

### #1 **Stephen Atree Williams, Occupational Health and Safety Officer, Australian National University**

#### **Overview**

The current ionizing radiation legislation is sound in its focus of action and objectives. However, radiation legislation should also provide an explicit requirement / process for assessment of risk to health from ionizing radiation exposure and recognise the contribution to this risk made by, background radiation and voluntary medical radiation.

On the basis of this recognition, the legislation should operationally define,

- a level of additional dose (eg. from occupational or accident sources) above background that represents a legally de minimis additional risk to an exposure cohort of finite size. Presumably, this de minimis additional dose would be about 50 mSv cumulative whole-of-life (roughly equivalent to the current dose limit for the Public);
- a cumulative dose cap to ionizing radiation dose; and
- a requirement for health surveillance for persons exposed at higher levels of cumulative dose.

It is the absence of a clear, quantitative statement on risk in the legislation that has everyone jumping at microSieverts (and not giving appropriate attention to Sieverts) and so costing the Australian community substantial resources.

#### **Health Risk Issues.**

The conservative linear dose-response (stochastic) model is appropriate for health-based issues related to a known human carcinogen (i.e. ionizing radiation). However, as indicated above, I have concerns at the way this model has been interpreted by the legislation, and particularly by:

- the absence of any consideration of natural (and voluntary medical) dose. Dose from such sources has a significant influence on the quantitative risk assessment for low occupational or accidental doses and this should be explicitly reflected in the legislation in the form of a dose-above-background defined as representing a legally de minimis additional risk,
- the simplistic "dose rate" method used in the legislation to set occupational dose limits.

My judgement is that current legislation has two major failings in this regard,

- a failure to define an occupational or accident dose that represents a legally de minimis additional risk (for an exposure cohort of finite size). This failure leads to substantial resources being applied to the control of activities that are, effectively, of zero additional risk.
- a failure to define a cumulative whole-of-life dose above which the risk to health becomes legally de manifestis. The current dose rate allows for cumulative whole-of-life doses of up to 1 Sv, giving a risk of fatal cancer of 1 in 20. Most USA health-based legislation has set the de manifestis risk from environmental carcinogens for an occupationally exposed cohort at 1 in 250 or lower risk (A.P. Atree-Williams, S. Atree-Williams, N.C. Marsh, *Australian Encyclopedia of Occupational Health and Safety*, Standards Australia, Publication CB-014-1998.). It is likely that Australian courts would be at least as conservative.

#### **Regulator Funding Issues.**

The current approach in most radiation legislation is for governments to fund the Regulator by levies on the regulated. This can be viewed as another contributor to inefficient regulatory activity and, hence, to poor performance.

Central government funding promotes efficient regulation, accurate risk management and effective business operations and, hence, is a good investment for the Australian community. It can also be cost effective if substantial fines are legislated for non-compliance and the Regulator focuses on encouraging compliance by identifying and fining non-compliers instead of focusing on fund-raising from the compliant.

**#2 Associate Professor Chris Hamilton,  
Department of Radiation Oncology and Centre for Clinical Radiation Research,  
Newcastle Mater Hospital**

These comments should be regarded as a personal viewpoint and not attributed to the Faculty of Radiation Oncology or the Trans Tasman Radiation Oncology Group.

In general terms, the thrust of the paper to achieve uniformity of legislation in relation to Radiation Protection Legislation is an excellent aim.

There should be a very clear distinction between practices involving radiation administration and radiation safety. Radiation safety issues should not be subject to competitive, anti-competitive or market forces. Radiation safety benchmarks, standards, equipment and professional requirements should be inviolate and vested in the hands of an independent (preferably governmental) body. Confusing radiation safety and protection issues with commercial and market issues represents a dangerous practice.

The precedents for this are well documented world wide and I note the Issues Paper does not refer to any of the ICRP reports or IAEA reports (eg. IAEA Safety report, number 17 eg. “Radiation Incidents”, British Institute of Radiology, 1994/1995, eg. Accident Prevention in Radiation Therapy, Draft no. 10, February 2000). Australian and international experience with respect to the Civil Aviation Authorities demonstrates this lesson well.

Market forces, competitive and anti-competitive forces should certainly be considered in the area of radiation delivery and practice where fees of various sorts are associated. There is no doubt that many aspects of radiation delivery can be regarded as a market commodity eg. radiation oncology, pharmaceuticals, many medical services, industrial x-rays as well as equipment sales service etc.

I was also unable to find a clear statement of separation between the roles of monitoring and of regulation/enforcement.

There should also be an effective and comprehensive national radiation incident monitoring system established in radiotherapy. Any legislative move, which would improve the climate or ability of any groups to perform this, will be supported.

Finally, I (and I am sure my entire profession) take enormous exception to the comments in attachment 3 (Reforming the Health Care Professions). Over the last 20 years, some 42 Radiation Oncology Workforce equipment and service reports have been published in Australia. These have been largely authored by radiation oncologists and/or the Faculty in collaboration with various State and Federal groups such as AMWAC. All of these documents have called for additional registrar training posts. Almost every State Department of Health has consistently failed to fund these additional training posts to an adequate level. Radiation Oncologists around the country have been insisting on more training posts for over 20 years in the professional press, the lay press and at every Federal and State Workforce Committee which has ever sat. All of this information is on the public record.

**#3 Gerlinde Lenz,  
Member, OH&S Policy Committee, Australian National University**

I disagree with some of the implications of Mr. Altree-William's submission (see #1 above).

- It is a peculiar idea to suggest medical irradiation is voluntary. There is no such thing as voluntary medical exposure to radiation. It may be the lesser evil, but that definitely does not make it voluntary. (In addition, I have the impression the medical profession in this country is rather generous with radiation, because any detrimental effects of that are much harder to prove and sue for than those of anything avoidable by use of radiation.)
- I don't quite see why 'jumping at microSieverts' (which even according to Mr. Altree-Williams may still lead to 'cumulative whole-of-life doses of up to 1 Sv') will keep anyone from 'giving appropriate attention to Sieverts'. Due care is indeed expensive for the managers of radiation use, but not 'jumping at microsieverts' may turn out be much more expensive - to others within the community, though.
- An occupational limit at a dose leading to one lethal cancer per 250 exposed still seems very high. After all, this seems to be meant in addition to unavoidable natural, medical and accident radiation. Would you drive a car if your chance of a fatal accident were this high?
- Trying to partially fund regulators by fines for non-compliance will render the regulator out of funds once the goal of compliance is reached, and will render the regulator interested in non-compliance. Neither seems desirable. If the government does not see itself as the principal user of the regulator's service, this must probably be seen as any other 'user pays' service.

This is not to say I agree with the rest of Mr. Altree-Williams submission, because I don't understand legal implications, and don't know how the limits mentioned are defined.

**#4 Dr Challon Murdock,  
Cardiologist, Geelong Cardiology Practice, Victoria**

As a cardiologist I have been operating imaging equipment for cardiac catheterisation, electrophysiologic studies and pacemaker insertion for fifteen years. This has almost exclusively been done in the presence of a radiographer with the exception from 1993 to 1999 when I was licensed to perform this procedure without the presence of a radiographer.

In doing this I have performed several thousand coronary angiograms, at least two thousand pacing procedures and at least one thousand electrophysiological studies.

I do not think that there are any issues regarding safety of operating the x-ray imaging equipment, which are not obtained during cardiology training and at subsequent practice.

In addition, one of the units undertaken in first year university was Micheal Phippies' Principles of Radiation and radiation safety were part of this course.

I do not think that practising cardiologists should need to obtain a licence to perform procedures, which they have been doing for decades.

**#5 Dr Keith Terry,  
Occupational and Environmental Radiation Consultant,  
Proprietor, Radiation-Wise, Shelley, Western Australia**

The current legislation arose from the need to control the use of radioactive substances and radiation generating equipment for the safety of workers, members of the public and the environment. Implementation of this legislation required certain services to be established and run by government departments.

The increase in the use of radiation in our society has seen the introduction and growth of a radiation protection industry. There are now non-government organisations and individual radiation consultants with the relevant expertise providing services that was once only available from government departments. Examples of these are personal radiation monitoring services providers, calibration facilities, compliance testing and a wide range of radiation advice.

The proposed revision of radiation legislation should recognise this growth in the commercial availability of radiation protection expertise. Legislation should be framed to accept “approved providers of services”. Furthermore, the regulators should be at arm’s length from the “approved providers” except in cases where no “approved” commercial service is available. This has largely occurred in compliance testing but not in the other examples listed above.

In the current situation I believe there is unfair competition between the Government departments that provide services and the commercial service providers. For instance, ARPANSA has GST exempt status for all its services, whilst the Radiation-Wise/Landauer dosimetry service has to charge its clients GST. Most of our clients can claim back the GST but the necessary paperwork and cash flow is an extra cost.

I know that the GST exempt status is a Treasury matter and not a radiation legislation matter, but it certainly does come into your terms of reference of “unfair competition”.

With the commercialisation of radiation protection services there is also the need to consider the international implications. I have recently gone through the exercise of obtaining regulatory approval from each individual State for the Radiation-Wise/Landauer personal radiation monitoring service. Accreditation of our service turned out to be a simple matter since the NVLAP accreditation of the Landauer dosimetry service was accepted by NATA through the Mutual Recognition Agreement, as being equivalent to NATA accreditation.

Traceability to the Australian Standards of Exposure was more troublesome. These Standards are not themselves traceable to International Standards, so we had to send equipment from Landauer (in the USA) to ARPANSA (in Melbourne) for calibration against the Australian Standards.

With much trade now becoming very much international in nature, the traceability, or mutual recognition agreements, of the Australian Standards of Exposures to International Standards needs urgent attention.

I realise that the traceability to Australian Standards is a matter of the National Measurement Act, and that the mutual recognition agreement is a National Measurement Laboratory issue, but it does have a bearing on satisfying radiation legislation, and can be seen as “unfair competition”. This is more so when our main competitor in personal radiation monitoring services is ARPANSA, which is also the custodian of the relevant Australian Standards

On another matter, as a Radiation Consultant, who operates Australia wide, it would be much simpler to have national uniformity in radiation legislation. However, even with the adoption of common legislation by States, I suspect that we will still have to deal with local interpretations in each State, the same as we experience now from different inspectors within a State.

### #6 Australian Dental Association

#### Introduction

The ADA supports the need for this review. We support the need for regulation in the use of devices that emit ionising radiation. However, we also believe that the plethora and inconsistency of current regulations existing in the various States not only prevent a logical regulation of these matters but add to the costs of operation of dental practices. There is a need in the public interest for protection of health and safety for such devices to be operated by personnel who are adequately trained in their use and who are subject to codes of practice which ensure that they are operated safely. There is also a need to restrict the operation of such devices and not to allow unfettered access to them.

However, these regulations should not unnecessarily impede the freedom of utilisation by trained personnel.

#### Objectives of the Legislation

The objective of any radiation protection legislation is primarily to protect the health and safety of the community. This aim cannot be contested but it is important consider the risks involved and how to best address them.

#### Dental radiography – the risks

The ADA is in favour of prescribing certain standards, maximum levels of exposure or dose limits in regulations, standards and codes of practice. However, there should be consideration given to the fact that routine exposure to dental radiography does not give rise to exposure levels of significant risk to the community.

The gonad dose for dental radiography is minimal, being 0.003% of annual background exposure. As a further illustration, one can compare an abdominal radiograph which gives 1.07mGy for women (507.5 days of equivalent natural exposure) with, on the other hand, a complete oral radiographic survey using E speed film and rectangular collimation, which gives only 0.001 mGy (4.1 days equivalent natural exposure).

It is considered that as the risk to both patients and community is extremely low in the case of dental radiography, there is no justification in applying the same regulations as are necessary for therapies involving more critical radiation doses.

Unfortunately regulation often tends to generalise and thus be over prescriptive and it does not take into account that dental radiography does not involve the same level of risk as other procedures. As example of this is in the NSW Radiation Guidelines, which require provision of protective clothing and lead shielding in walls – measures which are totally unnecessary in the dental surgery provided standard radiation hygiene procedures are followed.

In considering any of this legislation, it needs to be remembered that it applies to medical, scientific and veterinary sources of radiation. As far as dental X-ray machines are concerned, one would have to question whether it is necessary in the interest of public safety that both registration of equipment and the licensing of practitioners are required. There is little evidence that dental x-ray machines cause significant environmental problems or danger to the community. The level of radiation, which is produced by current machines, is minimal.

#### Impact of radiation protection regulation on other regulations

The practice of dentistry is already regulated through the various State and Territory Dental Boards. To engage in such practice, one must be a registered dentist and these dental legislative and regulatory requirements ensure that only trained and registered personnel are permitted to carry out the range of dental procedures, which include radiography. The Boards not only register dentists but their charter to act to protect the public involves their monitoring of dental practice and the power to impose penalties including suspension in the case of any breach.

The ADA is of the view that the imposition of additional licensing requirements for the operation of dental radiographic apparatus is superfluous, given this overriding regulation on dental practice.

### Restrictions to Competition

#### Unnecessary Regulation

Some of these regulatory requirements in themselves are plainly over-prescriptive. For example, when a new dental x-ray machine is purchased in Queensland, the following licensing requirements are applied: On purchase, (1) permit for approval, (2) permit to possess and (3) Compliance Certificate. Then to operate the equipment, (4) Licence to operate and thereafter, every three years, the equipment needs to undergo (5) a compliance test.

In NSW, the Radiation Control Regulations 1993 has been amended to require registration of all radiation apparatus used for diagnostic imaging, including that used for dental purposes. This State regulation is also over-prescriptive about the production of dental x-ray machines and their ancillary equipment. For example, it requires that timing devices have the actual figures displayed on them rather than icons, which is an unnecessary impost on the design and production of these items.

#### Exemptions

Whilst the legislation must provide for licensing of persons dealing with radioactive substances or the operation of ionising radiation apparatus or equipment, it is noted that exceptions are made in this regard for specified occupational groups. These exceptions recognise that the persons defined are competent to be involved in these operations without further licensing. Such persons recognised in various jurisdictions range from students to qualified and registered health professionals.

The operation of any apparatus that involves the emission of ionising radiation must be regulated. Only those whose training and expertise are appropriate for these functions should be permitted to deal in these matters. Consequently, the ADA supports the need for sensible regulation. The provision of exemptions from licensing must be based on a satisfaction that the occupational group so exempted are, per se, already satisfactorily trained in these tasks and subject to other regulations, which safeguard the health and safety of the community in this regard.

Dentists receive comprehensive instruction in physical sciences at a University level including radiation physics and are trained to operate dental radiographic equipment as part of their clinical training. This includes the relevant safety procedures necessary for the health and welfare of their patients.

There is clearly no necessity for them to undergo any additional training, testing or licensing. The various State and Territory dental regulatory authorities, such as the Dental Boards, have full carriage of these matters in the licensing for dental practice and the monitoring of practice standards. There is some inconsistency in this matter in the regulations in various jurisdictions and not all authorities exempt dentists.

There is little logic in imposing costs and complications when the health professional involved, ie the dentist, is already qualified and has had these qualifications accepted by a Dental Board in gaining registration to practise. It is submitted that registered dentists be granted exemption from licensing in all States and Territories.

#### Inconsistency in regulation

*Registration of equipment:* As long as various States have different radiation safety regulations, one can expect anomalies. In Western Australia, for example, the use of intra oral panoramic x-ray equipment is not allowed (unless a special case is made). It is believed that this is a unique situation and is an illustration of the general regulatory inconsistency between States and Territories.

*Licences to use dental x-ray equipment:* Similar inconsistencies occur between the various States and Territories. In Victoria, for example, a person registered as a dentist or as a dental specialist by the Dental Practice Board can apply for and will be issued with a licence to operate both intra-oral and extra-oral (OPG and cephalometric) equipment. Similar arrangements are in place in New South Wales and Western Australia, but not in South Australia and Queensland. In these latter States dentists wishing to operate extra-oral equipment have to either show that they have successfully completed an additional course of training or pass a test.

The ADA believes that regulatory differences between States and Territories add unnecessary costs to Australian businesses, especially for dentists who practice in more than one State or Territory, as in border areas. Uniformity in legislation would allow dentists to move from State to State with less impediment or cost and by minimising this upward pressure on fees, would benefit the community.

The rationale for the above-mentioned inconsistencies is unclear. The inconsistencies are confusing for the profession and the dental supply industry. They make the operation of dental practice unnecessarily

complicated, increase compliance costs and exert upward pressure on dental fees, to the detriment of the interests of the community.

### Compliance costs

The ADA questions the cost-benefit of registering all diagnostic imaging units. It is noted that the review team is to take into account “*the need to reduce compliance costs and paperwork burden on small businesses*”. In this regard, about 5,000 dental practices in Australia are currently affected by illogical and inconsistent regulations which exist in the various States and Territories. These regulations apply to both the equipment itself and to the operator.

In NSW dentists pay a fee of \$100 to register each x-ray unit and, in many solo practices, dentists are paying up to \$300 per practice or more to register these units. In larger clinics, payments of up to \$3,000 are involved in registration fees alone.

It is clear from the above examples that there is a need to review these regulatory requirements, not only to achieve consistency throughout Australia but also to avoid unnecessary paperwork and administrative procedures, which only increase costs to the community without any benefit.

