



# National Competition Policy Review of Radiation Protection Legislation

## **Draft Final Report**

February 2001

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## EXECUTIVE SUMMARY

Under the Competition Principles Agreement reached by the Commonwealth, States and Territories in 1994, all jurisdictions must review their legislation to ensure their legislation does not restrict competition unless it can be shown 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.

Any restriction must be removed if the review shows that it does not, on balance, benefit the community as a whole. Even if the benefits of the restrictions exceed costs or the legislation is not restrictive, there must be a further assessment to determine if the legislation's objectives can be achieved by other pro-competitive means.

In December 1998, the Council of Australian Governments (COAG) Senior Officials Group agreed to the conduct of a single joint national NCP review of radiation protection legislation. It was decided that the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) - an agency within the Commonwealth's Health and Aged Care portfolio - would coordinate the review.

All jurisdictions except Queensland agreed to participate in the review. The Review commenced on 7 August 2000. An Issues Paper was released for public comment on 16 October 2000. The public consultation period ended on 15 December 2000.

The Issues Paper described the objectives of the legislation and identified possible restrictions under the following categories:

- Restriction on entry or exit of firms or persons. Restrictions on the conduct of activities. Advantages to some firms or persons through exemptions.
- Strict and prescriptive technical standards for products or services or restrictions to the quality, level or location of goods and services.
- Restrictions on advertising and promotional activities.
- Compliance requirements that confer costs on businesses.

A list of questions was also posed in the Issues Paper. These questions were on the objectives of the legislation, national uniformity, regulation of occupational groups and professionals, the potential restrictions, regulatory styles and infrastructure, compliance costs and cost recovery.

A total of 30 submissions were received. There was strong support for the strict and prescriptive regulatory approach of the legislation. There was also support for "user-pays" principle for cost recovery to sustain the regulatory oversight of the authorities.

However, respondents strongly criticised the lack of national uniformity in the way in which radiation protection legislation has been written, and applied in Australia, with some respondents calling for a national licensing and registration system. Nevertheless, even

those who wanted a national licensing or registration system did not want States and Territories to surrender their power to administer and enforce radiation protection to an existing or new central body.

In considering options for national uniformity, the Review Team considered a recent report of the Legislation Reform Working Group of the National Public Health Partnership, which stressed that the choice ought to be driven by not just the mere desire for uniformity. Instead the report pointed out that the relevant factors should be the level of uniformity that is desired and is appropriate and the feasibility of the selected option.

In this respect, the Review Team noted that the Australian Health Ministers Conference had, in August 1999, approved the development of a National Directory for Radiation Protection. The National Directory would provide an overall agreed framework for radiation safety (ionising and non-ionising), with clear statements that can be adopted within existing Commonwealth and State/Territory legislative frameworks.

The lack of national uniformity impacts on the efficiency of the administration of radiation protection legislation among jurisdictions. It poses difficulties for users having to comply with different requirements in different jurisdictions. However, it has not risked public health and safety or the protection of the environment. As such the gradualist approach to achieving national uniformity through the National Directory for Radiation Protection is considered to be an adequate response.

The Review Team also considered the need to regulate radiation protection activities. It considered radiation risks, and in this regard, the main concern was the known risks posed by ionising radiation. It also considered potential or actual market failure in the context of the objectives of the legislation.

Objectives are worded differently in each jurisdiction's legislation. Nevertheless they are all geared towards the protection of public health and safety and the environment from the harmful effects of radiation. All the respondents supported the objectives and the Review Team also reached the conclusion that the objectives of the legislation are appropriate. However, recommendations have been to re-write the objectives in a nationally uniform manner.

The Review Team reached the conclusion that although radiation risk causing events have a low likelihood of occurrence, there is, nevertheless a need to adopt a precautionary approach as the consequences of a risk causing event can range from serious to catastrophic. As such, the Review Team has recommended that radiation protection needs a strict "command and control" style regulatory approach. Alternatives such as "negative licensing" or self regulation" are neither desirable nor feasible.

Nevertheless, the Review Team has recommended that legislation should, where appropriate, be re-written for a gradual shift to the

performance-based approach, only in areas where the immediate risk of non-compliance to public health and safety and the environment is assessed to be low.

Every potential restriction that was identified in the Issues Paper was analysed for its impact. A further benefits/cost analysis was undertaken for restrictions that were graded as having a “major” impact. As the legislation under review relates to health and safety, the Review Team decided to undertake a qualitative analysis. It was assessed that the time and resources required for a quantitative analysis were not justified. It was also evident that a quantitative analysis would be premised on contentious assumptions on the monetary values to be ascribed to life, health and safety.

Almost all the restrictions were found to be, on balance, of net public benefit and necessary to achieve radiation protection objectives. Nevertheless, recommendations have been made, where appropriate, for further action to improve the efficiency of the legislation.

The list of recommendations is as follows:

1. Jurisdictions to amend the objectives statement of their legislation to “the protection of public health and safety and the environment from the harmful effects of radiation”.
2. Jurisdictions to identify duplication and discrepancies between radiation protection legislation and other related legislation, standards or codes of practice and take action to minimise the duplication and discrepancies consistent with national uniformity policies.
3. Jurisdictions to include nationally consistent provisions in radiation protection legislation to protect the public from the harmful effects of non-ionising radiation.
4. Jurisdictions to retain the regulatory approach to achieve radiation protection objectives.
5. Jurisdictions to conduct a risk assessment of their legislation to identify low risk activities in the administration of radiation safety and take appropriate measures to regulate, if necessary, these activities using a performance-based approach. This is to be done in a nationally uniform manner within the framework of the National Directory for Radiation Protection.
6. Jurisdictions to incorporate risk management principles in the National Directory for Radiation Protection.
7. Jurisdictions to develop a uniform set of protocols on functions that can be outsourced to third-party service providers and establish national accreditation processes and guidelines for such providers. This could be done as part of the National Directory for Radiation Protection.
8. Jurisdictions to implement a sunset clause in their respective legislation that necessitates a review once in ten years.

9. Jurisdictions to participate fully and unconditionally in the formulation and implementation of the National Directory for Radiation Protection and conduct a review of its effectiveness and efficiency within three years of its commencement.
10. The National Directory for Radiation Protection should take account of all existing standards, including those produced by ARPANSA, the National Health and Medical Research Council, the National Occupational Health & Safety Commission and Standards Australia.
11. Standards and codes of practice that will be adopted in the National Directory for Radiation Protection are to be, as far as practicable, consistent with relevant recommendations of international organisations and international standards.
12. The current systems of licensing and registration of operators, radiation equipment and radioactive substances are to be retained.
13. Dentists will continue to be licensed to operate radiation equipment until the need to license dentists is reviewed as part of the development of the National Directory for Radiation Protection.
14. Jurisdictions to retain the prescriptive approach in their legislation.
15. Jurisdictions to take into account the needs of rural, remote and indigenous communities when formulating radiation protection policies.
16. Jurisdictions to remove any provision that restricts any licensee, holder of an exemption or registration from referring to that fact in any advertising or promotional material.
17. Jurisdictions to incorporate an administrative protocol in the National Directory for Radiation Protection for the application of mutual recognition principles to the grant of licences and registrations to inter-State/Territory applicants.
18. Jurisdictions should recover the cost of their regulatory oversight from licensing and registration fees except for activities that are of a public good nature.
19. Jurisdictions should agree on nationally uniform definitions for radiation incidents, accidents or emergencies and develop a national system to collect and collate information and publish a national register for radiation incidents.

## SECTION 1 – INTRODUCTION

### National Competition Policy

In April 1995 all Australian governments agreed on a National Competition Policy (NCP). Under this agreement, the Commonwealth, States and Territories must review their legislation<sup>1</sup> and ensure the legislation does not restrict competition unless it can be shown that:<sup>2</sup>

- 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.

Restrictions to competition usually impose costs on the community through higher prices, reduced consumer and business choice and obstacles to innovation and efficiency. However, sometimes, restrictions may be beneficial to the community as a whole, especially when the legislation is aimed at protecting public health and safety and the environment.

A restriction that, on balance, does not benefit the community as a whole must be removed. Even if the benefits of restrictions exceed costs or the legislation is not restrictive, there must be a further assessment to determine if the legislation's objectives can be achieved by other pro-competitive alternatives. Examples of types of restrictions include,<sup>3</sup>

- Legislatively created monopolies or special government-backed initiatives.
- Licensing schemes that restrict entry to particular businesses.
- Regulations that restrict entry to particular professions.
- Quota restrictions to preserve natural resources.
- Regulations that specify strict technical standards for products or services.
- Administratively determined pricing arrangements.

The National Competition Council (NCC) has suggested seven main ways in which legislation may limit competition. Legislation could limit competition if it directly or indirectly:<sup>4</sup>

- governs the entry or exit of firms or individuals into or out of markets;
- controls prices or production levels;
- restricts the quality, level or location of goods and services available;
- restricts advertising and promotional activities;
- restricts price or type of input used in the production process;
- is likely to confer significant costs on business; or
- provides advantages to some firms over others.

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<sup>1</sup> The word "legislation" is explained broadly in clause 5(1) of the Competition Principles Agreement of 11 April 1995 as "including Acts, enactments, Ordinances or regulations".

