RAC

RADIATION ADVISORY COUNCIL

ANNUAL REPORT 2002–03

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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 2002 to 30 June 2003. This report has been prepared in accordance with the provisions of the *Radiation Control Act 1990*.

Yours sincerely

SIMON A Y SMITH

Chairperson
Radiation Advisory Council

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CHAIRPERSON'S REVIEW

The Radiation Advisory Council had a productive and busy year advising the Minister for the Environment, the Hon. Bob Debus, and the Environment Protection Authority (EPA), on policy and regulatory matters.

Some of the major items referred to the Council for advice this year included the remake of the Radiation Control Regulation 2003 (to commence on 1 September 2003) and the preparation of a position paper for the Minister on whole body computed tomography (CT) scanning. The latter resulted in the implementation of regulatory controls by the EPA to restrict the use of CT scans on otherwise healthy individuals. The Minister for the Environment, together with the Minister for Health, the Hon. Craig Knowles, jointly announced the need for the changes on 12 November 2002.

Council also provided advice across a wide range of radiation matters including:

- scientific research proposals
- complex licence applications
- approaches for minimising the risk of radiation accidents occurring
- review of *Radiation Guideline No. 6 – Registration requirements and industry best practice for ionising radiation apparatus used in diagnostic imaging*, to be published in late 2003.

Next year the Council's primary focus will be on the provision of advice for the implementation of the Radiation Control Regulation 2003, the conditions for the registration of premises and therapy equipment, and draft guidelines to be developed for the *National Directory of Radiation Protection*.

A key change for 2003–04 is the formation of the new Department of Environment and Conservation (NSW) on 24 September 2003. The staff of the EPA are now incorporated within the Department. This change will not affect the work of the Council, whose advice will continue to be essential to the sound and effective implementation of the Radiation Control Act.

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

SIMON A Y SMITH
Chairperson

11 November 2003

RESPONSIBILITIES OF THE COUNCIL

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

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 is to consist of 16 members appointed by the Minister for the Environment. Membership of the Council is to consist of:

(a) the Director General or a member of staff of the EPA, 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 the Act and the making, amendment or repeal of regulations under the Act, and

(b) the administration of the 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 EPA, provide advice to the EPA 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.

Officers of the Radiation Control Section of the EPA support the work of the Council.

MEETINGS OF THE COUNCIL

During the reporting period ending 30 June 2002, the Council met nine 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 at Appendix 2.

COMMITTEES OF THE COUNCIL

Section 31 of the Act provides for the Council to establish committees to help it exercise its functions. The committees of the Council during 2002–03 were:

- Technical Committee

  The Technical Committee met on nine occasions during the 12-month period. This committee does much of the Council's technical work in the provision of advice to the EPA through the Council. It makes recommendations to the Council on:

  – matters such as applications for a licence 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.

- Course and Competencies Committee (formerly the Course Assessment Committee)

  The Course and Competencies Committee provides advice to the Council pertaining to proposed licensing and accreditation qualifications. Its role also encompasses making recommendations to the Council on emerging issues, technical developments and regulatory matters or policy development relating to suitability of or necessity for approved courses. The committee met three times during this period.

During this period, attendance by members at the meetings of both committees is shown in Appendix 1.

TABLE 1
Members of the Radiation Advisory Council and meeting attendance

Member	Appointed position	Meetings attended	Meetings eligible to attend
Mr Simon Smith (appointed 1/7/2002)	Chairperson (EPA member)	8	9
Ms Donna Campbell	Deputy to the EPA member	0	9
Dr Philip Pasfield	Radiologist	3	9
Mr John Robinson	Diagnostic radiographer	8	9
Mr Colin Hockings	Expert in industrial uses of radiation	9	9
Mr Michael Carter	Health physicist (term expired 7/2/2003)	5	6
	Expert in naturally occurring radioactivity (appointed 24/2/03)	3	3
Mr Jeremy Pigott (appointed 24/2/2003)	Health physicist	2	3
Dr George Larcos	Physician in nuclear medicine	6	9
Mr Lee Collins	Expert in non-ionising radiation	7	9
Mr Peter Dunphy	Expert in occupational health and safety (resigned 24/2/2003 – position yet to be filled)	5	6
	An officer from WorkCover NSW (appointed 24/2/2003)	2	3
Dr Ludmilla Robinson	Legal Practitioner	8	9
Dr Kathryn Crawford	Community representative	3	9
Ms Kathy Meleady	Department of Health	1	9
Dr Michael Izard	Radiation oncologist	7	9
Dr Donald McLean (term expired 7/2/2003)	Medical physicist	5	6
Dr Richard Smart (appointed 24/2/2003)		2	2
Mr Luke Platt	Minister's nominee	6	9

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

NATIONAL UNIFORMITY

In August 1999, the Australian Health Ministers' Council 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 the mechanism by which National Competition Policy (NCP) recommendations are to be addressed.

