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RADIATION ADVISORY COUNCIL

ANNUAL REPORT 1999–2000

Radiation Advisory Council Annual Report 1999–2000

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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 1999 to 30 June 2000. This report has been prepared in accordance with the provisions of the *Radiation Control Act 1990*.

Yours sincerely

D R LEECE
Chairperson
Radiation Advisory Council

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CHAIRPERSON'S REVIEW

The year 1999–2000 was one of transition for the Radiation Advisory Council. During the first half of the year, eight of the 14 members departed: three (including the chairperson) resigned; four retired when their appointments expired; and the appointment of one was terminated. All but one of these vacancies were filled by year's end, but this break in continuity disrupted the work of the Council.

The Council met five times during the first half of the year. The primary focus, in addition to the provision of advice to the Environment Protection Authority on licensing and related matters, was on an investigation of a series of accidents that have occurred over the last five years in the course of radiotherapy treatment to patients in NSW hospitals. The report on this investigation, entitled *A Review of the IAEA Safety Publications and NSW EPA Draft Guideline 7 for Standards of Safe Practice in Radiotherapy*, was submitted to the Minister for the Environment, and a copy was provided to the Health Care Complaints Commission (HCCC) and the Minister for Health.

The Council also reviewed and endorsed two guidelines: *Monitoring Devices*, designed to help employers to maintain radiation monitoring devices; and *Test Protocols for Parts 2–5 of Radiation Guideline No. 6—Registration Requirements and Industry Best Practice for Ionising Radiation Apparatus used in Diagnostic Imaging*.

During the second half of the year, the Council, which in effect was a new one, met three times. The primary focus was on induction of new members and review of the Council's governance arrangements, operating procedures and committees. The revised arrangements are described in Appendix 1. The Council's three-year strategic plan, covering the period from January 1999 to December 2001, was also reviewed, and the Council formulated a work program for 2000–01. The Council continued to provide advice to the Environment Protection Authority on licensing and related matters.

The main legislative change during the year was the commencement on 11 February 2000 of amendments to the Radiation Control Regulation that mandate the registration of diagnostic imaging apparatus. From February 2002, however, apparatus that is required to be registered or re-registered must at the time be shown to be compliant with the new standards. Owing to uncertainty caused by national uniformity negotiations, the remake of the Radiation Control Regulation 1993 was postponed until September 2001.

During 2000-01, the Council will review the *Radiation Control Act 1990* and the Radiation Control Regulation 1993, in light of the Minister's request and the desire of the Council of Australian Governments to move towards uniform national legislation. The opportunity will also be taken to consider the need to modernise other aspects of the NSW legislation. The Council intends to formulate advice on these matters and tender it to the Minister.

As the new chair of the Council, I wish to thank the members of the Council for their understanding and support during this difficult transitional year. I particularly appreciate their willingness to serve the cause of radiation protection in NSW in this very important way. I am also grateful for the unfailing support of the EPA's staff, particularly Ms Daniela Freschi-Nair. Without this support the Council could not function.

D R LEECE
Chairperson
31 July 2000

RESPONSIBILITIES OF THE COUNCIL

The Radiation Advisory Council ('the 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 ionising radiation, and harmful 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 therapeutic 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 14 members appointed by the Minister for the Environment. The membership of the Council is to consist of:

- (a) the Director-General or a member of staff of the Environment Protection 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) radiotherapist
- (m) medical physicist
- (n) 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;
 - (b) the administration of the Act and the regulations;

- (c) measures to prevent or minimise the dangers arising from radiation;
 - (d) the granting, renewal, suspension and cancellation of any licence, registration or accreditation under the Act; 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;
- (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 New South Wales Environment Protection Authority (EPA) support the work of the Council.

MEETINGS OF THE COUNCIL

During the reporting period ending 30 June 2000 the Council met eight times.

The attendance of members at meetings during this period is shown in Table 1.

The Council's governance arrangements and procedures are described in Appendix 1.

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 1999–2000 were:

- Medical Radiation Committee
- Health Physics Committee
- Non-Ionising Radiation Committee
- Radiation Safety Officer Committee
- Course Assessment Committee.

The Medical Radiation Committee and the Health Physics Committee met together as the 'Conjoint Committee' on 10 occasions during the 12-month period. These two committees do much of the Council's technical work. They make recommendations to the Council on matters such as applications for a licence, 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; and safety protocols for the use of ionising radiation. The Council, at its June 2000 meeting, disbanded these two committees and replaced them with a new Technical Committee with similar membership and terms of reference.