<sup>2</sup> *Competition Principles Agreement*, clause 5(1)(a) and 5(1)(b)

<sup>3</sup> *Guidelines for NCP Legislation Reviews*, Centre for International Economics, p.8

<sup>4</sup> *NCC Legislation Review Compendium*, 3rd Edition, December 1999

### NCP review of radiation protection legislation

In December 1998, the Council of Australian Governments (COAG) Senior Officials Group agreed to the conduct of a single joint national NCP review of radiation protection legislation<sup>5</sup>. It was decided that the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) - an agency within the Commonwealth's Health and Aged Care portfolio - would coordinate the review.

One of ARPANSA's aims is to promote national uniformity in radiation protection and nuclear safety policy and practices. To this end it formed the National Uniformity Implementation Panel (Radiation Control) in August 1998 as a working group of its Radiation Health Committee. It comprises officers from the Commonwealth, States and Territories' radiation protection agencies.

The NUIP (RC) is also the Steering Committee for this NCP review. The Committee approved the engagement of a temporary Project Manager to undertake the review. The Project Manager and a senior ARPANSA officer make up the Review Team. **Attachment 1** provides the Terms of Reference, the list of legislation to be reviewed, and the Review Team and Steering Committee's contact details.

The Project Manager started work on 8 August 2000. He produced a draft Issues Paper on 13 September 2000. The Paper was refined with input from the Steering Committee and released for public comment on 16 October 2000. The closing date for submissions was set at 30 November 2000 but following requests from some organisations and individuals, it was extended to 15 December 2000.

Following receipt of all submissions, the Review Team undertook the analysis phase and produced this Draft Final Report. This report has been approved by the Steering Committee to form the basis of the focussed consultation that is now underway.

All submissions on the Draft Final Report must be received no later than **30 MARCH 2001**.

Respondents are strongly urged to e-mail their submissions to the Project Manager at [selva.selvakumar@health.gov.au](mailto:selva.selvakumar@health.gov.au) or send the submission in a diskette to:

Mr. Selva Kumar  
Project Manager, NCP Review  
ARPANSA  
PO Box 655, Miranda, NSW 1490

The Project Manager can be contacted by phone at (02) 9545 8308.

**Unless marked confidential, all submissions may be made public and may be placed on the ARPANSA website.**

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<sup>5</sup> Queensland did not participating in this review as it had already completed a public benefits test for its Radiation Safety Act 1999 and Radiation Safety Regulation 1999.

At the end of the focussed consultation, a Final Report will be produced. It will be approved by the Steering Committee and submitted to the Australian Health Ministers' Conference (through the Australian Health Ministers' Advisory Council). The Australian Health Ministers' Conference will forward the Final Report with its comments to the Council of Australian Governments.

### Recent developments

The initial deadline for the completion of the NCP legislation review of all Commonwealth, State and Territory legislation was 31 December 2000. However, on 3 November 2000, COAG accepted a recommendation by the National Competition Council to extend the deadline for the NCP legislation review and reform program from 31 December 2000 to 30 June 2002.

All jurisdictions must complete their legislation reviews and implement appropriate reforms by 30 June 2002. Satisfactory implementation of reforms may include, where justified by a public interest assessment, having in place a firm transitional arrangement that may extend beyond the revised deadline.

### Draft final report

The Issues Paper for the NCP review of radiation protection legislation was produced to facilitate written submissions from stakeholders. It was NOT a policy document. Instead, it was a non-exhaustive attempt to clarify the objectives, and aspects of the legislation under review that could, in principle, restrict competition.

Similarly this Draft Final Report is NOT a policy document. The recommendations may change based on comments received during the focussed consultation stage. Even after the Final Report is published, the participating jurisdictions will be given the opportunity to respond to the recommendations. The implementation phase will commence only after all the participating jurisdictions have considered and responded to all the recommendations.

The rest of this Draft Final Report is organised as follows:

- **Section 2** describes the nature and magnitude of the industry that uses or is dependent on radiation equipment and substances.
- **Section 3** assesses the objectives of the legislation.
- **Section 4** assesses the regulatory approach. It considers radiation risks, market failure and economic problems, alternative regulatory designs and national uniformity issues.
- **Section 5** analyses the potential restrictions in the legislation under review.
- **Section 6** lists the different groups who were consulted on the Issues Paper and summarises the views of those who responded.

## SECTION 2 –THE INDUSTRY

Limited data was available to accurately define the extent of use of radiation equipment, radioactive substances and electronic products that emit non-ionising radiation and the number of people involved in the industry. Nevertheless a brief description of the nature and magnitude of the people, equipment and substances involved is possible based on Medicare payment data and the number of licences and registrations currently in force.

In a paper presented to the Australian Health Ministers Conference in 1999<sup>6</sup>, it was estimated that about 30,000 to 35,000 people make direct use of radiation in their employment and up to 100,000 Australians are influenced occupationally by radiation protection legislation. The paper surmised that the majority of those who use radiation products are health workers involved in the diagnostic or therapeutic use of X-rays or radioactive pharmaceutical products used in nuclear medicine.

Other major areas where radiation sources are used include:

- instruments for process control in the mining industry, steel and paper mills and cement factories;
- radiographing structures in the non-destructive testing industry (industrial radiography);
- the search for minerals;
- the mining and milling of radioactive ores;
- the measurement of soil density and moisture control; and
- consumer products (for example, smoke detectors and thoriated gas mantles)

As the major use for radiation equipment and substances is in the area of diagnostic or therapeutic use of X-rays or radioactive pharmaceutical products in nuclear medicine, an attempt was made to quantify the market based on Health Insurance Commission (HIC) data. The total number of services performed in diagnostic and therapeutic services involving radiation<sup>7</sup> during the period July 1999 to June 2000 was almost 9.1 million. In terms of Medicare payments these services totalled almost \$728 million<sup>8</sup>.

Adjusted for services falling outside Medicare (about 30%), gap payments (about 20%) and dental exposures (about 6 million exposures at about \$30 each) the value of total services provided that involved the use of radiation equipment or substances could be estimated at about \$1,350 million. Another way of defining the market in terms that are wider than just the health related services is to collate the number of licences and registrations that have been issued by the Commonwealth, States and Territories.

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<sup>6</sup> *Implementing National Uniformity of Radiation Protection Frameworks: A Background Paper prepared for the 22 April 1999 Australian Health Ministers Advisory Council and the 4 August 1999 Australian Health Ministers Conference by the National Uniformity Implementation Panel (Radiation Control) of the Radiation Health Committee of ARPANSA, p. 3*

<sup>7</sup> This covered computerised tomography, diagnostic radiology, nuclear medicine imaging, nuclear medicine (non-imaging), radiation oncology and therapeutic nuclear medicine.

<sup>8</sup> Based on figures from the Health Insurance Commission website

The table below is an estimate of the total number of licences and registrations based on data published or provided by authorities from the participating jurisdictions.

Total number of licences and registrations									
	VIC <sup>9</sup>	SA <sup>10</sup>	WA <sup>11</sup>	NSW <sup>12</sup>	TAS <sup>13</sup>	ACT <sup>14</sup>	NT <sup>15</sup>	CIH <sup>16</sup>	Total
Operator licences <sup>17</sup>	4939	4074	2688	12248	1395	306	226	313	
Equipment and substance registrations. Management licences and registration of premises	5815	2006	1405	5600		375	252		
Total	10754	6080	4093	17848	1395	681	478	313	41642

Unless a person falls within one of the exemption categories, operator licences are required by anyone who uses or deals with radioactive substances in any way.

The main categories of people who are licensed are radiologists, radiation oncologists, nuclear medicine specialists, general practitioners, chiropractors, dermatologists, dentists, dental therapists and hygienists, equipment testers and service technicians, veterinary surgeons, industrial radiographers, cardiologists, borehole loggers, moisture/density gauge operators and researchers.

A wide variety of medical and industrial equipment and material are also registered. These include all kinds of X-ray equipment, gauges, fluoroscopy equipment, lasers, diagnostic and therapeutic nuclear medicine, mineral analysers, chiropractic radiography equipment and gamma radiography sources.

Management licences and registration of premises cover all areas where unsealed radioactive sources are kept or used.

<sup>9</sup> Source: Radiation Advisory Committee Annual Report, 30 September 2000.

<sup>10</sup> Source: Figures provided by the Radiation Protection Branch, SA Department of Human Services.

<sup>11</sup> Source: Figures provided by the Radiological Council of Western Australia. These figures include those on equipment emitting non-ionising radiation.

<sup>12</sup> Source: NSW Radiation Advisory Council Annual Report 1999-2000 and figures provided by the Radiation Control Section of the NSW Environment Protection Authority. Note that NSW has just started registering radiation equipment. The registration figures represent diagnostic imaging equipment and fixed radiation gauges. The figures are expected to rise in the next few years as more equipment and premises are brought under the registration regime.

<sup>13</sup> Source: Radiation Advisory Council Annual Report 1999-2000. The figures include equipment emitting non-ionising radiation. Note that licenses cover both equipment and operators.

<sup>14</sup> Source: Figures provided by the Radiation Safety Section of the ACT Department of Health, Housing and Community Care.