The Directory is being developed and implemented through the National Uniformity Implementation Panel (Radiation Control), (the NUIP), 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 in the preparation of the Directory. Council considered and provided comments on the draft Directory at its December 2002 meeting.

REVIEW OF THE RADIATION CONTROL LEGISLATION

The Radiation Control Amendment Act 2002 (commenced 1 August 2002)

The *Radiation Control Amendment Act 2002* (Amendment Act) was developed as a result of the NCP review of radiation protection legislation in all the Australian jurisdictions, except Queensland. The Amendment Act alters the 'Object' of the Act; provides for review of the Act at regular intervals; provides for a reference to the National Directory for Radiation Protection and for the adoption of documents forming part of the *National Directory for Radiation Protection*; and for other purposes. The Amendment Act also altered the powers of the Council, to advisory.

Some of the key amendments made are:

- changes to the wording of the 'Object' of the Act in the interests of uniformity across jurisdictions
- addition of a provision for mandatory review of the Act at intervals of no greater than 10 years
- addition of a provision to refer to the *National Directory for Radiation Protection*
- addition of a power enabling documents placed onto the *National Directory for Radiation Protection* to be called up and given statutory effect in New South Wales
- amendment to the definition of 'environment' to achieve consistency with the more contemporary definition in the *Protection for the Environment Operations Act 1997*
- amendments to the powers of the Radiation Advisory Council from mandatory to advisory in relation to certain operational matters carried out by the EPA
- increases the in membership of the Council from 14 to 16 people, to include a representative from WorkCover NSW and a person with expertise in naturally occurring radioactivity.

In order to reflect its new advisory role, the Council, in conjunction with the EPA has developed an MOU that sets out the agreed way in which the two bodies will collaborate in fulfilling their responsibilities under the legislation. The MOU between the Council and the EPA is provided at Appendix 2.

Radiation Control Regulation 1993 (the Regulation)

The Regulation made on 1 September 1993 is required to be reviewed under the *Subordinate Legislation Act 1989* and was due for remake by 1 September 2002. Recognising the process of amending the Act, a postponement was granted for remaking of the Regulation by 1 September 2003. Council provided the EPA with advice on the drafting of the new Regulation. During the reporting period ending 30 June 2003, the Council also provided comments to the EPA on the Regulatory Impact Statement for the draft Regulation. The EPA incorporated the majority of Council's recommendations and released the documents for public comment on 2 June 2003.

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, possessing or selling any of the above substances and / or apparatus unless the person holds a current licence and complies with the conditions of the licence. An exemption from section 6 of the Act for specified categories of persons is provided in clause 8 of the Regulation.

Prior to the amendments of the *Radiation Control Amendment Act 2002*, which commenced on 1 August 2002, the EPA could only issue a licence on the recommendation of the Council. Although the EPA has now become the authority for dealing with applications for licence and variations to licences made under Part 2 of the *Radiation Control Act 1990*, the EPA is empowered by section 9A to seek and take into consideration 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 in relation to the determination of licence applications. During the reporting period, the Council provided advice to 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 2003, the EPA issued 1899 new licences, including 481 new licences for the use or sale of radioactive substances and 1418 new licences for the use or sale of radiation apparatus.

Table 2 summarises the occupational categories of new licensees.

Table 3 summarises the number of new licences issued by the EPA during the period 1992–93 to 2002–03.

During 2002–03 the EPA also renewed a total of 9157 licences: 1308 licences for radioactive substances and 7849 licences for radiation apparatus.

At the end of the reporting period, there were 1789 active licences for radioactive substances and 9267 active licences for radiation apparatus, totalling 11,056 active licences.

