THE ANNUAL REPORT OF

THE RADIATION ADVISORY COMMITTEE

FOR THE FINANCIAL YEAR ENDING JUNE 2016

RADIATION ADVISORY COMMITTEE

Melbourne, Australia

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The Hon Jill Hennessy MP
Minister for Health
Minister for Ambulance Services

Dear Minister

Pursuant to Section 110 of the *Radiation Act 2005*, the Radiation Advisory Committee submits the 2016 annual report of the Committee for presentation to Parliament.

Yours faithfully

Dr Dean Morris
Chair
RADIATION ADVISORY COMMITTEE

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RADIATION ADVISORY COMMITTEE

The Radiation Advisory Committee (the Committee) is established under Part 10 of the *Radiation Act 2005*. The term of appointment for the Committee is the period 17 August 2014 to 16 August 2017.

(i) Composition

The Committee met on 6 occasions from July 2015 to June 2016.

The members of the Committee for the period from July 2015 to June 2016 were:

Dr Dean Morris **(Chair)** Head of Operations Australian Synchrotron **Meetings attended: 5**	**Dr. David Bernshaw** Consultant Radiation Oncologist Peter MacCallum Cancer Centre **Meetings attended: 4**
Mr Russell Booth Chief Nuclear Medicine Technologist Medical Imaging Department St Vincent's Hospital **Meetings attended: 6**	**Dr Ray Budd** Consultant medical physicist **Meetings attended: 5**
Dr. Roslyn Drummond Radiation Oncologist Peter MacCallum Cancer Centre **Meetings attended: 6**	**Professor Robert Gibson** Radiologist Royal Melbourne Hospital **Meetings attended: 3**
Dr Russell Horney Physicist Department of Medical Imaging and Radiation Sciences Monash University **Meetings attended: 6**	**Dr. Ken Joyner** Director Joyner and Associates Telecommunications Consultancy **Meetings attended: 3**
Mr Paul Marks Senior Medial Radiation Scientist Australian Radiation Protection and Nuclear Safety Agency **Meetings attended: 6**	**Mr Christopher Perry** Chief Radiographer EMI Radiology East Melbourne **Meetings attended: 6**

Mr Paul Tomlinson Senior Technician ALS Industrial **Meetings attended: 5**	**Dr Joanna Wriedt** Physiologist, Epidemiologist and Lawyer **Meetings attended: 5**

(ii) Responsibilities

The Committee is to advise the Minister for Health or the Secretary of the Department of Health and Human Services, on any matters relating to the administration of the *Radiation Act 2005*, referred to it by the Minister or the Secretary including the following:

(a) The promotion of radiation safety procedures and practices.

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

(c) Recommendation of which radiation sources should be prescribed as prescribed radiation sources.

(d) Recommendation of the nature, extent and frequency of tests to be conducted on radiation apparatus and sealed radioactive sources.

(e) Codes of practice, standards or guidelines with respect to particular radiation sources, radiation practices or uses.

Section 110 of the Radiation Act requires that the Committee must give the Minister a report on its activities during a financial year no later than 1 November following that year.

1. Introduction

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

- the regulatory requirements for various ionising radiation practices;
- non-ionising radiation matters;
- justification and dose optimisation in medical radiation procedures.

The terms of reference for the Committee are provided in Appendix 1.

The Committee would like to thank the Radiation Team of the Department of Health and Human Services, in particular Mr Morrie Facci, for its continuing assistance and support.

2. Ionising radiation

2.1 Radiation amendment regulations

The Committee noted the progress regarding the development of the proposed Radiation Amendment Regulations. The proposed regulations are required to implement fully the changes with respect to the security of high consequence radioactive material and to prescribe the offences that would incur infringement notices and give effect to other requirements of the Radiation Act.

The committee was advised that the development of the proposed Radiation Amendment Regulations was proceeding with the aim of making the regulations during the second half of 2016.

The committee also noted that the current Radiation Regulations 2007 sunset in August 2017 and was advised that the department had commenced planning for their replacement.

2.2 Audit of the regulatory areas of the Department of Health & Human Services by the Auditor-General

The Auditor General made a number of recommendations in March 2015 to improve regulation within the department. The recommendations were contained in a report entitled 'Managing Regulator Performance in the Health Portfolio'.

