exist to ensure that no person receives a radiation dose in excess of the relevant dose limits. A relatively small amount of radioactive waste was present in the holding tank at the time and the facility in this case has not exceeded regulatory limits.

Incident	**Occurrences**	**Category**
Radiology		
Patient injury – observable acute radiation effect	1	Interventional fluoroscopy procedure
Incorrect patient imaged – failure to correctly identify patient against request form	10	Human error – failure to follow protocol
Incorrect patient imaged due to incorrect patient name being entered on request form	10	Human error – other

Incident	Occurrences	Category
Incorrect examination/anatomical site imaged – failure to image as per request form	12	Human error – failure to follow protocol
Incorrect examination/anatomical site imaged – failure to refer for correct examination/anatomical site	1	Human error – failure to follow protocol
Incorrect modality selected by MIT	2	Human error – failure to follow protocol
Duplication of imaging due to equipment failure	3	Multiple patients affect by one of these occurrences.
Unintended exposure to persons other than patient in the room	1	Human error – failure to follow protocol
Radiotherapy		
Incorrect treatment site	1	Human error
Exposure of roof worker	1	Human error – failure to follow protocol
Prescribed dose not able to be fully delivered due to non-compliant patient	1	Human error
Nuclear Medicine		
Incorrect radiopharmaceutical supplied or administered	11	Human error - failure to follow protocol
Incorrect patient imaged – failure to correctly identify patient against request form	1	Human error – failure to follow protocol
Extravasation of radiopharmaceutical	5	Protocol followed – IV administration failed after successful cannulation flush.
Radiopharmaceutical administered but scan not performed	10	Protocol followed – patient did not proceed with procedure.
Radiopharmaceutical administered but scan not performed - team requested a different diagnostic test or cancelled the original test.	2	Human error – communication between treating teams needed improvement
Radiopharmaceutical administered but scan not performed – patient's status changed and the diagnostic test was not performed or continued.	7	Protocol followed
Duplicate scan required - failure of infusion	1	Human error
Malfunction/incorrect use of equipment - spill of radiopharmaceutical	3	Equipment or human error
Loss of radioguidance sources	3	Human error

Incident	Occurrences	Category
Industrial		
Potential for exposure of persons – industrial radiography source guide damaged, source not able to return to holder.	1	Protocol followed – damage due to falling pipe.
Lost well logging source - recovered	1	Protocol followed
Vehicle incident whilst radioactive source on board	1	Protocol followed – vehicle rolled after accident.
Unintentional exposure of persons – fixed gauge not isolated	2	Human error - failure to follow protocol
Other		
Unintended release of radioactive substances to sewer	1	Human error

PROSECUTIONS

No prosecutions were initiated or finalised in 2020.

MEDICAL AND RELATED RADIATION MATTERS

Medical Compliance Testing

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

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

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

A summary of the compliance tests assessed in 2020 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 Radiation Protection and Nuclear Safety Agency (ARPANSA) Radiation Protection Series # 8 (2005) *Exposure of Humans to Ionizing Radiation for Research Purposes*, the Council assesses research projects which involve exposing humans to ionising radiation without proven benefits to the irradiated subjects and where the dose to any individual adult subject exceeds 5 mSv in any year.

In 2020, Council assessed and approved the radiation component of the research applications listed in attachment 4.

As part of a staged review of the Council's requirements relating to human research projects involving radiation, at its December meeting the Council agreed to further align with the Code of Practice and, among other amendments, increased the adult total effective dose threshold for projects requiring submission to the Council for approval to 20 mSv.

X-Ray Operator Course

X-ray operators are approved by the Radiological Council to perform basic radiography of the chest and extremities in remote and rural areas where radiology services are otherwise not available. A Radiological Council approved training course suitable as a prerequisite for approval of an x-ray operator has been run by Curtin University since 2013.

Radiation Oncology Medical Physicists

Radiation Oncology Medical Physicists are a core profession in the provision or safe and effective radiation oncology treatments. Their use of therapeutic and treatment planning radiation producing equipment and radioactive substances is regulated under the Radiation Safety Act.

Over the course of the year, the Radiological Council undertook a review of several of its requirements relating to licensed radiation oncology medical physicists. The review was extensive and included consultation within WA and nationally, including the relevant professional colleges and all public radiation oncology facilities in Australia. Two amendments were agreed following the review, relating to presence of physicists during clinical use of therapeutic irradiating apparatus and responsibility for release of equipment for clinical use.

The review did not affect the Council's requirements for compliance with the Radiation Oncology Practice Standards or the Australian Code for Radiation Protection in Medical Exposure.

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 2020 is included in attachment 3.

Standards for Council Examinations

In 2002, the Council agreed that greater control should be exercised over industrial radiation safety examinations and decided that while course providers may continue to invigilate examinations, all industrial papers would be returned to Council's officers for marking. In 2020, Council officers marked 421 industrial examination papers. The number of examinations marked in each category is listed in attachment 5.