TABLE 2
Number of new licences issued (listed by occupational category) to use or sell radioactive substances and ionising radiation apparatus in 2002–03

Occupational category	Radioactive substances	Ionising radiation apparatus
Dental	-	343
Medical—specialist	16	88
Medical—other and related	51	607
Servicing / installation	5	28
Educational	7	7
Safety	3	-
Management	4	7
Scientific / research	130	36
Engineering	18	7
Technical	146	53
Company (licence to sell)	66	128
Miscellaneous	35	114
TOTAL	**481**	**1418**

TABLE 3 Number of new licences issued by the EPA from 1992–93 to 2002–03			
Period	**Radioactive substances**	**Radiation apparatus**	**Total**
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

REGISTRATION OF SEALED RADIOACTIVE SOURCES, RADIATION APPARATUS AND PREMISES

Section 7 of the Act requires registration of sealed radioactive sources and certain prescribed radiation apparatus. Section 8 of the Act requires premises to be registered where unsealed radioactive substances are kept or used.

The purpose of registration is to:

- ensure that all sealed radioactive sources, radiation apparatus and premises in which unsealed radioactive sources 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, and
- enable up-to-date records to be kept of all sealed radioactive sources, certain radiation apparatus and premises in which unsealed radioactive sources are kept or used.

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

During the year ending 30 June 2003, the EPA granted 180 new applications and renewed 162 applications for registration of fixed radiation gauges. At the end of this period there were a total of 658 registrations for fixed radiation gauges.

During the year ending 30 June 2003, the EPA granted 925 new applications for registration of diagnostic imaging apparatus. Table 4 summarises the number of new diagnostic imaging apparatus registered by the EPA during the period 2000–01 to 2002–03.

TABLE 4 Number of diagnostic imaging apparatus registered from 2000–01 to 200203				
Equipment Type	**2000–01**	**2001–02**	**2002–03**	**Total as at 30 June 2003**
Fixed dental radiography	2592	168	453	2956
Fixed radiography	832	134	118	983
Fixed fluoroscopy	69	18	17	74
Fixed radiography / fluoroscopy	246	31	43	233
Fixed mammography	161	31	52	185
Computed tomography	174	22	59	215
Bone mineral densitometry	66	9	15	87
Mobile dental radiography	72	6	9	78
Mobile radiography	686	70	92	808
Mobile fluoroscopy	118	18	24	107
Mobile radiography / fluoroscopy	60	10	0	0
Mobile mammography	17	8	8	24
Panoramic radiography	265	43	35	326
TOTAL	**5358**	**568**	**925**	**6076**

The registration period for diagnostic imaging apparatus varies at 2 or 5 years and is dependent on the type of apparatus.

During the last reporting period, the Council also provided advice to the EPA on the review of *Radiation Guideline No. 6 – Registration Requirements and Industry Best Practice for Ionising Radiation Apparatus used in Diagnostic Imaging* (EPA 1999), at its July, August and September 2002 meetings.

It is anticipated that the remake of the Regulation in September 2003 will provide for commencement of registration of sealed sources, premises where unsealed radioactive substances are kept, and for some additional radiation apparatus.

ACCREDITATION OF RADIATION EXPERTS

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

Clause 11 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) calibrating ionising radiation apparatus used for medical therapy

(d) calibrating ionising radiation apparatus used for diagnostic purposes

(e) assessing radiation apparatus, sealed radioactive sources and premises that are required to be registered under sections 7 or 8 of the Act for the purpose of certifying compliance with the requirements for registration

(f) advising on the design of premises, in relation to radiation safety requirements, in which sealed radioactive sources or radiation apparatus prescribed under section 7(1) of the Act are kept or used

(g) assessing plans for premises in which sealed radioactive sources or radiation apparatus prescribed under section 7(1) of the Act are kept or used, for the purposes of certifying compliance with any requirements for registration under section 7(5) of the Act

(h) assessing the integrity of any shielding of premises in which sealed radioactive sources 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.

Under clause 11(2) of the Regulation, a CRE may be accredited as either a 'radiation assessor' or 'radiation consultant'.

A **radiation assessor** is a person whose accreditation under section 9 of the Act allows the person to only carry out the activities referred to in subclause 1(e) or (h) of the Regulation.

A **radiation consultant** is a person whose accreditation under section 9 of the Act allows the person to carry out any one or more of the activities referred to in subclauses 11(1)(a)–(d) or (f–g) of the Regulation, whether or not the Regulation also allows the person to carry out the activities referred to in subclauses 1(e) or (h).

