2012/2013

The Annual Report of Radiation Advisory Committee Victoria

for the financial year ending June 2013

THE ANNUAL REPORT OF

THE RADIATION ADVISORY COMMITTEE

FOR THE FINANCIAL YEAR ENDING JUNE 2013

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 2013 annual report of the committee for presentation to Parliament.

Yours faithfully

Dr David Bernshaw
Chair
RADIATION ADVISORY COMMITTEE

CONTENTS

RADIATION ADVISORY COMMITTEE

The Radiation Advisory 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 Radiation Advisory Committee met on 10 occasions from July 2012 to June 2013.

The members of the committee for the period from July 2012 to June 2013 were:

Dr. David Bernshaw (Chair) Consultant Radiation Oncologist Peter MacCallum Cancer Centre **Meetings attended: 9**	**Professor Robert Gibson** Deputy Head, Department of Radiology University of Melbourne **Meetings attended: 5**
Dr. Ken Joyner Director Joyner and Associates Telecommunications Consultancy **Meetings attended: 8**	**Dr. Roslyn Drummond** Radiation Oncologist Peter MacCallum Cancer Centre **Meetings attended: 8**
Mr Russell Booth Chief Nuclear Medicine Technologist Medical Imaging Department St Vincent's Hospital **Meetings attended: 9**	**Dr Graeme O'Keefe** Principal Scientist Austin Health **Meetings attended: 6**
Mr Christopher Perry Deputy Chief Radiographer Department of Radiology The Royal Melbourne Hospital **Meetings attended: 9**	**Dr Russell Horney** Physicist Department of Medical Imaging and Radiation Sciences Monash University **Meetings attended: 8**
Mr Paul Marks Senior Medial Radiation Scientist Australian Radiation Protection and Nuclear Safety Agency **Meetings attended: 8**	**Dr Joanna Wriedt** Physiologist/Epidemiologist, Lawyer **Meetings attended: 6**

Dr Dean Morris Head of Operations Australian Synchrotron **Meetings attended: 7**	**Dr Ray Budd** Consultant medical physicist **Meetings attended: 8**
Mr Paul Tomlinson Senior Technician ALS Industrial **Meetings attended: 7**	

(ii) Responsibilities

The Radiation Advisory Committee (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 Julian Marwick and Mr Morrie Facci, for their continuing assistance and support.

2. IONISING RADIATION

2.1 Research Projects Involving the Exposure of Humans to Ionising Radiation

The committee evaluated 20 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. Approval of other research projects involving radiation exposures of human volunteers was the responsibility of institutional human research ethics committees. A list of the research projects considered by the Radiation Advisory 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 Radiation Incidents

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

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.

The committee 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.

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 medical incidents should not be mandatory.

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 medical radiation incidents from July 2012 to June 2013 are provided in Appendix 3.

2.3 Licensing of Medical Specialists Using Fluoroscopy Apparatus

The committee discussed the licensing of medical specialists using fluoroscopy apparatus. The committee considered that medical specialists should not be solely relied on to perform fluoroscopy safely, especially during complex interventional procedures. Whilst there was agreement that radiographers should have a role, it did not consider that placing a condition on the use licence of a medical specialist to have a radiographer supervising fluoroscopy procedures would be feasible due to the difficulty enforcing the licence condition. Additional conditions placed on the management licence holders in possession of fluoroscopy apparatus appeared to be the best alternative.

The committee noted that there had been a suggestion to incorporate a requirement for such a team-based approach to fluoroscopy procedures into the radiation management plan of management licence holders. However the committee questioned whether it would be possible for the department to enforce such a measure. There was a potential difficulty relating to independent specialists who use fluoroscopy apparatus but who are not employed by the management licence holder that is authorised to possess the apparatus. It was agreed that in such circumstances, the specialist would need to agree to comply with any requirements placed on them by the management licence holder prior to being allowed to use the apparatus.

To strengthen the requirements it was suggested that conditions specifying requirements for supervision of fluoroscopy procedures by a radiographer be placed on both the use licence of the medical specialist and the management licence of the institution. By placing this specific condition on licences, the requirement for a team-based approach would be made more apparent to all stakeholders, helping to ensure that they clearly understood the requirements. The department has consulted with affected licence holders regarding the application of this new proposal.

2.4 Publication of Australian Diagnostic Reference Levels

The committee noted that ARPANSA had published results of its survey of Australian diagnostic reference levels (DRLs). The survey gathered individual practice data, which was collated and used to establish these national DRLs for common diagnostic imaging procedures.

The objective of developing DRLs is to establish a measure of indicative doses for current diagnostic imaging practice in Australia, allowing individual practices to compare their doses against those of their peers.

The survey collected data on multi detector computed tomography (MDCT) doses only, for various procedures and age groups. ARPANSA intends in the future to gather and publish data on other medical radiation imaging modalities such as interventional/fluoroscopic and general examinations, mammography and nuclear medicine.

