THE ANNUAL REPORT OF THE RADIATION ADVISORY COMMITTEE FOR THE FINANCIAL YEAR ENDING JUNE 2019

RADIATION ADVISORY COMMITTEE Melbourne, Australia

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The Hon Jenny Mikakos MLC Minister for Health Minister for Ambulance Services

Dear Minister

Pursuant to Section 110 of the *Radiation Act 2005*, the Radiation Advisory Committee submits the 2019 annual report of the Committee for presentation to Parliament.

Yours faithfully

Dr Joanna Lia Wriedt 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 2017 to 16 August 2020.

(i) Composition

The Committee met on 6 occasions from July 2018 to June 2019.

The members of the Committee were:

Dr Joanna Lia Wriedt	Dr David Bernshaw
(Chair)	Consultant Radiation Oncologist
Physiologist, Epidemiologist and Lawyer	Peter MacCallum Cancer Centre
Meetings attended: 5	Meetings attended: 6
Dr Ken Joyner	Dr Roslyn Drummond
Director	Radiation Oncologist
Joyner and Associates	Peter MacCallum Cancer Centre
Telecommunications Consultancy	
	Meetings attended: 3
Meetings attended: 4	
Associate Professor Eddie Lau	Mr Geoffrey Dick
Radiologist and Nuclear Medicine Specialist	Deputy Chief Radiographer and CT Supervisor
Austin Health	Medical Imaging Angliss Hospital
	Eastern Health
Meetings attended: 6	
	Meetings attended: 5
Dr Zoe Brady	Ms Min Ku
Chief Physicist	Professional Standards Manager
Alfred Radiology and Nuclear Medicine	Australian Society of Medical Imaging and
Department	Radiation Therapy
Alfred Health	
	Meetings attended: 4
Meetings attended: 6	
Dr Stephanie Keehan	Mr Simon Toomey
Medical Physics Registrar	Business Manager/Consultant Health Physicist
Alfred Radiation Oncology Department	SGS Australia Pty Ltd
Alfred Health	
	Meetings attended: 5
Meetings attended: 3	
Dr Fiona Charalambous	Dr Tomas Kron
Waste Safety	Director of Physical Sciences
Australian Radiation Protection and Nuclear	Peter MacCallum Cancer Centre and University
Safety Agency	of Melbourne
Meetings attended: 5	Meetings attended: 4

(ii) Responsibilities

The Committee is to advise the Minister for Health or the Secretary of the Department of Health and Human Services (the Department), 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.

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

1. Introduction

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

- Radiation stakeholder engagement.
- The regulatory requirements for various ionising radiation practices, including:
 - a) Licensing requirements in relation to proton beam therapy.
 - b) Licensing requirements in relation to computed radiography mammography X-ray units.
 - c) Personal monitoring requirements for computed tomography (CT) based baggage scanners.
- Non-ionising radiation matters.

The Committee continues to pay close attention to the use of and developments in the use of ionising radiation in the medical and the non-medical fields due to the risks associated with exposure to ionising radiation. These risks need to be balanced by the positive benefits associated with the use of ionising radiation.

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 stakeholder engagement strategy

The Victorian Auditor General (VAG) made a number of recommendations in March 2015 to improve regulation within the Department in a report entitled 'Managing Regulator Performance in the Health Portfolio'. The VAG report and its recommendations, together with the Department's response to the recommendations is detailed in section 2.2 of the Annual Report of the Radiation Advisory Committee for the Financial Year Ending June 2018, available at: https://www2.health.vic.gov.au/public-health/radiation/radiation-regulatory-framework/radiation-advisory-committee

As part of the radiation stakeholder engagement strategy, the Department developed the first edition of a newsletter for circulation to licence holders and other stakeholders. These newsletters aim to inform licence holders and other stakeholders of the legislation covering the use of radiation in Victoria and how that legislation is administered. The newsletter also informs licence holders regarding current and upcoming issues about which they need to be aware.

The first edition of the newsletter was tabled for the information of the Committee. The Committee had made some comments on the draft newsletter in the last financial year. These comments were addressed by the Department.