These various registration and licensing requirements impose significant costs on all dental practices. These costs involve registration fees, annual licensing fees, inspection fees and costs involved with the maintenance of associated records and documentation. There is no evidence that the collection of these fees benefit the user, the general public or the environment.

The regulations in place, which pertain to dental practice and the restrictions on who can practice dentistry are considered to be sufficient to ensure public health and safety, without additional regulations for the possession and operation of x-ray equipment.

### **Other issues**

While this review is concerned with radiation protection legislation there is an associated issue, which the ADA considers to be, in its nature, anti-competitive. One of the greatest impediments to competition in the provision of radiological services is the apparently discriminatory way that services provided are reimbursed. Some come under Medicare arrangements, while others of equal importance, are excluded from the Medicare system.

Medicare covers some services, for example OPGs, only if they are taken by a specialist (medically qualified) radiologist. In order to obtain the highest possible yield from diagnostic radiological examinations and reduce unnecessary radiographic procedures, suitably qualified and competent clinicians should perform the interpretation of these radiographs.

It is not in the best interest of patients when registered dental specialists in Dento-Maxillofacial Radiology are excluded from these arrangements, despite their training and expertise in this field. Indeed, many of these services could be performed in general practice dental surgeries without compromise in the quality and relevance to diagnosis and treatment planning. Many dentists feel that general radiologists are not equipped to accurately diagnose dental disease and it would be better if access to Medicare radiological procedures was available to the dental profession.

### **Summary**

- We support the need for a review of radiation protection legislation in order to protect the public.
- We support the requirement for restrictions on the operation of any ionising radiation emitting apparatus and that the operation of these devices should be restricted to appropriately trained and regulated personnel.
- The review should endeavour to achieve national consistency and eliminate the unnecessary costs to the community through over regulation and illogical variations to regulations among the States and Territories.
- The employment of exemptions from licensing for specific occupational groups, whose training and expertise can be assumed is supported.
- Registered dentists should be exempted from the need to acquire an additional licence to operate dental x-ray equipment.

**#7 Dr Richard Smart,  
Principal Physicist and Radiation Safety Officer,  
Department of Nuclear Medicine, The St George Hospital, Kogarah, NSW**

There have been a couple of instances in the last year that has made me aware of the extent of non-uniformity of the legislation. This submission is primarily related to the issue of national uniformity as discussed on page 5 of the Issues Paper.

### **Variation of exempt activity between States**

The disposal of used vials of Quadramet is a case in point. Quadramet is a radiopharmaceutical produced by ANSTO, containing  $^{153}\text{Sm}$ , for the palliation of bone pain arising from metastatic prostate or breast cancer. The presence of long-lived contaminants,  $^{152}\text{Eu}$  and  $^{154}\text{Eu}$ , poses problems for the management of used vials. The exempt activity in the various regulations varies from 40kBq in the ACT, Victoria and Western Australia to 1,000 kBq in Queensland to dispose of an activity of  $^{152}\text{Eu}$ , which is 25 times the legal limit in Victoria.

This issue has a major impact on the user, who must safely dispose of the material. It also has a commercial implication, as the supplier, ANSTO, is now required to collect the vials from the user and must store the vials for many years to allow the radioactivity to decay.

This is one example of the large differences in the regulations between States, and is one, which has had a significant impact on both the users and the manufacturer.

### **Definition and reporting of radiation accidents**

Most jurisdictions have defined what constitutes a “radiation accident”. The exception is the Commonwealth, which, in the ARPANS Regulations, specifies that a licensee must report an accident, but does not define an accident.

Definitions vary widely from one State to another. Some States define an accident in reference to the radiation dose that a person may have received, while other definitions relate to “dangerous events” even if no person was exposed during the accident.

The problem arises because ARPANSA (and its predecessor, ARL) maintains the Australian Radiation Incident Register, which collates accident reports from each State and Territory authority and attempts to provide statistics on radiation accidents. Although the Register currently contains information on over 100 incidents, it is very difficult to extract meaningful information from the Registrar due to the various definitions used. For example, the Register would show medical maladministration from Victoria and NSW and none from the other States, although medical radiation incidents are likely to be occurring equally across the country.

Users of radiation can learn from previous radiation incidents. To this end, it is essential that a common definition of an accident be adopted so that the Register can reflect the true situation in Australia.

### **Alternatives to the current legislation**

Questions 13 to 18 of the Issues Paper address alternatives to the existing legislation. I would like to address several of these questions.

- Question 14: A system of negative licensing is totally unsuitable to legislation, which deals with *Safety*. The long-term hazards of ionising radiation are very well known, as are the immediate hazards of instruments such as Class 4 lasers, which can produce significant skin burns and blindness. It would not be acceptable to allow anyone to operate such equipment without appropriate constraints, and only prohibit them from using the equipment once irreversible damage has occurred.
- Question 16: Self-regulation within an industry already occurs in this field. For example, diagnostic reference activities have been developed for use in nuclear medicine by the professional bodies (ANZSNM and ARPS). However, there will always be a need for regulated dose limits for occupational exposure and for exposure of members of the public. Australia will be failing in its responsibilities if it did not adopt the limits recommended by the ICRP and the IAEA.
- Question 17: I believe that a system of “mirror” legislation would provide the best level of protection for the Australian population, minimise duplication of effort, and remove many of the inequities that currently exist between the States and the Territories.

### #8 The Royal Australian and New Zealand College of Radiologists (RANZCR)

Radiation has many valuable uses in society, especially in the field of medicine. However, ionising radiation also produces harmful effects on humans and in the interest of public safety the College submits strongly that the use of ionising radiation should be regulated by regulations. The current system of regulation in Australia is similar to systems of other countries and the standards applied in Australia conform to international standards.

**Question 1 - Do the objectives of the legislation sufficiently cover all the issues? If not, what other issues should the objectives aim to address?**

**Question 2 - Are the provisions of the legislation consistent with the objectives? Are there any conflicts or contradictions?**

**Question 3 - Do you think that agencies are pursuing the original objective of radiation protection legislation or are they pursuing other objectives? You can assess this based on personal experience or against policy statements of State and Territory governments in the last few years.**

**Question 4 - Do you think any of the objectives specified in the legislation are out of date? Has there been any technical or market change in the last few years that have made the objectives more or less relevant or give rise to the need to specify either new or amended objectives?**

**Question 5 - Do you think that the objectives are focussed, capable of being monitored and tested and achievable? Should the objectives be modified, reprioritised, deleted, enlarged or accepted?**

**Question 6 - Is there any objective or any part of an objective in any of the legislation that is best addressed in some other existing legislation or if necessary, in some other new legislation?**

**Question 7 - Does any objective in the legislation of the participating jurisdictions impact negatively on any other policy objective of the jurisdictions in other areas, including (but not limited to) occupational health and safety, mining, transportation, public health and the environment?**

The objectives are considered to be satisfactory. Although there are some difference in objectives of the various Acts, they are generally consistent. It is the view of this College that the wording in the Commonwealth legislation is the most appropriate and relevant because it is the broadest: "...to protect the health and safety of people and to protect the environment from the harmful effects of radiation".

**Question 8 - Do the regulatory differences within and among governments add to the costs of Australian businesses? Do you think there is a compelling need to promote uniformity among the legislation of all the States and Territories to eliminate unnecessary duplication and enhance administrative efficiency?**

There are differences between the various Australian jurisdictions, particularly within the regulation under the Act. The College supports any process, which promotes and seeks to achieve uniformity between the legislation of all States and Territories.

**Question 9 - Are the standards and codes of practice referenced in the legislation suitable and relevant? Is there any justification for their retention? Can you suggest better ways to reference and use such standards and codes of practice?**

The standards and codes of practice are important and should be referenced. Standards are an essential part of the regulation or radiation. Codes of practice are also important but may need review over time.

**Question 10 - Could the current arrangements to partially recover the costs of regulatory oversight be improved? Should full cost recovery be introduced as it is in most professional registration areas? Could compliance costs and the paper work burden on small business be reduced**

Costs associated with regulation and licensing are significant and ultimately must be met by society. As the regulations are in place for public safety, it is reasonable that the Government meets some of the costs of administration. The College submits that there should be only partial recovery from the consumer. Costs should be kept as low as reasonably possible.

### **Question 12 - Are the current arrangements for regulating various occupational groups appropriate?**

As is the case in respect to many aspects of the various regulatory provisions, there are considerable differences among jurisdictions in the methods used to regulate occupational groups. Whilst these differences are acknowledged, it is the College view that the various ways in which this issue is addressed presently are operating satisfactorily overall. Clearly, it would be desirable for occupational groups to be regulated in a consistent manner across jurisdictions, with the principal focus being on quality and safety.

### **Question 14 - Is it feasible to have a system of negative licensing, where there is no requirement for licensing or registration but someone who deals with radioactive substances or radiation equipment unsafely is prohibited from further dealing with the substances or equipment?**

The College strongly opposes “negative licensing”. The current system of licensing should be retained.

### **Question 16 - Is total self-regulation with an industry developed code of conduct feasible?**

It is the College’s strong view that total self-regulation with an industry code of conduct is not feasible and is not in the interest of public safety.

### **Question 17 - Is a system of “mirror” legislation with all jurisdictions having the same legislation and a central body issuing standards and codes of practices desirable? If not, is there a need to develop some other system of maintaining radiation protection standards that achieves greater uniformity or consistency while jurisdictions continue to maintain their existing Acts and regulations?**

Uniformity of legislation is an important and appropriate objective. It should be promoted and pursued actively.

### **Question 18 - Is it desirable to have performance-based laws, regulations, standards and codes of practices that specify only the objectives of the legislation leaving it to the industry to demonstrate compliance through risk-based safety management or operational plans before a licence or registration is issued instead of prescribing the standards, maximum levels of exposure or dose limits in regulations, standards and codes of practices?**

The meaning and intent of this question is not clear.

### **Summary**

In general, the current system of regulation ionising radiation is satisfactory and should be retained. Some modification is desirable, particularly in promoting uniformity among jurisdictions. Non-ionising radiation also requires regulation with limits of exposure but the method of regulation could be different from that used in respect of ionising radiation.

**#9 E T Parrott,  
Managing Director, ADM Nuclear Pty Ltd, Seaford, Victoria**

Permission was not received to make this submission public.

### **#10 Australian Veterinary Association Ltd**

The AVA is the national body representing the veterinary profession in Australia. The profession is very diverse as it addresses the health and welfare of animals of all species, farm, aquatic and companion animals and zoo species, wildlife and laboratory animals.

The veterinary profession from the point of view of veterinary practice is mainly involved with the use of x-ray equipment. AVA is concerned about any proposal that would restrict the availability of x-ray services or make them too expensive for routine veterinary use.

While legislation varies among jurisdictions, we can quote the NSW Veterinary Surgeons Act, which requires that every veterinary hospital of Class A or B has its own x-ray equipment and is readily able to develop and examine the resultant radiographs. (Class C hospitals are essentially consulting rooms – usually a small branch practice and cases requiring x-rays are taken back to the main hospital.)

This is very different to the medical profession, where almost universally x-rays are done on a referral basis or in the hospital.

It is agreed that x-rays do pose a risk to the health of humans and animals and therefore need to be controlled. It is accepted that the x-ray equipment in each hospital must be licensed.

However, in order to contain costs and therefore client access, it is suggested that the primary means of ensuring that each piece of x-ray equipment is in good working order and used properly is that each licensed piece of equipment must be covered by a service contract with a competent servicing person. The contractor must regularly inspect, test and repair the equipment. The contractor must ensure that staff of the practice are properly trained in its safe use and must regularly report compliance and any problem to the registration body.

The policing by the registration body should be mainly by contractors. The only other area it should police is checking for unlicensed equipment.

**#11 Dr Gerald Laurence,  
Aduchem Pty Ltd, Burnside, South Australia****Necessity for regulatory control of the use of ionising regulation**

Current legislation is based on the need to protect users and members of the public from the harmful effects of ionising radiation.

The controls in general extends through restrictions on the use of ionising radiation to those who have demonstrated some competence and understanding (akin to the licensing of drivers) of the dangers through,

- registration of apparatus capable of generating ionising radiation with constraints on the safety of the apparatus and regular checks of the safety (akin to the checks on pressure vessels),
- registration (and regular checking) of sealed radioactive sources, and
- supervision (by registration, inspection and the imposition of basic safety standards) of premises and other locations where unsealed radioactive materials are used.

The serious public health risks in regimes where such registration and checks are unknown or inadequately administered are obvious in accidents in Brazil, Turkey, Thailand and Egypt.

In some jurisdictions, specific attention is placed on the mining and milling of radioactive ores (uranium, mineral sands).

The Issues Paper suggests (page 9) “precautionary controls....may still be relevant”. This is an unfortunate phrase for it suggests that there may be a public health choice in the matter. Controls are a major plank in public health and occupational safety programs and the past good record of radiation health in Australia should not be compromised by the use of the words “may still be relevant”.

The general provisions of the legislation relating to dose limits and exposure levels are widely recognised as being measurable with the required precision. These limits can be effectively incorporated in legislation. They do not detract from competition by the imposition of excessive costs for monitoring, record keeping and general compliance.

Experience as a radiation safety officer in two universities indicates that compliance costs per radiation worker are much smaller for ionising radiation issues than for other occupational health concerns such as electrical and chemical hazards.

**Legislative constraints and liability**

Although legislative controls imply compliance costs, these costs are not necessarily avoided in a non-regulatory climate. Insurance requirements (public liability, worker compensation, professional indemnity etc) may be considerably higher in the absence of legislated norms, which represent a community consensus on radiation safety. Prudence would suggest that users of ionising radiation would be wise to meet recognised standards (international in the absence of local) in order to reduce as much as possible the risks of being sued by workers or public, possibly many years after an alleged exposure.

Only a monitoring system of the kind recognised by most legislation could provide some protection.

**Structure of current legislation**

Experience indicates that in general the restriction listed on page 12 of the Issues Paper is unlikely to restrict competition (or are no more restrictive than the requirement for the licensing of medical practitioners). Licence and registration requirements are generally met without great expense or difficulty, and where exemptions are used, in SA, these apply either specifically to students undergoing training or to any persons working under the supervision of a licensed person and are not confined to special classes of commercial activity.

The prohibition in WA against advertising reference to being licensed or registered to use ionising radiation is strange. It would appear to prevent the public knowing that a person or organisation is capable of the responsible use of ionising radiation. In view of the progressive relaxation of other advertising bans in professional areas there would appear little reason for this to continue.

### Compliance costs

The costs listed in pages 21 to 24 of the Issues Paper are relatively small in South Australia. Institutions with 500 radiation workers supervised by 100 licensed persons, working in 200 laboratories (about 100 registered premises) using unsealed radioactive materials incur direct fee compliance costs of about \$8,000 to \$10,000 a year, roughly \$15 per head.

Indirect compliance costs for radiation monitoring services, record keeping and the provision of a radiation safety officer are similar. As noted above, these indirect costs would be incurred even without legislation, in order to provide prudential protection to the organisation and might actually increase if regulation was abandoned, as it could be thought wise to make certain that all possible precautions were taken.

Current compliance costs are very very much less than workers compensation costs.

### Effects of restriction – regularity differences among States

While more mutual recognition of licenses etc is most desirable, detailed uniformity of legislation is not necessarily desirable in a Commonwealth of separate States, particularly in an area with as much emotional baggage as radiation health. We already have local government areas and some States declared “nuclear free”. Successive Commonwealth governments cannot agree on the number of uranium mines. There is also the emotional “not in our State” approach to any form of national waste repository.

A single national authority would not necessarily increase administrative efficiency and could stifle activities that are important for just one or two States.

The standards and codes of practice currently referenced are not always the most relevant. There can be some objection to the use of standards, which are drawn up by an essentially private body, such as the Australian Standards Association. These standards may not necessarily incorporate views contrary to the creators of the standards and which are not necessarily subject to legislative oversight.

While full cost recovery might be possible for regulatory control through licences, registrations etc, some aspects of legislative oversight would be expected to continue to be publicly funded. These include costs of dealing with emergencies, costs of advisory bodies, the provision of public information and educational services etc. Essentially public health issues not directly linked to individual radiation users.

In South Australia, the compliance costs are already minimal and represent no significant burden on businesses large or small.

In most cases, the specific arrangements for occupations such as health professionals are appropriate but need to be monitored to ensure they remain so without changing professional training and continuing professional development.

### Recommended approach

Much of the legislation (like much of the occupational health and safety legislation) is written in a very prescriptive fashion. In many cases, the legislation does not examine the hoped for effect of a regulation but continues an historic restriction, which can be traced back to the safety requirements of the Manhattan Project rules!

Rules for the fixtures, fittings and finishes in laboratories using unsealed radioactive sources are a good example (and are also an example of how Standards Australia can be just/more prescriptive as any State legislation). Most regulations have not taken into account new building methods and materials and that replacement may be safer and easier than decontamination.

The public health and worker health issues are too important for “negative” licensing to be contemplated. In many cases, the unsafe practices may take years to show an effect in the health of workers or the public. It would be as absurd as allowing anyone to drive without a licence until they are involved in a dangerous accident.