The DRLs for MDCT procedures can be found at:
http://www.arpansa.gov.au/services/ndrl/current.cfm

2.5 Code of Practice for the Security of Radioactive Sources

The committee was advised that the department intended to take the necessary measures to implement the ARPANSA Code of Practice *Security of Radioactive Sources*, particularly the requirement for the accreditation of assessors of source security plans and source transport security plans.

2.6 Requirements for reporting of radiotherapy incidents

A Principal Specialist at a Melbourne radiotherapy centre sought clarification on incident reporting requirements for radiation therapy treatments.

The specialist was concerned that the current reporting requirements, set out in the department's publication *Mandatory reporting of radiation incidents – management licence holder's responsibilities*, required reporting of variations in treatment doses that were commonly encountered during low dose-rate brachytherapy and total body irradiation treatments. The requirements specified that a dose delivered to tissue which differs from the total prescribed treatment dose by greater than 10% was reportable. The view of the specialist was that the possibility of such variations was known and accepted by radiation oncologists prior to commencement of treatment.

The committee's view was that the intention of the mandatory reporting requirements was to capture anomalous or accidental misadministration of radiation, rather than variations which had been anticipated and accepted prior to treatment.

The department subsequently revised the incident reporting requirements to clarify the reporting of such incidents.

2.7 Industrial Action by Medical Physicists

The committee was advised that Victorian medical physicists were taking industrial action over pay levels and working conditions. The industrial action involved the suspension of commissioning of new radiotherapy equipment and software.

The action had been motivated by difficulties in recruiting medical physicists in Victoria, and differences in pay levels compared with other states. The physicists claimed that the lack of available medical physics expertise in Victoria would lead to an increased risk of radiation incidents occurring.

The committee agreed that it had no role in the industrial matter but considered it was necessary to monitor any impact the situation may have on radiation safety at radiotherapy centres. It was agreed that the expertise provided by medical physicists was critical to the safe operation of radiotherapy facilities.

2.8 Regulatory requirements for cyclotron facilities

The committee was presented with a draft document which had been developed by the department to be applied as a condition of licence for cyclotron facilities. The committee was advised that current conditions for such facilities did not provide details sufficient to cover the complexities of cyclotron facilities.

The committee reviewed the draft document and suggested that there should be a requirement for a decommissioning plan which sets out the arrangements for management of radioactive waste at the time of decommissioning.

The department intends to undertake consultation with all cyclotron facilities in Victoria prior to making the document a mandatory requirement.

2.9 Australian Clinical Dosimetry Service (ACDS)

The new Australian Clinical Dosimetry Service (ACDS) set up by ARPANSA will provide medical physicists and radiation therapists at radiotherapy centres with a source of independent checks for equipment and patient doses. Although such checks are already being performed in-house, the new service will make them readily available and enable a national approach to ensure the quality of all radiotherapy treatments. The ACDS will work with the radiotherapy facilities to prioritise the types of treatments most in need of independent checks, and to carry these out when required.

The simplest of the measurements provided by the service is an output check. This confirms that the linear accelerator is delivering the dose that the control system has been programmed to deliver. More complicated checks include measuring the beam profile and the energy of the radiation. The most important and complicated check, however, involves using a phantom. This phantom is treated in exactly the same way as a real patient. It is imaged, the radiation dose is prescribed, and a computer-generated treatment plan is developed. The phantom is then placed on a treatment table and treated. Inside the phantom, radiation detectors are used to determine where the radiation was delivered and the dose. In this way, the entire treatment process can be checked.

Dr Ivan Williams, Director ACDS, presented the results of the pilot program for the survey of basic output checks for Australian radiotherapy centres. Overall the doses were reasonably accurate with little scatter about the mean. Dr Williams stated that the three year term of the ACDS pilot survey would end on 31 December 2013. If it is determined at that time that the ACDS become an ongoing service, the committee considered that it would assist medical centres using radiotherapy to comply with the Victorian requirement to implement a quality assurance program.

2.10 Inspection by the Department of Medical Practices Using CT Scanners

The committee was advised of the results of inspections by the department of compliance of medical diagnostic radiology practices employing computed tomography (CT).

The inspections showed that there was a general lack of awareness regarding the requirements of the Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation published by ARPANSA. Justification of procedures was generally poorly documented. Although radiologists at some practices insisted that all referrals for CT procedures were approved by a radiologist before going ahead, radiographers at the same practices said that this was not the case. There appeared to be the general attitude that a procedure requested by a general practitioner was justified. Optimisation of radiation doses was carried out to varying degrees at different practices. Large hospitals that employed medical physicists carried out optimisation better than smaller practices with no medical physicist.

