2011/12

The Annual Report of the Radiation Advisory Committee Victoria

for the financial year ending June 2012

THE ANNUAL REPORT OF

THE RADIATION ADVISORY COMMITTEE

FOR THE FINANCIAL YEAR ENDING JUNE 2012

RADIATION ADVISORY COMMITTEE
Melbourne, Australia

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The Hon. David Davis MLC
Minister for Health

Dear Minister

Pursuant to s. 110 of the *Radiation Act 2005*, the Radiation Advisory Committee submits the 2012 annual report of the committee for presentation to parliament.

Yours faithfully

Dr David Bernshaw
Chairperson
RADIATION ADVISORY COMMITTEE

CONTENTS

RADIATION ADVISORY COMMITTEE

The Radiation Advisory Committee is established under Part 10 of Victoria's *Radiation Act 2005*. The previous term of the committee expired on 16 August 2011. Dr John Heggie and Mr Peter Burns did not apply for reappointment. The committee wishes to thank Dr Heggie and Mr Burns for the invaluable service that they have given over many years.

The term of appointment for the new committee is the period from 17 August 2011 to 16 August 2014. The Minister for Health reappointed Dr David Bernshaw, Dr Ken Joyner, Dr Roslyn Drummond, Professor Robert Gibson, Dr Graeme O'Keefe, Mr Russell Booth and Dr Russell Horney. The Minister appointed Mr Christopher Perry, Mr Paul Marks, Dr Joanna Wriedt, Dr Dean Morris, Dr Ray Budd and Mr Paul Tomlinson as new members. The committee met on 11 occasions from July 2011 to June 2012.

(i) Composition

The members of the committee for the period from July 2011 to June 2012 were as follows.

Dr John Heggie **(Chairperson to August 2011)** Consultant Medical Physicist **Meetings attended: 1**	**Dr David Bernshaw** **(Chairperson from September 2011)** Consultant Radiation Oncologist Peter MacCallum Cancer Centre **Meetings attended: 11**
Dr Ken Joyner Director Joyner and Associates Telecommunications consultancy **Meetings attended: 11**	**Mr Peter Burns** **(to August 2012)** Health Physicist **Meetings attended: 2**
Professor Robert Gibson Deputy Head, Department of Radiology The University of Melbourne **Meetings attended: 6**	**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 **(from September 2012)** Deputy Chief Radiographer Department of Radiology The Royal Melbourne Hospital **Meetings attended: 7**	**Dr Russell Horney** Physicist Department of Medical Imaging and Radiation Sciences Monash University **Meetings attended: 7**
Mr Paul Marks **(from September 2012)** Senior Medial Radiation Scientist Australian Radiation Protection and Nuclear Safety Agency **Meetings attended: 8**	**Dr Joanna Wriedt** **(from September 2012)** Physiologist, Epidemiologist, Lawyer **Meetings attended: 9**
Dr Dean Morris **(from September 2012)** Head of Operations Australian Synchrotron **Meetings attended: 9**	**Dr Ray Budd (from September 2012)** Consultant Medical Physicist **Meetings attended: 9**
Mr Paul Tomlinson **(from September 2012)** 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 referred to it by the Minister or the Secretary, including the following:

(a) the promotion of radiation safety procedures and practices

(b) the criteria for licensing persons to use radiation sources and the qualifications, training or experience required for licensing

(c) which radiation sources should be prescribed as prescribed radiation sources

(d) 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 the activities it undertook during a financial year no later than 1 November following that year.

1. INTRODUCTION

Throughout the year the committee considered a number of issues, including:

- the regulatory requirements for various radiation practices
- radiation incidents
- non-ionising radiation matters
- research projects involving the irradiation of human volunteers
- the implementation of the *Code of Practice for the Security of Radioactive Sources* (2007).

The committee adopted formal terms of reference during the year. The terms of reference are provided in Appendix 1.

The committee would like to thank the department's Radiation Team, 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 14 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 (HREC). A list of the research projects considered by the committee is provided in Appendix 2.

2.2 Radiation incidents

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

Of the reports of unintentional or unnecessary exposures to medical patients:

- fourteen involved an unintended computed tomography scan being performed on a patient
- seven involved the maladministration of a radiopharmaceutical to a patient
- one involved the incorrect field size of a radiotherapy treatment field
- one involved incorrect targeting for a radiotherapy treatment
- one involved unintended diagnostic radiography being performed on a patient.

