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**RADIATION ADVISORY COUNCIL**

**ANNUAL REPORT 2003–04**

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Department of Environment and Conservation (NSW)

59–61 Goulburn Street, Sydney

PO Box A290, Sydney South NSW 1232

Phone: (02) 9995 5000 (switchboard)

Phone: 131 555 (NSW only—information and publications requests)

Fax: (02) 9995 5999

TTY: (02) 9211 4723

E-mail: [info@environment.nsw.gov.au](mailto:info@environment.nsw.gov.au)

Website: [www.environment.nsw.gov.au](http://www.environment.nsw.gov.au)

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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 2003 to 30 June 2004. This report has been prepared in accordance with the provisions of the *Radiation Control Act 1990*.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Simon A Y Smith'.

SIMON A Y SMITH

Chairperson  
Radiation Advisory Council

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## Chairperson's review

The year 2003–2004 saw the Environment Protection Authority (EPA), which administers the *Radiation Control Act 1990* and the Radiation Control Regulation 2003, become part of the Department of Environment and Conservation (DEC), which was formed in September 2003. This change has not affected the work of the Council. The EPA has remained a statutory body under environment protection legislation, although the DEC exercises regulatory activities on behalf of the EPA.

During the year, the Council met 11 times and provided advice to the EPA on policy and regulatory matters.

Some major items referred to the Council for advice during the reporting period included:

- a review of comments on the Draft Radiation Control Regulation 2003 and Regulatory Impact Statement, and proposed amendments to the Act and the Regulation.
- input into and endorsement to publish *Toxicity Grouping of Radionuclides for Regulatory Purposes*, proposing modification to Schedule 1 of the Regulation (with the view to use it in the national uniformity process). The paper was prepared by members of the Council in conjunction with DEC staff.
- input into the submission to the Joint Parliamentary Select Committee of Inquiry into the Transportation and Potential Storage of Nuclear Waste in NSW.
- a review of the *National Directory for Radiation Protection*, Edition 1.0, and the accompanying Regulatory Impact Statement.
- a review of three Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Draft Codes and accompanying Regulatory Impact Statements.

The Council also initiated a major review of radiography practices in cardiac catheterisation laboratories and investigated the regulation of magnetic resonance imaging equipment.

During the year, the Council also advised the EPA on a wide range of radiation matters including scientific research proposals; licence applications; and approaches for minimising the risk of radiation accidents occurring.

The Council's primary focus next year will be on providing advice on the implementation of registration requirements commenced under the Act and Regulation, recommendations arising from the review of radiography in cardiac catheterisation laboratories, and draft guidelines to be developed for the *National Directory of Radiation Protection*.

I would like to thank all members of the Council for their contribution and commitment, and the DEC Radiation Control Section staff for their continued support of the Council and its committees.



SIMON A Y SMITH  
Chairperson  
30 October 2004

## 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 is constituted under section 29 of the Act and 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 of the Council
- (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 Authority (EPA) is part of the Department of Environment and Conservation (DEC). Officers of the Radiation Control Section of DEC support the work of the Council.

## **Meetings of the Council**

During the reporting period ending 30 June 2004, the Council met 11 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 minor modifications of the MOU at the October and November 2003 meetings.

## **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.

The Technical Committee met on 11 occasions during the 12-month period. This committee does much of the Council's technical work by providing advice to DEC through the Council. It makes recommendations to the Council on:

- applications for licences and accreditation, including 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.

Attendance by members 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. The Course and Competencies Committee was held in abeyance during the reporting period.

<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 Simon Smith	Chairperson	8	11
Dr Philip Pasfield	Radiologist	6	11
Mr John Robinson	Diagnostic radiographer	10	11
Mr Glen Burt	Deputy	1	
Mr Colin Hockings	Expert in industrial uses of radiation	10	11
Mr Michael Carter	Expert in naturally occurring radioactivity	10	11
Mr Jeremy Pigott	Health physicist	8	11
Dr George Larcos	Physician in nuclear medicine	11	11
Mr Lee Collins	Expert in non-ionising radiation	8	11
Mr Peter Dunphy	An officer of WorkCover Authority	6	11
Dr Ludmilla Robinson	Legal practitioner	8	11
Dr Kathryn Crawford	Community representative	6	11
Ms Kathy Meleady (re-appointed 29 June 2004)	NSW Department of Health	4	11
Dr Michael Izard (re-appointed 11 July 2004)	Radiation oncologist	9	11
Dr Richard Smart	Medical physicist	8	11
Mr Luke Platt	Minister's nominee	5	11
Mr Stephen Altree-Williams (appointed 16 August 2003)	Occupational Health & Safety	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 legislation.