2.2 Proton beam radiotherapy

The Committee was advised regarding the proton beam therapy centre proposed for a hospital in Melbourne in the coming years. There are several proton beam facilities around the world and they are used to treat various localised types of cancer such as brain and ocular cancers. The likelihood of complications for a given treatment regimen with proton beam therapy might be lower than for alternative treatments. Proton beams are considered particularly advantageous for paediatric patients.

The Department asked the Committee to reflect on the regulation of proton beam therapy, including the appropriateness of applying a licence condition on a proton beam therapy centre that, in the main, restricts the use of proton beam therapy to certain types of cancers.

The Committee was briefed on this issue in order to set the scene for more detailed questions and matters regarding the proposed proton beam centre that the Department would bring to future meetings for the Committee's consideration.

2.3 FLASH radiotherapy

The Committee advised the Department that FLASH radiotherapy is an emerging pre-clinical technology for the treatment of cancer that, in experimental models, has shown reduced toxicity for healthy tissue compared with other technologies. The Committee also advised that the large number of controls required in this technology, to ensure that a given dose is delivered with the very high dose rate involved, may present issues in terms of the regulation of FLASH radiotherapy. The Committee would maintain a watching brief on FLASH radiotherapy with (at minimum) an annual review of the technology.

2.4 Guidelines for personal radiation monitoring service providers

The Committee was advised that the Department was developing accreditation guidelines for the assessment and approval of personal radiation monitoring services (PRMS) providers and the associated personal dosimeters issued by the PRMS providers. The Committee was asked to comment on a draft of the guidelines.

The Committee considered that there was a need for guidance from the Department about reporting requirements, including wearing periods; wearers who work at multiple sites; and requirements for dose report formats. The Committee also suggested one option may be to have a requirement for PRMS providers to provide dose reports that can be uploaded on-line in a format compatible with the Australian National Radiation Dose Register (ANRDR). The ANRDR is maintained by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

The Committee was supportive of the requirement in the draft guidelines that the dosimetry service provide dose reports for each dosimeter within four weeks of the processing date.

The Department would take these comments into consideration in the next version of the draft guidelines, to be tabled at a future meeting of the Committee.

2.5 Justification for the use of computed radiography (CR) mammography X-ray equipment

The Department sought advice from the Committee as to whether or not there was sufficient justification for the gradual phasing out of CR mammography equipment. This was based on the fact that the use of CR mammography equipment is associated with a lower breast cancer detection rate and a higher radiation dose compared to digital radiography (DR) mammography.

CR mammography uses a phosphor-based plate which is read by a special mammography CR reader unit and then digitized for input into a computer. DR mammography is more like a digital camera connected directly to a computer. DR mammography units have a detector that directly passes the X-ray image to the computer.

The Department advised the Committee that further investigation regarding the use of CR mammography was warranted and that the Department would obtain more data on the use of CR mammography equipment to quantify the impact of phasing out of the technology. In particular, the Department would determine whether licence holders who currently use CR mammography equipment eventually intend to replace the equipment with DR mammography equipment. The Committee agreed with this approach.

2.6 Radiation safety requirements for CT based baggage scanners

The Committee reviewed the draft document *Radiation safety requirements for CT based units used for security or quality control purposes* developed by the Department. The Committee was advised that management licences issued by the Department authorising radiation practices involving computed tomography (CT) based units for examination of articles for security or quality control purposes would have a condition imposed on them requiring licence holders to meet the requirements in this document, when it is finalised.

The Department sought the Committee's advice as to whether it considered personal radiation monitoring (PRM) of security staff members advisable, given that CT-based technology is new in this area. The Committee could see the advantages of both PRM and area monitoring using PRM devices. It also thought that the monitoring of security staff members could perhaps create a concern regarding radiation amongst them, where none may have existed before.

The Department would take this advice into consideration and present the final document to the Committee.

2.7 Control of Ultraviolet Germicidal Irradiation Units

The Committee was advised that the Department had been approached by a hospital medical physicist expressing concern regarding the lack of controls in place for ultraviolet germicide irradiation (UVGI) units used in hospitals to sterilise operating theatres and their contents. The Department has the power to regulate prescribed non-ionising radiation equipment, such as these UVGI units, but has not at this stage prescribed these units.

The Committee believed that the control of these units must include very robust interlocks or systems in place to ensure that no person is exposed to excessive levels of UV.