These recommendations are summarised in the committee's annual report for 2015 available at: https://www2.health.vic.gov.au/public-health/radiation/radiation-legislation-and-standards/radiation-advisory-committee

The committee was advised of the progress that the department was making in the implementation of the response to the recommendations of the Auditor-General.

The recommendations that have been particularly addressed by the department in the 2015/6 year have involved clearly defining the regulatory outcomes that the department is seeking to achieve and in the development of establishing a stakeholder engagement plan.

The Radiation Team's business plan now includes specific statements about the team's regulatory objectives and regulatory goals.

The regulatory objective is that stated in the Radiation Act 2005 - to *'protect the health and safety of persons and the environment from the harmful effects of radiation'.*

The regulatory goals which have been developed are:

- radiation protection principles underpin the use of radiation;
- informed stakeholders;
- radioactive material is stored securely and where authorised is disposed of safely and responsibly;
- to be prepared to respond to radioactive material incidents; and
- to be a sustainable and responsive best practice regulator.

To address the need for the Radiation Team to improve the way that it engages with its various stakeholders, the Radiation Team has commenced development of a stakeholder communication and engagement plan which will incorporate stakeholder mapping for the various radiation practices which are regulated and the identification of the best means of engaging with those stakeholders.

The committee requested that the stakeholder communication and engagement plan matters be discussed at its August 2016 meeting.

2.3 Issues in relation to disposal of radioactive material in the mineral sands industry

The committee was advised that Iluka Resources Limited (Iluka) has been mining mineral sands in the west of Victoria since 2005. Part of their operation includes disposing of waste by-products generated by their mineral separation plant in Hamilton into the disposal pit at its Douglas mine site, known as Pit 23.

Disposal into Pit 23 of the by-products of mining activities at the Douglas mine site, which produced Heavy Mineral Concentrate (HMC), and of the by-products from the processing of HMC at the Hamilton Mineral Separation Plant (MSP) commenced in 2011. Pit 23 has also been used for the disposal of by-product arising from mining activities around Ouyen and South Australia.

The department briefed the Committee on Iluka's proposal to continue the processing of HMC from its operations in South Australia (and possibly from proposed mines in NSW in the future) at the Hamilton MSP. This involved Iluka seeking authorisation from the Environment Protection Authority (EPA) and Horsham Rural City Council (HRCC) to continue to dispose of the waste by-products arising from the processing of heavy mineral concentrate at their Hamilton mineral separation plant into Pit 23.

The department advised that it had worked closely with HRCC and EPA and provided a submission to both bodies that assessed the health implications to the local community in relation to Pit 23. It should be noted that radiation practices such as the disposal of by-product material to the Douglas site's Pit 23 will continue to need to be regulated by the department regardless of the outcome of the current land use applications to HRCC and the EPA.

The department advised that in May 2016, the EPA informed the department and other stakeholders that it had assessed the works approval application from Iluka Resources to continue disposing of radioactive materials in Pit 23 at its Douglas Mine in western Victoria. EPA found that neither pollution nor environmental hazard has occurred or is likely to occur in the future as a result of current or proposed disposal activities.

Radon monitoring

In a related matter, the department advised that there had been some community concern about radon levels in the area adjacent to Pit 23 following the release of monitoring results by the Kanagulk Landcare Group (KLG).

Radon concentration is measured in units of becquerel per cubic metre (Bq/m^3).

KLG reported levels ranging from about 30 to 60 Bq/m^3.

Iluka, as part of its regulatory compliance monitoring regime, measured radon concentrations around Pit 23 and has found them to be consistent with pre-mining levels measured with the same type of monitor (< 12 Bq/m^3).

In response to community concern about reported levels of radon, the department advised that it commenced a 12 month outdoor radon monitoring program to monitor radon and to understand the inconsistencies in radon levels already monitored. Three types of radon monitors were used by the department: Real-time radon monitoring equipment and two different types of long-term track-etch monitors.

The department advised that real-time radon monitoring with two calibrated laboratory-type monitors had been performed at various locations, at different times of day and at different times of year. Track-etch monitors had been deployed by the department for varying periods (six weeks, three months, and six months).

When the department's results from all techniques were examined, two of the three sets of monitoring results were consistent with each other and showed that the current levels of radon are not measurably different from the pre-mining levels.

The department advised that the type of monitors used by KLG, supplied by the Australian Radiation Protection and Nuclear Safety Agency, did not provide consistent results. The department advised that it had discussed this finding with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

The department informed the committee that ARPANSA has advised that it changed to a new radon track-etch monitoring system in early 2016.