<sup>15</sup> Source: Territory Health Services Annual Report 1999-2000, p. 85 and figures provided by the THS. Registration figures represent registered medical equipment only. Radioactive sources are not separately registered but are listed in a licence application.

<sup>16</sup> Source: Regulatory Branch, ARPANSA. This figure includes 3 facility licences and 26 combined licenses (which included 310 individual source licenses that cover operators, equipment, substances and premises).

<sup>17</sup> Licenses issued to Nuclear Medicine Technologists, diagnostic and therapeutic radiographers under legislation (Victoria, Tasmania and the Northern Territory) that is not the subject the current NCP review is not included in these figures.

Based on the total number of licences and registrations issued by all the jurisdictions, it is evident that the legislation under review covers a sizeable number of people, radiation equipment and radioactive substances.

It is also evident from the records maintained by the jurisdictions that the number of applications for licences and registrations is increasing every year. This is especially the case in the diagnostic and therapeutic use of radiation equipment and radioactive substances, where interventional radiology procedures, nuclear medicine and laser techniques are becoming popular to replace traditional surgical procedures.

## SECTION 3 – OBJECTIVES OF THE LEGISLATION

### The legislation in general

In the early to mid-1900s, radioactive substances and X-rays were used mainly for medical and dental radiology and in radiotherapy. However, from about 1950, it was evident that new uses in medicine and industry and the availability of large quantities of radioactive material and radiation apparatus, would, if not controlled or regulated, be a hazard to their users and to the general public.

In the early 1950s the Commonwealth initiated a program to encourage States and Territories to put in place appropriate controls and safety measures for ionising radiation and radioactive materials. The result was legislation passed in the various States and Territories commonly named “Radioactive Substances Act”.

Many States and Territories reviewed their legislation between 1970 and 1990 leading to the legislation that is now the subject of this NCP review. The legislative scheme in all the participating jurisdictions can be described under three broad headings as follows:

- Regulatory Controls: This comprises similar systems of licensing or registration of persons, radioactive sources, radiation facilities, apparatus, equipment and premises of unsealed radioactive sources. In addition the Acts and regulations contain several provisions to control activities related to the use of or any dealing with radiation equipment and radioactive substances.
- Enforcement: This is done through inspectors or other authorised persons who have wide ranging powers, duties and obligations in routine and emergency situations to enforce compliance with the legislation.
- Administration: All jurisdictions, (except the NT) have a council or committee each with wide ranging functions to ensure the objectives of the legislation are being achieved. These councils or committees may not only advise the relevant Minister or chief executive but also approve or reject (NSW, WA and the ACT only) an application for a licence or registration.

Although detailed provisions differ in each jurisdiction, this general scheme is found in all the legislation. The effects of most of the provisions are common to all jurisdictions but some jurisdictions have unique provisions. In a nutshell, a person dealing with radioactive substances or radiation apparatus will have to:

- apply for licences or registration certificates;
- pay prescribed fees;
- keep records;
- disseminate information to employees and radiation workers;
- post appropriate signs and notices;
- comply with certain directions in routine and emergency situations;
- monitor levels of radiation exposure and doses;
- write and submit reports; and
- apply for periodic renewal of licences or registration certificates.

### The objectives

Objectives may be identified from the legislation, second reading speeches, management plans and annual reports, ministerial statements and the actions, impacts or evidence of those affected by the legislation.<sup>18</sup> The objectives of the legislation under review are:

- “...to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation”. (Commonwealth)<sup>19</sup>
- “An Act to provide for the safe use, transportation and disposal of radioactive materials and irradiating apparatus and for related purposes” (Australian Capital Territory).<sup>20</sup>
- “...to secure the protection of persons and the environment from exposure to ionising radiation and harmful non-ionising radiation, to the maximum extent that is reasonably practicable, taking into account social and economic factors and recognising the need for the use of radiation for therapeutic purposes” (New South Wales).<sup>21</sup>
- “...to minimise any negative health impact of radiation on the NT population and to ensure that beneficial radioactive materials and devices use sound scientific practices and follow legislative controls.”(Northern Territory)<sup>22</sup>
- “...to ensure that exposure of persons to ionizing radiation is kept as low as reasonably achievable, social and economic factors being taken into account”. (South Australia)<sup>23</sup>
- “...the provision of regulating mechanisms for the control of radiations that may be harmful to man”. (Tasmania)<sup>24</sup>
- “...to protect persons and the environment from exposure to ionizing radiation to the maximum extent possible while recognising the need for use of radiation for medical, research and industrial purposes”. (Victoria)<sup>25</sup>
- “...to protect public health and to maintain safe practices in the use of radiation” (Western Australia)<sup>26</sup>

It is clear that the overriding objective of the legislation is the safety of people and the environment. Although the word, “safety” is not always expressly used, this intent is evident from the use of words such as “control” and “protect” in the legislation and statements in reports made by agencies administering the relevant legislation.

There is also an express or implied intention to balance the need for safety with,

- Business and commerce;
- Training of radiation workers and related professionals;
- Innovation and research;
- The use of radiation for medical diagnostic and therapeutic purposes; and
- the many and varied industrial uses.

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<sup>18</sup> *Guidelines for NCP Legislation Reviews*, Centre for International Economics, p.29.

<sup>19</sup> Section 3, Australian Radiation Protection and Nuclear Safety Act 1998, No. 133.

<sup>20</sup> Radiation Act 1983 (ACT), Long Title.

<sup>21</sup> Section 3, Radiation Control Act 1990 (NSW).

<sup>22</sup> Territory Health Services Annual Report 1998/99, p.77.

<sup>23</sup> Section 23, Radiation Protection and Control Act 1982 (SA). See also the Long Title to the Act, which states: “An Act to provide for the control of activities related to radioactive substances and radiation apparatus, and for protection against the harmful effects of radiation”.

<sup>24</sup> Second Reading Speech notes, Radiation Control Act 1977 (Tas).

<sup>25</sup> Regulation 1(b), Health (Radiation Safety) Regulations 1994 (Vic).

<sup>26</sup> Radiological Council of Western Australia, 1999 Annual Report, p.1

The NCP review guidelines<sup>27</sup> require a review to:

- assess if all objectives are consistent with each other and with other policy objectives of government;
- assign priorities between competing objectives;
- determine if objectives that are being pursued in practice vary or differ from the original objectives when the legislation was enacted, and if not, determine the appropriateness of the objectives that are now being pursued.
- assess whether the objectives are focussed, capable of being monitored and tested and achievable.
- assess whether the objectives being pursued are relevant in terms of contemporary problems, challenges and community attitudes; and
- determine if objectives should be modified, re-prioritised, deleted, enlarged or accepted.

### Consistency and priorities

Although each jurisdiction implements its radiation protection legislation differently, the objectives of the legislation reflect a consistent theme of the protection of health and safety. The issue of priorities of objectives does not arise.

There was no adverse comment in the submissions on the consistency of the legislative provisions with their respective objectives or other government policies. The Review Team also did not discover any evidence that demonstrated inconsistencies between the objectives and the legislative provisions.

However, the issue of national uniformity in the objectives of the legislation arose. This was evident in the submissions. Many respondents were concerned that the words in the objectives differed among the jurisdictions. Support was expressed for a uniform statement of objectives in all the jurisdictions' legislation. In this respect, the aim of the ARPANSA legislation was supported as appropriate because it is a broad and unqualified statement.

The Review Team agrees that there is a need for objectives to be written in each enabling Act in a straightforward, simple and broad manner. This is important, as the effectiveness of all other provisions in the legislation and the feasibility of policy options for radiation safety administration will be judged against the objectives. The Review Team supports the need for uniform statements of objectives in all the Acts of the jurisdictions.

#### RECOMMENDATION 1

JURISDICTIONS TO AMEND THE OBJECTIVES STATEMENT OF THEIR LEGISLATION TO “THE PROTECTION OF PUBLIC HEALTH AND SAFETY AND THE ENVIRONMENT FROM THE HARMFUL EFFECTS OF RADIATION”.

Radiation protection objectives are also found in other legislation in areas such as mining and occupational health and safety. While there

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<sup>27</sup> *Guidelines for NCP Legislation Reviews*, Centre for International Economics, p.32.

is nothing to suggest that the legislation under review impacts negatively on other legislation, unless clarified, users may be confused about whether radiation protection legislation operates exclusively or is complementary to other legislation.

For example, the public consultation revealed that there are some discrepancies between radiation protection legislation and other related legislation and standards.<sup>28</sup> Some of these alleged discrepancies do not relate to legislation but instead to voluntary standards such as those produced by Standards Australia or the National Health and Medical Research Council.

A detailed study of the radiation protection legislation of each participating jurisdiction against other State/Territory or Commonwealth legislation, regulations, standards or codes of practice is beyond the scope of this review. However, the Review Team feels there is scope for a study to identify discrepancies or duplication and make recommendations to streamline legislation.

