

The logo consists of the letters 'RAC' in a white, serif font, positioned on a dark magenta rectangular background that is tilted at an angle.

**RADIATION ADVISORY COUNCIL**

**ANNUAL REPORT 2004–05**

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The Honourable Bob Debus, MP  
Minister for the Environment

Dear Minister

It is my pleasure to forward to you for presentation to the Parliament of New South Wales the Annual Report of the Radiation Advisory Council for the period 1 July 2004 to 30 June 2005. This report has been prepared in accordance with the provisions of the *Radiation Control Act 1990*.

Yours sincerely

A handwritten signature in cursive script, appearing to read "C. Lambertson", followed by a period.

**CRAIG LAMBERTON**

Chairperson  
Radiation Advisory Council  
30 October 2005

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## Chairperson's review

The New South Wales *Radiation Control Act 1990* (the Act) and the Radiation Control Regulation 2003 (the Regulation) is administered by the Minister for the Environment. In September 2003, the Environment Protection Authority (EPA), the 'authority' under the Act, became part of the Department of Environment and Conservation (DEC) but remained a statutory body under environment protection legislation. DEC however exercises regulatory activities on behalf of the EPA and supports the Radiation Advisory Council in its work.

During the year, the Council met 10 times and provided advice to DEC on policy and regulatory matters. Of particular significance this year was the:

- review of three Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) draft Codes of Practice that will eventually form part of the *National Directory for Radiation Protection* (the National Directory) and will be required to be referenced by each jurisdiction in their radiation protection legislation
- finalisation of the findings of the Cardiac Catheterisation Laboratories Working Party (CCLWP). The CCLWP was formed by the Council to consider whether radiography equipment could be used by professionals other than radiographers in cardiac catheterisation laboratories. Council endorsed the CCLWP recommendations not to licence a person unless that person had met the competencies developed by the CCLWP.
- formation of a Committee to address the issue of the design and testing of the shielding of registered premises and the facilities where radioactive substances, sealed radioactive sources and radiation apparatus are kept and/or used; and to develop accreditation prerequisites for Consulting Radiation Experts (CREs) assessing shielding
- review of the ANSTO application for a licence to operate the new reactor at Lucas Heights.

The Council also provided advice across a wide range of radiation matters including scientific research proposals; radiation accidents; licensing and registration requirements resulting from the introduction of new technology to the Australian market; and the assessment of radiation safety courses.

Next year, the Council's primary focus will be on providing advice on amendments to the radiation control legislation in view of the requirements contained in the National Directory; ARPANSA draft codes and guidance material for inclusion in the National Directory; and the development of standards for shielding and accreditation requirements for CREs.

I would like to thank all members of the Council for their valuable contribution and commitment to the important work of the Council. I would also like to express my thanks to the DEC Radiation Control staff in supporting the Council and its committees.



**CRAIG LAMBERTON**  
Chairperson  
30 October 2005

## Responsibilities of the Council

The Radiation Advisory Council (the Council) is constituted under section 29 of the *Radiation Control Act 1990* (the Act).

The object of this Act is to:

..secure the protection of persons and the environment from exposure to harmful ionising and non-ionising radiation to the maximum extent that is reasonably practicable, taking into account social and economic factors and recognising the need for the use of radiation for beneficial purposes.

Section 33(1) of the Act requires that ‘as soon as practicable after 30 June (but on or before 31 December) in each year, the Council is to prepare and forward to the Minister a report of its work and activities for the 12 months ending on 30 June in that year’.

## Constitution of the Council

The Council consists of 16 members appointed by the Minister for the Environment. Membership of the Council consists of:

- (a) the Director General or a member of staff of the Authority, who is to be the Chairperson
- (b) a medical practitioner who is a specialist in radiology
- (c) a radiographer with expertise in the field of human diagnostic radiography
- (d) a person with expertise in the industrial uses of radiation
- (e) a person with expertise in health physics
- (f) a medical practitioner who specialises in nuclear medicine
- (g) a person with expertise in non-ionising radiation
- (h) a person with expertise in occupational health and safety
- (i) a person who is a legal practitioner of at least 7 years’ standing
- (j) a person who represents community interests
- (k) an officer of the Department of Health
- (l) a radiation oncologist
- (m) a medical physicist
- (n) an officer of the WorkCover Authority
- (o) a person with expertise in naturally occurring radioactivity
- (p) a person chosen by the Minister.

## Functions of the Council

Section 30 of the Act prescribes the functions of the Council, namely:

- (1) The Council is to advise the Minister on:
  - (a) proposed amendments to this Act and the making, amendment or repeal of regulations under this Act, and
  - (b) the administration of this Act and the regulations, and
  - (c) measures to prevent or minimise the dangers arising from radiation, and
  - (d) the granting of exemptions authorised by the regulations for periods exceeding 60 days, and
  - (e) such other matters relating to radiation safety as the Minister considers appropriate.
- (2) Any such advice may be given either at the request of the Minister or without any such request.
- (2A) The Council may at any time, and must on the request of the Authority, provide advice to the Authority about licences, registrations and accreditations under Part 2.
- (2B) The advice provided to the Authority may be general or specific, as the circumstances require.
- (3) The Council has such other functions as are conferred or imposed on it by or under this or any other Act.

The Department of Environment and Conservation NSW (DEC) exercises responsibilities and powers in the name of the Environment Protection Authority (EPA)<sup>1</sup>. DEC officers of the Radiation Control Section support the work of the Council.

## Meetings of the Council

During the reporting period ending 30 June 2005, the Council met 10 times. The attendance of members at meetings during this period is shown in Table 1.

The Memorandum of Understanding (MOU) between the Council and the EPA is found in Appendix 2. The Council proposed modifications to the MOU at the March 2004 meeting and finalised changes to the document at the November 2004 meeting.

## Committees of the Council

Section 31 of the Act enables the Council to establish committees to help it exercise its functions. The Council has two committees, a Technical Committee and a Course and Competencies Committee.

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<sup>1</sup> In September 2003 the EPA became part of DEC.

At the December 2004 meeting, the Council stated that it wished to be flexible in terms of whether the Technical Committee should meet every month. It agreed that the Committees of the Council should operate only when the need arose.

The Technical Committee considers Council's technical work by providing advice to DEC through the Council. The committee met on two occasions during the 12-month period and provided advice to the Council on:

- applications for licences, including the competency requirements and conditions to attach to licences for the use of radiation apparatus and radioactive substances
- the use of ionising radiation on humans for medical research studies
- safety protocols for the use of ionising radiation
- radiation accidents
- radiation safety courses.

Membership of the Technical Committee is shown in Appendix 1.

