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**RAC**

**RADIATION ADVISORY COUNCIL**

**ANNUAL REPORT 2005 06**

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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 2005 to 30 June 2006. This report has been prepared in accordance with the provisions of the *Radiation Control Act 1990*.

Yours sincerely

A handwritten signature in cursive script that reads "C. Lambertson".

**CRAIG LAMBERTSON**

Chairperson  
Radiation Advisory Council  
November 2006



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## Chairperson's review

The Council met nine times during the year and provided the Department of Environment and Conservation NSW (DEC) with policy and regulatory advice on a wide range of radiation matters including the review of national codes, radiation accidents, licensing and registration requirements and the assessment of radiation safety courses.

During the year, the work and activities of the Council that were of particular significance included:

- the review of four Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) draft Codes of Practice and a standard that will eventually form part of the National Directory for Radiation Protection (NDRP) and will be required to be referenced by each jurisdiction in their radiation protection legislation
- the work of the Council's Shielding Committee which commenced the drafting of guidance material for developing safe shielding criteria for premises in NSW where radioactive substances are kept or used and where radiation apparatus is used
- the work of the Council's Exemption Levels for Radionuclides Committee which commenced work on examining the implications of adopting the NDRP Schedule exemption levels and the merits of continuing to exempt activities according to the current thresholds set by the *Radiation Control Act 1990*
- two off-site visits, the first to a gamma sterilisation plant and the second to the Australian Nuclear Science and Technology Organisation (ANSTO) Opal Reactor and Waste Facilities, initiated as a means to keep the Council informed of current technology and emerging issues in radiation protection
- the consideration of the findings of the paper, *Radiopharmaceutical maladministrations in NSW*, that was presented to the Council. The findings included the radiation accidents in nuclear medicine that were reported to the Environment Protection Authority (EPA) and Council between February 1999 and February 2004.
- the consideration of its Strategic Direction 2006–2009 and review of the Memorandum of Understanding between the Council and the EPA.

The Council's priorities over the next three years will focus on a review of the regulatory model for radiation control in NSW to ensure an efficient and effective regime for controlling risks to human health and the environment; identification of emerging issues in radiation protection; and identification of procedures and rules to prevent or minimise dangers arising from radiation exposure in the environment. These priorities reflect both the ongoing fundamental issues of radiation protection as well as the changing state of the circumstances within which these issues must continue to be addressed.

I would like to thank all members and deputies of the Council for their valuable contribution and commitment to the important work of the Council. On behalf of the Council I would like to thank the DEC Hazardous Materials and Radiation Section staff for their excellent work in supporting the Council and its committees.



**CRAIG LAMBERTON**  
Chairperson  
September 2006

## 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 of the Act.
  - (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 Hazardous Materials and Radiation Section support the work of the Council. The terms EPA and DEC will therefore be used interchangeably through this document.

## Meetings of the Council

During the reporting period ending 30 June 2006, the Council met 9 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 I. The Council reviewed the MOU at the December 2005 meeting and no significant changes were proposed therefore the MOU was not amended.

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

<b>TABLE 1</b>			
<b>Members of the Radiation Advisory Council and meeting attendance</b>			
<b>Member</b>	<b>Appointed position</b>	<b>Meetings attended</b>	<b>Meetings eligible to attend</b>
Mr Craig Lamberton	Chairperson	9	9
Mr Simon Smith	Deputy	0	0
Dr Philip Pasfield (Re-appointed 7 February 2006)	Radiologist	5	9
Dr Andrew Scott (Re-appointed 7 February 2006)	Deputy	3	4
Mr John Robinson (Re-appointed 7 February 2006)	Diagnostic radiographer	7	9
Mr Glen Burt (Re-appointed 7 February 2006)	Deputy	1	2
Mr Colin Hockings	Expert in industrial uses of radiation	8	9
Mr Michael Carter (Re-appointed 7 February 2006)	Expert in naturally occurring radioactivity	9	9
Mr Brian Holland (Re-appointed 10 April 2006)	Deputy	0	0
Mr Jeremy Pigott (Re-appointed 10 April 2006)	Health physicist	6	8
Dr Geoffrey Schembri	Physician in nuclear medicine	5	9
Assoc. Prof. Lee Collins, AM (Re-appointed 7 February 2006)	Expert in non-ionising radiation	7	9
Mr Howard Ackland (Re-appointed 7 February 2006)	Deputy	2	2
Ms Tara McCarthy (Appointed 10 April 2006)	An officer of WorkCover Authority NSW	1	3
Mr Mark Moskvitch (Appointed 10 April 2006)	Deputy	2	2
Dr Ludmilla Robinson (Re-appointed 7 February 2006)	Legal practitioner	8	9
Mr John Clark (Re-appointed 10 April 2006)	Deputy	1	1
Dr Cameron Hazlehurst (Appointed 16 August 2005)	Community representative	9	9
Ms Lea Maher (Re-appointed 7 February 2006)	Deputy	0	0