The committee noted that the radon monitoring results of the department (and Iluka) continue to show that the risks to the health of workers, the public and the environment are insignificant as a result of radon from the mining operations. In general, the committee was satisfied that the health risks from any of the radiation exposure pathways resulting from the Douglas mining activities are negligible.

The committee was supportive of the Department's work in this area and of the department's conclusion that health risks from any of the radiation exposure pathways resulting from the Douglas mining activities are negligible.

2.4 Proposed amendment number 7 to the National Directory for Radiation Protection

The department advised the committee that the proposed amendment to the National Directory for Radiation Protection lists a series of levels for the disposal of various types of radioactive material below which no regulatory authorisation is required. Disposal of amounts of radioactive material in excess of those levels is still possible but would require specific authorisation. The main difference with the current Victorian situation is that the proposed levels for discharges to sewer are generally more conservative than the already low levels used in Victoria. The current Victorian levels were based on an earlier draft of the national directory.

The proposed amendment also establishes levels for the disposal of radioactive material to landfill. This is not currently permitted in Victoria. Introduction of the option in Victoria would require consultation with other stakeholders such as the Environment Protection Authority because of their role in regulation of landfills.

The implication of the national adoption of proposed Amendment No.7 is that jurisdictions would need to take steps to implement it within their existing regulatory frameworks.

The most obvious implementation issue which has been identified to date is that the department will need to consider issuing specific authorisations for discharges to sewer from most, if not all, sites where certain types of nuclear medicine procedures are performed. For example, this is likely to include sites administering iodine-131 (used in some types of radiotherapy) to patients. In a hospital setting, these substances are usually excreted from the body whilst the patient is an in-patient. This means that a proportion of the material administered to a patient will enter the sewer system from the hospital. Even this small amount could potentially exceed the proposed levels. To avoid this potential problem, a hospital would need to obtain specific authorisation from the department based on a risk assessment.

The proposed amendment is awaiting endorsement by the Council of Australian Governments.

2.5 Proposed Adoption of the Code for the Safe Transport of Radioactive Material (2014)

The committee noted that, in December 2014, ARPANSA published a new version of the *Code for the Safe transport of Radioactive Material*. The new code is based on the most recent 2012 revisions to the relevant international regulations published by the International Atomic Energy Agency (IAEA).

The main changes to the previous 2008 transport code are administrative, grammatical or clarifying in nature. As a result, ARPANSA assessed that there would be little or no cost to industry apart from the initial familiarization with the new requirements.

ARPANSA advise that transport of radioactive materials by air and international waterways already incorporate the 2012 version of the international standard. They expect that any company involved with the import or export of radioactive material is already familiar with the requirements of the 2012 IAEA Regulations.

The main differences between the 2008 and 2014 transport codes most relevant to Victoria are:

- Replacement of the obligation to have a 'quality assurance program' with the new obligation to have a 'management system'.
- The requirement to notify of a non-compliance has been extended to include the consignee, carrier and any affected organisation. Previously this obligation applied only to the consignor.
- Changes to the marking requirements for 'overpacks' and 'excepted packages'.
- Documentation requirements before the first shipment of a package occurs.
- New requirements specified for the retention of documents.
- A new format for the consignor's declaration.

The department advised that it considered it important to take the necessary action to require compliance with the 2014 code to reduce the potential for problems for those licence holders needing to import or export radioactive material. This potential for a problem is particularly the case with the consignor's declaration.

The department advised that it will move to vary the relevant management licences to replace the current requirement to comply with the 2008 code with the requirement to comply with the 2014 code. The 2014 code can be found at:
http://www.arpansa.gov.au/publications/codes/rpsc-2.cfm

2.6 Draft Code for Radiation Protection in Planned Exposure Situations

ARPANSA has prepared a draft code of practice for radiation protection in planned exposure situations that is based on the section on planned exposure situations in the International Atomic Energy Agency (IAEA) publication *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards; General Safety Requirements' Part 3*.

The proposed code sets out the requirements in Australia for the protection of occupationally exposed persons, the public and the environment in planned exposure situations. The primary means of controlling exposure in planned exposure situations is by good design of facilities, equipment, operating procedures and through training.