The Course and Competencies Committee advises the Council on licensing and accreditation qualifications. Its role also involves making recommendations to the Council on emerging issues, technical developments and regulatory matters or policy development relating to the suitability of or necessity for approved courses. Although the Course and Competencies Committee was held in abeyance during the reporting period Council considered matters pertaining to the work of the Committee.

<b>TABLE 1</b>			
<b>Members of the Radiation Advisory Council and meeting attendance</b>			
<i>Member</i>	<i>Appointed position</i>	<i>Meetings attended</i>	<i>Meetings eligible to attend</i>
Mr Craig Lamberton (Appointed 5 October 2004)	Chairperson	7	8
Mr Simon Smith (Resigned 5 October 2004 as Chair; Appointed Deputy on 5 October 2004)	Deputy	1	2
Dr Philip Pasfield	Radiologist	6	10
Dr Andrew Scott (Appointed 29 June 2004)	Deputy	2	4
Mr John Robinson	Diagnostic radiographer	9	10
Mr Glen Burt	Deputy	1	1
Mr Colin Hockings (Term Expired 27 May 2005)	Expert in industrial uses of radiation	9	10

<b>TABLE 1 (continued)</b>			
<b>Members of the Radiation Advisory Council and meeting attendance</b>			
<i>Member</i>	<i>Appointed position</i>	<i>Meetings attended</i>	<i>Meetings eligible to attend</i>
Mr Michael Carter	Expert in naturally occurring radioactivity	10	10
Mr Brian Holland (Appointed 29 June 2004)	Deputy	0	0
Mr Jeremy Pigott	Health physicist	7	10
Dr George Larcos (Term Expired 13 August 2004)	Physician in nuclear medicine	0	1
Dr Geoffrey Schembri (Appointed 6 December 2004)		4	6
Assoc. Prof. Lee Collins, AM	Expert in non-ionising radiation	7	10
Mr Howard Ackland (Appointed 29 June 2004)	Deputy	3	3
Mr Peter Dunphy	An officer of WorkCover Authority NSW	4	10
Mr Ken Mikl (Appointed 29 June 2004)	Deputy	2	6
Dr Ludmilla Robinson	Legal practitioner	9	10
Mr John Clark (Appointed 5 October 2004)	Deputy	0	1
Dr Kathryn Crawford (Resigned 17 May 2005)	Community representative	5	8
Ms Lea Maher (Appointed 29 June 2004)	Deputy	1	4
Ms Kathy Meleady	An officer of the Department of Health	4	10
Dr Denise Robinson (Appointed 29 June 2004)	Deputy	3	6
Dr Michael Izard	Radiation oncologist	6	10
Dr Mary Dwyer (Appointed 5 October 2004)	Deputy	3	3
Dr Richard Smart	Medical physicist	7	10
Mr Paul Cardew (Appointed 29 June 2004)	Deputy	2	3
Mr Luke Platt (Term expired 27 May 2005)	Minister's nominee	6	9
Mr Stephen Altree-Williams (Resigned 19 July 2004)	Occupational health and safety	1	1
Mr Jon D'Astoli (Appointed 5 October 2004)		6	8

The Council granted leave to all members who were unable to attend meetings. In many instances, absent members tendered written advice on agenda items that were considered by the Council and its committees.

## **National uniformity**

In August 1999, the Australian Health Ministers' Conference agreed that the approach to national uniformity would be through the development of the *National Directory for Radiation Protection* (the Directory) as a means by which the nine Australian jurisdictions, including the Commonwealth, would achieve national uniformity in radiation protection frameworks.

The Directory is being developed and implemented through the National Uniformity Implementation Panel (Radiation Control), a working party of the Radiation Health Committee facilitated by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

Comments on the draft Directory version 1.0 were sought from key stakeholders as part of the agreed process for resolving issues arising from the preparation of the Directory. Version 1.0 of the Directory was endorsed by the Australian Health Minister's Advisory Committee in May 2005.

During the year, the Council advised DEC on three ARPANSA draft documents that were issued for public comment:

- Exposure of Human subjects to Ionising Radiation for Medical Research Purposes
- Pre-disposal Management of Radioactive Waste and Safety Guide
- Safe Use of Radiation in Veterinary Science

These draft documents will eventually form part of the Directory.

During the period the Council also provided advice to DEC on the:

- progress on the National Uniformity in Radiopharmaceutical Labelling
- proposed Schedule for the National Directory – Waste Definitions and Classification System for Australia
- progress on the National Directory Regulatory Impact Statement
- outcomes of the independent Cost-benefit Analysis of the Draft Radiation Protection Standard for the Occupational Exposure to Ultraviolet Radiation
- progress on the Regulation of Surgical, Cosmetic and Entertainment Lasers and the draft report on Laser Provisions for the National Directory for Radiation Protection, and the accompanying draft document, Review of Controls and Adverse Effects.

## **Licences to use, possess and sell radioactive substances and radiation apparatus**

Section 6 of the Act regulates the use and sale of radioactive substances and radiation apparatus. Specifically, section 6(2) prohibits a person from using, selling or possessing radioactive substances or radiation apparatus unless they hold a current licence and comply

with its conditions. An exemption from section 6 of the Act for specified categories of persons is provided in clause 8 of the Radiation Control Regulation 2003 (the Regulation).

The EPA is the authority for dealing with licence applications and variations to licences made under Part 2 of the *Radiation Control Act 1990*. It is empowered by section 9A of the Act to seek and consider the advice provided by the Council on such matters. The Council is empowered under section 30 of the Act to provide generic or specific advice to DEC on Part 2 applications.

The MOU between the Council and the EPA sets out the way in which the two parties agree to work with each other on determining licence applications. During the reporting period, the Council advised DEC on the granting of all non-routine licence applications and recommended inclusions to its standing advice on routine licence applications.

During the reporting period the Council:

- considered and endorsed standard criteria for 'licence to use' for industrial gauging
- provided advice on the interpretation of supervision requirements for undergraduate diagnostic radiographers in paid employment and recommended that until a person has completed their course of training they must be supervised
- considered and endorsed the proposal to licence veterinary nurses from the Veterinary Nurses Council
- endorsed the amendments to the dental hygienist and dental therapists criteria for gaining a radiation licence as required by the new dental practice legislation
- endorsed the proposal to exempt nurses from licensing when re-initiating low dose rate after-loaders (through an amendment to radiation legislation)
- reviewed the restricted diagnostic radiography licence condition in terms of practices employing remote operators (e.g. general medical practitioners or registered nurses) instead of radiographers, and recommended refinement of licence conditions and NSW Health protocols
- endorsed criteria for a 'licence to use' medical fluoroscopy for medical practitioners working in a specialised area who are not recognised by the Health Insurance Commission
- noted the proposal to delay the licensing of medical physicists in nuclear medicine and diagnostic radiology until there is a sufficient number of accredited medical physicists in the respective disciplines
- considered information on the operation and hazards of the Ronan Continuous Level Detector, and endorsed proposed changes to the 'licence to use' condition for installing and/or servicing of devices containing radioactive substances arising from new technology
- considered an initial paper on the regulation of the Z Backscatter Van Screening system
- considered an initial paper on the use of total body acquisition scans using bone densitometry for body composition analysis
- considered an initial paper on compliance issues regarding the introduction of digital mammography units in the Australian market

- considered an initial paper regarding licensing and registration requirements for the i-Cat cone beam 3B dental imaging system. Council classified this apparatus as dental computed tomography.

