THE ANNUAL REPORT OF

THE RADIATION ADVISORY COMMITTEE

FOR THE YEAR ENDING SEPTEMBER 2005

RADIATION ADVISORY COMMITTEE
Melbourne, Australia

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Hon Bronwyn Pike MP
Minister for Health

Dear Minister

Pursuant to Section 108AK(10) of the Health Act 1958, the Radiation Advisory Committee submits the 2005 annual report of the Committee for presentation to Parliament.

Yours faithfully

Professor B M Tress
Chairman
RADIATION ADVISORY COMMITTEE

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RADIATION ADVISORY COMMITTEE

The term of appointment for the previous Committee was 1 June 2002 to 31 May 2005. On 31 May 2005, the Committee was dissolved. A new Committee was subsequently appointed by the Minister for Health for the period 17 August 2005 to 16 August 2008. However, in accordance with Schedule 1 of the Radiation Act 2005, the Committee will be abolished on 1 September 2007. A new Radiation Advisory Committee will be established on that day.

(i) COMPOSITION

The Radiation Advisory Committee met on eight occasions from October 2004 to September 2005. The Committee met informally on three occasions during this period. The minutes of these meetings were ratified at the September 2005 meeting. The members of the Radiation Advisory Committee during this period were:

CHAIRMAN
Professor Brian M. Tress
Department of Radiology
University of Melbourne
Appointed 1 June 2002 to 31 May 2005
Appointed 17 August 2005 to 1 September 2007
Meetings Attended: 4

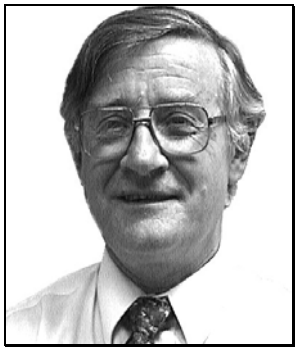
Dr. Geza Benke
Research Fellow
Dept of Epidemiology & Preventive Medicine
Monash Medical School
Appointed 1 June 2002 to 31 May 2005
Appointed 17 August 2005 to 1 September 2007
Meetings Attended: 8

Dr. David Bernshaw
Consultant Radiation Oncologist
Peter MacCallum Cancer Centre
Appointed 1 June 2002 to 31 May 2005
Appointed 17 August 2005 to 1 September 2007
Meetings Attended: 10

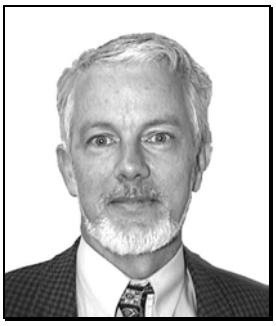
Mr. Philip Brough
Chief Medical Imaging Technologist
Department of Medical Imaging
Geelong Hospital
Appointed 1 June 2002 to 31 May 2005
Appointed 17 August 2005 to 1 September 2007
Meetings Attended: 10

Mr. Peter Burns
Director
Environmental and Radiation Health Branch
Australian Radiation Protection & Nuclear Safety Agency
Appointed 1 June 2002 to 31 May 2005
Appointed 17 August 2005 to 1 September 2007
Meetings Attended: 8

Ms. Christy Fejer
Occupational Health and Safety Consultant
Appointed 1 June 2002 to 31 May 2005
Appointed 17 August 2005 to 1 September 2007
Meetings Attended: 7



Dr. John Heggie
Director
Department of Medical Engineering and Physics
St. Vincent's Hospital
Appointed 1 June 2002 to 31 May 2005
Appointed 17 August 2005 to 1 September 2007
Meetings Attended: 9



Dr. Michael Kelly
Director of Nuclear Medicine
Alfred Hospital
Appointed 1 June 2002 to 31 May 2005
Meetings Attended:6

Dr. Ken Joyner
Director
Global EME Strategy & Regulatory Affairs
Motorola Australia Pty Limited
Appointed 1 June 2002 to 31 May 2005
Appointed 17 August 2005 to 1 September 2007
Meetings Attended: 10

Professor Robert Gibson
Deputy Head, Department of Radiology
University of Melbourne
Appointed 17 August 2005 to 1 September 2007
Meetings Attended: 3

Dr. Roslyn Drummond
Radiation Oncologist
Peter MacCallum Cancer Centre
Appointed 17 August 2005 to 1 September 2007
Meetings Attended: 2

SECRETARY
Ms Caroline Isakow
Radiation Safety Program
Department of Human Services

(ii) RESPONSIBILITIES

The Radiation Advisory Committee was established by the Minister for Health under the Health Act 1958 to advise the Minister or the Secretary of the Department, on any matters relating to the administration of the radiation legislation referred to it by the Minister or the Secretary including the following:

(a) the promotion of radiation safety procedures and practices;

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

(c) recommending the criteria for the registration of radiation apparatus and sealed radioactive sources;

(d) recommending research projects involving the irradiation of human volunteers for approval;

(e) recommending the nature, extent and frequency of periodic safety assessments of radiation apparatus and sealed radioactive sources;

(f) codes of practice with respect to particular radioactive substances and uses of ionising and non-ionising radiation; and

(g) any matter which the Minister agrees the Committee should consider and report on.

1. INTRODUCTION

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

- the licensing requirements of various occupational groups;
- new ionising radiation apparatus;
- a review of the *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005)*;
- reviews of conditions of registration and licence for various registration categories and occupational groups
- proposals to set up diagnostic radiology screening programs
- review of the Coroner's Act 1985
- radiation incidents
- non-ionising radiation matters; and
- a variety of research projects involving the irradiation of human volunteers.

Regarding the review of research projects involving the exposure of volunteers to radiation, this occupies a considerable amount of the Committee's time and effort. The Committee believes that the process used by the Department to approve research projects is warranted, as it is important that the radiation detriment from any project can be justified when compared with the benefits and outcomes from that project. The role of the Committee in approving research projects may change in future in accordance with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) publication *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005)*.

The Committee was advised of the progress of the development of the Radiation Act 2005. The Committee was informed that the purpose of this Act is to protect the health and safety of persons and the environment from the harmful effects of radiation.

The introduction of new legislation would be a major undertaking by the Radiation Safety Program, and would provide a regulatory regime in Victoria that would be consistent with other Australian states and territories.

As with previous years, non-ionising radiation issues still concern the public. The possible health effects of exposure to electromagnetic fields, mobile phones radiation and such sources were considered by the Committee over the past year. There has been insufficient evidence to alter the Committee's view on possible health effects.

The Committee would like to thank the Radiation Safety Program for their continuing assistance and support throughout the year. In particular, Caroline Isakow who provided secretarial support to the Committee.

The completion of the 2002 to 2005 term of the Committee saw the departure of Dr Michael Kelly, after twelve years of service. The Committee would like to thank Dr Kelly for his service in providing expertise in the field of Nuclear Medicine. This time also saw the departure of Mr Paul Einsiedel from the Radiation Safety Program. The Committee thanks Mr Einsiedel for his assistance with Committee issues, particularly in the area of medical physics and regulatory affairs, as well as his administrative support in the preparation of previous annual reports.

2. IONISING RADIATION

2.1 Radiation Act 2005

The Committee was kept informed of the development of the bill for the Radiation Act 2005. This bill was based upon the *National Directory for Radiation Protection* which was developed by the Radiation Health Committee, ARPANSA. The Directory was agreed to by the health ministers from the States, Territories, and the Commonwealth. In superseding sections 108AA to 108AK of the Health Act 1958, the Radiation Act 2005 will result in substantial changes to the regulatory system in Victoria, including but not limited to:

- The requirement for practices to hold a 'management licence', which may authorise the conduct of a radiation practice including the following activities:
    - possessing, selling, repairing, maintaining, or disposing of a radiation source;
    - testing a radiation source where that testing does not involve using a radiation source;
    - transporting, mining, or processing radioactive material;
    - decommissioning a radiation facility;
    - procuring or arranging research involving the irradiation of persons;
    - or any other activity conducted in relation to a radiation source that may result in exposing a person or the environment to radiation, but not the actual use by a natural person of a radiation source;
- The requirement for natural persons using radiation sources to hold a 'use licence', which may authorise a person to use a radiation source for a specific purpose;
- The requirement for a person constructing a major radiation facility to hold a 'facility construction licence', which may authorise construction of certain types of radiation facilities prescribed by regulations;
- The introduction of 'approved testers' who are individuals approved by the Secretary to conduct tests on radiation sources prescribed by regulations to determine whether sources meet radiation safety standards.

The Committee was informed that under section 146 of the Radiation Act 2005, the Health (Radiation Safety) Regulations 1994 continue to be in force until sections 108AA to 108AK of the Health Act 1958 are repealed on 1 September 2007. Additionally, all other provisions of the Radiation Act except sections 1 and 2 will come into force on 1 September 2007. The Committee was advised that the Radiation Act 2005 received royal assent on 20 September 2005.

2.2 Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes

The Committee was presented with the recent publication by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) *Radiation Protection Series 8: Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005).* It was noted that the new code of practice placed greater responsibility on institutional human research and ethics committees in deciding whether research projects are justified.

Under the code, medical physicists have responsibility for calculating radiation doses to participants in research projects. The Committee recommended that the Code be implemented on a trial basis in Victoria before its inclusion in the National Directory for Radiation Protection. The Committee recommended that the Radiation Safety Program implement the following model on a trial basis:

- Institutions conducting research projects involving ionising radiation are to have the project reviewed by a Human Research and Ethics Committee (HREC). This review must be conducted in accordance with the Code.

- A dose assessment must be provided by a medical physicist. The medical physicist must be:

  - qualified to perform the appropriate dosimetric calculations, measurements, and monitoring

  - approved by the Radiation Safety Program to make dose estimates in the specialty relevant to the research project

  - accredited by the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM), or have an equivalent level of training as determined by the Radiation Safety Program

- Projects involving radiation doses exceeding the dose constraints set out in the Code must be submitted to the Radiation Safety Program for approval.

- The Radiation Safety Program must be notified of any projects that have been approved by the HREC. This notification must include the project title, a summary of the project, the name of the principal researcher, where the research is to be carried out, the name of the medical physicist who performed the dose assessment and a copy of this assessment, the type of procedures, and the number of participants. The information relating to approved projects will be forwarded to the Committee for review on a trial basis.

- Approved projects will be listed on the institution's licence to conduct research involving human volunteers

- The Radiation Safety Program must be notified when an approved project has been completed.

There is to be a clear audit process for institution HRECs to ensure that research projects are assessed in accordance with the code.

The Committee noted that presently the availability of appropriately qualified radiology medical physicists is limited, and this may be of particular concern in country areas. However it would still be necessary for institutions in country areas to obtain a dose assessment from an approved medical physicist.