Mining and Milling of Radioactive Ores

The mining, milling, processing, certain exploration activities and the transport of radioactive ores are subject to the Radiation Safety Act and subsidiary legislation.

The Council has an independent role to ensure the appropriate oversight of the radiation safety aspects of the mining and milling of radioactive ores and this includes –

- the review of radiation management plans.
- approvals of Radiation Safety Officers.
- the review of occupational and environmental reports.
- conducting independent monitoring and surveillance.
- conducting inspections and audits.

The mining and milling of radioactive ores are also subject to Part 16 of the Mines Safety and Inspection Regulations under the Mines Safety and Inspection Act. These regulations are administered through the Department of Mines, Industry Regulation and Safety (DMIRS).

Low Level Radioactive Waste Facilities

Council has been continuing to liaise with the proponent and review documentation associated with a proposal for a privately owned and commercially operated low level radioactive waste facility in Western Australia. The assessment process is continuing and is expected to be completed in 2021. Independent technical advice is also being sought to determine the proposed facility's compliance with the applicable safety standards. Liaison has also continued with several federal government agencies and the regulators of other state and territory jurisdictions. As at the end of 2020, the site is only authorised for the storage of naturally occurring radioactive material.

The existing State owned and operated low level intractable waste disposal facility has also been in contact with Council with regards to proposals for a disposal operation in 2021 for low level radioactive waste.

MISCELLANEOUS

COVID-19

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

Automatic Mutual Recognition

In 2020 the Council was advised of the proposal to establish a scheme for automatic mutual recognition for the purposes of streamlining occupational registration processes for applicants working in more than one jurisdiction. The Intergovernmental Agreement on the Automatic Mutual Recognition of Occupational Registration was signed at the National Cabinet meeting in December 2020. The Radiological Council will work through the potential consequences of the agreement on licensing in 2021.

Integrated Regulatory Review Service Mission to Australia

The Radiological Council participated in the International Regulatory Review Service (IRRS) offered by the International Atomic Energy Agency (IAEA) through the Commonwealth's Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). The purpose of the IRRS mission was to perform a peer review of Australia's regulatory frameworks for nuclear and radiation safety. The scope of the review included all facilities and activities regulated in Australia, with the exception of the uranium mining industry and the management of waste containing naturally occurring radioactive material (NORM).

In the initial phase of the review, prior to the visit from the IRRS team of international radiation safety experts, a self-assessment was conducted in 2017-2018. The self-assessment process allowed for an internal analysis, benchmarking the regulatory framework for radiation against international best practice IAEA safety standards.

The IRRS team recognised that many of its recommendations and suggestions confirmed or elaborated on the actions identified by Australia's jurisdictions as a result of their self-assessments.

As part of the IRRS, the Council identified that the Western Australian regulatory framework generally conforms to the requirements outlined under the IRRS modules undertaken. The key findings against each module are being used in the ongoing development of an action plan. The Radiation Health Expert Reference Panel (RHERP) under enHealth is tasked with the management and implementation of the action plan.

Radiation Health Committee

The Radiation Health Committee (RHC) is a body established to advise the Chief Executive Officer of ARPANSA and its Radiation Health & Safety Advisory Council on matters relating to radiation protection, formulating draft national policies, codes and standards for consideration by the Commonwealth, States and Territories.

Western Australia has representation on the RHC through the Secretary of the Radiological Council who attends the committee meetings tri-monthly.

A list of publications approved by the RHC and published by ARPANSA in 2020 is in attachment 6.

Environmental Health Standing Committee

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

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

Consequently a Radiation Health Expert Reference Panel (RHERP) has been established under enHealth to provide expert advice on specific issues as directed by the Environmental Health Standing Committee (enHealth). A draft of a National Strategy for Uniformity of Radiation Protection and Nuclear Safety Regulation in Australia is being finalised for consultation in 2021.

National Directory for Radiation Protection

At the Australian Health Ministers' Conference held in June 2004, the Ministers endorsed the adoption of the National Directory for Radiation Protection, Edition 1, as the Framework for National Uniformity in Radiation Protection.

Further development of the National Directory continued in 2020 through the national Radiation Health Committee and the Radiation Health Expert Review Panel under enHealth.

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

Personal Radiation Monitoring Services

Council currently recognises six organisations for the provision of a personal radiation monitoring service in accordance with the Regulations –

- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)
- Global Dosimetry Solutions
- Global Medical Solutions Australia
- Landauer Australasia
- National Radiation Laboratory, New Zealand
- SGS Radiation Services Pty Ltd

Appendix 1: Registration and Licensing

Registrations

Section 28 of the Act requires prescribed radioactive substances, x-ray equipment and electronic products, together with the associated premises, to be registered. Registrants may include individuals, companies, organisations or institutions.

All x-ray equipment is prescribed while prescribed electronic products include lasers and transilluminators.