The public health issue similarly suggests that self-regulation is not sensible. The term industry is misleading. There is no “ionising radiation industry” as such. Research institutions using radioactive materials have little in common with uranium mines. Dentists are unconnected with radiotherapy practices. Borehole loggers, grape growers and heavy industry are similarly diverse. As there is no “industry” there can be no self-regulation. If it is treated as 20 or more separate “industries”, why should they arrive at similar rules for the protection of workers and the public.

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“Mirror” legislation is only an improvement on current practice if the central body drawing up standards and codes of practice is answerable to advisory bodies and legislatures in each State and Territory. The development of as much consistency as necessary is desirable. The general recognition of a single set of dose limits is an example. But if legislation is aimed at prescribing how things shall be done, there will inevitably be differences in detail.

On the other hand, agreement on goals and desirable results can go hand in hand with differences in detail in achieving those goals. These differences in detail will represent no serious impediment to operations across different legislations because the ends remain the same.

### **Summary**

The use of general national goals for radiation safety coupled with State and Territory legislative goals rather than prescriptive details will maintain an adequate safety to workers and the public while avoiding the detailed legislative and compliance nightmare of the overly prescriptive legislation the USA.

**#12 Mrs Bronwyn Nicholson Mr Kevin Pitstock**  
**Honorary Secretary Deputy Chairman**  
**Accreditation Board – Australia and New Zealand Society of Nuclear Medicine**

#### **The Accreditation Board of the ANZSNM**

The ANZSNM Accreditation Board, (the Board), is a sub committee of the Australia and New Zealand Society of Nuclear Medicine (ANZSNM). The ANZSNM is a society covering different professions with a common interest in the field of nuclear medicine. The membership comprises nuclear medicine specialists, nuclear medicine technologists, physicists, pharmacists, chemists and nurses. All these professional groups work within very specific guidelines that protect both the radiation worker and the general public.

The Board sets standards for education and training of Nuclear Medicine Technologists (NMT's) in Australia. This standard is recognised by NOOSR and the Department of Immigration as the basis for overseas skills recognition for immigration purposes.

The ANZSNM recognises the standard for Nuclear Medicine Technologists (NMT) as an accreditation. This is based on education and postgraduate training, covering all aspects of the safe use and handling of radioactive substances. Any NMT holding accreditation will satisfy the requirement for licensing, registration or any other pertinent legislation in any state of Australia.

#### **The NCP Review**

The Board believes that the concept of national consistency in radiation protection legislation is long overdue.

The essence of all the State legislation is the protection of the community from inappropriate use of radioactive substances and radiation apparatus, and this remains a valid concern. There is potential harm to many individuals and the environment if radioactivity or ionising radiations are misused. While all the various legislations are appropriate individually, repetition and inconsistencies are present.

There are many differences between the States with respect to radiation protection legislation. The majority of these differences are in the administration of the various acts and the appropriate requirements for licensing or registration of practitioners who use radioactivity and radiation equipment, the apparatus and premises where they are used. For example, persons working in the field of Nuclear Medicine have been required to satisfy different legislation depending where they reside. This creates difficulties for persons or organisations that wish to cross State borders.

Persons not adequately educated in the appropriate use, administration and handling of ionising radiation put the general public, colleagues and the environment at risk. The review must take into account the protection of the public when reviewing whether the requirements for persons working with radioactivity or radiation apparatus are appropriate.

A national policy would cut through the confusion caused by the current differing State and Territory Legislation. A nuclear medicine professional working in Western Australia should expect to work under the same national policies and regulations if transferring to Victoria, and such consistencies should exist nationally.

#### **Questions Raised in the Issues Paper**

The Board, is concerned mainly with the education and training of Nuclear Medicine Technologists. ANZSNM, our parent body, has made a separate submission on all the issues raised in the paper. The Board has chosen to address the issues of the appropriateness of current arrangements for regulating various occupational groups as raised in question 12.

It is important to recognise that persons involved in the practice of Nuclear Medicine Technology require specific qualifications to carry out these duties in a manner that puts the public and environmental safety at the forefront. The use of unsealed radioactive sources together with the preparation and administration of radiopharmaceuticals to humans, as is required in nuclear medicine, is a practice that makes nuclear medicine unique from other imaging modalities that utilise ionising radiations.

There are added hazards associated with unsealed sources that do not apply to ionising radiation apparatus, such as contamination and disposal of radioactive wastes. There are inherent dangers of misadministration of radiopharmaceuticals to patients by persons with inadequate education in nuclear medicine technology.

Attention to these fundamental differences has been recognised by the medical profession and the nuclear medicine community in the evolution of nuclear medicine technology as a profession in its own right. Tertiary institutions have also recognised these differences by offering separate Bachelor degree courses in nuclear medicine technology.

Much of the current legislation recognises NMT's as a separate profession from Medical Imaging Technologists or diagnostic radiographers, who deal with ionising radiation apparatus. The legislation applies different qualification standards and licensing requirements to those persons. This is not uniform across all the legislations. This discrepancy should be addressed by this review.

Currently, entry level into any of the Medical Imaging professions is the completion of an approved undergraduate degree or an approved postgraduate diploma. Each of these qualifications is based on a specific modality and their needs. Each course is approved as an appropriate educational standard by the particular professional body for an entry-level practitioner in that specific profession.

For persons wishing to work in nuclear medicine technology as an entry-level practitioner, there are five undergraduate courses and one postgraduate course offered at tertiary institutions in Australia. These universities are the University of Newcastle, RMIT, University of South Australia, University of Sydney and Charles Sturt University. Several of these Universities offer higher degree courses in the medical imaging professions.

The Board approves these courses by ensuring that the course covers all elements of nuclear medicine technology. A significant portion of the course must include radiation physics, radiation biology and protection, radio pharmacy, as well as other health science subjects relevant to a practitioner.

A general qualification in medical imaging does not adequately equip a person to undertake the duties of a Nuclear Medicine Technologist, neither does a nuclear medicine qualification prepare a person to competently perform diagnostic or therapeutic radiography

It is important that radiation protection legislation recognises the differences in the medical imaging professions and the need for appropriate qualifications for all persons undertaking any of the medical imaging professions, be it nuclear medicine technology, diagnostic radiography or radiation therapy.

The maintenance of these separate professions is of paramount importance when discussing public safety in the context of radiation protection. The professions should all be recognised individually in any radiation protection legislation. This is currently the case in some but not all the legislations.

### Summary

Nuclear Medicine Technologists require a specific tertiary qualification to become an entry-level practitioner. This level of education ensures that technologists have the required knowledge and training to safely handle unsealed radioactive sources.

Uniformity of legislation and policy would allow all Nuclear Medicine Technologists to work under the same guidelines Australia-wide.

Current legislation is inconsistent across the states. The classifications of medical imaging professionals (Nuclear Medicine Technologist, Diagnostic Radiographer and Radiation Therapist), need to be written into the legislation to recognise the inherent differences between the professions, and the need to be qualified in the appropriate field to ensure public safety.

**#13 Dr Joseph Young  
Managing Director, Australian Radiation Services Pty Ltd, Victoria**

**Personal Dosimetry Service (PDS) Providers**

There are currently several PDS providers in Australia. All providers are required to apply the GST to the services they provide. ARPANSA who are also a PDS provider are not required to charge the GST for this service. This is clearly an unfair trading situation.

We feel that ARPANSA should not be a PDS provider. As holders of the National Standard for Exposure and Absorbed Dose, ARPANSA should regulate the PDS providers to ensure that the results provided by them are accurate and reliable. Thus the data can be used with confidence in a court of law.

With several PDS providers currently operating in Australia it is essential that the National Dose Registry is fully operational, staffed and funded, and that dose results from all service providers are submitted to the register. ARPANSA as Australia's premier radiation protection agency must ensure that this information is maintained and kept up to-date.

**Calibration of Radiation Survey/Contamination Monitors**

There are numerous radiation survey and contamination monitor calibration services in operation within Australia. ARPANSA is in an ideal position to ensure that these service providers are calibrating radiation-monitoring equipment using internationally recommended methods and that the results are accurate and reliable. ARPANSA staff could visit private enterprise calibration service providers on a routine basis to ensure the methods used are acceptable and the results obtained are traceable to Australian National Standards. ARPANSA officers should perform a routine inspection and measurement of the output from sources used to calibrate survey monitors every 5 years to confirm traceability to National Standards.

**Uniformity of Regulations**

It is essential that uniform radiation regulations be in operation throughout Australia. Private enterprise, no matter where they are based in Australia, should be able to apply consistent and uniform criteria to work they are undertaking in any State or Territory of Australia. Rather than have individual State by State approval would it be possible to have National accreditation/recognition of companies and individuals who provide radiation protection services/advice to industry and government departments?

**Source Disposal**

ARPANSA needs to specify clear and concise instructions to the private sector for the disposal of radiation sources for Commonwealth agencies. This has not been the case. ARPANSA staff must be made aware that "windows of opportunity" to **legally** dispose of an unwanted source are limited - in fact, some are less than two weeks and they occur on a random basis. It is also essential that the approval for disposal be issued almost immediately to accredited disposal companies. Failure to do this can result in a missed disposal opportunity. Therefore a source may become a corporate heirloom and/or it is highly probable that future disposal costs will be significantly higher. This cost is not borne directly by ARPANSA but the Department concerned.

**ARPANS Act and Regulations**

It appears that the ARPANS Act and Regulations also affect/impact private enterprise as well as Commonwealth Agencies. Private enterprise is already well regulated by the various States and Territory Radiation Protection Legislation. Is more legislation necessary? Is State legislation being duplicated at the Commonwealth level?

The main problem with the ARPANS legislation is the interpretation of the written word. What is written is not necessarily how the regulation is applied.

In summary we believe that one of ARPANSA's main objectives should be to facilitate uniformity of radiation health regulations throughout Australia. In addition to the many other roles it offers, (eg. maintenance of radiation standards, providing advice on radiation matters etc.), ARPANSA should ensure that private sector service providers have traceability to National Standards, are suitably accredited and that any results produced by the service providers are accurate, reliable and legal in a court of law.

**#14 Cardiac Society of Australia and New Zealand (Victorian Division)**

The current Victorian regulations, under the Health Act 1958, require the operators of radiation equipment, including cardiologists, to hold a valid radiation licence. Until recently it has been assumed by many of our members that they are exempt from this requirement if a licensed radiographer is operating the x-ray equipment. Additionally, under the previous regulations cardiologists who held a Radiation Safety Licence were able to operate a Cardiac Catheterisation Laboratory without a radiographer.

Recently the Victoria regulations have been altered so even if a cardiologist holds a licence, a radiographer is also required. Our members feel that these regulations are anti-competitive, restrictive and cause unnecessary costs.

We acknowledge that utmost importance of patient safety in the use of radiation emitting equipment. In particular, we feel that all Cardiac Catheterisation Laboratories should be operated with the cooperation of a suitably qualified radiologist or radiation physicist. This would ensure that equipment and all protocols performed conform to fundamental standards of radiation safety.

However, we feel strongly that the presence of a radiographer within the Cardiac Catheterisation Laboratory on a case by case basis does not ensure radiation safety. The data tabulated below from Geelong Hospital shows that the presence of a radiographer does not have a statistically significant influence on the radiation dose or the duration of the procedure.

**Procedure and Fluoroscopy Times – Geelong Hospital**

	With Radiographer	No Radiographer	P Value
Total Number of Procedures	4,212	2,198	
Procedure Duration (mins)	21.2 ± 20.5	21.8 ± 17.9	Not Significant
Total Number of Procedures	4,234	2,204	
Screening Time (mins)	5.7 ± 6.2	5.7 ± 5.3	Not Significant

In particular, in teaching hospitals it is often our members’ experience that junior radiographers are provided for the Cardiac Catheterisation Laboratories, and the Cardiologists in fact supervise these junior radiographers.

Our members fail to see the logic of paying for licenses that do not allow them to operate independently.

Our members also report that the legal compulsion to have a radiographer in the Cath Lab has led to over award payments being made to radiographers to secure their employment. At least one major teaching hospital in Melbourne has encountered great difficulty in recruiting suitably qualified radiographers to work in their Catheter Labs.

It is the consensus of the Victorian Division that cardiologists should be able to obtain a licence to operate x-ray equipment in Cardiac Catheterisation Laboratories. The requirement that a radiographer must be present, at all times, is unnecessarily restrictive and adds considerably to the cost of operating a Cardiac Catheterisation Laboratory.

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**#15 Dr Joseph Wong**  
**President**  
**Australia and New Zealand Society of Nuclear Medicine Inc (ANZSNM)**

**Mrs Heather Hodges**  
**Immediate Past President**

Permission was not received to make this submission public.

**#16 Federal Secretary,  
Australia and New Zealand Society of Nuclear Medicine Inc (ANZSNM)****General Policy of the ANZSNM**

The ANZSNM considers legislation to be essential. An open competitive market is not appropriate due to the nature of the materials used in nuclear medicine and the potential for harm to users, patients, the public and the environment.

However, because of the above considerations and the existence of discrepancies and differences between States in the regulation of radiation protection, the ANZSNM supports the creation of uniform, Australia-wide legislation, after appropriate consultation.

**Important Considerations in the Creation of uniform Radiation Protection Legislation**Licensing of Individuals

All workers in nuclear medicine require licensing, which reflects a minimum standard of safe practice, based on appropriate qualifications and accreditation, determined by the appropriate professional body. This should include provision for continuing education in order to maintain accreditation.

The licensing of workers should be centralised and done in consultation with the professional bodies and should therefore be recognised in all States and Territories without the need for a transfer fee and/or reapplication as such fees are anti-competitive and restrictive.

In the case of emerging technologies such as hybrid machines (eg CT/PET) provision should be made for licence holders for the practice of nuclear medicine to gain an additional licence to operate this equipment, upon demonstration that they have undergone appropriate training – as determined by the appropriate professional body. In this instance it should be noted that undergraduate course in nuclear medicine technology in Australia already contain a radiographic component and therefore Nuclear Medicine Technologists have some familiarity with radiographic equipment.

Exemptions

Exemptions can be made in the case of students (undergraduate and post-graduate), researchers, those undertaking a Professional Development Year and Registrars, provided there is supervision from an appropriately licensed person. However, any such person exempted from holding a licence must have knowledge and training in radiation safety, biology and protection. This is not anti-competitive, as the purpose is to ensure protection of both the workers and the general public.

Licensing of Workplaces

All nuclear medicine practices require licensing to ensure that minimum safety and protection standards are met, again to ensure protection of the workers and the public, not to protect the industry from competition.

Cost of Licensing

The fees set for licensing of individuals and workplaces should be on a cost-recovery basis only. It should be noted here that the members of the Accreditation Board of the ANZSNM receive no payment for their work and that accreditation is run as a non-profit undertaking. Keeping the cost of licensing as low as possible would be a definite encouragement to fair competition.

**#17 Mrs Margaret Lennon  
Dental Therapist, West Moonah, Tasmania**

As a member of a dental team, Dental Therapists are licensed in a variety of ways in various States or Territories to take radiographs.

For example, In Tasmania, Dental Therapists, are restricted to working for the Department of Health and Human Services and are licensed through this organisation. A permit outlining the limitation on the types of radiographs that can be prescribed and exposed by this group is issued to each Dental Therapist every year.

The majority of the Dental Therapists in Tasmania hold a qualification from the University of Adelaide gained in 1995 as an upgrade of existing qualification from the School of Dental Therapy Tasmania.

There are several Dental Therapists who were trained at the Westmead Training School in NSW. The training in radiography varies slightly in each institution. This results in a restriction below their skill level for those trained in NSW according to the permit, as the permit is issued in line with the SA qualifications.

In each State and Territory, the NCP review of Dental Registration Legislation is also taking place. As a result of this review, the restrictions previously placed on Dental Therapists are being addressed allowing for practice in the private sector.

Dental Therapists practice a limited range of dental procedures for children. The legislation under review will contain codes of practice outlining guidelines for safe practice. These codes will be linked to the scope of training applicable to the curricula leading to the qualifications entitling the person to registration under the provisions of the Act.

I feel that the permit issued by the Radiation Control Board is unnecessary as the scope of practice of Dental Therapists and indeed other dental auxiliaries should be clearly outlined in the Dental Registration Legislation in each State and Territory.

May I suggest that linking the particular section relevant to scope of practice for auxiliaries from the Dental Registration Acts to the Radiation Protection Legislation in each State or Territory should ensure the safety of both the public and workforce. This should also reduce the extra administrative processes involved in the issuing of permits.

**#18 Australian College of Physical Scientists and Engineers in Medicine****Introduction : The ACPSEM**

The Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) is an incorporated professional society representing scientists and engineers employed in the health care industry in all States of Australia and in New Zealand. The ACPSEM currently has 370 members in six branches. The College represents the interests of its members in dealings with other professional and Government bodies

The ACPSEM provides accreditation programs in radiotherapy physics and in radiological physics. A further accreditation program in radiation safety is offered in conjunction with the Australian Radiation Protection Society and the Australian Institute of Occupational Hygienists. A certification program is offered (in conjunction with the Royal Australian College of Radiologists) in quality assurance for mammography equipment". The College has a website at <http://www.physics.otago.ac.nz/~acpsem/>, holds an annual conference, *Engineering and Physical Sciences in Medicine*, in one of the State capital cities and publishes a quarterly Journal, *Australasian Physical and Engineering Sciences in Medicine*. Codes of Practice, position papers, scientific papers and technical notes are published in areas of interest to this review. Twenty recent relevant examples are listed below.