The Council has provided standing advice to the EPA on the pre-requisites that applicants should be required to meet to be eligible to be accredited as consulting radiation experts in the category of diagnostic imaging and fixed radiation gauges.

During the year ending 30 June 2003, the EPA accredited a total of 19 CREs in the category of diagnostic imaging.

Table 5 summarises the total number of CREs accredited by the EPA as at 30 June 2003.

TABLE 5 Total number of CREs accredited as at 30 June 2003			
Category	**Equipment**	**Radiation consultant (RC) Radiation assessor (RA)**	**Number CREs registered**
Diagnostic imaging	Mammography	RC	16
	Dental (intra-oral, OPG and cephalometry)	RA	28
	Dental (intra-oral, OPG and cephalometry) Radiography Fluoroscopy Computed tomography Bone mineral densitometry (including veterinary and chiropractic)	RC	5
	Radiography Fluoroscopy Computed tomography Bone mineral densitometry (including veterinary and chiropractic)	RA	47
Premises*	Low and medium level laboratories	RC	0
Industrial	Fixed radiation gauges	RA	13
TOTAL			**109**

* Accreditation pending commencement of section 8 of the Act

VOLUNTARY EXPOSURE TO IONISING RADIATION FOR SCIENTIFIC OR RESEARCH PURPOSES

Clause 20 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 Ionising Radiation to Human Subjects in Medical Research* (1984).

The NHMRC guideline requires that the approval of the EPA 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 2003, the EPA submitted four medical research studies involving the use of radioactive substances or radiation apparatus to the Council for expert advice, all of which were recommended for approval. These studies are listed in Appendix 3.

APPOINTMENT OF RADIATION SAFETY OFFICERS AND RADIATION SAFETY COMMITTEES

Clause 28 of the Radiation Control Regulation provides for the EPA, on the recommendation of the Council, to require an employer to appoint a Radiation Safety Officer (RSO) and / or a Radiation Safety Committee (RSC) for a workplace. If such a direction is made, the Council may also advise on the appropriate qualifications required by the RSO and the functions of the RSO and RSC.

The Radiation Safety Officer Committee (now in recess) was established by the Council to review:

- the organisations that should be required to appoint an RSO and an RSC
- the knowledge and skills required by a person who is to be appointed as an RSO
- the functions of an RSO and an RSC.

The RSO Committee produced two documents to help implement clause 28. The first document, *RAC Statement on Radiation Safety Officers and Radiation Safety Committees*, provided advice to the Director General of the EPA on:

- types of organisations that need to appoint a radiation safety officer and a radiation safety committee
- recommended qualifications needed for appointment as a radiation safety officer
- recommended functions of a radiation safety officer and a radiation safety committee.

The second document *Recommendations for Radiation Safety Officers and Radiation Safety Committees*, was developed to help employers fulfil their responsibilities under clause 28 of the Regulation and was released by the EPA for public comment in April 2002.

The Council at its May 2003 meeting provided additional comments on the final draft of the guideline. The EPA indicated that the guidance document was scheduled to be published in the latter part of 2003.

RADIATION ACCIDENTS

Clause 24 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 25 and 26 of the Regulation.

Although not formally part of the Council's role, the work of the Council continues to involve review of, and providing advice on, reports of radiation accidents.

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 and / or further training. In specific circumstances, enforcement action may be warranted. Delivery of these types of responses are the responsibility of the EPA.

The Council may recommend to refer serious accidents to the Health Care Complaints Commission.

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

The need for a nationally uniform system of classification for radiation incidents and accidents and the need to develop a cost-effective national system to collect and collate information and publish a national register for radiation incidents is highlighted as one of the 19 recommendations made in the *National Competition Policy Review of Radiation Protection Legislation, May 2001*. The Radiation Health Committee, established by the *Australian Radiation Protection and Nuclear Safety Act 1998*, is in the process of developing the Australian Radiation Incident Register.

During the reporting period ending 30 June 2003, the EPA was informed of 12 instances where radiation accidents may have occurred involving 12 individuals. A further two incidents were reported to the Council. These have not been included in the above data as Council is awaiting further information on the details of the incidents. Council is particularly concerned with one of the reports which indicated that up to 60 individuals may have been involved in the incident and may have received a significant radiation dose to organs other than prescribed. This matter involves a public hospital, and is now a matter of public record.

The Council investigated and considered each case and, where appropriate, made recommendations that, in its opinion, would reduce the risk of similar accidents recurring.