Radioactive substances that exceed the exempt quantities prescribed in the regulations are subject to registration. A small number of devices containing radioactive substances in excess of the exempt limits, but which pose a minimal hazard to users, have been exempted by regulation from control under the Act.

The numbers of devices and sealed radiation sources registered as at 31 December 2020 are included in attachment 7.

Licences

Section 25 of the Act requires persons who manufacture, store, transport, sell, possess, install, service, maintain, repair, use, operate or otherwise deal with prescribed radioactive substances, x-ray equipment or electronic products to be licensed or, where permitted, work under the direction and supervision of a licensee.

Section 29 of the Act also creates an offence for a person to sell any prescribed substances or devices unless they require the purchaser to produce evidence that they hold a relevant licence or are otherwise exempted by the Act or regulations. Sales also must be notified in writing to the Council, without delay, identifying the purchaser and the particulars of the relevant licence or exemption.

Exemptions from Licence

A licence is not required where a general exemption is provided by the regulations or where a person has been granted an individual exemption from licence. The regulations nevertheless specify the minimum qualifications or training required for these radiation workers.

Temporary Permits

The shortest period for which a licence or registration can be granted is 12 months. However, for shorter periods an application may be made for a Temporary Permit. Permits cannot exceed a duration of 3 months. 56 Temporary Permits were current as at 31 December 2020.

Conditions, Restrictions and Limitations

A range of performance and safety requirements for radioactive substances, x-ray equipment and the prescribed electronic products are specified in the regulations. However, additional safety measures may be applied by the Council under Section 36 of the Act through conditions, restrictions and limitations applied to registrations, licences, temporary permits and exemptions.

Failure to comply with a condition is an offence.

Attachment 8 shows the types and numbers of licences and registrations (or individual exemptions) granted or renewed in 2020.

Commonwealth Government Agencies and Contractors

The Radiation Safety Act does not apply to Commonwealth agencies or to their employees (or contractors) who might use radiation in Western Australia. Those agencies are regulated by ARPANSA under the Commonwealth Government's Australian Radiation Protection and Nuclear Safety Act 1999.

Appendix 2: Licence Prerequisites

Before a licence may be granted, the Council has an obligation to ensure that an applicant has appropriate qualifications, competence and experience (Section 33).

Protocols have been developed which prescribe the prerequisite qualifications and experience necessary for a wide range of radiation uses. Some qualifications are recognised by the Council because an appropriate degree of radiation safety training is inherent in gaining those qualifications. However, other applicants may be required to attend a recognised radiation safety course and pass an examination. The Council has authority to impose examinations under the Radiation Safety (Qualifications) Regulations.

Persons who are not required to hold a licence themselves but who must work under the direction and supervision of a licensee may also be required to hold certain qualifications or to have undergone additional radiation safety training. These requirements may be imposed by regulation or through conditions, restrictions and limitations imposed under Section 36. The registrant for the premises where the individual works is primarily responsible for ensuring compliance with these criteria.

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

Attachment 1: Radiological Council

MEMBERS OF THE RADIOLOGICAL COUNCIL

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

2020 MEETING ATTENDANCE

	11 FEB	10 MAR	14 APR	9 JUN	14 JUL	11 AUG	8 SEP	10 NOV	8 DEC
Dr A Robertson	✓	✓	A	✓	✓	✓	✓	✓	✓
Dr R Bangor-Jones	A	A	A	D/O	A	O	O	D/O	O
Dr R Price	✓	✓	✓	✓	✓	✓	✓	✓	✓
A/Prof R Francis	✓	✓	✓	✓	A	✓	✓	✓	✓
Dr E Thomas	✓	✓	✓	✓	✓	✓	✓	✓	✓
Dr C Hewavitharana	A	✓	✓	✓	✓	✓	✓	✓	✓
Mr D Kwiatkowski	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ms H Parry	A	D	D	D	D	A	D	D	A
Mr C Whennan	✓	A	R						
Mr N Tsurikov	✓	✓	A	✓	✓	✓	✓	✓	A
Mr F Harris	✓	✓	A	A	✓	✓	✓	✓	✓
Mr C Storm	O	O	A	A	O	O	A	O	O

✓ attended D deputy A apology O observer R retired

Attachment 2: Legislation Amendments

RADIATION SAFETY ACT

None

RADIATION SAFETY (GENERAL) REGULATIONS

Health Regulations Amendment (Fees and Charges) Regulations 2020 Pt.6

Amendment to fees (Schedule XV).

Government Gazette 26 June 2020 SL2020/97

RADIATION SAFETY (QUALIFICATIONS) REGULATIONS

Health Regulations Amendment (Fees and Charges) Regulations 2020 Pt.7

Amendment to fees for examinations (Schedule 2).