The Non-Ionising Radiation Committee did not meet during the year. The Council, at its June 2000 meeting, formally disbanded the Committee, as it had completed its task, and decided that a working group would be formed to help the Council on the issue of lasers when required.

TABLE 1			
Members of the Radiation Advisory Council and Meeting Attendance			
Member	Appointed position	Meetings attended	Meetings eligible to attend
Mr J Macinante (resigned 17/12/99) Dr D Leece (appointed 23/12/99)	Chairperson (EPA member)	3 3	5 3
Ms D Campbell	Deputy to the EPA member	0	2
Dr G Bigg-Wither (retired 25/11/99) Dr Phillip Pasfield (appointed 09/05/00)	Radiologist	3 1	5 2
Mr J Robinson	Diagnostic radiographer	4	8
Mr C Hockings	Expert in industrial uses of radiation	6	8
Dr R Rosen (retired 25/11/99) Mr M Carter (appointed 08/02/00)	Health physicist	5 3	5 3
Dr C Larcos	Physician in nuclear medicine	6	8
Mr L Collins	Expert in non-ionising radiation	6	8
Mr A Niven (retired 25/11/99) Mr P Dunphy (appointed 02/06 /00)	Expert in occupational health and safety	5 0	5 1
Dr L Robinson	Barrister	5	8
Ms E Akmentins (retired 25/11/99) Dr K Crawford (appointed 08/02/00)	Community representative	5 1	5 3
Professor S Boyages (appointed 13/5/99) (appointment terminated 06/10/99) Position became vacant, as member was absent without leave from four consecutive meetings.	Department of Health	0	4
Dr G Stevens (resigned 07/03/00) Dr M Izard (appointed 02/06/00)	Radiotherapist	0 1	6 1
Dr L Oliver (retired 25/11/99) Dr D McLean (appointed 08/02/00)	Medical physicist	5 2	5 3
Ms J Collins	Minister's nominee	6	8

The Radiation Safety Officer Committee was established by the Council on 21 February 1997 as a Working Group, and was upgraded to a Committee of the Council on 18 April 1997. The Radiation Safety Officer Committee was established to review the following:

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

The Committee was also allocated tasks of developing guidelines for Radiation Safety Committees and preparing guidelines on the management and reporting of radiation accidents.

The Radiation Safety Officer Committee completed these tasks at the beginning of the reporting period and is now in abeyance as a standing committee of the Council, to be reconvened when required.

It is anticipated that the RSO Statement and proposed guideline developed by the Committee will undergo public consultation in the latter part of 2000.

Council endorsed the establishment of a Course Assessment Committee on 20 February 1998. This Committee was formed to review all courses in which candidates enrol in order to fulfil conditions for obtaining a licence to use radioactive substances and radiation apparatus. It was intended that this Committee would establish competencies in radiation protection that would have to be met by successful candidates. One-third of the Course Assessment Committee is comprised of people who are not members of the Council. This Committee did not meet during the year, and the Council, at its June 2000 meeting, initiated a review of the Committee.

Members of the three committees of the Council that were active during the year are listed in Appendix 2.

AMENDMENT TO THE RADIATION CONTROL REGULATION 1993

The Radiation Control Regulation 1993 (the Regulation):

- contains provisions relating to the licensing of people to use certain radioactive substances and radiation apparatus
- prescribes activities that may be carried out only by an accredited radiation expert
- regulates the use of radiation apparatus and radioactive substances in the workplace and requires employers to supply certain information to people who are likely to be exposed to radiation in the course of their employment
- requires the radiation doses received by people in the course of their employment to be monitored
- regulates the disposal and transport of radiation apparatus and radioactive substances and the discharge of radioactive substances
- requires employers to take certain action in the event of a radiation accident
- enables the Director-General to direct an employer to appoint a radiation safety officer or radiation safety committee or both for a workplace
- allows exemptions from certain provisions of the Act and the Regulation.

The Regulation was amended by the Radiation Control Amendment Regulation 2000 on 11 February 2000. The major amendments relate to the initiation of registration for all radiation apparatus used in diagnostic imaging. They also prescribe part of the *Radiation Guideline No. 6* (EPA 1999) as the applicable requirements for registration.

As a consequence of these amendments, all X-ray equipment, such as that used for medical, dental, chiropractic and veterinary diagnostic purposes, will need to be registered with the EPA before 11 August 2000. There is a two-year period of grace for compliance with the standards: equipment that is required to be registered or re-registered after 11 February 2002 will need to comply with the new standards.