The program of inspections carried out by the department has been instrumental in improving the compliance of medical practices with the requirements of the code of practice, in particular the justification and optimisation requirements.

2.11 Presentation on Radiation Protection in Medical Imaging

Mr Anthony Wallace, Manager, Diagnostic Imaging and Nuclear Medicine Section, Medical Radiation Services Branch of ARPANSA, gave a presentation to the committee on radiation protection in the area of diagnostic medical imaging. Mr Wallace pointed out that there was a lack of education on radiation protection of the patient provided to medical professionals. He also pointed out that a lack of medical physicists in Australia meant that adequate radiation protection expertise was not available to all practices.

In particular Mr Wallace stressed the importance of medical physicists in the optimisation of radiation dose. He believed that the justification of medical procedures also need to be improved. In practice a medical imaging request is often treated as an order form by the practice, with the requested imaging procedure not undergoing a proper justification process.

2.12 Presentation on Mineral Sands

Dr Brad Cassels, Expert Advisor, Radiation Team, briefed the committee on the background to mineral sand mining in Australia, its relevance to the Victorian economy and the radiation aspects of the practice of such mining and the small but manageable radiation challenges it presents.

2.13 Human Radiosensitivity – Report of the Independent Advisory Group on Ionising Radiation

The committee reviewed the report Human Radiosensitivity (RCE-21) published in March 2013 by the Independent Advisory Group on Ionising Radiation, which reports to the UK Health Protection Agency.

The report concludes that the weight of evidence clearly shows that people differ in the way that they respond to ionising radiation exposure and that these differences can be seen to affect both the risk of radiation-induced cancer and (at higher doses) the extent of tissue damage. The evidence comes from human epidemiology and is backed up by cellular studies and animal studies. Both

genetic and environmental (including lifestyle) factors are involved and currently the clearest example is the effect of cigarette smoking on radiation-induced lung cancer. Considering the uncertainties on risk estimates below 100 mSv (the approximate limit of direct epidemiological evidence), it is hard to justify consideration of individual variation when setting limits for radiation exposure.

2.14 Australian Paper on Childhood and Adolescent Cancer Risk Related to Computed Tomography (CT) Scans

John D Mathews et al published a paper on childhood and adolescent cancer risk related to computed tomography (CT) scans on 22 May 2013. This paper is available at http://www.bmj.com/highwire/filestream/646273/field_highwire_article_pdf/0/bmj.f2360.full.pdf. The study identified 10.9 million individuals aged 0-19 years on 1 January 1985 or born between 1 January 1985 and 31 December 2005 from Australian Medicare records. All exposures to CT scans funded by Medicare during 1985-2005 were identified for this cohort. Cancers diagnosed in cohort members up to 31 December 2007 were obtained through linkage to national cancer records.

The number of cancers recorded was 60,674, including 3,150 in 680,211 people exposed to a CT scan at least one year before any cancer diagnosis. The mean duration of follow-up after exposure was 9.5 years. Overall cancer incidence was 24% greater for exposed than for unexposed people, after accounting for age, sex, and year of birth (incidence rate ratio (IRR) 1.24 (95% confidence interval (CI) 1.20 to 1.29); $P<0.001$). The authors also observed a dose-response relation with the IRR increasing by 0.16 (95% CI 0.13 to 0.19) for each additional CT scan. The IRR was also greater after exposure at younger ages. There was an excess of 608 cancers in people exposed to CT scans (147 brain, 356 other solid, 48 leukaemia or myelodysplasia, and 57 other lymphoid). The absolute excess incidence rate for all cancers combined was 9.38 per 100,000 person years at risk. The average effective radiation dose per scan was estimated as 4.5 mSv.

The authors conclude that medical practitioners will increasingly need to weigh the undoubted benefits of CT scans in clinical practice against the potential risks in order to justify each decision to carry out a CT scan. Fortunately, many radiologists are now aware of the risks, and technological advances have already allowed CT scan doses to be reduced below those used in earlier decades. Nevertheless, decision tools to assess the need for CT objectively are still not used routinely. For example, minor head trauma or suspected appendicitis are often managed using CT, rather than by observation, ultrasound, or magnetic resonance imaging. Imaging for head trauma still accounts for most CT scans in children.

2.15 Future Directions for the Radiation Advisory Committee

The committee reflected on its functions and considered that, in future, it would shift its emphasis to provide advice of a more strategic nature in relation to matters presented to it for consideration by the department.

3. NON-IONISING RADIATION

3.1 Health Effects from Radiofrequency Electromagnetic Fields – Report of the Independent Advisory Group on Non-Ionising Radiation

The Advisory Group on Non-Ionising Radiation, which reports to the UK Health Protection Agency, published the report *Health Effects from Radiofrequency Electromagnetic Fields* in April 2012.