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

Comments on the draft Directory were sought from key stakeholders as part of the agreed process for resolving issues arising from the preparation of the Directory. The Council considered and provided comments on the draft Directory Edition 1.0 at its March 2004 meeting.

The Council raised concerns regarding the radionuclide exemption levels found in Schedule 3 of the Directory. A paper entitled *Toxicity Grouping of Radionuclides for Regulatory Purposes* was prepared by several members of the Council and the DEC for use in the national uniformity process. The paper was proposed as a replacement for Schedule 1 of the Radiation Control Regulation 2003 (the Regulation).

During the year, the Council advised DEC on three ARPANSA draft documents and accompanying regulatory impact statements:

- Code of Practice and Safety Guide for Portable Density/Moisture Gauges Containing Radioactive Sources
- Code of Practice: Exposure Of Human Subjects to Ionising Radiation for Medical Research Purposes
- Recommendations for Intervention in Emergency Situations Involving Radiation Exposure.

These codes will eventually form part of the Directory.

## Review of the radiation control legislation

### *Radiation Control Act 1990*

During the reporting period, the Council provided comments to DEC on proposed amendments to the *Radiation Control Act 1990* (the Act) made through the Statute Law (Miscellaneous Provisions) Act 2004, which commenced on 1 July 2004. The key amendments were:

- changing the name of 'sealed radioactive source' to 'sealed source devices' and modifying its definition to be consistent with the use of this term in other jurisdictions
- minor administrative amendments.

## Radiation Control Regulation 2003

The Radiation Control Regulation 2003 (the Regulation) commenced on 1 September 2003. The Regulation replaces the Radiation Control Regulation 1993, which was repealed on 1 September 2003 by the *Subordinate Legislation Act 1989*.

The Council provided comments to DEC on the draft Radiation Control Regulation 2003 and accompanying regulatory impact statement.

The key changes to the Regulation were:

- commencing the registration of premises where radioactive substances are kept, radiotherapy apparatus and all sealed radioactive sources
- mandatory occupational and public radiation exposure limits
- the mandatory requirement for users of neutron-emitting devices to wear personal monitoring devices
- the mandatory requirement for dosimeter service providers to notify employers if an employee has been exposed to excessive amounts of radiation
- a new provision to allow the EPA to attach conditions to the approval of area and personal monitoring devices
- new and increased fees for licensing, registration and accreditation
- new and increased penalties for offences under the Act
- the addition of a provision for the issue of Penalty Infringement Notices.

Further changes were made to the Regulation by the Radiation Control Amendment Regulation 2004, which commenced on 1 July 2004. The Council provided comments on the following amendments:

- exempting premises where certain low-risk radioactive substances are kept or used from the registration requirements imposed on occupiers of premises under section 8 of the Act
- extending an existing exemption from the requirement for users of gas chromatography detectors to be licensed under section 6 of the Act, to persons who sell or possess that equipment
- exempting owners of certain low-risk devices from registration requirements under section 7 of the Act
- ensuring that record-keeping requirements that are only relevant to area monitoring devices (used to monitor radiation levels at premises) are not applied to personal monitoring devices (used to detect and measure an individual's cumulative exposure to radiation)
- changing the name of 'sealed radioactive source' to 'sealed source devices' and modifying its definition to be consistent with the use of this term in other jurisdictions.

The Council also advised DEC on other minor amendments.

## 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 Regulation.

Although the EPA is the authority for dealing with licence applications and variations to licences made under Part 2 of the *Radiation Control Act 1990*, the EPA is empowered by section 9A 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 the EPA on the granting of all non-routine licence applications and recommended inclusions to its standing advice on routine licence applications.

For the reporting period ending 30 June 2004, the EPA issued 2098 new licences, including 207 new licences for the sale/possession of radioactive substances, and 1891 new licences for the use of radiation apparatus.

During 2003–04 the EPA also renewed 9520 licences—9196 licences to use and 324 licences to sell/possess radioactive substances or radiation apparatus.

At the end of the reporting period, there were 11,771 active licences.

Table 2 summarises all new licence conditions issued during the reporting period and is grouped by occupational categories.