In the Australian context, the requirements for planned exposure situations apply to the following practices:

- The production, supply, provision and transport of radioactive material and of devices that contain radioactive material, including sealed sources and unsealed sources, and of consumer products;
- The production and supply of devices that generate radiation, including linear accelerators, cyclotrons, and fixed and mobile radiography equipment;
- The use of radiation or radioactive material for industrial, veterinary, agricultural, legal or security purposes, including the use of associated equipment, software or devices where such use could affect exposure to radiation;
- The use of radiation or radioactive material for education, training or research, including any activities relating to such use that involve or could involve exposure to radiation or exposure due to radioactive material;
- The mining and processing of raw materials that involve exposure due to radioactive material.

The proposed code is not intended to apply to existing exposure situations, emergency exposure situations other than where the emergency situation arises from the planned activity, or exposure of a person to radiation received as a patient undergoing medical diagnosis or therapy, as a volunteer in medical research, or non-occupational exposure received as a consequence of assisting an exposed patient. These exposure situations are expected to be dealt with by later ARPANSA publications in the Radiation Protection Series or, in the case of medical exposures, by the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)* published by ARPANSA and supporting safety guides.

The committee noted the department's concerns regarding the first version of the planned exposure code particularly in relation to applying a 'one size fits all' approach whereby all radiation practices might be required to comply with the code regardless of the risks presented by that practice. The committee discussed this issue and, in general, expressed similar concerns. The department provided ARPANSA comments and feedback on the draft code.

The second version of the code was released for public comment and subsequently considered by the Radiation Health Committee of ARPANSA at its meeting on 15 June 2016. The department felt that, while the second version of the planned exposure code was an improvement in that it would allow the regulator to decide where a graded approach to regulation would apply, implementation of the code would still be a challenge.

The department advised that it will continue to keep the committee informed of developments in relation to this proposed code.

2.7 Draft Code for Radiation Protection in Medical Exposure

The committee was advised that ARPANSA had prepared a draft code for Radiation Protection in Medical Exposure (the medical code). The medical code is intended to replace the existing *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)* published by ARPANSA. ARPANSA had considered the IAEA publication GS-R-3, *The Management System for Facilities and Activities*, in developing the medical code. The department will consider the medical code, when published, in developing any new conditions on licences authorising medical radiation practices.

The proposed code has not yet been finalised.

2.8 Safety Guide on Radiation Protection of the Environment (2015)

The committee was briefed by the department as to the scope and intent of the recently published ARPANSA Safety Guide on Radiation Protection of the Environment. The reasons for the safety guide are based in international shifts towards specific protection of the environment independent of considerations of humans in that environment. The conceptual framework parallels that of protection of humans. The code, however, gives consideration to the development of reference organisms that live in the environment. Organisms are represented by simplified mathematical models to permit the calculation of external and internal radiation doses using publicly available scientific computer codes that have the ability to add user-defined organisms in the cases of unique Australian flora and fauna. The department will be seeking the advice of the committee in future considerations as to how the safety guide can be used to effect the requirements for protection of the environment in accordance with the scope of the Radiation Act.

2.9 Security of portable density/moisture gauges

Portable density/moisture gauges (PDMGs) are devices incorporating a small amount of radioactive material and are typically used to assess the level of compaction in road construction materials.

The committee was advised that a number of PDMGs have been stolen in Victoria in recent years. The majority of these thefts are from vehicles when they are parked overnight. The last one was taken from an open tray utility vehicle overnight. It was secured in the utility vehicle using nylon straps. There have also been thefts from closed tray utility vehicles and vehicles have been stolen which have happened to contain PDMGs.

At present, the licence holder has to comply with the requirements of the *Code of Practice and Safety Guide for Portable Density/Moisture Gauges Containing Radioactive Sources 2004* published by ARPANSA, which requires that the PDMG is secured at all times when being transported. This could be interpreted as being secure to prevent damage or falling off the vehicle, or to prevent theft. There is no further clarification on what is meant by secure at this time.

The department commenced a programme of inspections of companies authorised to possess PDMGs in February 2016. The aim of this was to gain a better understanding of methods of security currently being used during transport, with the intention of developing more prescriptive guidance for licence holders if required.

Following review of the information collected by the department during the inspections conducted up to the end of June 2016, it is proposed to vary existing management licences to mandate the methods which can be used to secure PDMGs during transport. Proposed methods of securing the PDMGs include:

- securing in a closed vehicle (i.e. van or closed tray ute),
- securing in a locked tool cabinet attached to an open tray ute, securing in a locked frame attached to an open tray ute,

- securing with chains locked to anchor points on an open tray ute.

