

**THE ANNUAL REPORT OF
THE RADIATION ADVISORY COMMITTEE
FOR THE FINANCIAL YEAR ENDING JUNE 2007**

RADIATION ADVISORY COMMITTEE

Melbourne, Australia

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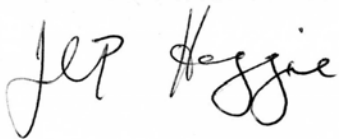
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Daniel Andrews MLA
Minister for Health

Dear Minister

Pursuant to Section 108AK(10) of the *Health Act 1958*, up to 31 August 2007, and Section 110 of the *Radiation Act 2005*, from September 1 2007, the Radiation Advisory Committee submits the 2007 annual report of the Committee for presentation to Parliament.

Yours faithfully

A handwritten signature in black ink, appearing to read 'JHP Heggie', is written over a faint, light-colored rectangular stamp.

Dr John Heggie
Acting Chair
RADIATION ADVISORY COMMITTEE

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RADIATION ADVISORY COMMITTEE

The Radiation Advisory Committee is established under Section 108AK(1) of the *Health Act 1958*, up to 31 August 2007, and Section 110 of the *Radiation Act 2005*, from September 1 2007. The term of appointment for the Committee was the period 17 August 2005 to 16 August 2008. However, in accordance with Schedule 1 of the Radiation Act 2005, the Committee was abolished on 1 September 2007. A new Radiation Advisory Committee was established on that day that consisted of the same members as the old Committee.

(i) Composition

The Radiation Advisory Committee met on six occasions from October 2006 to June 2007. The members of the Radiation Advisory Committee during this period were:



CHAIR (until December 2006)

Professor Brian M. Tress

Department of Radiology
University of Melbourne

Meetings Attended: 2



Dr. Geza Benke

Research Fellow

Dept of Epidemiology & Preventive Medicine
Monash Medical School

Meetings Attended: 1



Dr. David Bernshaw

Consultant Radiation Oncologist
Peter MacCallum Cancer Centre

Meetings Attended: 5



Mr. Philip Brough
Chief Medical Imaging Technologist
Department of Medical Imaging
Geelong Hospital

Meetings Attended: 4



Mr. Peter Burns
Director
Environmental and Radiation Health Branch
Australian Radiation Protection & Nuclear Safety Agency

Meetings Attended: 3



Ms. Christy Fejer
(Until December 2006)
Occupational Health and Safety Consultant

Meetings Attended: 2



Dr. John Heggie (Acting Chair from February 2007)
Director
Department of Medical Engineering and Physics
St. Vincent's Hospital

Meetings Attended: 5



Dr. Ken Joyner
Director
Global EME Strategy & Regulatory Affairs
Motorola Australia Pty Limited

Meetings Attended: 1



Professor Robert Gibson
Deputy Head, Department of Radiology
University of Melbourne

Meetings Attended: 6



Dr. Roslyn Drummond
Radiation Oncologist
Peter MacCallum Cancer Centre

Meetings Attended: 4

(ii) Responsibilities

The Radiation Advisory Committee is to advise the Minister for Health or the Secretary of the Department of Human Services, on any matters relating to the administration of Section 108AA to Section 108AK of the *Health Act 1958*, up to 31 August 2007, and of the *Radiation Act 2005*, from September 1 2007, 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 the criteria for the registration of radiation apparatus and sealed radioactive sources (from 1 September 2007, the system of registration of radiation sources was replaced by a system, under the *Radiation Act 2007*, of licensing to possess 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.

1. INTRODUCTION

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

- implementation of the *Radiation Act 2005*;
- the licensing, registration and training requirements for various radiation practices;
- new ionising radiation apparatus;
- the implementation of the *ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes 2005*;
- radiation incidents;
- non-ionising radiation matters; and
- a variety of research projects involving the irradiation of human volunteers.