2.3 Change of conditions to Company/Institutions licences regarding therapeutic administration of Iodine-131

Following an incident involving administration of a therapeutic dose of iodine-131 to a pregnant female, the Committee recommended that further conditions be added to Company/Institution licences at centres where therapeutic administrations of iodine-131 are performed. It was proposed that the new conditions state that therapeutic administrations of iodine-131 must not be performed on females of child-bearing age without a Qualitative Serum Beta-HCG

pregnancy test being performed prior to and on the same day as the therapeutic procedure. The Committee was informed that a number of rural nuclear medicine centres would be unable to perform the pregnancy test and receive the result from their pathology service within the same day, thus precluding the administration of a radiopharmaceutical on the same day as the pregnancy test. The Committee determined that this was not the case at major nuclear medicine centres such as in the Melbourne metropolitan area. Therefore, the Committee recommended the new conditions state that a Qualitative Serum Beta-HCG pregnancy test must be performed on females of child-bearing age prior to a therapeutic administration of Iodine-131, preferably on the same day and no earlier than 24 hours prior to the scheduled time of the procedure.

2.4 Peripheral Quantitative Computed Tomography (pQCT) – Stratec XCT 3000 & SA+

The Committee was advised that a Victorian university had purchased two Peripheral Quantitative Computed Tomography (pQCT) scanners. These units were the first of their type to be used in Victoria. The Stratec XCT 3000 is designed to perform bone mineral densitometry on humans. The Stratec Research SA+ is designed to perform bone mineral densitometry on small animals such as rats and mice. The Committee was informed that the pQCT modality allows more information to be obtained than the traditionally used DEXA scanners. One deficiency of DEXA is that it does not sufficiently explain bone strength. The QCT modality enables real volumetric density measurements and can non-invasively estimate the fracture and bending strength of in-vivo bones. pQCT can also monitor metabolic changes quickly and precisely. Additionally histomorphometric parameters like endosteal and periosteal circumferences, and total and cross sectional bone areas can be determined in-vivo. The Committee and the Radiation Safety Program agreed that the Stratec machines should be permitted to be registered in Victoria, as they had received approval from the Therapeutic Goods Administration, and the Consumer Electronics Association. The Committee indicated that initially the Stratec XCT 3000 pQCT scanner should only be registered for the purpose of research involving human volunteers, and that the Research SA+ scanner should only be registered for use with animals. It was agreed that operators currently holding a licence for DEXA equipment should be allowed to use pQCT scanners, provided they have undergone training provided by the manufacturer.

2.5 Proposed training course in Bone Densitometry to be offered by the Australian and New Zealand Bone Mineral Society (ANZBMS)

The Committee was informed of a proposed training course to be offered by the Australian & New Zealand Bone & Mineral Society (ANZBMS). The course was to be offered to people wishing to use bone mineral densitometers for research purposes. The Committee reviewed a draft of the course material that was submitted to the Radiation Safety Program, and noted the following:

- Participants would be required to have satisfactorily completed a university degree in science, nursing, or medical radiation technology to gain entry to the course.

- The course would consist of a formal set of lectures over 2 days. A complete set of the lecture notes would be provided to the students one month prior to the lectures for study purposes. Students would be expected to have gone through the material in detail prior to the lectures.

- A two-hour multiple choice examination would be administered one week after the formal lectures.

- While the technical content of the course material is accurate, it will need to be altered to reflect the requirements of sections 108AA to 108AK of the Health Act 1958 and the Health (Radiation Safety) Regulations 1994.

- There was a lack of adequate training courses available for bone mineral densitometry in Victoria, and this course will fulfil a much needed educational requirement.

The Committee agreed that the content of the course material submitted was sufficient to provide adequate training for persons wishing to operate bone mineral densitometers for research purposes.

2.6 DEXA proposal to screen self referred patients

The Committee was informed that the Radiation Safety Program had been contacted by a bone density technologist at a Victorian hospital requesting advice whether that hospital could gain approval to offer a bone densitometry screening service. It was the hospital's belief that patients seemed to be deterred from having scans due to the cost of the examination. The hospital had queried whether a referral from a medical practitioner is required in order for the scan to be done. The Committee was informed that current conditions of registration for DEXA equipment state that a written referral is required for all examinations and reports are to be issued by a medical practitioner. The Committee indicated that the submission had not thoroughly addressed one of the fundamental principles of radiation protection, that being justification, as outlined in the ARPANSA publications *Recommendations for Limiting Exposure to Ionizing Radiation (1995)* and *National Standard for Limiting Occupational Exposure to Ionizing Radiation (republished 2002)*. The hospital had not fully demonstrated the net benefits from the introduction of this programme when compared to the risk associated with the DEXA. The Committee stated that internationally accepted guidelines, namely, *Appendix 1: The NSC Criteria (UK) - The NSC Criteria, The Criteria for appraising the viability, effectiveness and appropriateness of a screening programme* exist to enable screening programs to be justified. Consequently, the Committee recommended that, as outlined in the current conditions of registration for the equipment, a medical practitioner should refer all patients presenting to the bone densitometry department of the hospital for a DEXA examination. Furthermore, a specialist in medical imaging should interpret and provide a written report on the results of each scan performed by the densitometer.

2.7 Request to perform DEXA on patients without a referral

The Committee received a submission from a private company enquiring as to whether a DEXA scanning service could be offered without the requirement of patients being referred from a medical practitioner. In its submission, the company stated that it aims to develop a clinical and scientific body composition assessment and analysis service with considerable health, social and welfare benefits for its customers. It also indicated that:

- It would not perform scans of the spine and femur;

- It was envisaged that approximately 4000 people per year per DEXA unit could be scanned;

- Reports of results will not be signed or examined by medical personnel;

In presenting this item to the Committee the Radiation Safety Program highlighted the following aspects of the submission:

- The company was requesting to perform DEXA scans without a referral.

- They had indicated that their intended customers would be Medical Practitioners

including general practitioners and specialists who have patients with weight-related conditions and others with a broad range of medical-related conditions.

- The company also seemed to indicate that pre-employment and medico-legal DEXA scans would be offered to various organisations.

Finally, the Radiation Safety Program reminded the Committee that current requirements for DEXA examinations would preclude the company from offering a DEXA service without referrals being obtained.

It was the view of the Committee that most radiological procedures can be considered as 'measurements' and it is the interpretation of these measurements that is the diagnostic aspect. Therefore, the Committee did not agree with the interpretation that DEXA for body composition assessment was a measurement procedure and not a diagnostic procedure and therefore a medical referral was not required.

The Committee was also of the view that, regardless of the radiation dose being delivered, performing DEXA scans without a referral from a medical practitioner cannot be justified under internationally accepted ICRP principles. Finally, the Committee was of the opinion that the company in their submission had not fully demonstrated the net benefits from the introduction of this programme when compared to the risk associated with the radiation exposure from the DEXA examinations.

Overall, the Committee believed that DEXA examinations could only be justified if there was a valid referral for the procedure by a medical practitioner.

2.8 Guidelines regarding radiography and nuclear medicine technology students, interns and professional development year trainees

The Committee was provided with the revised copy of the document entitled: 'Guidelines regarding radiography and nuclear medicine technology students, interns and professional development year trainees'.

Recent concerns raised with the Radiation Safety Program regarding the supervision of undergraduates, professional development year (PDY) technologists, and interns prompted the Program to revisit this document with the intention of circulating to the wider medical radiation community. The Committee was informed that in conducting the review of the Australian Institute of Radiography (AIR) and Australian and New Zealand Society of Nuclear Medicine (ANZSNM) documentation regarding staffing requirements, the Radiation Safety Program had identified the following conflict with this document and the ANZSNM guidelines:

"Interns and PDY technologists are not permitted to work in on-call situations without appropriate on-site supervision."

Whereas the ANZSNM guidelines state:

"If a PDY technologist agrees to participate in the on call roster they may only do so after 6 months work experience. It is essential that either a Nuclear Medicine Specialist or accredited technologist supervise on-call experiences, either in person or over the telephone."

The Radiation Safety Program had sought the views of the Medical Radiation Technologists Board (MRTB) in relation to this matter, and they agreed with the Radiation Safety Program's preference to not allow supervision to occur via telephone hook-up. The Committee agreed with the views of the Radiation Safety Program and the MRTB that PDY technologists must be supervised in

person and not over the telephone and should not be included on any on-call rosters unless a qualified nuclear medicine technologist is on-site. As such, the Committee recommended that the ANZSNM be alerted to this discrepancy, and the document be made public.

2.9 Concerns raised at a rural Victorian hospital regarding nurses performing radiographic examinations

The Committee was informed that the Radiation Safety Program had received correspondence from a medical imaging technologist (MIT) at rural hospital expressing concerns that the healthcare network management were in the process of obtaining licences for three nurses to 'replace' radiographers at the hospital. These nurses had completed the five-day training program offered by the South Australian Environmental Protection Agency – Radiation Protection Division. The Committee was reminded that this training course is recognised by the Radiation Safety Program for General Practitioners to obtain a licence to perform extremity radiography in Victoria. The chief executive officer of the healthcare network claimed that having the three nurses licensed would assist the part time radiographer fulfil their service needs primarily when the radiographer is not available or present. At the time, the hospital had a radiographer employed four days per week. The Committee was informed that the MIT had indicated that the licensing of these nurses was occurring to reduce costs as the healthcare network was not prepared to employ a radiographer for 5 days a week or pay a radiographer to be on-call for the fifth day. Finally, the MIT had also raised some further concerns and had claimed that radiologists would not be reporting on films. It was the view of the Committee that a hierarchy approach should be used to provide radiography services throughout Victoria, especially in rural areas. That is, radiography should, where possible, be performed by trained medical imaging technologists (MITs) and when MITs are not available to provide the service it should be provided by General Practitioners. Finally, if both these professional groups are not available then trained nurses should undertake radiography services. The Committee noted that the MIT had indicated that the hospital has general practitioners licensed to operate x-ray equipment at the hospital. The Committee indicated that there did not seem to be enough information provided by both the MIT and the healthcare network to enable a decision to be made regarding issuing licences to these nurses. Therefore, until further information could be provided no action would be taken.

2.10 Application from a nurse for a licence to operate DEXA equipment for clinical purposes

The Radiation Safety Program received an application for an operator licence by a nurse. The nurse wished to be licenced to operate DEXA equipment in Victoria for clinical purposes.

The applicant had worked in the UK for 6 years, and had been trained there to operate a bone densitometry scanner; acting as the primary operator in her department. She had also completed a radiation protection course while in the UK and had received extensive on the job training. The nurse had submitted details of the radiation protection module she has completed as well as a disc with her assignments, which formed part of her training.