The committee considered that the best method was firmly securing the PDMG inside a closed tray ute or, in the case of an open tray ute, securing it in a locked frame attached to the ute.

The committee supported the actions taken by the department to address the security of PDMGs.

2.10 Changes to management licence conditions authorising medical imaging procedures in relation to medical justification

The committee was advised that the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)* published by ARPANSA has been imposed as a condition of management licence and use licence in respect of radiation sources used for medical purposes since 2010.

Under the Radiation Act 2005, the responsible person in respect of a radiation source must hold a management licence that authorises the possession of that radiation source and the operator must hold a use licence that authorises the use of that radiation source. However, the radiation medical practitioner is not required to hold a licence to perform the role of the radiation medical practitioner as defined by the Code. The radiation medical practitioner is the practitioner responsible for the overall conduct of the procedure involving the exposure of the patient to ionizing radiation. In nuclear medicine, this person will normally be a nuclear medicine specialist, in radiation oncology, this person will normally be a radiation oncologist and in diagnostic or interventional radiology, this person will usually be a radiologist, but might also be, for example, a cardiologist or, for limited procedures, a general practitioner. As radiation medical practitioners may not necessarily use a radiation source, they do not necessarily need a use licence under the Radiation Act.

Prior to October 2015, the Code's requirement that the radiation medical practitioner undertake the justification and optimisation processes specified by the code were not enforceable under the condition of management licence that required the responsible person to comply with relevant sections of the medical code.

In October 2015, following two months of consultation with relevant licence holders, the department imposed a new condition on all management licence holders authorised to possess radiation sources for medical purposes. This condition gives effect to all of the requirements of the code pertaining to justification and optimisation by imposing an obligation on the management licence holder to ensure that the responsibilities of the radiation medical practitioner as specified in the code are met.

This new condition requires the management licence holder to ensure that the responsibilities of the radiation medical practitioner are met and details regarding approval of procedures are recorded.

The committee supported these developments and commended the department's work in this area.

2.11 Proposed exemption of low risk radiation practices from licensing requirements

The committee was advised that the audit report by the Victorian Auditor General (see 2.2 above) contained a number of findings, including one that *'regulators have not taken a systematic, risk-based approach and do not fully understand the impact of their regulatory activities'*.

To assist in addressing this recommendation a systematic review of radiation practices for 2015 was conducted to determine the radiation detriment to the Victorian population from each practice.

Intra-oral dental X-ray practices accounted by far for the largest number of licences authorising low risk practices.

The department advised that it is investigating the merits of a proposal to exempt both individuals and body corporates (e.g. companies) from licensing in relation to the use, possession and disposal of intra-oral dental x-ray units.

The proposal would see a conditional exemption made using the power of section 16 of the Radiation Act 2005. The proposed exemption would require compliance with the *Code of Practice for Radiation Protection in Dentistry (2005)* published by ARPANSA.

The continued licensing of this type of practice results in a significant administrative workload for the department principally due to the large number of licences involved. The question for the department is whether this is an appropriate use of resources that could be better spent targeting higher risk radiation practices.

The committee noted that concerns might be raised if Victoria adopted this approach when no other states/territories are considering it.

The committee advised that it would be helpful to consider the residual risk, if any, after introducing the exemption and to compare radiation doses from intra-oral dental procedures with doses from other radiation practices.

The committee also advised that the department should seek comment from the Australian Dental Association (ADA) and the Australian Health Practitioner Regulation Agency (AHPRA).

The committee supported consultation on the proposal to make a conditional licensing exemption for dental intra-oral X-ray units.

2.12 Radiation Protection of the Patient module

The committee was advised that an educational tool called the *'Radiation Protection of the Patient Module'* developed by ARPANSA in collaboration with the medical sector had been published on ARPANSA's web site (http://www.arpansa.gov.au/rpop/module/index.cfm). The module was designed to increase understanding of the radiation safety aspects of medical imaging. The module's aim is to provide information for referrers to help ensure that radiation use is justified and patients are not exposed unnecessarily. It is also important for referrers to have information available in order to communicate the benefits and risks of medical imaging modalities to patients.

The committee believed that this was an excellent development and that it would assist in reducing the radiation dose to the population by decreasing the number of unnecessary procedures. The committee noted that the course complemented the work carried out by the department to ensure that medical radiation procedures are justified and that radiation doses from these procedures are optimised.

