THE ANNUAL REPORT OF

THE RADIATION ADVISORY COMMITTEE

FOR THE FINANCIAL YEAR ENDING JUNE 2011

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 2011 annual report of the committee for presentation to Parliament.

Yours faithfully

Dr John Heggie
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 2008 to 16 August 2011.

(i) Composition

The Radiation Advisory Committee met on 11 occasions from July 2010 to June 2011.

The members of the committee for the period from July 2010 to June 2011 were:

<table>
<tr>
<td> 
Dr. John Heggie (Chair)
Consultant medical physicist

Meetings attended: 8</td>
<td> 
Dr. David Bernshaw
Consultant Radiation Oncologist
Peter MacCallum Cancer Centre

Meetings attended: 9</td>
</tr>
<tr>
<td> 
Mr. Peter Burns
Health Physicist

Meetings attended: 6</td>
<td> 
Professor Robert Gibson
Deputy Head, Department of Radiology
University of Melbourne

Meetings attended: 7</td>
</tr>
</table>

Dr. Roslyn Drummond
Radiation Oncologist
Peter MacCallum Cancer Centre

Meetings attended: 6

Dr. Ken Joyner
Director
Joyner and Associates
Telecommunications Consultancy

Meetings attended: 7

Dr Graeme O'Keefe
Principal Scientist
Austin Health

Meetings attended: 9

Dr Russell Horney
Physicist
Department of Medical Imaging and Radiation Sciences
Monash University

Meetings attended: 8

Mr Russell Booth
Chief Nuclear Medicine Technologist
Medical Imaging Department
St Vincent's Hospital

Meetings attended: 10

Mr Stephen White
Chief Nuclear Medicine Technologist
Cabrini Health

Meetings attended: 4

Associate Professor Rob Davidson
Head of Discipline, Medical Radiations
RMIT University

Meetings attended: 2
Resigned effective after meeting of 7 October 2010

(ii) Responsibilities

The Radiation Advisory 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; and
- research projects involving the irradiation of human volunteers.

The committee would like to thank the Radiation Team of the Department of Health for their continuing assistance and support.

2. IONISING RADIATION

2.1 Proposed research projects involving irradiation of human volunteers

The committee evaluated proposed research projects where doses to volunteers exceeded 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), and where there was no benefit to volunteers who are patients. 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 1.

2.2 Radiation incidents

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

Of the reports of inadvertent exposures:

- Twenty one involved an unintended computed tomography (CT) scan being performed on a patient.
- One involved misalignment of a radiotherapy treatment field.
- One involved an incorrect superficial radiotherapy dose due to a calibration error.
- Two involved unintended radiographic sequences being performed on a patient.
- Six involved the maladministration of a radiopharmaceutical to a patient.

In addition to the incidents involving inadvertent patient exposures, the following incidents were reported:

- An americium-241/beryllium source became detached from the source rod when the source rod was being retracted into its housing by a postgraduate university student. The source was retrieved and reattached to the source rod by the Radiation Safety Officer of the university.

- Spillage of radioactive material occurred at a radiopharmaceutical supply company. A glass vial in a lead pot was dropped when the lid of the lead pot became detached. The company has taken a number of steps to prevent a recurrence of this type of incident. This includes reminding staff to ensure that the lids of lead pots are properly secured and that pots being carried are supported by hand from underneath while being moved.

The committee made recommendations to the department on action 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.

Follow-up actions by practices designed to prevent recurrences were monitored. Information was circulated to radiological practices generally explaining common errors that can lead to radiation 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.

2.3 Importation of handheld dental radiography units

The committee was advised that concerns had been raised within the veterinary community regarding the importation of a handheld x-ray device designed for dental radiography.

A unit that had been imported from China had been tested by the South Australian Environment Protection Authority and had been found not to comply with all of the requirements of the *Code of Practice for Radiation Protection in Dentistry* published by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Specific concerns included the lack of a "dead-man" timer (a timer in which radiation production terminates upon release of the exposure switch) and the fact that the operator had to be closer than 2 metres to initiate an exposure.