The Committee was advised that she had recently received practical training in DEXA operation, and had also completed a half-day training session in radiation protection in DEXA which consisted of individual training at the private radiology practice where she was working. The DEXA module that she had previously completed was part of the accredited Bone Densitometry Training Scheme, which was run by the National Osteoporosis Society in the UK.

The Committee agreed that in the UK because of a shortage of qualified staff, there seemed to be allowance for people to be licensed to perform DEXA scans for clinical purposes. However the Committee believed there were enough qualified medical radiation technologists in Victoria to cover the demand for operators of DEXA units for clinical purposes, and that there was no special need to allow other professions to obtain licences.

Therefore the Committee recommended that the nurse not be allowed to obtain a licence for clinical use of bone mineral densitometry apparatus.

2.11 Approval of Veterinary Nurses to Operate X-Ray Equipment

The Committee's advice was sought on licensing of veterinary nurses, and the suitability of the certificate IV course offered by the Australian Veterinary Nurse Resource Centre (AVNRC).

The Committee was provided with correspondence from the Veterinary Practitioners Registration Board of Victoria VPRB (Victoria) summarising their assessment of the course. In summary the specialist in veterinary radiology appointed by the VPRB (Victoria) indicated that:

"this course is broadly comparable to the level of training received by veterinary practitioners in their undergraduate course at the University of Melbourne in relation to the safe operation of veterinary x-ray equipment", and "If nurses have completed this course they would have the necessary skills and competency to carry out plain radiographical examinations unassisted."

Furthermore, the VPRB (Victoria) also indicated that it is usual for an animal to be anaesthetised prior to any radiological examination, and that a registered veterinary practitioner would need to be present to do this. Finally, the VPRB (Victoria) believed that a registered veterinary practitioner should continue to maintain an overall responsibility of the taking of veterinary radiographs.

Based on the advice received, the Radiation Safety Program proposed to issue licences to operate plain radiographic x-ray equipment to veterinary nurses following the successful completion of this course. The restrictions on these operator licences would be identical to the conditions placed on licences issued to veterinarians. While the Radiation Safety Program accepted the views of the VPRB (Victoria) in relation to the use of an anaesthetic agent, it was considered to be outside the competency-based requirements with respect to the safe operation of x-ray equipment. The conditions of licence would still require the use of an anaesthetic agent where applicable.

The Committee endorsed the action proposed to licence suitably qualified veterinary nurses.

2.12 Review of Coroners Act 1985

The committee was informed that a review of the Coroners Act (1985) was taking place. The Victorian Parliament Law Reform Committee had circulated a discussion paper on this review and has suggested that the Committee may be interested in commenting. The Committee was advised that some cultural practices require family members of recently deceased persons to touch the remains soon after death. In addition, some practices require burial of the body within 24 hours of death. The Committee agreed that all radioactive corpses should be treated with the same precautions by staff regardless the origin of the radioactivity. Additionally, the Committee agreed that in cases where a deceased person has been administered radiopharmaceuticals shortly before death, the risk of internal exposure of others to radioactive substances due to transfer via physical contact would be negligible. In addition, the external radiation hazard would also be negligible.

The Committee agreed that deceased persons who have recently undergone an

administration of a radiopharmaceutical should be handled in accordance with the guidelines that have been published by the Radiation Safety Program: *Information for people handling deceased persons containing radiopharmaceuticals*.

2.13 Australian Orthopaedic Association code of conduct: Radiation safety practices in operating theatres

The Committee was informed that the Australian Orthopaedic Association (AOA) had written to chief executive officers of hospitals notifying them of their Code of Conduct for Orthopaedic Surgeons in Relation to Exposure to Ionising Radiation. The Committee noted that the AOA sought the assistance of hospitals in ensuring compliance with this code of conduct at all times by orthopaedic surgeons. The AOA had advised its members that they should refrain from using irradiating apparatus during surgery unless all protective equipment stipulated by the code was available. The Committee noted that the code stated that orthopaedic surgeons must use lead acrylic glasses, lead gowns with reinforcement of the abdominal region for female staff who may be pregnant, ceiling and table mounted lead glass screens, and mobile lead glass screens. The Committee was pleased to see that the AOA is encouraging its members to become more aware of issues associated with the use of ionising radiation. However the use of protective eyewear or lead glass screens was seen as unnecessary for orthopaedic procedures, as they would not significantly reduce radiation doses to surgeons. The Committee was concerned that the letter from the AOA to hospitals and its code of conduct used language that inferred an unrealistically high risk to surgeons from radiation exposure. Additionally, the Committee agreed that the code should be altered to reflect current state regulatory requirements with regard to licensing of orthopaedic surgeons.

2.14 Standard Risk Statements for Referred CT Examinations

The Committee was provided with a copy of a "Paediatric CT Information And Consent" form used by the Royal Children's Hospital. It was also indicated that Southern Health uses a similar consent and risk communication form also for CT examinations of paediatrics. It was noted that when a paediatric CT examination was requested, typically the requesting or referring physician would weigh up the risks of the procedure against the benefits. It was considered unusual for the radiology department to have the patient 'sign off' on the procedure. However, the Committee noted that the referring physicians usually have little knowledge of the radiation doses that are delivered during radiological examinations and the risk associated. Additionally, the Committee questioned why the Royal Children's Hospital required consent for CT examinations only. It was indicated that consent forms currently exist for a limited number of procedures where the perceived risk is high (i.e. biopsies, angiograms etc.). The Committee was concerned that the consent form appeared to be quoting risks associated with the radiation exposure of adults. Since this particular consent form dealt specifically with the exposure of paediatrics it was thought that this made the consent form confusing and possibly misleading. Furthermore, it also seems that the authors of the consent form have either converted or confused stochastic and deterministic effects. Overall, based on the circumstances where this type of consent would be used the Committee considered that consent forms could be construed as duress or active consent.

The Committee did not support the introduction of such consent forms of this nature except for procedures where there was a greater risk of deterministic events occurring.

2.15 Review of conditions of registration for CT scanners

The Committee was reminded that the Radiation Safety Program had recently implemented new conditions for registration of CT scanners. These conditions were to replace the rescinded publication: *Code of Practice For the use of Computed Tomography (CT) Equipment in Victoria.*

The Committee was informed that a rural medical practice had applied for an exemption to one proposed condition. This condition required a radiologist to be available on-site to supervise all stages of a CT procedure. This condition was in place in case a patient had a reaction to a contrast medium. It was agreed that off-site supervision would only be suitable under emergency circumstances if a tele-radiology service of a sufficient standard is available to at the centre. The Committee recommended that until formal feedback had been received from the Royal Australian and New Zealand College of Radiologists (RANZCR) on this issue there was no cause to rescind the condition.

2.16 Exemption from personal monitoring for operators performing plain dental radiography

The Radiation Safety Program queried whether it was necessary to require operators performing plain dental radiography to use personal radiation monitoring. Considering the very low doses that are generally received by operators during plain dental radiography, the Program requested that the Committee consider the merits of not requiring operators, conducting only plain dental radiography, from the requirement to use personal monitoring. The Health (Radiation Safety) Regulations 1994 require that any person or class of persons that are likely to be exposed to radiation in excess of one millisievert in any one year must wear an approved personal monitoring device. The Committee agreed that it was highly unlikely that any person operating only plain dental radiography units would receive a dose in excess of one millisievert in one year. Consequently, The Committee recommended that operators who use only plain dental radiography apparatus be excused from the requirement to use personal monitoring. Additionally, it was agreed that many operators may choose to continue using personal monitoring despite this not being a requirement.

2.17 Radiation Incident Report form

After a spate of incidents involving recent reports of incorrect radiation exposures at Victorian hospitals, the Committee recommended that a reporting form for radiation incidents be introduced to encourage further compliance with the Health (Radiation Safety) Regulations (1994). The Radiation Safety Program designed this form and submitted to the Committee for comment. It was intended that the *Radiation Incident Report* form would be completed by the Radiation Safety Officer where there has been a reportable case of an abnormal or unplanned exposure, out of control radiation source, damaged or malfunctioning source, loss or theft of a source, radioactive contamination, or unintentional or accidental release of a radioactive substance as defined by the Regulations. The Committee was generally satisfied with the content of this form, and agreed that the introduction of this form was a step in the right direction and its use should be publicised amongst all users of ionising radiation throughout Victoria.

The Radiation Safety Program indicated that it would be sending copies to Radiation Safety Officers at relevant organisations.

2.18 Radiation Incidents

Under the Health (Radiation Safety) Regulations 1994 certain circumstances involving sources of radiation must be reported to the Department. A written report must be provided to the Department as soon as possible and within 5 working days if:

- any person has or may have received a radiation dose exceeding 1 millisievert effective dose as a result of an abnormal or unplanned radiation exposure.
- a source of radiation is or has been out of control.
- a source of radiation is damaged or malfunctioning in a manner which could result in a person receiving a higher equivalent dose than under normal circumstances.
- there has been an unintentional or accidental release of a radioactive substance in excess of the concentration levels specified in the Regulations.
- a surface has been significantly contaminated by a radioactive substance.

If an irradiating apparatus or radioactive source is or has been lost or stolen, it must be reported *immediately* to the Department.

The Committee was advised of 18 reportable cases during the year. Of these cases, 11 involved a CT or fluoroscopy scan of an incorrect patient, 7 involved a maladministration of a radiopharmaceutical, and one involved a possibly inappropriate administration of a radiopharmaceutical.

Almost all cases involving a CT or fluoroscopy procedure on an incorrect patient were due to an incorrect patient identification label being placed on the referral form for the procedure, or staff failing to correctly identify the patient before the procedure.

Radiopharmaceutical maladministrations, including patients being administered with an incorrect radiopharmaceutical or a nuclear medicine procedure being performed on an incorrect patient, generally occurred because of mistakes with patient identification labels, and staff not properly identifying radiopharmaceuticals before procedures.

The radiation risks to patients as a result of unnecessary diagnostic procedures are generally considered to be extremely small.

The Committee was advised of a case that occurred in September 2004 where a therapeutic dose of Iodine-131 was administered to a pregnant female. The patient was receiving treatment for hyperthyroidism. The standard procedure before a therapeutic Iodine procedure is to perform a Quantitative Serum Beta-HCG pregnancy test prior to the administration. However the patient refused to have this test, stating that she had a contraceptive implant in her arm. On this advice a decision was made by the consultant nuclear medicine physician in attendance to proceed with the procedure without performing a pregnancy test. In December 2004, the patient stated that she was pregnant. It was determined that she had been pregnant for 6 weeks at the time of the therapeutic Iodine procedure. The Committee was reminded that a similar incident occurred in 1998, and the Radiation Safety Program had produced an information sheet on iodine treatment and pregnancy and distributed it to nuclear medicine departments. In response to the most recent case, the Committee recommended that a condition of Company/Intuition licences be implemented which requires a Quantitative Serum Beta-HCG pregnancy test to be performed on all women of child-bearing age prior to a therapeutic administration of iodine-131.