For the reporting period ending 30 June 2005, DEC issued 2,270 new licences, including 267 licences for the sale/possession and 2,003 licences to use radiation apparatus or radioactive substances. The total number of new licences (2,270) is the number of actual individual new applications resulting in a licence being issued. The sum (2,541) of new licences for radioactive substances and ionising radiation apparatus in Table 2 is greater because it includes those with conditions added (variations) to individual licences.

During 2004–05 DEC also renewed 9,854 licences – 9,394 licences to use and 460 licences to sell/possess radioactive substances or radiation apparatus.

At the end of the reporting period, there were 12,124 active licences.

Table 2 summarises new licences, including those with conditions added to use or sell/possess radioactive substances and ionising radiation apparatus. These were issued during the reporting period, and are grouped by occupational category.

<b>TABLE 2</b>		
<b>Number of new licences (including variations) listed by occupational category issued in 2004–05</b>		
<i>Occupational category</i>	<i>Radioactive substances</i>	<i>Ionising radiation apparatus</i>
Dental	0	474
Medical—specialist	17	101
Medical—other and related	82	815
Servicing/installation	24	59
Educational	5	2
Safety	1	1
Management	11	4
Scientific/research	126	35
Engineering	17	15
Technical	45	45
Other	0	32
Company (licence to sell)	163	166
Rural	0	0
Miscellaneous	38	0
Veterinary*	2	261
<b>Total</b>	<b>531</b>	<b>2010</b>

\* Veterinary figures were previously reported under Miscellaneous

Table 3 summarises the number of new licences issued by DEC during the period 2000–01 to 2004–05.

<b>TABLE 3</b>			
<b>Number of new licences (including variations) issued from 2000–01 to 2004–05</b>			
<i>Period</i>	<i>Radioactive substances</i>	<i>Radiation apparatus</i>	<i>Total</i>
July 2000–June 2001	299	1255	1554
July 2001–June 2002	397	1167	1564
July 2002– June 2003	481	1418	1899
July 2003–June 2004	686	1947	2633
July 2004 – June 2005	531	2010	2541

## **Registration of sealed source devices, radiation apparatus and premises**

Section 7 of the Act requires registration of sealed source devices and certain prescribed radiation apparatus. Section 8 of the Act requires premises to be registered where radioactive substances, which are not contained in a sealed source device, are kept or used.

The purpose of registration is to:

- ensure that all sealed source devices, radiation apparatus and premises in which radioactive substances are kept or used are registered and comply with specified minimum standards, which are designed to optimise the protection of individuals and the environment from exposure to ionising radiation
- enable up-to-date records to be kept of all sealed source devices, certain radiation apparatus and premises where radioactive substances are kept or used.

Registration of diagnostic imaging equipment commenced in August 2000. The registration of therapy apparatus commenced on 1 February 2004 and the registration of sealed source devices and registration of premises where radioactive substances are kept or used commenced on 1 July 2004. A summary of each category and the number of registrations in each category is provided below. The Council expects more registrations to occur in the last two categories once registration requirements in these areas have been fully realised.

The EPA is the authority for dealing with applications for registration made under Part 2 of the Act. It is empowered by section 9A of the Act to seek and consider the advice provided by the Council on such matters. The Council is empowered under section 30 of the Act to provide generic or specific advice to DEC on Part 2 applications. The MOU between the Council and the EPA sets out the way in which the two parties agree to work with each other on determining registration applications.

The Council at the July 2004 meeting provided advice to DEC on the information to be provided to stakeholders on the registration of sealed source devices and premises.

The Council at the August 2004 meeting considered whether dental equipment should continue to be required to be registered. The Council advised DEC that it supported the

continuation of registration of dental machines as a means to minimise exposure to radiation to the public from dental equipment.

### Registration of diagnostic imaging apparatus

During the year ending 30 June 2005, DEC issued 821 new registrations and renewed 527 registrations for diagnostic imaging apparatus as shown in Table 4.

<b>TABLE 4</b>		
<b>Number of diagnostic imaging apparatus registered between July 2004 and June 2005</b>		
<i>Equipment type</i>	<i>New</i>	<i>Renewed</i>
Fixed Dental Radiography	465	95
Fixed Radiography	80	15
Fixed Fluoroscopy	7	39
Fixed Radiography/Fluoroscopy	26	101
Fixed Mammography	34	88
Computed Tomography	55	83
Bone Mineral Densitometry	11	2
Mobile Dental Radiography	6	
Mobile Radiography	64	14
Mobile Fluoroscopy	33	47
Mobile Radiography/Fluoroscopy	14	23
Mobile Mammography	2	16
Panoramic Radiography	24	4
<b>Total</b>	<b>821</b>	<b>527</b>

Table 5 gives the number of new diagnostic imaging apparatus registered by DEC between 2000 and 2005.

<b>TABLE 5</b>					
<b>Number of new diagnostic imaging apparatus registered between 2000 and 2005</b>					
<i>Equipment type</i>	<i>2000–01</i>	<i>2001–02</i>	<i>2002–03</i>	<i>2003–04</i>	<i>2004–05</i>
Fixed dental radiography	2592	168	453	381	465
Fixed radiography	832	134	118	70	80
Fixed fluoroscopy	69	18	17	10	7
Fixed radiography/fluoroscopy	246	31	43	41	26
Fixed mammography	161	31	52	28	34
Computed tomography	174	22	59	72	55
Bone mineral densitometry	66	9	15	16	11
Mobile dental radiography	72	6	9	10	6
Mobile radiography	686	70	92	57	64
Mobile fluoroscopy	118	18	24	38	33
Mobile radiography/fluoroscopy	60	10	0	10	14
Mobile mammography	17	8	8	5	2
Panoramic radiography	265	43	35	24	24
<b>Total</b>	<b>5358</b>	<b>568</b>	<b>925</b>	<b>762</b>	<b>821</b>

The total number of diagnostic imaging apparatus registered on 30 June 2005 was 6,583. The registration period for diagnostic imaging apparatus is 2 or 5 years, depending on the type of apparatus.

### **Registration of therapy apparatus**

From 1 February 2004, radiation apparatus used or intended to be used for radiotherapy or radiotherapy planning purposes had to be registered with the EPA under the Radiation Control Regulation 2003. Radiotherapy apparatus is registered for a 2-year period.