### RECOMMENDATION 2

JURISDICTIONS TO IDENTIFY DUPLICATION AND DISCREPANCIES BETWEEN RADIATION PROTECTION LEGISLATION AND OTHER RELATED LEGISLATION, STANDARDS OR CODES OF PRACTICE AND TAKE ACTION TO MINIMISE THE DUPLICATION AND DISCREPANCIES CONSISTENT WITH NATIONAL UNIFORMITY POLICIES.

## Variance

There is no evidence to suggest that agencies administering radiation protection legislation are not pursuing the original objective of the legislation. None of the submissions raised this as an issue.

## Contemporary relevance

The problems that are now being addressed by legislation have not abated over time. Instead, we have seen rapid development in new uses for radioactive substances and radiation apparatus. This is especially evident in medical diagnosis where there has been an apparent increase in the per capita radiation dose from ionising radiation. The widespread uses of radiation indicate that precautionary controls (be it in the form of legislation or otherwise) are still highly relevant to ensure the safety of people and the environment from the harmful effects of radiation.

This finding is supported by submissions received at the public consultation stage. All the submissions that addressed this issue agreed that the objectives of the legislation do not just continue to be relevant, but have in fact become even more significant over time due to the widespread use of radiation and radioactive substances for medical diagnostic and therapeutic purposes and industrial uses.

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<sup>28</sup> See Submission #26 (by some members of the NSW Radiation Advisory Council) in Attachment 3.

The very fact that legislation provides for the strict control of radiation is also a huge boost to public confidence. Recent history in the field of nuclear and radiation sciences has not been without public scepticism over the safety levels that are in place. The absence of legislative mechanisms to control and protect public health and safety and the environment would undeniably exacerbate such scepticism and concerns. This has been recognised by major international organisations, such as the International Atomic Energy Agency and the OECD's Nuclear Energy Agency, which have been very active in recent years to encourage member countries to enact effective legislation for radiation protection.

### Non-ionising Radiation

There remains one issue in dealing with contemporary relevance of the objectives, and that is the marked absence of a systematic approach to the regulation of non-ionising radiation. At present only the Commonwealth, WA and Tasmania regulate the use or dealing with non-ionising radiation apparatus or equipment. All other States, and the NT have the power to regulate non-ionising radiation but do not do so. The ACT cannot regulate non-ionising radiation, as non-ionising radiation is not defined in its Act.

The use of electronic equipment that emits non-ionising radiation has grown dramatically in the last few years. Examples are the increasing use of lasers and radiofrequency devices, eg mobile telephones. The hazards associated with high powered lasers are well documented and not disputed. However, there is still considerable media debate and much scientific research into the hazards that might possibly be associated with radiofrequency emissions, such as from the antennas of mobile telephones.

The harmful acute effects that can arise from exposure to high levels of non-ionising radiation are known and well documented, but the evidence related to chronic low level exposure to electromagnetic fields (eg mobile telephones) in general is yet to be conclusively identified and documented.

Nevertheless, there is a need for a nationally uniform approach to the control of non-ionising radiation, especially the use of lasers and some radiofrequency devices. Standards dealing with the use of lasers are available from Standards Australia but these have no legislative effect unless prescribed by a regulatory authority.

Tasmania and Western Australia have regulations dealing with lasers and electronic products that emit non-ionising radiation. The Commonwealth prescribes certain apparatus that emit non-ionising radiation when energised as controlled apparatus that require licensing.

In some jurisdictions, Occupational Health & Safety Authorities regulate exposure to non-ionising radiation, however this legislation is outside the scope of this review. In addition, the Australian

Communications Authority regulates the telecommunications industry, and that legislation is also outside the scope of this review.

Stakeholders' submissions pointed to the need for a nationally consistent approach to the control of non-ionising radiation, in particular the control of the increasing use of lasers. The review team agrees that there is a need for a nationally uniform approach to the regulation of non-ionising radiation.

### RECOMMENDATION 3

JURISDICTIONS TO INCLUDE NATIONALLY CONSISTENT PROVISIONS IN RADIATION PROTECTION LEGISLATION TO PROTECT THE PUBLIC FROM THE HARMFUL EFFECTS OF NON-IONISING RADIATION.

## Are the objectives focussed and measurable?

The question here relates to the objectives of the legislation under review, that is, whether they are focussed, capable of being monitored and tested, achievable and whether they should be modified, re-prioritised, deleted, enlarged or accepted.

There are provisions in the legislation for dose limits and exposure levels. These provisions have as their scientific basis internationally recognised recommendations from the International Commission on Radiological Protection that are based on extensive research into radiation doses and biological effects. While dose limits are set at an arbitrarily low level to minimise any potential adverse impact on health, they have their origins in quantifiable epidemiological research.

Other parts of the legislation, which require compliance with specific rules on safety administration are also focussed and authorities are able to assess against objective standards to ensure that safety administration is being achieved in line with legislation or licence/registration conditions. For example, the strict rules on the appointment of radiation safety officers and also other rules regarding signs, storage and disposal and transport are all based on specific requirements in the legislation or standards and codes of practice.

Based on the review of the legislative provisions, the Review Team feels that the objectives are focussed and measurable.

However, the question arises as to whether provisions on dose limits and maximum levels of exposure are in themselves appropriate in the context of the risks that these provisions are designed to manage. This is dealt with in Section 5.

## SECTION 4 –IS THERE A NEED TO REGULATE?

### The risks

In the previous section it was concluded that the paramount aim of the legislation – to protect the health and safety of people and the environment – is appropriate. In that context, it is now necessary to consider the risks that need to be managed.

### Ionising radiation

When ionising radiation is absorbed in the body it causes chemical reactions that can alter the normal functions of the body. At high doses (above 1 sievert) this can result in massive cell death, organ damage and possibly death. At lower doses the acute effects mentioned above are unlikely to occur. However, it is possible for effects to develop many years after exposure, eg cancer.

The Radiation Health Committee<sup>29</sup> developed Australia's general ionising radiation protection standards from the recommendations of the International Commission on Radiological Protection (ICRP 60 – 1990). It was published in 1995 as Radiation Health Series No: 39 (RHS 39). The RHS 39 incorporates the “National standard for limiting occupational exposure radiation (NOHSC: 1013 -1995).

The ICRP estimated that averaged over the population the probability of fatal cancer is 1 in 20,000 per millisievert (mSv). If the damage occurs in the testes or ovaries then hereditary effects in descendants may become apparent. The ICRP estimates a probability for adverse hereditary effects of 1 in 100,000 per mSv.

The ICRP has recommended the following limits on exposure to ionising radiation:

- General public exposure: 1 mSv per year.<sup>30</sup>
- Occupational exposure: 20 mSv per year (averaged over 5 years).<sup>31</sup>

These limits are over and above exposure from natural background and medical radiation. Background radiation consists of cosmic rays from space, radioactive materials present in the earth and the human body. Natural radiation exposure typically contributes about 2 mSv per year for each person.

In Australia the average annual exposure of radiation workers is about one-fifth of the natural background, although in particular industries (non-destructive testing, some branches of surgery and the mineral

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<sup>29</sup> The RHC is now a statutory committee with duties and obligations spelled out in the Australian Radiation Protection and Nuclear Safety Act 1998.

<sup>30</sup> In special circumstances, a higher value of effective dose could be allowed in a single year, provided that the average over 5 years does not exceed 1 mSv per year.

<sup>31</sup> With the further provision that the effective dose shall not exceed 50mSv in any single year.

sands industry) some workers experience annual doses approaching the limit<sup>32</sup>.

The detrimental effects of excessive radiation doses are self-evident. Radiation exposure does not inevitably lead to the induction of cancer. Instead, the probability of cancer goes up with increasing radiation dose. For radiation protection purposes it is assumed that there is no threshold dose and that the probability of cancer is directly proportional to dose.

Radiation risks are unique because of the invisible nature of ionising radiation, the long-term hazards from excessive exposure, the stochastic nature of potential harm from ionising radiation, the differing physical properties of different radioactive nuclides and the limited ability to neutralise exposure once administered.

A strong safety culture exists in Australia. This has been fostered by the regulatory controls that have existed since the 1950s. As such, it can be argued that the likelihood of a risk causing event under the current system of regulatory controls is low. However, the consequences of such an event, if and when it occurs, could range from serious to catastrophic.

A paper prepared by a national committee in 1997<sup>33</sup> also argued that practices involving exposure to ionising radiation ought to be subject to certain safety standards to protect individuals exposed to ionising radiation. These practices include the production and use of radioactive materials and radiation sources (including X-ray apparatus), the management of radioactive waste and the operation of nuclear installations and particle accelerators.

### Non-ionising radiation

The issue of non-ionising radiation was dealt with in Section 3 above and a recommendation has already been made (See Recommendation 3).

### Feedback from public consultation

Respondents to the Issues Paper were very supportive of the regulatory approach to deal with radiation risks and the harmful effects of ionising and non-ionising radiation. There were strong comments against confusing radiation safety and protection issues with commercial and market issues.

Respondents argued that deregulating radiation protection would represent a dangerous practice as an open competitive market is not appropriate in the use of radiation equipment and substances due to the nature of the materials used in nuclear medicine and the potential for harm to users, patients, the public and the environment.

