THE ANNUAL REPORT OF

THE RADIATION ADVISORY COMMITTEE

FOR THE FINANCIAL YEAR ENDING JUNE 2014

RADIATION ADVISORY COMMITTEE

Melbourne, Australia

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Hon David Davis MLC
Minister for Health

Dear Minister

Pursuant to Section 110 of the *Radiation Act 2005*, the Radiation Advisory Committee submits the 2014 annual report of the Committee for presentation to Parliament.

Yours faithfully

Dr David Bernshaw
Chair
RADIATION ADVISORY COMMITTEE

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RADIATION ADVISORY COMMITTEE

The Radiation Advisory Committee (the Committee) is established under Part 10 of the *Radiation Act 2005*. The term of appointment for the Committee was the period 17 August 2011 to 16 August 2014.

(i) Composition

The Committee met on 10 occasions from July 2013 to June 2014.

The members of the Committee for the period from July 2013 to June 2014 were:

Dr. David Bernshaw (Chair) Consultant Radiation Oncologist Peter MacCallum Cancer Centre **Meetings attended: 8**	**Professor Robert Gibson** Radiologist Royal Melbourne Hospital **Meetings attended: 9**
Dr. Ken Joyner Director Joyner and Associates Telecommunications Consultancy **Meetings attended: 9**	**Dr. Roslyn Drummond** Radiation Oncologist Peter MacCallum Cancer Centre **Meetings attended: 9**
Mr Russell Booth Chief Nuclear Medicine Technologist Medical Imaging Department St Vincent's Hospital **Meetings attended: 8**	**Dr Graeme O'Keefe** Principal Scientist Austin Health **Meetings attended: 4**
Mr Christopher Perry Chief Radiographer EMI Radiology East Melbourne **Meetings attended: 8**	**Dr Russell Horney** Physicist Department of Medical Imaging and Radiation Sciences Monash University **Meetings attended: 6**
Mr Paul Marks Senior Medial Radiation Scientist Australian Radiation Protection and Nuclear Safety Agency **Meetings attended: 7**	**Dr Joanna Wriedt** Physiologist, Epidemiologist and Lawyer **Meetings attended: 7**

Dr Dean Morris Head of Operations Australian Synchrotron **Meetings attended: 10**	**Dr Ray Budd** Consultant medical physicist **Meetings attended: 8**
Mr Paul Tomlinson Senior Technician ALS Industrial **Meetings attended: 9**	

(ii) Responsibilities

The Committee is to advise the Minister for Health or the Secretary of the Department of Health, on any matters relating to the administration of the *Radiation Act 2005*, referred to it by the Minister or the Secretary including the following:

(a) The promotion of radiation safety procedures and practices.

(b) Recommendation of the criteria for the licensing of persons and the qualifications, training or experience required for licensing.

(c) Recommendation of which radiation sources should be prescribed as prescribed radiation sources.

(d) Recommendation of the nature, extent and frequency of tests to be conducted on radiation apparatus and sealed radioactive sources.

(e) Codes of practice, standards or guidelines with respect to particular radiation sources, radiation practices or uses.

Section 110 of the Radiation Act requires that the Committee must give the Minister a report on its activities during a financial year no later than 1 November following that year.

1. INTRODUCTION

Throughout the year a number of issues were considered by the Committee including:

- the regulatory requirements for various radiation practices;
- radiation incidents;
- non-ionising radiation matters;
- research projects involving the irradiation of human volunteers; and
- justification and dose optimisation in medical radiation procedures.

The terms of reference for the Committee are provided in Appendix 1.

The Committee would like to thank the Radiation Team of the Department of Health, in particular Mr Morrie Facci, for its continuing assistance and support.

2. IONISING RADIATION

2.1 Research Projects Involving the Exposure of Humans to Ionising Radiation

The Committee evaluated 51 research proposals in which doses to participants were proposed to exceed the dose constraints specified in the *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005)* published by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). These proposals included some participants who would not receive a direct benefit from the proposed radiation exposures. A list of the research projects considered by the Committee is provided in Appendix 2. All of the research projects were endorsed by the Committee, sometimes subject to minor changes, such as in the radiation dose estimates and the wording of the radiation risk statement in the patient information documentation.

2.2 Regulation of Research Projects Involving the Exposure of Humans to Ionising Radiation

The Department developed a paper for the consideration of the Committee that presented a model for changing the regulatory approach to research involving the exposure of humans to ionising radiation. The paper required that the processing of research projects by the RAC and the Department, as a method to assess a licence holder's regulatory compliance, no longer take place. The approach outlined in the paper involves the assessment via a process of auditing, by authorised officers of the Department, both of a licence holder's research governance and of the organisational framework through which the licence holder maintains standards necessary to comply with the requirements of the Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes. The Committee discussed the issues associated with the intended approach to such regulation and emphasised the continued need for independent authoritative advice, pertaining both to the process of justification for radiation procedures and to the statements of radiation risk, being available to human research ethics committees (HRECs). The Committee endorsed the approach to the regulation of research presented in this paper.