The Radiation Act requires that the Committee give the Minister a report on its activities during a financial year no later than 1 November following that year. The annual report of the Committee for the year ending September 2006 reports on material considered by the Committee up to the end of September 2006. The current report will only cover the period from October 2006 to June 2007 inclusive.

In past annual reports of the Committee, a summary was included of the numbers of authorisations issued by the Department. Under the Radiation Act, however, the Secretary of the Department, in respect of each financial year, must publish a report that describes the activities of the Secretary under this Act, including a summary of all authorities issued, renewed, suspended, cancelled, varied, transferred or surrendered during that year. As such a summary of authorisations will not henceforth be included in the Committee's annual report.

With the implementation of the Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes as a condition of relevant management licences, the role of the Committee has changed. Historically, the Committee has reviewed proposed research projects involving exposure of human participants to ionising radiation. However, with the Code in force, human research ethics committees of institutions are now responsible for approving most of the radiation procedures used in research projects. In the few trials where specified dose constraints are exceeded and there is no benefit to volunteers who are patients the research projects must still be submitted to the Committee for approval.

The Committee would like to thank the Radiation Safety Section of the Department of Human Services, in particular Mr Julian Marwick, for their continuing assistance and support.

2. IONISING RADIATION

2.1 Radiation Act 2005

The *Radiation Act 2005* and *Radiation Regulations 2007* came into effect on 1 September 2007.

The Committee monitored the progress of the implementation of the *Radiation Act 2005*, and the development of the Radiation Regulations. The purpose of the Act is to protect the health and safety of persons and the environment from the harmful effects of radiation. Among the major tasks associated with the implementation of the Act were the introduction of a third-party equipment inspection program, communication of the impact of the new Act and Regulations to stakeholders, and management of the transitional period.

Under the Act, prescribed radiation sources may only be used if they have a valid certificate of compliance. Certificates of compliance may only be issued by testers approved under the Act for that purpose. The implementation of the inspection program was seen by the Committee as an important step towards improving radiation safety in Victoria, and reducing exposures received by users of radiation and patients undergoing radiological procedures. The Committee noted the importance of implementation of the inspection program in a manner that ensured sufficient testers were available and equipment owners were given a reasonable opportunity to comply with the requirements of the Act.

The final drafts of the radiation safety standards for compliance of prescribed radiation sources, to be used by testers approved under the Radiation Act 2005, were provided to the Committee for information.

2.2 Research involving irradiation of human volunteers

The Committee continued to monitor the trial stage of the implementation of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes 2005*. During the trial stage in Victoria, the Committee evaluated proposed research projects only where dose constraints specified in the code of practice were exceeded and where there was no benefit to volunteers who were patients. Approval of other research projects involving radiation exposures of human volunteers was the responsibility of institutional human research ethics committees.

The Committee was pleased with the results of the trial and advised that the Radiation Safety Section should continue with the use of the code of practice as standard procedure.

Under the code, an approved medical physicist must provide an assessment of the radiation dose expected to be received by participants. Medical physicists wishing to gain approval from the Radiation Safety Section to perform dose assessments under the code need to be accredited by the Australasian College of Physical Scientists and Engineers in Medicine. Physicists not possessing accreditation may receive approval if they are eligible for membership of the Australasian College of Physical Scientists and Engineers in Medicine and have a minimum of five years experience in regularly carrying out dose assessments for research projects. In the case of physicists who are eligible for membership of the Australasian College of Physical Scientists and Engineers in Medicine, but who have not carried out dose assessments of research projects regularly for at least five years, approval may be granted if they have performed 10 dosimetry calculations and have had them assessed by a medical physicist who has already been approved to carry out dose calculations.

The Radiation Safety Section provided to hospital ethics committees a list of medical physicists who had been approved to carry out dose assessments.

A list of the research projects approved by the Committee is provided in Appendix 1.