- Position Paper – Requirements for Radiation Oncology Physics in Australia and New Zealand– Australas. Phys. Eng. Sci. Med in Press
- Guidance levels for diagnostic radiology in Victoria T.J. Boal, P.F.Einsiedel and I. Cardillo Australas. Phys. Eng. Sci. Med. Vol 23 Number 1 2000 pp 7-14.
- *Technical Note* The 1998 Australian external beam radiotherapy survey and IAEA/WHO TLD postal dose quality audit R. Huntley and J. Izewska Australas. Phys. Eng. Sci. Med. Vol 23 Number 1 2000 pp21-29.
- Simulation studies of optimum energies for DXA: dependence on tissue type, patient size and dose model G.J. Michael and C.J. Henderson Australas. Phys. Eng. Sci. Med. Vol 22 Number 4 2000 pp 126-135.
- Patient Doses from Neuroradiological Procedures T. Boal and R. Dixon Australas. Phys. Eng. Sci. Med. Vol 22 Number 4 2000 pp 153-162.
- *Technical Report* A survey of patient dose and image quality factors for CT scanners in Victoria T.J. Boal, J. C. Hedt and P. Einsiedel Australas. Phys. Eng. Sci. Med. Vol 22 Number 3 1999 pp 103-112.
- *Technical Report* Local shielding of high dose rate brachytherapy in an operating theatre. R. Septhon, K.R. Das, J. Coles, W. Toye and P. Pinder Australas. Phys. Eng. Sci. Med. Vol 22 Number 3 1999 pp 113-117
- An investigation into the impact of anatomical variation upon mean glandular dose produced within a standard breast L. E. Wilkinson, J.C.P. Heggie and P.N. Johnston. Australas. Phys. Eng. Sci. Med. Vol 22 Number 2 1999 pp 53-63.
- A Survey of Radiation Doses to Adults from Diagnostic Radiology in Victoria J. Cardillo, T.J. Boal and J. C. Hedt Australas. Phys. Eng. Sci. Med. Vol 22 Number 2 1999 pp 64-72.
- *Technical Report* Physical Characteristics of an Automatic Exposure Control used in conjunction with a Treatment Simulator T. Williams, A skov, T. Kron, S Bazley, L. Duggan Australas. Phys. Eng. Sci. Med. Vol 22 Number 1 1999 pp 8-12
- A survey of Fluoroscopic Equipment in Victoria T.J. Boal, K.W. Dessent, M. Facci Australas. Phys. Eng. Sci. Med. Vol 21 Number 4 1998 pp 161-169.
- Empirical Shielding Design Data for Facilities Administering I131 for Thyroid Carcinoma Australas. Phys. Eng. Sci. Med. Vol 21 Number 4 1998 pp 170-178.
- *Technical Note* Shielding Properties of Fibre Cement Wallboard D. Thiele, G. Goodwin, K. Coakley Australas. Phys. Eng. Sci. Med. Vol 21 Number 3 1998 pp 152-154
- Paediatric doses from diagnostic radiology in Victoria T. Boal, I. Cardillo, P. Einsiedel Australas. Phys. Eng. Sci. Med. Vol 21 Number 2 1998 pp 57-67.

- Radioactivity Measurements of Ytterbium-169 Brachytherapy Sources M.S. MacPherson, J.J. Battista Australas. Phys. Eng. Sci. Med. Vol 21 Number 1 1998 pp 18-23.
- *Technical Note* Determination of CT Scanner Radiation Output: Correction factors for partial irradiation of thimble and pencil ionisation chambers by collimated fan beams P. Cross Australas. Phys. Eng. Sci. Med. Vol 21 Number 1 1998 pp 29-31.
- Health Technology Assessment in Australia: The Role of AHTAC B. Kearney, E. Willis Australas. Phys. Eng. Sci. Med. Vol 20 Number 4 1997 pp 193-197.
- Early experience of the European Medical Devices Vigilance System H. Randall Australas. Phys. Eng. Sci. Med. Vol 20 Number 4, 1997 pp 203-206.
- *Technical Note* Determination of Correct AEC Function with Computed Radiography Cassettes L.E. Wilkinson, J.C.P. Heggie Australas. Phys. Eng. Sci. Med. Vol 20, No. 3 1997 pp 186-191.
- Position Paper *Recommendation for the safe use of external beams and sealed sources in radiation oncology.* M. Millar, J. Cramb, R. Das, T. Ackerly, G. Brown, D. Webb Australas. Phys. Eng. Sci. Med. Vol 20, No. 3 SUPPLEMENT pp 1-35.

The ACPSEM welcomes the opportunity to comment on the National Competition Policy Joint National Review of Radiation Protection Legislation. Indeed the Victorian/Tasmanian branch lodged a submission two years ago as part of the review of Victoria's Health Act 1958 that is now included in this review. Many members are highly active on a day to day basis in a wide spectrum of radiation protection issues and are therefore appropriately qualified to comment on these matters.

### General comments on the Review Paper

Although entitled as a national review, Mr Kumar's covering letter and note 5 on page 2 ('Queensland is not participating in the review as it recently completed a public benefits test for its Radiation Safety Act 1999.') indicate that this is not the case. The lack of participation by Queensland is of considerable concern as to the validity and applicability of the outcomes at a national level.

### Responses to specific questions

#### Q1. Do the objectives of the legislation sufficiently cover all the issues? If not, what other issues should the objectives aim to address?

In a direct sense, the objectives adequately cover the issues. In a more indirect way, the legislation also provides a degree of public confidence in the use of ionizing radiation for medical purposes. The general public however still has a high degree of scepticism of radiation and all matters nuclear which can result in patient consent being withheld.

#### Q2 Are the provisions of the legislation consistent with the objectives? Are there any conflicts or contradictions?

Yes, the provisions of the legislation are consistent with the objectives.

#### Q3 Do you think that agencies are pursuing the original objective of radiation protection legislation or are they pursuing other objectives?

Yes, the agencies are pursuing the original objective of radiation protection legislation.

#### Q4 Do you think any of the objectives specified in the legislation are out of date? Has there been any technical or market change in the last few years that have made the objectives more or less relevant or give rise to the need to specify either new or amended objectives?

The objectives are not out of date. The increasing use of radiation and the complexity of the radiation technology since the objectives were introduced and the increased estimate of risk introduced by the ICRP make it more important that strong legislation is in place to ensure the safety of the public. In this point it is worth noting that a revision of legislation would give an opportunity for bringing it up-to-date with the changes in technology.

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Q5 Do you think that the objectives are focussed, capable of being monitored and tested and achievable? Should the objectives be modified, reprioritised, deleted, enlarged or accepted?

The objectives are satisfactory as they stand.

Q6 Is there any objective or any part of an objective in any legislation that is best addressed in some other existing legislation or if necessary, in some other new legislation?

It is essential that radiation safety be addressed specifically in legislation designed for that purpose and not subsumed into other legislation.

Q7 Does any objective in the legislation of the participating jurisdictions impact negatively on any other policy objective of the jurisdictions in other areas, including, (but not limited to) occupational health and safety, mining, transportation, public health and the environment?

No objective is seen to impact negatively on other jurisdictions. However, there is presently some overlap between mining legislation and radiation safety legislation.

Q8 Do the regulatory differences within and among governments add to the costs of Australian businesses? Do you think that there is a compelling need to promote uniformity among the legislation of all the States and territories to eliminate unnecessary duplication and enhance administrative efficiency?

There are additional costs associated with companies having to deal with different legislation in different States. Uniformity is preferred, however this should not be at the cost of reducing control to the level of the lowest common denominator presently available in State jurisdictions. Furthermore, it would be desirable to standardise the nomenclature used in the legislation to minimise confusion.

Q9 Are the standards and codes of practice referenced in the legislation suitable and relevant? Is there any justification for their retention? Can you suggest better ways to reference and use such standards and codes of practice?

The existing Standards and Codes of Practice are essential to ensure that appropriate levels of safety are maintained. Modern communication techniques should be used to advise of, and make available, updates to these standards.

Q10 Could the current arrangements to partially recover the cost of regulatory oversight be improved? Should full cost recovery be introduced as it is in most professional registration areas? Could compliance costs and paper work burden on small business be reduced?

Inevitably improvements are always possible. Full cost recovery should be continued or introduced where necessary.

Q11 Is there related legislation under radiation protection that needs to be considered in this review? If so, what is it and what is its impact on the radiation protection legislation under review?

Not to our knowledge.

Q12 Are the current arrangements for regulating various occupational groups appropriate?

Yes, arrangements for regulation of occupational groups are appropriate.

Q13 Can any provision of any legislation be modified or re-written so that is less prescriptive and yet achieve the relevant objectives?

The legislation needs to be prescriptive to ensure radiation safety.

Q14 Is it feasible to have a system of negative licensing, where there is no requirement for licensing or registration but someone who deals with radioactive substances or radiation equipment unsafely is prohibited from further dealing with the substances or equipment?

No, a system of negative licensing is not feasible. Only by inspection and reporting to a statutory authority is it possible to determine whether organisations are in breach of safety standards. There are many instances where non-existent or inadequate regulatory control has led to accidents and in some instances even death.

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Retrospective action is not beneficial to the injured, especially as radiation incidents may affect a large population base prior to detection.

Q15 Is it feasible to have a system of providing better information to consumers and remove of some of the restrictions on entry and exit of firms or persons or restrictions on the conduct of their activities?

No. In general, consumers do not have, nor can attain, the depth of training to be able to make judgements regarding their safety when it comes to matters concerned with radiation.

Q16 Is total self regulation with an industry developed code of conduct feasible?

There is no reason to believe that self-regulation will operate more effectively in the radiation industry than in other fields. Indeed it may be argued that self-regulation could lead to over-servicing and the application of excessive and unwarranted radiation. This would be expressly in contradiction of the basic tenets of radiation protection relating to the ALARA principle; namely, justification and optimisation.

Self-regulation based on a code of conduct implies a feedback mechanism. This does not occur except in the direst circumstances. With radiation exposures, it can be difficult to identify cause and effect of radiation detriment owing to the long latency. The Government's role is to regulate to ensure the safety of the population from the hazards of ionizing radiation. Both testers and testing standards should be regulated. If testers are not regulated the testing regimes and schedules must be strictly specified for all users of radiation, including diagnostic radiology, radiation therapy, nuclear medicine and all industrial and laboratory applications. Either the testers or the test procedures (preferably both) must be regulated.

Q17 Is a system of mirror legislation with all jurisdictions having the same legislation and a central body issuing standards and codes of practice desirable? If not, is there a need to develop some other system of maintaining radiation protection standards that achieves greater uniformity or consistency while jurisdictions continue to maintain there existing Acts and regulations?

It would be preferable if all States had similar if not identical legislation. However as noted in Q8 this should be by strengthening legislation in some States rather than by decreasing it in others. At present NH&MRC codes which are derived from International codes are accepted by most, if not, all State jurisdictions. Furthermore, legislation should address uniformity of training and qualifications for all the professions involved. Also a practical enhancement to the current situation is to have a designated national register of radiation incidents endorsed by all state and territory legislation.

Q18 Is it desirable to have performance based laws, regulations, standards and codes of practices that specify only the objectives of the legislation leaving it to the industry to demonstrate compliance through risk-based safety management or operational plans before a license or registration is issued instead of prescribing the standards, maximum levels of exposure or dose limits in regulations, standards or codes of practices?

It is not considered desirable to specify broad objectives and leave it to the industry to demonstrate compliance through their own risk-based assessment. The effects of radiation are difficult to detect and have a long latency period of 10 to 15 years. Substantial reduction in radiation safety standards could be introduced without the change being readily attributable in the short term. However the effect would be a significant increase in the incidence of cancer in the population in the longer term. The only safe way of dealing with radiation is to define acceptable levels of exposure (based on accepted risk estimates) and put legislation and controls in place to ensure that such levels are not exceeded.

### **#19 Dental Hygienists' Association of Australia Inc.**

The DHAA supports the recommendations pertaining to radiation safety and the usage of trained personnel allowed to use ionised equipment for the procedure of dental x-rays.

It is important to ensure that such persons have a good and current knowledge of radiation safety, this will include:

- Handling/maintenance of x-ray equipment.
- Usage of protective gear, for example, lead apron with neck shield.
- Correct dosage required for desired x-ray production.
- Correct dark room techniques.
- Careful handling and washing of x-rays.
- Careful labelling and storage of x-rays.
- Usage of personnel radiation monitoring badges.

All of the above recommendations in radiation safety will reduce the unnecessary exposure to additional radiation for the general public and dental personnel.

**#20 Population Health Division,  
Commonwealth Department of Health and Aged Care**

The purpose of this paper is to provide Population Health Division's (PHD) comments on the recently released *National Competition Policy Review of Radiation Protection Legislation - Issues Paper 2000*.

PHD supports the general view in the Issues Paper that the Radiation Protection Legislation could be streamlined. However, this approach should be adopted on the basis of firm assurances that public health and safety remain of the highest priority. PHD could not endorse any changes to the current system that would mean a decline in the protection of public health and safety.

The Division has a strong interest in many aspects covered by the Review and would appreciate the opportunity to comment further on the Review's Final Report and Recommendations.

**Section 2 - Objectives of the legislation under review**

The guidelines for a National Competition Policy Review specify that the objectives of the legislation under review be clarified. The Issues Paper lists objectives of the various pieces of legislation (consolidated from various sources such as the legislation itself, annual reports and Second Reading Speeches) under review in Section 2 and these objectives vary to some degree. Commonwealth legislation makes a clear statement of protecting people and the environment without qualification while other objectives seek the protection of people without including environment and use qualifiers based on practicality, social and economic factors. It is acknowledged that this variation may have occurred depending on jurisdictional differences such as complementary and interrelated legislation and drafting styles, and the time at which they were introduced. It does not necessarily follow that they are aiming at different levels of protection but rather have a different scope within that particular tool. The examples highlight the variations arising from the variant contexts for each piece of legislation.

However, a statement of objectives in the Act provides a useful framework within which it intends to work. They are structured as a guide as to the scope and purpose of the Act, assisting government in enactment/implementation and the judiciary in interpretation. In this context, PHD would suggest that the Review Team should consider achieving greater consistency in the objectives with regards to ionising and non-ionising radiation. The objectives of some State/Territory legislation cover these issues while others do not and this variation clearly impacts on overall legislative provisions.

On the issue of objectives, it is pertinent to mention the National Public Health Partnership Legislation Reform Working Group's recently commissioned study - *The Application Of Risk Management Principles In The Public Health Legislation* (attached) which discusses how principles of risk assessment and risk management can be reflected in public health legislation. This report builds on the New Zealand Report, *The Development of Public Health Risk Management Methodology to Inform Decision Making and* examines how "objectives" provision and ideas such as precautionary principles can provide structures that allow principles of risk assessment and risk management to be included in public health legislation. The Review Team may wish to consider these issues due to the uncertainty about safe exposure levels of radiation and as the document suggests " *a statutory risk management process has the ability to deal with uncertainty, where for example the effect of exposures is uncertain...* "

**Section 3 – Nature of Restrictions to Competition**Scheme and structure of the legislation

In general, PHD is of the view that the Radiation Protection Legislation should refer to:

- establishing a base level of necessary protection for consumers and ensuring this is covered consistently across jurisdictions for both the benefit of consumers, and surety and equity of costs for industry;
- ensuring radiation workers, with lower levels or no formal qualifications, are provided adequate information and screening protection in relation to injurious levels of radiation; and
- ensuring adequate mechanisms for accessible information to Aboriginal and Torres Strait Islander consumers (and other consumers from culturally diverse backgrounds) in relation to:
  - ≡ the benefits and risks of diagnostic tools using radioactive materials,
  - ≡ alternative sources of advice in relation concerns about contamination, and

- environmental hazards and accidents and facilitating effective compliance with directives aimed at avoiding contamination in these circumstances.

### Specific provisions relating to occupational licensing, registration or exemptions

The provisions described under this heading for the various jurisdictions seem to overall represent a whole menu of protection options, which are covered in different combinations in the separate acts of the jurisdictions. Expert advice is needed as to what is the basic unit of protection necessary to public protection and this should be made consistent nationally. This would be of benefit to both consumers (in being assured a basic level of protection anywhere in Australia) and presumably to companies operating nationally with the same cost imposts.

Northern Territory: The NT Act does not apply to any person lawfully possessing, using or operating irradiating apparatus in accordance with the Radiographers Act 1976 in relation to that apparatus. This suggests that it does cover others using irradiating materials for diagnostic purposes in similar terms to NSW and ACT. There should be a recommendation for consistency in this regard.

South Australia: The South Australian legislation states that any irradiation of human beings for the purposes of research cannot be conducted without first obtaining the approval of the proper authority. PHD would like to suggest that such provisions should be consistent with or make reference to National Health and Medical Research Council (NH&MRC) Ethical Guidelines on Human Research.

Western Australia: In Western Australia, regulations prohibit the employment of a person under the age of 16 as a radiation worker. PHD is of the view that this provision should be considered by the Review Team with respect to the Radiation Safety legislation in general.

### Strict and prescriptive technical standards for products or services or restrictions to the quality, level or location of goods and services.