2.3 Radiation Incidents

The Committee continued to review reports of radiation incidents, accidental radiation exposures and maladministrations reported to the Radiation Team.

It is important to note that the Radiation Regulations 2007 prescribe radiation dose limits both for members of the public and for occupationally exposed persons. Section 22 of the Radiation Act 2005 creates an offence for a management licence holder to knowingly, recklessly or negligently cause another person to receive a radiation dose greater than the dose limits prescribed in the regulations. It should be noted, however, that section 22 does not apply to a radiation dose received during the course, or for the purpose, of any treatment for, or diagnosis of, an illness or injury.

The Committee believes that, in the interests of open reporting, the identification of staff members involved in these incidents should not be mandatory.

These incidents are summarised in the Annual Report of the activities of the Secretary of the Department of Health in the administration of the Radiation Act 2005.

The Committee noted that the majority of incidents still relate to unintentional or unnecessary exposures to medical patients. It should be noted, however, that the number of such incidents are insignificant in comparison with the number of medical radiation procedures carried out in Victoria during the year.

The Committee has, in the past, made recommendations to the department on actions that it considered appropriate. The actions varied depending on the specific incident but generally included:

- Provision of specific advice in relation to identification of patients.
- The recommended use of ‘time out’ processes to minimise errors.
- Confirmation of current practices at the premises concerned.
- Confirmation that practices had been changed since the incident i.e. that lessons had been learnt.
- Provision of technical advice as to how to estimate the radiation dose correctly.
- Writing to management licence holders about lessons learnt from the incidents.

In the future, the Committee intends to focus on the trends apparent in reported incidents and to determine if there is a regulatory approach that can be recommended to the department to address these trends.

Summary figures for radiation incidents from July 2012 to June 2013 and July 2013 to June 2014 are provided in Appendix 3.

One of the incidents that the Committee was advised of involved an industrial radiography company where what appeared to be a radioactive contaminant was detected after an industrial radiography source was retracted back into the source container after an exposure. Following the necessary exposure, the radiographers retracted the source. Upon source retraction, a “click” was heard which seemed to indicate that the source had returned successfully to the container. On going to retrieve the exposed film, however, they noticed that their radiation monitors indicated that a radioactive source was still located at the position of the film. They suspected that the source had not been retracted, perhaps because the source pigtail had become disconnected from the wind-out cable.

The radiographers were not able to retrieve what they thought was the pigtail from the guide tube after a few attempts to wind the source back in to the source container. As a result, they sawed off the end of the brass source stop at the tip of the guide tube and wound the source out into an emergency storage container designed for such circumstances. This operation was carried out over

an area of gravel near the site of the radiography. They confirmed by visual inspection and radiation measurement that the pigtail was in the emergency storage container.

They removed the emergency storage container to a distance and returned to the site of the radiography. They found that there were still areas with significant radiation levels, now in the area of the gravel where they had sawn off the source stop. It seemed likely at this point that a fragment or contaminant of some sort had become dislodged from the source and fallen out the end of the guide tube after the source stop was sawn off.

The contaminant was eventually recovered and identified as iridium-192 (^{192}Ir), the same isotope as used in the pigtail source. The contaminant was about the size of a grain of sand and may have resulted from deficiencies in the ^{192}Ir sealed source manufacturing process.

The Department notified licensed industrial radiography companies in Victoria, the Australian Institute of Non Destructive Testing, state and territory regulatory authorities, ARPANSA and the overseas supplier of the source.

2.4 Radiation Amendment Act 2013

The Committee was advised that the Radiation Amendment Act 2013 was passed by the Victorian Parliament. It commenced on 1 June 2014. The Act gives effect to the Victorian Government's decision to ban commercial tanning services from the end of 2014. It also strengthens the security around high consequence radioactive material.

The Radiation Amendment Act amends the Radiation Act 2005 to:

- provide for security plans for the possession and transportation of high consequence sealed sources and high consequence groups of sealed sources; and
- prohibit the commercial operation of tanning units; and
- empower the Secretary to issue improvement notices or prohibition notices for contraventions; or likely contraventions of the Act or regulations under the Act; and
- make other minor and consequential amendments to the Act.