Government Gazette 26 June 2020 SL2020/97

RADIATION SAFETY (TRANSPORT OF RADIOACTIVE SUBSTANCES) REGULATIONS

None

Attachment 3: Compliance Testing

Medical

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

Category	A	B	C	Total
CT	79	-	2	81
Dental – cone beam CT	34	-	1	35
Dental – intraoral	815	-	-	815
Dental – panoramic and/or cephalometric	171	-	1	172
Fluoroscopic – fixed	36	-	2	38
Fluoroscopic – fixed C or U arm	30	-	2	32
Fluoroscopic – mobile	121	-	4	125
Mammography	60	-	-	60
Radiographic – fixed	139	-	3	142
Radiographic – mobile	75	-	1	76
Total	1560	0	16	1576

Industrial – Fixed Gauges

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

Category	A	B	Total
Density	375	11	386
In-stream analysis	13	-	13
Level	112	7	119
Other	8	-	8
Total	508	18	526

[1] Equipment deemed to be non-compliant may continue to be used for a further three months while the problem is being addressed provided that the reason for non-compliance does not significantly increase the radiation dose to the patient. A re-test is then required. Of the 20 re-tests conducted during 2020, 95% resulted in the equipment being granted either a compliance or conditional compliance certificate.
[2] Equipment that has been assessed as non-compliant cannot be used until it has been re-tested and issued with a certificate of compliance.

Attachment 4: Research Project Applications Assessed

Research Project Title
The Role of Neuroinflammation in Hypertension: Minocycline for Resistant Hypertension, A Randomized, Double-Blind Placebo-Controlled Trial.
A Phase 3, Randomized, Double-blind Trial of Pembrolizumab (MK-3475) Plus Enzalutamide Plus ADT Versus Placebo Plus Enzalutamide Plus ADT in Participants With Metastatic Hormone-Sensitive Prostate Cancer (mHSPC)
A Phase 3, randomised, double blind study of adjuvant Nivolumab versus placebo for participants with Hepatocellular carcinoma who are at high risk of recurrence after curative hepatic resection or ablation.
The Australian Dementia Network (ADNeT): Screening for trials and longitudinal research on trials ready cohort (TRC)
A phase 1/2, Dose Escalation and Expansion Study of BGB-10188, a Phosphatidylinositol 3-Kinase Delta (PI3Kδ) Inhibitor, Combined with Zanubrutinib in Patients With Mature B-Cell Malignancies and Combined With Tislelizumab in Patients With Solid Tumors.
An open-label, randomised, multicentre, phase III study of irinotecan liposome injection, oxaliplatin, 5-fluorouracil/leucovorin versus nab-paclitaxel plus gemcitabine in subjects who have not previously received chemotherapy for metastatic adenocarcinoma of the pancreas.
A Phase III, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of alpelisib (BYL719) in combination with nab-paclitaxel in patients with advanced triple negative breast cancer with either phosphoinositide-3-kinase catalytic subunit alpha (PIK3CA) mutation or phosphatase and tensin homolog protein (PTEN) loss without PIK3CA mutation.
A multicentre, open-label, randomized phase III study to evaluate the efficacy and safety of the combination of Belantamab Mafodotin, Bortezomib, and Dexamethasone (B-Vd) compared with the combination of Daratumumab, Bortezomib and Dexamethasone (D-Vd) in participants with relapsed/refractory multiple myeloma.
The International AML Platform Consortium (IAPC) trial.
A Phase 1/2 Open-Label Rolling-Arm Umbrella Platform Design of Investigational Agents With or Without Pembrolizumab or Pembrolizumab Alone in Participants with Melanoma (KEYNOTE-U02): Substudy 02C
Repeatability of quantitative measures in metastatic prostate cancer using Prostrate Specific Membrane Antigen (PSMA) based PET
Persistent lung and arterial inflammation following COVID pneumonia.
An Open-Label Study to Assess the Anti-Tumor Activity and Safety of REGN1979, an Anti-CD20 X Anti-CD3 Bispecific Antibody, in Patients with Relapsed or Refractory B-Cell Non-Hodgkin Lymphoma.
Reducing sympathetic activity through ultrasound-based renal denervation in excessive cardiovascular risk populations – A pilot proof of concept and safety study with the paradise denervation system.