2.19 Research Projects Involving Human Volunteers

During the year the Committee reviewed 58 new or continuing research projects. Research involving exposure of human volunteers to ionising radiation requires approval from both the institution's ethics committee and the Department of Human Services.

Each project was reviewed in some detail in respect to the National Health and Medical Research Council (NHMRC) document *Administration of Ionizing Radiation to Human Subjects in Medical Research (1984)* and the ICRP principle that radiation practices must be justified. Institutions proposing to carry out research involving exposure of

human volunteers to ionising radiation must provide:

- copies of the research protocol;
- the participant information sheet;
- estimates of the radiation doses to participants; and
- evidence of approval by the institution's ethics committee.

The Committee reviewed this information before approval of the research was given. The 58 research projects reviewed by the Committee are listed in appendix 1.

Of the 58 research projects reviewed, 4 were approved as presented, 44 were approved subject to modifications or further information. This normally required either:

- revised or more detailed radiation dose estimates;
- modification of the radiation risk statements in the participant information sheets; or
- approval from the institute's ethics committee.

There were 4 research projects where further information was sought from the principal researchers prior to their submissions being considered by the Committee.

In reviewing the projects the Committee determined that 6 projects did not require its approval. This decision was based on the clause of *Administration of Ionizing Radiation to Human Subjects in Medical Research (1984)*, which states:

> *Where the person irradiated is a patient who may benefit from the procedure, the justification for the irradiation can be judged in the same way as for other medical exposures. Nevertheless, because of the experimental nature of the procedure, it should still be subject to thorough review by the ethics committee.*

Of the projects submitted to the Committee for consideration, a number involved the irradiation of human volunteers under the age of 18 years. For persons under the age of 18, ARPANSA states in its Radiation Protection Series No. 1 *Recommendations for limiting exposure to ionizing radiation (1995)* (republished March 2002) that:

> *Volunteers should, where practicable, be over 40 years of age, and preferably over 50. Persons under the age of 18 should normally not be permitted to be exposed to radiation as volunteers in medical research. Young children, in particular, are not in a position to give informed consent. However, if an ethics committee regards a special case as justified, exposure of the children should conform to a cumulative effective dose of 5 mSv by age 18 years and be permitted only if the information sought cannot be obtained using adult volunteers, and only with the approval of those legally responsible for the child.*

In examining research proposals that involved the irradiation of minors, the Committee had to ensure that the radiation exposure could be justified on the basis that:

- the research project did indicate a beneficial outcome;
- each project submission presented a satisfactory case for the need to irradiate volunteers of this age group;
- the research in question could not be carried out using volunteers over 40 years of age; and
- the cumulative radiation dose to the volunteers from all research would be less than 5 mSv.

Given the possible sensitivities of the irradiation of children, the Committee wished to be assured that the ethics committees of the institutions had assessed the proposal in respect of the ARPANSA recommendation noted above.

3. NON-IONISING RADIATION

3.1 Article: *'902MHz Mobile Phone does not Affect Short Term Memory in Humans'* by C. Haarala et al, Bioelectromagnetics 2004; 25:452-456.

The authors studied the effects of mobile phone exposure on human short-term memory performance. This study was a replication with methodological improvements to a previous study by the same authors. The improvements included multi-centre testing and a double-blind design. A total of 64 subjects (32 men) in two independent laboratories performed a short term memory task which posed a varying memory load on the subjects' memory. The subjects performed the task twice, once each under EMF and sham exposure. Reaction time and accuracy of the responses were recorded. The authors could not replicate their previous results: the exposure had no effect on reaction time or on the accuracy of the subjects' answers.

The Committee noted that a number of published studies have reported changes in human cognitive function with head exposure to mobile phone frequencies but subsequent or replication studies had not been able to reliably confirm the original research reports. The Committee concluded that there is currently no clear evidence in support of a mobile phone-related effect on cognitive effects in humans.

3.2 Article: *'Mobile Phone Use and the Risk of Acoustic Neuroma'* by S. Lönn et al Epidemiology 2004; 15(6):653-659.

In this population-based case-control study the authors identified all cases age 20 to 69 years diagnosed with acoustic neuroma during 1999 to 2002 in certain parts of Sweden. Controls were randomly selected from the study base, stratified on age, sex, and residential area. Detailed information about mobile phone use and other environmental exposures was collected from 148 (93%) cases and 604 (72%) controls. The overall odds ratio for acoustic neuroma associated with regular mobile phone use was 1.0 (95% CI = 0.6 –1.5). Ten years after the start of mobile phone use the estimated relative risk increased to 1.9 (95% CI = 0.9–4.1); when restricting to tumors on the same side of the head as the phone was normally used, the relative risk was 3.9 (95% CI = 1.6 –9.5). The authors concluded their findings do not indicate an increased risk of acoustic neuroma related to short-term mobile phone use after a short latency period. However, the data suggest an increased risk of acoustic neuroma associated with mobile phone use of at least 10 years' duration.

This article is one of a large number of publications expected from the so-called Interphone Study which is an international collaboration coordinated by the World Health Organization's cancer research institute, IARC (International Agency for Research on Cancer). It involves 13 nations and looks at the incidence of head and neck cancers in mobile phone users. It is the largest epidemiological study in this area.

IARC commented that the results were based on 12 exposed cases. To date, few studies have included sufficient numbers of cases among long-term users to allow a definitive conclusion about a possible association between mobile telephone use and the risk of acoustic neuroma. These results therefore need to be confirmed in other studies before firm conclusions can be drawn. Results of other national components of the Interphone Study should be published in the next two years. It is of interest to note that the results of the Danish acoustic neuroma study were published last year and, although also based on small numbers, did not support the results from the Swedish study.

The first paper from the international analyses, which will cover over 1000 cases of

acoustic neuroma, is expected to be published this year.

3.3 Article: *'Long-Term Mobile Phone Use and Brain Tumor Risk'* by S. Lönn et al Am J Epidemiol 2005;161:526–535.

The authors identified all cases aged 20–69 years who were diagnosed with glioma or meningioma during 2000–2002 in certain parts of Sweden. Randomly selected controls were stratified on age, gender, and residential area. Detailed information about mobile phone use was collected from 371 (74%) glioma and 273 (85%) meningioma cases and 674 (71%) controls. For regular mobile phone use, the odds ratio was 0.8 (95% CI = 0.6, 1.0) for glioma and 0.7 (95% CI = 0.5, 0.9) for meningioma. Similar results were found for more than 10 years' duration of mobile phone use. No risk increase was found for ipsilateral phone use for tumours located in the temporal and parietal lobes. Furthermore, the odds ratio did not increase, regardless of tumour histology, type of phone, and amount of use. This study includes a large number of long-term mobile phone users, and the authors conclude that the data do not support the hypothesis that mobile phone use is related to an increased risk of glioma or meningioma.

This study was the Swedish part of the Interphone Study investigating malignant glioma or meningioma.

3.4 Article: 'Cellular telephones and risk for brain tumors. A population-based, incident case-control study' by H. C. Christensen et al Neurology 2005;64:1189–1195.

The objective of this study was to evaluate a possible association of glioma or meningioma with use of cellular telephones, using a nationwide population-based case–control study of incident cases of meningioma and glioma. The authors ascertained all incident cases of glioma and meningioma diagnosed in Denmark between September 1, 2000, and August 31, 2002. They enrolled 252 persons with glioma and 175 persons with meningioma aged 20 to 69. The authors also enrolled 822 randomly sampled, population-based controls matched for age and sex. Information was obtained from personal interviews, medical records containing diagnoses, and the results of radiologic examinations. For a small number of cases and controls, the authors obtained the numbers of incoming and outgoing calls. They evaluated the memory of the respondents with the Mini-Mental State Examination and obtained data on socioeconomic factors from Statistics Denmark. There were no material socioeconomic differences between cases and controls or participants and non-participants. Use of a cellular telephone was associated with a low risk for high-grade glioma (OR, 0.58; 95% CI = 0.37 to 0.90). The risk estimates were closer to unity for low-grade glioma (1.08; CI = 0.58 to 2.00) and meningioma (1.00; CI = 0.54 to 1.28).

The authors concluded that the results do not support an association between use of cellular telephones and risk for glioma or meningioma.

This study was the Danish part of the Interphone Study investigating malignant glioma or meningioma.

3.5 Article: 'Use of cellular telephones and brain tumour risk in urban and rural areas' by L. Hardell et al Occup Environ Med 2005;62:390–394.

The authors investigated the association between the use of cellular or cordless telephones and the risk for brain tumours in different geographical areas, urban and rural areas.

Patients aged 20–80 years, living in the middle part of Sweden, and diagnosed between 1 January 1997 and 30 June 2000 were included. One control matched for sex

and age in five year age groups was selected for each case. Use of different phone types was assessed by a questionnaire. The number of participating cases was 1429; there were 1470 controls. An effect of rural living was most pronounced for digital cellular telephones. Living in rural areas yielded an odds ratio (OR) of 1.4 (95% CI = 0.98 to 2.0), increasing to 3.2 (95% CI = 1.2 to 8.4) with >5 year latency time for digital phones. The corresponding ORs for living in urban areas were 0.9 (95% CI = 0.8 to 1.2) and 0.9 (95% CI = 0.6 to 1.4), respectively. This effect was most obvious for malignant brain tumours. The authors concluded that in future studies, place of residence should be considered in assessment of exposure to microwaves from cellular telephones, although the results in this study must be interpreted with caution due to low numbers in some of the calculations.

This publication contains a large number of statistical comparisons and uses small numbers in some calculations – a point acknowledged by the authors. Surprisingly the paper does not mention the report from Swedish Interphone Study (see above) by Lönn et al that concluded: "This study includes a large number of long-term mobile phone users, and the authors conclude that the data do not support the hypothesis that mobile phone use is related to an increased risk of glioma or meningioma."

3.6 Article: 'Case–control study of the association between the use of cellular and cordless telephones and malignant brain tumors diagnosed during 2000–2003.' by L. Hardell et al Environmental Research Published Online.