<b>TABLE 1 (continued)</b>			
<b>Members of the Radiation Advisory Council and meeting attendance</b>			
<b>Member</b>	<b>Appointed position</b>	<b>Meetings attended</b>	<b>Meetings eligible to attend</b>
Ms Kathy Meleady	An officer of the Department of Health	3	9
Dr Denise Robinson (Resigned 26 May 2006)	Deputy	0	6
Dr Michael Izard	Radiation oncologist	8	9
Dr Mary Dwyer	Deputy	0	1
Dr Richard Smart (Re-appointed 7 February 2006)	Medical physicist	8	9
Mr Paul Cardew (Re-appointed 7 February 2006)	Deputy	0	1
Mr Luke Platt (Re-appointed 5 July 2005)	Minister's nominee	4	9
Mr Jon D'Astoli (Appointed 5 October 2004)	Occupational health and safety Expert	7	9
Mr David Lloyd-Jones (Appointed 5 July 2005)	Deputy	2	2

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.

## **Committees of the Council**

Section 31 of the Act enables the Council to establish committees to help it exercise its functions. The Council dissolved two of its committee's, the Technical Committee and the Course and Competencies Committee as they were no longer considered necessary to carry out the work of the Council.

In the last period the Council established the Shielding Committee (later re-named the Shielding Assessment and Verification Committee, to reflect the expansion of the Committee's Terms of Reference) and the Exemption Levels for Radionuclides Committee.

### ***The Shielding Assessment and Verification Committee***

The Shielding Assessment and Verification Committee was established to address the accreditation required for Consulting Radiation Experts (CREs) to certify premises in NSW where radioactive substances are kept or used and where radiation apparatus is used.

The Committee is to carry out this work by determining:

1. the technical criteria necessary for proper safe shielding of registered premises. This may be done by a guideline prepared by the committee or by reference to technical documents published by other professional or government organisations.
2. the criteria required for CREs to be accredited by DEC. The accreditation criteria will depend on the hazard level of the practices/premises that the CREs are to certify as being compliant with the requirements of the Radiation Control Regulation 2003.
3. a classification of CREs to be accredited
4. an outline of the administrative mechanism of how DEC, in collaboration with the Council, will issue these CREs with a certificate of accreditation.

During the reporting period the committee met on two occasions and was well advanced in developing the first draft of the guidance document.

### **Exemption levels for the Radionuclides Working Group**

With the endorsement of the *National Directory for Radiation Protection* (the Directory), NSW is obliged to look at adopting the exemption levels specified in Schedule 4 of the Directory as a basis for setting regulatory thresholds. These threshold levels vary significantly from those currently imposed by the Radiation Control Act.

The Working Group was established to examine the implications of adopting the Directory Schedule exemption levels and the merits of continuing to exempt activities according to the current thresholds set by the Act.

During the reporting period, the committee discussed the exemptions levels that will be required, and commenced the drafting of guidance documents which will be considered by the Council on completion.

### **Proposed future committees**

As a result of discussions pertaining to its strategic direction 2006–2009, the Council considered the establishment of two additional committees, the Regulatory Review and Reform Committee and the National Directory Committee.

The Regulatory Review and Reform Committee is proposed to review the current NSW regulatory regime to ensure that the regulation of radiation in NSW is both efficient and effective in controlling risks to human health and the environment.

The National Directory Committee is proposed to provide advice to Council and DEC on the priorities and suitability of documents within the Directory and to advise on their outcomes and impacts (legislative, financial and operational) for DEC, other NSW government agencies and NSW as a whole.

## National uniformity

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

The Directory is being developed through the Radiation Health Committee and 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. Council provided comment on Version 1.0 of the Directory in the last period. This version was endorsed by the Australian Health Minister's Advisory Committee in May 2005. The second edition of the Directory is not anticipated to be released for public comment until the latter part of 2006.

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

- *Code of Practice, Safety Guide and Regulatory Impact Statement - Radiation Protection in Dentistry* (2005).
- *Code of Practice, Safety Guide and Regulatory Impact Statement – Safe Use of Fixed Radiation Gauges* (2005). The Council provided additional advice on the code and safety guide at its May 2006 meeting as a result of the documents being released for a further round of public consultation.
- *Radiation Protection Standard – Occupational Exposure to Ultraviolet Radiation*.
- *Regulatory Impact Statement – Code of Practice on the Safe Use of Radiation in Veterinary Science*. The draft Code of Practice Safe Use of Radiation Veterinary Science was reviewed by Council at its March 2005 meeting.
- *Code of Practice for Security of Radioactive Sources*.

These draft documents will eventually form part of the Directory.

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

- *National Directory for Radiation Protection Edition 1.0 – Consideration of exemption levels for radionuclides and the process for determining what the exemption level should be as they differ from the levels imposed by the Radiation Control Regulation*.
- Alternatives to radioactive sources that could be misused. Council advised DEC that the issues identified by it be referred to the Radiation Health Committee for consideration at the national level.
- Review of the radiation awareness paper *Risk of Health Effects from Ionising and Non-Ionising Radiation* which Council initially endorsed in 2001.
- World Health Organization *Draft Framework Guiding Public Health Policy Options in Areas of Scientific Uncertainty* with particular reference to Electric and Magnetic Fields (EMFs).
- Discussion Paper: *Developing Standards for Radiation Treatment Services in Australia*. The aim of the paper is to determine, promote and assess the quality of radiation treatment delivery to patients in Australia.