The Department would consider this issue further and liaise with Worksafe. The Department would also consider how these units are controlled, if at all, in other Australian jurisdictions and overseas and what is done with similar UVGI units in other areas, such as the food industry.

2.8 National Directory for Radiation Protection (NDRP)

The Committee was advised by the Department that the latest version of the National Directory for Radiation Protection (NDRP) had been endorsed by the Radiation Health Committee (RHC) of ARPANSA. The purpose of the NDRP is to provide an overall agreed framework for radiation safety, for both ionising and non-ionising radiation, together with clear regulatory statements to be adopted by the Commonwealth, states and territories.

2.9 National radiation governance

The Committee was advised by the Department that the issues of the lack of national uniformity in radiation regulation and the application of radiation regulation across Australia had been discussed by Australia's Environmental Health Standing Committee (enHealth), a standing committee of the Australian Health Protection Principal Committee (AHPPC).

One of the outcomes of these discussions was that national radiation safety policy items, such as the NDRP, would now be considered by enHealth. It is intended that these items would then progress to AHPPC and the Council of Australian Governments (COAG) for consideration. EnHealth also noted that a national strategy for radiation safety was needed as per the draft recommendations of the IRRS (see section 2.16 below).

The Department was of the view that the involvement of enHealth in achieving national uniformity might be beneficial, despite reservations expressed by the Committee that such involvement might add another layer of bureaucracy to the process of achieving national uniformity, a process that has met with only limited effect.

2.10 Code for Disposal of Radioactive Waste by the User (2018)

The Committee was advised that ARPANSA had published *RPS C-6 Code for Disposal of Radioactive Waste by the User (2018)*.

The Committee was advised that the Department would develop a proposal on how it would implement the Code, particularly in relation to approvals that would be required in cases where institutions dispose of waste in excess of the limits in the Code.

2.11 Code of Radiation Protection Requirements for Industrial Radiography (2018)

The Committee was advised that ARPANSA had published *RPS C-3 Code of Radiation Protection Requirements for Industrial Radiography (2018).* The relevant sections of the code would eventually be imposed as conditions of licence for management licences authorising industrial radiography practices and use licences authorising the use of industrial radiography sources.

2.12 Guide for Radiation Protection in Emergency Exposure Situations (2019)

The Committee was advised that the Department had held a workshop, in conjunction with ARPANSA, on radiological material emergency preparedness and response in July 2018. The workshop was a forum for stakeholders to discuss the requirements of the (then draft) Guide for Radiation Protection in Emergency Exposure Situations and the response of the Department and other organisations to radiation emergencies.

ARPANSA published RPS G-3 Guide for Radiation Protection in Emergency Exposure Situations (2019) in May 2019.

The purpose of this guide is to outline the Australian framework for establishing the level of preparedness and response required in order to effectively respond to a nuclear or radiological emergency, to mitigate and minimise consequences of emergencies, including impact on health, and to protect occupationally exposed persons, members of the public and the environment from the harmful effects of ionising radiation in emergency exposure situations.

The Committee was advised that the Department would need to work with emergency service organisations and other national organisations to determine how best to move forward in applying the principles set out in the Guide.

2.13 Emergency management – approach to radiation emergencies

Three members of the Committee had attended the workshop on radiological material emergency preparedness and response (see 2.12 above) and thought it had been very valuable but that it had raised a number of issues in relation to the medical response aspects of radiation emergencies.

The Committee was advised that the Department had developed an operational plan for chemical, biological, radiological, nuclear and explosives (CBRNe) events during 2017 but it

was recognised that more detailed planning was required for radiological events. A project had therefore been initiated by the Department to develop an operational plan specifically for radiological emergencies. The project is proposed to have five working groups dealing with radiation monitoring, hazard containment and risk assessment; incident coordination and governance; epidemiology and surveillance; health sector engagement; and communications.

The Committee nominated three of its members, all actively working in the medical field, to be on the health sector engagement working group. The working group would provide advice to the Department concerning health sector issues and how they could be addressed. The group would be used by the Department once it starts to consider its emergency response and that of other organisations in light of the Guide for Radiation Protection in Emergency Exposure Situations.

The Committee considered it important that the Department liaise with ARPANSA. The Department advised that it would liaise with ARPANSA as needed.