The authors performed a case–control study on the use of cellular and cordless telephones and the risk for brain tumours diagnosed during 2000–2003. They report the results for malignant brain tumours with data from 317 cases (88%) and 692 controls (84%). The use of analogue cellular phones yielded odds ratio (OR) of 2.6 and a 95% confidence interval (CI) of 1.5–4.3, increasing to OR = 3.5 and 95% CI = 2.0–6.4 with a > 10-year latency period. Regarding digital cellular telephones, the corresponding results were OR = 1.9, 95% CI = 1.3–2.7 and OR = 3.6, 95% CI = 1.7–7.5, respectively. Cordless telephones yielded OR = 2.1, 95% CI = 1.4–3.0, and with a > 10-year latency period, OR = 2.9, 95% CI = 1.6–5.2. The OR increased with the cumulative number of hours of use and was highest for high-grade astrocytoma. A somewhat increased risk was also found for low-grade astrocytoma and other types of malignant brain tumours, although not significantly so. In multivariate analysis, all three phone types studied showed an increased risk.

The results of both these studies by Hardell are also inconsistent with the results of the Swedish arm of the Interphone Study and an article *'Incidence trends of adult primary intracerebral tumors in four Nordic countries'* by S. Lönn et al Int. J. Cancer; 2004:108, 450-455 which concluded:

The overall incidence of all intracerebral tumors ranged from 8.4–11.8 for men and 5.8 –9.3 for women, corresponding to an average annual increase of 0.6% for men (95% confidence interval [CI] = 0.4, 0.7) and 0.9% for women (95% CI = 0.7, 1.0). The increase in the incidence was confined to the late 1970s and early 1980s and coincided with introduction of improved diagnostic methods. This increase was largely confined to the oldest age group. After 1983 and during the period with increasing prevalence of mobile phone users, the incidence has remained relatively stable for both men and women.

3.7 Article: 'Case-Control Study on Cellular and Cordless Telephones and the Risk for Acoustic Neuroma or Meningioma in Patients Diagnosed 2000–2003' by L. Hardell et al Neuroepidemiology 2005;25:120–128.

The authors performed a case-control study on the use of cellular and cordless telephones and the risk for brain tumours. They report the results for benign brain tumours with data from 413 cases (89% response rate), 305 with meningioma, 84 with acoustic neuroma, 24 with other types and 692 controls (84% response rate). For meningioma, analogue phones yielded odds ratio (OR) = 1.7, 95% confidence interval (CI) = 0.97–3.0, increasing to OR = 2.1, 95% CI = 1.1–4.3 with a 10-year latency period. Also digital cellular phones and cordless phones increased the risk to some extent. For acoustic neuroma, analogue phones gave OR = 4.2, 95% CI = 1.8–10 increasing to OR = 8.4, 95% CI = 1.6–45 with a 15-year latency period, but based on low numbers. Digital phones yielded OR = 2.0, 95% CI = 1.05–3.8, whereas for cordless phones OR was not significantly increased. In the multivariate analysis, analogue phones represented a significant risk factor for acoustic neuroma.

This publication from the Hardell group shares many of the limitations of previous studies, in particular, the large number of statistical comparisons and the small numbers used in some calculations – a point acknowledged by the authors. The results of this study may simply be mirroring a reported increase in intracranial meningiomas due to the increased detection rates following the introduction of CT scans in the late 1970's. In an article ***'Incidence of intracranial meningiomas in Denmark, Finland, Norway and Sweden, 1968- 1997'*** by L. Klaeboe et al Int. J. of Cancer Published Online: 28 Jun 2005 concluded:

In summary, our results provide some support for the idea that the introduction of computed tomography in the late 1970s has had an impact on the detection of cases in people aged 60 and over. The decrease in the rate or detection postmortem has affected the incidence time trend, but it also coincides with widespread use of new imaging technologies. The increasing trend shown for the female:male ratio in the group aged 35-59 years is consistent with the possibility that increasing use of hormones may affect the incidence of meningiomas in women.

3.8 Article: *'Mobile phones, mobile phone base stations and cancer: a review'* by J. E. Moulder et al Int. J. Radiat. Biol., 2005;81(3):189 – 203

This review summarizes the current state of evidence concerning whether the RF energy used for wireless communication might be carcinogenic. Relevant studies were identified by searching MedLine with a combination of exposure and endpoint terms. This was supplemented by a review of the over 1700 citations assembled by the Institute of Electrical and Electronics Engineers (IEEE) International Committee on Electromagnetic Safety as part of their updating of the IEEE C95.1 RF energy safety guidelines. Where there were multiple studies, preference was given to recent reports, to positive reports of effects and to attempts to confirm such positive reports. Biophysical considerations indicate that there is little theoretical basis for anticipating that RF energy would have significant biological effects at the power levels used by modern mobile phones and their base station antennas. The epidemiological evidence for a causal association between cancer and RF energy is weak and limited. Animal studies have provided no consistent evidence that exposure to RF energy at non-thermal intensities causes or promotes cancer. Extensive in vitro studies have found no consistent evidence of genotoxic potential, but in vitro studies assessing the epigenetic potential of RF

energy are limited. Overall, a weight-of-evidence evaluation shows that the current evidence for a causal association between cancer and exposure to RF energy is weak and unconvincing. However, the existing epidemiology is limited and the possibility of epigenetic effects has not been thoroughly evaluated, so that additional research in those areas will be required for a more thorough assessment of the possibility of a causal connection between cancer and the RF energy from mobile telecommunications.

3.9 Article: 'Controversial Cytogenetic Observations in Mammalian Somatic Cells Exposed to Radiofrequency Radiation' by Vijayalaxmia and G. Obeb Rdaiation RES. 2004;162:481–496.

This paper reviews the investigations published in scientific journals during 1990–2003 and attempts to identify probable reason(s) for the conflicting results. From their examination of 53 studies, the authors conclude that the preponderance of evidence shows that RF EMF is not genotoxic, and that many of the studies reporting positive results may have had experimental deficiencies. Most importantly, the increased genotoxicity observed in cells exposed to RF radiation could be related to RF radiation induced hyperthermia and may not be due to the RF-radiation exposure itself. There is documented evidence that hyperthermia, >39ºC, has numerous effects in mammalian cells, including alterations in cell proliferation and viability, induction of DNA strand breaks, SCE and micronuclei, and inhibition of the repair of DNA damage. Historically, there has been a 10% incidence of sporadic and non-reproducible positive results in micronucleus tests in *in-vivo* investigations in rodents. The authors also discuss significant confounding issues associated with *in-vitro* experiments and possible random chance leading to a positive effect due the multiple end points studied without appropriate statistical procedures.

3.10 Further controversial cytogenetic observations and reports.

There was media interest in a study from Germany, which is part of the EU funded REFLEX project (VERUM Foundation, 2004). This has reported effects of radiofrequency (RF) fields on cells in culture and has led to suggestions that mobile phones may cause cancer. It was performed by a partnership of 12 research groups from seven European countries, under the co-ordination of the Verum Foundation in Munich. In response the National Radiological Protection Bureau (NRPB) now the Health Protection Agency in the UK stated:

The reported effects appear to show very high levels of specificity with regard to cell type, exposure condition and the biological endpoint under consideration. Taken together, the results may suggest that certain types of exposure can cause genetic damage in certain cell types. However, if RF fields do cause genotoxic or carcinogenic effect, a consistent pattern of responses would be expected. Similarly these responses would be expected to be consistent in different cell types exposed to the same fields. Evidence of a consistent dose-response relationship would also strengthen the plausibility of any response.

While some responses do seem to have been repeated by different laboratories, others do not appear to have been seen consistently across the project. Also some only occurred in one cell type and not in others, and some changes were observed at one field intensity but not at higher or lower intensities.

Overall this inconsistency does not suggest that robust responses have been observed and the extent to which experimental artefacts may be operating is unclear. The physiological significance of some of the reported changes, for example in the changes in gene and protein expression, were commented on by the authors themselves and their biological relevance questioned.

3.11 Article: 'Mobile Phones and Health. Report by the Board of NRPB.' ; Doc NRPB 15(5) 1-116 (2004).

The Board of National Radiological Protection Bureau (NRPB) published a major document on mobile phones and health. The review updates an earlier report published in 2000 by the UK Independent Expert Group on Mobile Phones and Health (IEGMP, Chairman Sir William Stewart). The main conclusion is that there is no hard evidence at present that the health of the public, in general, is being affected adversely by the use of mobile phone technologies, but uncertainties remain and a continued precautionary approach to their use is recommended until the situation is further clarified. The report made a number of recommendations in line with the use of a precautionary approach including:

particular attention be given to how best to minimise exposure of potentially vulnerable sub-groups such as children and to consider the possibility that there may be other sub-groups who may be particularly sensitive to radiowaves.

In response to the NRPB report the US Food and Drug Administration stated - http://www.fda.gov/cellphones/

FDA agrees with the NRPB on its conclusions that there is "no hard evidence of adverse health effects on the general public" from exposure to radiofrequency energy while using wireless communication devices.

With regards to the safety and use of cell phones by children, the scientific evidence does not show a danger to users of wireless communication devices including children.

3.12 EMR information package launched

The Australian Communications Authority (ACA) launched a comprehensive information package on electromagnetic radiation (EMR) and mobile phone towers. The package, Mobile Phone Towers and EMR – Information for Communities and Local Councils, was developed by the ACA and the ARPANSA. It aims to address community concerns about EMR and health issues, particularly those associated with the installation of mobile phone infrastructure, by providing information on electromagnetic emissions, the deployment of mobile phone towers, use of mobile phone handsets and associated health issues. The package includes a series of ACA and ARPANSA fact sheets and frequently asked questions, the ACA's Mobile phones, your health and radiofrequency electromagnetic radiation and Telecommunications Facilities – Information for rural communities' brochures, and a DVD Mobile Communications and Health. A web portal, which contains all the information in the package, can be accessed through emr.aca.gov.au.

3.13 Article: 'Advances in childhood leukaemia: successful clinical-trials research leads to individualised therapy.' by D. S. Ziegler et al MJA 2005; 182: 78–81.

The authors commented:

Exposure to electromagnetic fields has been ruled out as playing any significant role.

In response to this article Dr B Hocking wrote to the editor of the MJA stating:

The role of magnetic fields in childhood leukaemia cannot be "ruled out", given the substantial epidemiological evidence, the international classification of magnetic fields as a possible carcinogen, and the subtlety of gene–environment interactions.

Ziegler et al responded:

Hocking states that electromagnetic fields cannot be ruled out as a cause of childhood leukaemia. However, several large studies

have all failed to find any association between childhood exposure to electromagnetic radiation and leukaemia. The two pooled meta-analyses Hocking refers to both found no increased incidence of leukaemia with exposure to electromagnetic fields of < 0.4 microtesla. Although there was an increased risk of leukaemia with exposure to ≥0.4 microtesla, 99.2% of children with leukaemia had not received such a high level of exposure. In addition, both studies acknowledged the potential for selection bias. As such, for the overwhelming majority of children with leukaemia, exposure to electromagnetic fields does not play any significant causative role. Although we agree its effect cannot be ruled out for the remaining < 1% of patients, it should not be given undue epidemiological weight.