The Committee reviewed the proposed new version of the Department of Human Services Human Research Ethics Committee module 4 form (for research projects involving ionising radiation) and guidelines. These are to be completed by researchers as part of their submission to gain approval to conduct research involving the irradiation of human participants. The Committee was generally happy with the content of the form and guidelines, and suggested some minor changes to clarify the researcher's responsibilities.

2.3 Radiation incidents

The Committee continued to review reports of accidental radiation exposures and maladministrations reported to the Radiation Safety Section.

Of the reports of unplanned exposures, seven involved a computed tomography scan of an incorrect patient, five involved the maladministration of a radiopharmaceutical, one involved the spillage of a radiopharmaceutical, one involved a fluoroscopic procedure performed on an incorrect patient, one involved a full skeletal radiographic survey of an incorrect patient, and one involved unintentional exposure to a Sr-90 calibration source. Common causes of the medical accidental exposures were found to be failure of staff members to follow correct patient identification procedures and incorrect protocols being used for scans. Follow-up actions by practices designed to prevent recurrences were monitored. Information was circulated to medical practices generally explaining common errors that can lead to radiation incidents.

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

2.4 Request for nurses to perform chest radiography

The Committee was notified that the Radiation Safety Section had received a request to allow nurses to perform chest radiography as a part of health checks on people wishing to be granted visas for entry into Australia. The company involved was contracted by the Commonwealth Department of Immigration and Citizenship.

The Committee was not satisfied that there was justification to approve this request, as there were many radiology centres in Melbourne that could provide these services. However, since the proponent was to be contracted by an agency of the Commonwealth, the Committee advised that the matter fell within the jurisdiction of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) and that the proponent would need to contact ARPANSA to obtain approval.

2.5 Licensing and registration requirements for the Metriscan bone mineral densitometer

The Committee was advised that the Radiation Safety Section had received a submission requesting authorisation to sell the Metriscan bone mineral densitometer unit.

The Committee reviewed the literature provided in the submission, and noted that the design of the unit is such that a person placed their hand in the designated area to have it scanned in order to obtain bone densitometry information. The dose rates were expected to be similar to those received by a DEXA scanner.

The Committee was satisfied that the use of the unit in accordance with current requirements for DEXA scanners would be justified, and recommended approval of the sale and registration of the unit subject in the following conditions:

- Registration should only be permitted for clinical environments where the unit could be operated by appropriately qualified and authorised persons.
- Only persons with the appropriate authorisations, such as radiographers and nuclear medicine technologists, should be permitted to use bone densitometry equipment for diagnostic purposes.

- Authorised persons wishing to operate the Metriscan system should undergo the user orientation program conducted by the supplier of the equipment.

2.6 Application for registration of Imaging Iluma cone beam volumetric dental CT unit

The Committee was advised that the Radiation Safety Section had received an application for registration of an Imaging Iluma cone beam volumetric dental CT unit.

This was the first time an application had been received by RSS for Imaging Iluma equipment. The Committee also noted that dental CT equipment was generally used in specialised dental centres or radiology centres, and it was unlikely it would be used in standard dental practices due to its high cost. The application had indicated that the unit would be operated by a radiographer.

The Committee reviewed the application, and noted that there was no information regarding the level of training to be provided on the operation of the equipment, nor was justification provided as to the level of shielding that had been indicated in the application. It was agreed that this information would need to be provided before this application could be approved. It was also noted from the promotional images provided that the radiographs could include a region of the skull extending up to the orbits. It was recommended that the applicant be advised to ensure the irradiated area be limited to the area of diagnostic interest.

3. NON-IONISING RADIATION

3.1 ARPANSA standard for low frequency electric and magnetic fields

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) draft *Radiation Protection Standard for Exposure Limits to Electric and Magnetic Fields 0 Hz - 3 kHz* was released for public comment in December 2006.