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

Section 6 of the *Radiation Control Act 1990* 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 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 the EPA 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 endorsed:

- the criteria and licence conditions to use dual energy x-ray absorptiometry (DXA) for bone mineral analysis and/or body composition analysis
- licensing requirements for the I-Cat Beam 3D dental imaging system and amendment to current licence conditions to use apparatus for dental radiography
- licensing requirements for Newtom 3G Dental Volumetric Tomograph
- standard criteria for the granting of the licence to use radioactive substances for borehole logging without further referral to the Council
- the following eleven radiation safety courses for the purposes of licensing:
  - *Radiation Safety in Borehole Logging Operations* conducted by RADSMART for the purpose of licensing individuals to use radioactive substances for borehole logging (S35)
  - *Radiation Safety for Laboratory Staff* conducted by RADSMART for the purposes of licensing individuals to use radioactive substances for analytical purposes (S5); and/or to use radioactive substances for scientific or research purposes (S8)
  - *Radiation Safety with Portable X-ray Tube XRF Devices* conducted by RADSMART for the purposes of licensing individuals to use portable x-ray fluorescence (XRF) radiation apparatus for analysis (IA19)
  - *Use of Portable Radioisotope XRF Analysers* conducted by RADSMART for the purposes of licensing individuals to use radioactive substances in a portable x-ray fluorescence (XRF) analyser (S19)
  - *I-Cat Initial On-site Training* provided by Body Logic Australia for the purposes of licensing individuals to use dental CT for dental radiography (IA24)
  - *Radiation Safety for Cone Beam Dental Digital Tomography Apparatus* provided by Gammasonics Radiological Services Pty Ltd for the purpose of licensing users, who

meet all pre-requisites for licensing, to use dental Computed Tomography (CT) for dental radiography (IA24)

- *Bone Densitometry Courses and Certification Examinations: Clinical Track and Technologist Track* conducted by International Society of Clinical Densitometry and University of Western Australia for the purposes of licensing individuals to use radiation apparatus for dual energy x-ray absorptiometry (IA27 – Tier 1)
- *General Radiation Awareness and Cabinet X-Ray* conducted by Australian Radiation Services Pty Ltd for the purposes of licensing individuals to install and service x-ray equipment (IA10)
- NSW Hospital and University Radiation Safety Officers Group Computed Tomography Safety Course for Nuclear Medicine Technologists conducted by various NSW Department of Health Area Health Services for the purposes of licensing individuals to use CT radiation apparatus for nuclear medicine technology (IA16)
- *Radiation Safety Training on the Use of Niton Field Portable XRF Analyser X-ray Tube* conducted by JBS Technologies Pty Ltd for the purposes of licensing individuals to use portable x-ray fluorescence (XRF) radiation apparatus for analysis (IA19).

In addition the Council:

- provided advice on the unsuitability of three courses for the purposes of gaining a license for borehole logging
- considered a submission for a non-routine licence and recommended that a tier 1 licence to use dual-energy X-ray absorptiometry (DXA) apparatus for total body composition analysis be granted to the applicant
- provided advice on the initial consideration of licensing requirements for the Z Backscatter Vans to be used for security operations and recommended that the matter be referred to the Radiation Health Committee for consideration at the national level
- recommended that an applicant not be granted a licence to undertake radiography in a cardiac catheterisation laboratory due to insufficient demonstration of the applicant's skills in the use of fluoroscopy in cardiac catheterisation laboratories
- provided advice on whether two individuals had the appropriate qualifications and experience to conduct a radiation safety course in fluoroscopy. The Council advised that both individuals were sufficiently qualified to conduct the approved course
- recommended that an applicant not be granted a variation to a licence to use dental CT as the applicant had insufficient knowledge in the use of CT for diagnostic purposes.

For the reporting period ending 30 June 2006, DEC issued 2069 new licences, including 151 licences for the sale/possession and 1918 licences to use radiation apparatus or radioactive substances.

During 2005–06 DEC also renewed 10,462 licences – 9850 licences to use and 612 licences to sell/possess radioactive substances or radiation apparatus.

At the end of the reporting period, there were 12,832 active licences.

Table 2 summarises new licences applications, 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) issued in 2005–06</b> <b>listed by occupational category</b>		
<b>Occupational category</b>	<b>Radioactive substances</b>	<b>Ionising radiation apparatus</b>
Dental	0	484
Medical—specialist	21	103
Medical—other and related	209	817
Servicing/installation	19	56
Educational	6	3
Safety	5	2
Management	7	3
Scientific/research	140	37
Engineering	22	7
Technical	188	52
Other	2	15
Company (licence to sell)	78	116
Rural	1	0
Miscellaneous	44	14
Veterinary**	0	167
<b>Total</b>	<b>742*</b>	<b>1876*</b>

\* Includes licence variations to existing licences.