At the end of the reporting period there were a total of 73 registered therapy apparatus. Table 6 summarises the number of registrations for each type of therapy apparatus between 2003–04 and 2004–05.

<b>TABLE 6</b>		
<b>Number of therapy apparatus registered during 2003–04 to 2004–05</b>		
<i>Equipment type</i>	<i>2003–04</i>	<i>2004–05</i>
Kilovoltage therapy x-ray (superficial/orthovoltage)	17	0
Linear accelerator	38	4
Simulator	14	0
<b>Total</b>	<b>69</b>	<b>4</b>

## Registration of sealed source devices

The registration of sealed source devices commenced on 1 July 2004. Owners of sealed source devices were required to register them with the EPA by 1 August 2004.

From 1 July 2004, Fixed Radiation Gauges (FRGs) were classified as ‘sealed source devices’, in accordance with the modification of the definition of ‘sealed radioactive source’ under the *Statute Law (Miscellaneous Provisions) Act 2004*. FRG registrations are renewed every 2 years. At the end of the period DEC renewed 243 FRGs and there were a total of 628 active FRG registrations.

At the end of the reporting period, DEC registered a total number of 523 sealed source devices including FRGs, as shown in Table 7.

<b>TABLE 7</b>	
<b>Number of sealed source devices registered during 2004-05</b>	
<i>Equipment type</i>	<i>Total as at 30 June 2005</i>
Borehole logging	11
Soil Moisture Density & Moisture Determination	242
Density Gauge	38
Neutron Probe	52
Industrial Radiography	28
XRF Analyser	20
Portable Gauge	9
Beta backscatter thickness testing	1
Self-shielded irradiator	12
Therapy device	16
Analyser	2
Nuclear Medicine Gamma Camera	13
Fixed Radiation Gauges (new registrations)	79
<b>Total</b>	<b>523</b>

## Registration of premises where radioactive substances are kept or used

From 1 July 2004, under section 8 of the *Radiation Control Act 1990*, premises on which a radioactive substance that is not contained in a sealed source device is kept or used, must be registered with DEC. At the end of the reporting period, DEC registered a total number of 251 premises where radioactive substances are kept or used. Table 8 summarises the number and category of premises registered by DEC during 2004–05.

<b>TABLE 8</b>			
<b>Category and number of premises registered where radioactive substances are kept or used during 2004–05</b>			
<i>Premises category</i>	<i>High</i>	<i>Medium</i>	<i>Low</i>
Medicine (Government Hospital)	3	32	29
Medicine (Private Hospital)	1	21	25
Research (Government)	0	1	10
Research (University)	5	18	59
Research (Private)	0	1	10
Radioanalytical	0	1	2
Sterilisation	1	0	0
Store only for radioactive sources	0	3	23
Radiopharmacy	0	1	0
Industrial	1	0	1
Medicine (Private Practice)	0	0	2
Teaching (University)	0	0	0
Other	0	0	1
<b>Total</b>	<b>11</b>	<b>78</b>	<b>162</b>

## Accreditation of radiation experts

Section 9 of the Act provides that the EPA is responsible for accrediting CREs, and through section 9A of the Act may seek the Council's advice on accreditation matters. The activities of a CRE are set out in the Radiation Control Regulation 2003 as follows:

- (a) advising on the design of premises to be registered under section 8 of the Act in relation to radiation safety requirements,
- (b) assessing plans for premises to be registered under section 8 of the Act in relation to radiation safety requirements for the purpose of certifying compliance with the requirements necessary for registration,
- (c) measuring and assessing radiation doses from ionising radiation apparatus used for medical therapy,
- (d) measuring and assessing radiation doses from ionising radiation apparatus used for diagnostic purposes,
- (e) advising on the design of premises, in relation to radiation safety requirements, in which sealed source devices or radiation apparatus prescribed under section 7(1) of the Act are kept or used,

- (f) assessing plans for premises in which sealed source devices or radiation apparatus prescribed under section 7(1) of the Act are kept or used, for the purpose of certifying compliance with any requirements for registration under section 7(5) of the Act,
- (g) assessing radiation apparatus, sealed source devices and premises that are required to be registered under section 7 or 8 of the Act for the purpose of certifying compliance with the requirements for registration,
- (h) assessing the integrity of any shielding of premises in which sealed source devices or radiation apparatus prescribed under section 7(1) of the Act are kept or used for purposes of certifying compliance with the requirements for registration.

At the June 2005 meeting, the Council endorsed the recommendation to form a Committee to address the issue of the design and testing of the integrity of the shielding of registered premises and facilities where radioactive substances, sealed sources and radiation apparatus are kept and/or used. The Council also recommended that the Committee develop the criteria for accrediting CREs for the purposes of premises shielding. The Council agreed that the Committee be comprised of members of the Council, a DEC staff member, a NSW Health representative and nominated relevant external experts.

During the year ending 30 June 2005, DEC accredited 13 CREs and renewed 12 CREs in the category of diagnostic imaging. CREs accredited from 1 July 2003 are required to renew their accreditation annually. These accreditations are shown in Table 9, including the total number of accreditations as at 30 June 2005.

<b>TABLE 9</b>				
<b>Number of new and renewed accreditations and the total number of accreditations as at 30 June 2005</b>				
<b>Category</b>	<b>Equipment</b>	<b>Number of accreditations issued</b>	<b>Number of accreditations renewed</b>	<b>Total number of accreditations</b>
Diagnostic imaging	Mammography	4	3	26
	Dental (intra-oral, OPG and cephalometry)	2	2	32
	Dental (intra-oral, OPG and cephalometry) Radiography Fluoroscopy Computed tomography Bone mineral densitometry (including veterinary and chiropractic)	0	1	8
	Radiography Fluoroscopy Computed tomography Bone mineral densitometry (including veterinary and chiropractic)	7	6	62
Industrial	Fixed radiation gauges	0	0	11
<b>Total</b>		<b>13</b>	<b>12</b>	<b>139</b>

## **Voluntary exposure to ionising radiation for scientific or research purposes**

Clause 22 of the Regulation prohibits a person from exposing any other person to ionising radiation for scientific or research purposes, except in accordance with the document published by ARPANSA, *Administration of Ionizing Radiation to Human Subjects in Medical Research* as in force from time to time.

The guideline requires the approval from the EPA in studies where:

- the radiation dose to any individual subject in any year exceeds 5 millisieverts
- the radiation dose to a child or other persons incapable of giving informed consent exceeds 0.5 millisieverts
- the radiation dose to a baby, infant or foetus exceeds 0.1 millisieverts.