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<sup>32</sup> “*Implementing National Uniformity of Radiation Protection Frameworks*: A Background Paper prepared for the 22 April 1999 Australian Health Ministers Advisory Council and the 4 August 1999 Australian Health Ministers Conference by the National Uniformity Implementation Panel (Radiation Control) of the Radiation Health Committee of ARPANSA, p.4

<sup>33</sup> *Guidance for the Development of a Uniform National Framework for Radiation Protection*, by Dr J McNulty, (“The McNulty” Report) October 1997, p.2

Respondents also argued that there is a need for government authorities to be able to rely on strong legislation that empowers them to ensure compliance with safety standards and provisions.

The serious consequences of the possible risks from the unregulated use of radiation equipment and radioactive substances is the reason why the Review Team regards that there is a need for a precautionary approach and that legislation and regulations are essential to achieve radiation protection objectives.

### Market failure and economic problems

The question here is whether an unrestricted market for the use of radioactive substances and radiation equipment and other related activities is doomed to fail. Completely open and unrestricted markets may deliver efficient economic outcomes but may not always deliver the most effective social outcomes. Market failure exists when markets fail to operate effectively due to certain (potential or actual) economic problems. In such situations, the “market failure” argument can be used to support legislative intervention.

However legislative intervention must be justified by demonstrating that but for the legislation it may not be possible to<sup>34</sup>:

- improve economic efficiency;
- achieve certain social welfare, distributional or equity targets;
- achieve certain environmental targets;
- improve occupational or consumer health and safety;
- influence regional development;
- attract investment; or
- facilitate adjustment.

For our purposes, the issues of occupational or consumer health or safety are of significance. Also important is the question of environmental targets. In order to demonstrate that legislative intervention is necessary for effective radiation protection, we must consider the economic problems that may warrant a regulatory approach. Such problems in the area of radiation protection are “externalities” and “information asymmetry”.

### Externalities

Externalities are simply side effects, which impose costs on the community but the person who caused the effect does not have to bear the cost of the side effect. The most common example is a factory, which discharges waste water into a river. The cost of doing so is external to the factory and there is no incentive for the factory to reduce the discharge without some form of regulatory intervention.

In the case of radiation protection, externalities may arise if users of radiation equipment or radioactive substances expose the public to

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<sup>34</sup> *Guidelines for NCP Legislation Reviews*, Centre for International Economics, p.30.

harmful levels of radiation through unsafe handling, administration or disposal. The resultant costs on the community could be through the burden that is imposed on the public health system. Some mechanisms are available for agencies to recover clean-up costs. However, the potential exists for the community to be burdened with social costs from externalities. In addition to the obvious public health costs, other costs could include loss of income, insurance, work cover, counselling, legal and other judicial costs associated with inquiries and reports.

There is also an increasing trend towards the corporatisation of activities that involve the use of radiation equipment and radioactive substances. While corporatisation enables businesses and firms to engage in more capital intensive activities, it also, by definition, makes it incumbent on corporations to account to their shareholders.

Profit motive per se is not in itself undesirable. However, when profit motives are driving factors in the conduct of activities that can adversely affect public health and safety or the environment, then there is a need to consider the externalities that can result from these activities. In the area of radiation protection there is a need to protect public health and safety and the environment from unscrupulous corporations that could opt for lower safety standards to cut costs.

The low incidence of serious accidents or incidents in Australia involving ionising or non-ionising radiation suggests that from a purely rational economic perspective, it may be possible to argue that legislative intervention may be inappropriate, as the likelihood of an externality is low.

Nevertheless, the potential for externalities to occur continues to be a legitimate reason for legislative intervention for radiation protection for the following reasons:

- The need for a precautionary approach to manage radiation risks, which are typically “low likelihood-serious consequence” risks.
- The uncertain consequences of exposure to radiation, the effects of which may remain latent for long periods.
- The assumption for radiation protection purposes that there is no threshold dose and that the probability of cancer is directly proportional to dose.

### Information asymmetry

Information asymmetry arises when information that is available to one group of persons may not be available to another. This problem may arise even in markets that are highly competitive. A fundamental requirement of an efficient competitive market is that people are able to make informed choices. However, in some markets sellers and service providers typically have better knowledge. This may be because it may be too costly for consumers to acquire the knowledge. Alternatively, the level of knowledge required to make an informed choice may be so technically and scientifically complex that it would be unreasonable to expect consumers to acquire the required levels of knowledge before they make their purchasing decisions.

Where there is inadequate information, consumers may simply buy the cheapest goods or service to their detriment. The reverse side of the coin is that consumers may pay excessive amounts for premium services, believing that the price reflects the quality, when it may not be the case. Either way, consumer choice is reduced and goods and services may not reflect their true value.

It is not uncommon for secondary markets to develop to provide the required level of consumer information. This can be through consumer magazines, certification services or agents. Different types of insurance and product warranties may also emerge in the market to help overcome the problem of information asymmetry.

The key question here is whether information that is available to users of radioactive substances and radiation equipment through licensing and registration schemes, especially of occupational groups, will continue to be available in an open and unrestricted market.

In this respect it is important to note that many of the goods and services that consumers confront in relation to radiation equipment and radioactive substances are “experience goods”, the quality of which is determinable only after purchase or consumption.

In addition, consumers of nuclear medicine, radiography and radiology services, are often one-time purchasers. Such consumers are unlikely to have adequate knowledge to make an informed choice, making them particularly susceptible to health and safety risks that may arise from any misuse. Even in the area of non-ionising radiation the increasing use of lasers for cosmetic purposes and the risk associated with the unsafe use of such lasers supports the argument for legislative intervention to address the problem of information asymmetry in the area of radiation protection.

Considering that any harmful effect from ionising radiation exposure may not be evident until much later and in view of the possibility of long term adverse effects, it is critical that information asymmetry problems in the area of radiation protection are controlled by the most effective means.

### Responses to externalities and information asymmetry

Typically governments intervene to redress the problems of externalities by,

- the outright prohibition of certain activities (eg, drunk driving);
- imposing a tax or surcharge (“polluter pays” principle); or
- imposing certain minimum safety standards (exposure levels, emission standards, dose limits).

Methods of dealing with information asymmetry have included:

- Licensing schemes to ensure that only appropriately qualified persons supply goods and services that are potentially hazardous.
- Accreditation to indicate who is appropriately qualified to provide the goods or services without prohibiting others from the market.
- Minimum standards.

- Minimum information requirements (labelling, safety information, safety record, etc).

The market imbalance that externalities and information asymmetry could create is clearly a major source of support for the regulatory approach to radiation protection. This view is supported by the submissions received at the public consultation stage. Generally respondents felt that the economic incentives for suppliers of equipment and services may not sufficiently motivate them to ensure lowest possible exposure from the use of radiation equipment and radioactive substances.

### Advantages and disadvantages of regulation

From the discussion so far, it is evident that a regulatory approach to achieving radiation protection objectives has the following advantages:

- Greater assurance to the public that the use of radiation and radioactive substances and the associated activities have met stringent quality controls in production, service delivery and waste disposal leading to higher public confidence in occupational and consumer health and safety as well as environmental protection, based on:
  - ≡ The imposition of strict exposure levels and dose limits that represent the outcome of proper risk analysis by regulators.
  - ≡ The minimisation of misinformation, which can be caused by information asymmetry.
  - ≡ The minimisation of fraudulent or opportunistic behaviour by ensuring that every person dealing with radiation equipment or radioactive substances is properly licensed or registered.
  - ≡ The minimisation of the effects of externalities that can impose high costs on the community especially where such externalities can potentially cause significant damage to the health and safety of persons or the environment.
- In a nutshell, the regulation of radiation protection activities through legislation protects the health and safety of people and the environment by ensuring a precautionary approach to the control of any activity involving radiation equipment or radioactive substances.

However, the regulatory approach also has certain disadvantages. Even where the regulation is meant to address health and safety concerns, costs are borne by the industry and the regulator for administration, compliance and enforcement activities due to the need to adhere to prescribed standards, codes of practice and procedures. Such costs may accrue from:

- The need for users of radiation equipment and radioactive substances to meet certain prescribed standards or additional costs to implement, monitor and report on certain specific quality control systems.
- Administrative costs to users in the application for licences, registration, record keeping, reporting and the like.
- Administrative costs to governments to establish and maintain regulations, including monitoring and enforcement activities.
- The stifling of technological innovation due to the high level of prescriptive content in the legislation.

- The inability of regulation to efficiently reflect changes in the external environment over time.

In evaluating the advantages and disadvantages of regulation in the context of radiation protection objectives, there is a need to transcend a mere economic analysis. A compelling reason for this is that radiation protection objectives are primarily to protect public health and safety and the environment.

### International obligations

The International Atomic Energy Agency published the IAEA's Basic Safety Standards<sup>35</sup> in 1996 to assist countries developing or reviewing their legislation and to set a common internationally agreed framework for radiation protection legislation.

The BSS set out the basic principles and requirements for ionizing radiations to achieve effective radiation protection and safety for the full range of practices and sources that could give rise to radiation exposure. It includes recommendations made by the International Commission on Radiological Protection (ICRP) and also takes into account the findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).

The BSS was jointly sponsored by the IAEA, International Labour Organisation (ILO), the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD/NEA), the Pan American Health Organisation (PAHO), the Food and Agricultural Organisation (FAO) and the World Health Organisation (WHO). It reflects the consensus of experts from over fifty countries who participated in the drafting.