The report concludes that, while there are still limitations to that published research that preclude a definitive judgement, the evidence considered overall has not demonstrated any adverse health effects of radiofrequency (RF) field exposure levels below internationally accepted guideline levels. There are possible effects on electroencephalogram (EEG) patterns, but these have not been conclusively established, and it is unclear whether such effects would have any health consequences. There is increasing evidence that RF field exposure below guideline levels does not cause symptoms and cannot be detected by people, even by those who consider themselves sensitive to RF fields. The accumulating evidence on cancer risk, notably in relation to mobile phone use, is not definitive, but overall is in the direction of no material effect of exposure. There are few data, however, on risks beyond 15 years from first exposure.

3.2 Ban on Commercial Tanning Units in Victoria

The committee noted that the Victorian government announced that it intended to introduce legislation to ban commercial tanning units, effective from 31 December 2014. The committee will continue to monitor this issue.

3.3 Journal Articles Reviewed by the Committee

AW Wood. *How dangerous are mobile phones, transmission masts and electricity pylons?*. Arch Dis Dhild 2006; **91**: 361 – 366). In this review Wood states that, of the various sources of electromagnetic fields (EMF), the association between elevated power-frequency magnetic fields and childhood leukaemia is the only identified hazard. Causality has not been established for this association, but if it were, estimates put the percentage of childhood leukaemia cases attributable to power-frequency magnetic fields at around 1%. The lack of consistent evidence from long term animal experiments and of a credible mechanism of interaction between low level magnetic fields and cellular regulatory processes are two strong lines of evidence against causation. Some precautions with respect to the forms of EMF emissions may be warranted, but given the enormous societal benefits of electric power and efficient communication, any such precautionary measures should take these benefits into account and also be commensurate with informed estimates of the magnitude of putative risk.

De-Kun Li, Jeannette R. Ferber, Roxana Odouli and Charles P. Quesenberry Jr. A Prospective Study of In-utero Exposure to Magnetic Fields and the Risk of Childhood Obesity. Scientific Reports 27 July 2012; **2**: Article number 540. The authors conducted a prospective study to examine whether *in-utero* exposure to magnetic fields (MFs) increases the risk of childhood obesity. Participating women carried a meter measuring MF levels during pregnancy and 733 of their children were followed up to 13 years to collect clinically recorded information on growth patterns with 33 weight measurements per child on average. Prenatal exposure to high MF level was associated with increased risk of being obese in offspring than those with lower MF level (odds ratio = 1.69, 95% confidence interval: 1.01–2.84). The association existed only for

persistent obesity, but not for transitory (unlikely) obesity. The study, however, neglected to address numerous possible confounding factors an so it is difficult reach any conclusion from the study.

3.4 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 to suggest that exposure to radiofrequency radiation can increase the risk of chronic health effects such as cancer. However, the committee acknowledges the current public concerns over mobile phones and their base stations and will continue to review the relevant research literature.

3.5 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 additional evidence reviewed by the committee during the year has not altered its position.