In addition to the incidents involving unintentional or unnecessary patient exposures the following incident was reported:

- spillage of technetium-99m in a nuclear medicine department.

The committee made recommendations to the department on actions that it considered appropriate. The actions varied depending upon 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; that is, 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.

Follow-up actions designed to prevent recurrences were monitored.

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 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 Radiation Regulations. It should be noted, however, that s. 22 of the Radiation Act 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.

2.3 Change to dose limit for the lens of the eye recommended by the International Commission on Radiation Protection

The committee noted that in April 2011 the International Commission on Radiation Protection (ICRP) lowered its occupational exposure dose equivalent limit for the lens of the eye to 20 millisieverts (mSv) averaged over five years, with the dose in any single year not to exceed 50 mSv. Previously the limit had been 150 mSv over 12 months. The ICRP revised its limit due to recent epidemiological evidence suggesting a lower threshold dose for tissue reaction effects for the lens of the eye.

2.4 Inspection protocol for computed tomography scanners

The committee reviewed a paper developed by the department's Radiation Team entitled *Compliance Inspections of Medical Practices Authorised to Possess Computed Tomography Apparatus*. The paper was intended to provide guidance to Radiation Team members when they carried out inspections of computed tomography apparatus.

2.5 Code of practice for industrial radiography

The committee was advised that the National Health and Medical Research Council's *Code of practice for the safe use of industrial radiography equipment (1989)*, which was still used as a condition of management and use licences, was 22 years old. The committee was invited to comment on the code or request that the code be revised. However, the committee considered that although there had been some changes in equipment used in the intervening period, overall the code was satisfactory.

2.6 Radiation shielding requirements

The committee reviewed a new document published by the department's Radiation Team that outlined the requirements for radiation shielding at licensed radiation practices.

The document had been distributed to licence holders to provide a clearer understanding of regulatory requirements relating to radiation shielding. Under the policy, requirements for assessment and installation of shielding vary depending upon the class of radiation source.

There is currently no process in place to verify that the designed shielding is actually installed at an installation prior to issuing a licence. The committee was advised that further work by the Radiation Team would be required to develop a rigorous regulatory approach to ensure adequate shielding is in place at radiation practices.

2.7 Inspections of superficial radiotherapy X-ray units

The committee was advised that the Radiation Team had initiated a program of inspections of superficial radiotherapy facilities in Victoria. The program was initiated in response to a practice found to be not complying with the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)*, compliance with which is a condition of licence.

The committee agreed that the inspection program was warranted and wished to receive further details of the noncompliant practice.

2.8 Application for approval of industrial radiography radiation safety course

The committee was advised that the department's Radiation Team had received a submission from an industrial radiography company requesting approval of an internal training program for industrial radiographers. The company was seeking to have the course approved as a prerequisite for applying to the department for a use licence authorising the use of industrial radiography apparatus.

The course material and examination provided was reviewed. It was agreed that there would need to be multiple versions of the examination, each with different questions. In addition, the regulatory aspects of industrial radiography needed to be included. It was recommended that a health physicist review the course material for technical accuracy.

2.9 Media coverage of nurses performing radiography at a regional hospital

The committee was advised about media coverage of the radiography service at a rural community hospital where nurses were licensed to take radiographs. It was noted that the department had commissioned two separate reviews of the quality of the radiographs taken by the nurses. The quality of images was found to be satisfactory.

2.10 Licensing of medical specialists to use fluoroscopy X-ray units

The Australian Institute of Radiography wrote to the committee expressing concerns over a change of licence conditions for medical specialists who use fluoroscopy equipment. The changes relate to the removal of conditions requiring the presence of a radiographer during high dose fluoroscopy procedures. The department's Radiation Team presented a discussion paper to the committee regarding policies for licensing medical specialists to use fluoroscopy apparatus.

It was noted that there had been a suggestion to incorporate a requirement for a team-based approach into the radiation management plan of management licence holders, rather than placing conditions on use licence holders that require the presence of a radiographer. However, the committee questioned whether it would be possible for the department to enforce such a measure. The committee was of the opinion that radiographers should be present during high dose fluoroscopy procedures and in control of the operating factors of the fluoroscopy apparatus, as well as monitoring exposure time and other factors during a procedure that may affect optimisation or patient safety.

There was a potential area of complexity 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 under such circumstances the specialist would need to agree to comply with any requirements placed upon them by the management licence holder prior to being allowed to use the apparatus.