The Committee stated that the operational plan had to be clear about the roles and responsibilities associated with the various functions in the plan.

The Committee will be consulted on the emerging draft of the operational plan and this might involve holding a special meeting of the Committee.

2.14 Draft ARPANSA codes and guides

The Committee was advised that ARPANSA Code for Radiation Protection in Medical Exposure (the medical code) was to be published in 2019. The medical code is intended to replace the existing *RPS14 Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)* published by ARPANSA. As of the end of June 2019 the code of practice had not yet been published.

The Department will consider the medical code, when published, in developing any new conditions on licences authorising medical radiation practices.

The Committee was advised that the Code for Maximum Exposure to Radiofrequency Fields – 100kHz to 300GHz (RPS3) was being revised.

2.15 Radiation Act Annual Report for the financial year ending 30 June 2018

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 2005
- 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 commenced in that year.

The Committee was provided with a copy of the Radiation Act Annual Report for the financial year 2017 -2018 for information.

The Committee noted that, in Appendix 1, the incidents listed under "Excessive patient dose during an interventional or fluoroscopic procedure" were not actually cases of excessive exposure. The skin entrance doses were high, due to the complexity of the (often life-saving) procedure but were not excessive, given the circumstances. The Department would replace the word "excessive" with "high" in future reports.

2.16 Integrated Regulatory Review Service mission of International Atomic Energy Agency (IAEA)

The Committee was advised that the IAEA Integrated Regulatory Review Service (IRRS) mission visited Australia during 5–16 November 2018. The IRRS reviewed Australia's national, legal and governmental framework for nuclear and radiation safety against the IAEA's Safety Standards. The mission reviewed all Australian States and Territories, as well as the Commonwealth. A follow-up mission will be conducted in 2021-22.

The IRRS report had been published on ARPANSA's website and the report would be placed as an agenda item for the August 2019 meeting of the Committee.

2.17 Australian Radiation Incident Register (ARIR) annual report for 2017

The Committee noted the ARIR annual report. The report contains details of radiation incidents that meet the criteria in the National Directory for Radiation Protection (NDRP), published by ARPANSA, that occurred in Australia in 2017. Incidents submitted to the ARIR are analysed and the results published to raise awareness of common hazards and to identify and promote practices which could prevent future incidents.

The Committee suggested that it would be a good idea to send a copy of the report to licence holders so that they may derive learning benefits from incidents covered in the report. The Committee was advised that the Department would include a link to the annual report in the second edition of the Radiation Team's newsletter.

2.18 Radon in Victorian Show Caves

The Department advised the Committee that a 1996 national assessment of radon levels in Australian tourist caves conducted by ARPANSA concluded that estimates of radiation dose for all cave tour guides in Australia was less than the occupational radiation dose limit of 20 millisievert (mSv) per year – the annual occupational radiation dose limit. The 2017 International Commission on Radiological Protection (ICRP) Publication 137 *Occupational Intakes of Radionuclides: Part 3* provided new dose coefficients to calculate the effective dose from radon exposure in workplaces. For tourist caves, the ICRP Publication 137 specifies dose conversion coefficients for radon that are four times larger than the 1996 ones.

The Department has liaised with Parks Victoria with a view to ensuring that the radiation doses to the tour guides are reassessed in order that work practices may be modified and/or underground working periods revised, if necessary, to ensure that radiation doses to the tour guides continue to remain acceptably low.

2.19 Mineral sands mining projects in Victoria

The Department advised the Committee that there were several mineral sands mining projects being developed in Victoria, with environmental impact statements currently being developed by two companies for mineral sands mining. These projects will present staffing issues for the Radiation Team of the Department because of the time that will need to be spent on the regulation in this area.

The Department would keep the Committee appraised of any issues that arise in relation to mineral sands mining projects.

2.20 The Department's new radiation licensing database

The Committee was updated on the Department's new radiation licensing database. The new database was scheduled to be launched mid-2019. Initially, it would only be used for use licences, approved testers and approved assessors but over the ensuing months it would be developed to include management licences.

The system will verify the details of licence holders, approved testers and approve assessors when they are registered. They will then be able to:

- Download a copy of their licence.
- Apply for variations to an existing licence or approval.
- Make credit card payments.
- Update their contact details.