<b>TABLE 2</b> <b>Number of new licence conditions issued (listed by occupational category) to use or sell radioactive substances and ionising radiation apparatus in 2003–04</b>		
<i>Occupational category</i>	<i>Radioactive substances</i>	<i>Ionising radiation apparatus</i>
Dental	0	421
Medical—specialist	17	103
Medical—other and related	115	917
Servicing/installation	9	47
Educational	9	3
Safety	2	1
Management	12	4
Scientific/research	190	48
Engineering	10	11
Technical	196	41

Company (licence to sell)	103	143
Rural	6	0
Miscellaneous	17	208
<b>TOTAL</b>	<b>686</b>	<b>1947</b>

Table 3 summarises the number of new licences issued by the EPA during the period 1992–93 to 2003–04.

Due to changes in the data system, the statistics for the last financial year are based on the number of **licence conditions** issued. This differs from previous years' data which was based on the number of **licences** issued.

<b>TABLE 3</b> <b>Number of new licences issued by the EPA from 1992–93 to 2003–04</b>			
<i>Period</i>	<i>Radioactive substances</i>	<i>Radiation apparatus</i>	<i>Total</i>
July 1992–June 1993	290	722	1012
July 1993–June 1994	347	716	1063
July 1994–June 1995	454	1102	1556
July 1995–June 1996	415	1695	2110
July 1996–June 1997	371	734	1105
July 1997–June 1998	364	776	1140
July 1998–June 1999	383	752	1135
July 1999–June 2000	295	882	1177
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

## 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 that 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.

Although the EPA is the authority for dealing with applications for registration, the Council continues to provide advice to DEC on specific and generic registration matters.

## Registration of fixed radiation gauges

During the reporting period the EPA issued 70 new registrations and renewed 251 registrations of fixed radiation gauges (FRGs). FRGs are renewed every two years. At the end of the period there were a total of 636 registrations for FRGs.

From 1 July 2004, FRGs became 'sealed source devices', in accordance with the modification of the definition of 'sealed radioactive source' under the *Statute Law (Miscellaneous Provisions) Act 2004*.

## Registration of diagnostic imaging apparatus

During the year ending 30 June 2004, the EPA issued 762 new registrations for diagnostic imaging apparatus. Table 4 gives the number of new diagnostic imaging apparatus registered by the EPA between 2000 and 2004.

<b>TABLE 4</b> <b>Number of diagnostic imaging apparatus registered between 2000 and 2004</b>				
<i>Equipment type</i>	<i>2000–01</i>	<i>2001–02</i>	<i>2002–03</i>	<i>2003–04</i>
Fixed dental radiography	2592	168	453	381
Fixed radiography	832	134	118	70
Fixed fluoroscopy	69	18	17	10
Fixed radiography/fluoroscopy	246	31	43	41
Fixed mammography	161	31	52	28
Computed tomography	174	22	59	72
Bone mineral densitometry	66	9	15	16
Mobile dental radiography	72	6	9	10
Mobile radiography	686	70	92	57
Mobile fluoroscopy	118	18	24	38
Mobile radiography/fluoroscopy	60	10	0	10
Mobile mammography	17	8	8	5
Panoramic radiography	265	43	35	24
<b>TOTAL</b>	<b>5358</b>	<b>568</b>	<b>925</b>	<b>762</b>

The total number of diagnostic imaging apparatus registered on 30 June 2004 was 6506. The registration period for diagnostic imaging apparatus is 2 or 5 years, depending on the type of apparatus.

The Council provided advice to the DEC on a strategy for managing unregistered diagnostic imaging equipment at its December 2003 meeting.

DEC reviewed *Radiation Guideline No. 6 – Registration Requirements and Industry Best Practice for Ionising Radiation Apparatus used in Diagnostic Imaging* and the Council provided advice to the DEC on the document at its October and November 2003 meetings.

### 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 Regulation. Radiotherapy apparatus is registered for a 2-year period.

At the end of the reporting period, DEC registered 69 new therapy apparatus. Table 5 summarises the number of registrations for each type of therapy apparatus.

<b>TABLE 5</b> <b>Number of therapy apparatus registered during 2003–04</b>	
<i>Equipment type</i>	<i>Total as at 30 June 2004</i>
Kilovoltage therapy x-ray (superficial/orthovoltage)	17
Linear accelerator	38
Simulator	14
<b>TOTAL</b>	<b>69</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.