In the year ending 30 June 2005, DEC submitted 9 medical research studies involving the use of radioactive substances or radiation apparatus to the Council for expert advice, all of which were recommended for approval. These studies are listed in Appendix 3.

During the reporting year the Council also provided advice to DEC on the ARPANSA Draft Code of Practice, *Exposure of Human Subjects to Ionising Radiation for Medical Research Purposes*, and the accompanying Regulatory Impact Statement. The Council provided comments on the draft documents that were initially released for public comment in February 2004. Council considered and provided comments to the post consultation and Radiation Health Committee version at the December 2004 meeting.

The ARPANSA Code of Practice was finalised in May 2005 and replaces the Radiation Health Series No. 12, *Administration of ionizing radiation to human subjects in medical research*, of the National Health and Medical Research Council.

In line with the requirements of the ARPANSA code and the Regulation, all scientific or research projects in NSW, now require the approval of the relevant Human Research Ethics Committees before commencement. Under this new protocol it will not be necessary for DEC or the Council to be involved with the review of any research proposals involving the use of radiation on human subjects.

Although applications for research are no longer required to be submitted to DEC for approval, the EPA (now a part of DEC) is still the regulatory authority responsible for ensuring compliance with the new Code.

## **Radiation accidents**

Clause 26 of the Regulation specifies the types of incidents that are classified as radiation accidents for the purposes of the Act. The mandatory requirements imposed on an employer in regard to the reporting and recording of radiation accidents are outlined in clauses 27 and 28.

Accidents are normally caused by either deficiency in the relevant management systems, or failures on the part of individuals to implement those systems correctly. Where investigations reveal the former, the Council normally recommends that new procedures be developed and implemented. Where an individual is at fault, the Council usually

recommends counselling or further training. In specific circumstances, enforcement action may be warranted. The Council may also recommend referral of serious accidents to the Health Care Complaints Commission (HCCC). DEC has standing advice to refer all matters considered significant by the Council to the Commission. The Council at the February 2005 meeting endorsed objective measures for recommending referral of radiation accidents to the HCCC.

The Council emphasises that it is vital that accidents are consistently reported, not just because of a legal requirement, but because the knowledge gained can help to develop processes and procedures that reduce the risk of similar accidents occurring in the future.

Through the impetus of the National Competition Policy Review of Radiation Protection Legislation the Australian Radiation Incidents Register (Register) has been developed under the direction of the Radiation Health Committee, which was established by the *Australian Radiation Protection and Nuclear Safety Act 1998*. Each jurisdiction must forward their reports of radiation incidents to ARPANSA for compilation in the Register

During the reporting period ending 30 June 2005, DEC was informed of 31 instances where radiation accidents may have occurred, involving 39 people. The Council considered each case and, where appropriate, made recommendations that, in its opinion, would reduce the risk of similar accidents recurring. The Council also recommended that DEC inform the relevant professional bodies and universities of these accidents as a means of disseminating the knowledge gained.

A summary of the accidents and subsequent recommendations made by the Council has been grouped by categories of accidents: nuclear medicine (19), therapy (5), radiology (5) and other (2).

### **Nuclear Medicine**

- A patient received 200 MBq of Tc99m Sestamibi followed by 800 MBq Tc99m-MDP instead of 1001 MBq Tc99m Sestamibi for a cardiac rest-scan. The effective dose to the patient from the wrongly administered radiopharmaceutical was calculated by the facility at 4.6 millisieverts.

The Council requested that the effective dose calculations be revisited by the facility as it appeared that the initial 200 MBq of Tc99m Sestamibi was not included in the calculations. At the time of writing this report this information was not available.

- A patient received 829 MBq of Tc99m Sestamibi instead of 829 MBq of Tc-99m HDP for a bone scan due to the patient misidentification. The effective dose to the patient from the wrongly administered radiopharmaceutical was 7.5 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring. The Council also recommended that the facility consider bar coding radiopharmaceuticals.

- A patient received 100 MBq of TI-201 for a resting heart study instead Tc-99m Sestamibi for a whole-body scan. The patient was booked for the wrong diagnostic procedure. The effective dose to the patient from the wrongly administered radiopharmaceutical was 22 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

- A patient received 375 MBq of Tc-99m Sestamibi for a myocardial perfusion study instead of stress ECG only. The patient was booked for the wrong diagnostic procedure. The effective dose to the patient from the wrongly administered radiopharmaceutical was 3.18 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

- A patient received 270 MBq Tc99m Hepatolite for liver/spleen imaging instead of 270 MBq Tc99m Hepatate for bone marrow imaging due to the incorrect radiopharmaceutical being selected. The effective dose to the patient from the wrongly administered radiopharmaceutical was 4.6 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

- A patient received 1200 MBq of Tc99m Sestamibi, a cardiac scan agent, instead of 1000 MBq of Tc99m HDP, a bone scan agent because the radiopharmaceutical label was not read. The effective dose to the patient from the additional radiopharmaceutical administered was 10 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

- A patient received 113 MBq Tc99m DMSA instead of 68.4 MBq Tc99m DMSA. The error occurred as a result of misreading the weighting machine used to obtain the patients weight for calculation of the required dose. The effective dose to the patient from the additional radiopharmaceutical administered was 1.3 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring however the Council recommended further information be provided regarding the accident. This information was received and noted. Council recommended that universities providing nuclear medicine training be provided with information on nuclear medicine accidents to use as a teaching tool.

- A patient received 1000 MBq of Tc99m Pertechnetate instead of 1000 MBq Tc99m Sestamibi for a cardiac scan due to the radiopharmaceutical being dispensed from the wrong vial. The effective dose to the patient from the wrongly administered radiopharmaceutical was 9.7 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

The Council also recommended that the ARPANSA Committee developing the Code of Practice for Radiation Protection in Nuclear Medicine include colour coding on pots only, and that this information be provided in the safety guide. In addition, those

universities that provide nuclear medicine training should be provided with information on nuclear medicine accidents. This information can be used as a teaching tool to emphasise the need for an error checking culture as part of the training.

- A patient received 40 MBq Tc99m-Technegas and 125 MBq Tc99m-MAA for a lung scan other than prescribed due to the wrong patient's addressograph label being attached to a lung scan request form. The effective dose to the patient from the wrongly administered radiopharmaceuticals was 2.0 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

- A patient received 958 MBq Tc99m Sestamibi instead of Tc99m HDP for a bone scan due to the incorrect labelling of radiopharmaceutical by the supplier. The effective dose to the patient from the wrongly administered radiopharmaceutical was 7.9 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

- A patient received 500 MBq Iodine-131 instead of 200 MBq Iodine-131 due to incorrect labelling of radiopharmaceutical activity by the supplier. The effective dose to the patient from the administered radiopharmaceutical was 21.6 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

- A patient was wrongly administered a repeat of MBq F-18 FDG for a whole body PET CT scan due to documentation error and communication deficiencies during staff changeover. The effective dose to the patient from the administered radiopharmaceutical was 6.7 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

- A patient received 1.0 GBq Tc99m HDP for a bone scan instead of 1.0 GBq Tc99m Pertechnetate for a thyroid scan due to the label on the radiopharmaceutical being misread. The patient received an estimated whole body dose of 5.7 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring. The Council also recommended that the activity of purchased doses be checked in the calibrator prior to use.