These initiatives were undertaken by the EPA on the advice provided to the Minister by the Council. They will enhance public safety and protect patients, users and the general public from unnecessary exposure to ionising radiation. The amendments:

- prescribe radiation apparatus used for medical diagnostic, veterinary and dental purposes as 'prescribed radiation apparatus' for which registration is required under section 7 of the *Radiation Control Act 1990*
- prescribe Schedule 1 of *Radiation Guideline No. 6* as the 'applicable requirements' of the Regulation for registration (see section 7(5) of the Act)
- set registration periods for the prescribed radiation apparatus and specify a registration process
- provide a means under the provisions of clause 8 of the Regulation whereby medical registrars in ophthalmology, dermatology and rheumatology can gain exemptions from licensing requirements
- exempt from the licensing requirements of section 6 of the Act registered nurses and medical staff working in a hospital who may be required to inject patients with a radiopharmaceutical
- repeal clause 9 of the Regulation (which requires certain licensees to be supervised) on the grounds that it unfairly discriminated against medical technologists over other professional groups and made that group unfairly responsible for any breaches of the Regulation
- incorporate three additional activities into clause 11 of the Regulation, which provides a mechanism for assessing the design, adequacy and integrity of radiation shielding to be undertaken by accredited Consulting Radiation Experts.

LICENCES TO USE AND SELL RADIOACTIVE SUBSTANCES AND RADIATION APPARATUS

Section 6 of the Radiation Control Act regulates the use and sale of radioactive substances and radiation apparatus. Specifically, section 6(2) prohibits a person from using 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.

Section 6 of the Act provides for the EPA to grant licences and impose conditions on licences on the recommendation of the Council. Following the Council's recommendation, the Radiation Control Section of the EPA issues a licence.

In considering licence applications, the Council was aware of its responsibilities under section 6(5) of the Act. Namely, the Council is not to recommend that a licence, or a temporary licence, authorising a person to use anything to which this section applies be granted unless it is satisfied:

- (a) that the applicant is a natural person and is a fit and proper person to hold the licence; and
- (b) that the applicant has appropriate knowledge of the principles and practices of radiation hygiene and protection applicable to the activities proposed to be carried on by the applicant in pursuance of the licence.

For the reporting period ending 30 June 2000, 1181 licence applications were received, of which, on the advice of the Council, the EPA approved 1177. The Council recommended the granting of 295 new licences for the use or sale of radioactive substances and 882 new licences for the use or sale of radiation apparatus. These numbers represent 25.1% and 74.9%, respectively, of the total number of 1177 new licences approved and issued during the year. 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 1999–2000.

During 1999–2000 the EPA also renewed a total of 11,071 licences: 2538 licences for radioactive substances and 8533 licences for radiation apparatus. At the end of the reporting period, there were 2833 active licences for radioactive substances and 9415 active licences for radiation apparatus, totalling 12,248 active licences.

TABLE 2		
Number of new licences issued (listed by occupational category) to use or sell radioactive substances and ionising radiation apparatus in 1999–2000		
Occupational category	Radioactive substances	Ionising radiation apparatus
Dental	–	215
Medical—specialist	8	410
Medical—other and related	41	34
Servicing/installation	7	11
Educational	9	4
Safety	3	1
Management	6	10
Scientific/research	67	30
Engineering	13	3
Technical	106	40
Company (licence to sell)	18	7
Miscellaneous	17	117
TOTAL	295	882

TABLE 3
 Number of new licences issued by the EPA from 1992–93 to 1999–2000

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

REGISTRATION OF SEALED RADIOACTIVE SOURCES, RADIATION APPARATUS AND PREMISES

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

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, and which are required to be registered, comply with specified minimum standards 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 radioactive sources, certain radiation apparatus and premises in which unsealed radioactive sources are kept or used.

The Council has recommended that the EPA grant registration of fixed radiation gauges and prescribed radiation apparatus if the application satisfies all applicable requirements of the Regulation. During the year ending 30 June 2000 there were 50 new applications for registration granted.

Registration of fixed radiation gauges has commenced and, from 11 August 2000, registration will be mandatory for radiation apparatus used for medical, veterinary and dental diagnostic purposes.

To allow full implementation of the provisions of the Act in relation to the registration of sealed radioactive sources, certain radiation apparatus and laboratories in which unsealed radioactive sources are kept or used, there is a need to develop and establish guidelines that set out minimum standards as registration requirements.