### 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 the EPA. It is the responsibility of the occupier to ensure that the premises are registered by 29 September 2004.

### Accreditation of radiation experts

Section 9 of the Act provides that the EPA is responsible for accrediting consulting radiation experts (CREs), and through section 9A of the Act may seek the Council's advice on accreditation matters.

Clause 12 of the Regulation prescribes the following as the activities of a CRE:

- (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 year ending 30 June 2004, the EPA accredited a total of 15 CREs in diagnostic imaging.

Table 6 summarises the total number of accreditations issued by the EPA as at 30 June 2004.

<b>TABLE 6</b> <b>Total number of accreditations issued as at 30 June 2004</b>		
<i>Category</i>	<i>Equipment</i>	<i>Number of accreditations issued</i>
Diagnostic imaging	Mammography	18
	Dental (intra-oral, OPG and cephalometry)	31
	Dental (intra-oral, OPG and cephalometry) Radiography Fluoroscopy Computed tomography Bone mineral densitometry (including veterinary and chiropractic)	5
	Radiography Fluoroscopy Computed tomography Bone mineral densitometry (including veterinary and chiropractic)	53
Industrial	Fixed radiation gauges	11
<b>TOTAL</b>		<b>107</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 National Health and Medical Research Council (NHMRC) guideline, *Administration of Ionizing Radiation to Human Subjects in Medical Research* (1984).

The guideline requires approval of the EPA to be obtained 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 2004, the EPA submitted 16 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 except for one. These studies are listed in Appendix 3.

The Council also provided advice to the EPA on the ARPANSA Draft Code of Practice, 'Exposure of Human Subjects to Ionising Radiation for Medical Research Purposes', and accompanying Regulatory Impact Statement at its February 2004 meeting. This code of practice if approved will replace the previous NHMRC (1984) guideline.

## 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. The EPA 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.

The National Competition Policy Review of Radiation Protection Legislation (May 2001) recommended developing:

- a nationally uniform system of classification for radiation incidents and accidents
- a cost-effective national system to collect and collate information on radiation incidents
- a national register for radiation incidents.

An Australian Radiation Incidents Register (ARIR) has since 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 ARIR. The committee is fine-tuning the reporting requirements for these incidents.

During the reporting period ending 30 June 2004, the EPA was informed of 23 instances where radiation accidents may have occurred, involving 51 people. Two incidents involved 27 individuals. The Council investigated and 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 the EPA inform the relevant professional bodies of these accidents as a means of disseminating the knowledge gained.

A summary of the accidents and subsequent recommendations made by the Council follows:

- A patient received a therapeutic dose exceeding 20% of the prescribed dose during treatment with an iodine-125 eye plaque. The patient received 120Gy rather than 100Gy of the prescribed dose. The cause was due to an incorrect value entered for the tumour depth at the treatment planning stage.

The Council reviewed the incident and the controls instigated by the facility 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 report sent to the Council in the last period stated that a potential 60 patients had received a therapeutic dose exceeding 10% of the prescribed dose between 1992–2003. A follow-up report provided to the Council found that only 11 patients from a possible 60 patients had received an extra dose of 10 Gy to the upper airways and oesophagus from a 370 GBq Iridium source. The cause was due to a systematic operator error made in the use of the software planning package. The effective dose to patients was 1.7 Sieverts.

The Council reviewed the incident, the root cause analysis undertaken by an independent review panel, and the controls instigated by the facility 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 report sent to the Council in the last period stated that a potential 16 patients had received a therapeutic dose exceeding 10% of the prescribed dose during 1996–1997. A follow-up report provided to Council advised that 16 patients had received therapeutic doses in the range of 10–13% of the prescribed dose due to an error in equipment calibration.

The Council reviewed the incident and the controls instigated by the facility 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 938 MBq of Tc99m Pertechnetate instead of Tc99m Hydroxy Methylene Diphosphonate (HDP) for a bone scan. The effective dose to the patient from the wrongly administered radiopharmaceutical was 12 mSv.

The Council reviewed the incident and the controls instigated by the facility 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 661MBq Tc99m Pertechnetate instead of Tc99m Hydroxy Methylene Diphosphonate (HDP) for a bone scan. The effective dose to the patient from the wrongly administered radiopharmaceutical was 9.2 mGy.

The Council reviewed the incident and the controls instigated by the facility 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 however recommended that the EPA investigate this facility because a similar accident occurred within a year.