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

- A patient received 800 MBq of Tc-99m HDP instead of 200 MBq of Tc-99m MAA for a perfusion lung scan. The effective dose arising from wrongly administered radiopharmaceutical to the patient was 5.2 millisieverts.

  Council recommended that further controls be instigated by the facility to correct deficiencies in standard operating procedures, in order to prevent the recurrence of similar accidents. The Council also recommended that the organisation provide feedback on how the new protocols implemented by the organisation are working.

- A patient received 370 MBq of Tc-99m HMPAO, a cerebral blood flow agent, instead of Tc-99m MDP, a bone agent. The effective dose to the patient from the wrongly administered radiopharmaceutical was 3.44 millisieverts.

  Council recommended that further information be sought in order to assess the cause of the accident. Council reviewed the additional information and was satisfied that its

recommendations requesting the facility to correct deficiencies in its standard operating procedures, in order to prevent the recurrence of similar incidents, had been instituted.

- Two patients received Tc-99m Sodium Pertechnetate, a thyroid and stomach agent, instead of Tc99m hydroxy methylene Diphosphonate (HDP), a bone agent. Patient number one received 874 MBq and patient number two received 849 MBq. The effective dose to the patients from the wrongly administered radiopharmaceutical was 11.4 millisieverts (patient No. 1) and 11 millisieverts (patient No.2).

  Council reviewed the incident and the controls instigated by the facility to correct deficiencies in its standard operating procedures and were satisfied with the steps taken by the organisation to prevent recurrence of this type of incident.

- A patient received 900 MBq of Tc-99m Sestamibi, a cardiac imaging agent, instead of Tc99m HMPAO, for cerebral blood flow imaging. The effective dose to the patient from the wrongly administered radiopharmaceutical was approximately 8.1 millisieverts.

  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 taken by the organisation to prevent recurrence of this type of incident.

- A patient received 400 MBq of I-131 Sodium Iodide, normally used to treat overactive thyroid, and 50 MBq of Ga-67, to be used for a whole body scan. The absorbed dose to the patient's thyroid from the wrongly administered radiopharmaceutical was 60-70 Gy.

  Council recommended that the accident report be referred to the Health Care Complaints Commission (HCCC) for investigation.

- A patient received 986 MBq of Tc-99m Pertechnetate, to be used for a gated heart pool scan, instead of Tc-99m Methoxyisobutylisonitrile (MIBI), to be used for a cardiac scan. The effective dose to the patient from the wrongly administered radiopharmaceutical was 13 millisieverts.

  Council recommended that further controls be instigated by the facility to correct deficiencies in standard operating procedures, in order to prevent the recurrence of similar accidents.

- A patient received 160 MBq of Tc 99m Sestamibi, a cardiac imaging agent, instead of Tc 99m MDP, used for bone scans.

  Council sought further information in regards to the accident. Council recommended that further controls be instigated by the facility to correct deficiencies in standard operating procedures, in order to prevent the recurrence of similar accidents.

- A patient received Tc-99m Hydroxy methylene Diphosphonate (HDP), a bone agent, instead of Tc-99m Sestamibi, a cardiac imaging agent. The effective dose to the patient from the wrongly administered radiopharmaceutical was 2.3 millisieverts.

  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 taken by the organisation to prevent recurrence of this type of incident.

- A patient received an effective dose of 1.8 millisieverts as a result of having to undertake a repeat cerebral CT scan because of incorrect calibration of the CT scanner.

  Council recommended that further information be sought in order to assess the cause of the accident. This information was not available at the time of writing this report.

- A patient received 121 MBq of TI-201 Chloride, used to assess cardiac stress, as a result of a failed procedure. The test was rescheduled for another day. The effective dose to the patient from the administered radiopharmaceutical was 6.8 millisieverts.

  Council recommended that further information be sought in order to assess the cause of the accident. This information was not available at the time of writing this report.

- A patient received 500 MBq of Tc 99m Tetrofosmin (used for resting myocardial perfusion) instead of Tc 99m Sodium Pertechnetate (used for a gated heart scan). The effective dose to the patient from the wrongly administered radiopharmaceutical was 3.75 millisieverts.

  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 taken by the organisation to prevent recurrence of this type of incident.

- The incineration of 400 MBq S-35 not intended for disposal.

  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 taken by the organisation to prevent recurrence of this type of incident.