Guidelines developed for radiation apparatus and sealed radioactive sources used for therapeutic purposes, and for premises in which unsealed radioactive sources are kept and used, have been developed jointly by the EPA and the Council. These guidelines have been endorsed by the Council, have undergone a cost-benefit analysis, and are soon to be released by the EPA for public comment.

ACCREDITATION OF RADIATION EXPERTS

Section 9 of the Radiation Control Act provides for the accreditation of Consulting Radiation Experts (CREs) by the EPA, on the recommendation of the Council. 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.

Currently, 20 people are accredited by the EPA as CREs: 12 people are accredited for assessing fixed radiation gauges; and eight for assessing premises where unsealed radioactive substances are kept or used.

The Council, for the period 1999–2000, recommended the accreditation of seven CREs, and a further four subject to the applicants completing an EPA induction seminar on the Act, Regulation and relevant guidelines.

PERSONAL RADIATION MONITORING

Under clause 15 of the Radiation Control Regulation, an employer must ensure that an occupationally exposed person in his or her employ using ionising radiation in the following fields is issued with an approved personal monitoring device (PMD) for detecting and measuring cumulative exposure to ionising radiation:

- radiotherapy
- industrial radiography
- nuclear medicine
- scientific research in medium- or high-level radiation laboratories
- diagnostic radiology.

The Regulation does not exclude any other person, or category of people, from being issued with a PMD if the person elects to wear a monitor.

During the reporting period ending 30 June 2000, nine occupational high-dose cases were reported to the Council.

VOLUNTARY EXPOSURE TO IONISING RADIATION FOR SCIENTIFIC OR RESEARCH PURPOSES

Clause 20 of the Radiation Control 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 mSv
- the radiation dose to a child or other persons incapable of giving informed consent exceeds 0.5 mSv
- the radiation dose to a baby, infant or foetus exceeds 0.1 mSv.

In the year ending 30 June 2000, the Council recommended that the EPA approve 12 medical research studies involving the use of radioactive substances or radiation apparatus. 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 also determines the appropriate qualifications required by the RSO and determines the functions of the RSO and RSC.

The Radiation Safety Officer Committee 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.

In the last reporting period, the RSO Committee produced two documents to help implement clause 28. The first, *RAC Statement on Radiation Safety Officers and Radiation Safety Committees*, provided advice on the types of organisation that need to appoint a radiation safety officer and a radiation safety committee; the qualifications needed for appointment as a radiation safety officer; and the functions of a radiation safety officer and a radiation safety committee. The second document, *Radiation Control Guideline No. 17, Radiation Safety Officers and Radiation Safety Committees*, was developed to help employers fulfil their responsibilities under clause 28 of the Regulation. The Council recommended that the EPA adopt both documents.

During 1999–2000, the EPA undertook a regulatory impact assessment of the documents. The documents and the impact analysis will be released by the EPA for public comment in the near future.

RADIATION ACCIDENTS

Clause 24 of the Radiation Control Regulation specifies the types of incidents that are classified as radiation accidents for the purposes of the Radiation Control 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.

Accidents are normally caused by either deficiencies 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 normally recommends counselling and /or further training. In specific circumstances, disciplinary action may be warranted. The Council may also refer more serious accidents to the Health Care Complaints Commission.

During the reporting period ending 30 June 2000, the EPA was informed of five instances where a radiation accident may have occurred. The Council investigated and considered each case individually 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 was wrongly administered 220 MBq of Tc-99m DMSA.
- After reviewing this accident the 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 was wrongly administered 941 MBq of pertechnetate.
- The Council reviewed the cause of this accident and determined that it was caused by a person not following established procedures correctly. The Council recommended that the standardisation of labelling for radiopharmaceuticals be raised by the EPA at the next Radiation Health Committee meeting.
- A patient was wrongly administered 120 MBq of Tc-99m DMSA.
- The Council reviewed the accident and 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 was injected with a therapeutic dose of Yttrium-90 that differed from the prescribed dose by 37.5%.

This accident occurred before the commencement of the *Radiation Control Act 1990* and was reported to the Council following an audit. The Council noted the report of the accident and determined that the accident was caused by a person not following established procedures correctly.

- A patient unintentionally underwent a repeat nuclear medicine examination.