- Two radiation therapists were exposed to radiation while in the treatment room when a linear accelerator was emitting a beam. The dose received by each radiation therapist was of the order of 0.01 millisieverts.

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

- A patient received 850 MBq of Tc-99m Methoxyisobutylisonitrile (MIBI) instead of Tc-99m MDP. The patient received an effective dose of 7.65 millisieverts from the wrongly administered radiopharmaceutical.

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

- Three patients received 800 MBq of Tc-99m Sestamibi instead of Tc-99m Hydroxy Methylene Diphosphonate (HDP). The effective dose to each patient from the wrongly administered radiopharmaceutical was 6.8 millisieverts. The cause of the accidents was due to the medical practice receiving and using mislabelled radiopharmaceuticals from the supplier.

The Council recommended that the EPA investigate the supplier and that the supplier put in place further controls to correct deficiencies in standard operating procedures, to prevent similar accidents from recurring.

- A patient received 350 MBq of Tc-99m Colloid instead of Tc-99m Disofenin. The effective dose to the patient from the wrongly administered radiopharmaceutical was 2.06 millisieverts. The cause of the accident was due to the medical practice receiving and using mislabelled radiopharmaceuticals from the supplier.

The Council recommended that the EPA investigate the supplier and that the supplier put in place further controls to correct deficiencies in standard operating procedures, to prevent similar accidents from recurring.

- A patient scheduled to receive a renal scan utilising 300 MBq Tc-99m-MAG3 was injected incorrectly with Tc-99m Pertechnetate. The effective dose to the patient from the maladministration of radiopharmaceuticals was 3.5 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 1.255 GBq Tc-99m MDP instead of Tc-99m Tetrofosmin for a cardiac stress test. The total excess effective dose arising from the accident to the patient was 7.15 millisieverts.

The Council recommended that the facility instigate further controls to correct deficiencies in standard operating procedures, to prevent similar accidents from recurring. The Council also recommended that the organisation provide feedback on the new protocols it was implementing.

- A patient scheduled to receive a bone scan received 850 MBq Tc-99m MIBI, a heart scanning agent, instead of 887 MBq of Tc-99m Hydroxymethylene Diphosphonate (HDP). The effective dose to the patient from the wrongly administered radiopharmaceutical was 7.65 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 a VQ lung scan instead of DTPA scan (aerosol lung study). The effective dose to the patient from the maladministration was 3.755 millisieverts.

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

- A patient received two administrations of 190 MBq of Tc-99m Pertechnetate for a thyroid scan when one was prescribed. The effective dose to the patient from the wrongly administered radiopharmaceutical was 2.5 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.

- Six patients received additional radiation from misaligned therapy exposures.

The Council recommended that the facility instigate further controls to correct deficiencies in standard operating procedures, to prevent similar accidents from recurring. The Council recorded the report as six separate accidents and, after requesting and considering a root cause analysis of all the accidents, asked the organisation to provide an action plan to prevent such accidents from recurring.

- A patient wrongly received a CT lumbar spine scan due to patient misidentification. The effective dose from the wrongly administered radiopharmaceutical was 14 millisieverts.

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

- A patient received 700 MBq of TC99m-Pertechnetate instead of 160 MBq of Tc-99m – MAA for a perfusion lung scan. The effective dose from the wrongly administered radiopharmaceutical 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.

- A patient received an unplanned exposure from a CT scan for pulmonary embolism due to patient misidentification.

The Council recommended that the facility instigate further controls to correct deficiencies in standard operating procedures, to prevent similar accidents from recurring. The Council also requested that the organisation provide a root cause analysis of the accident.

Table 7 summarises the number of accidents reported to the EPA during the period 1994–95 to 2003–04.

**TABLE 7**  
**Radiation accidents**

<i>Year</i>	<i>Number of accidents reported</i>
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

## **Parliamentary inquiry into the transportation and storage of nuclear waste in NSW**

The Council provided DEC with input into the Parliamentary Inquiry into the Transportation and Storage of Nuclear Waste in NSW. The Parliamentary Committee made 27 recommendations in its report, which was forwarded to the Premier of NSW and the Prime Minister of Australia. The Premier has since sought further advice from DEC to prepare a formal response to the Commonwealth on the recommendations made in the report. The Council will be consulted and may be requested to provide further advice to DEC on this matter.

## **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. 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 party is now assessing the skills and knowledge of all parties working in CCLs in terms of the safe operation of radiography equipment.