\*\* Veterinary figures were previously reported under Miscellaneous

Table 3 summarises the number of new licences issued by DEC during the period 2000–01 to 2005–06.

<b>TABLE 3</b> <b>Number of new licence applications (including variations) issued</b> <b>from 2000–01 to 2005–06</b>			
<b>Period</b>	<b>Radioactive substances</b>	<b>Radiation apparatus</b>	<b>Total</b>
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
July 2005–June 2006	742	1876	2618*

\*Includes licence variations to existing licences.

## Registration of radiation apparatus, sealed source devices, 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, radiation apparatus, sealed source devices 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.

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 addresses the way in which the two parties agree to work with each other on determining registration applications.

During the reporting period the Council provided advice to DEC on registration requirements as follows:

- Newtom 3G Dental Volumetric Tomograph

Council considered that the apparatus is essentially the same as the i-Cat Beam 3D dental imaging system and that it is appropriate for this equipment to be classified as dental CT.

- I-Cat Beam 3D dental imaging system

Council endorsed the registration requirements for the i-Cat Beam 3D dental imaging system.

- Z Backscatter Vans to be used for security operations

Council recommended that the matter be referred to the Radiation Health Committee for uniform regulatory controls to be imposed.

- Nomad Portable X-ray System

The Council at its October 2005 meeting considered an application requesting the exemption of certain registration requirements for the Nomad Portable X-ray System in order for it to be registered for use for dental diagnostic imaging purposes. The Council did not support the proposal and recommended that the matter be referred to the Radiation Health Committee and that the Committee through consultation with each jurisdiction establish a consensus on the use of these portable units on humans. The Council did however recommend that the apparatus could be permitted to be used only on inanimate objects until a national decision had been made on the use of this type of equipment.

Table 4 provides a list of items that are currently registered by DEC and their registration commencement dates. A summary of each registration category and the number of registrations in each category is provided in Tables 5 to 9.

<b>TABLE 4</b>	
<b>Registration categories and commencement dates</b>	
<b>Registration categories</b>	<b>Commencement dates</b>
Diagnostic imaging apparatus	11 August 2000
Cyclotrons	1 December 2001
Therapy apparatus	1 February 2004
Sealed source devices	1 July 2004
Premises where radioactive substances are kept or used	1 July 2004

### Registration of diagnostic imaging apparatus

During the year ending 30 June 2006, DEC issued 896 new registrations and renewed 2148 registrations for diagnostic imaging apparatus as shown in Table 5.

<b>TABLE 5</b>		
<b>Number of diagnostic imaging apparatus registered during 2005–06</b>		
<b>Equipment type</b>	<b>Registered</b>	<b>Renewed</b>
Fixed Dental Radiography	422	1027
Fixed Radiography	119	368
Fixed Fluoroscopy	16	15
Fixed Radiography/Fluoroscopy	19	61
Fixed Mammography	26	49
Computed Tomography	65	73
Dental Computed Tomography	3	0
Bone Mineral Densitometry	27	34
Mobile Dental Radiography	10	27
Mobile Radiography	101	303
Mobile Fluoroscopy	38	40
Mobile Radiography/Fluoroscopy	7	15
Mobile Mammography	4	10
Panoramic Radiography	39	126
<b>Total</b>	<b>896</b>	<b>2148</b>

Table 6 gives the number of new diagnostic imaging apparatus registered by DEC between July 2000 and June 2006.

<b>TABLE 6</b>						
<b>Number of new diagnostic imaging apparatus registered between July 2000 and June 2006</b>						
<b>Equipment type</b>	<b>2000–01</b>	<b>2001–02</b>	<b>2002–03</b>	<b>2003–04</b>	<b>2004–05</b>	<b>2005–06</b>
Fixed dental radiography	2592	168	453	381	465	422
Fixed radiography	832	134	118	70	80	119
Fixed fluoroscopy	69	18	17	10	7	16
Fixed radiography/fluoroscopy	246	31	43	41	26	19
Fixed mammography	161	31	52	28	34	26
Computed tomography	174	22	59	72	55	65
Dental computed Tomography	0	0	0	0	0	3
Bone mineral densitometry	66	9	15	16	11	27
Mobile dental radiography	72	6	9	10	6	10
Mobile radiography	686	70	92	57	64	101
Mobile fluoroscopy	118	18	24	38	33	38
Mobile radiography/fluoroscopy	60	10	0	10	14	7
Mobile mammography	17	8	8	5	2	4
Panoramic radiography	265	43	35	24	24	39
<b>Total</b>	<b>5358</b>	<b>568</b>	<b>925</b>	<b>762</b>	<b>821</b>	<b>896</b>

The total number of diagnostic imaging apparatus registered by DEC as at 30 June 2006 was 6403. The registration period for diagnostic imaging apparatus varies between 2 or 5 years, depending on the type of apparatus.