Research Project Title
A Phase III, Open-Label, Randomized Study of Atezolizumab and Tiragolumab Compared with Durvalumab in Patients with Locally Advanced, Unresectable Stage III Non-Small Cell Lung Cancer who have not Progressed After Concurrent Platinum-Based Chemoradiation.
A randomised phase 2 study of 177Lu-PSMA617 theranostic plus docetaxel vs docetaxel in metastatic hormone-naïve prostate cancer
A Phase III Randomized, Double-blind, Placebo-controlled, Multicentre Study Evaluating the Efficacy and Safety of GDC-9545 Combined with Palbociclib Compared with Letrozole Combined with Palbociclib in Patients with Estrogen Receptor-Positive, HER2-Negative Locally Advanced or Metastatic Breast Cancer.
Prospective, multicentre trial evaluating FET-PT in Glioblastoma.
A Placebo-Controlled,Double-Blind,Parallel-Group,18 month study with an open-label extension phase to confirm safety and efficacy of BAN2401 in subjects with early Alzheimer's Disease.
A Phase 2 trial of durvalumab (MEDI4736) and tremelimumab with chemotherapy in metastatic Epidermal Growth Factor Receptor (EGFR) mutant non-squamous non-small cell lung cancer (NSCLC) following progression on EGFR Tyrosine Kinase Inhibitors (TKIs).
A randomized phase 2 trial of Osimertinib with or without stereotactic radiosurgery for EGFR mutated Non-Small Cell Lung Cancer (NSCLC) with brain metastases.
A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 2 Study of the Efficacy and the Safety and Tolerability of BMS-986278 in Participants with Pulmonary Fibrosis.
A multicenter, Randomised, Double-blind, Chronic-dosing, Parallel-group, Placebo-controlled Phase 3 Study to Evaluate the Efficacy and Safety of Benralizumab 100 mg in Patients with Moderate to Very Severe Chronic Obstructive Pulmonary Disease (COPD) with a History of Frequent COPD Exacerbations and Elevated Peripheral Blood Eosinophils.
Hearing Aids to Support Cognitive Functions of Older Adults at Risk of Dementia: The HearCog Trial
A randomized double-blind, phase 3 study of Tucatinib or Placebo in combination with Ado-Trastuzuman Emtansine (T-DM1) for subjects with unrespectable locally advanced or metastatic HER2+Breast Cancer.
A Phase Ib, Open Label, Multicohort Study of the safety and efficacy, and Pharmacokinetics of Tiragolumab in combination with Atezolizumab and Chemotherapy in patients with Triple-Negative Breast Cancer.
A Phase II, randomised, open-label, multicenter study evaluating the efficacy and safety of GDC-9545 compared with physician's choice of Endocrine Monotherapy in patients with previously treated Estrogen Receptor Positive, HER2 Negative Locally Advanced or Metastatic Breast Cancer.
A Phase 2 Open-Label Study Evaluating Tolerability and Efficacy of Navitoclax Alone or in Combination with Ruxolitinib in Subjects with Myelofibrosis.
To assess the safety and tolerability, pharmacokinetics, whole body biodistribution and radiation dosimetry of Copper-64-labelled TLX592 (^{64}Cu-TLX592).

Research Project Title
A Phase 3 Randomized, Placebo-controlled, Double-blind Study of Niraparib in Combination with Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone for the Treatment of Participants with Deleterious Germline or Somatic Homologous Recombination Repair (HRR) Gene-Mutated Metastatic Castration-Sensitive Prostate Cancer (mCSPC).
Multi-Organ Denervation to Reduce Sympathetic Drive, A Single Blinded, Multi-Center, Prospective Feasibility Study.
Prospective, Multi-Center, Single-Arm, Feasibility Study to Assess the Safety and Performance With the SUNDANCE™ DruG Coated Balloon for the Treatment of De Novo or Restenotic Lesions in Infra-Popliteal Arteries.
BIOTRONIK First-in-Human assessment of the safety and clinical performance of a sirolimus derivative-coated balloon (Bright DCB) in the treatment of subjects with de Novo lesions in the superficial femoral and proximal popliteal artery.
EMBER: A Phase 1a/1b Study of LY3484356 Administered as Monotherapy and in Combination with Anticancer Therapies for Patients with ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers.
A longitudinal cohort study of dementia with Lewy bodies – Unravelling the confounding influences of Alzheimer's disease and cerebrovascular disease in dementia with Lewy bodies.
The feasibility of 18F-FMISO imaging of atherosclerotic and non-atherosclerotic intra-arterial hypoxia.
The GLORIA Study: A Phase 3, Randomized, Open-Label Study of the Anti-Globo H Vaccine Adagloxad Simolenin (OBI-822)/OBI-821 in the Adjuvant Treatment of Patients with High-Risk, Early-Stage Globo H-Positive Triple Negative Breast Cancer
EFC15935: A randomized, multicenter, double-blind phase 3 study of SAR439859 plus palbociclib versus letrozole plus palbociclib for the treatment of patients with ER (+), HER2 (-) breast cancer who have not received any prior systemic anti-cancer treatment for advanced disease.
The Australian Imaging, Biomarkers and Lifestyle (AIBL) Flagship Study of Ageing.
DESTINY: A Phase 3, multicentre, randomised, open-label, active-control study of trastuzumab deruxtecan (T-DXd) versus trastuzumab emtansine (T-DM1) in subjects with high-risk HER2-positive primary breast cancer who have residual invasive disease in the breast or axillary lymph nodes following neoadjuvant therapy.
Probucol in Alzheimer's (PIA) - Study
An Open-label, Randomized Phase 3 Study to Evaluate Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with MK-6482 and Lenvatinib (MK-7902), or MK-1308A in Combination with Lenvatinib, versus Pembrolizumab and Lenvatinib, as Firstline Treatment in Participants with Advanced Clear Cell Renal Cell Carcinoma (ccRCC).
Zirconium-Girentuximab PET in Urothelial Cancer Patients (ZiP UP)
A Phase 3, Randomized, Double-Blind, Placebo-Controlled study of Acalabrutinib in combination with Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (R-CHOP) in subjects ≤65 years with previously untreated Non-Germinal Center Diffuse Large B-Cell Lymphoma