The committee was advised that ARPANSA intended to develop a module covering radiation protection of medical personnel.

2.13 Radiation Act Annual Report 2015

Section 134 of the Radiation Act requires that the Secretary publish a report for each financial year that:

- describes the activities of the Secretary under the Radiation Act
- includes a summary of all authorities issued, renewed, suspended, cancelled, varied, transferred or surrendered during that year
- includes all radiation incidents investigated in that year
- includes a summary of all prosecutions for offences against the Radiation Act or the Radiation Regulations 2007 commenced in that year.

The committee was provided with a copy of the Radiation Act Annual Report for the financial year 2014 -2015 for information.

The committee noted that the higher number of medical incidents in comparison with previous years might be due, in part, to a greater awareness of the requirement to report incidents and the increasing number of medical imaging procedures carried out. The committee nevertheless noted that the number of incidents was very small in comparison with the number of medical imaging procedures carried out.

2.14 Research paper on risks of low-dose ionising radiation exposure

The committee discussed a paper by Klervi Leuraud, David B Richardson, Elisabeth Cardis et al that reported on an international cohort study examining the risk of death from leukaemia and lymphoma in radiation-monitored workers (Lancet Haematol 2015; 2: e276–81).

The authors of this paper quantified associations between protracted low-dose radiation exposures and leukaemia, lymphoma, and multiple myeloma mortality among radiation-monitored adults employed in France, the UK, and the USA. The authors assembled a cohort of 308,297 radiation-monitored workers employed for at least 1 year by the Atomic Energy Commission, AREVA Nuclear Cycle, or the National Electricity Company in France; the Departments of Energy and Defense in the USA; and nuclear industry employers included in the National Registry for Radiation Workers in the UK. The cohort was followed up for a total of 8.22 million person-years.

The authors ascertained deaths caused by leukaemia, lymphoma, and multiple myeloma. They used Poisson regression to quantify associations between estimated red bone marrow absorbed dose and leukaemia and lymphoma mortality.

Doses were accrued at very low rates (mean 1.1 mGy per year; standard deviation 2.6 mGy per year). The excess relative risk of leukaemia mortality (excluding chronic lymphocytic

leukaemia) was 2.96 per Gy (90% confidence interval (CI) 1.17–5.21; lagged 2 years), most notably because of an association between radiation dose and mortality from chronic myeloid leukaemia (excess relative risk per Gy 10.45, 90% CI 4.48-19.65).

The authors conclude that this study provides strong evidence of positive associations between protracted low-dose radiation exposure and leukaemia.

The committee noted that this paper supports the linear-no threshold (LNT) hypothesis for elevated cancer risk due to radiation exposure.

2.15 Paper on nuclear medicine incident reporting in Australia

The committee noted a paper by G. Larcos, L. T. Collins, A. Georgiou and J. I. Westbrook (*Nuclear medicine incident reporting in Australia: control charts and notification rates inform quality improvement*. Internal Medicine Journal 45 (2015): 609-617).

The authors used control charts to identify factors contributing to special cause variation (indicating higher than expected rates) in nuclear medicine maladministrations and evaluated the impact of heterogeneous notification criteria and extent of underreporting among jurisdictions and individual facilities.

The authors found that unexpected increases in maladministration notifications predominantly relate to incident 'clusters' affecting multiple patients. They conclude that the bulk preparation of radiopharmaceuticals is a vulnerable process and merits additional safeguards and that maladministration notification rates in Australia are heterogeneous. They consider that adopting uniform maladministration notification criteria among states and territories and methods to overcome underreporting are warranted.

The committee agreed with the recommendations and noted that, in Victoria, open notification of such incidents was encouraged.

2.16 Paper on wrong-patient or wrong-study errors

The committee also noted a paper by Rubio EI and Hogan L (Time-Out: It's Radiology's Turn—Incidence of Wrong-Patient or Wrong-Study Errors. AJR:205, November 2015).

In this retrospective study performed at a tertiary care paediatric hospital in the USA, monthly radiology incident reports from January 2009 through December 2014 were reviewed for documentation of wrong-patient or wrong-study events. The date, imaging modality, nature of the event, and number of imaging studies for this time period by year were recorded and analysed. These data were tracked before and after implementation of the two-person verification system in July 2012.