The Standard specifies limits of human exposure to electric and magnetic fields in the frequency range 0 Hz to 3 kHz, to prevent adverse health outcomes. The limits are defined in terms of basic restrictions, for exposure of all or a part of the human body, in terms of dosimetric quantities internal to the body. Reference levels in terms of quantities that are readily measurable are also provided as a practical means of showing compliance with the basic restrictions. In particular, the standard specifies basic restrictions for occupational exposure and general public exposure with corresponding derived reference levels as a function of frequency. The standard also includes schedules and annexes providing a detailed rationale, and literature reviews of epidemiologic research and studies on low level effects, along with information on precautionary approaches to exposure to 0 Hz to 3 kHz electric and magnetic fields.

3.2 Mobile phone use and cancer risk

A study by Schüz et al (*Cellular Telephone Use and Cancer Risk: Update of a Nationwide Danish Cohort*. Journal of the National Cancer Institute, Vol. 98, No.23, December 6, 2006: 1707 – 1713) investigated cancer risk in a cohort of Danish mobile phone users who were followed up for 21 years. Standardised incidence ratios (SIRs) were calculated by dividing the number of observed cancers in the cohort by the number expected in the Danish population. Overall, 3391 cancers were observed with 3825 expected, yielding a significantly decreased SIR of 0.89 (95% confidence interval [CI] = 0.86 to 0.92). A substantial proportion of this decreased risk was attributed to

deficits of lung cancer and other smoking-related cancers. No excesses were observed for cancers of the brain or nervous system (SIR = 0.95; 95% CI = 0.81 to 1.12) or of the salivary gland (SIR = 0.72; 95% CI = 0.29 to 1.49) or for leukaemia (SIR = 0.97; 95% CI = 0.78–1.21), cancers of a priori interest. Risk for these cancers also did not vary by duration of cellular telephone use, time since first subscription, age at first subscription, or type of cellular telephone (analogue or digital). Analysis of brain and nervous system tumours showed no statistically significant SIRs for any subtype or anatomic location. The authors conclude that the results of this investigation, the first nationwide cancer incidence study of cellular phone users, do not support the hypothesis of an association between use of these telephones and tumours of the brain or salivary gland, leukaemia, or other cancers.

The Committee noted that the results of a 13-nation study (the Interphone Study), coordinated by the International Agency for Research on Cancer, would be available later this year.

3.3 The Committee's view on possible health effects of power frequency electromagnetic fields.

The additional evidence reviewed by the Committee concerning possible health effects of power frequency electromagnetic fields has not altered the Committee's position that based on the total database of scientific research, there is insufficient evidence to conclude that exposure to normally encountered environmental levels causes adverse health effects in humans.

3.4 The Committee's view on possible health effects of radiofrequency radiation

The Committee considers there is no substantive evidence to suggest that exposure to radiofrequency radiation can increase the risk of chronic health effects such as cancer. The study by Schüz et al (3.2 above) provided evidence to support this view. However, the Committee acknowledges the current controversy over mobile phones and their base stations and will continue to review the relevant research literature.

APPENDIX 1**RESEARCH PROJECTS APPROVED BY THE COMMITTEE**

TITLE OF RESEARCH PROJECT
A randomized, double-blind, placebo-controlled, multi-centre phase III study to evaluate the efficacy and safety of Pazopanib (GW786034) compared to placebo in patients with locally advanced and/or metastatic renal cell carcinoma
An open-label extension study to assess the safety and efficacy of Pazopanib in subjects with renal cell carcinoma previously enrolled on protocol VEG105192
A randomized, double-blind, multi-centre, placebo-controlled study of adjuvant Lapatinib in women with early-stage ErbB2 over expressing breast cancer (protocol number: HREC 2006:178)
A randomised study to evaluate the effects of cinacalcet plus low dose vitamin D on vascular calcification in subjects with chronic kidney disease (CKD) receiving haemodialysis
A dose-range finding study of SB-751689 in post-menopausal women with osteoporosis