APPENDIX 1 TERMS OF REFERENCE OF THE RADIATION ADVISORY COMMITTEE

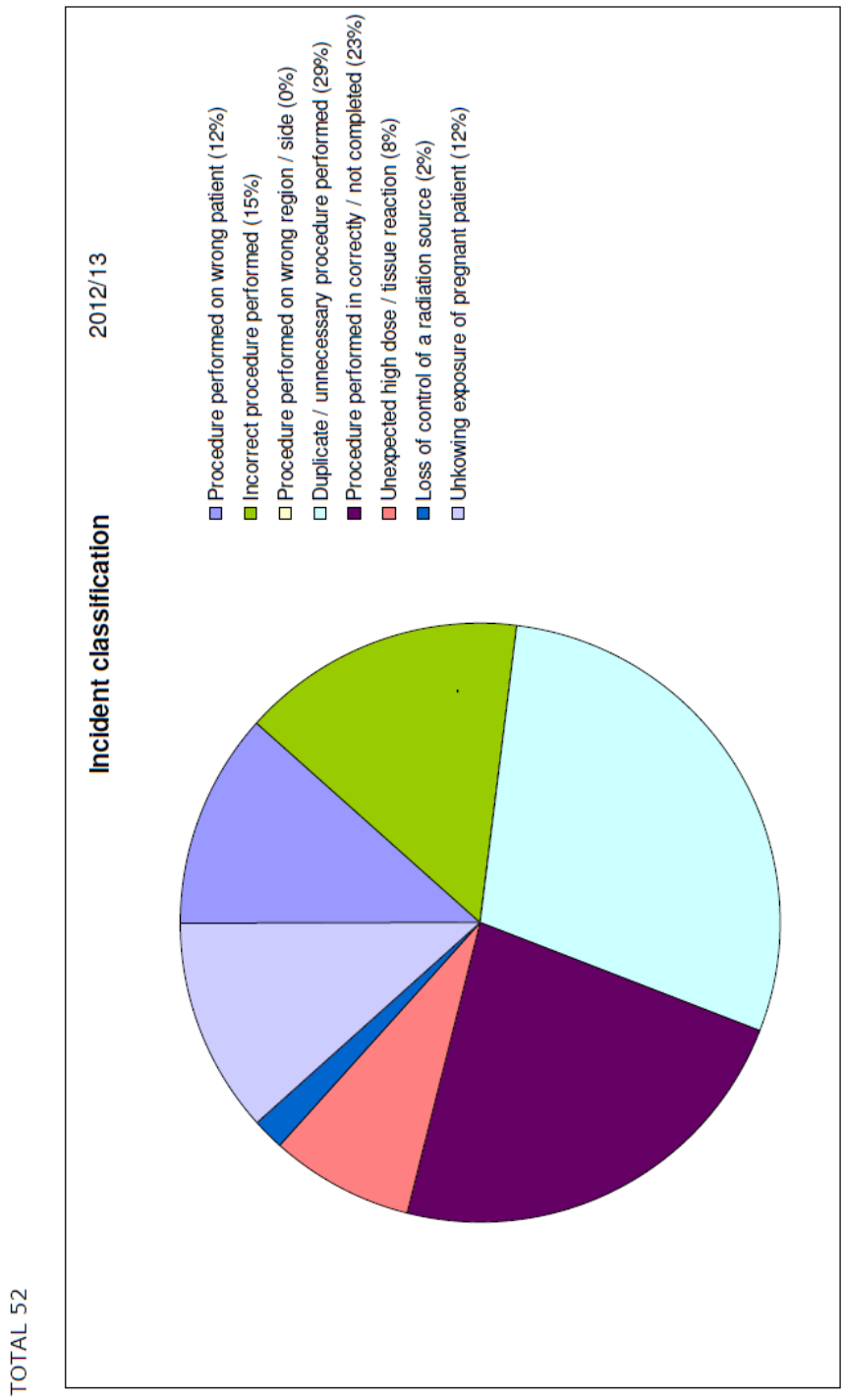
1. The Radiation Advisory Committee (RAC) is established under the Radiation Act 2005 and provides advice to the Minister for Health or the Secretary on protecting the health and safety of persons and the environment from the harmful effects of radiation, with a view to adopting best practice for radiation 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.