Research Project Title
A Phase 3, Randomized Study of Amivantamab and Lazertinib Combination Therapy Versus Osimertinib Versus Lazertinib as First-Line Treatment in Patients with EGFR-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer.
A Randomized, Open-label Phase 3 Study of Combination Amivantamab and Carboplatin Pemetrexed Therapy, Compared with Carboplatin-Pemetrexed, in Patients with EGFR Exon 20ins Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer.
A Phase II/III Randomized, Double-Blind, Placebo-Controlled, Cognitive Endpoint, Multicenter Study of Potential Disease Modifying Therapies in Individuals at Risk for and with Dominantly Inherited Alzheimer's Disease.
BGB-A317-A1217-301: Phase 3, Randomized, open label study to compare Tislelizumab (BGBA317) plus Anti-TIGIT Monoclonal Antibody BGB-A1217 plus Concurrent Chemoradiotherapy (cCRT) followed by BGB-A317 plus BGB-1217 Versus cCRT followed by Durvalumab in previously untreated, locally advanced, unresectable Non-Small Cell Lung Cancer (NSCLC).
The Australian-mulitdomain Approach to reduce Dementia Risk by protecting brain health With lifestyle intervention study (AU ARROW).
A Phase 2, Single-Arm, Open-label Clinical Trial of Pembrolizumab Plus Lenvatinib in participants with first-line Advanced/Metastatic Non-clear Cell Renal Cell Carcinoma (nccRCC).
An Open-Label, Multicenter, Phase 1b/2 Study of the Safety and Efficacy of KRT-232 in Combination with Acalabrutinib in Subjects with Relapsed/Refractory Diffuse Large B-cell Lymphoma or Relapsed/Refractory Chronic Lymphocytic Leukemia
Takotsubo cardiomyopathy: Truly a syndrome of cardiac catecholamine excess?

Attachment 5: Industrial Radiation Safety Examinations

Current at 31 December 2020

Category	2020	2019	2018	2017	2016
Borehole Logging	87	46	24	29	20
Fixed Gauges	85	119	83	109	68
Industrial Radiography	15	33	30	49	46
Industrial Radiography (Advanced)	0	1	0	0	4
Industrial Radiography (Assistant)	83	97	109	57	78
Portable Gauges	78	80	61	50	18
Portable Gauges (WA Requirements)	3	14	8	3	2
Transport	22	54	25	42	22
Service – Cabinet X-ray	3	16	2	5	1
Service – Industrial Radiography (X-ray)	0	1	0	0	0
Service – X-ray Analysis	0	2	0	0	1
X-ray Analysis – Use	1	0	0	0	0
X-ray Analysis – Use and Restricted Service	44	47	111	48	30
Total	421	510	453	392	290

Attachment 6: List of Australian Radiation Protection and Nuclear Safety Agency publications for 2020

	Title
RPS C-1	Code for Radiation Protection in Planned Exposure Situations (Rev.1) (2020)
RPS G-4	Guide for Classification of Radioactive Waste (2020)

Attachment 7: Registered Irradiating Apparatus, Electronic Products and Radioactive Substances (sealed sources)

Current at 31 December 2020

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

Category	A	B
Bone densitometry	65	-
Cabinet x-ray equipment	199	-
Calibration	1	753
CT	131	-
SPECT-CT and PET-CT	38	-
Dental – intraoral	2444	-
Dental – panoramic and/or cephalometric	503	-
Dental – cone beam CT	57	-
Education and research	20	960
Fluoroscopic – fixed	80	-
Fluoroscopic – mobile	136	-
Gauges – density/level	10	3485
Gauges – in stream analysis	2	84
Gauges – logging	35	395
Gauges – neutron moisture/density portable	-	439
Gauges – other	-	327
Irradiator	-	48
Isotope Production	1	-
Laser – entertainment	202	-
Laser – industrial	215	-
Laser – medical	371	-
Laser – other medical	384	-
Laser – podiatry	17	
Laser – research	179	-
Linear accelerator	23	-
Mammography	66	-
Non-destructive testing	221	126
Non-destructive testing – crawler control	-	16
Portable mineral analyser	-	8
Radiographic – fixed	357	-
Radiographic – mobile	390	-

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

Category	A	B
Sealed Sources – other	-	174
Simulator	6	-
Special purpose x-ray	46	-
Static detection/measurement	-	3
Static elimination	-	14
Storage	-	344
Superficial radiotherapy	2	-
Test source	2	-
Therapy	4	27
Therapy – HDR brachytherapy	-	2
Transilluminator	127	-
Tracer Studies	-	131
X-ray analysis	697	-
Total	7034	7392

Attachment 8: Licences and Registrations

Current at 31 December 2020

Including individual exemptions granted under Section 6 of the Act.