- A patient received 900 MBq Tc99m MDP for a bone scan instead of 400 MBq Tc99m Sestamibi for a cardiac scan due to the absence of appropriate labelling on the syringe. The effective dose to the patient from the wrongly administered radiopharmaceutical was 5.5 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

- A patient received 1.02 GBq Tc99m Pertechnetate instead of 1.02 GBq Tc99m HDP for a bone scan due to the label on the radiopharmaceutical being misread. The effective dose to the patient from the wrongly administered radiopharmaceutical was 13.3 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

- A patient received 1.1 GBq Tc99m Pertechnetate instead of 1 GBq Tc99m HDP for a bone scan due to the radiopharmaceutical being drawn from the wrong pot. The effective dose to the patient from the administered radiopharmaceutical was 14.3 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring, however Council also recommended that syringes be labelled when drawn up.

- A patient received 200 MBq of Tc99m Technegas instead of 50 MBq of Tc99m Technegas for a lung scan due to incorrect settings on gamma camera. The effective dose to the patient from the wrongly administered radiopharmaceutical was 2.25 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

- A patient received 400 MBq Tc99m Pertechnetate instead of 200 MBq of Tc99m MAA for a lung scan due to correct radiopharmaceutical label being attached to incorrect radiopharmaceutical pot that contained pertechnetate. The effective dose to the patient from the wrongly administered radiopharmaceutical was 5 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

- A patient received 50 MBq Tc99m Pertechnetate instead of 800 MBq of Tc99m Pertechnetate due to the date on the radiopharmaceutical container label being misread resulting in the administration of the decayed pertechnetate. The effective dose to the patient from the administered radiopharmaceutical was 0.5 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

## Therapy

- A patient undergoing radiotherapy treatment for breast cancer received 70 Gray in 25 fractions instead of 45 Gray in 25 fractions to the breast as a result of miscalculation of dose during treatment planning. The patient received an additional therapeutic dose of 25 Gray in 25 fractions due to a calculation error during treatment planning.

The Council reviewed the incident and due to the seriousness of the accident recommended that the DEC approach all hospital therapy departments recommending that they need to implement independent checking methods when administering a radiation therapy dose and that all checks should refer back to the prescription. The Council also recommended that the lessons learned from this accident be shared across

the health system to prevent similar accidents from occurring. DEC referred the accident to the HCCC.

- A patient received a therapeutic dose 15% above that prescribed from a linear accelerator over a series of treatments. The patient received 46 Gray instead of 40 Gray to the treatment area and 20 Gray instead of 12 Gray outside of the patient's treatment area. The accident was the result of incorrect data being entered in the setup program of the linear accelerator.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

- Three people including one pregnant woman working at a medical facility were each exposed up to 3 microsieverts following the repair of a linear accelerator. The neutron safety interlock was not re-enabled resulting in the linear accelerator being operated with the neutron door open.

The Council requested that the facility provide further information. At the time of writing this report this information was not available.

## **Radiology**

- The Council considered the root cause analysis of a radiation accident reported to Council in the last period where a CT scan was undertaken on the wrong patient due to patient misidentification. The effective dose to the patient from the CT scan was 11.75 millisieverts.

The Council noted the root cause analysis and the controls the facility had instigated to correct deficiencies in its standard operating procedures, to prevent similar accidents from recurring.

- A patient wrongly received a CT scan due to patient misidentification. The effective dose to the patient from the CT scan was 0.6 millisieverts.

The Council recommended that the facility instigate further controls to correct deficiencies in standard operating procedures, to prevent similar accidents from recurring.

- A CT scan provided to a pregnant woman. The estimated dose to the foetus was 9 millisieverts.

The Council recommended that the facility instigate further controls to correct deficiencies in standard operating procedures, to prevent similar accidents from recurring and requested further details of the accident. This information requested was not available at the time of writing this report.

- A patient wrongly received a CT scan due to patient misidentification. The effective dose to the patient from the CT scan was 5.5 millisieverts.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

- A patient wrongly received a cerebral CT Scan instead of a renal colic CT scan. The effective dose to the patient from the incorrect CT scan was 3.9 millisieverts.

The Council noted the report and requested that the facility provide further information on the accident. At the time of writing this report, this information was not available.

- A patient received a neck CT Scan due to incorrect patient details on request form and addressograph. The patient received an effective dose of 11 millisieverts and the thyroid received an absorbed dose of 55 mGy.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

### Other

- A radiation accident involving a spill of iodine-131 where the sewerage pipe that carries the radioactive waste to a dedicated tank became blocked causing the spill of contaminated sewerage. Nine individuals were identified as having various levels of contact with the spillage and eight of these were referred to ANSTO for thyroid monitoring, the remaining individual was not tested as it was considered he did not need to undergo special thyroid monitoring due to the circumstances. Of these one had a positive thyroid uptake reported as 6.9 kilobecquerel and an estimate of external gamma dose of 170 microsieverts. This individual received a total effective dose of 0.6 millisieverts. The effective dose to the other individuals from the spillage was approximately between 3 to 85 microsieverts.

The Council reviewed the incident report and requested further information on the dose estimate received by the person who sustained the highest radiation exposure from the incident. Council reviewed the final incident reports, the additional information and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

- Misuse of Radiation Apparatus – an individual intentionally placed himself into a cabinet style x-ray radiation apparatus.

The Council reviewed the incident and the controls the facility had instigated to correct deficiencies in its standard operating procedures, and requested further information on the dose the individual received. The Council was provided with additional information and was satisfied with the steps the organisation had taken to prevent this type of incident from recurring.

### Amendment to RAC Annual Report 2003–04 Radiation Accidents

In the last period Council considered a radiation accident recorded on page 13, last dot point of the Annual Report where a patient received 661 MBq Tc99m Pertechnetate instead of Tc99m Hydroxy Methylene Diphosphonate (HDP) for a bone scan. The report states that the effective dose to the patient from the wrongly administered radiopharmaceutical was 9.2 mGy. The dose was re-calculated and it was discovered that the wrong unit 'absorbed dose' was used instead of 'effective dose'. The effective dose to the patient from the wrongly administered radiopharmaceutical was 8.6 millisieverts. Table 10 summarises the number of accidents reported to DEC during the period 1994–95 to 2004–05.