Over 72 months, 45 reported wrong-patient or wrong-study events were confirmed. The data were analysed before and after implementation of a two-person verification system implemented in July 2012, midway through the study period. Over the first 42 months, 36 wrong-patient or wrong-study occurrences were identified, corresponding to an average of one error every 35 days, with the number of days between events ranging from 3 to 150. After implementation of the verification process, nine events were documented over 30 months, corresponding to an average of one error every 101 days, with the maximum number of days between events exceeding 410.

The committee noted that the implementation of a "time-out" verification process was in place in most medical imaging centres in Victoria.

2.17 Use of dual-energy X-ray absorptiometry (DEXA) to assess body fat

The committee noted that there seemed to be a proliferation of the use of DEXA to analyse body composition (such as proportion of fat), where there was no medical justification for such use, e.g. amongst persons concerned with body image. Mr Wain advised the committee that the department had initiated an investigation of this use and would take any necessary action to stop this trend.

The department advised the committee that management licences authorising the possession of medical imaging equipment had conditions placed upon them which included required that the management licence holder have a system in place to ensure justification of medical procedures as required by the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)* published by ARPANSA (see section 2.10 of this report).

3. Non-ionising radiation

3.1 Enforcement action taken by the Department of Health and Human Services in relation to illegal use of commercial tanning units in Victoria

The Committee was advised that, on 1 January 2015, the department had cancelled all radiation management licences that authorised the possession of commercial tanning units. It is now an offence to possess or sell a commercial tanning unit, or conduct a commercial tanning practice (solarium). A person must not provide, or offer to provide the use of, a tanning unit, or operate or offer to operate a tanning unit for fee or reward.

The department continues to investigate the illegal use of commercial tanning units in Victoria and had commenced legal action in relation to one matter.

3.2 Proposed Regulation of intense pulsed light sources (IPLs) and Lasers

The committee was advised that ARPANSA has released a consultation regulatory impact statement (RIS) examining options which include the possible regulation of intense pulsed light sources and lasers used for beauty or cosmetic therapy. The consultation RIS is available at: http://www.arpansa.gov.au/publications/drafts/index.cfm

A number of options are being assessed by ARPANSA, including maintaining the status quo, education, and mandatory licensing of operators. Input from the relevant stakeholders has occurred. No decision has yet been made.

3.3 Publications and journal articles reviewed by the committee

Hocking B. Electrical Hypersensitivity (EHS). J Health Saf Environ 2014, 30(3): 349 356.

In this paper, the author states that increasing numbers of patients are presenting with symptoms attributed to electrical hypersensitivity. The mismatch between the patient's attribution of their illness to low levels of electromagnetic fields and the doctor's medical model of the pathophysiology of disease creates potential for a mutually unsatisfactory outcome. This paper provides an overview of Electrical Hypersensitivity Syndrome (EHS) and an approach to its management. Management involves applying principles generally used for medically unexplainable symptoms. This requires developing sufficient rapport to avoid direct conflict over different concepts of illness. Consideration needs to be given to a range of diagnostic possibilities while avoiding over investigation. Management may involve a range of models including reassurance or the somatisation of symptoms and, when appropriate, referral. Special problems may arise regarding diagnostic tests, strategies for avoidance of electromagnetic fields and medico-legal matters.

It should be noted, however, that the Australian Radiation Protection and Nuclear Safety Agency, in its pamphlet Electromagnetic Hypersensitivity states that "on the basis of current scientific information, there is no established evidence that EHS is caused by electromagnetic fields at levels below exposure guidelines. ARPANSA acknowledges that the health symptoms experienced by the affected individuals are real and can be a disabling problem, and advise those affected to seek medical advice from a qualified medical specialist."

Conclusion: This paper provides an overview of Electrical Hypersensitivity Syndrome and an approach to its management.

Soffritti M, Tibaldi E, Padovani M, Hoel DG et al. Life-span exposure to sinusoidal-50 Hz magnetic field and acute low-dose γ radiation induce carcinogenic effects in Sprague-Dawley rats. International Journal of Radiation Biology, 2016, 92(4): 202-214.