	X-ray and/or Electronic Products		Radioactive Substances		TOTAL	
	2020	2019	2020	2019	2020	2019
Licences	6750	6195	2349	2228	9099	8423
Registrations	2242	2127	421	432	2663	2559
TOTAL	8992	8322	2770	2660	11762	10982
Change from 2019	+ 8.1%		+ 4.1%		+ 7.1%	

Attachment 8 (cont)

Purposes for Licences and Exemptions from Licence – total current as at 31 December 2020

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

Total	Purpose
20	Bone Densitometry
3	Bone Densitometry (Exemption)
105	Cabinet X-ray Equipment
58	Compliance Testing - Diagnostic X-ray Equipment
558	Compliance Testing - Radioactive Gauges
11	Cyclotron Operation
5	Cyclotron Servicing
5	Education (Apparatus)
27	Education (Substances)
486	Fluoroscopy - Medical
80	Fluoroscopy - Medical (Exemption)
37	Fluoroscopy - Medical (Non-Specialist Exemption)
14	Fluoroscopy - Podiatry (Exemption)
2	Fluoroscopy - Veterinary
5	Gamma Irradiator - Use
557	Gauges - Industrial
7	Gauges - Industrial (Installation)
1	Gauges - Level (CO2)
310	Gauges - Logging
539	Gauges - Moisture and/or Density (Portable)
5	Gauges - Other (Apparatus)
59	Gauges - Other (Substances)
2	Installation of X-ray Equipment
2	Installation of X-ray Equipment - Dental
5	Lasers - Acupuncture
1	Lasers - Astronomy
12	Lasers - Chiropractic
203	Lasers - Dental
6	Lasers - Educational
30	Lasers - Entertainment
408	Lasers - Hair Removal (Exemption)
82	Lasers - Industrial
337	Lasers - Medical
1	Lasers – Osteopathy (Exemption)
7	Lasers - Other
128	Lasers - Physiotherapy

Total	Purpose
40	Lasers - Podiatry (Exemption)
62	Lasers - Research
90	Lasers - Service
89	Lasers - Superficial Cosmetic (Exemption)
21	Lasers - Tattoo Removal (Exemption)
24	Lasers - Veterinary
1	Manufacture of X-ray Equipment
2	Medical Physics
27	Medical Physics - Radiotherapy (Apparatus)
15	Medical Physics - Radiotherapy (Substances)
87	Medical Radiation Technology - Diagnostic Nuclear
1238	Medical Radiation Technology - Medical Imaging
24	Medical Radiation Technology - Nuclear Medicine - Diagnostic CT
226	Medical Radiation Technology - Radiation Therapy Irradiating Apparatus
304	Medical Radiology
4	Non-Medical Irradiation
5	Nuclear Medicine - Calibration and QC Sources
44	Nuclear Medicine - Diagnostic
35	Nuclear Medicine - Therapeutic
1	Nuclear Medicine - Therapy (Endocrinology)
5	Nuclear Medicine - Veterinary
6	Pathology Tests
20	Portable Mineral Analysers
425	Portable Mineral Analysers (X-ray)
3	Possession of X-ray Equipment - Diagnostic Medical
2	Possession of X-ray Equipment - Diagnostic Medical and Dental
3	Quality Assurance Procedures
35	Radioactive Ores - Analytical Laboratories
14	Radioactive Ores - Exploration
19	Radioactive Ores - Mining and/or Processing
13	Radioactive Substances - Calibration Sources
1	Radioactive Substances - Medical
38	Radioactive Substances - Sale
41	Radioactive Substances - Service of Devices
17	Radioactive Substances - Tracer Studies (Industry)
26	Radiography - Chiropractic (Extended)
162	Radiography - Chiropractic (Restricted)
434	Radiography - Industrial (Gamma)
443	Radiography - Industrial (X-ray)
1	Radiography - Mammography Screening (Exemption)