<b>TABLE 10 Radiation accidents</b>	
<b>Year</b>	<b>Number of accidents reported</b>
July 1994–June 1995	8
July 1995–June 1996	7
July 1996–June 1997	6
July 1997–June 1998	8
July 1998–June 1999	14
July 1999–June 2000	5
July 2000–June 2001	10
July 2001–June 2002	15
July 2002–June 2003	14
July 2003–June 2004	23
July 2004–June 2005	31

The Council acknowledges that the increase in the number of radiation accidents may be as a result of increased reporting due to DEC undertaking an education campaign to raise awareness of the need to report accidents.

## **Radiography in cardiac catheterisation laboratories**

DEC, on the Council's recommendation, formed a joint working party consisting of members from the Council, DEC and the NSW Department of Health to explore whether radiography equipment could be used by professionals other than radiographers in cardiac catheterisation laboratories (CCLs). The working party met on several occasions during the reporting period

The working party recommended that the CCLs and the Hospital and Universities Radiation Safety Officers Group be surveyed to explore aspects of radiography in CCL and to assist in forward planning for the sector. The survey was conducted in December 2003 and a progress report was provided to the Council in February 2004. Other jurisdictions were also asked to provide details on the licensing and registration provisions imposed on cardiologists carrying out cardiac catheterisation procedures, and the radiographer's role in these procedures.

The working group in June 2004 analysed the results of the survey and recommended a list of skills and knowledge that are required to undertake the radiography role safely. These were then compared and analysed with the skills and knowledge required by all the professionals working in CCLs. Criteria for the minimum requirements were created and the working party concluded that those that meet the competency level to undertake the

radiographers role in CCLs should be issued with a licence. The Council endorsed the working party's recommendations at the 20 May 2005 meeting.

## **ANSTO application for a licence to operate the new reactor at Lucas Heights**

ANSTO submitted an application to ARPANSA on 1 December 2004 for a licence to operate the replacement research reactor. DEC sought comments from the Council on the publicly released documentation with the operating licence application at the RAC April 2005 meeting.

## **International radiation draft documents**

During the reporting period Council considered the following International Commission on Radiological Protection (ICRP) and International Atomic Energy Agency (IAEA) draft documents:

- ICRP draft document – 2005 ICRP Recommendations
- IAEA draft documents:
  - Safety Fundamentals – Principles of Nuclear, Radiation, Radioactive Waste and Transport Safety DS298
  - Safety Guide – Borehole Facilities for the Disposal of Radioactive Waste
  - Safety Requirements DS338 – Management Systems
  - Safety Guide DS336 – Management System for the Safety of the Treatment, Handling and Storage of Radioactive Waste
  - Safety Guide DS337 – Management System for the Safety of Radioactive Waste Disposal
  - Safety Guide – Arrangements for Preparedness for a Nuclear or Radiological Emergency



## Appendix 1: Membership of the Technical Committee of the Council during 2004–05

<b>Technical Committee</b>	
<i>Member</i>	<i>Membership category</i>
Mr Craig Lamberton (Appointed 5 October 2004)	Representative of the Authority
Mr Simon Smith (Appointed 5 October 2004)	Deputy
Dr Philip Pasfield	Radiologist
Dr Andrew Scott (Appointed 29 June 2004)	Deputy
Mr John Robinson	Diagnostic radiographer
Mr Glen Burt	Deputy
Dr George Larcos (Term expired 13 October 2004)	Physician in nuclear medicine
Dr Geoff Schembri (Appointed 6 December 2004)	
Dr Kathryn Crawford (Resigned 17 May 2004)	Community representative
Ms Lea Maher (Appointed 29 June 2004)	Deputy
Mr Michael Carter	Naturally occurring radioactivity
Mr Brian Holland (Appointed 29 June 2004)	Deputy
Mr Colin Hockings (Term expired 27 May 2005)	Industrial radiographer
Assoc. Prof. Lee Collins, AM	Expert in non-ionising radiation
Mr Howard Ackland (Appointed 29 June 2004)	Deputy
Dr Richard Smart	Medical physicist
Mr Paul Cardew (Appointed 29 June 2004)	Deputy
Dr Michael Izard	Radiation oncologist
Dr Mary Dwyer (Appointed 5 October 2004)	Deputy
Mr Jeremy Pigott	Health physicist

## **Appendix 2: Memorandum of Understanding between the EPA and the Radiation Advisory Council**

### **Statement of common intent**

This Memorandum of Understanding has been agreed between the Environment Protection Authority (EPA) and the Radiation Advisory Council (Council) to document the practical aspects of the way that each will work with the other to advance radiation safety in New South Wales. Both the Council and the EPA are committed to a cooperative and collaborative partnership with the aim of advancing the objectives of the Act. This Memorandum of Understanding shall be reviewed annually and remain in force until such time as both parties agree otherwise.

The roles and responsibilities for each body are set out in the *Radiation Control Act 1990* (the Act). Fundamentally, the Council provides expert advice to the EPA and the Minister for the Environment across all radiation safety matters, while the EPA has responsibility for administering the regulatory functions provided by the Act. This Memorandum of Understanding includes an agreement on how advice from the Council will be utilised by the EPA in the details of issuing licences, registrations and accreditations.

The Council also has a key role in helping the EPA develop radiation safety policy for New South Wales. The EPA has responsibility for formally adopting and giving effect to such policies. The EPA must also take into account New South Wales Government policy, any direction from the Minister for the Environment and other advice it receives in developing and implementing policy. In recognition of Council's special expertise, the EPA will engage openly, early and in detail with the Council in the development of radiation safety policy matters.

### **Agreed details of how the Council and EPA collaborate**

#### **1. Development of regulatory guidelines and policies**

The EPA will provide the Council with drafts of any new or amended guidelines, policies or standards that are developed or reviewed by the EPA or other external bodies. The EPA will seek the formal advice of the Council at each stage in the process of the development of these guidelines, policies and standards. This consultation will include the results of any feedback obtained in community consultation processes. The Council will also be formally requested to endorse the final products of the development of guidelines, policies and standards.

#### **2. Provision of advice from the Council to the Minister**

Section 30 of the Act gives the functions of the Council in relation to provision of advice to the Minister.

- (1) The Council is to advise the Minister on:
  - (a) proposed amendments to this Act and the making, amendment or repeal of regulations under this Act, and
  - (b) the administration of this Act and the regulations, and
  - (c) measures to prevent or minimise the dangers arising from radiation, and

- (d) the granting of exemptions authorised by the regulations for periods exceeding 60 days, and
  - (e) such other matters relating to radiation safety as the Minister considers appropriate.
- (2) Any such advice may be given either at the request of the Minister or without any such request.

The Council may also provide advice to the EPA from time to time, as it sees fit and on issues that it considers to be of relevance, at the request of the EPA or of its own accord.