### **Registration of cyclotrons**

From 1 December 2001 the Radiation Control Amendment Regulation 2001 prescribed cyclotrons as radiation apparatus that require registration under the Radiation Control Act. In June 2002 DEC registered one cyclotron. Cyclotrons are required to be registered every two years.

### **Registration of therapy apparatus**

From 1 February 2004, radiation apparatus used or intended to be used for radiotherapy or radiotherapy planning purposes was required to be registered with the EPA under the Radiation Control Regulation 2003. Radiotherapy apparatus are required to be registered every 2 years.

Table 7 summarises the number of registrations for each type of therapy apparatus between 2003-04 and 2005-06.

<b>TABLE 7</b>				
<b>Number of therapy apparatus registered during 2003-04 to 2005-06</b>				
<b>Equipment type</b>	<b>2003-04</b>	<b>2004-05</b>	<b>2005-06</b>	
			<b>New</b>	<b>Renewed</b>
Kilovoltage therapy x-ray (superficial/orthovoltage)	17	0	3	25
Linear accelerator	38	4	3	9
Simulator	14	0	0	14
<b>Total</b>	<b>69</b>	<b>4</b>	<b>6</b>	<b>48</b>

At the end of the reporting period there was a total of 66 registered therapy apparatus.

### Registration of sealed source devices

The registration of sealed source devices commenced on 1 July 2004. The registration period for sealed source devices including fixed radiation gauges is every 2 years

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*. At the end of the period, DEC renewed 224 FRGs totalling 637 active FRG registrations.

During the reporting period, DEC registered 147 new sealed source devices including FRGs, as shown in Table 8.

<b>TABLE 8</b>		
<b>Number of new sealed source devices registered during 2004-05 and 2005-06</b>		
<b>Equipment type</b>	<b>2004-05</b>	<b>2005-06</b>
Borehole logging	11	8
Soil moisture density & moisture determination	242	30
Density gauge	38	22
Neutron probe	52	1
Industrial radiography	28	14
XRF analyser	20	3
Portable gauge	9	1
Beta backscatter thickness testing	1	0
Self-shielded irradiator	12	2
Therapy device	16	3
Analyser	2	0
Nuclear medicine gamma camera	13	0
Fixed radiation gauges (new registrations)	79	63
<b>Total</b>	<b>523</b>	<b>147</b>

At the end of the reporting period there was a total of 1131 registered sealed source devices including FRGs.

### 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.

Table 9 summarises the number and category of premises registered by DEC between 2004–05 and 2005–06.

<b>TABLE 9</b>						
<b>Category and number of new premises registered during 2004–05 and 2005–06 where radioactive substances are kept or used</b>						
<b>Premises category</b>	<b>2004–05</b>			<b>2005–06</b>		
	<b>High</b>	<b>Medium</b>	<b>Low</b>	<b>High</b>	<b>Medium</b>	<b>Low</b>
Medicine (Government Hospital)	3	32	29	0	0	0
Medicine (Private Hospital)	1	21	25	0	2	2
Research (Government)	0	1	10	0	2	0
Research (University)	5	18	59	0	5	17
Research (Private)	0	1	10	0	1	3
Radioanalytical	0	1	2	0	0	0
Sterilisation	1	0	0	0	0	0
Store only for radioactive sources	0	3	23	0	2	7
Radiopharmacy	0	1	0	0	0	0
Industrial	1	0	1	0	1	0
Medicine (Private Practice)	0	0	2	0	0	0
Teaching (University)	0	0	0	0	0	0
Other	0	0	1	2	0	0
<b>Total</b>	<b>11</b>	<b>78</b>	<b>162</b>	<b>2</b>	<b>13</b>	<b>29</b>

At the end of the reporting period, there was a total of 292 active registered premises where radioactive substances are kept or used.

## 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.

During the last period 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 Committee is in the process of developing the criteria for accrediting CREs for the purposes of premises shielding and preparing an accompanying guideline.

During the year ending 30 June 2006, DEC accredited 13 CREs and renewed 36 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 10, including the total number of accreditations as at 30 June 2006.

**TABLE 10**  
**Number of new and renewed accreditations and the total number of accreditations**  
**as at 30 June 2006**

Category	Equipment	Number of accreditations issued	Number of accreditations renewed	Total number of accreditations
Diagnostic imaging	Mammography	0	6	24
	Dental (intra-oral, OPG and cephalometry)	9	9	41
	Dental (intra-oral, OPG and cephalometry)			
	Radiography			
	Fluoroscopy	0	2	6
	Computed tomography			
	Bone mineral densitometry (including veterinary and chiropractic)			
	Radiography			
	Fluoroscopy			
	Computed tomography	4	17	64
	Bone mineral densitometry (including veterinary and chiropractic)			
Industrial	Fixed radiation gauges	2	2	13
<b>Total</b>		<b>13*</b>	<b>36*</b>	<b>148*</b>

\*The total number of accreditations is based on the number of accreditations conditions issued, not the actual number of accreditations, that is, a person may be accredited for more than one type of apparatus.