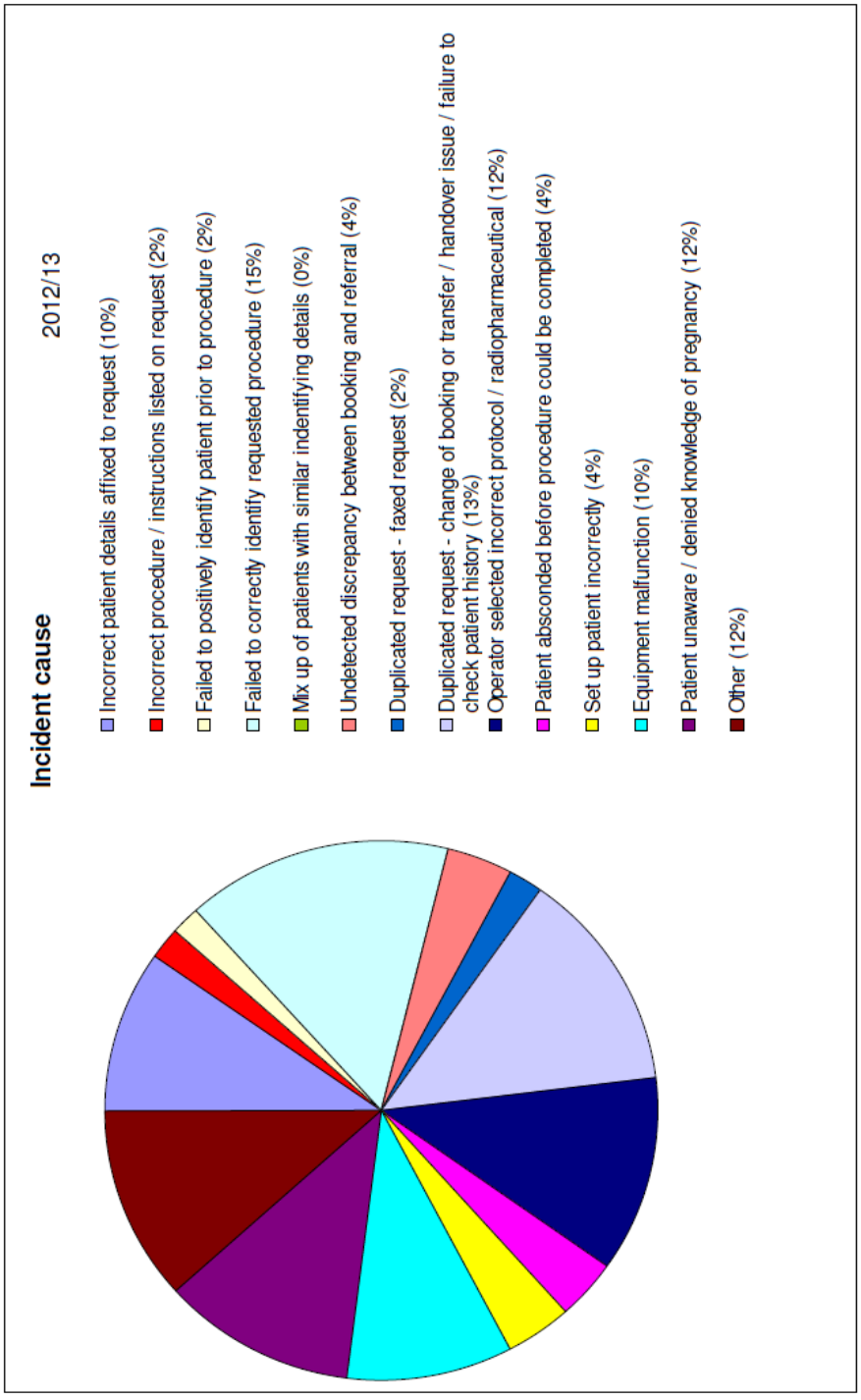
APPENDIX 2 RESEARCH PROJECTS CONSIDERED BY THE COMMITTEE

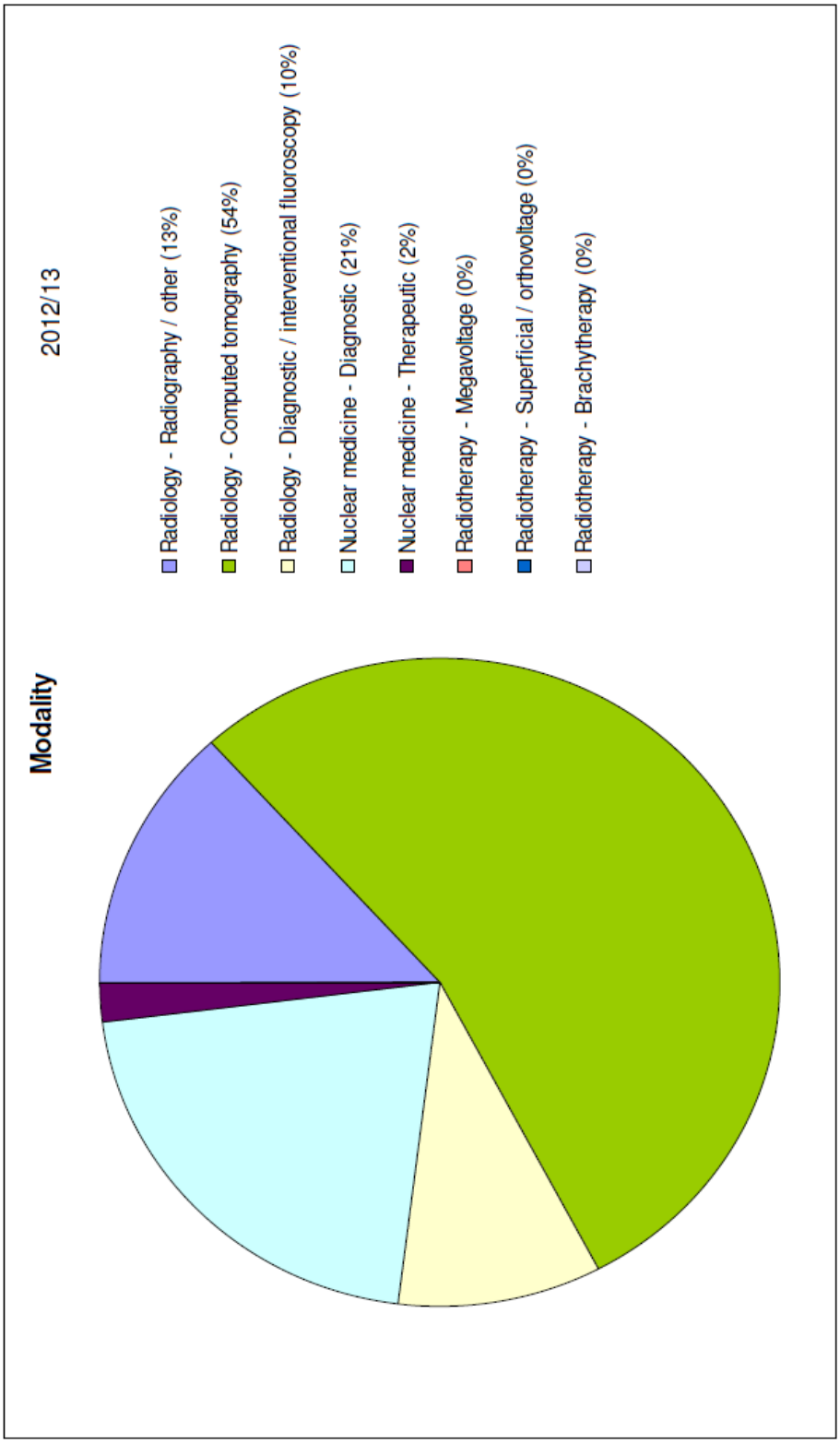
TITLE OF RESEARCH PROJECT
Identification and characterisation of risk factors for atrial arrhythmias in chronic kidney disease (CKD) patients
REPRISE II: REpositionable Percutaneous Replacement of Stenotic Aortic Valve through Implantation of Lotus™ Valve System – Evaluation of Safety and Performance
A Phase 1b Study Evaluating the Safety and Tolerability of ABT-199 in Combination with Rituximab in Subjects with Relapsed Chronic Lymphocytic Leukemia
Early Assessment of Response to Chemotherapy / Targeted Therapy in Metastatic Breast Cancer Using Sequential 18F-FDG PET
A randomized, double-blind, multicenter study of Denosumab compared with Zoledronic Acid (Zometa) in the treatment of bone disease in subjects with newly diagnosed Multiple Myeloma
A Phase 3, Randomized, Double-Blind, Multicentre Study Comparing Oral MLN9708 plus Lenalidomide and Dexamethasone versus Placebo plus Lenalidomide and Dexamethasone in Adult Patients with Relapsed and/or Refractory Multiple Myeloma
TElmisartan in the management of abDominal aortic aneurYsm (TEDY)
A Randomised Phase II Double-Blind Placebo-Controlled Study of regorafenib in Refractory Advanced Oesophago-Gastric Cancer (AOGC)
Evaluation of the DC Devices IASD System in the Treatment of Patients with Heart Failure with Preserved Ejection Fraction
A Phase 3, open-label, multicentre, 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 RCHOP-like therapy
A Double-Blind, Randomised, Placebo Controlled, Dose Ranging Study to Evaluate the Efficacy and Safety of PF04236921 in Subjects with Crohn's Disease who are ANTITNF Inadequate Responders
A 64-Wk Ph 3 Randomized Double-Blind Placebo-Controlled Parallel Design Study to Evaluate Efficacy &Safety/Tolerability of Subcutaneous SCH 900222/MK-3222, Followed by an Optional Long-Term Safety Extension Sub-Study with Moderate-to-Severe Chronic Plaque Psoriasis.
A Multicentre, Non-Randomised Controlled Study of the Safety, Performance, Quality of Life and Cost Effectiveness Outcomes of the Edwards SAPIEN XT™ Transcatheter Heart Valve in an Australian Population