## **Regulation of magnetic resonance imaging equipment**

At the December 2003 meeting, the Council recommended that DEC investigate whether it should begin to regulate magnetic resonance imaging (MRI) machines as higher field strength MRI machines are being brought into Australia. The Council also discussed the matter at its April and May 2004 meetings, and after considering the advice provided by DEC, recommended that the potential regulation of high field strength MRI equipment be referred to the Radiation Health Committee of ARPANSA.

**Appendix 1: Membership of committees of the Council during 2003–04**

<b>Technical Committee</b>		
<i>Member</i>	<i>Membership category</i>	<i>Meetings attended</i>
Mr Simon Smith	Representative of the Authority	3
Dr Philip Pasfield	Radiologist	6
Mr John Robinson	Diagnostic radiographer	10
Mr Glen Burt	Deputy	1
Dr George Larcos	Physician in nuclear medicine	9
Dr Kathryn Crawford	Community representative	1
Mr Michael Carter	Naturally occurring radioactivity	10
Mr Colin Hockings	Industrial radiographer	9
Mr Lee Collins	Expert in non-ionising radiation	8
Dr Richard Smart	Medical physicist	8
Dr Michael Izard	Radiation oncologist	9
Mr Jeremy Pigott	Health physicist	8

## **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 its 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. These latter include the Radiation Health Committee formed under the *Australian Radiation Protection and Nuclear Safety Act 1998*, as a result of the development of the National Directory for Radiation Protection.

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*.

## **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 1999, 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**

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

24 December 2002

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

### **St George Cancer Care Centre**

- Systemic Targeted Alpha Immunotherapy for Metastatic Melanoma
- Advanced Renal Cell Carcinoma
- A phase III Randomized Study of Cetuximab (Erbix<sup>™</sup>, C225) and Best Supportive Care Versus Best Supportive Care in Patients with Pretreated, Metastatic Epidermal Growth Factor Receptor (EGFR) Positive Colorectal Carcinoma
- Comparison of CT Pulmonary Angiography with Conventional Pulmonary Angiography in the Diagnosis of Pulmonary Embolism

The Council did not recommend approval of this trial on the basis that the use of pulmonary angiography is considered to be an obsolete and invasive procedure which delivers a higher dose than using CT scans. The Council considered that the selection process and the exposure of patients to a higher dose of radiation is inappropriate when there is another less invasive procedure which exposes patients to much lower levels of radiation.

### **Liverpool Hospital**

- Comparative Evaluation of the Impact of FDG PET and Gallium on the Clinical Management of Patients with Low Grade Non-Hodgkin's Lymphoma (LGNHL)
- The Influence of PET in the Management of Head and Neck Cancers
- Impact on Patients of Positron Emission Tomography (PET) in Oesophageal and Gastro-oesophageal Junction Cancer in Australia

### **Prince of Wales Hospital**

- PET in the Evaluation of Dementia

### **St Vincent's Hospital**

- Granulocyte-colony Stimulating Factor (G-CSF) mobilised

### **Kendle International Pty Ltd**

- Phase 1b, Open-label, Clinical Trial to Evaluate the Safety of Tc-99m labelled Anti-fibrin De-immunised Monoclonal Antibody Fragment in the Detection of Deep Venous Thrombi (DVT)

### **Royal Prince Alfred Hospital**

- Impact of PET Scanning in Uterine Cancer
- Amendment to Trial Measurement of Cerebral Glucose Metabolism in Normal Volunteers (approved by RAC 2000)

### **John Hunter Hospital**

- The Pulmonary Embolus Diagnostic Trial

### **Westmead Hospital**

- CT Dose Minimisation Study Using Noise Optimisation Using Algorithm
- A Phase III Randomised Study of Cetuximab and Best Supportive Care Versus Best Supportive Care in Patients With Pre-treated Metastatic Epidermal Growth Factor Receptor (EGFR) Positive Colorectal Cancer
- Combined Modality Therapy for Locally Advanced Non-small Cell Lung Cancer Using Non-platinum Based Chemotherapy Regime

## **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
MGy	Milligray
MBq	Megabecquerels
MOU	Memorandum of Understanding
NCP	National Competition Policy
NHMRC	National Health and Medical Research Council
NUIP	National Uniformity Implementation Panel
RAC	Radiation Advisory Council
RHC	Radiation Health Committee