Council reviewed the accident and 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 number of accidents reported to the EPA during the period 1994–95 to 1999–2000 was:

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

During the period July 1999 to June 2000 there were five accidents reported, of which two occurred because a person did not follow established procedures or implement them correctly, and three occurred because of deficiencies in the standing operating procedures of the facility in question.

NON-IONISING RADIATION

The proliferation in the use of laser equipment led the Council, in 1998, to recommend to the Minister that there was a need to initiate regulatory controls over the use of certain types of laser equipment. The Minister supported this recommendation.

A committee of inquiry into cosmetic surgery in NSW was established under the *Health Administration Act 1982*. The report of the committee, *The Cosmetic Surgery Report—Report to the NSW Minister for Health* (Health Care Complaints Commission 1999) also supported the recommendations of the Council with respect to the need for regulatory control of lasers used for health-related and cosmetic purposes.

The committee further recommended establishment of the Cosmetic Surgery Credentialling Council be established to facilitate development of guidelines and accreditation of training programs for the use of lasers by registered cosmetic surgery providers.

The Environment Protection Authority and NSW Health supported the recommendations of the committee that licensing and registration for the use of class 3B and 4 lasers be introduced under the Act.

The committee's recommendation that a Cosmetic Surgery Credentialling Council (CSCC) be established is currently the subject of discussions between NSW Health and the Australian Medical Association (NSW Branch). Once established, the CSCC will liaise with the Radiation Advisory Council to ensure a uniform approach to the accreditation of training programs for the use of lasers in cosmetic surgery.

PROVISION OF ADVICE TO THE MINISTER

During the reporting period, the Council provided the Minister with advice on the following issues:

- proposed transfer of responsibility for administration of the *Radiation Control Act 1990*

The Council recommended against any transfer of responsibility for administration of the *Radiation Control Act 1990* from the Minister for the Environment to the Minister for Health. The Minister responded that the government had examined options for the management of the radiation control function in NSW and that it would remain within his portfolio.

- a review of the IAEA Safety Publications and NSW EPA *Draft Guideline 7 for Standards of Safe Practice in Radiotherapy*

The Council prepared a report to the Minister on a series of accidents that have occurred over the last five years involving maladministration of radiotherapy treatments to patients in NSW hospitals. Three of the cases involved inappropriate radiation doses and contributed to the death of the patients. The report, *A Review of the IAEA Safety Publications and NSW EPA Draft Guideline 7 for Standards of Safe Practice in Radiotherapy*, contains a series of recommendations directed towards minimising the risk of occurrence of such serious radiation accidents. The Minister provided a copy of the report to the Health Care Complaints Commission and the Minister for Health.

- the Council's concern regarding the adequacy of EPA resources to carry out the EPA's administrative and regulatory responsibilities under the *Radiation Control Act 1990* and *Radiation Control Regulation 1993*

The Council voiced its concern about the EPA's slowness to implement guidelines and policy documents developed by the Council that would minimise unnecessary exposure of the public and occupational workers and would reduce the risk of radiation accidents occurring. The government subsequently increased the resources available for staffing of the Radiation Control Section.

APPENDIX 1: GOVERNANCE ARRANGEMENTS AND PROCEDURES OF THE COUNCIL AS AT JUNE 2000

General duties and responsibilities of Council members

Members of the Council owe their fiduciary duty solely to the Council when exercising their duties as a member of the Council. This requires members to act in good faith in the best interests of the Council, irrespective of the separate interests of any organisation, agency or profession that they might belong to or represent on the Council. These fiduciary duties are owed individually by each member.

Each member of the Council more generally also has a duty to:

- act honestly and in good faith
- exercise care, skill and diligence
- exercise the powers, duties and responsibilities of the Council for the purpose for which they were conferred
- retain his/her discretionary powers
- avoid conflicts of interest.

Conflicts of interest and disclosures

Members must at all times avoid situations in which there is a real possibility of conflict arising between their personal interests or professional duties and the duty owed to the Council.

Such a conflict may exist when a member has a direct pecuniary interest in a matter that is before the Council. Alternatively, a conflict may occur when an issue listed for discussion by the Council involves an institution or organisation to which a member owes a duty in a professional context.

Consequently, members must be attuned to the possibility of conflicts of duty or interest arising between their duties to the Council and their personal and professional affairs. Therefore, when a member believes that such a situation may occur, whether it be actual or potential, full disclosure of the conflicting interest or duty must be made to the Council.