Equipment intended for use in veterinary medicine did not require approval from the Therapeutic Goods Administration. The ARPANSA *Code of Practice for Radiation Protection in Veterinary Medicine* has the same requirements for the timer and minimum distance of 2 metres from the X-ray tube (and animal).

Although the Radiation Team has not yet seen a prototype unit for evaluation, based on the testing conducted by the EPA South Australia it is likely that the units would not meet the

requirements of the ARPANSA *Code of Practice for Radiation Protection in Veterinary Medicine*.

2.4 Research involving irradiation of human volunteers

The committee was advised of a research ethics and governance forum held in Melbourne in March 2010 to discuss research involving irradiation of human volunteers. The forum had been arranged by the Coordinating Office for Human Research Ethics, Department of Health and was attended by a broad cross-section of individuals involved with human research projects.

The committee was advised that various issues had been discussed, including the streamlined approval of multi-site projects. There had been some concern that there was still room for improvement in efficiency of these processes. There was also some concern as to the judgement of which procedures are considered to form part of standard care of patients and which are considered additional to standard care. The committee noted that judgements on standard care varied from institution to institution. The lack of radiation expertise on human research ethics committees was also a matter that required some attention.

The Manager of the Legionella and Radiation Safety Section advised the committee regarding proposed changes to approval processes for research projects that involve exposing humans to ionising radiation. The proposal aimed to devolve consideration of justification and radiation approvals to human research ethics committees (HRECs).

Under the proposed approval process, the department would ensure that HRECs had access to expertise to provide advice with regard to justification of radiological procedures, alternate procedures that did not involve the use of ionising radiation, and other radiation related advice. The department would be notified of a project upon approval by the HREC.

This process would address concerns that the radiation approval process was too time-consuming and provided an obstacle to final approval of a project.

The committee expressed concern that researchers and HRECs do not have a uniformly good understanding of ionising radiation dosimetry and the possibility of using alternate procedures that did not involve exposure to ionising radiation to obtain comparable clinical information.

The committee reviewed the regulation of research involving exposure of volunteers to ionising radiation in other states and territories. Queensland, South Australia, Western Australia, and Tasmania had some form of regulation of research involving irradiation of human volunteers. The remaining states and territories did not regulate the radiation aspects of human research. South Australia and Western Australia had schemes similar to Victoria where compliance with the Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes was a mandatory requirement, and projects above the dose constraints specified in the code required a more rigorous level of approval.

The committee requested that the Radiation Team investigate these issues further and develop a more detailed set of options for presentation to the committee.

2.5 Security scanning devices at airports

Mr Kalaiziovski, Senior Regulatory Officer, ARPANSA provided the committee with a presentation on the use of security scanning devices at airports which utilise both ionising and non-ionising radiation.

The committee was advised that the Commonwealth Government is to fund the roll-out of x-ray backscatter and millimetre wave scanning devices to international airports in Australia. There had been public concern expressed over these devices overseas because of the privacy issues related to the technology's ability to take images of contraband material hidden under clothing. The issue of justification of radiation exposure also needed to be considered in the case of the X-ray devices.

Mr Kalaiziovski advised that ARPANSA was seeking to develop model licence conditions and guidance material with the aim of building consistent regulation of the X-ray backscatter devices across the jurisdictions. However it still remained to be seen how the jurisdictions would regulate these devices. It was also noted that the millimetre wave devices, although not producing ionising radiation, would still be subject to regulation by the Australian Communications and Media Authority.

2.6 Proposed teleradiology system

The committee was advised that the Radiation Team had received a request from a diagnostic imaging practice for approval of a proposed teleradiology system which would involve two rural centres and one Melbourne centre.

The committee noted that a similar request was received in 2006. The committee at that time determined that teleradiology technology could be used at centres that were capable of transmitting radiological images without any loss of image quality.

The committee examined the current proposal and agreed that collection and transmission of data could be carried out without loss of image quality. The committee stressed, however, that reporting had to be carried out using diagnostic quality reporting workstations capable of displaying at least 12-bit contrast depth.