Storage and Disposal: PHD is of the view that the regulation should be consistent in this regard and there should be a strict enforcement of legislative provisions. The provisions state that a person may be required to maintain a detailed record for a prescribed period of time of all radioactive substances disposed of or discharged from the premises. A less onerous requirement may be to have an authorised manner in which disposal will occur, with compliance linked to a person's licence, and for this to be subject to random, unnotified, audit.

Dangerous Situations: Provision should be made for effective communication with indigenous communities (and other culturally diverse communities). It is recognised that quick action is required under such circumstances – a list of Indigenous organisations to contact in order to act as an intermediary in such a situation would be useful in ensuring that local Aboriginal and Torres Strait Islander people understand the risks, and are able to comply with directions for remedial action. Provisions should cover the need in remote communities for authorities, to ensure adequate local training and infrastructure, to work in partnership with the community to facilitate prompt remedial action.

Rules and guidelines for radiation workers: Under these rules radiation workers may be required by legislation to ensure that they use in a proper manner all apparatus, instruments, devices, clothing, shields and accessories supplied and to observe all proper procedures laid down by a radiation safety officer. In some cases radiation workers are also required to ensure that they comply with all relevant requirements prescribed in their jurisdiction's relevant radiation protection Act and regulations. Such provisions should be nationally consistent and should ensure compliance with local regulations.

Duty to inform: These provisions should be nationally consistent, with compliance linked to the licences of supervisors. Radiation workers with little formal qualification may have no other source of protection. These provisions should be subject to random audit.

Duty to ensure compliance: This should be a nationally consistent requirement, with compliance linked to the licence.

Personal monitoring: These should be routinely monitored by an external independent agency, with deviations from normal levels checked out by the external agency directly with the worker affected. This would serve to protect the worker from cover-ups by the employer; alternatively it may reveal other factors external to the work environment that may have impinged on the reading.

Dose limits or exposure levels: Under these provisions, non-compliance should be linked to supervisors licence, with significant financial penalties.

Radiation incidents, accidents or emergencies: A measure should be determined to indicate the point at which an independent agency must investigate – depending on the extent of the incident.

### Effects of the Restrictions

#### Recommending alternatives

PHD is of the view that it is important to clarify the objectives of the legislation as this would then assist in determining the overarching purpose of legislation as well as considering regulatory options. For example if the purpose of the legislation is to regulate the industry, regulatory options such as self regulation or negative licensing could be considered as a useful tool. However if the purpose of the legislation is to protect public health and safety, then regulation needs to be based on precautionary approach. While any health and safety comparison of benefits and risks can be difficult because of the necessity to base risk assessments on predictive science, there are additional difficulties when dealing with risks for which there is no safety threshold such as for ionising radiation. Any exposure could cause harm, just as any bullet under gunfire may be fatal, even though the probability of being hit reduces with the reduction in the number of shots.

As suggested earlier, PHD would like to emphasise that the public health and safety should be of paramount consideration in the review of the Radiation Protection Legislation.

#### Analysing the effects of radiation - "Market failure"

PHD is of the view that the issue of market failure should be considered in the context of public health and safety. In the exposure of people to man-made sources of radiation with products and services, the consumer may not be in a position to adequately judge the nature of the risks and whether the risks outweigh the benefits. They may not be able to judge the skill and qualifications of the persons trusted to use radiation sources in the safest manner. The economic incentives for suppliers of equipment and services may not be sufficient to ensure lowest exposure from the use of equipment and materials because the externalities if applicable, could be long term. There are a number of externalities with regards to radiation that should also be addressed. One example would be the issue of safe exposure levels of radiation. If the public is, or was to be exposed, there may be cost factor borne by the health system. The other issue is of safe disposal. It is these various externalities that need to be considered while reviewing the legislation.

**#21 Roger Alsop****Principal Consultant, Roger Alsop Consulting, North Ryde, NSW**

This submission is based on the COAG Agreement of 1998 aiming for uniformity and consistency in this important area of public health.

We wholly support the concept of the same rules being applied nationally for radiation protection of the public and the environment throughout Australia (and its Territories) in order to achieve the stated aim of the ARPANS Act of uniformity, consistency and practicability, as well as being reasonable and enforceable. Obviously, those “rules” should also be directly compatible with the world’s “best practice” international standards. Much of the operational procedures are actually covered in Australian Standards, for example, AS2243, 4 & 5, together with their associated Standards, yet not recognised under all present legislation.

Although the States and Territories have carried out the responsibility of radiation protection in Australia for many years, it is inevitable that there will be differences between the various jurisdictions regardless of the intentions and integrity of the operative health physicists involved. Some differences will automatically arise because of the differences in supportive legislation that may already apply in interrelated Acts within individual jurisdictions, making the process of uniformity between jurisdictions so much more difficult, let alone any political differences in attitudes to radiation protection and safety that may come into play.

Unfortunately, the opportunity for consistency of radiation legislation throughout Australia has been lost once, let us not lose it again.

Even with the Mutual Recognition Agreements recognising the radiation protection legislation (plus other legislation) of the different States and Territories, perhaps even with exactly the same wording of their respective radiation protection legislation the very fact of State/Territory border limitations still impedes the ideas of uniformity, consistency and practicability.

However, possibly by making use of the National Disaster approach and associated Emergency legislation model, which can cross State/Territory borders, the concept of ready accessibility to local centres of radiation protection could allow for the advantages of uniformity, consistency, practicability and accessibility under the umbrella of ARPANSA itself! Also, should there ever be a radiation emergency, the appropriate national base command structure would already be in operation.

Let me turn to some specific issues of interest.

Given the situation of an international company making use of radiation technology for the betterment of its facilities and the environment generally, and committing itself to the provision of radiation instrumentation for its various divisions throughout Australia (and internationally), similar in many respects to a CSIRO Division having interstate laboratories, should the company be required to maintain a library of radiation licenses, reporting to the various licence issuers, for every instrument movement within the individual jurisdictions for which the licences are issued. Or should such company be treated on an equivalent footing to a similar Division of CSIRO, under one licence? Although there are several Australian companies to which the above scenario could apply, this is a real situation only recently presented to us, highlighting both issues of lack of uniformity and potential excessive paperwork in appeasing the wishes of several radiation protection authorities, compared with the presumed single licence agreement enjoyed by a Commonwealth government entity. If the analogy were a little closer in this instance, the comparison may well constitute unfair commercial advantage too between a CSIRO Division and a national operating company’s research division in a similar field!

With ARPANSA as the primary radiation protection and nuclear safety authority in Australia it is fitting that it should provide these services from such a standpoint without the dilemma of being both regulator and provider of services, especially personal dosimetry. We note that the current “Fact Sheet” detailing Australia’s National Authority on Radiation Protection and Nuclear Safety, and again this dilemma of “Regulator” and “Supplier” arises in the competition with commercial dosimetry services, yet simultaneously, the maintenance of Australian primary standards of “exposure” and “absorbed dose”. And although we appreciate the historical situation, as well as the necessity of having such services available nationally and for international comparisons, it would seem that the role of ARPANSA itself will continue to develop along the path of overall Australian Radiation Protection Agency consistent with world’ best practice recommendations. International globalisation will eventually push all countries into the acceptance of commercial services (as appropriate and at world prices) under internationalised “standards”, personal radiation dosimetry services included.

### #22 **Legislation Reform Working Group Commonwealth Department of Health and Aged Care,**

The purpose of this paper is to consider some of the issues outlined in the recently released *National Competition Policy Review Of Radiation Protection Legislation - Issues Paper 2000* and provide the Legislation Reform Working Group's comments on those issues.

#### **Legislation Reform Working Group**

The Legislation Reform Working Group (LRWG) is a sub-committee of the National Public Health Partnership Group (NPHPG). It is a national forum for discussing current and emerging matters relevant to public health legislation and is comprised of representatives from State, Territory and Commonwealth public health agencies. It works toward modernisation of public health legislation and encouraging best practice to facilitate regulation review and reform activities, and development of national consistency of public health legislative approaches as appropriate. Hence it has a strong interest in the review of the Radiation Protection Legislation, in the context of public health law reform.

It should be noted that LRWG's comments do not seek to represent views of jurisdictions, but to present the views of an expert body focussing on public health law reform issues at a broad level.

#### **The Review**

The Council of Australian Governments' (COAG) Senior Officials Group agreed to the joint review of Radiation Protection Legislation under the National Competition Policy in December 1998. It was also decided that the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) - an agency within Commonwealth's Health and Aged Care portfolio - would coordinate the review.

Among the objectives of ARPANSA is the promotion of national consistency in radiation protection and nuclear safety policy and practices. The National Uniformity Implementation Panel (Radiation Control) was formed in August 1998 to examine practical legislative, regulatory and administrative options to achieve greater national consistency in radiation protection legislation and regulations. It comprises officers from the Commonwealth, States and Territories' radiation protection agencies and is a working group of ARPANSA's Radiation Health Committee.

#### **General Comments**

The Issues Paper raises complex issues relating to the Radiation Protection Legislation. In the process of reviewing the anti-competitive aspects of legislation, it discusses the objectives of the legislation, identifies possible restrictions and provides a framework for the analysis of the effects of the restrictions identified in the paper.

The achievement of greater national consistency and efficiency is broadly in line with LRWG's area of interest.

LRWG would emphasise that (as stated in the Issues Paper), any change to the current system must ensure that the protection of public health and safety is the paramount consideration, and that any proposed revisions that emerge from the review process ensure the maintenance of proper radiation protection standards.

#### **Specific Issues**

##### Issues Paper

It would be useful in the Issues Paper to have the distinction drawn between types of radiation and to have an indication of whether the Paper intends to focus on ionising radiation. The reference at the top of page 7 to "controls and safety measures for ionising radiation and radioactive materials" indicates the focus is on ionising radiation, but then other sections of the Paper refer to the need to establish safety standards for non-ionising radiation as well. The scope of the Paper in this respect should be made clear in the Terms of Reference since it will impact on the costs and benefits of the legislation reviewed.

The Issues Paper occasionally refers to Regulations without indicating the principal Act. Where Regulations are referred, it would be preferable to refer to the main Act, which confers the power to make the Regulations.

##### Section 2 – Objectives of the Legislation (Question 1 to 7 of the Issues Paper refer)

The key essence of public health law has been described as providing protection to the community and broadly speaking, the objectives outlined, though varied, capture this intention.

However, as outlined in the Issues Paper, “objectives”, are not part of all the State and Territory legislation and have been identified from various sources such as the legislation itself, annual reports and Second Reading Speeches. The objectives have been identified correctly but are varied in content. For example, some objectives are qualified by requirements of practicality, social and economic factors and others consider issues such as the environment while some others do not include any reference to the environment. There are also variations in inclusion of non-ionising radiation. Despite these variations, the objectives reflect a consistent theme of protecting persons and the environment from the harmful effects of radiation. The objectives do impact on the **scope** of the legislation.

The Review Team should consider the issue of greater consistency in objectives and scope further, taking into account local State and Territory factors. The Review Team should also consider including a statement of objectives in the Radiation Protection Legislation.

A 1998 Report published by the National Public Health Partnership (*Public health in Australia – New Perspectives; Australian Institute Of Health Law And Ethics*, 1998 Page 36) notes that objectives are increasingly being included in the public health legislation as they can be seen to strengthen public health laws by giving them clarity, coherence and direction. The document puts a strong case for the inclusion of objectives in public health legislation. It points out that though the language of public health is rich with value statements and aspirations they will simply remain aspirations, with no public commitment, if they are not included in a legislative framework – “Incorporating them within legislation is one way of ensuring that this does not occur. It is a way of seeking to ensure that these values give the legislation and its administration **direction** and **meaning**”(Ibid. paragraph 3, page 32).

Should a decision be taken to include a statement of objectives in the Radiation Protection legislation, the objectives identified in the Issues Paper from a variety of sources would need to be refined before they are put into statutory form.

The LRWG commissioned report, “The Application of Risk Management Principles in Public Health Legislation” should also be considered within the context of objectives. The paper discusses how principles of risk management and risk assessment can be incorporated into public health legislation.

### Section 4 - Effects of the Restrictions and National Uniformity/Consistency (Question 8 to 18 of the Issues Paper refer)

A greater degree of national consistency in the Radiation Safety legislation would be beneficial for consumers, businesses and for public health in general. A nationally consistent approach will be particularly useful for national operators who are required to have multiple licences and to comply with differing requirements. This has been overcome to some extent since the *Mutual Recognition Acts* have allowed a person registered in one jurisdiction to operate in another. However, it has been indicated that mutual recognition may result in a “lowest common denominator” outcome because licensing requirements are not uniform from State to State with some States having more stringent requirements than others. (*Public Health Law In Australia: Its Current State And Future Direction*; Chris Reynolds and Ian Bidmeade; 1997; Page 64).

Jurisdictions also have varied requirements through occupational licensing, registration or exemption provisions. A more consistent approach seeking to provide a base line protection reflecting best practice would benefit consumers irrespective of where they are located.

LRWG recently published a study - *Implementation options for national legislative schemes*” (<http://hna.ffh.vic.gov.au/nphp/legtools/options/index.htm>) by the Centre for Comparative Constitutional Studies at the University of Melbourne, which canvasses in some detail the various options for implementing national schemes. It discusses the relative merits of alternative legislative schemes. It notes that adoption of model legislation by reference may have the ability to achieve higher levels of consistency than other schemes.

Legislative options available include:

- Exercise of Commonwealth powers.
- States and Territories ceding their powers to the Commonwealth.
- Model legislation adopted by reference or enacted as mirror legislation.
- Mutual recognition.

When developing a national legislative scheme, the goal of which is to achieve a high degree of legislative consistency between jurisdictions, it is critical to recognise the import principle of the sovereignty of the Parliament of each State and Territory.

## **Attachment 3 – Public Consultation - Submissions**

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In considering the questions outlined above, the Review team may also wish to refer to the LRWG commissioned publication *Public Health Law In Australia – New Perspectives Chapter 3: Harmonisation Of Public Health Law in Australia*.

### Summary

LRWG would advocate emphasis on the protection of public health and safety as the paramount consideration in regulating with respect to radiation safety. This is particularly important where regulatory and non-regulatory options, such as self-regulation through voluntary codes of conduct or negative licensing, are being assessed and analysed.

### #23 Victorian Radiation Advisory Committee

#### Introduction

The Victorian Radiation Advisory Committee (RAC) was established in 1983 to advise the Minister or Chief General Manager (the Secretary) on any matters relating to the administration of the provisions of the Health Act relating to radiation safety. A key element of its role is the provision of advice on minimising the radiation exposure of the people of Victoria.

It is the considered view of the RAC that the current system of registration of sources of ionizing radiation and licensing of users is an effective way of minimising radiation exposures to occupationally exposed workers and members of the public. It is on that basis that the Committee reviewed the National Competition Policy: Joint National Review of Radiation Protection Legislation Issues Paper.

RAC has addressed the various questions asked on pages 10, 28 and 33 of the Issues Paper in the context of the current Victorian legislation.

#### Responses to Questions

##### Question 1: Objectives of the Victorian Legislation

The objectives of the Victorian legislation are: “to protect persons and the environment from exposure to ionizing radiation to the maximum extent possible while recognising the need for the use of radiation for medical, research and industrial purposes”. It is considered that the legislation adequately covers this objective.

##### Question 2: Conflicts or contradictions

The provisions of the legislation are consistent with the objectives. No conflicts or contradictions have become apparent in the application of the Health (Radiation Safety) Regulations promulgated in 1994.

##### Question 3: Are agencies pursuing objectives other than the original objectives?

In Victoria the Department of Human Services through the Radiation Safety Unit continues to pursue the original aim of minimising radiation exposures. Many services are provided free, eg. advice to the public; preparation and publication of policy advice documents; preparation and wide distribution of a radiation protection newsletter. Other services; calibrations, inspections, shielding calculations are provided on a cost recovery basis. The fees charged are based on the complexity of the safety issues involved. The Victorian Government does not see the provision of radiation safety services as a revenue raising process.

##### Question 4: Are the objectives of the legislation out of date?

No. The need to protect persons and the environment does not change with time. The changes in the use of different ionizing radiation modalities by a widening range of medical specialists makes the objective of ‘protecting persons’ even more relevant.

##### Question 5: Are objectives focussed, capable of being monitored, tested and achievable?

Yes. It is accepted nationally that adoption of international standards and recommendations provide satisfactory bases for levels of protection. Control procedures, radiation exposures etc can be monitored and tested against those standards and assessments can be made on the achievement, or otherwise, of the radiation safety objectives.

##### Question 6: Other or new legislation

A weakness in the Victorian legislation is the lack of control of Non-Ionizing Radiation (NIR). This would best be achieved by extending current regulations (one class of lasers is controlled by the Crimes Act). There is a need to up-date current Victorian legislation to take account of new and changing technologies using radiation both NIR and IR.

##### Question 7: Negative impacts on other jurisdictions

Radiation Safety legislation does impact on other jurisdictions but not necessarily negatively. Examples are: NORM, which has implications for the EPA; mineral sand mining, implications for mining regulations; Code of Practice for the Transport of Radioactive Substances, implications for the general transport of dangerous goods.

## **Attachment 3 – Public Consultation - Submissions**

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The implementation of radiation control procedures could also have implications for the Workcover Authority but in practice, these have not been found to be negative.