Disclosure of interest

Where a member has a potential conflict of interest in relation to any matter before the Council, the member must disclose that interest and the nature of it at the beginning of the meeting called to discuss the matter. Provision for such disclosures will normally be made at Agenda Item 2—Adoption of Draft Agenda and Disclosure of Interests. Any disclosures made are to be recorded in the minutes.

Action to prevent a conflict from arising

A potential conflict having been disclosed, it is the duty of the meeting to determine what further action, if any, may be needed to prevent a conflict from arising. Such action could include:

- noting the potential conflict and its nature, and taking these into account during debate on the issue
- directing that the member abstain from any vote that may be called on the matter
- allowing the member to confirm the facts of the matter, but requiring the member to abstain from any discussion of it, or

- requiring the member to leave the meeting during discussion and debate on the matter,

or some combination of the above. The more drastic of these actions would normally be reserved for a conflict involving direct pecuniary interest.

Where action is taken to prevent a conflict, the nature of that action must be recorded in the minutes.

In the unusual event of serious ongoing conflict, the question of the member's continued membership of the Council may need to be considered.

Possible conflicts between the Council and EPA positions

The EPA is represented on the Council through the chair. The EPA, therefore, is entitled to put a position at Council meetings, as, indeed, is each of the 14 members of the Council.

While it is desirable for the Council to reach consensus on matters before it, Schedule 1 to the *Radiation Control Act 1990* provides in clauses 10(2) and 11 for voting to resolve a matter. A decision supported by a majority of votes cast at a Council meeting at which a quorum is present is the decision of the Council. The person presiding at any Council meeting has a deliberative vote and, in the event of an equality of votes, has a second or casting vote.

The voting provisions of Schedule 1 are to apply to any situation where consensus cannot be reached, including those involving differences of position between the EPA (and/or other public authorities) and other members of the Council.

Exercise of due diligence

Each member of the Council is expected to display the degree of care, skill and diligence that it is reasonable to expect from a member of the Council.

'Reasonable expectation' takes into account the knowledge, skill and experience that the member brings to the Council and could be reasonably expected to bring to it, bearing in mind the distribution of members and the fact that each member of the Council brings different expertise to it. Care and diligence also include the concept of acting honestly in the discharge of one's duties.

Members of the Council, being part-time, are not bound to give continuous attention to the affairs of the Council.

Meeting procedures

Schedule 1 to the *Radiation Control Act 1990* provides that the procedure for calling meetings of the Council and for the conduct of business at those meetings is, subject to the Act and Regulations, to be as determined by the Council.

The Council normally determines its schedule of meetings for the financial year at the last meeting that it holds in the previous year. Normally, no fewer than four and no more than 12 regular meetings are to be scheduled in any financial year.

If an urgent matter arises at short notice, the chairperson is authorised to convene a special meeting if he/she judges that the situation so warrants.

Schedule 1 to the Act provides:

- that the quorum for a meeting is eight members
- that the presiding member will be the Chairperson or, in the chairperson's absence, another member elected by the members present
- for the resolution of issues by voting, with a decision supported by a majority of votes cast at a meeting at which a quorum is present becoming the decision of the Council. The person presiding has both a deliberative vote and, in the event of an equality of votes, a second or casting vote
- that the office of a member will become vacant when a member 'is absent without leave from four consecutive meetings, of which reasonable notice has been given'
- that a member is paid such allowances as the Minister determines. (Non-government employees are entitled to sitting fees.)

The agenda for Council meetings are normally to be structured as per the pro forma in Schedule 1 at the end of this appendix.

Council may specify other meeting procedures from time to time.

Standing advice

Council has specific duties under sections 6-10 of the *Radiation Control Act 1990* to advise the EPA on aspects of the exercise of the EPA's regulatory powers. For a number of these matters of a common routine type, it is feasible to provide advice generically. Matters for which the Council has provided generic advice are listed in Schedule 2 at the end of this appendix. The Council may add to this schedule from time to time.

For all other matters upon which the EPA may act only on the recommendation of the Council, the Council expects the EPA to refer each matter individually to the Council so that the Council can consider the matter and make a recommendation to the EPA on it.

Committees

The Council forms committees from time to time, in accordance with section 31 of the *Radiation Control Act 1990*, to help it formulate advice to the Minister or the EPA. These committees are chaired by a Council member and may consist of both Council members and non-members. The latter are one means by which the Council can expand the range of expertise available to it.

Committees are generally bound by the Act, the Regulation and these governance and operating procedures, plus the terms of reference and any other directions given by the Council.