The proposal indicated that if the network which supported the proposed teleradiology system was inoperable, couriers would be used to transport hard copy images for reporting. The committee considered that this arrangement could pose problems for more complex CT procedures, such as studies that require contrast administration. In such cases, a radiologist may not be immediately available on site to supervise the procedure. The committee therefore recommended that in the event of a loss of transmission capability such as a network failure or planned maintenance period, only emergency CT examinations should be permitted if there is no radiologist available for on-site supervision.

2.7 Proposed changes to regulation of the sale and disposal of radioactive material

The Manager of the Legionella and Radiation Safety Section advised the committee of proposed changes to regulation of the sale and disposal of radioactive material that were to be introduced in Victoria.

Under the proposed changes, in addition to the current requirement to be authorised to sell the sources, companies wishing to sell sealed radioactive sources would need to hold a licence that authorised possession of the sources, if those sources were held in Victoria prior to sale. This differed from the existing arrangements whereby an exemption was in place from the requirement to be authorised to possess a radiation source if an authorisation to sell radiation sources was held.

It was also proposed that licence holders who store disused radioactive material would require their licences to be varied to authorise the storage of the material.

Sealed sources classified as category 1, 2 or 3 under the ARPANSA code of practice *Security of Radioactive Sources* would be subject to more stringent requirements for notification of acquisition of the sources. The existing 14 day grace period for notification of acquisition of a radioactive source would be reduced in the case of these category 1, 2 or 3 sources.

2.8 Use of cone beam volumetric dental X-ray units

The Medical Radiation Practitioners Board of Victoria wrote to the committee regarding the use of cone beam volumetric dental X-ray units. Concerns had been raised with the board concerning the marketing of cone beam volumetric dental X-ray units to dentists as well as the justification and optimisation of the radiologic procedures utilising them. There had been claims that there was a trend of unnecessary procedures being ordered, without proper justification and optimisation.

The Radiation Team had conducted preliminary investigations into this issue. This involved undertaking inspections of dental practices, and seeking to view patient referrals to determine whether the cone beam procedures were justified and whether any optimisation was carried out.

The committee was advised that, in relation to the practices investigated, referrals had not been found to contain any clinical notes or description of the clinical need for imaging. This appeared to indicate that the procedures may not have been justified. It was noted that the ARPANSA Code of Practice *Radiation Protection in Dentistry* did not provide stringent requirements in relation to justification of imaging procedures. Given that there have been developments in imaging technologies , there are perceived deficiencies in the code in relation to the use of newer technologies.

The Radiation Team will provide the committee with a final report on industry trends in the use of dental volumetric computed tomography scanners, once investigations are complete.

2.9 Referral of patients for radiological imaging procedures by nurse practitioners

The committee was advised that the Radiation Team had received a request from a hospital regarding the department's policy on acceptance of referrals for radiologic imaging procedures from nurse practitioners and other health related practitioners such as physiotherapists, as part of the process of developing a "fast track" program for patients attending the emergency department for attention.

The current status of such referrals was reviewed. Some hospital emergency departments permitted nurse practitioners to request plain radiographs of extremities. There were some concerns, however, about the possibility of nurse practitioners requesting CT procedures. Although a radiologist would still be responsible for justifying and overseeing the performance of a CT scan, there was a possibility that a radiologist might not always be immediately available.

Although the hospital had provided documentation on their fast-track program, it was unclear whether the requesting of CT scans was in the scope of this program. The committee asked the Radiation Team to request more details from the hospital in question regarding the scope of the fast-track program for nurse practitioners.

3. NON-IONISING RADIATION

3.1 Brain cancer incidence trends in relation to cellular telephone use in the United States

In a study by Inskip PD, Hoover RN and Devesa SS, Neuro-Oncology, July 16 2010, brain cancer incidence trends were investigated in relation to cellular telephone use in the United States.