- Preliminary accident report advising the EPA that up to 60 patients may have received a therapeutic dose exceeding 10% of prescribed dose from 1992–2003

  Council recommended that prior to referral of the report it would need to consider the full report. The full report will provide a detailed assessment of the actual number of patients involved and the dose that each patient received. The full report was not available at the time of writing this report.

- 16 patients that potentially exceeded 10% difference from prescribed dose in 1996–97

  Council sought further information in regards to the accident. This information was not available at the time of writing this report.

Table 6 summarises the number of accidents reported to the EPA during the period 1994–95 to 2002–03.

TABLE 6 Radiation accidents	
Year	**Number of accidents reported**
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

WHOLE BODY CT SCANS

During the reporting period, the Council raised concerns with regard to newspaper advertisements that encouraged otherwise healthy people to undergo whole body computerised tomography (CT) scanning. Council considered that whole body CT scanning of people without the referral by an independent medical practitioner was not justified. The issues that caused concern were that the CT scan delivers a relatively high dose of radiation; increases the long-term risks of developing cancer; and the fact that there is no evidence of the net benefits from undertaking the procedure. Council were also concerned that the risks of developing cancer are increased because there is no limitation on the number of times a person may undergo the procedure.

Council prepared a position paper for the Minister on whole body CT scanning, recommending that a media release be issued to inform the public of the risks and the limitations associated with this procedure and that the EPA apply specific licensing and registration conditions to restrict the use of CT scans. The position paper can be found on the EPA's radiation website at www.epa.nsw.gov.au/radiation/.

On 26 September the NSW Department of Health issued a media release, which included reference to the Council's concerns, regarding the procedure.

The EPA has since developed and implemented new licence and registration conditions as recommended by the Council.

APPENDIX 1: MEMBERSHIP OF COMMITTEES OF THE COUNCIL DURING 2002–03

Technical Committee		
Member	**Membership Category**	**Meetings attended**
Mr Simon Smith	EPA Representative	8
Dr Philip Pasfield	Radiologist	4
Mr John Robinson	Diagnostic radiographer	9
Dr George Larcos	Physician in nuclear medicine	6
Dr Kathryn Crawford	Community representative	3
Mr Michael Carter	Health physicist (1/7/2002 – 23/2/2003 Naturally Occurring Radioactivity (from 23/2/2003)	5 3
Mr Colin Hockings	Industrial radiographer	9
Mr Lee Collins	Expert in non-ionising radiation	6
Dr Donald McLean (term Expired 27/2/2003) Dr Richard Smart (appointed 24/2/2003)	Medical physicist	5 2
Dr Michael Izard	Radiation Oncologist	7
Mr Jeremy Pigott (appointed 24/2/2003)	Health Physicist	1

Course and Competencies Committee		
Member	**Membership Category**	**Meetings attended**
Mr John Robinson (Chairperson)	Diagnostic radiographer	3
Dr Kathryn Crawford	Community representative	1
Mr Michael Carter	Health physicist	3
Mr Colin Hockings	Industrial radiographer	2
Mr Lee Collins	Expert in non-ionising radiation	3
Dr Donald McLean	Medical physicist	3

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,

(b) administration of this Act and the regulations,

(c) measures to prevent or minimise the dangers arising from radiation,

(d) the granting of exemptions authorised by the regulations for periods exceeding 60 days,

(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 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 on 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
Environment Protection Authority

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)

Concord Repatriation General Hospital

- Evaluation of Saphenous Vein Graft Disease by Intravascular Ultrasound and Computer Tomography

Prince of Wales Hospital

- A double-blind, randomised, placebo controlled, parallel-group, multicenter phase III study to assess the impact of rosuvastatin treatment in patients with established systolic chronic heart failure

Royal Prince Alfred Hospital

- Assessment of Risk Factors in Coronary 54-74 Bypass Grafts Study – coronary CT angiograms

St George Hospital and Westmead Hospital

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

ABBREVIATIONS

ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
CRE	Consulting radiation expert
EPA	Environment Protection Authority
HCCC	Health Care Complaints Commission
MBq	Megabecquerels
MOU	Memorandum of Understanding
NCP	National Competition Policy
NHMRC	National Health and Medical Research Council
NUIP	National Uniformity Implementation Panel
RA	Radiation assessor
RC	Radiation consultant
RAC	Radiation Advisory Council
RHC	Radiation Health Committee
RSO	Radiation Safety Officer