## 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 of the Regulation.

Accidents are normally caused by either deficiency in the relevant management systems, or failures on the part of individuals to implement those systems correctly or a combination of both. Where investigations reveal deficiency in the management systems 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 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*. All jurisdictions have agreed to forward any radiation accident data they receive to ARPANSA for placement in the national register.

During the last period the Council recommended that information on radiation accidents be provided to stakeholders through quarterly or annual newsletters as a means of disseminating lessons learnt from reported radiation accidents. During the reporting period ending 30 June 2006, DEC was informed of 33 instances where radiation accidents may have occurred, involving 35 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 as a matter of practice requests DEC to inform the relevant professional bodies and universities of significant accidents as a means of disseminating the knowledge gained.

A summary of all the accidents reported to Council and subsequent recommendations of the Council is grouped by categories of accidents and is provided below.

### **Nuclear Medicine**

- A patient received 235 MBq of Tc99m Phytate Colloid for a repeat liver/spleen scan. The cause of the repeat scan was due to the incorrect preparation of the radiopharmaceutical. The effective dose to the patient from the repeat scan was calculated at 3.3 millisieverts.

The Council reviewed the accident 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 requested that the practice provide DEC with the report from the laboratory investigation for review.

- Three patients received 820 MBq of Tc99m MIBI due to repeat cardiac scans. The cause of the repeat scans was due to unreported data from the gamma camera being lost when a software upgrade occurred. The effective dose to each patient from the repeat scan was 7.4 millisieverts.

The Council reviewed the accident 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.

- Twelve radiation accidents had occurred at a practice between June 2001 and April 2005. The practice only recently became aware that such accidents had to be reported:
  - A patient received the wrong radiopharmaceutical  $^{99m}\text{TcO}_4$  for a cardiac test. The effective dose to the patient was 3.04 and millisieverts.
  - A patient received the wrong radiopharmaceutical  $^{99m}\text{TcO}_4$  for a cardiac test. The effective dose to the patient was 2.68 millisieverts.
  - A patient received the wrong radiopharmaceutical  $^{99m}\text{TcO}_4$  for a myocardial perfusion study. The effective dose to the patient was 2.77 millisieverts.

- A patient received Tc HDP bone agent reconstituted with myoview. The effective dose to the patient was 4.78 millisieverts.
- A patient received Tc 99m HDP bone agent reconstituted with SestaMIBI. The effective dose to the patient was 4.87 millisieverts.
- A patient received HDP reconstituted with myoview. The effective dose to the patient was 4.29 millisieverts.
- A patient received HDP reconstituted with myoview. The effective dose to the patient was 4.43 millisieverts.
- A patient received HDP vial reconstituted with myoview. The effective dose to the patient was 4.6 millisieverts.
- Cardiac patient injected with Tc99m instead of MIBI. The effective dose to the patient was 5.63 millisieverts.
- A patient received HDP vial oxidised. The effective dose to the patient was 4.97 millisieverts.
- A patient received HDP vial oxidised. The effective dose to the patient was 4.59 millisieverts.
- A patient received HDP oxidised bone agent. The effective dose to the patient was 4.51 millisieverts.

The Council recommended that further documentation be provided on each accident and that DEC investigate why the practice was not aware of its regulatory obligation to report such accidents. DEC issued the practice with a notice to review its procedures through an approved consultant and that the practice appoint a Radiation Safety Officer. A notice was issued by the DEC and appropriate responses and actions were undertaken.

- A patient received 936 MBq Tc99m Per technetate instead of Tc99m ECD (Neurolite) for a brain scan due to the incorrect radiopharmaceutical being selected. The effective dose to the patient was 4.78 millisieverts.

The Council recommended that as this accident is a repeat of similar accidents which occurred at the same practice during the past year that the practice be issued with a notice requiring it to undergo an external review of its practice by an approved auditor and that the practice be required to appoint a Radiation Safety Officer. A notice was issued by DEC. DEC was satisfied with the controls the facility had instigated to correct deficiencies in its standard operating procedures.

- A pregnant patient wrongly received a nuclear medicine VQ scan due to the wrong patient label being placed in the patient's medical notes. The patient received 40 MBq of Tc99m Technegas and 186 MBq of Tc99m MAA. The effective dose to the patient was estimated to be 2.3 millisieverts. For clinical reasons it was not necessary to calculate the foetal dose.

The Council reviewed the accident 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 606 MBq Tc99m Sestamibi instead of 978 MBq Tc99m MDP for a bone scan due to the wrong radiopharmaceutical being selected. The effective dose to the patient from the wrongly administered radiopharmaceutical was 3.8 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. Council received the additional information and was satisfied with the response.

- A patient received 1040 MBq of Tc99m Pertechnetate instead of Tc99m Sestamibi for a cardiac rest/stress study due to the wrong radiopharmaceutical vial being selected. The effective dose to the patient from the wrongly administered radiopharmaceutical was 12.5 millisieverts.

The Council reviewed the accident 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 814 MBq of Tc99m MDP due to patient misidentification. The effective dose to the patient from the wrongly administered radiopharmaceutical was 4.6 millisieverts.