At present there are two standing committees:

- Technical Committee
- Course Assessment Committee.

The membership and terms of reference of the Technical Committee are described in Schedule 3 of this appendix. The Course Assessment Committee is under review.

Delegations

Chairperson

The chairperson of the Council is authorised to:

- sign correspondence on behalf of the Council
- answer routine correspondence addressed to the Council
- be the public spokesperson for the Council on matters on which the Council has determined a position
- convene unscheduled meetings at short notice in emergency situations.

Induction of new members

There is a formal procedure for induction of new members. It includes:

- a reading package, including copies of
 - the *Radiation Control Act 1990*
 - the Radiation Control Regulation 1993
 - the most recent Radiation Advisory Council Annual Report
 - the most recent Radiation Advisory Council Strategic Direction Statement
 - a list of Council members and their professional contact details
 - any governance and operating procedures statement that may be extant
 - a list of Council committees, their terms of reference and membership
 - the current Council work program
 - the Council's policy document, *Radiation Control Act 1990, Licence Type Conditions and Qualification Requirements for the Use and Sale of Radioactive Substances and Radiation Apparatus*
 - background information on the EPA
- a briefing covering the above matters and the current issues before the Council.

Schedule 1: Radiation Advisory Council model agenda

Introductory items

1. Opening of meeting
 - 1.1 Opening remarks
 - 1.2 Membership/ attendance
2. Adoption of draft agenda and disclosure of interests
3. Minutes of previous meeting

Discussion items

4.)
5.) as required
6.)

Committee reports

7. Technical Committee Report
8. Other committee reports as required

Non-discussion items (unless 'starred' at Agenda Item 2)

9.)
10.) as required
11.)

Concluding items

12. Other business
13. Next meeting

Note: Council will normally 'note' non-discussion items, essentially treating them as information items, unless they have been 'starred' for discussion at the meeting.

Schedule 2: Standing advice

The Council recommends that the EPA exercise its statutory powers in relation to the following matters without seeking further advice from the Council, subject to the specific case satisfying the detail in the relevant recommendation.

Date	Agenda Item	Issue	Recommendation
16/12/94	7.1	Minor variations to licence	The EPA may grant a variation to a licence where the variation sought is minor.
01/04/96	6.8	Registration of fixed radiation gauges	The EPA may grant a certificate of registration where an accredited assessor has so recommended.
20/06/97	7.9	Expired licences	Where an applicant's licence has expired, the EPA may grant a licence of the same type within a period not exceeding 28 days from the expiry date.
21/08/98	3.3	Standard licence applications	The EPA may grant a licence where the predetermined minimum qualifications recommended by the Council are met (standard licence).
16/06/00	6.0	Non-standard licence applications	The EPA may grant a non-standard licence during periods when the Council is in recess, subject to such approvals being ratified by the Council at its next meeting.

Schedule 3: RAC Technical Committee membership, terms of reference and operating procedures

Terms of reference

- provide advice to the Radiation Advisory Council pursuant to sections 6, 7, 8, 9 and 10 of the *Radiation Control Act 1990* and clauses 6, 14, 17, 18, 20 and 28 of the Radiation Control Regulation 1993 pertaining to proposed licensing, registration and accreditation determinations
- provide advice on other regulatory matters that the Council may refer to it from time to time
- when requested by the EPA, provide advice on research protocols involving the use of radioactive substances or other matters requiring technical expertise
- of its own motion, make recommendations to the Council on emerging issues, technical developments, regulatory matters or policy development.

Membership

Committee members are to be appointed by the Council, and the committee is to consist of the following persons:

- a physician in nuclear medicine and/or a radiologist and/or a radiotherapist
- a medical physicist
- a health physicist
- a diagnostic radiographer
- an industrial radiographer
- an expert in non-ionising radiation
- a community representative
- the chair of Council as independent chair (to be reviewed in six months).

The chairperson is to be appointed by the Council and must be a member of the Council. Otherwise, committee membership is not confined to members of the Council.

Standing operating procedures

- Meetings are to be held at least monthly, prior to the monthly Council meeting, unless otherwise decided by the Council.
- The chairperson is to chair the meeting unless unable to attend, in which case the meeting is to elect another Council member to the chair for that meeting.
- The Chairperson is to report the Committee's recommendations to the Council. Reporting is to be by exception and is to highlight any matters that the committee considers that the Council as a whole should discuss or determine.
- The report to the Council is to be the official record of the Committee's deliberations. Separate minutes need not be maintained.
- A quorum for a meeting is four specialist members. Notwithstanding this requirement, if the members present do not have the expertise to provide the advice needed on a particular matter, the committee is not to make a recommendation to the Council until the necessary advice has been obtained.