A number of implications flow from the implementation of the Amendment Act. For example, there would be increased workload implications for the department in managing the new security requirements. It was also noted that possession and operation of a tanning unit for non-commercial purposes would not be illegal under the amendments, but that there was likely to be a move to ban the importation and manufacture of tanning units.

2.5 Radiation Amendment Regulations

The Committee was updated on the development of the proposed Radiation Amendment Regulations. The proposed regulations are required to implement fully the changes with respect to the security of high consequence radioactive material and to prescribe the offences that would incur infringement notices and give effect to other requirements of the Radiation Act. The Committee was advised that the proposed regulations would be drafted together with a regulatory impact assessment.

2.6 Proposed Course for Veterinary Surgeons Using Iodine-131 for Treatment of Feline Thyroid Disorders

The Committee was requested to provide comments on a proposed course for veterinary surgeons using iodine-131 for treatment of feline thyroid disorders, developed by a Melbourne radiation service provider. The Committee made some comments on the course and these were taken into consideration by the Department. The course was added to the list of approved courses for veterinary surgeons using iodine-131.

2.7 Radiation Team Work Program for 2014-2015

The Department advised the Committee that in 2014 the Department would focus on regulatory compliance in relation to:

(a) medical radiation practices involving computed tomography;

(b) medical radiation practices involving linear accelerators;

(c) medical radiation practices involving interventional fluoroscopy;

(d) industrial radiation practices involving industrial radiography;

(e) radiation practices that involve the possession of sealed sources and sealed source apparatus;

(f) industrial radiation practices involving mineral sands mining and processing; and

(g) radiation practices involving the transport of security enhanced radioactive sources.

It was deemed by the Department that these radiation practices either involved larger radiation doses to the Victorian population than other practices or were associated with sealed radioactive sources whose safe use, security and proper disposal, if appropriate, needed to be ensured.

The Committee found this information useful and expressed its thanks to the Department for providing it.

2.8 Issues in Relation to Disposal of Radioactive Material in the Mineral Sands Industry

The Department gave a presentation to the Committee on mineral sands mining and briefed the Committee on the issues in relation to disposal of radioactive by-products of mineral sand processing by a mineral sands mining company with operations in Australia. The material in question originates from a mineral separation plant and is being disposed of in a pit that resulted from previous mining activities. Some residents living in the immediate surrounds of the pit are raising concerns in relation to the disposal of the material.

2.9 Fundamentals for Protection against Ionising Radiation (2014)

The Committee was advised of the ARPANSA publication *Fundamentals for Protection against Ionising Radiation (2014)*. This is a high level document that outlines the fundamental principles underpinning radiation protection and it aims to bring Australia's approach to radiation protection into line with that of the International Atomic Energy Agency. The publication provides an understanding of the effects of ionising radiation and associated risks for the health of humans and of the environment. It further explains how radiation protection, safety and security can work individually and collectively to manage radiation risks. Finally, it presents ten principles and their

application in the management of radiation risks. The publication is the top tier document in the Australian national framework to manage risks from ionising radiation as laid out in the ARPANSA's Radiation Protection Series. It is not mandatory and provides the underpinning science and radiation protection principles.

2.10 Presentations on Industrial Radiography, Borehole Logging and Fixed Industrial Gauges

The Department gave presentations to the Committee on industrial radiography, borehole logging in the oil and gas industry and fixed industrial gauges incorporating a radiation source. The Committee found these presentations useful and expressed its thanks to the Department for them. The presentations would enhance the Committee's ability to provide advice to the Department on industrial radiation issues.

2.11 Future Directions for the Radiation Advisory Committee

The Committee again reflected on its functions and considered that, in future, it would shift its emphasis to provide advice of a more strategic and policy nature in relation to matters presented to it by the department for consideration. This emphasis would be given impetus by the new regulatory approach to research involving the exposure of humans to ionising radiation to be adopted by the department, detailed in section 2.2 above, which would relieve the Committee of tasks of a more operational nature.

3. NON-IONISING RADIATION

3.1 Ban on Commercial Tanning Units in Victoria

As mentioned in section 2.4 above, the Radiation Amendment Act amends the Radiation Act 2005 to prohibit the commercial operation of tanning units as of the end of 2014. The Committee was advised that the Victorian Government announced an assistance package for commercial solaria businesses as part of the ban on commercial tanning practices. To assist practices in relation to costs associated with the removal of commercial tanning units from a premise, the Department of Health would provide a disposal assistance grant of $2000 per commercial tanning unit for units collected before 30 June 2014 or $1000 for units collected between 1 July and 31 December 2014. Through authorised contractors, a licence holder would arrange for the collection and disposal of any commercial tanning units that were legally authorised to be possessed through a management licence issued by the Department.