To strengthen the requirements it was suggested that the requirement for supervision of fluoroscopy procedures by a radiographer be placed on both the use licence and the management licence. By making specific conditions of licence, the requirement for a team-based approach would be more visible to all stakeholders, helping to ensure that they clearly understood the requirements. The committee requested more information to be collected on this matter, including feedback from key stakeholders.

3. NON-IONISING RADIATION

3.1 International Commission on Non-Ionizing Radiation Protection on mobile phone use and the risk of brain cancers

The International Commission on Non-Ionizing Radiation Protection (ICNIRP) conducted a review (Environ Health Perspect 119(11): 1534–1538; 2011) of the studies that had examined whether there is a link between mobile phone use and the main types of brain cancer: glioma and meningioma.

The ICNIRP notes that, because of deficiencies in exposure measurement due to recall misclassification, and misidentification of users in records-based studies, it is doubtful that the studies could have reliably detected a small effect, if one existed. The data available were mainly for up to 10 years of exposure and to a lesser extent for a few years beyond this.

The ICNIRP concludes that the 'possibility of a small or a longer term effect could not be ruled out. Nevertheless, while one cannot be certain, the trend in the accumulating evidence is increasingly against the hypothesis that mobile phone use causes brain cancers'.

3.2 Journal articles reviewed by the committee

Schüz et al. (Am J Epidemiol 174(4): 416–422; 2011) studied the risk of vestibular schwannoma in relation to long-term mobile phone use in a Danish nationwide study. The authors found no evidence that mobile phone use is related to the risk of vestibular schwannoma. They note, however, that due to the usually slow growth of vestibular schwannoma and possible diagnostic delay, further surveillance is indicated.

Frei et al. (BMJ 2011; 343: d6387) carried out an update of a Danish cohort study on the use of mobile phones and the risk of brain cancers. The authors concluded 'there were no increased risks of tumours of the central nervous system, providing little evidence for a causal association'. The authors note 'as a small to moderate increase in risk for subgroups of heavy users or after longer induction periods than 10–15 years cannot be ruled out, further studies with large study populations, where the potential for misclassification of exposure and selection bias is minimised, are warranted'.

Ahlbom and Feychting (BMJ 2011; 343: d6605) noted that the study by Frei et al. had two important methodological advantages over most other studies. First, it was based on a computerised cohort that was followed passively in registries, so it avoided the need to contact people. Consequently the problem of non-response and selection bias was eliminated. Second, it used digitised subscriber data obtained from the operators rather than retrospective questionnaire or interview information obtained from users. This circumvented the recall bias that is present in other studies.

They also noted one weakness of the study where having a mobile phone subscription is not equivalent to using a mobile phone. Conversely, some users will be non-subscribers. The resulting misclassification would dilute any association between mobile phone use and cancer risk.

Little et al. (BMJ 2012; 344: e1147) determined the compatibility of two recent reports of glioma risk (the Interphone study, Int J Epidemiol 2010; 39: 675–94; and Hardell et al., Int J Oncol 2011; 38: 1465–74) with observed trends in the United States.

They concluded that raised risks of glioma with mobile phone use as reported by Hardell et al. are not consistent with observed incidence trends in United States population data, although the United States data could be consistent with the modest excess risks in the Interphone study.

3.3 AMI Meter Electromagnetic Field Survey Preliminary Report: Prepared for Department of Primary Industries

The Department of Primary Industries presented the committee with the *AMI Meter Electromagnetic Field Survey Preliminary Report* on measurements of radiofrequency radiation levels in the vicinity of advanced meter infrastructure meters (also known as 'smart meters').

The committee noted that, while the number of homes included in the survey was only 16, the level of radiofrequency radiation was very low, as expected, and well below the maximum recommended exposure level in the radiation protection standard *Maximum Exposure Levels to Radiofrequency Fields – 3 kHz to 300 GHz* (2002) published by ARPANSA.

The committee reiterated its position that there is no substantive evidence to suggest that exposure to radiofrequency radiation (for example, from advanced meter infrastructure meters) increases the risk of chronic health effects such as cancer.

3.4 ICNIRP Statement on Health Issues Associated with Millimeter Wave Whole Body Imaging Technology

The committee reviewed a statement published by the ICNIRP (Health Physics 102(1): 81–82; 2012) that addresses the new generation of whole-body image scanners installed in many airports and other security checkpoints worldwide. These scanners emit microwave radiation and form an image by processing the waves scattered by the object or person being scanned. ICNIRP concluded that the human exposures resulting from the use of these scanners are about a tenth of its recommended guidelines for members of the public.