The brain cancer incidence rates between 1992 and 2006 were trending downward or unchanged with the exception of the population aged between 20 – 29 years. Among the female population aged 20 – 29, there was a statistically significant increasing trend between 1992 and 2006, but not for males. This trend was driven by frontal lobe cancers. No increases were apparent for temporal or parietal lobe cancers, or cancers of the cerebellum, which involve the parts of the brain more likely to be exposed to radiofrequency radiation. Overall, these incidence data do not provide support for the view that cellular phone use increases the incidence of brain cancer.

3.2 Effects of cell phone radiofrequency signal exposure on brain glucose metabolism

Volkow ND et al (JAMA (2011) 305(8): 808 - 813) carried out a study to evaluate if acute cell phone exposure affects brain glucose metabolism, a marker of brain activity. In healthy participants and compared with no exposure, 50-minute cell phone exposure was associated with increased brain glucose metabolism in the region closest to the antenna. This finding is of unknown clinical significance.

3.3 Magnetic fields and childhood leukaemia

L Kheifets et al (Pooled analysis of recent studies on magnetic fields and childhood leukaemia, Br J Cancer (2010) 103: 1128 – 1135) found a weak association between magnetic fields and childhood leukaemia. In the combined results, the risk increased with increase in exposure but the estimates were not statistically significant. The odds ratios for exposure categories of 0.1 - 0.2 μT, 0.2 – 0.3 μT and ≥ 0.3 μT, compared with < 0.1 μT were 1.07 (95% confidence interval (CI) 0.81 – 1.41), 1.16 (95% CI 0.69 – 1.93) and 1.44 (95% CI 0.88 - 2.36) respectively.

The authors state that *although our results are compatible with no effect, when considering all studies combined, our findings suggest a small increase in risk with increasing exposure, regardless of the model chosen*. The strength of the latter part of this statement is, however, weakened by the authors' admission that their findings are compatible with no effect.

3.4 IARC classification of radiofrequency electromagnetic fields as possibly carcinogenic to humans

The International Agency for Research on Cancer (IARC) reviewed the evidence for a link between exposure to radiofrequency (RF) electromagnetic fields and various types of cancer. Overall the data were evaluated as being limited among users of wireless telephones for glioma and acoustic neuroma, and inadequate to draw conclusions for other types of cancers. The evidence from occupational and environmental exposures was similarly judged inadequate.

IARC classified radiofrequency electromagnetic fields as possibly carcinogenic to humans (Group 2B), based on an increased risk for glioma, a malignant type of brain cancer.

The 2B category is used for agents for which there is limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals. It may also be used when there is inadequate evidence of carcinogenicity in humans but there is sufficient evidence of carcinogenicity in experimental animals. In some instances, an agent for which there is inadequate evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals together with supporting evidence from mechanistic and other relevant data may be placed in this group. An agent may be classified in this category solely on the basis of strong evidence from mechanistic and other relevant data. In the case of RF, there is limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals.

3.5 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.

3.6 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 RESEARCH PROJECTS CONSIDERED BY THE COMMITTEE

TITLE OF RESEARCH PROJECT
The TEAM trial (Tasigna efficacy in advanced melanoma): A randomized, phase III, open label, multi-center, two-arm study to compare the efficacy of Tasigna® versus dacarbazine (DTIC) in the treatment of patients with metastatic and/or inoperable melanoma harboring a c-Kit mutation.
A Phase III randomized, double blind, placebo controlled multi-center study of panobinostat for maintenance of response in patients with Hodgkin's lymphoma who are at risk for relapse after high dose chemotherapy and autologous stem cell transplant.
Amyloid imaging with Florbetapir in older Australians.
Multicentre, randomised, double blind, placebo controlled, parallel group two year study to evaluate the effect of subcutaneous RO4909832 on cognitive and function in prodromal Alzheimer's Disease.
A multicenter, randomized, double-blind, phase 3 Study of Ramucirumab (IMC-1121B) drug product and best supportive care (BSC) versus placebo and BSC as second-line treatment in patients with hepatocellular carcinoma following first-line therapy with Sorafenib.
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.