3.2 Journal Articles Reviewed by the Committee

Kenneth R. Foster and Richard A. Tell. Radiofrequency energy exposure from the Trilliant smart meter. Health Phys. 105(2):177Y186; 2013.

This paper reviews radiofrequency (RF) field levels produced by electric utility meters equipped with RF transceivers (so-called smart meters), focusing on meters from one manufacturer (Trilliant, Redwood City, California, USA, and Granby, Quebec, Canada). As with other smart meters, this meter incorporates a low powered radiofrequency transceiver used for a neighbourhood mesh network operating in the 2.45 gigahertz (GHz) frequency band. Calculations based on a free space propagation model indicate that peak RF field intensities are in the range of 10 milliwatts per square metre (mW/m^2) or less at a distance of more than 1 to 2 m from the meters. However, the duty cycle of transmission from the meters (the fraction of time that they are transmitting) is very low (‹1%), resulting in an average exposure about 100,000 times lower than the Australian exposure limit. Limited measurements, conducted in two houses with the meters, were unable clearly to distinguish emissions from the meters from the considerable electromagnetic clutter in the same frequency range from other sources, including Wi-Fi routers and, when it was activated, a microwave oven. These preliminary measurements highlighted the difficulties that would be encountered in characterizing the RF exposures from these meters in homes when there are background signals from other household devices in the same frequency range. RF transmitters in wireless-equipped smart meters operate at similar power levels and in similar frequency ranges as many other digital communications devices in common use, and exposure levels due to them are very far below Australian exposure limits.

<u>Conclusion</u>: Time-averaged exposure levels measured at 1 to 2 metres from smart meters in this study are approximately 100,000 times lower than the Australian exposure limit.

ARPANSA Preliminary Measurements of Radiofrequency Transmissions from a Mesh Radio Smart Meter. Technical Report Series No. 163.

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) has undertaken some preliminary RF measurements of an installed mesh network smart meter at the home of a staff member in a suburb of Melbourne. It must be emphasised that these measurements by ARPANSA cannot be considered representative of all smart meters.

A typical RF pulse from the smart meter had an average intensity of 7 mW/m^2 measured at a distance of half a metre from the smart meter with the door to the meter box open. This is 0.00015% of the instantaneous exposure limit in the ARPANSA RF standard for the general public. The measured level with the meter box door closed, or on the other side of the wall on which the meter was mounted was about 20 times lower. The RF transmissions that were measured were not continuous and occurred less than 0.08% of the time that the measurements took place.

The RF electromagnetic energy transmitted in a single pulse from the smart meter is similar to that from a car remote unlocking fob and much less than a single GSM SMS transmission.

The measurements do not provide any indication of why smart meter transmissions would provoke symptoms in people otherwise unaffected by other wireless technologies such as mobile phone handsets. The low levels and short transmission times make any effects highly unlikely.

Conclusion: Measurements made by ARPANSA at 0.5 metre from a smart meter indicated that the time-averaged exposure level was almost one million times lower than the Australian exposure limit.

Poulsen AH et al. Mobile phone use and the risk of skin cancer: A nationwide cohort study in Denmark. Am J Epidemiol; 1 – 8, June 20, 2013.

In a nationwide cohort study, 355,701 private mobile phone subscribers in Denmark from 1987 to 1995 were followed up through 2007. Incidence rate ratios (IRRs) for melanoma, basal cell carcinoma and squamous cell carcinoma were calculated, adjusting for age, calendar period, educational level, and income. Separate IRRs for head/neck tumours and torso/leg tumours were compared to further address potential confounders. No overall increased risk for basal cell carcinoma, squamous cell carcinoma or melanoma of the head and neck was observed. Among men, the IRR for melanoma of the head and neck was 1.20 (95% confidence interval (CI): 0.65 - 2.22), whereas the corresponding IRR for the torso and legs was 1.16 (95% CI: 0.91 - 1.47), yielding a corrected IRR of 1.04 (95% CI: 0.54 - 2.00). A similar risk pattern was seen among women, though it was based on smaller numbers.

Conclusion: This study did not show any increased risk of skin cancer associated with use of mobile phones.

Gosselin M-C, Kühn S and Kuster N. Experimental and numerical assessment of low frequency current patterns from UMTS and GSM mobile phones. Phys Med Biol: 58 (2013) 8339 – 8357.