2.21 Risk management approach to radiation regulation

The Committee was advised that the Department had developed a system of assessing the risks which may impact on the Department's ability to achieve its regulatory outcomes. This system involved an assessment and rating of the risks associated with various radiation practices and was developed as a result of the Victorian Auditor-General's 2015 report (see section 2.1 above) on regulatory areas managed by the Department. This report stated that the "regulators are a considerable way off applying the type of systematic, risk-based approach that is required to significantly improve regulatory outcomes".

The radiation practice risk assessment system was being reviewed by the Department. The Committee would be asked to comment on the 2019 risk assessment and rating for the various radiation practices prior to the system being used.

2.22 Safety reflections

Towards the end of the 2018-2019 financial year, the Committee decided to include, as an agenda item for its meetings, an opportunity for the members of the Committee to contribute a reflection on more broader safety considerations so as to place radiation safety considerations into the perspective of a wider picture of safety.

2.23 Revision of Terms of reference of the Radiation Advisory Committee

The Committee considered that it was timely to revise its terms of reference as they had been developed in 2012. The Committee considered that the terms of reference should be reviewed at least every three years (the term of the Committee). The Committee will finalise the revision of its terms of reference in the 2019-2020 financial year.

The current terms of reference are attached as Appendix 1 of this annual report.

3. Non-ionising radiation

3.1 Lasers and intense pulsed light (IPL) sources

The Committee noted media reports that highlighted the potential for both short term and permanent harm to the eyes and skin if laser and IPL devices are used incorrectly by operators with insufficient training, knowledge or experience.

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

The Committee noted 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 (solarium) or conduct a commercial tanning practice. 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 with a view to prosecution of serious offenders. The Committee was kept apprised by the Department of the main enforcement actions taken by the Department regarding offences in relation to tanning units. Enforcement actions taken by the Department, including those in relation to tanning units, are detailed in the Annual Reports of the activities of the Secretary of the Department under the Act, available at:

https://www2.health.vic.gov.au/public-health/radiation/radiation-regulatoryframework/radiation-laws/annual-report

3.3 5G mobile phone network

The Committee advised the Department regarding the introduction of the 5G network. The 5G network is the fifth generation of mobile radiocommunications networks. It will overlay and complement the current 4G network and enable virtually instantaneous connectivity to billions of devices.

The Committee advised the Department that ARPANSA had been receiving an influx of enquiries expressing concerns regarding the health effects of radiofrequency radiation from the 5G network and advised that the Department should be aware of this as an emerging issue.

3.4 Publications and journal articles reviewed by the Committee

National Toxicology Program (NTP) of the US Department of Health and Human Services animal study.

The Committee noted that this was the largest animal study looking at possible radiofrequency radiation effects on rats to date. The Committee discussed the report in which the NTP stated "the levels and duration of exposure to radiofrequency radiation were much greater than that which people experience with even the highest level of cell phone use'. So, these findings should not be directly extrapolated to human cell phone usage." The Committee noted there were a number of methodological deficiencies in the study and difficulties in the interpretation of the results. Dr Joyner advised that there would be repeat studies by other research groups to

determine whether or not the NTP findings can be reproduced.

Karipidis K, Elwood M, Benke G, et al. Mobile phone use and incidence of brain tumour histological types, grading or anatomical location: a population-based ecological study. BMJ Open 2018;8:e024489. doi:10.1136/bmjopen-2018-024489.

Dr Ken Karipidis of ARPANSA, one of the authors of the Australian study, gave a presentation on the study to the Committee.

The study showed no increase in brain cancer over the period 1982 to 2013 but Dr Karipidis reminded the Committee that the study was an ecological study and, as such, suffered from the drawbacks associated with such studies.

Nilsson J, Järås J, Henriksson R et al. No Evidence for Increased Brain Tumour Incidence in the Swedish National Cancer Register Between Years 1980-2012. ANTICANCER RESEARCH 39: 791-796 (2019).

The study showed no increase in brain cancer over the period 1980 to 2012. The study covered age groups not covered by the study of Karipidis et al, discussed above.

3.5 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. In light of ongoing public interest and concerns over mobile phones, base stations and smart meters, the Committee will continue to maintain a watching brief.

3.6 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 2017;
 - 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.