3.14 Article: 'Childhood cancer in relation to distance from high voltage power lines in England and Wales: a case-control study' by G Draper et al BMJ 2005 330(4)

The objective of this case control study was to determine whether there is an association between distance of home address at birth from high voltage power lines and the incidence of leukaemia and other cancers in children in England and Wales. Cancer registry records of 29,081 children with cancer, including 9,700 with leukaemia aged 0-14 years and born in England and Wales, 1962-95 were studied. Controls were individually matched for sex, approximate date of birth, and birth registration district. No active participation was required. National Grid records were used to determine the distance from home address at birth to the nearest high voltage overhead power line in existence at the time. The results showed that compared with those who lived > 600 m from a line at birth, children who lived within 200 m had a relative risk of leukaemia of 1.69 (95% confidence interval 1.13 to 2.53); those born between 200 and 600 m had a relative risk of 1.23 (1.02 to 1.49). There was a significant ($P < 0.01$) trend in risk in relation to the reciprocal of distance from the line. No excess risk in relation to proximity to lines was found for other childhood cancers. The authors concluded that there is an association between childhood leukaemia and proximity of home address at birth to high voltage power lines, and the apparent risk extends to a greater distance than would have been expected from previous studies. About 4% of children in England and Wales live within 600 m of high voltage lines at birth. If the association is causal, about 1% of childhood leukaemia in England and Wales would be attributable to these lines, though this estimate has considerable statistical uncertainty. There is no accepted biological mechanism to explain the epidemiological results; indeed, the relation may be due to chance or confounding.

3.15 Article: 'Day care in infancy and risk of childhood acute lymphoblastic leukaemia: findings from UK case-control study.' by C Gilham et al. BMJ, doi:10.1136/bmj.38428.521042.8F (published 22 April 2005).

The United Kingdom childhood cancer study (UKCCS) is a large population based case-control study of childhood cancer across 10 regions of the UK. The participants were 6305 children (aged 2-14 years) without cancer; 3140 children with cancer (diagnosed 1991-6), of whom 1286 had acute lymphoblastic leukaemia (ALL). The aim was to test the hypothesis that reduced exposure to common infections in the first year of life increases the risk of developing ALL. The authors reported that increasing levels of social activity were associated with consistent reductions in risk of ALL and a dose-response trend was seen.

These results support the hypothesis that reduced exposure to infection in the first few months of life increases the risk of developing acute lymphoblastic leukaemia.

Professor Mel Greaves FRS, Head of the Section of Haemato-Oncology, The Institute of Cancer Research, UK commented:

The UKCCS project has been the most exhaustive and detailed study ever conducted into identifying possible causes of leukaemia in children.

Analysis of the huge amount of data collected from over 1,500 families who had a child diagnosed with leukaemia during the course of the study is still ongoing.

However, it is clear that perceived risk factors such as living near sources of electromagnetic fields or natural radiation like radon are not principal causes, if at all, of leukaemia in children.

The epidemiological evidence fits with the known biology of the disease and points to an abnormal response in a child's immune system to infection favouring the outgrowth of blood cells which have been carrying a chromosomal/genetic lesion acquired before birth during foetal development. The timing or pattern of infections very early in life appears to be critical as is, most probably, the genetic background of the individual at risk.

The Committee considered this a compelling article.

3.16 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. However, the Committee acknowledges the current controversy over mobile phones and base stations and will continue to review the relevant research literature.

3.17 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 supported the Committee's position that overall, there is insufficient evidence to conclude that exposure to power frequency electric and magnetic fields, normally encountered in the environment, causes adverse health effects in humans.

APPENDICES

APPENDIX 1 - TABLES OF RESEARCH PROJECTS

(i) Research Projects Approved by the Committee

LICENSEE PRINCIPAL RESEARCHER RESEARCH WORK LOCATION	RESEARCH PROJECT TITLE
Austin Health Professor Ego Seeman Department of Endocrinology	Open-Label Study To Determine How Prior Therapy With Alendronate Or Risedronate In Postmenopausal Women With Osteoporosis Influences The Clinical Effectiveness Of Teriparatide: HMR4003B/404
Royal Melbourne Hospital Dr. Joe Sasadeusz Victoria Infectious Diseases Service	Randomized, Double-Blind, Multicentre Study To Compare The Safety And Efficacy Of Viramidine To Ribavirin In Treatment-Naïve Patients With Chronic Hepatitis C
Austin Health Dr Nilupul Perera Department of Neurology	The Influence Of Inflammation On The Survival Of The Ischaemic Penumbra And Clinical Outcome In Stroke
St Vincent's Hospital Ms Sue Brenton	A Multicentre, Double-Blind, Placebo-Controlled Randomised Trial Of The Efficacy, Safety And Tolerability Of 1.0mg Of R03300074 In Patients With Symptomatic Emphysema Secondary To Alpha-1-Antitrypsin Deficiency

(ii) Research Projects Recommended for Approval by the Committee Subject to Modifications or Further Information	
Royal Children's Hospital Dr. Justin Brown	A Controlled, Randomised Parallel Group Study Comparing The Effects Of Oral Oestrogen With Transdermal Oestrogen When Used For Pubertal Induction And Continued Hormone Replacement In Turner Syndrome
Box Hill Hospital Professor Hatem Salem	A Comparison Of The Oral Anticoagulant LY517717 Difumarate To Subcutaneous Enoxaparin For The Prevention Of Venous Thromboembolic Events (VTE) Post-Total Hip Replacement (THR) And Post-Total Knee Replacement (TKR) Surgery LY517717 Difumarate. Protocol H8G-MC-EPBB(A)
Southern Health – Monash Medical Centre A/Prof William Sievert Department of Medicine	A Randomised, Double Blind Trial Of Ldt (Telbivudine) Versus Lamivudine In Adults With Decompensated Chronic Hepatitis B And Evidence Of Cirrhosis. Protocol NV-02B-011
Southern Health - Monash Medical Centre Prof Peter Kerr	Study Of Tight Fluid Control On Nutritional And Inflammatory Parameters
Box Hill Hospital Professor Chris Bladin	A Randomised, Observed-Blind, Placebo-Controlled, Dose-Escalation Study of Reconstituted High-Density Lipoprotein (rHDL) in Patients with Acute Stroke
Wangaratta Base Hospital Mr Robert Williams Department of Nuclear Medicine	A Study To Evaluate The Addition Of Dipyridamole To Repeat Negative Sestamibi Parathyroid Imaging
Baker Heart Research Institute Dr Elisabeth Lambert	Sympathetic Nerve Activity and Carotid Blood Flow Measurements in Patients with Postural Tachycardia Syndrome and Healthy Subjects

(ii) Research Projects Recommended for Approval by the Committee Subject to Modifications or Further Information	
St Vincent's Hospital Dr Matthew Conron Department of Respiratory Medicine	A Multi-center, randomised, double-blind, placebo-controlled Phase 2a dose-response study of the safety, and tolerability, of two doses (2.5 and 5.0mg) of R03300074 given 4 weeks to patients with moderate to severe symptomatic COPD with emphysema
Royal Melbourne Hospital Dr Abe Rubinfeld Department of Respiratory Medicine	A Double-Blind, randomized, Placebo-Controlled, Multi-centre, Parallel-Group, Dose-Ranging Study of L-000883191 in Patients with COPD
Monash Medical Centre – Southern Health Assoc. Professor Geoff Littlejohn	A Randomized, Double-Blind, Controlled, Parallel Group Study Of The Safety And Prevention Of Structural Joint Damage During Treatment With MRA Versus Placebo, In Combination With Methotrexate, In Patients With Moderate To Severe Active Rheumatoid Arthritis. Protocol No. WA17823
Monash Medical Centre – Southern Health A/Prof Eng Gan	A Phase III Randomised, Parallel Group, Double-Blind, Active Controlled Study To Investigate The Efficacy And Safety Of Two Different Dose Regimens Of Orally Administered Dabigatran Etexilate Capsules ((150 Or 220mg Once Daily Starting With Half Dose (I.E. 75 Or 110mg) On The Day Of Surgery)) Compared To Subcutaneous Enoxaparin 40 Mg Once Daily For 28-35 Days, In Prevention Of Venous Thromboembolism In Patients With Primary Elective Total Hip Replacement
The Alfred Hospital A/Prof Rachelle Buchbinder	Efficacy And Safety Of Vertebroplasty For The Treatment Of Painful Osteoporotic Spinal Compression Fractures: A Randomised Double-Blind Placebo-Controlled Trial
Western Hospital Dr Shen Lim	Multidetector-Row Computed Tomographic Angiography And Magnetic Resonance Angiography In The Assessment Of Carotid Artery Stenosis In Patients At Risk Of Stroke

(ii) Research Projects Recommended for Approval by the Committee Subject to Modifications or Further Information

Southern Health – Monash Medical Centre A/Prof Eng Gan Haematology Department	Once-Daily Oral Factor Xa Inhibitor BAY 59-7939 In Patients With Acute Symptomatic Deep-Vein Thrombosis. The Einstein-DVT Dose-Finding Study.
Southern Health – Monash Medical Centre A/Prof Jim Cameron Cardiovascular Research Centre	A Phase III, 18-Month, Multicenter, Randomized, Double-Blind, Active-Controlled Clinical Trial To Compare Rosiglitazone Versus Glipizide On The Progression Of Atherosclerosis In Subjects With Type 2 Diabetes Mellitus And Cardiovascular Disease – Avandia AVD100521 Study
Deakin University A/Prof Shona Bass Centre of Physical Activity and Nutrition Research	The Effects Of Weightlifting Exercise On Bone Mineral Density, Bone Shape And Body Height During Adolescence
Austin Health Professor Mary Galea	Can Vibration Training Restore Bone Strength And Change Muscle Function In Individual With Chronic Spinal Cord Injury?
The University of Melbourne Alexander Bennett	Clinical Predictors of the Response to Glucosamine Sulphate in Chronic Knee Pain

(ii) Research Projects Recommended for Approval by the Committee Subject to Modifications or Further Information	
Barwon Health Dr John Amerena	04/75 Dr John Amerena: Placebo Controlled Double Blind Dose Ranging Study of the Efficacy and Safety of SSR149744C 50, 100, 200, or 300mg OD, with Amiodarone as Calibrator for the Maintenance of Sinus Rhythm in Patients with Recent Atrial Fibrillation/Flutter
The University Of Melbourne Dr Rana Hinman School of Physiotherapy	Knee malalignment and quadriceps strengthening in medial knee osteoarthritis
Austin Hospital A/Prof Ego Seeman	A Randomised, Double-blind, Placebo-controlled, Parallel group, Multicentre, Two-tear Phase III Study to determine the Efficacy and Safety of Risedronate Therapy Administered 35mg once a week in Men with Osteoporosis
The University of Melbourne A/Prof Kim Bennell School of Physiotherapy	Effects of shoe insoles on symptoms and disease progression in knee osteoarthritis
The Alfred Hospital Dr Anita Wluka Dept. of Epidemiology & Preventative Medicine	The effect of weight loss on knee cartilage volume
Southern Health – Monash Medical Centre Dr Nigel Stepto Cardiovascular Research Centre	'Role of Exercise in Treatment of Women with Polycystic Ovary Syndrome: Mechanisms of Action'