Mobile phones in operation have prominent spectral components in the low-frequency (LF) and radio-frequency (RF) ranges. While the exposure to RF fields from mobile phones has been comprehensively assessed in the past, the LF fields have received much less attention. In this study, LF fields from mobile phones were assessed experimentally and numerically for the global system for mobile (GSM) and universal mobile telecommunications system (UMTS) communication systems. The LF magnetic field induced by currents in phones using the UMTS is two orders of magnitude lower than that induced by GSM. Knowing that the RF exposure from the UMTS is also two orders of magnitude lower than from GSM, it is now possible to state that there is an overall reduction of the exposure from this communication system.

Conclusion: Exposure to low frequency magnetic fields from the universal mobile telecommunications system (UMTS) communication system is much lower than from the GSM system.

Ostiguy G et al. Smart Meters and Routers Radiofrequency Disturbances Study with Pacemakers and Implantable Cardiac Defibrillators. PACE 2013; 00:1–10.

Prior to this study, there was no scientific literature that examined radiofrequency (RF) interference from "smart meters" with cardiac implantable electronic devices (CIEDs). The objective of this in vitro study was to assess any potential interference with Medtronic CIEDs (Medtronic Inc., Minneapolis, Minnesota, USA). The study concluded that Landis+Gyr smart meters, Landis+Gyr routers and Schlumberger smart meters do not interfere with the functioning of the Medtronic CIEDs tested when their separation was, 10 cm, 6 cm and 15 cm respectively.

Conclusion: Landis+Gyr smart meters, Landis+Gyr routers and Schlumberger smart meters do not interfere with the functioning of the Medtronic cardiac implantable electronic devices.

IEEE Committee on Man and Radiation: COMAR Technical Information Statement Radiofrequency Safety and Utility Smart Meters, September 25, 2013.

This Technical Information Statement describes smart meter technology as used with modern electric power metering systems and focuses on the radio frequency (RF) emissions associated with their operation relative to human RF exposure limits. Smart meters typically employ low power (about 1 watt or less) transmitters that wirelessly send electric energy usage data to the utility company several times per day in the form of brief, pulsed emissions in the frequency bands of 902 to 928 megahertz (MHz) and 2.4 to 2.48 gigahertz (GHz) or on other nearby frequencies. Most smart meters operate as wireless mesh networks where each smart meter can communicate with other neighbouring meters to relay data to a data collection point in the region. This communication process includes RF emissions from smart meters representing energy usage as well as the relaying of data from other meters and emissions associated with maintaining the meter's hierarchy within the wireless network. As a consequence, most smart meters emit RF pulses throughout the day, more at certain times and less at others. However, the duty cycle associated with all of these emissions is very small, typically less than 1%, and most of the time far less than 1%, meaning that most smart meters actually transmit RF fields for only a few minutes per day at most. The statement concludes that the low peak power of smart meters and the very low duty cycles lead to the fact that accessible RF fields near smart meters are far below both Australian and international RF safety limits whether judged on the basis of instantaneous peak power densities or time-averaged exposures. This conclusion holds for smart meters alone or installed in large banks of meters.

Conclusion: Accessible radiofrequency radiation exposure levels near smart meters are far below both Australian and international RF safety limits, both singly or installed in large banks of meters.

Pettersson D, Mathiesen T, Prochazka M et al. Long-term Mobile Phone Use and Acoustic Neuroma Risk, Epidemiology, February 2014.

The authors conducted a population-based, nation-wide, case control study of acoustic neuroma in Sweden. Eligible cases were persons aged 20 to 69 years, who were diagnosed between 2002 and 2007. Controls were randomly selected from the population registry, matched on age, sex, and residential area. Postal questionnaires were completed by 451 cases (83%) and 710 controls (65%). Ever having used mobile phones regularly (defined as weekly use for at least 6 months) was associated with an odds ratio (OR) of 1.18 (95% confidence interval (CI) 0.88 to 1.59). The association was weaker for the longest induction time (≥10 years) (1.11, 95% CI 0.76 to 1.61) and for regular use on the tumour side (0.98, 95% CI 0.68 to 1.43). The OR for the highest quartile of cumulative calling time (≥680 hours) was 1.46 (95% CI 0.98 to 2.17). Restricting

analyses to histologically confirmed cases reduced all ORs; the OR for ≥680 hours was 1.14 (95% CI 0.63 to 2.07). A similar pattern was seen for cordless land-line phones, although with slightly higher ORs. Analyses of the complete history of laterality of mobile phone use revealed considerable bias in laterality analyses. The findings of this study do not support the hypothesis that long- term mobile phone use increases the risk of acoustic neuroma. The study suggests that phone use might increase the likelihood that an acoustic neuroma case is detected and that there could be bias in the laterality analyses performed in previous studies.

Conclusion: The findings of this study do not support the hypothesis that long-term mobile phone use increases the risk of acoustic neuroma.