The Council reviewed the accident 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 800 MBq of Tc99m Sestamibi instead of TC99m MDP for a bone scan due to the wrong radiopharmaceutical being selected and placed in a lead pot with a bone scan label. Initial calculations by DEC estimated that the effective dose to the patient from the wrongly administered radiopharmaceutical was 7.2 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 that further details of the accident be provided. The information requested was not available at the time of writing this report.

- A patient received 1000 MBq of Tc99m Pulmolite instead of 1000 MBq of Tc99m Pertechnetate due to the wrong radiopharmaceutical being selected. The effective dose to the patient was 11 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 that further details of the accident be provided. Additional details of the accident were provided. Council noted the response.

- A patient received a bone mineral density (BMD) scan instead of a radioisotope bone scan due to the referral being misread. The effective dose to the patient was 170 microsieverts.

The Council reviewed the accident 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 a repeat lung scan due to the first scan showing non-specific distribution of the injected Tc99m throughout the body rather than being concentrated in the lungs. The estimated effective dose from the abnormal radiopharmaceutical behaviour to the patient was calculated at 1.76 millisieverts.

The Council requested further information from the facility be provided once the manufacturer of the radiopharmaceutical had undertaken an analysis of the content of the returned vial.

- A patient received a repeat Tc99m ECD scan as the initial scan was delayed due to the decision that the patient be given a pregnancy test prior to the scan. The pregnancy test was negative and the administration of the radiopharmaceutical proceeded after a top up of activity to allow for the delay due the extended time between radiopharmaceutical preparation and administration. A repeat scan was undertaken as there was no take-up of the radiopharmaceutical. This resulted in the patient receiving an additional effective dose of 7.4 millisieverts.

The Council reviewed the accident 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.

Although outside of Council's role, Council considered the ethical issues arising from the accident, specifically that the patient was not told of the radiopharmaceutical error because of the patient's mental status and recommended that DEC suggest that the facility refer the accident to the Clinical Governance Unit of the relevant Health Service to address the ethical issues raised.

- The wrong patient was given a whole body scan and received 850 MBq Tc-99m MDP. The error occurred due to the incorrect patient being booked for the scan. The patient received 4.34 millisieverts from the incorrect procedure.

The Council recommended that further information regarding the details of the accident be provided as it was not clear to the Council how the error had occurred and as to what steps had been taken to minimise this type of accident.

## Therapy

- A patient received 10 MV x-rays from a linear accelerator instead of an electron beam. The patient received an effective dose of 430 millisieverts.

The Council noted that the cause of the accident was due to human error and confirmed that it was unlikely that the patient would experience deterministic effects from the exposure. Referral of the accident to the HCCC was not recommended.

The Council reviewed the accident 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 undergoing a palliative radiotherapy treatment received a therapy dose of radiation to tissue outside the prescribed treatment area as a result of the treatment couch being moved due to a collision with the electronic portal imaging device. The couch was not repositioned to the correct co-ordinates after the collision. The patient received 4 Gray to the tissue not intended to be irradiated.

The Council noted that the cause of the accident was due to human error and indicated that it was unlikely that the patient would experience deterministic effects from the exposure.

The Council reviewed the accident 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 undergoing radical external beam treatment for cancer localised to the pelvis received approximately 1–1.5 Gray being delivered to the regions of the patient’s upper leg instead of the intended pelvic area due to the patient not being aligned correctly.

Council noted that the error was uncommon and that there are processes in place that should have prevented the accident. The Council reviewed the accident 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.

### **Radiology**

- A patient wrongly received a chest CT scan due to patient misidentification. The effective dose to the patient from the CT scan was 3.3 millisieverts.

The Council requested further information on the details of the accident. This information was provided and the Council reviewed the accident 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 receiving a chest x-ray received an overexposure as a student radiographer selected the incorrect automatic exposure control (bucky) that the patient was positioned against. The contributing factors to the accident were that the student was not under immediate supervision at the time of the incident and that the apparatus was that of an old design that allows exposure even when a film cassette is not in the selected bucky. The effective dose to the patient has been estimated to be less than 1 millisievert.

The Council reviewed the accident 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 chest CT scan due to the incorrect identification label being attached to the medical request form. The effective dose to the patient from the CT scan was 9 millisieverts.

The Council reviewed the accident 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 mobile veterinary x-ray apparatus in a silver carry case was stolen from the back seat of a car when the car was broken into. At the time of writing this report the apparatus had not been recovered.

Council noted the report.

- Council considered an initial report of two high dose readings recorded on dose monitors worn by two employees. The two employees received readings of 29 millisieverts and 18.2 millisieverts respectively.

Council requested that further information be requested from the practice relating to apparent poor work practices and that DEC explore whether the licensee and/or the employer should be issued with a Penalty Infringement Notice. DEC is currently investigating the incident.

- Follow up actions from accidents reported in the last period:

### **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 calculation be revisited by the facility, as it appeared that the initial 200 MBq of Tc99m Sestamibi was not included in the calculations. The facility recalculated the effective dose and advised that an error had been made and that the effective dose to the patient was in fact 6.4 millisieverts.