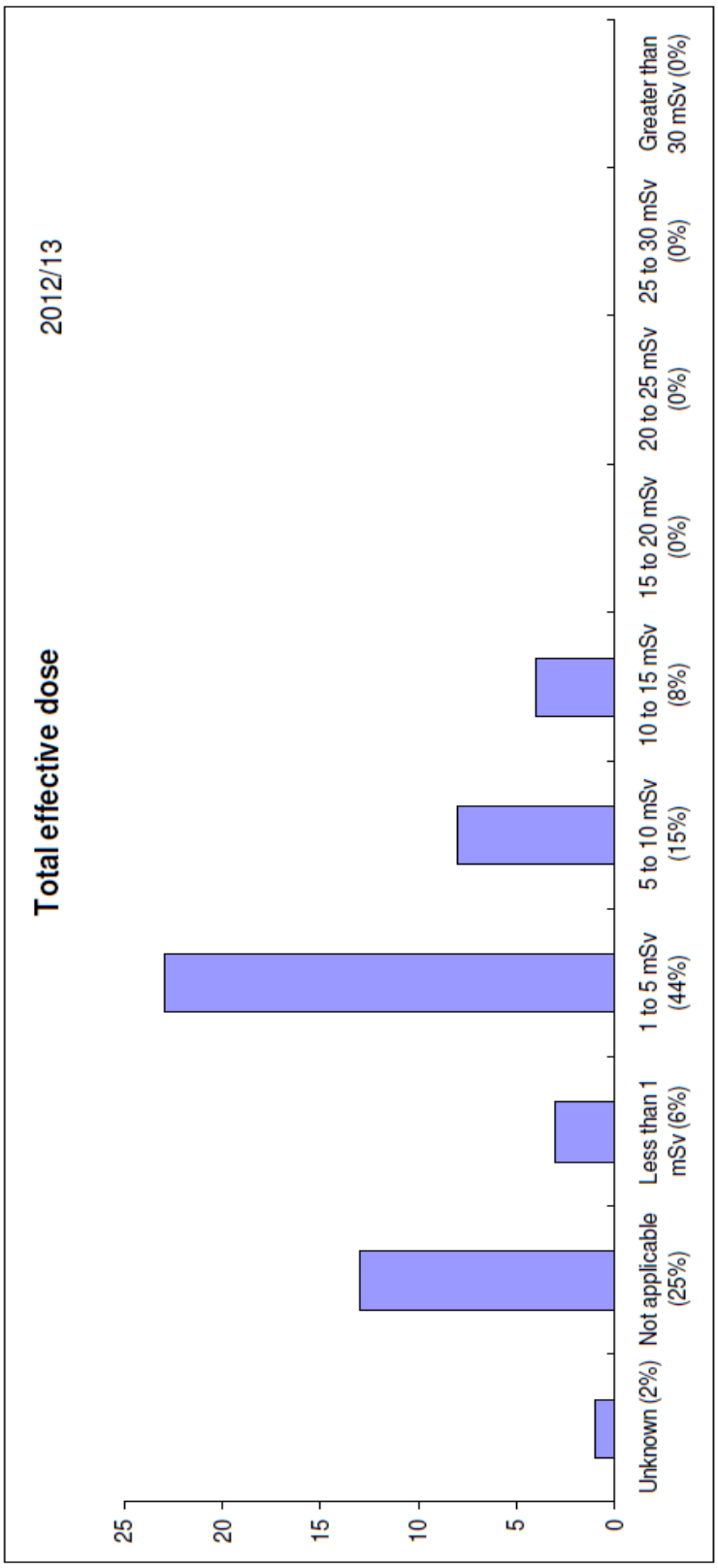
A Phase 3, Double-Blind, Placebo-controlled Study of Vemurafenib Versus Vemurafenib Plus GDC-0973 in Previously untreated BRAFV600 Mutation-Positive Patients with Unresectable Locally Advanced or Metastatic Melanoma
Double-Blind, Randomised, Placebo Controlled, Dose Ranging Study to Evaluate the Efficacy and Safety of PF04236921 in Subjects with Crohn's Disease who are ANTITNF Inadequate Responders
A Randomized, Open-label, Phase 3 Trial of A+AVD Versus ABVD as Frontline Therapy in Patients With Advanced Classical Hodgkin Lymphoma
'A randomized, multicenter, open-label, phase 3 study of the Bruton's Tyrosine Kinase Inhibitor PCI-32765 versus Chlorambucil in patients 65 years older with treatment-naïve Chronic Lymphocytic Leukemia or small Lymphocytic Lymphoma
'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)
A Randomized, Open-label, Phase 3 Trial of A+AVD Versus ABVD as Frontline Therapy in Patients With Advanced Classical Hodgkin Lymphoma
A three-arm, randomized, open label, phase II study of everolimus in combination with exemestane versus everolimus alone versus capecitabine in the treatment of postmenopausal women with estrogen receptor positive, locally advanced, recurrent, or metastatic breast cancer after recurrence or progression on prior letrozole or anastrozole - HREC/13/MH/39