Under the BSS, the primary responsibility for radiation protection and safety is placed on the operator. However, governments have the responsibility for setting and enforcing standards through a system of regulation. The BSS presume that a national infrastructure is in place, including legislation and regulations, and a regulatory authority is empowered to authorise, inspect and enforce the legislation and regulations. The BSS is also premised on the existence of a licensing or registration regime.

The following requirements are set down in the BSS for the protection of people from the harmful effects radiation:<sup>36</sup>

- Radiation protection requirements that include limitation of radiation doses to individuals and optimisation of protection and safety so that individual doses, the number of people exposed and the likelihood of exposure are all kept as low as reasonably achievable.
- Management requirements to establish a safety culture through quality assurance programs to reduce the contribution of human error to accidents and provide the qualified expertise necessary to observe the standards.

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<sup>35</sup> *The International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources*, (BSS), IAEA Safety Series No. 115, 1996

<sup>36</sup> *Guidance for the Development of a Uniform National Framework for Radiation Protection*, by Dr J McNulty, ("The McNulty" Report) October 1997, p.3

## Section 4 –Is there a need to regulate?

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- Technical requirements to ensure the security of sources from theft or damage and those sources remain within regulatory control.
- Defence-in-depth measures in facility design and operating procedures to prevent accidents, to mitigate the consequences of accidents and to restore safety following an accident.
- Good engineering practice throughout the life (siting, design, construction, operation and decommissioning) of a radiation source or practice.
- Verification of safety by carrying out safety assessments to identify and determine the magnitudes of radiation exposures during normal operation and accidents, and to assess the provisions for protection and safety. For nuclear installations and other prescribed radiation practices this is to be documented in a Safety Analysis Report.
- Procedures and equipment for monitoring operations and verifying compliance with safety requirements and standards.
- Maintenance of appropriate records and reports.
- Intervention requirements to reduce or avoid radiation exposure or its likelihood from accidents or chronic exposure to natural sources.

The BSS continues to be a major source of international support for the regulatory approach to achieve radiation safety objectives. In addition, discussion and reports at international forums continue to bear out the need for some form of control to be exercised over the use of radiation sources and equipment.

A paper prepared in 1994 for the OECD/NEA<sup>37</sup> asserted that radiation protection requires an effective infrastructure, which includes adequate laws and regulations, a well-structured complex of experts and a safety culture, shared by everyone involved.

Another paper prepared in 1999 for the OECD/NEA<sup>38</sup> recognised a regulator's dual role of promoting safety culture as well as evaluating the safety culture of licensees through performance or process-based inspections and other methods. Implicit in this paper was the continuing need for an infrastructure of regulatory controls.

Last year the NEA's Committee on Radiation Protection and Public Health (CRPPH) published a critique of the current system of radiation protection<sup>39</sup>. The paper was critical of several areas of the current radiation protection system stemming from ICRP 60<sup>40</sup> and made suggestions for improvement. The recommendations called for legislation, regulation or standards to be clear, coherent and based on extensive consultation with stakeholders, especially the non-scientific community. The paper did not canvass any option for the deregulation of radiation protection.

The Review Team acknowledges that exposures from small quantities of radioactive materials and from some radiation emitting devices are so low and the associated risks are so small that these items may not

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<sup>37</sup> *Radiation Protection Today and Tomorrow: An assessment of the Present Status and Future Perspectives of Radiation Protection*, paper prepared for the Committee on Radiation Protection and Public Health (CRPPH) of the Nuclear Energy Agency of the OECD, 1994, p.2

<sup>38</sup> *The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture*, paper prepared for the Committee of Nuclear Regulatory Activities (CNRA) of the Nuclear Energy Agency of the OECD, June 1999, p. 9

<sup>39</sup> *Critical Review of the System of Radiation Protection: First Reflections of the OECD Nuclear Energy Agency's Committee on Radiation Protection and Public Health (CRPPH)*, April 2000.

<sup>40</sup> The concepts covered were "Clarity and Coherence, Justification, Optimisation, Collective Dose, Dose limits, Triviality, Public Protection and Protection of the Environment".

require regulation. A starting point for setting the quantities of radioactive materials and the radiation emitting devices that may not require regulation would be the exemption levels and criteria in the IAEA’s Basic Safety Standards.

Nevertheless, the potentially serious consequences from a single or cumulative effects of radiation exposure, the uncertainty of the outcome and the possibility of latent effects that may only manifest sometime after exposure means that, on balance, a regulatory approach to achieve radiation protection objectives will yield a net public benefit.

### RECOMMENDATION 4

JURISDICTIONS TO RETAIN THE REGULATORY APPROACH TO ACHIEVE RADIATION PROTECTION OBJECTIVES.

## Alternative regulatory approaches

Even with a regulatory approach inefficiencies may still impose costs. Thus, there is a need to examine if there are more efficient ways of regulating. The question now is not if there is a need to regulate but how to regulate efficiently.

Regulatory costs can be minimised by either using pro-competitive forms of regulation or removing restrictive provisions that are unnecessary or not of net public benefit. The latter is the subject of Section 5 below.

As it has already been concluded that jurisdictions need to retain the regulatory approach, the alternatives that will be considered here are only those that could improve the legislation. Non-regulatory alternatives, such as “self-regulation” and “negative licensing” are not being considered.

### Performance-based regulation

Performance-based regulation is the opposite of the prescriptive or command and control type regulations. Instead of prescribing both the objectives and the rules, regulations would only specify the outcomes to be achieved and leave it to an applicant for a licence or registration to demonstrate the effectiveness and efficiency of the approach the applicant will take to achieve those objectives.

The performance-based approach has the potential to provide greater flexibility and encourage innovation. Government agencies may spend less resources to write and update detailed rules. The performance-based approach necessarily involves industry participants undertaking risk analysis and risk management. As such, this approach avoids the over-generalisation of risks that may occur in writing prescriptive regulations to capture a wide range of situations and activities.

However, the performance-based approach can add additional costs to small businesses, which usually have limited resources to address flexible approaches or to conduct detailed risk analysis. This may lead to decisions based on inadequate analysis or information. In some cases, monitoring costs for government agencies may be higher than the traditional monitoring and enforcement systems employed in a prescriptive approach. This could be due to the lack of established standards or disputes within the authority on whether the compliance model demonstrated by an industry participant is sufficient to achieve the outcomes that were specified in the legislation.

The performance-based approach is also inappropriate to regulate activities that require a high level of safety and for which the risk of a breach would have very serious consequences. As such, activities of even large firms or corporations, which can afford to conduct their own risk assessment and management, may need to be regulated through the prescriptive approach if their activities require high levels of safety and may cause externalities that can adversely affect public health and safety.

There is still a general reluctance in Australia to accept performance-based approaches in the area of radiation protection. This is well illustrated by the submissions to the Issues Paper.

The general view was that leaving it to the industry to demonstrate compliance would not work as private firms are profit motivated and would invariably select low cost control systems and compromise on safety standards. This is of particular concern in radiation safety as the effects of ionising radiation exposure cannot necessarily be traced to a particular source and have a long latency period of 10 to 15 years. Defining acceptable levels of exposure and putting in place legislation to ensure that such levels are not exceeded is a safer approach.

The Council of Australian Governments<sup>41</sup> calls on regulators to move away from overly prescriptive standards towards performance-based standards. According to COAG, regulations could reference standards or a number of standards and there should be no restriction on the use of other standards as long as objectives of the legislation are met.

However, COAG also cautions regulators that prescriptive requirements may be needed to ensure public safety in high-risk areas. In particular COAG makes several references in its guidelines to the fact that a prescriptive approach may be unavoidable in regulations that deal with public health and safety.

The Review Team acknowledges that a shift to performance-based regulations to achieve radiation protection objectives has to be approached very cautiously mainly because of the assessment above that although the likelihood of a radiation risk causing event may be low, the consequences of such an event could be serious to catastrophic.

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<sup>41</sup> *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standards-Setting Bodies*, Council of Australian Governments, November 1997.

Even if a performance-based approach is to be adopted for particular activities in radiation safety administration, this has to be gradual and only after a thorough risk analysis to determine which activities may be regulated through an outcome-based approach.

Where performance-based approaches are to be adopted, the implementation has to be accompanied by substantial industry efforts to educate the industry on risk analysis and management. Experience in some jurisdictions in other areas (such as marine safety) demonstrates that a well-defined transition plan is required to overcome the resistance to performance-based approaches.

Agencies can introduce a performance-based approach to radiation protection legislation gradually without immediately exposing the regulatory regime to the risks that could arise from a performance-based approach. The transition to a performance-based approach could be aided by using a “dual track” method with either “safe harbour” or “waiver/variance” provisions in regulations<sup>42</sup>.

- Safe harbour provisions in performance-based regulations enable firms that do not have the resources to comply with the outcomes-based approach to elect to use certain prescribed rules or specified standards. This enables firms that prefer to comply with prescribed rules to have the option to do so while others use the performance-based approach.
- Alternatively, regulations can continue to be prescriptive but may contain provisions that empower agencies to grant waivers or variances on a case-by-case basis to firms that demonstrate compliance through alternative means.