### **3. Correspondence**

When requested by the Council to prepare correspondence on their behalf, the EPA will present a draft of the correspondence for comment. After amendments to the draft have been prepared in light of the comments offered by the Council, the EPA will submit a final version for endorsement prior to signing by the Chair.

The timeframes for the preparation of drafts and presentation of final versions of correspondence for endorsement by the Council will be managed by the EPA to accommodate the workload of the Radiation Control Section at the time.

Finalised correspondence, which has been mailed out, and correspondence received, will be tabled by the EPA at the next Council meeting subject to the deadlines for submission of business papers for that meeting.

### **4. Storage of documents**

Records of meetings, including agendas, minutes, and all documents associated with the meetings of the Council are kept by the EPA. These records will, as far as is possible, be kept in electronic format and will be made available to the members of the Council upon request to the EPA, in a timely manner.

### **5. Provision of secretariat support**

The EPA will provide secretariat support to the Council and all its committees. This support will include the:

- preparation and distribution to Council members of the agendas for meetings of the Council and committees;
- the taking of minutes and their distribution to members; and
- the preparation of any correspondence requested by the Council.

### **6. Development of procedures**

The EPA and the Council will further develop the system of generic advice for applications to the EPA for licences, registrations and accreditations and the EPA will continue to refer applications not covered by the generic advice to Council. The EPA will also seek the advice of the Council in regard to radiation accidents and incidents, and their investigation, and in regard to the assessment of research applications.

The EPA will seek active input from the Council on strategic and policy matters. These will include substantive input into any review or development of legislation, and emphasis on

the development of standards, codes of practice and guidelines. There will be substantial activity during the development of the *National Directory for Radiation Protection*.

While recognising that the RAC performs an advisory function, and the EPA is the decision maker, the parties agree to work through disagreement as follows:

- That there will be an opportunity for discussion, including consideration of the decision making process of both the RAC and the EPA;
- The EPA will advise Council if it has formed a view that it intends to make a decision which is inconsistent with RAC advice, and will provide an opportunity for discussion about the differences;
- Council may request the EPA to provide an independent facilitator, and the EPA agrees to consider each such request in good faith;
- If the EPA decides to proceed in a manner inconsistent with RAC advice, it will provide the RAC with a written explanation of why it has decided to do so.

## **7. Determinations for licensing, registration and accreditation**

The EPA is the determining Authority for applications for licences, registrations, accreditations and variations to licences and accreditations, made under Part 2 of the *Radiation Control Act 1990*. The EPA is empowered by section 9A of the Act to seek and take into consideration the advice of the Council on such matters.

Section 30 (2A and 2B) of the Act empowers the Council to provide advice to the EPA on Part 2 applications at any time and requires the Council to do so when so requested by the EPA. The advice provided by the Council may be generic or specific, as the circumstances require.

The Council has provided the EPA with generic advice on Part 2 applications and this advice, known as 'standing advice' is recorded at Schedule 2 of the Council's *Corporate Governance and Operating Procedures* manual. It is the duty of the EPA to maintain the standing advice in Schedule 2 up-to-date. Part 2 applications that are fully covered by the standing advice at Schedule 2 are known as 'routine applications'. Part 2 applications that are not covered, or are only partly covered, by the standing advice are known as 'non-routine applications'.

Before an officer with the delegated Authority to do so determines a Part 2 application, s/he must have regard to relevant requirements of Part 2 of the Act, the Radiation Control Regulation 2003, and the standing advice of the Council.

Unless the Director General has agreed in writing to the following procedure being varied, the officer:

- may approve any routine application without first seeking the specific advice of the Council on the application; but
- before approving any non-routine application must seek and take into consideration the advice of the Council on the application; and
- before refusing any application must seek and take into consideration the advice of the Council on the application.

Normally the Director General will only approve a variation in this procedure in an emergency, in which case the concurrence of the Council to the determination is to be sought retrospectively as soon as practicable.

**LISA CORBYN**  
**Director General**  
**Department of Environment and Conservation**

8 July 2004

**SIMON A Y SMITH**  
**Chairperson**  
**Radiation Advisory Council**

5 July 2004

## **<sup>2</sup>Appendix 3: Advice provided on medical research studies (involving administration of ionising radiation to humans)**

### **Westmead Hospital**

- Vasodilator Induced Stress in Concordance with Adenosine (Vision-304)
- Multi Centre, Phase Ib Safety Study of Anti-Fibrin Humanised Monoclonal Antibody (Thrombo View ) in the Detection of Pulmonary Emboli

### **Newcastle Mater Misericordiae Hospital**

- BCIRG 006 A Randomised Study of 3 Different Adjuvant Treatments for Early Her2 Positive Breast Cancer
- Roche Metastatic Bone Pain Study IV Protocol No. BO18040

### **Royal North Shore Hospital**

- 99m-Technetium-Aprotinin Scintigraphy in Amyloidosis Pilot Study
- Multi Centre, Phase Ib Safety Study of Anti-Fibrin Humanised Monoclonal Antibody (Thrombo View ) in the Detection of Pulmonary Emboli

### **St George Hospital**

- Evaluation of two doses of SR31747A (75mg and 125 mg) in non-metastatic androgen-independent prostate cancer Protocol EFC 5378
- Multi Centre, Phase Ib Safety Study of Anti-Fibrin Humanised Monoclonal Antibody (Thrombo View) in the Detection of Pulmonary Emboli
- Phase 3, Double-Blind, Placebo-Controlled Study of Maintenance Pemetrexed plus Best Supportive Care Versus Best Supportive Care Immediately Following Induction Treatment of Advanced Non-Small Cell Lung Cancer
- Amended Proposal – Protocol for Systemic Targeted Alpha Immunotherapy for Metastatic Melanoma (Original trial considered by RAC August 2003)
- A phase III Randomised Open-label, Multi-Centre Study Comparing GW572016 and Capecitabine (Xeloda) versus Capecitabine in Women with Refractory Advanced or Metastatic Breast Cancer

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<sup>2</sup> Exposure of Human Subjects to Ionising Radiation for Medical Research Purposes (RPS No. 8) requires that all scientific or research projects in NSW from May 2005 require approval of the relevant Human Research Ethics Committees. Under this new protocol it will not be necessary for the DEC to review any research proposals involving the use of radiation on human subjects.

## Abbreviations

ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
CCL	Cardiac catheterisation laboratories
CRE	Consulting radiation expert
DEC	Department of Environment and Conservation
EPA	Environment Protection Authority
Gy	Gray
HCCC	Health Care Complaints Commission
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
MBq	Megabecquerels
MOU	Memorandum of Understanding
NHMRC	National Health and Medical Research Council
NUIP	National Uniformity Implementation Panel
RAC	Radiation Advisory Council