The Council reviewed the accident 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.

### **Radiology**

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

Council noted that this type of event is not required to be reported under the Radiation Control Regulation however Council recommended that the facility investigate further controls to correct deficiencies in standard operating procedures, to prevent similar accidents from recurring and requested further details of the accident. Council noted the response.

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

The Council reviewed the accident and the controls the facility had instigated to correct deficiencies in its standard operating procedures in the last period. Council was satisfied with the steps the organisation had taken to prevent this type of incident from recurring however requested the facility provide further information on the accident. The facility provided the additional information. Council noted the advice.

### **Therapy**

- Three people including one pregnant woman working at a medical facility were each exposed to 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 reviewed the accident and the controls the facility had instigated to correct deficiencies in its standard operating procedures in the last period. Council was satisfied with the steps the organisation had taken to prevent this type of incident from recurring however requested the facility provide further information on the accident. The facility provided the additional information. Council noted the advice.

### Categories of radiation accidents reported during 2004-2006

Table 11 provides a summary of accidents reported to DEC during 2004-05 and 2005-06 by specific accident category.

<b>TABLE 11</b>		
<b>Categories of accidents reported between 2004-05 and 2005-06</b>		
<b>Accident category</b>	<b>2004–05</b>	<b>2005–06</b>
Nuclear medicine	19	25
Therapy	5	3
Radiology	5	3
Other	2	2
<b>Total</b>	<b>31</b>	<b>33</b>

A recently completed study of accidents in nuclear medicine showed that maladministration in nuclear medicine is uncommon in NSW, with approximately 8–9 reported incidents per 100,000<sup>1</sup> procedures.

Data obtained from the Health Insurance Commission (HIC) database for therapeutic procedures (radiation oncology and nuclear medicine) showed that there were 259,794<sup>2</sup> procedures carried out in NSW during 2004–05 and 2,839,834<sup>2</sup> diagnostic radiology procedures carried out during the same period.

Council acknowledges that there is a need for further analysis in terms of the number of accidents reported to DEC and the number of procedures undertaken annually in each category.

### Number of radiation accidents reported during 2001–2006

Table 12 summarises the number of accidents reported to DEC during the period 2001–02 to 2005–06.

<b>TABLE 12</b>	
<b>Radiation accidents reported during 2001-02 to 2005-06</b>	
<b>Year</b>	<b>Number of accidents reported</b>
July 2001–June 2002	15
July 2002–June 2003	14
July 2003–June 2004	23
July 2004–June 2005	31
July 2005–June 2006	33

<sup>1</sup>Tam Yenson, George Larcos, Lee T Collins, 'Radiopharmaceutical maladministrations in NSW', *Nuclear Medicine Communications* 26 (11):1037–1041, November 2005, Lippincott Williams & Wilkins

<sup>2</sup> Medicare figures do not include CT and diagnostic procedures undertaken in the public health system where a rebate is not paid.

The Council acknowledges that the increase in the number of reported radiation accidents during the last period was due to one facility reporting 12 accidents that occurred at the facility between June 2001 and April 2005. Council acknowledged that the increase in the reporting of radiation is also due to DEC raising awareness of the need to report accidents.

### **Radiopharmaceutical maladministrations in NSW during 1999–2000 to 2003–04**

In 2004 DEC assisted Dr Larcos (then a member of Council) and colleagues in reviewing radiation accident reports occurring in nuclear medicine, reported to the EPA between February 1999 and February 2004, with the view of developing a paper to evaluate the frequency, type, causes and adverse effects of reported nuclear medicine radiopharmaceutical maladministrations in NSW.

The findings of the paper concluded that nuclear medicine maladministrations in NSW are uncommon, with approximately 8–9 incidents per 100,000 procedures. The paper also highlighted that most maladministrations are the consequence of incorrect radiopharmaceutical dispensing and those which involved diagnostic radiopharmaceuticals (approximately 99% of all nuclear medicine procedures) resulted in no immediate adverse effects from the exposure.

The paper *Radiopharmaceutical maladministrations in NSW* by Tam Yenson, George Larcos and Lee Collins was recently published in the journal *Nuclear Medicine Communications*.

Dr Larcos presented the findings of the paper to a meeting of the Council in May 2006.

The Council agreed that the findings of the paper should be used as a means for contributing to the education of users of radioactive substances, and highlighting common errors in nuclear medicine.

## **Appendix I: 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

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\* In 2003 the EPA became part of DEC.

- (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 Hazardous Materials and Radiation 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

## **Abbreviations**

ANSTO	Australian Nuclear Science and Technology Organisation
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
CRE	Consulting radiation expert
CT	Computed Tomography
DEC	Department of Environment and Conservation NSW
EPA	Environment Protection Authority
FRG	Fixed radiation gauge
HCCC	Health Care Complaints Commission
HIC	Health Insurance Commission
MBq	Megabecquerels
MOU	Memorandum of Understanding
RAC	Radiation Advisory Council