### Question 8: Costs to Australian Business, need for uniformity

There is a strong case to be made for national uniformity of registration and licensing. The present differences between Australian States and Territories can impose unnecessary costs and time delays on businesses setting up in different states or transferring from one state to another.

### Question 9: Relevance and suitability of referenced Codes of Practice

There is considerable value in referencing Codes of Practice in legislation as in theory they can be more readily changed and updated than can legislation. The Codes of Practice cited in Victorian legislation are considered to be both suitable and relevant. A major weakness is the length of time it takes to change or update existing Codes.

### Question 10: Full cost recovery, burden of paperwork

Full cost recovery for work done is appropriate given private practitioners may wish to provide services such as calibrations, compliance testing etc. that are part of regulatory oversight. The paperwork burden on small business is not considered to be excessive given that equipment is registered annually and operator licenses last for two years. Reductions in compliance costs would be difficult to achieve given the work and expertise needed to confirm that, say, a mammography unit is operating in optimum mode.

### Question 11: Other legislation

The only other relevant legislation could be the Victorian Nuclear Activities (Prohibitions Act) 1983. This Act, known colloquially as the ‘Nuclear Free State’ Act, prohibits activities associated with the nuclear fuel cycle such as uranium mining and nuclear reactor construction and operation. It does not specifically mandate provisions on general radiation safety matters.

### Question 12: Are current regulatory arrangements appropriate?

No. There needs to be clearer sanctions that can be implemented to ensure that recalcitrant operators comply with regulations. This is particularly so with certain medical specialities and industrial radiography.

### Question 13: Re-write of regulations to be less prescriptive

The current Victorian regulations are not considered to be unduly prescriptive. For instance they have not affected the establishment of businesses providing services, utilising ionizing radiation, that could be considered of limited value to the recipients.

### Question 14: Negative Licensing

Negative licensing is inappropriate for radiation protection purposes. To stop somebody from using ionizing radiation after they have caused radiation damage is not going to help the irradiated worker or overexposed patient. Radiation protection is based on pre-emptive control not *post hoc* management.

### Question 15: Provision of better information to remove entry restrictions

This would be an inappropriate approach to control of radiation safety. For example an oil company employing a company to carry out some industrial radiography procedures shouldn't be expected to determine if they are working correctly, conforming to the regulations and employing all the relevant safety procedures. They should be able to rely on the licensing of the radiography company and its employees by the appropriate regulatory authority.

### Question 16: Self-Regulation

Total self-regulation is inappropriate where public and employee health is the concern. There are recent examples of regulatory controls being re-introduced after a period of self-regulation,.

### Question 17: Mirror Legislation

Uniform legislation with a central body issuing standards would be a suitable solution to the question of uniformity. Each State must maintain its own registration and licensing system or care would need to be taken

## **Attachment 3 – Public Consultation - Submissions**

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to ensure that one particular State's fees were not cheaper or licenses more readily obtainable thus allowing operators to seek the easiest or cheapest option.

### Question 18: Desirability of performance based laws

Leaving industry to demonstrate radiation safety compliance through risk based safety management would have limited effectiveness. Where public health and safety is concerned standards have to be set and met. The laws governing traffic are a suitable example. Speed limits and driving requirements (eg.<.05% alcohol in the blood) are all set by regulation and have to be met by road users.

### **Conclusion**

It is the view of the Victorian Radiation Advisory Committee that there would be certain advantages in moving to national uniformity in radiation protection legislation.

However the Committee is opposed to any changes that would weaken the present regulatory and control regime.

### #24 Australian Diagnostic Imaging Association

The Australian Diagnostic Imaging Association welcomes this opportunity to comment on the Issues Paper released by ARPANSA as part of its review of radiation protection and safety legislation.

In short, ADIA feels that the various pieces of legislation covering radiation protection are adequate in all jurisdictions, and as such, it would strongly oppose any proposal which would relax either the regulations covering the acceptable levels of exposure to patients, or the level of qualification need by practitioners operating radiation-emitting equipment.

In addressing the fundamental question of this review, that legislation should not restrict competition unless it can be demonstrated that:

- the benefits of the restrictions to the community as a whole outweigh the costs; and
- the objectives of the legislation can only be achieved by restricting competition,

the Association would agree that the legislation governing the use of radioactive materials is restrictive to competition. We do, however, believe that the two points above can be demonstrated, as outlined below.

#### Levels of Radiological Exposure

It has been proven worldwide that there is some health risk associated with exposure to radiation, even at low levels. It is therefore absolutely vital for the well being of patients that the level of radiation exposure is kept to a minimum at all times.

In 1985, the National Health & Medical Research Council released a paper (*Recommendations for Minimising Radiological Hazards to Patients*) which made recommendations as to the acceptable level of exposure to patients. This advice received greater weight the following year when, following further research into estimates of radiation doses experienced by individuals at Hiroshima and Nagasaki, the acceptable level of radiation was revised down further.

These estimates were incorporated into the 1990 recommendations of the International Commission on Radiological Protection - the document upon which all Australian legislation is based.

ADIA believes there is a sound basis of scientific and medical research, which supports the current protection framework, and would strongly oppose any proposal, which would see patients, exposed to higher levels of radiation.

#### Qualifications of Practitioners

The other way in which we can ensure the safety of the community is through comprehensive qualification and licensing regulations for those practitioners performing radiological procedures.

It is the responsibility of all practitioners involved in an incident of care involving a radiological procedure to act with the risk factors, which may be involved, in mind. Referring GPs and clinicians must consider carefully the appropriateness of a particular type of diagnostic test before ordering. Radiographers must be properly trained and licensed to operate radiation-emitting equipment. Radiologists and nuclear medicine physicians must have the expertise to choose appropriate examinations and correctly interpret tests to minimise the risk of misdiagnosis or further exposure to radiation through repeat testing.

ADIA believes that the current strict licensing and qualification regimes for each of the practitioners involved in an incident of care involving radiological exposure are highly appropriate. The Association would strongly oppose any measure, which reduces the level of qualification needed for an individual, or licensing needed for the site where these procedures are being undertaken.

#### Legislative Restrictions to Competition

ADIA understands that the licensing and qualification levels needed by practitioners in this area may be seen as restrictive to competition, however the welfare of patients must be placed above the impulse for competition. With an issue that so directly and fundamentally affects the risk factors involved in radiological procedures, we believe that it is always preferable to err on the side of caution in any regulatory environment.

A strong, enforceable legislative framework is the best way to ensure patient safety is not compromised by a real or perceived lack of expertise on the part of any of the practitioners involved in the radiological procedure.

### **Harmonisation of Legislation**

ADIA is not, in principle, opposed to the consolidation and harmonisation of the various jurisdictions' radiation safety legislation. The Association would, however, strongly oppose a 'lowest common denominator' approach that would see the level of protection available to patients reduced. Indeed, we feel that some jurisdictions' legislation could be further strengthened to provide greater protection to patients, and would welcome the opportunity to expand on this in detail at a later date

### **Further Consultation**

ADIA understands that the Review Steering Committee will be holding focussed consultations with stakeholder groups following the drafting of its report, and would welcome the opportunity to make representations and/or comments on the draft recommendations.

### #25 WorkCover Corporation (South Australia)

WorkCover Corporation considers the safe use, transportation and storage of radioactive substances as of great concern to South Australia. In particular, WorkCover Corporation emphasises the need for legislation to provide safe system of work within workplaces and working environments in industries, organisations and bodies associated with radioactive materials.

Generally, the Corporation is supportive of the current radiation protection legislation in South Australia, namely:

- Radiation Protection and Control Act 1982;
- Ionising Radiation Regulations 2000; and
- Radiation Protection and Control (Transport of Radioactive Substances) Regulations 1991.

The Corporation has made contact with ms Jill Fitch, Director – Radiation Protection branch, South Australian Department of Human Services, to discuss concerns in regard to non-ionising radiation, in particular, the increasing use of lasers across many industries.

The Corporation notes that section 3.2.31 of the Occupational Health Safety and Welfare Regulations 1995 calls up Australian Standards AS 2211 and AS2397 for the manufacture and construction of lasers and the use of lasers in the building industry. Other employers are subject to a general duty of care and a broad requirement to manage hazards whilst using lasers within the workplaces. Whilst it may not be a true NCP issue, WorkCover Corporation considers some scope for the national review to address laser use within the workplace.

### **#26 NSW Radiation Advisory Council (submission from some members only) c/- NSW Environment Protection Authority**

**Q1 - Do the objectives of the legislation sufficiently cover all the issues? If not, what other issues should the objectives aim to address?**

The objectives of the legislation nationally are in general fairly broad, and should remain so. An important objective of the legislation is to balance, on the one hand, the need for protection of the community/environment against adverse effects of radiation and, on the other hand, the benefit of legitimate medical and industrial uses. To this end the NSW objectives are quite comprehensive.

**Q2 - Are the provisions of the legislation consistent with the objectives? Are there any conflicts or contradictions?**

The International Commission on Radiation Protection (ICRP) recommendations, on which most national radiation legislation in the world is based, while understandable to the specialist who has knowledge of their historical development can be confusing to others. Thus ICRP applies different approaches to public exposure, occupational exposure, exposure to radon gas, and exposure to natural radiation. These differences can manifest in legislation, however potential anomalies could be avoided with careful wording.

The legislation nationally is intended to protect people and the environment but where it actually names specific groups of people to be protected, it may need to ensure that it still covers all people.

**Q3 - Do you think that agencies are pursuing the original objective of radiation protection legislation or are they pursuing other objectives? You can assess this based on personal experience or against policy statements of State and Territory governments in the last few years.**

The agencies do pursue the original objectives but in some instances those objectives may need to be reviewed regularly.

**Q4 - Do you think any of the objectives specified in the legislation are out of date? Has there been any technical or market change in the last few years that have made the objectives more or less relevant or give rise to the need to specify either new or amended objectives?**

The objectives are not out of date. The changes being discussed by the ICRP will change many of the details but not the basic objective to protect people and the environment. The implication in the question that market change should be a factor in radiation safety is of concern. Public and environmental safety is not and should not be driven by market forces but by acceptable national and international standards of safety.

**Q5 - Do you think that the objectives are focussed, capable of being monitored and tested and achievable? Should the objectives be modified, reprioritised, deleted, enlarged or accepted?**

Nationally, there is scope for greater uniformity in objectives. It may not be possible, however, to retain their essential breadth and at the same time make their attainment achievable.

**Q6 - Is there any objective or any part of an objective in any of the legislation that is best addressed in some other existing legislation or if necessary, in some other new legislation?**

The objectives are not best addressed in some other existing legislation. It is best to keep all radiation legislation together. Radiation is often covered in more than one piece of legislation, making compliance and overview difficult. Regulations made under the legislation must support the objectives in specific and general ways. It would be difficult, if not impossible, to achieve this via other legislative routes.

**Q7 - Does any objective in the legislation of the participating jurisdictions impact negatively on any other policy objective of the jurisdictions in other areas, including (but not limited to) occupational health and safety, mining, transportation, public health and the environment?**

There are discrepancies in the objectives of legislation and/or policies, for example:

- mining legislation in NSW exempts certain mining activities from the Radiation Control Act yet does not adequately deal with radiation matters;
- the radiation limits in the recent draft drinking water guidelines issued by the National Health and Medical Research Council are based on achievability rather than risk assessment;

- standards issued by Standards Association of Australia in places conflict with state legislation; and
- licensing procedures of ARPANSA are different to state licensing procedures – the ARPANSA Act only applies to Commonwealth entities but the different approach contributes to confusion.

The different jurisdictions revise their legislation to different timetables so even if they intend to be the same they are not because their revisions are out of step.

**Q8 – Do the regulatory differences within and among governments add to the costs of Australian businesses? Do you think there is a compelling need to promote uniformity among the legislation of all the States and Territories to eliminate unnecessary duplication and enhance administrative efficiency?**

To a point, the regulatory differences within and among governments could add to the costs of Australian businesses, particularly the lack of uniformity and differing requirements for licensing. Other examples of increased cost are:

- a small NSW business producing abrasive-blasting material with a low activity concentration initially was prevented from selling the material in Queensland. The Queensland regulations had been based on what could be achieved by Queensland companies not on a risk assessment. The company could have gone out of business but hired a consultant and succeeded in getting Queensland Health to revise its regulations based on risk assessment;
- a NSW heavy mineral sand mining company mining just over the Victorian border was required to demonstrate that no-one would receive more than a radiation dose of 10  $\mu$ Sv per year (about one two hundredth of the natural radiation dose that they receive) as a result of the mining operation. This was demonstrated but added to the cost of setting up the operation;
- licensees being required to apply for and renew a licence in several states to carry out the same tasks in each of those states;
- where training courses are not recognised between states meaning that a person may have to pay to complete a recognised course in each state to obtain a licence to permit them to carry out similar activities in each of those states;
- radiation terms/quantities, requirements for reporting of maladministration, and guidelines, should be uniform nationally, whereas at present they vary among jurisdictions;
- the requirements for disposal of radiation waste should be uniform and specified; and
- the recent Commonwealth government initiative to support site rather than personal licensing adds a new inconsistency.

**Q9 – Are the standards and codes of practice referenced in the legislation suitable and relevant? Is there any justification for their retention? Can you suggest better ways to reference and use such standards and codes of practice?**

Generally, the standards and codes of practice referenced in the legislation are suitable and relevant but the different States revise their regulations at different times, and may not update a regulation each time the code that is called up is updated. This can lead to some regulations calling up obsolete codes at different times.

Standards and codes should be referenced in such a way that they can easily be changed without the need for legislative changes, but without the cumbersome need to either accept the entire document or to quote all the words required (which could be quite lengthy and introduce typographic errors during reproduction).

**Q10 - Could the current arrangements to partially recover the costs of regulatory oversight be improved? Should full cost recovery be introduced as it is in most professional registration areas? Could compliance costs and the paper work burden on small business be reduced?**

The current arrangements to partially recover the costs of regulatory oversights could be improved, for example a simple change would be to move to longer licence validity periods, and possibly a single licence document with all relevant licences quoted. Another would be to use “on the spot” fines, which are vastly cheaper than prosecution for relatively minor breaches, yet provide a strong message of regulatory intent to the users. Compliance costs, where practicable, should be low, as high compliance costs encourage non-compliance.

**Q11 – Is there related legislation affecting radiation protection that needs to be considered in this review? If so, what are they and what are the impacts on the radiation protection legislation under review?**

The mining industry legislation and some general Occupational Health and Safety (OH&S) legislation are examples of legislation affecting radiation protection that need to be considered in the review. Radiation aspects of mine sites are excluded from the NSW Radiation Control Act but may affect areas outside the mine site. Once a mine site has been rehabilitated and is no longer classed as a mine site, any remaining radiation problems would have to be dealt with under the Radiation Control Act.

**Q12 – Are the current arrangements for regulating various occupational groups appropriate?**

The current arrangements for regulating most occupational groups are appropriate when used in conjunction with accreditation/education/professional standards promoted by those same organisations; however, it is important that the legislation be backed by a robust and flexible regulatory arm.

The underlying theme that entry into a profession is "restrictive" is debatable. It is important not to confuse the maintenance of professional standards, that are essential to public health protection and professional 'duty of care', with restrictive trade practices.

**Q13 – Can any provision of any legislation be modified or re-written so that it is less prescriptive and yet achieve the relevant objectives?**

The legislation should define objectives and may recommend means to achieve these objectives. Alternative means should be allowed providing they can be shown to be as good as any prescribed means.

The public concern with radiation is such that it expects government to control exposure. Voluntary schemes are too easily ignored, especially when the regulator has no resources to provide a strong oversight, and the decision to prosecute is of necessity driven by a cost benefit approach (ie. only prosecute if there is a high chance of success given the costs involved).

Non-prescriptive outcomes-based regulatory schema are rarely as effective as traditional 'command and control' measures. Their enforcement generally is extremely difficult and their public credibility is low. While commercially attractive within an economic rationalist construct, practicability considerations dictate that they should only be considered where the risk to public health and safety is low.

**Q14 - Is it feasible to have a system of negative licensing, where there is no requirement for licensing or registration but someone who deals with radioactive substances or radiation equipment unsafely is prohibited from further dealing with the substances or equipment?**

Members of the Radiation Advisory Council (RAC) generally are of the view that it is not feasible to have a system of negative licensing. "Legislation by prosecution" is the antithesis of what radiation protection aims to achieve. This notion begs the question that if a Chernobyl occurred, would the subsequent prosecution satisfy the victims and their families, and the general public?

**Q15 – Is it feasible to have a system of providing better information to consumers and remove some of the restrictions on entry and exit of firms or persons or restrictions on the conduct of their activities?**

While web-literate consumers could be better informed of radiation legislation via electronic and web based means, this is no substitute for general protection of public health and safety by governments, for which they have a clear 'duty of care'. It is important that community representatives remain integral members of state radiation advisory bodies. Attention to the safety of persons and the environment must remain paramount and the commercial interests of an individual should not supplant those of the wider community.

There is a concern that any significant involvement of vested interests (apart from the consultation and information process) in the regulatory process could potentially weaken legislation for the benefit of those interests, and possibly to the detriment of the occupationally exposed, the public, and the environment.