3.3 The Committee's View on Possible Health Effects of Radiofrequency Radiation

The additional evidence reviewed by the Committee during the year has not altered its position that there is no substantive evidence linking exposure to radiofrequency radiation to an increased risk of cancer or other adverse health events. However in light of public concerns over mobile phones, base stations and smart meters the Committee will continue to review the relevant research.

3.4 The Committee's View on Possible Health Effects of Power Frequency Electromagnetic Fields.

The Committee's position is that, based on the total database of scientific research, there is insufficient evidence to conclude that exposure to normally encountered environmental levels of power frequency electromagnetic fields causes adverse health effects in humans. The Committee will continue to review relevant research in this area.

APPENDIX 1 TERMS OF REFERENCE OF THE RADIATION ADVISORY COMMITTEE

1. The Radiation Advisory Committee (RAC) is established under the Radiation Act 2005 and provides advice to the Minister for Health or the Secretary on protecting the health and safety of persons and the environment from the harmful effects of radiation, with a view to adopting best practice for radiation safety in Victoria.
2. The RAC may provide advice on matters including:
    - administration and amendments of the Radiation Act 2005 and the Radiation Regulations 2007;
    - licensing of persons and companies to use radiation sources and conduct radiation practices;
    - inspection and testing of radiation sources;
    - new radiation sources and technologies;
    - development, implementation and review of state and national codes, standards and guidelines;
    - transportation, storage and disposal of radioactive materials;
    - security of radioactive sources;
    - radiation incidents;
    - medical research proposals involving ionising radiation;
    - non-ionising radiation matters including:
        - solaria and their regulation;
        - health effects of radiofrequency electromagnetic fields (including mobile communications);
        - health effects of extremely low frequency (ELF) electromagnetic fields (including power frequency fields); and
        - lasers and intense pulsed light (IPL) sources.
    - the promotion and improvement of radiation safety in Victoria;
    - developments that impact on best practice for radiation safety; and
    - any other matter put to it by the Radiation Team of the department.
3. The RAC meets on the first Thursday of every month, excluding January.
4. A minimum of five members constitutes a quorum for meetings of the RAC.
5. The RAC regulates its own proceedings.
6. The RAC may establish sub-committees and working groups to consider specific issues, and may recommend that the department engage additional expert contractors to support these entities.
7. From time to time the RAC may invite visitors to its meetings in order to hear submissions or information from them, or to take or ask questions.
8. Secretarial support for the RAC is provided by the Radiation Team.
9. The RAC will provide an annual report to the Minister for each financial year, no later than 1st November following that year.

APPENDIX 2 RESEARCH PROJECTS CONSIDERED BY THE COMMITTEE

TITLE OF RESEARCH PROJECT
A Dose-Finding Phase 1 Study of Tas-120 in Patients with Advanced Solid Tumors with or without Fibroblast Growth Factor/Receptor (Fgf/Fgfr)-Related Abnormalities followed by a Phase 2 Study in Patients with Advanced Solid Tumors or Multiple Myeloma with Fgf/Fgfr)-Related Abnormalities.
A Double-Blind, Randomized, Placebo-Controlled, Dose-Ranging Study To Evaluate The Efficacy And Safety Of Pf-04236921 In Subjects With Crohn's Disease Who Are Anti-Tnf Inadequate Responders (Andante).
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men with Non-Metastatic (M0) Castration-Resistant Prostate Cancer (SPARTAN).
A Multicenter, Randomized, Open-Label, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib (E7080) Versus Sorafenib in First Line Treatment of Subjects With Unresectable Hepatocellular Carcinoma.
A multicentre, multicountry study to calibrate Florbetapir (18F) PET imaging data to the centiloid scale based on 11C-PiB.
A Multinational, Phase 3, Randomized, Double Blind, Placebo Controlled, Efficacy and Safety Study of Enzalutamide in Patients With Nonmetastatic Castration Resistant Prostate Cancer.
A Phase 2 Study of patients treated for relapsed Follicular Lymphoma: with Revlimid・ consolidation added to Rituximab maintenance therapy in those remaining PET positive (RePLY).
A phase 2, Open-Label Study of Rucapribin Patients with Platinum-Sensitive, Relapsed, High-Grade Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.
A Phase 3 Study to Evaluate the Efficacy and Safety of Dinaciclib or Ofatumumab in Subjects with Refractory Chronic Lymphocytic Leukemia (CLL).
A Phase 3, Open-label, Multicenter, Randomized Study of Sequential Zevalin (ibritumomab tiuxetan) versus Observation in Patients at Least 60 Years of Age with Newly Diagnosed Diffuse Large B-cell Lymphoma in PET-negative Complete Remission After R-CHOP or R-CHOP-like Therapy (Spectrum, Zest).
A Phase 3, Randomized, Double-blind, Controlled Study of Cabozantinib (XL184) vs. Placebo in Subjects with Hepatocellular Carcinoma Who Have Received Prior Sorafenib.
A Phase 3, Randomized, Double-blind, Controlled trial of Cabozantinib (XL184) vs. Mitoxantrone plus Prednisone in men with previously treated symptomatic castration-resistant prostate cancer (XL184-306 COMET-2)
A Phase 3, Randomized, Double-Blind, Placebo Controlled Study Evaluating the Efficacy and Safety of Idelalisib (GS 1101) in Combination with Bendamustine and Rituximab for Previously Treated Indolent Non-Hodgkin Lymphomas.
A Phase 3, Randomized, Double-Blind, Placebo Controlled Study Evaluating the Efficacy and Safety of Idelalisib (GS 1101) in Combination with Rituximab for Previously Treated Indolent Non-Hodgkin Lymphomas.
A Phase I Multiple Ascending Dose Study of ASLAN002 (BMS-777607) in Subjects With Advanced or Metastatic Solid Tumours.
A Phase I, open-label, dose escalation study of LDK378 in pediatric patients with malignancies that have a genetic alteration in anaplastic lymphoma kinase (ALK).
A Phase I/II Trial of the combination of BRAF and EGFR inhibition in BRAF V600E mutant metastatic colorectal, advanced or metastatic lung adenocarcinoma and other cancers: The EViCT (Erlotinib and Vemurafenib In Combination Trial) Study.
A Phase III Randomized Study of Bbi608 and Best Supportive Care versus Placebo and Best Supportive Care in Patients With Pretreated Advanced Colorectal Carcinoma.