Total	Purpose
1	Radiography - Medical (Direction and Supervision)
4	Radiography - Security
919	Radiography - Veterinary
3	Radioguidance - Medical (Radioactive Substances)
128	Radiology - Dental
13	Radiology - Veterinary
23	Radiopharmaceutical Manufacture and Dispensing
29	Radiotherapy - Medical (Apparatus)
21	Radiotherapy - Medical (Substances)
1	Radiotherapy - Medical Superficial
11	Research
43	Research - Unsealed Radioactive Substances
10	Research - X-ray
37	Sale of Electronic Products
95	Sale of X-ray Equipment
34	Service of X-ray Equipment - Analytical
40	Service of X-ray Equipment - Cabinet
30	Service of X-ray Equipment - Dental
142	Service of X-ray Equipment - Diagnostic
4	Service of X-ray Equipment - Diagnostic (Extended)
3	Service of X-ray Equipment - Industrial NDT
36	Service of X-ray Equipment - Linear Accelerators
6	Service of X-ray Equipment - Other
5	Service of X-ray Equipment - Superficial X-ray Therapy
15	Special Purpose Enclosed X-ray Equipment
1	Static Detection
1	Static Electricity Measurement
1	Static Elimination
6	Storage (Apparatus)
28	Storage (Substances)
20	Transilluminators
173	Transport
110	X-ray Analysis - Use
307	X-ray Analysis - Use and Service (Restricted)
3	X-ray Irradiator
5	X-ray - Industrial

Attachment 8 (cont)

Purposes for Registrations and Exemptions from Registration – total current as at 31 December 2020

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

Total	Purpose
26	Bone Densitometry
13	Bone Densitometry (Exemption)
89	Cabinet X-ray Equipment
2	Cyclotron Operation
2	Disposal of Radioactive Waste
9	Education (Apparatus)
16	Education (Substances)
27	Education – Demonstration Radioactive Sources (Exemption)
6	Fluoroscopy – Medical
1	Fluoroscopy – Podiatry
2	Gamma Irradiator
136	Gauges – Industrial
3	Gauges – Level (CO2)
19	Gauges – Logging
45	Gauges – Moisture and/or Density (Portable)
14	Gauges – Other (Apparatus)
7	Gauges – Other (Substances)
3	Lasers – Acupuncture
1	Lasers – Analyser
1	Lasers – Astronomy
10	Lasers – Chiropractic
125	Lasers – Dental
3	Lasers – Educational
42	Lasers – Entertainment
66	Lasers – Hair Removal
43	Lasers – Industrial
1	Lasers – Manufacture
161	Lasers – Medical
1	Lasers – Osteopathy
4	Lasers – Other
49	Lasers – Physiotherapy
15	Lasers – Podiatry
7	Lasers – Research
7	Lasers – Sale, Service, Maintenance and Testing
15	Lasers – Storage

Total	Purpose
31	Lasers – Superficial Cosmetic
5	Lasers – Tattoo Removal
15	Lasers – Veterinary
2	Manufacture of X-ray Equipment
145	Medical Radiology
2	Non-Medical Irradiation
24	Nuclear Medicine – Diagnostic
19	Nuclear Medicine – Computed Tomography
9	Nuclear Medicine – Therapeutic
3	Nuclear Medicine – Veterinary
6	Pathology Tests
6	Portable Mineral Analysers
233	Portable Mineral Analysers (X-ray)
13	Radioactive Ores – Analytical Laboratories
8	Radioactive Ores – Exploration
39	Radioactive Ores – Mining and/or Processing
12	Radioactive Substances – Calibration Sources
1	Radioactive Substances – Medical
7	Radioactive Substances – Sale
2	Radioactive Substances – Service of Devices
2	Radioactive Substances – Tracer Studies (Industry)
14	Radiography – Chest Screening
45	Radiography – Chiropractic
798	Radiography – Dental
1	Radiography – Forensic
27	Radiography – Industrial (Gamma)
34	Radiography – Industrial (X-ray)
13	Radiography – Mammography Screening
44	Radiography – Medical (Operator)
10	Radiography – Medical (Unrestricted)
61	Radiography – Medical Ancillary (Referrals)
1	Radiography – Security
276	Radiography – Veterinary
4	Radioguidance – Medical (Radioactive Substances)
41	Radiology – Dental
3	Radiology – Veterinary
2	Radiopharmaceutical Manufacture and Dispensing
11	Radiotherapy – Medical (Apparatus)
6	Radiotherapy – Medical (Substances)
2	Radiotherapy – Veterinary (Apparatus)
2	Regulatory Authority
5	Research (Substances)

Total	Purpose
11	Research – Unsealed Radioactive Substances
9	Research – X-ray
4	Sale of Electronic Products
25	Sale of X-ray Equipment
51	Security of Radioactive Sources
15	Service of X-ray Equipment
11	Special Purpose Enclosed X-ray Equipment
1	Static Electricity Measurement
2	Static Elimination
55	Storage (Apparatus)
51	Storage (Substances)
13	Transilluminators
15	Transport
128	X-ray Analysis
1	X-ray Irradiator

ABBREVIATIONS

General Terminology

ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
CT	Computed Tomography
CT/SPECT	Computed Tomography/Single-Photon Emission Computed Tomography
DMIRS	Western Australian Department of Mines, Industry Regulation and Safety
enHealth	Environmental Health Standing Committee
HDR	High Dose Rate
IRRS	International Regulatory Review Service
MIT	Medical Imaging Technologist
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)