**Q16 – Is total self-regulation with an industry developed code of conduct feasible?**

Members of RAC are not aware of any evidence of self-regulation having worked successfully.

**Q17 – Is a system of “mirror” legislation with all jurisdictions having the same legislation and a central body issuing standards and codes of practices desirable? If not, is there a need to develop some other system of maintaining radiation protection standards that achieves greater uniformity or consistency while jurisdictions continue to maintain their existing Acts and regulations?**

It could be desirable to have a system of legislation with all jurisdictions having the same legislation and a central body issuing standards and codes of practice for a core content. However, States must be empowered to mandate additional requirements where considered necessary, particularly for environment protection. The members of the RAC are wary of a “lowest common denominator” result since this could in certain circumstances produce unacceptably low standards.

**Q18 – Is it desirable to have performance-based laws, regulations, standards and codes of practices that specify only the objectives of the legislation leaving it to the industry to demonstrate compliance through risk-based safety management or operational plans before a licence or registration is issued instead of prescribing the standards, maximum levels of exposure or dose limits in regulations, standards and codes of practices?**

A so-called ‘performance-based’ approach may be attractive commercially at first glance, but in practice is likely to be, with few exceptions, extremely difficult and costly to enforce and is unlikely to deliver the degree of public health and safety protection that the Australian community demands.

Dose and other limits must be prescribed – these are the performance criteria. “Performance based” in relation to radiation protection must mean complying with internationally recommended limits (which are risk limits).

It should be noted that OH&S legislation is being made ever more prescriptive, mainly because of the failure of voluntary or laissez faire systems.

### #27 Australian Nursing Federation (Victorian Branch)

The Australian Nursing Federation (ANF) (Victorian Branch), has previously made a detailed submission in relation to a similar review undertaken last year. Essentially, our position on the need to maintain strict requirements under Government regulation in relation to the use of radiation remains unchanged.

Due to time constraints, we are not in a position to address each question in the Issues Paper one by one. It should also be noted that it is not possible for us to address certain questions, which are identified in the Issues Paper, such as whether there has been an unfair financial burden on industry. Firstly, we do not have access to any specific research in this area. Secondly, it is our position that any business or person operating in this industry *must* carry a high level of responsibility, due to the very nature of the substance involved and the associated potential hazards to both the public and particular occupations, which can cause serious harm or death. In this sense, cost to business must be a secondary consideration to ensuring the health and safety of all persons who may be affected by the use of radiation.

It is entirely appropriate that the highest standards are maintained in relation to the operation, etc. of apparatus, or anyone dealing in any way with a radioactive substance. Such standards will not maintain themselves. It is essential that Government, through legislation, has at its disposal specific mechanisms that will enable the active monitoring and regulation of the industry to ensure compliance with those standards. Our comments therefore remain largely unchanged from our previous submission, and are as follows:

#### **General Comments:**

The serious hazards associated with exposure to radiation justify the most rigorous regulatory controls to be applied. The consequences of exposure, either from a single exposure to a large dose, or from repeated, long term low level exposure, are serious illnesses. Effects from high doses include radiation sickness, burns, drastic blood changes, and internal haemorrhaging. Victims exposed to both high doses, or to low-level doses over a long period, are at high risk of developing various cancers, often resulting in death.

Nurses face exposure to radiation hazards from operating or working near irradiating apparatus such as X-ray machines or nursing patients who have been given a radioactive substance for diagnostic or therapeutic purposes. Nurses are particularly concerned about the potential risks to both themselves as an occupational group, and to patients, if current regulations in the use of radiation apparatus and substances are relaxed or lifted. The benefits to industry and the community of maintaining strict controls under current legislation, far outweigh any costs relating to the administration of the legislation, licensing and registration procedures, etc., and any possible impact on competition policy. In our submission, there is no evidence that the requirements of the legislation are unnecessarily or unreasonably restrictive, or have had a negative impact on the industry.

#### **Specific comments are as follows:**

##### Registration of Radiation Apparatus and Radioactive Sources:

The registration system allows proper records to be kept with a central authority about the location and nature of apparatus and substances. This will ensure that problems/hazards are identified and addressed more quickly and effectively, thus providing a higher level of protection for all concerned.

The potential risk to health workers, patients, and members of the public should equipment and the use of radioactive substances not meet appropriate standards or satisfy safety requirements, are too great and too serious to relax the current requirements in respect of registration. Requirements in relation to registration under the legislation are therefore entirely appropriate.

##### Occupational Licensing System

In regard to licensing of operators, we believe that it is imperative that the current system of licensing continues. It is of fundamental importance that operators be required to meet appropriate standards regarding training, qualifications and experience, before they are allowed to operate equipment or deal with apparatus. Again, the potential risks of harm and fatal consequences to people who may be exposed to harmful levels of radiation if the operator is incompetent or does not rigorously follow appropriate safety processes and procedures are too great to relax the current licensing provisions. There is also a risk that unscrupulous people will fall through the system, resulting in uncontrolled use or misuse of radiation apparatus and radioactive substances.

### Alternative Proposals to the Current Licensing System:

Alternative proposals such as negative licensing and self-regulation have been examined in the past. These alternative systems would not provide adequate levels of protection. Negative licensing means inappropriate people will only be stopped from practising once an incident occurs. Given the risks associated with radiation, this is totally unacceptable, and will do little to promote or ensure that safety standards are met. This is a reactive approach, which will be of no help to victims of unsafe practices once they have already occurred.

Self-regulation is also not an alternative, which we would consider appropriate. Self-regulation has been largely discredited, with industries usually sticking to the lowest common denominator as their yardstick in determining the standards to be adhered to. The problem is that codes, etc. developed by industries whose prime motive is profit over and above everything else, would not have the impartiality or integrity to maintain appropriate standards. Another problem with this approach is that there is no provision for enforcement of or compliance with any standard, which may be developed under such a process.

This is an area which both warrants and justifies stringent government regulation. We would not allow someone who was not a registered doctor to operate on us and we should not allow unlicensed persons, who may or may not have appropriate qualifications and training to use radiation apparatus, or handle radioactive substances.

### Penalties for Radiation Safety Offences:

Given the hazards associated with radiation, and the consequences of exposure, which can be fatal, it is important that significant deterrents are in place for contraventions of failure to comply with relevant legislative requirements. It is therefore entirely appropriate to maintain significant penalties under the legislation for such offences, including the potential to impose financial penalties, cancel licences or registration, etc.

### National Competition Policy & Cost Issues:

Reference is made in the review to cost issues, for example, whether the costs to business in relation to administration, registration and licensing, are unreasonably burdensome. Firstly, financial cost is only one factor that should be considered. Safety issues in this instance would far outweigh the relatively negligible additional costs resulting from maintaining requirements for registration and licensing. Secondly, the economic costs of illness and injury both to the individuals affected, the healthcare system, and therefore the community, should exposure to radiation occur, would far outweigh the costs of licensing of operators and maintaining a registration system for apparatus and substances. Such costs would include medical treatment and support for victims and their families, potential workers compensation costs, and other legal liability costs, which may result if exposure occurs.

Clearly in considering the question of cost to business, the potential cost to those same businesses of workers compensation in the case of occupational exposure, possible damages claims by the public, damage to the business, etc. should an incident occur, must also be weighed up in any question of cost. The enormous human costs to victims of radiation exposure and their families must also be considered.

We do not believe that the licensing system involves an unreasonable restriction on the right to practice the licensed activity, because it is entirely appropriate, given the activity involved, to put measures into place which will ensure that the work is carried out safely. The occupational licensing system is simply the most effective way to ensure that this occurs.

The licensing and registration system currently required under the legislation does not prevent any person with the appropriate training and qualifications to practice the activity. Relaxation of the licensing system, however, could well have the opposite effect. It may result in *unfair competition*. Operators who may have cheaper overheads by employing less qualified people, and saving money by not meeting appropriate standards in maintenance and testing of equipment, will have an unfair advantage over their competitors, even though they may be placing their staff, patients and others at risk.

### Conclusion:

Given the serious health effects associated with this extremely dangerous and hazardous substance, we are strongly of the view that that the Government has a crucial role to play to protect the health and welfare of the community by maintaining the current regulations. We believe that this overrides any concerns about restriction on competition in an area that justifies and requires stringent regulation.

(Note: In making this submission, requirements pursuant to Part V - Radiation Safety of the Victorian Health Act 1958 as amended, have been considered).

### #28 Commonwealth Scientific and Industrial Research Organisation (CSIRO)

National radiation protection legislation that underpins an effective system of controls is important because it provides consistency for organisations operating across State borders.

This submission is in two parts:

- Part 1 - Importance of national measurement standards; and
- Part 2 - General efficiency of ARPANSA.

#### **PART 1: MEASUREMENT STANDARDS**

The CSIRO National Measurement Laboratory has provided the following comments.

##### Introduction

In order to provide confidence that radioactive substances are being managed effectively, it is necessary at various points in the management cycle to make measurements based on the quantities of activity, exposure or absorbed dose. For these measurements to be credible, they must be traceable to national physical standards and performed by competent individuals and organisations. In creating a legislative structure that permits appropriate levels of competition, the principles of traceability and competence must be maintained.

##### Background

Under the National Measurement Act 1960, CSIRO has responsibility for maintaining and disseminating Australia's standards of physical measurement. In the case of standards relating to ionising radiation, this responsibility has been delegated by formal agreement to ARPANSA (for standards of exposure and absorbed dose) and to ANSTO (for standards of activity). Only measurements that are traceable to these standards have legal traceability in terms of the National Measurement Act and Regulations.

To demonstrate traceability to the national standards for ionising radiation, users of measurement equipment or reference materials must have these items calibrated directly by the holders of the national standards or by an appropriate second-level calibration laboratory. A second-level calibration laboratory would be deemed appropriate if its own equipment was calibrated with traceability to the national standards and it could demonstrate competence through accreditation by the National Association of Testing Authorities, Australia (NATA).

Having obtained traceably calibrated equipment a user needs to demonstrate competence. If the user is a testing service, the appropriate route would be to obtain accreditation by NATA. If the user is providing a medical service (for example: a doctor, nurse or radiographer), other provisions such as the registration of the individual by professional bodies may be more appropriate.

These issues have been the subject of extensive discussions initiated by the Radiation Protection Branch of the NSW Environment Protection Authority during the formulation of guidelines for the regulatory regime in New South Wales. The issues raised by the NSW EPA with the CSIRO National Measurement Laboratory, with the National Standards Commission (which has responsibility for maintaining the National Measurement Act) and with user groups would provide a platform for addressing the legislative framework at national level.

##### Comments on specific questions raised in the Issues Paper

*Q1 Do the objectives of the legislation sufficiently cover all the issues? If not, what other issues should the objectives aim to address?*

It is appropriate that the primary issue in the legislation should be the safety of people and the environment. However the comment from the Northern Territory legislation ... "to ensure that beneficial radioactive materials and devices use sound scientific practices and follow legislative controls" ... refers to a significant element of achieving safe and effective usage of radioactive material. The legislation should ensure that the decisions relating to usage and control of radioactive materials are based on measurements that are defensible and engender confidence. The tests of whether the legislation is effective in achieving this goal should be:

- are measurements traceable to national physical standards; and
- are measurements being made by competent persons?

*Q6 Is there any objective or any part of an objective in any of the legislation that is best addressed in some other existing legislation or, if necessary, in some other new legislation? and*

*Q11 Is there related legislation affecting radiation protection that needs to be considered in this review? If so, what is it and what is its impact on the radiation protection legislation under review?*

Wherever measurement-related issues arise in the radiation protection legislation, reference should be made to the provisions of the National Measurement Act 1960 and the National Measurement Regulations.

*Q8 Do the regulatory differences within and among governments add to the costs of Australian businesses? Do you think there is a compelling needs to promote uniformity among the legislation of all the States and Territories to eliminate unnecessary duplication and enhance administrative efficiency?*

The framework for demonstrating traceability and competence in measurement operates at national level. Therefore it would be appropriate for all States and Territories to adopt uniform guidelines, whether in legislation or in subordinate Codes of Practice, that use this national framework.

### Effects of measurement-related issues on competition principles

In regard to the criteria for identifying restrictions on competition that were provided in the Issues Paper, the following comments are made. These comments assume a model that requires measurements to be traceable to national physical standards and to be made by competent persons and organisations.

- Entry or exit
  - ⇒ Entrants to the market must meet the same conditions as existing services i.e. they must have equipment calibrated with traceability to national standards and they must be competent to perform the task (which, for testing services, will mean accreditation by NATA).
  - ⇒ Where licences or registrations exist, they could not be traded until the incoming party demonstrated competence through accreditation.
  - ⇒ The requirements for traceability and competence will provide an advantage in regard to international mutual recognition or acceptance. There is a great deal of international activity already underway to ensure global mutual recognition of measurements that are traceable to national physical standards and performed by organisations accredited by a third-party body such as NATA.
- Prescriptive controls on standards and quality of production and supply of goods and services; and compliance costs

The requirements to demonstrate traceability and competence could be considered restrictive because there is only one national route to demonstrate compliance with these requirements. There will also be compliance costs in obtaining calibrations and meeting accreditation fees.

However the alternative of not prescribing these controls would leave the market open to unscrupulous operators that provide measurements with no verifiable foundation and therefore no credibility. It would frustrate the key aim of providing safety for people and the environment.

### Conclusion

It is possible to formulate a legislative framework for radiation protection that embodies the requirements for traceability of measurements to national physical standards and competence of the individuals and organisations that make measurements. A framework that incorporates these requirements is not in conflict with the principles of competition.

Moreover it is essential that the framework be formulated in this way if there is to be confidence in measurement and if the goal of providing safety for people and the environment is to be realised.

## **PART 2: GENERAL EFFICIENCY OF ARPANSA**

The following observations were provided by the CSIRO Occupational Health, Safety and Environment group and refer mainly to Commonwealth legislation - *Australian Radiation Protection and Nuclear Safety Act 1998*.

### Introduction

Twenty-one CSIRO Divisions use ionising and non-ionising radiation and have applied for ARPANSA Licences. The CSIRO Chief Executive is the Licence Applicant and the Chief of each Division the Licence

Nominee. There are currently some problems with ARPANSA granting of the licences to agencies. CSIRO is committed to radiation safety and has a comprehensive Radiation Safety Policy and a supporting Radiation Safety Manual to ensure that the risks of exposure to radiation are minimised.

### Operational Issues

CSIRO has identified the following difficulties with the ARPANS Act and how it is administered:

- **Rollover of licences** - Confusion has arisen because of the change from being State licensed to being ARPANSA *applicants for licences*. Under the ARPANS Act *Licence Applicants* are not covered, only licence holders. In fact Regulation 38 explicitly states that:
  - ⇒ "Under subsection 31 (1) of the Act, a controlled person must not deal with a controlled material or controlled apparatus unless: *the dealing is authorised by a source licence*".
  - ⇒ This situation could have been avoided by ARPANSA issuing interim licences after receipt of licence applications to cover all existing activities.
- **Information management** - ARPANSA uses a very inefficient and out-moded application system based on coloured sheets of paper. This has generated considerable work in converting information from electronic databases on to the coloured sheets required by ARPANSA. ARPANSA needs to consider changing the licensing application process to a more user friendly electronic means. (*The web licensing packs are also set up as PDF files that do not allow amendments/responses by applicants.*)
  - ⇒ ARPANSA has made requests for additional information for licence applications that appear quite excessive, for example: listing every laboratory room in a single building where a particular radioisotope is being used. Previous understanding with ARPANSA was to nominate the building only and not the individual rooms for each radionuclide. Such demands are considered excessive, adding costs and not conducive to establishing safety consciousness.
- **Costing and pricing** - The fee structure introduced by ARPANSA has produced a considerable cost burden on CSIRO Divisions. For example; UV lamps used for mineral identification are freely available to members of the public for approx. \$200 but for a CSIRO Division to hold such a lamp entails an ARPANSA fee of \$300.
- **Provision of advice** - The Act establishes that ARPANSA should "provide advice on radiation protection, nuclear safety and related issues (Clause 13, (1) (b))". Evidence to date indicates that ARPANSA is reluctant at times to provide advice on specific actions to be taken on matters, or to provide advice on the most appropriate monitoring equipment to be used, eg radon monitors.

### #29 Australia and New Zealand Association of Physicians in Nuclear Medicine

Nuclear medicine has proven itself as the investigation of choice for many important clinical diseases and for many conditions has an essential role in providing diagnostic information where the simpler first line examination has been equivocal or non-diagnostic. Nuclear medicine scanning produces functional information that is not provided by other imaging modalities such as CT, ultrasound and MRI.

The most frequent reasons for the utilisation of nuclear medicine services are for the investigation of myocardial ischaemia and viability, as well as the staging and diagnosis of cancer, especially in the bone, but also in soft tissue. In addition, isotope imaging remains an integral and essential modality for the investigation of a number of other conditions, including:

- unexplained bone pain
- bone and joint infection
- occult bony fractures and sports injuries
- life threatening pulmonary emboli
- renal disease in childhood
- renal hypertension
- differentiating between various forms of hyperthyroidism.

All nuclear medicine studies have to be referred by other medical practitioners and more than 70 per cent of referrals for nuclear medicine studies are from specialists.