A placebo controlled clinical, multicentre, randomised, double blind trial to evaluate the safety and effectiveness of IK-5001 for the prevention of remodelling of the ventricle and congestive heart failure after acute myocardial infarction (Preservation 1 Trial).
A prospective, double-blind, randomised, placebo controlled clinical trial of intracoronary infusion of immuno-selected, bone marrow derived Stro 3 mesenchymal precursor cells (MPC) in the treatment of patients with ST elevation myocardial infarction.
A randomised, blinded, Placebo-controlled, dose finding study to assess safety and efficacy of the oral thrombopoietin receptor agonist, eltrombopag, administered to subjects with acute myelogenous (AML) receiving inductive chemotherapy.
A randomised, controlled, double-blind phase III trial to compare the efficacy, safety and pharmacokinetics of GP2013 plus Cyclophosphamide, Vincristine, Prednisone vs. MabThera® plus Cyclophosphamide, Vincristine, Prednisone, followed by GP2013 or MabThera® maintenance therapy in patients with previously untreated, advanced stage follicular lymphoma.
A randomized, double blind, placebo-controlled, multicenter phase III study of regorafenib in patients with hepatocellular carcinoma (HCC) after sorafenib.
A Randomized, Double-blind, Multi-center Phase 2 Trial of Denosumab in Combination With Chemotherapy as First-line Treatment of Metastatic Non-small Cell Lung Cancer.
A Randomized, Double-blind, Placebo-controlled Phase 3 Study of the Bruton's Tyrosine Kinase (BTK) Inhibitor, PCI-32765 (Ibrutinib), in Combination with Bendamustine and Rituximab (BR) in Subjects With Newly Diagnosed Mantle Cell Lymphoma.
A Randomized, Multicenter, Open-label, Phase 3 Study of the Bruton's Tyrosine Kinase Inhibitor PCI-32765 versus Chlorambucil in Patients 65 Years or Older with Treatment-naive Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma.
A Randomized, Multi-Center, Placebo-Controlled, Parallel Group Study to Determine the Effects of AMG 145 Treatment on Atherosclerotic Disease Burden As Measured By Intravascular Ultrasound in Subjects Undergoing Coronary Catheterization.
A Randomized, Multicentre, Open-Label, Phase III Trial comparing Trastuzumab Plus Pertuzumab Plus A Taxane Following Anthracyclines Versus Trastuzumab Emtansine Plus Pertuzumab Following Anthracyclines As Adjuvant Therapy In Patients With Operable Her2-Positive Primary Breast Cancer.
A Randomized, Open-label, Phase 3 Trial of A+AVD Versus ABVD as Frontline Therapy in Patients With Advanced Classical Hodgkin Lymphoma.
A study to evaluate the DC Devices, Inc. IASD System II to REDUCE Elevated Left Atrial Pressure in Patients with Heart Failure.
ABSORB Clinical Investigation: A Clinical Evaluation of the BVS Everolimus Eluting Coronary Stent System in the Treatment of Patients with de novo Native Coronary Artery Lesions.
An international phase III randomised trial of dose-fractionated chemotherapy compared to standard three-weekly chemotherapy, following immediate primary surgery or as part of delayed primary surgery, for women with newly diagnosed epithelial ovarian, fallopian tube or primary peritoneal cancer.
An Open-label Extension Study in Patients 65 Years or Older With Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL) Who Participated in Study PCYC-1115-CA (PCI-32765 Versus Chlorambucil).
An open-label, multicentRE, Phase IIIb study with INTRAVENOUS administration of PERTUZUMAB, subcutaneous trastuzumab, AND A TAXANE in patients with HER2-positive metastatic breast cancer (SAPPHIRE).
Apposition Assessed Using Optical Coherence Tomography of Chromium Stents Eluting Everolimus from Cobalt versus Platinum Alloy Platforms.
Assessment of radiation dose reduction and image quality of single acquisition, two contrast-injection computed tomography chest/abdomen/pelvis scans compared to the two phase imaging protocol for disease staging of oncology patients.
Assessment of the movement of the acromioclavicular (AC) joint by the 4D CT scanner when