### RECOMMENDATION 5

JURISDICTIONS TO CONDUCT A RISK ASSESSMENT OF THEIR LEGISLATION TO IDENTIFY LOW RISK ACTIVITIES IN THE ADMINISTRATION OF RADIATION SAFETY AND TAKE APPROPRIATE MEASURES TO REGULATE, IF NECESSARY, THESE ACTIVITIES USING A PERFORMANCE-BASED APPROACH. THIS IS TO BE DONE IN A NATIONALLY UNIFORM MANNER WITHIN THE FRAMEWORK OF THE NATIONAL DIRECTORY FOR RADIATION PROTECTION.

### Risk assessment and management

The Review Team considered a recent paper released by the Legislation Reform Working Group (LRWG) of the National Public Health Partnership.<sup>43</sup> The paper made certain recommendations on how public health legislation can be written to ensure that risk management is undertaken.

Many of the recommended approaches are already present in the radiation protection legislation under review. These include,

- Licensing provisions.
- Obligations to report mishaps.

<sup>42</sup> See *Improving the Cost Effectiveness of Government: Alternatives to Command and Control Regulation*, by Brian Mannix, OECD, May 1994 (as reproduced in *From Red Tape to Results*, NSW Cabinet Office, February 1995).

<sup>43</sup> *The Application of Risk Management Principles in Public Health Legislation*, Legislation Reform Working Group, National Public Health Partnership, June 2000.

- Powers to inspect premises.
- Powers to conduct inquiries.
- The use of standards and codes of practice (see below).
- The defence of due diligence.

The paper recommends that risk management principles should be entrenched in public health legislation to ensure that the regulators and the regulated are compelled to analyse risks and hazards from policy formulation through to legislative action.

A detailed consideration of exactly how risk management principles could be entrenched into the legislation under review is beyond the scope of this review, which is essentially concerned with the competitiveness or anti-competitiveness of the legislation under review. However, the Review Team feels that there is scope for the current radiation protection legislation to be improved further through the application of risk management principles.

### RECOMMENDATION 6

JURISDICTIONS TO INCORPORATE RISK MANAGEMENT PRINCIPLES IN THE NATIONAL DIRECTORY FOR RADIATION PROTECTION.

### Codes of practice and standards

The use of codes of practice and standards complement both the prescriptive and performance-based approaches. Codes and standards represent consensus, as they are the result of agreed principles, measures, processes, performances and outcomes.

The Regulatory Impact Assessment processes required by COAG ensure that codes and standards are developed only after adequate consultation with the community. They enable an efficient and effective way to ensure that international standards and best practice approaches are efficiently incorporated without having to undergo the more cumbersome processes that are required for amendments to legislation. They are particularly useful for achieving national uniformity in radiation protection.

The Review Team notes that standards and codes of practice are already in extensive use for radiation safety through primarily the National Health and Medical Research Council's Radiation Health Series. The Review Team has been told that these standards and codes of practice are now being reviewed in conjunction with the development of the National Directory for Radiation Protection and the new standards and codes of practice will be published as the ARPANSA Radiation Protection Series.

### Third party certification

Third party certification is a useful device for authorities to divest themselves of certain regulatory functions and to foster competition among firms that wish to provide accredited services to the industry. For such a scheme to work there must be clear and defined standards

for use by the industry and the accredited third-party certification service providers.

The advantages of using third party certification to outsource some of the government's functions is that there will be an immediate cost-saving for the government and opportunities will be created for firms and persons to provide accredited services in a competitive environment. However, costs to users could increase. Outsourcing may also require authorities to spend more on resources to enact clearly defined standards for the industry to ensure that certification processes are objective and reliable.

In the area of radiation safety, the need to protect public health and safety and the environment implies that there is a need for authorities to retain a certain level of direct control over the activities of licensees and registration holders. It is also evident from the discussion above on the need to regulate that it is impossible for regulatory authorities to outsource all their regulatory functions as that would adversely affect the retention of independent expertise available to the authorities. The difficulties involved in ensuring that there is no misuse of the certification practices by unscrupulous third party certification service providers in a totally self-regulated environment is also a major consideration.

Third-party certification is already in use by some jurisdictions for the testing and certification of equipment. However, once again, there is no nationally consistent approach to issues such as what activities can be left to third-party certification and the standards for the licensing or accreditation of third-party service providers.

A recent report by a committee of the OECD/NEA<sup>44</sup> considered the question of third-party certification. The report concluded that third-party certification could benefit regulatory effectiveness and efficiency but cautioned that the cost-effectiveness of such approaches as well as the merits of involving outsiders in regulatory affairs have to be assessed.

The report recommended that formal accreditation should only be pursued if the regulatory authority is convinced that it will bring some extra benefits. It was also noted that third-party certification may be of benefit only if quality standards can be readily established.

The Review Team feels that there is merit in jurisdictions considering the devolution of some activities to accredited third party service providers. However, there is a need for a nationally coordinated approach to ascertain what activities can be outsourced to third-party providers and how service providers will be licensed or accredited. There is also a need to ensure that certification services are performed against well defined national standards.

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<sup>44</sup> *Improving Regulatory Effectiveness*, Committee on Nuclear Regulatory Activities, Nuclear Energy Agency, OECD, January 2001, p.24.

### RECOMMENDATION 7

JURISDICTIONS TO DEVELOP A UNIFORM SET OF PROTOCOLS ON FUNCTIONS THAT CAN BE OUTSOURCED TO THIRD-PARTY SERVICE PROVIDERS AND ESTABLISH NATIONAL ACCREDITATION PROCESSES AND GUIDELINES FOR SUCH PROVIDERS. THIS COULD BE DONE AS PART OF THE NATIONAL DIRECTORY FOR RADIATION PROTECTION.

### Sunset clauses

A common method to ensure that regulation remains current and up-to-date is by “sunset clauses” that require all legislation to have a fixed expiry date. This forces agencies to re-visit their legislation to ensure they are up-to-date. The consequences of not reviewing legislation before its expiry date are serious. Unless “renewed” on the expiry date, legislation would lose its force.

The Review Team notes that under the Competition Principles Agreement, jurisdictions are required to conduct competition policy reviews of their legislation once every ten years. While sunset clauses are already a feature in some of the legislation, there is a need to entrench this requirement in all the jurisdictions’ legislation.

The Review Team acknowledges that due to the different commencement dates of each jurisdiction’s radiation protection legislation, the ten-yearly review may not necessarily be a national review. Nevertheless, jurisdictions are encouraged to co-ordinate their reviews nationally.

### RECOMMENDATION 8

JURISDICTIONS TO IMPLEMENT A SUNSET CLAUSE IN THEIR RESPECTIVE LEGISLATION THAT NECESSITATES A REVIEW ONCE IN TEN YEARS.

## National uniformity

Under the Terms of Reference for this NCP review, the Review Team is required to consider the need to promote consistency between regulatory regimes and efficient regulatory administration through improved coordination to eliminate unnecessary duplication.

Accordingly the Issues Paper canvassed opinions from the respondents on the question of national uniformity. Respondents were asked if there was a compelling need to promote national uniformity in the area of radiation protection.

All the respondents strongly supported the need for national uniformity. However, the submissions on how national uniformity was to be achieved were divided. Some respondents preferred a national system with one Act that was “mirrored” by all jurisdictions. Nevertheless, most respondents maintained the need for jurisdictions to administer their own licensing and registrations systems even if a national Act was adopted. The general feeling was that jurisdictions

are better equipped to effectively monitor compliance and respond to emergencies and crisis situations.

Although there was overwhelming support for national uniformity, respondents also cautioned against the “lowest common denominator” approach. The general view was that standards might be raised but not lowered to achieve national uniformity.

The Review Team considered a paper<sup>45</sup> prepared for the Legislation Reform Working Group on options for national legislative schemes in public health. A key observation in the paper was that the choice for policy makers ought to be driven by not just the mere desire for uniformity. Instead there is also a need to consider the appropriate level of uniformity that is desired and whether it is achievable.

A key driver for the achievement of national uniformity in the area of radiation protection is the infrastructure available through the committee structure established under the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

Under Section 15(1)(a) of the Australian Radiation Protection and Nuclear Safety Act 1998, the Chief Executive Officer of ARPANSA is charged with the responsibility of the promotion of “uniformity of radiation protection and nuclear safety policy and practices across jurisdictions of the Commonwealth, States and Territories”.

The Radiation Health Committee, which was established under Section 22 of the 1998 Act, has the following functions to be performed on the request of the CEO of ARPANSA:

- (a) .....
- (b) to develop policies and to prepare and draft publications for the promotion of uniform national standards of radiation protection.
- (c) To formulate draft national policies, codes and standards in relation to radiation protection for consideration by the Commonwealth, the States and the Territories.
- (d) From time to time review national policies, codes and standards in relation to radiation protection to ensure that they continue to substantially reflect world best practice.
- (e) .....

To this end ARPANSA has formed the National Uniformity Implementation Panel (Radiation Control) as a working group under the Radiation Health Committee comprising senior officers of agencies of all jurisdictions that are responsible for the administration of their respective radiation protection legislation.