Specialists providing nuclear medicine services are highly trained. Nuclear medicine is a sectional specialty of internal medicine and radiology and, irrespective of the specialist background, all trainees need to complete a minimum of two years' full time training in this field, in addition to training in internal medicine or radiology before being recognised by the State Specialist Qualifications Advisory Committee. The training program is supervised and assessed by the Joint Specialist Advisory Committee (JSAC) in Nuclear Medicine of the Royal Australasian College of Physicians and the Royal Australian and New Zealand College of Radiologists.

The strengthening of regulatory and licensing arrangements in recent times has ensured that medical practitioners performing nuclear medicine examinations using radioisotopes are suitably qualified to carry out these examinations safely and effectively.

#### **Australian and New Zealand Association of Physicians in Nuclear Medicine (ANZAPNM)**

The Australian and New Zealand Association of Physicians in Nuclear Medicine (ANZAPNM) is the peak body representing the specialty of nuclear medicine in Australia. As such, the ANZAPNM takes an active role in promoting and advancing the clinical practice of nuclear medicine and is a source of advice on all matters pertaining to nuclear medicine.

The ANZAPNM has responsibility for the accreditation of sites for advanced training in nuclear medicine according to a set of Training Site Accreditation Guidelines and manages other components of the nuclear medicine training program. This includes the registrars' continuous assessment program and the annual Basic Sciences Course in Nuclear Medicine, which is a mandatory component of the advanced training program.

No restriction is placed by either the JSAC or the ANZAPNM on the number of trainees by way of restricting numbers of trainees. The number is determined increasingly by State funding and factors such as staffing numbers, patient study numbers and infrastructure of those sites. The aim is to ensure that an appropriate level and quality of training is provided.

The ANZAPNM has ongoing responsibility for the implementation and monitoring of a range of quality and other measures in nuclear medicine. This includes the development of an accreditation program, currently being implemented, and the credentialling of specialists in nuclear medicine.

#### **Background**

Under the 1995 National Competition Policy (NCP) Agreement between all Australian Governments, there was a requirement to review legislation to ensure it did not restrict competition unless it could be demonstrated that

- the benefits of the restriction to the community as a whole outweigh the costs; and

- the objectives of the legislation can only be achieved by restricting competition.

At the same time it has been recognised that such restrictions may be beneficial to the community as a whole.

Where the NCP Review has shown that restrictions to competition do not, on balance, benefit the community as a whole, the restrictions are to be removed from legislation. Where there is deemed to be a benefit that exceeds the cost, or the legislation is not deemed restrictive, the NCP Review is to assess whether the objectives of the Review as stated above, can be achieved by “other better means”.

Examples of types of restrictions listed in the *Review of Radiation Protection Legislation Issues Paper* include: regulations which restrict entry to particular professions, legislative controls that restrict the quality, level of goods and services available, and that governs the entry or exit of firms or individuals into or out of markets.

- it is noted that the review is to take into account the following:
- retention of restrictive legislation only where the benefits to the community demonstrably outweigh costs and where objectives of legislation can only be achieved by restricting competition;
- in assessing (a) above, regard should be had *inter alia* to effects on public health and safety, occupational health and safety and the environment;
- promotion of consistency across regulatory regimes;
- suitability and impact of standards and codes of practice embedded in legislation; and
- reduction of compliance burden.

The Issues Paper notes that as a result of substantial legislative review in the 70s and 80s a range of legislation was enacted to address the following:

- the need to ensure that individuals dealing with radioactive substances or radiation apparatus have adequate training, qualifications and knowledge to ensure they carry out these activities in a way which will not harm either themselves, other persons, or the environment;
- the need to ensure the location of all radioactive substances, radiation apparatus and electronic products using radiation is known, their use is recorded, regulated and controlled appropriately, and they do not cause harm to individuals or the environment;
- the need to ensure storage, transport or disposal of any radioactive substance or radiation apparatus is done safely without harm to individuals or the environment.

The Issues Paper points out the similarities between the objectives of the various legislation being reviewed, summarised in general terms as protecting the health and safety of certain occupational groups, the community and the environment through safe handling of radioactive materials, while recognising the need for such materials for medical, research and industrial purposes.

The Review has sought advice on the matter of whether the current legislation continues to address its original objectives, or has pursued other objectives. For example, whether legislation is more concerned with revenue raising than public safety issues.

The role of precautionary controls has been raised in terms of the extent to which, in an environment where there is an expansion of potential applications for both ionizing and non-ionizing radiation, such legislative or other controls are relevant to maintain a high level of safety in the use of radioactive substances and radiation apparatus. As such, in the context of this review the question is being posed as to whether and how much such controls may be relaxed in order to increase the competitive environment of the use of radioactive substances and radiation apparatus.

### **The Role of Regulation in relation to Radioactive Substances and Radiation Apparatus**

The use of radioactive products and radiation apparatus carries a significant burden of responsibility since any accident or maladministration may have catastrophic effects for the patient or health care professionals, or other individuals involved. Strict training, licensing, credentialling / re-certification, technical and operational maintenance guidelines are fundamental to reducing to the lowest achievable level the possibility of such incidents.

The ANZAPNM believes there is a significant role for regulation in relation to radiation. From the perspective of nuclear medicine, the following are seen as important issues:

- the move towards uniformity in licensing and disposal guidelines;
- the inclusion of radiation protection matters within dedicated legislation;

- the need for uniform terms for description of radiation;
- facilitation of the development of uniform requirements for reporting maladministration;
- maintenance of appropriate professional and technical training, continuing education and re-certification;
- regulation of radiation products and apparatus;
- encouraging appropriate use of nuclear medicine procedures;
- maintenance of positive regulatory controls on the use of radiation products and apparatus
- development and regular review of guidelines and/or regulation for the operation of facilities using radiation for any purpose.

### **Uniformity in Licensing and disposal guidelines**

The ANZAPNM supports the move towards uniformity in licensing of facilities and operations. At present there are significant differences between States and the cost of compliance with such regulation may therefore vary. It is suggested that the licensing framework ultimately used as the basis for uniform radiation protection regulation needs to include both societal and economic perspectives, as is the case in New South Wales. Similarly, it is appropriate to have uniform guidelines for the disposal of radioactive materials.

### **Inclusion of radiation protection matters within dedicated legislation**

The inclusion of provisions relating to radiation protection in a variety of legislation increases the complexity of compliance. It is recommended that radiation protection be addressed within the one act.

### **Uniform terms for description of radiation**

At present, different terms may be used for describing radiation. These should be standardised across all jurisdictions. Conformity with recent ARPANSA legislation may be worthwhile.

### **Facilitation of the development of uniform requirements for reporting maladministration**

It is noted that only Victoria and NSW currently require reporting of maladministration. The development of uniform requirements for the reporting of maladministration will enable baseline and prospective data to be collected on the use of radioactive products that will assist in the maintenance of high standards across Australia.

### **Maintenance of appropriate professional and technical training, continuing education and re-certification**

The process of training nuclear medicine specialists has been outlined earlier in this document. The ANZAPNM believes the current advanced training system ensures the maintenance of high standards in the training of nuclear medicine specialists. The training reflects the essentially "tertiary" nature of the specialty. The training positions are not limited; however, hospitals seeking recognition as training sites must satisfy a set of guidelines which ensure a minimum standard of training is achieved and that the registrar has the requisite level of knowledge to perform nuclear medicine studies and administer radiopharmaceuticals safely. There is regular review of training sites to ensure that standards are maintained.

In order to ensure that nuclear medicine specialists maintain currency, mandatory continuing medical education (CME) is being introduced. The ANZAPNM fully supports such moves as a way of ensuring that currency of knowledge is maintained. Credentiailling on a bi-annual basis is also being introduced as a means of ensuring that any medical practitioner performing nuclear medicine services has the appropriate specialist recognition, maintains the currency of their radiation licensing and maintains their knowledge through CME. It should be noted that such processes are now actively encouraged and/or required by the Commonwealth Government as part of its overall "push" for quality assurance in the delivery of all medical services.

In relation to technical staff, the ANZAPNM understands that the Australian and New Zealand Society of Nuclear Medicine has made a submission which addresses technical issues.

### **Regulation of radiation products and apparatus**

The ANZAPNM believes there is value in having regulation with respect to radiation products and apparatus.

### **Development and regular review of guidelines and/or regulation for the operation of facilities using radiation for any purpose**

The ANZAPNM has been developing, with the support of the Commonwealth Department of Health and Aged Care, an accreditation program for nuclear medicine practices. This program will draw together and assess a range of elements of the operation of nuclear medicine facilities and is aimed at maintaining consistent quality in the delivery of nuclear medicine services. The ANZAPNM regards the systematic review and assessment of guidelines and service provision as important self-regulatory processes.

### **Encouragement of appropriate use of nuclear medicine procedures**

The ANZAPNM supports the appropriate use of nuclear medicine procedures and thus strongly supports a system, which ensures that only appropriately trained and recognised specialists undertake nuclear medicine procedures. The ANZAPNM believes the provisions in place support a high level of training of nuclear medicine specialists, and subsequent CME and re-certification are not restrictive.

### **Maintenance of positive regulatory controls on the use of radiation products and apparatus**

The ANZAPNM strongly opposes any proposition that a system of "negative licensing" be instituted – that is, that there be no or very minimal licensing until such time as it has been demonstrated that an individual or entity has practised or operated unsafely. As stated above, radiation is a valuable tool in many clinical applications but its improper, ill-judged or careless use or handling can have significant and widespread consequences.

Accordingly, with respect to nuclear medicine, the ANZAPNM supports the continuation of controls *inter alia* in relation to:

- the production, transport and disposal of radioactive materials and radiation apparatus;
- who can administer radioactive materials and use radiation apparatus;
- occupational health and safety issues for those working in this specialty (medical profession, technical, nursing and administrative staff);
- the protection of the public;
- the manufacturing and supply process in so far as the regulatory controls ensure maintenance of the quality of the product supplied and its safe delivery;

### **Conclusion**

The ANZAPNM believes there is no evidence to suggest that the current arrangements with respect to the professional elements of nuclear medicine represent any abuse of self-regulation, nor unnecessary limitation on competition or restriction on training. The ANZAPNM is actively promoting the development of mechanisms to ensure there is appropriate accountability by nuclear medicine specialists for the services they deliver.

At all times it must be recognised that the specialty of nuclear medicine involves the use of radioisotopes and, as such, there will always remain a need for strict controls regarding training, licensing, continuing education, operational procedures and on product quality control. Any moves to lessen such controls should be approached with caution.

**#30 Australian Association of Private Radiation Oncology Practices****Radiation Oncology**

Radiation oncology is the specialty dealing with the delivery of radiation therapy, primarily for cancer treatment, both curative and palliative.

It is a complex specialty involving the delivery of therapy in a series of attendances which form part of a treatment regimen designed according to the site and stage of the cancer, the health and well-being of the patient, and on the basis of past history and treatments (surgical, chemotherapeutic and other radiation). Actual radiation treatment follows a complex process of consultation, planning and simulation in order that the radiation dose delivered to the site can be as closely targeted as possible to achieve the maximum delivery to the cancer while minimising potential damage to surrounding tissues and organs.

Radiation oncology treatment facilities are an integrated network of systems from simulation, through planning and dosimetry, to treatment delivery on high energy linear accelerator therapy machines and including treatment verification and QA. Departments require treatment machines (single photon or dual modality linear accelerators), simulators, planning computers and complex integrated networking systems which link the different items of equipment delivering different parts of the treatment regimen described above. Linear accelerators deliver external beam therapy. Facilities may also provide stereotactic radiosurgery, or brachytherapy, where radiation is delivered via sources which travel through fine hollow wires that are inserted directly into the targeted tissue.

Radiation oncology requires a range of highly trained and skilled specialist, technical and nursing staff. Radiation oncologists undertake two to three years' advanced training post-radiation oncology Fellowship. Technical staff includes medical physicists, who will typically have higher degree or doctorate qualifications, and radiation therapists – radiographers with special training in the operation of radiation oncology equipment.

Radiation oncology is a technologically sophisticated and complex specialty where the objective is to deliver the prescribed radiation dose to the targeted area, while minimising the impact on surrounding tissue and organs. This requires sophisticated three dimensional planning of treatment, simulation of the prescribed treatment, a range of quality checks and the actual delivery of the radiation dose. The commissioning, calibration and quality checks required to ensure treatment machines maintain beam integrity are fundamental to the safe operation of a radiation oncology facility. The increasing advancement of machine technology has not diminished the need for highly trained staff to maintain quality assurance checks.

**Background**

The 1995 National Competition Policy (NCP) Agreement between all Australian Governments, contained a requirement that all relevant legislation be reviewed to ensure it did not restrict competition unless it could be demonstrated that

- (i) the benefits of the restriction to the community as a whole outweigh the costs; and
- (ii) the objectives of the legislation can only be achieved by restricting competition.

although it was recognised that such restrictions may be beneficial to the community as a whole.

The assumption underpinning the Review is that irrespective of whether benefits are perceived as outweighing costs, “better ways” of achieving the objectives of the Review are to be considered.

Types of restrictions listed in the *Review of Radiation Protection Legislation Issues Paper* include: regulations which restrict entry to particular professions, legislative controls that restrict the quality, level of goods and services available, and that governs the entry or exit of firms or individuals into or out of markets.

The Issues Paper notes that as a result of substantial legislative review up to the 1990s a range of legislation was enacted to address the need to ensure:

- individuals dealing with radioactive substances or radiation apparatus have adequate training, qualifications and knowledge to ensure they carry out these activities in a way which will not harm either themselves, other persons, or the environment;
- the location of all radioactive substances, radiation apparatus and electronic products using radiation is known, their use is recorded, regulated and controlled appropriately, and they do not cause harm to individuals or the environment; and that

- storage, transport or disposal of any radioactive substance or radiation apparatus is done safely without harm to individuals or the environment.

The Review has sought advice on whether the current legislation continues to address its original objectives, or over time has pursued other objectives.

The role of precautionary controls has been raised in terms of the extent to which, in an environment where there is an expansion of potential applications for both ionizing and non-ionizing radiation, such legislative or other controls are relevant to maintain a high level of safety in the use of radioactive substances and radiation apparatus. In the context of this review the question raised is whether and how much such controls may be relaxed in order to increase the competitive environment of the use of radioactive substances and radiation apparatus.

### **The Role of Regulation in relation to Radioactive Substances and Radiation Apparatus**

The safe and effective delivery of radiation therapy requires staff who are trained and experienced, delivering services using equipment and facilities which are designed, constructed and maintained according to strict requirements. The experiences of the UK where poorly calibrated equipment resulted in incorrect radiation doses being delivered to patients highlights the importance of maintaining strict controls over this area of health care. This relates to both patient safety and staff occupational health and safety issues.

As such, the Association believes there is a significant role for continuing regulation in relation to radiation oncology given the potential hazards to public health and safety in the event of inappropriate use of radiation and no justification for any substantive change in the regulation of this medical specialty.

Nevertheless, there are areas where improvement could be made, as follows:

- achievement of greater uniformity in licensing. Currently there are state variations (for example, in relation to the configuration of facilities and the number of type of staff required). This has an impact both on national strategic planning and also the cost of delivering services where there may be significantly higher costs in one State.
- the introduction of uniform terms for the description of radiation;
- facilitation of the development of uniform requirements for reporting on both service delivery and radiation incidents.

At present, there are regulations governing licensing of specialists and technical staff who are involved in delivering radiation therapy. While supporting such licensing in general terms to ensure individuals are appropriately qualified, the requirement for the facility to pay for the licences of large numbers of staff results in a significant cost. The separate licensing of support staff in this manner is also creating a separate level of responsibility in the minds of some medical insurers / indemnity organisations, which are increasingly demanding, separate levels of insurance for different categories of staff.

Nevertheless, the role of regulation and self-regulation in maintaining appropriate professional and technical training and continuing education is recognised and is not regarded as inappropriate. As stated above, a specialty which is dealing with potentially hazardous materials and equipment (if used inappropriately) must be regulated to ensure only those which the necessary training and experience, and ongoing education, should deliver such services.

In the absence of appropriate controls there is significant potential for equipment and staff to deliver the wrong dose of radiation – the Association does not believe it to be the intent of national competition policy that patients are placed at risk.

It is considered important that there be no diminution of regulatory controls on the use of radiation products and apparatus on the basis of “it will probably be all right”. The current evidence is that regulatory control, in general terms, has provided the appropriate framework for delivering radiation therapy in a safe environment, with appropriately trained and recognised staff, properly constructed and operated facilities, and using equipment which is well maintained in accordance with accepted standards, appropriate for the purpose. Apart from relatively minor adjustments, there appears no justification for change.

The process of training radiation oncologists based on an advanced training system (post FRANZCR) which ensures the maintenance of high standards in the training. The training reflects the essentially "tertiary" nature of the specialty.

In order to ensure that radiation oncologists maintain currency in their knowledge, continuing medical education (CME) is encouraged. Accreditation and credentialing processes are being discussed.

### **Conclusion**

The Association believes there is no evidence to suggest that the current arrangements with respect to the professional elements of radiation oncology represent a departure from the principals being pursued under the National Competition Policy. It needs to be recognised clearly that there are areas of medicine where there is a need for regulatory control in the interests of public health and safety and the occupational health and safety of those involved in the delivery of radiation therapy.