- Members are to declare any interest that they have in matters on the agenda at the start of each meeting. These declarations are to be recorded in the minutes, together with the action, if any, taken to avoid conflict.
- Decisions are to be by consensus. Where consensus cannot be reached, the various views are to be provided in the report to the Council.
- In other respects, the committee is to follow the procedures of the Council, as applicable.
- The EPA will provide staff /administrative support for the committee.

APPENDIX 2: MEMBERSHIP OF COMMITTEES OF THE COUNCIL DURING 1999–2000

Medical Radiation and Health Physics Committees		
Member	Profession	Meetings attended
Dr L Oliver (Chairperson)	Medical physicist	5
Dr D Leece (appointed Chair of Council 23/12/99)	Chief Scientist NSW EPA	4
Dr C Bigg-Wither	Radiologist	3
Dr P Pasfield (appointed 09/05/00)		1
Mr J Robinson	Diagnostic radiographer	6
Dr C Larcos	Physician in nuclear medicine	5
Mr A Niven	Occupational hygienist	0
Peter Duriphy (appointed 02/06/00)	Expert in health and safety	0
Ms E Akmentins	Community representative	5
Dr K Crawford (appointed 08/02/00)		2
Dr R Rosen	Health physicist	5
Mr Michael Carter (appointed 08/02/00)		4
Mr C Hockings	Industrial radiographer	7
Mr L Collins	Expert in non-ionising radiation	7
Ms L Plues (or nominee)	Environment Protection Authority representative	9

Radiation Safety Officer Committee	
Member	Profession
Dr R Rosen (Chairperson)	Health physicist
Dr L Oliver	Medical physicist
Mr P Colgan	Environment Protection Authority representative
Mr C Hockings	Industrial radiographer
Mr J Button	Health physicist
Mr A Niven	Occupational hygienist
Ms J Towson	Medical physicist
Dr R Smart	Medical physicist
Mr J Robinson	Diagnostic radiographer
Mr J D'Astoli	Risk manager
Mr L Collins	Medical physicist
Mr L Potapof	Environment Protection Authority representative

This committee was in abeyance from 16 July 1999.

APPENDIX 3: APPROVED MEDICAL RESEARCH STUDIES (INVOLVING ADMINISTRATION OF IONISING RADIATION TO HUMANS)

Prince of Wales Hospital

- Review—Myocardial Perfusion in Patients Receiving Endovascular Radiotherapy for In-stent Restenosis
- An Evaluation of The Guidant Galileo™ Intravascular Radiotherapy System in the Treatment of In-stent Restenosis. Galileo™ Inhibit Protocol 99-408

Royal Prince Alfred Hospital

- Measurement of Cerebral Glucose Metabolism in Normal Volunteers

St George Hospital

- Role of Tc-99m Labelled Modified Recombinant Plasminogen Activator in the Detection of Recurrent Deep Venous Thrombosis
- Randomised Phase II Trial of Gemcitabine and Docetaxel Versus Gemcitabine and Carboplatin in Patients with Recurrent or Metastatic Transitional Cell Carcinoma of the Urothelium
- Phase 111, Open Label, Randomised, Parallel, Active Control Study to Evaluate Efficacy and Safety of Histrelin Subdermal Implant in Patients with Metastatic Prostate Cancer
- Accuracy of Tc-99m rt-PA in the Detection of DVT in High Risk Patients
- Scottish Randomised Trial in Ovarian Cancer
- Evaluation of 90Y-Octreo-Ther for Patients with Small Cell Lung and Advanced Breast Cancer
- A Randomised, Double-blind, Phase 111 Comparative Trial of 2 Doses of ZD1839 (IRESSA™) in Combination with Paclitaxel and Carboplatin Versus Placebo in Combination with Paclitaxel and Carboplatin in Chemotherapy-naïve Patients with Advanced (Stage 111 or IV) Non-small Cell Lung Cancer 23-35

St Vincent's Hospital

- A Phase 1/11 Clinical Study of Using I¹³¹ Immunoconjugate for the Treatment of Relapsed Non Hodgkins Lymphoma
- Randomised Control Trial of Biventricular Pacing Versus Maximal Medical Management in Patients with Systolic NYHA Class 111- IV Heart Failure