stressed and forced to sublux by tension being placed on a tight glenohumeral posterior capsule.
Continued efficacy and safety monitoring of solanezumab, an antiamyloid ß antibody in patients with Alzheimer's disease.
Effect of Passive Immunization on the Progression of Mild Alzheimer's Disease: Solanezumab (LY2062430) Versus Placebo.
Effects of ivabradine on plaque burden, morphology and composition in patients with clinically indicated coronary angiography. A randomised double-blind, placebo controlled international multicentre study. (MODIFY).
EVOLVE II QCA: A Prospective Multicenter Trial to Assess the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY™ Stent System) for the Treatment of Artherosclerotic Lesion(s).
International Study of Comparative Health Effectiveness with Medical and Invasive Approaches.
Mechanisms and consequences of renal denervation in chronic kidney disease.
NeoPHOEBE: Pi3k inhibition in Her2 OverExpressing Breast cancer: A phase II, randomized, parallel cohort, two stage, double blind, placebo controlled study of neoadjuvant trustuzumab + BKM120 in combination with weekly pacltaxel in HER2 positive, PiK3CA wild type and PiK3CA mutant primary breast.
Phase 1 Study of NY-ESO-1 vaccine in Combination with Ipilimumab in Patients with Unresecable or Metastatic Melanoma, for whom Treatment with Ipilimumab is Indicated.
Phase 3 Accelerated BEP Trial: A randomised phase 3 trial of accelerated versus standard BEP chemotherapy for patients with intermediate and poor-risk metastatic germ cell tumours.
Phase I study of vinorelbine, cyclophosphamide and Rapamycin for recurrent malignancies in children (Rap-CV).
Phase Ib/II multicenter study of Buparlisib plus Carboplatin or Iomustine in patients with recurrent Glioblastoma Multiforme (GBM).
Pilot study to assess Glenoid custom instrumentation in patients undergoing shoulder arthroplasty.
Renal denervation to improve outcomes in patients with end-stage renal disease.
VERITAS: An Evaluation of the Veniti Vidi Retrievable Inferior vena cava filter system in patients at risk for pulmonary embolism.

APPENDIX 3 SUMMARY FIGURES FOR RADIATION INCIDENTS FROM 1 JULY 2013 TO 30 JUNE 2014

TYPE OF INCIDENT	NUMBER OF INCIDENTS IN 2013-2014
Contamination (nuclear medicine)	4
Nuclear medicine - extravasation/spillage	8
Damaged or malfunctioning source	1
Nuclear medicine - unlabelled pharmaceutical	6
CT or X-ray procedure - wrong body part	7
Unnecessary nuclear medicine procedure	1
Wrong, unnecessary or repeat CT or X-ray procedure	57
Diagnostic procedure on pregnant patient	16
Fluoroscopy - high skin dose	8
Nuclear medicine - incorrect radiopharmaceutical or activity (Bq)	6
Therapeutic procedure - wrong tissue	2
Nuclear medicine scan failed due to patient problems	3
Radioactive contaminant attached to an industrial radiography source	1
Member of the public finding radioactive or potentially radioactive material	2
Activation of radiation monitor alarm at entrance of waste disposal facility	26
Activation of radiation monitor alarm at entrance of scrap metal recycling facility	2
Inappropriate disposal of a radiation gauge containing a radioactive source	1
Nuclear density/moisture gauge run over by a road construction vehicle	1