APPENDIX 3 SUMMARY FIGURES FOR MEDICAL RADIATION INCIDENTS FROM JULY 2012 TO JUNE 2013




Incident cause
2012/13
Incorrect patient details affixed to request (10%)
Incorrect procedure / instructions listed on request (2%)
Failed to positively identify patient prior to procedure (2%)
Failed to correctly identify requested procedure (15%)
Mix up of patients with similar indentifying details (0%)
Undetected discrepancy between booking and referral (4%)
Duplicated request - faxed request (2%)
Duplicated request - change of booking or transfer / handover issue / failure to check patient history (13%)
Operator selected incorrect protocol / radiopharmaceutical (12%)
Patient absconded before procedure could be completed (4%)
Set up patient incorrectly (4%)
Equipment malfunction (10%)
Patient unaware / denied knowledge of pregnancy (12%)
Other (12%)


2012/13
Modality
Radiology - Radiography / other (13%)
Radiology - Computed tomography (54%)
Radiology - Diagnostic / interventional fluoroscopy (10%)
Nuclear medicine - Diagnostic (21%)
Nuclear medicine - Therapeutic (2%)
Radiotherapy - Megavoltage (0%)
Radiotherapy - Superficial / orthovoltage (0%)
Radiotherapy - Brachytherapy (0%)


Total effective dose
2012/13
25
20
15
10
5
0
Unknown (2%)
Not applicable (25%)
Less than 1 mSv (6%)
1 to 5 mSv (44%)
5 to 10 mSv (15%)
10 to 15 mSv (8%)
15 to 20 mSv (0%)
20 to 25 mSv (0%)
25 to 30 mSv (0%)
Greater than 30 mSv (0%)