The committee did not believe that concern was warranted regarding the possibility of chronic health effects as a result of exposure to the microwaves emitted from the scanners.

3.5 Media release by the New South Wales Minister for the Environment and Minister for Heritage regarding the ban on commercial tanning units

The committee noted that the New South Wales Government had 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.

3.6 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 increases 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.

3.7 The committee's view on possible health effects of power frequency electromagnetic fields

The committee's position is that, based on the entire 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 committee is established under the Radiation Act and provides advice to the Minister for Health or the Secretary of the department 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 committee may provide advice on matters including:
   - administration and amendments of the Radiation Act 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
     - solaria and their regulation
     - health effects of radiofrequency electromagnetic fields (including mobile communications)
     - health effects of extremely low frequency electromagnetic fields (including power frequency fields)
     - lasers and intense pulsed light sources
   - the promotion and improvement of radiation safety in Victoria
   - developments that impact on best practice for radiation safety
   - any other matter put to it by the Radiation Team of the department.
3. The committee meets on the first Thursday of every month, excluding January.
4. A minimum of five members constitutes a quorum for committee meetings.
5. The committee regulates its own proceedings.
6. The committee may establish subcommittees 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 committee 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 committee is provided by the Radiation Team.
9. The committee will provide an annual report to the Minister for Health for each financial year, no later than 1 November following that year.

APPENDIX 2 RESEARCH PROJECTS CONSIDERED BY THE COMMITTEE

Title of research project
A Placebo Controlled, Multicenter, Randomized, Double Blind Trial to Evaluate the Safety and Effectiveness of IK-5001 for the Prevention of Remodeling of the Ventricle and Congestive Heart Failure after Acute Myocardial Infarction
A Phase III, Multicenter, Open-label Randomized Trial Comparing the Efficacy of GA101 (RO5072759) in Combination with CHOP (G-CHOP) versus Rituximab and CHOP (R-CHOP) in Previously Untreated Patients with CD20-positive Diffuse Large B-cell Lymphoma (DLBCL)
REPRISE I: Repositionable Percutaneous Replacement of Stenotic Aortic Valve through Implantation of Lotus Valve SystEm – Feasibility Study
Randomized, Open Label, Multi-Center Study Comparing Cabazitaxel at 20mg/m2 and at 25mg/m2 Every 3 Weeks in Combination with Prednisone for the Treatment of Metastatic Castration Resistant Prostate Cancer Previously Treated with a Docetaxel-Containing Regimen
An Evaluation of the Biodistribution and Imaging Characteristics of ABT-806i (111In-ABT-806) in Subjects with Advanced Solid Tumor Types Likely to Express Epidermal Growth Factor Receptor (EGFR)
A Randomised, Double-Blind, Placebo-Controlled Trial to Evaluate the Safety, Tolerability and the Biological and Cognitive Effects of VEL015 (Sodium Selenate) in Patients with Mild to Moderate Alzheimer's Disease – a Pilot Study
A Phase I Study to Determine the Maximum Tolerated Dose (MTD) of LBH589 in Paediatric Patients with Refractory Solid Tumours including Central Nervous System (CNS) Tumours
A Phase 2 Study of LY2157299 Monohydrate Monotherapy or LY2157299 Monohydrate plus Lomustine Therapy Compared to Lomustine Monotherapy in Patients with Recurrent Glioblastoma
A Phase II, Double-Blind, Placebo-Controlled, Randomized Study Evaluating the Safety and Efficacy of Carboplatin/Paclitaxel and Carboplatin/Paclitaxel/Bevacizumab with and without GDC-0941 in Patients with Previously Untreated Advanced or Recurrent Non-small Cell Lung Cancer
Long-term Angiographic Results and Clinical Outcome of Radial Artery Grafts
Renal Denervation in Patients with Uncontrolled Hypertension
Changes in Cardiac Magnetic Resonance Imaging (MRI) and Cardiovascular Biomarkers Following Renal Transplantation and Extended Hours Dialysis
A Phase I Study of 4-(N-(S-Penicillaminylacetyl)amino) Phenylarsonous Acid (PENAO) Given as a Continuous Intravenous Infusion to Patients with Advanced Solid Tumours
A Multi-centre, Randomized, Phase 3 Study of Sequential Pralatrexate Versus Observation in Patients with Previously Undiagnosed Peripheral T-cell Lymphoma who Have Achieved an Objective Response following Initial Treatment with CHOP-based Chemotherapy (PROFOUND Study)

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