(ii) Research Projects Recommended for Approval by the Committee Subject to Modifications or Further Information

Western Hospital Dr Kean Soon	CT Angiography to Facilitate Percutaneous Coronary Intervention of Chronic Total Coronary Occlusions (CATCACTO Study)
A/Prof Jonathan Shaw International Diabetes Institute	A One-Year, Open, Randomised, Parallel, Three-Arm Study, Comparing Exubera ® (Insulin Dry Powder Pulmonary Inhaler) vs. Avandia ® (rosiglitazone maleate) as Add-on Therapy vs. Exubera ® Substitution Sulfonylurea in Patients with Type 2 Diabetes, Poorly Controlled on Combination Sulfonylurea and Metformin Treatment. Protocol #A2171017.
Barwon Health A/Prof Richard Bell	Biphosphonate And Anastrozole Trial - Bone Maintenance Algorithm Assessment (BATMAN)
Southern Health – Monash Medical Centre Dr Amanda Wood	Effects Of Repetitive Transcranial Magnetic Stimulation (Rtms) On Mood, Serotonin1A Binding Potential, Neuropsychological Performance, And Connectivity Of The Dorsolateral Prefrontal Cortex In Healthy Controls
The University of Melbourne A/Prof Kim Bennell School of Physiotherapy	The Role Of Subchondral Bone In Knee Osteoarthritis- Reliability Study
Western Hospital Mr Harry Tsigaras	'Comparison Between A Cementless Monoblock (One-Piece) Trabecular Metal Tibial Tray And A Cementless Modular (Two-Piece) Titanium Tibial Tray In Total Knee Replacement
The University of Melbourne A/Prof Kim Bennell School of Physiotherapy	Role Of Musculoskeletal Biomechanical Factors In Cartilage Loss In Those Who Undergo Partial Medical Meniscectomy

(ii) Research Projects Recommended for Approval by the Committee Subject to Modifications or Further Information	
Royal Melbourne Hospital Dr Peter Wong	A randomised, double-blind, placebo controlled, parallel group study of the safety and efficacy of MRA in patients with moderate to svere active rheumatoid arthritis and an inadequate response to current DMARD therapy
Box Hill Hospital Dr Richard Simpson, Eastern Clinical Research Unit	A One-year, open, randomized, parallel, three-arm study, comparing Exubera (insulin dry powder pulmonary inhaler) vs Avandia (rosiglitazone maleate) as add-on therapy vs Exubera substitution of sulfonylurea in patients with type 2 diabetes, poorly controlled on combination sulfonylurea and metformin treatment
Austin Health A/Prof Richard MacDonell	A Phase 2, Double-blind, Placebo-controlled, Randomized, Dose-ranging Study of Multiple Subcutaneous Injections of Human Monoclonal Antibody to IL-12p40 (CNTO 1275) in Subjects with Relapsing-remitting Multiple Sclerosis
Austin Health Dr Henry Ma	Studies of the Ischemic Penumbra in Acute stroke using PET and ^{18}F-Fluoromisonidazole
Box Hill Hospital Professor Michael Grigg	Phase 3, Multicenter, Multi-National, Randomised, Partial Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Alfimeprase in Subjects with Acute peripheral Arterial Occlusion (NAPA-2)
Barwon Health A/Prof Mark Kotowicz	A 3-Year, Double-Blind Extension To CZOL44H2301 To Evaluate The Long Term Safety And Efficacy Of Zolendronic Acid In The Treatment Of Osteoporosis In Postmenopausal Women Taking Calcium And Vitamin D
Box Hill Hospital Dr Paul Coughlin	Once-Daily Oral Direct Factor Xa Inhibitor Bay 59-7939 In Patients With Acute Symptomatic Deep-Vein Thrombosis. The Einstein-DVT Dose-Finding Study
Box Hill Hospital Professor Chris Bladin	A Randomised Trial To Establish The Effects Of Early Intensive Blood Pressure Lowering On Death And Disability In Patients With Stroke Due To Acute Intracerebral Haemorrhage (INTERACT)

(ii) Research Projects Recommended for Approval by the Committee Subject to Modifications or Further Information	
Royal Melbourne Hospital Mr Gabriel Silver Department of Neurology	Randomised, Double-Blind, Placebo Controlled, Multi-Centre, Parallel Groups Confirmatory Efficacy and Safety Trial of Activated Recombinant Factor VII (NovoSeven ® / Niastase ®) in Acute Intracerebral Haemorrhage
Box Hill Hospital. Professor Hatem Salem	A Dose Ranging Trial for the Evaluation of the Safety, Tolerability and Efficacy of Odiparcil in the Prevention of Venous Thromboembolism Following Total Knee Replacement Surgery
Royal Melbourne Hospital A/Prof Andrew Grigg	A Multi-Centre Phase 111 Open-Label Randomized Study In Patients With Advanced Follicular Lymphoma Evaluation That Benefit Of Maintenance Therapy With Ritumab After Induction Of Response With Chemotherapy Plus Rituximab In Comparison With No Maintenance Therapy
Royal Melbourne Hospital Professor Stephen Davis	A Prospective, Randomised, Double Blind, Placebo-Controlled, Single Bolus, Multinational, Multicenter, Parallel Group, Dose Ranging Study Of Desmoteplase (INN) In The Indication Of Acute Stroke
The Geelong Hospital Professor Geoff Nicholson	A Phase 111, Multicenter, Double-Blind, Randomized, Active-controlled, Parallel Group, Non-inferiority Study Comparing 150 mg Risedronate Monthly with 5 mg Risedronate Daily in the Treatment of Postmenopausal Osteoporosis as Assessed at 12 and 24 months

(iii) Research Projects requiring further information before being considered by the Committee	
Monash University Dr Nellie Georgiou-Karistiani	Improved Intelligibility In A Brain Injured Speaker By Use Of Adaptive Role-Playing
Box Hill Hospital and Maroondah Hospital Professor Hatem Salem	A Phase III, Randomised, Parallel-Group, Double-Blind, Active Controlled Study To Investigate The Efficacy And Safety Of Two Different Dose Regimens Of Orally Administered Dabigatran Etexilate Capsules [150 Or 220 Mg Once Daily Starting With A Half Dose (I.E.75 Or 110 Mg) On The Day Of Surgery] Compared To Subcutaneous Enoxaparin 40 Mg Once Daily For 8 ± 2 Days, In Prevention Of Venous Thromboembolism In Patients With Primary Elective Total Knee Replacement Surgery. RE-MODEL (Thromboembolism Prevention After Knee Surgery)
Box Hill Hospital and Maroondah Hospital Professor Hatem Salem	A Phase III Randomised, Parallel Group, Double-Blind, Active Controlled Study To Investigate The Efficacy And Safety Of Two Different Dose Regimens Of Orally Administered Dabigatran Etexilate Capsules [150 Or 220 Mg Once Daily Starting With Half Dose (I.E. 75 Or 110 Mg) On The Day Of Surgery] Compared To Subcutaneous Enoxaparin 40 Mg Once Daily For 28-35 Days, In Prevention Of Venous Thromboembolism In Patients With Primary Elective Total Hip Replacement Surgery. RE-NOVATE (Extended Thromboembolism Prevention After Hip Surgery)
Box Hill Hospital Professor Chris Bladin	A Randomised, Double-Blind, Placebo-Controlled, Single Bolus, Multinational, Multi-Centre, Parallel Group, Dose Ranging Study Of Desmoteplase (INN) In The Indication Of Acute Stroke

(iv) Research Projects Submitted that did not Require Committee Approval	
Southern Health - Monash Medical Centre Professor R Thomas	Using gene expression profiles to predict the response to chemoradiotherapy in patients with oesophageal cancer
Box Hill Hospital Dr Paul Fogerty	A Phase 3, Randomised, Double-Blind, Parallel-Group, Multinational Trial of Intravenous Telavancin Versus Vancomycin for Treatment of Hospital-Acquired Pneumonia with a Focus on Patients with infections Due to Methicillin-Resistant Staphylococus Aureus
Royal Melbourne Hospital A/Prof. Rowan Walker Department of Nephrology	Assessment of Enverolimus in addition to Calcineurin Inhibitor Reduction in Maintenance Renal Transplant Recipients (ASCERTAIN). CREC 2004.256
Royal Melbourne Hospital and Western Hospital Dr Richard de Boer	HREC Project 2004.234- A Randomised, Double-Blind Multicentre 2-Stage Phase III Study Of Bevacizumab In Combination With Cisplatin And Gemcitabine In Patients With Advanced Or Recurrent Non-Squamous Non-Small Cell Lung Cancer, Who Have Not Received Prior Chemotherapy. Protocol No. BO17704A
Royal Melbourne Hospital and St Vincent's Hospital Dr Nathan Better	Protocol AUS-001-I-PE – Multi Centre, Phase Ib Safety Study Of Anti-Fibrin Humanised Monoclonal Antibody (DI-DD3B6/22-80B3) Fab' Protein Fragment (Thromboview®) Conjugated With Technetium-99m In The Detection Of Pulmonary Emboli
Royal Melbourne Hospital A/Prof Andrew Grigg	A Randomized Two-Arm, Multicenter, Open-Label Phase 11 Study of BMS-354825 Administered Orally at a Dose of 70 mg Twice Daily or 140 mg Once daily in Subjects with Chronic Myeloid Leukemia in Accelerated Phase or in Myeloid or Lymphoid Blast Phase or with Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia who are Resistant to Intolerant to Imatinib Mesylate (Gleevec)

Appendix 2 – Summary of Authorisations

(i) Operator Licences

(i) Summary of Operator Licences as of 30 September 2005	
Category	**Type of radiation source permitted to be dealt with**
Radiologist Total: 308	Irradiating apparatus: 268 Irradiating Apparatus & Unsealed Radioactive Sources: 40
Radiation Oncologist Total: 51	Irradiating apparatus: 5 Sealed Radioactive Sources: 1 Irradiating Apparatus & Sealed Radioactive Sources: 21 Irradiating Apparatus, Sealed & Unsealed Radioactive Sources: 24
Nuclear Medicine Specialist Total: 39	Unsealed Radioactive Sources: 35 Irradiating Apparatus & Sealed Radioactive Sources: 1 Sealed & Unsealed Radioactive Sources: 1 Irradiating Apparatus & Unsealed Radioactive Sources: 2
General Medical Practitioner (G.P.) Total: 172	Irradiating apparatus: 172
Dentist Total: 2207	Irradiating apparatus: 2207
Chiropractor Total: 225	Irradiating apparatus: 225