In 2002 the International Agency for Research on Cancer classified extremely low frequency magnetic fields (ELFMF) as a possible carcinogen on the basis of epidemiological evidence. Experimental bioassays on rats and mice performed up to now on ELFMF alone or in association with known carcinogens have failed to provide conclusive confirmation. This study looked at the carcinogenic effects of combined exposure to 50 Hz magnetic fields and acute γ-radiation in Sprague-Dawley rats. The authors studied groups of male and female Sprague-Dawley rats exposed from prenatal life until natural death to 20 or 1000 μT 50Hz MF and also to 0.1 Gy γ-radiation delivered as a single acute exposure at 6 weeks of age. The results of the study showed significant carcinogenic effects for the mammary gland in males and females for 1000 μT 50Hz MF and 0.1 Gy γ-radiation together and a significant increased incidence of malignant schwannomas of the heart as well as increased incidence of lymphomas/leukaemias in males. The authors state that their results call for a re-evaluation of the safety of non-ionizing radiation. The magnetic field level of 1000 μT should be compared to the 24 hour guideline limit for members of the public of 100 μT.

Conclusion: Significant carcinogenic effects were observed for the mammary gland in male and female Sprague-Dawley rats for 1000 μT 50Hz magnetic fields and 0.1 Gy γ-radiation together.

McNoll N et al. European Code against Cancer 4th Edition: Ionising and non-ionising radiation and cancer. Cancer Epidemiology 39S (2015) S93–S100.

The authors identify inhalation of naturally occurring radon as the major source of radiation in the population. Indoor exposure to radon and its decay products is an important cause of lung cancer; radon may cause approximately one in ten lung cancers in Europe. The authors go on to describe a process for reducing indoor radon exposure. The authors state that "non-ionising types of radiation (those with insufficient energy to ionise molecules)– including extremely low-frequency electric and magnetic fields as well as radiofrequency electromagnetic fields – are not an established cause of cancer and are therefore not addressed in the recommendations to reduce cancer risk". These recommendations are contained in a separate paper (Schüz et al. European Code against Cancer 4th Edition: 12 ways to reduce your cancer risk. Cancer Epidemiology 39S (2015) S1–S10.).

Conclusion: The authors state that non-ionising types of radiation are not an established cause of cancer.

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

The scientific papers reviewed by the committee during the year have not altered the committee's position that there is no substantive evidence linking exposure to radiofrequency radiation to an increased risk of cancer or other adverse health events. However in light of public concerns over mobile phones, base stations and smart meters the Committee will continue to review the relevant research.

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

The committee's position, based on the research reviewed by the committee, is that there is no substantive evidence to conclude that exposure to normally encountered environmental levels of power frequency electromagnetic fields causes adverse health effects in humans. The committee will continue to review relevant research in this area.

Appendix 1 - Terms of reference of the Radiation Advisory Committee

1. The Radiation Advisory Committee (RAC) is established under the Radiation Act 2005 and provides advice to the Minister for Health or the Secretary on protecting the health and safety of persons and the environment from the harmful effects of radiation, with a view to adopting best practice for radiation safety in Victoria.
2. The RAC may provide advice on matters including:
    - administration and amendments of the Radiation Act 2005 and the Radiation Regulations 2007;
    - licensing of persons and companies to use radiation sources and conduct radiation practices;
    - inspection and testing of radiation sources;
    - new radiation sources and technologies;
    - development, implementation and review of state and national codes, standards and guidelines;
    - transportation, storage and disposal of radioactive materials;
    - security of radioactive sources;
    - radiation incidents;
    - medical research proposals involving ionising radiation;
    - non-ionising radiation matters including:
        - solaria and their regulation;
        - health effects of radiofrequency electromagnetic fields (including mobile communications);
        - health effects of extremely low frequency (ELF) electromagnetic fields (including power frequency fields); and
        - lasers and intense pulsed light (IPL) sources.
    - the promotion and improvement of radiation safety in Victoria;
    - developments that impact on best practice for radiation safety; and
    - any other matter put to it by the Radiation Team of the department.
3. The RAC meets on the first Thursday of every second month, starting February.
4. The RAC may call an extraordinary meeting as required or upon request by the Department of Health and Human Services.
5. A minimum of five members constitutes a quorum for meetings of the RAC.
6. The RAC regulates its own proceedings.
7. The RAC may establish sub-committees and working groups to consider specific issues, and may recommend that the department engage additional expert contractors to support these entities.
8. From time to time the RAC may invite visitors to its meetings in order to hear submissions or information from them, or to take or ask questions.
9. Secretarial support for the RAC is provided by the Radiation Team.

10. The RAC will provide an annual report to the Minister for each financial year, no later than 1st November following that year.