(i) Summary of Operator Licences as of 30 September 2005

Category	Type of radiation source permitted to be dealt with
Dermatologist Total: 3	Irradiating apparatus: 3
Ophthalmologist Total: 19	Sealed Radioactive Sources: 17 Sealed & Unsealed Radioactive Sources: 2
Other Medical Specialist Total: 65	Irradiating apparatus: 61 Unsealed Radioactive Sources: 4
Dental Therapist Total: 211	Irradiating apparatus: 211
Tester Total: 74	Irradiating apparatus: 27 Sealed Radioactive Sources: 2 Irradiating Apparatus & Sealed Radioactive Sources: 39 Irradiating Apparatus, Sealed & Unsealed Radioactive Sources: 6
Radiation Apparatus Service Technician Total: Sealed 268	Irradiating apparatus: 166 Sealed Radioactive Sources: 46 Irradiating Apparatus & Sealed Radioactive Sources: 51 Irradiating Apparatus, Sealed & Unsealed Radioactive Sources: 5
Researcher (with human volunteers) Total: 47	Irradiating apparatus: 37 Sealed Radioactive Sources: 1 Unsealed Radioactive Sources: 8 Sealed & Unsealed Radioactive Sources: 1

(i) Summary of Operator Licences as of 30 September 2005

Category	Type of radiation source permitted to be dealt with
Veterinarian Total: 701	Irradiating apparatus: 679 Irradiating Apparatus & Sealed Radioactive Sources: 12 Irradiating Apparatus & Unsealed Radioactive Sources: 9 Irradiating Apparatus, Sealed & Unsealed Radioactive Sources: 1
Industrial Radiographer Total: 285	Irradiating apparatus: 76 Sealed Radioactive Sources: 7 Irradiating Apparatus & Sealed Radioactive Sources: 202
Radiation Consultant Total: 4	Sealed & Unsealed Radioactive Sources: 3 Irradiating Apparatus, Sealed & Unsealed Radioactive Sources: 1
Dental Hygienist Total: 90	Irradiating apparatus: 90
Cardiologist Total: 73	Irradiating apparatus: 72 Unsealed Radioactive Sources: 1
Borehole Logger Total: 50	Sealed Radioactive Sources: 47 Irradiating Apparatus & Sealed Radioactive Sources: 3

(i) Summary of Operator Licences as of 30 September 2005

Category	Type of radiation source permitted to be dealt with
Portable Moisture/Density Meter Operator Total: 299	Irradiating apparatus: Sealed Radioactive Sources: 299 Unsealed Radioactive Sources: Irradiating Apparatus & Sealed Radioactive Sources: Sealed & Unsealed Radioactive Sources: Irradiating Apparatus & Unsealed Radioactive Sources: Irradiating Apparatus & Unsealed Radioactive Sources:
Paramedical Worker Total: 37	Irradiating apparatus: 30 Unsealed Radioactive Sources: 7
Radiologist & Nuclear Medicine Specialist Total: 28	Irradiating Apparatus & Unsealed Radioactive Sources: 28
Dental Therapist & Dental Hygienist Total: 25	Irradiating apparatus: 25
Service Technician & Tester Total: 8	Irradiating apparatus: 3 Sealed Radioactive Sources: 3 Irradiating Apparatus & Sealed Radioactive Sources: 1 Sealed & Unsealed Radioactive Sources: 1

(i) Summary of Operator Licences as of 30 September 2005

Category	Type of radiation source permitted to be dealt with
Service Person & Industrial Radiographer Total: 1	Irradiating Apparatus & Sealed Radioactive Sources: 1
Veterinarian & Dentist Total: 1	Irradiating Apparatus & Sealed Radioactive Sources: 1
Cardiologist & Researcher Total: 1	Irradiating Apparatus & Unsealed Radioactive Sources: 1
Vascular Surgeon Total: 26	Irradiating Apparatus: 26
Dental Assistant Total: 3	Irradiating Apparatus: 3
Veterinary Nurse Total: 6	Irradiating Apparatus: 3

(i) Summary of Operator Licences as of 30 September 2005

Category	Type of radiation source permitted to be dealt with
Synchrotron Accelerator Physicist Total: 6	Irradiating Apparatus: 6
Urologist Total: 4	Unsealed Radioactive Sources: 4
Radioisotope Application Engineer Total: 9	Sealed Radioactive Sources: 9

Total number of people licensed to deal with

- irradiating apparatus: 4402
- sealed radioactive sources: 429
- unsealed radioactive sources: 59
- irradiating apparatus and sealed radioactive sources: 332
- sealed and unsealed radioactive sources: 8
- irradiating apparatus and unsealed radioactive sources: 80
- irradiating apparatus, sealed and unsealed radioactive sources: 38

TOTAL NUMBER OF OPERATOR LICENSEES: 5348

(ii) Company/Institution Licences

(ii) Summary of Company/Institution Licences as of 30 September 2005	
Category	**Type of radiation source permitted to be dealt with**
Sales Total: 139	Irradiating Apparatus: 53 Sealed Radioactive Sources: 53 Unsealed Radioactive Sources: 18 Irradiating Apparatus & Sealed Radioactive Sources: 12 Sealed & Unsealed Radioactive Sources: 3
Industrial Total: 9	Unsealed Radioactive Sources: 9
Hospital Total: 15	Unsealed Radioactive Sources: 15
Pathology Laboratory Total: 10	Unsealed Radioactive Sources: 10
Education / Research Total: 42	Irradiating Apparatus: 1 Unsealed Radioactive Sources: 41
Research with Human Subjects Total: 26	Irradiating Apparatus, Sealed & Unsealed Radioactive Sources: 26
Radiotherapy Total: 3	Unsealed Radioactive Sources: 3
Nuclear Medicine Total: 57	Unsealed Radioactive Sources: 57

(ii) Summary of Company/Institution Licences as of 30 September 2005

Category	Type of radiation source permitted to be dealt with
Government Departments Total: 3	Unsealed Radioactive Sources: 3
Veterinary Total: 8	Unsealed Radioactive Sources: 8
Manufacture / Possession of Radioactive Sources Total: 1	Sealed Radioactive Sources: 1
Category	**Number of Company/Institution licences to transport radioactive substances**
Transport of Radioactive Substances	15
Transport of Low Level Waste	5

(ii) Summary of Company/Institution Licences as of 30 September 2005

Category	Type of radiation source permitted to be dealt with
Total number of organisations licensed to deal with – irradiating apparatus: 54 – sealed radioactive sources: 54 – unsealed radioactive sources: 164 – irradiating apparatus and sealed radioactive sources: 12 – sealed and unsealed radioactive sources: 3 – irradiating apparatus and unsealed radioactive sources: 0 – irradiating apparatus, sealed and unsealed radioactive sources: 26 Total number of organisations licensed to transport radioactive substances: 20 **TOTAL NUMBER OF COMPANY/INSTITUTION LICENSEES: 333**	

(iii) Registrations

(iii) Summary of Registrations as of 30 September 2005

Category	Irradiating Apparatus	Sealed Radioactive Sources	Total
Fixed Plain Radiography	466	0	466
Fixed Fluoroscopy/ Image Intensifier	194	0	194
CT Scanner	154	0	154
Linear Accelerator	36	0	36
Radiotherapy	0	14	14
Dermatology	1	1	2
Ophthalmology	0	19	19
Dental	2159	0	2159
Chiropractic	66	0	66
Plain Radiography (General Practitioner)	24	0	24
X-ray Analysis	66	0	66
Irradiation Cell	0	3	3
Borehole Logging	0	32	32
Radiation Gauge	13	403	416
Portable Soil Moisture/Density Meter	0	153	153

(iii) Summary of Registrations as of 30 September 2005

Category	Irradiating Apparatus	Sealed Radioactive Sources	Total
Industrial Radiography	68	44	112
Veterinary	395	5	400
Calibration	2	130	132
Teaching	17	59	76
Other Industrial	22	98	120
Research	13	22	35
Other Medical	5	11	16
Mammography	160	0	160
OPG / Cephalometric unit	240	0	240
Cyclotron	3	0	3
Bone Mineral Densitometer	66	0	66
Mobile Image Intensifier	142	0	142
Condensor Discharge Mobile X-ray Unit	61	0	61
Lab Irradiator	0	8	8
Lithotripter	5	0	5
Industrial Radiography Crawler Guide Source	0	10	10

(iii) Summary of Registrations as of 30 September 2005

Category	Irradiating Apparatus	Sealed Radioactive Sources	Total
Veterinary Dental Unit	11	0	11
Therapy Simulator	5	0	5
Cabinet X-ray Equipment	70	0	70
Gas Chromatog.Electron Capture Detectors	0	21	21
Mobile Plain Radiography X-ray Unit	63	0	63
Hybrid SPECT-PET/CT scanner System	5	0	5
Superficial / Orthovoltage	11	0	11
TOTAL	**4543**	**1033**	**5576**

ABBREVIATIONS AND DEFINITIONS

ACA

Australian Communications Authority

AIR

Australian Institute of Radiography

AOA

Australian Orthopaedic Association

ANZBMS

Australian and New Zealand Bone Mineral Society

ACPSEM

Australasian College Physical Scientists & Engineers in Medicine

AVNRC

Australian Veterinary Nurse Resource Centre

ARPANSA

Australian Radiation Protection and Nuclear Safety Agency

CT

computed tomography

the Department

the Department of Human Services Victoria

DEXA

dual energy x-ray absorptiometry

the Directory

ARPANSA Publication:

National Directory for Radiation Protection Edition 1.0

EMF

electromagnetic field

EMR

electromagnetic radiation

EU

European Union

HREC

human research and ethics committee

ICRP

International Commission on Radiologic Protection

MHz

Megahertz, a unit of frequency

(1 MHz = 1,000,000 Hz)

MIT

medical imaging technologist

MJA

Medical Journal of Australia

MRTB

Medical Radiation Technologists Board

mSv

millisievert, a unit of equivalent and effective dose (1 mSv = 0.001 Sv)

NHMRC

National Health and Medical Research Council

PDY

professional development year

pQCT

peripheral quantitative computed tomography

RANZCR

Royal Australian and New Zealand College of Radiologists

RF

radiofrequency

Secretary

The Secretary, Department of Human Services Victoria

Tesla

a unit of magnetic flux density

VPRB

Veterinary Practitioners Registration Board