In early 1999, the NUIP (RC) prepared a paper, which was submitted to the Australian Health Ministers Conference proposing a framework for the attainment of national uniformity in radiation protection.

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<sup>45</sup> *Implementation Options for National Legislative Schemes in Public Health*, paper prepared for the Legislation Reform Working Group of the National Public Health Partnership by the Centre for Comparative Constitutional Studies, The University of Melbourne, September 1999.

### National Directory for Radiation Protection

After considering several options, including “template” and “mirror” legislation and the extension of mutual recognition principles to radiation protection, the NUIP (RC) recommended the consolidation of radiation protection standards and administrative guidelines into a document called the “National Directory for Radiation Protection”.

The Review Team noted that the particular option was selected because although the lack of national uniformity created administrative inefficiencies there was no evidence to suggest that the disparity in legislation impacted the health or safety of people or the environment. In addition, two jurisdictions were reluctant to immediately adopt a higher degree of national uniformity through template or mirror legislation and as such the decision was made to recommend a gradualist approach to the resolution of national uniformity issues in radiation protection legislation.

The National Directory would contain both mandatory and guidance provisions for adoption by Commonwealth, States and Territories in all areas covered by the existing radiation protection legislation. These provisions would be written into the National Directory following extensive consultation and agreement by jurisdictions. Such provisions could include ‘model’ licence conditions to cover similar practices in a uniform way in all jurisdictions. National radiation protection standards and codes of practice will also be included in the Directory.

Jurisdictions would use the provisions contained in the National Directory when undertaking amendments to their Acts, regulations and policies. If the provisions were carefully drafted it might also be possible to lift entire sections directly into legislation with minimum additional drafting effort. In time, it would be easy to use the National Directory for “template” or “mirror” legislation, if a higher degree of national uniformity is desired.

The Australian Health Ministers Conference accepted the proposal at their meeting on 4 August 1999. The approach that was approved can be summarised as follows:

- The National Directory for Radiation Protection shall be a national guidance document that will provide an overall agreed framework for radiation safety, including both ionising and non-ionising radiation, together with clear regulatory statements that are able to be adopted within existing Commonwealth and State/Territory legislative frameworks.
- The Radiation Health Committee would manage the development and amendments to the directory based on an agreed issue resolution process. Decisions shall be a majority vote of 10 out of the 13 members of the Committee. There shall be full consultation with relevant stakeholders, including the advisory committees and councils that exist in the jurisdictions.
- Final approval for changes to the National Directory shall be by the AHMC.
- Upon approval of the provisions in the National Directory, the regulatory elements of the National Directory shall be adopted as soon as possible using existing Commonwealth and State/Territory regulatory frameworks.

## Section 4 –Is there a need to regulate?

- Ministers recognised that a variety of agencies have legislated responsibilities for aspects of radiation safety (eg, mines, occupational health and safety and transport agencies) and these agencies are to be actively involved in measures to progress national uniformity, including the development of the National Directory.
- Ministers agreed that the adoption of uniform national regulatory controls (eg, via mirror legislation) will be considered further following the completion of the initial draft of the National Directory and in light of the recommendations of the NCP review of radiation protection legislation.

The Review Team has noted that the development of the National Directory is underway and standards and codes of practice (both existing and proposed) will be reviewed or developed and released in stages for public consultation as part of the Regulatory Impact Assessment processes. The revised and new standards and codes will be re-named “Radiation Protection Series” to distinguish them from the “Radiation Health Series”, which will be superseded in stages.

As the National Directory would be a cooperative effort, it is expected that the agreed provisions would not face too many hurdles in being implemented by each jurisdiction, through their respective legislative processes. However, in the absence of an inter-governmental agreement, it is possible for any jurisdiction to implement legislative changes, which are inconsistent with the National Directory.

Nevertheless, the Review Team feels that if followed through to its successful completion, the National Directory will be a major source for uniform national practices to achieve radiation safety and administrative efficiency. Ample time and opportunity must be given for the National Directory to work.

### RECOMMENDATION 9

JURISDICTIONS TO PARTICIPATE FULLY AND UNCONDITIONALLY IN THE FORMULATION AND IMPLEMENTATION OF THE NATIONAL DIRECTORY FOR RADIATION PROTECTION AND CONDUCT A REVIEW OF ITS EFFECTIVENESS AND EFFICIENCY WITHIN THREE YEARS OF ITS COMMENCEMENT.

### RECOMMENDATION 10

THE NATIONAL DIRECTORY FOR RADIATION PROTECTION SHOULD TAKE ACCOUNT OF ALL EXISTING STANDARDS, INCLUDING THOSE PRODUCED BY ARPANSA, THE NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL, THE NATIONAL OCCUPATIONAL HEALTH & SAFETY COMMISSION AND STANDARDS AUSTRALIA.

### RECOMMENDATION 11

STANDARDS AND CODES OF PRACTICE THAT WILL BE ADOPTED IN THE NATIONAL DIRECTORY FOR RADIATION PROTECTION ARE TO BE, AS FAR AS PRACTICABLE, CONSISTENT WITH RELEVANT RECOMMENDATIONS OF INTERNATIONAL ORGANISATIONS AND INTERNATIONAL STANDARDS.

## SECTION 5 – BENEFITS AND COSTS OF THE RESTRICTIONS

The review team had, in the Issues Paper, identified the following four categories of restrictions in the legislation under review:

- Category 1 - Restriction on entry or exit of firms or persons. Restrictions on the conduct of activities. Conditions in licences. Advantages to some firms or persons through exemptions.
- Category 2 - Strict and prescriptive technical standards for products or services or restrictions to the quality, level or location of goods and services.
- Category 3 - Restrictions on advertising and promotional activities.
- Category 4 - Compliance requirements that confer costs on businesses.

Several possible restrictions were identified and described under the above categories in Section 3 of the Issues Paper, which are reproduced in **Attachment 2** of this report. The rest of this section is an evaluation of the restrictions to answer the following key questions of the NCP review:

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

The Review Team decided to proceed with a qualitative analysis due to the nature of the legislation that is being reviewed. Radiation protection legislation aims to protect the health and safety of people and the environment. Quantification of the costs and benefits of the health and safety of people and the environment is necessarily subjective and premised on contentious assumptions.

The qualitative approach to benefit-cost analysis is also recommended by most of the participating jurisdictions' guidelines for the conduct of NCP legislation reviews where the subject of the legislation is the protection of health and safety. The guiding principle is that a quantitative analysis is required only if the legislation being reviewed has a serious effect on the economy as a whole and relates to economic rather than social objectives. A qualitative approach is adequate when the objectives of the legislation under review involve mainly issues of health and safety.

It was felt that an equally rigorous analysis could be conducted qualitatively by considering the advantages and disadvantages of the restrictions instead of attempting to quantify the concepts. For simplicity, the words "benefits" and "costs" are used synonymously with the words "advantages" and "disadvantages".

As only some of the legislation under review address non-ionising radiation and the provisions of the legislation among jurisdiction differ in detail, the analysis in this section is only at a conceptual level. Some of the analysis may not apply to some jurisdictions.

## Section 5 – Benefits and Costs of the Restrictions

The analysis in this section is presented under the following headings for each of the sub-categories of restrictions:

- Impact: Only restrictions assessed to have a major impact on competition by creating a potential barrier to entry or being potentially prescriptive or by imposing compliance costs are assessed further. Restrictions assessed to have a minor impact on competition are retained without further assessment.
- Advantages/Disadvantages: These are assessed qualitatively for restrictions assessed to have a major impact on competition.
- Necessity: The question here is whether the restriction is necessary to achieve the legislation's objectives.

### Category 1 - Restrictions on entry, exit and conduct of activities. Conditions and exemptions

#### Licensing and registration

##### Impact

- **MAJOR** - These provisions create potential barriers to entry through licensing and registration requirements by limiting participation to persons, firms or organisations who meet certain defined standards, hold certain qualifications or possess certain experience. Conditions can also be imposed in licences and registrations and authorities also have the power to exempt some persons from these requirements.

##### Advantages

- Only qualified persons with the appropriate knowledge, experience and fitness will be allowed to use or deal with radiation equipment and radioactive substances.
- Conditions can be imposed in circumstances where the risk to public and environmental health and safety is high.
- Public confidence is boosted by certainty in the quality of goods and services. Consumers can feel assured that licences and registrations have been issued only after stringent checks to ensure that the person has complied with all safety standards and equipment has been serviced and maintained to the required standards.
- Consumers have another avenue to seek redress by complaining about practitioners' conduct to government agencies instead of seeking redress only through professional associations or boards.
- The threat of revocation of licence or registration ensure that licensees and registration holders are motivated to maintain safety standards.
- Authorities can maintain a record of all licensees and registrations. This would enable proper audits and safety checks by inspectors and this is in the public interest, as it will ensure high safety standards are maintained.
- Consequently the risk of illness, fatality or injury through the harmful effects of radiation is reduced.

##### Disadvantages

- It could lead to less than optimum number of participants in the market leading to lower productivity due to lack of competition, which can lead to higher costs and higher prices. Lack of competition means firms may not have the incentive to explore more efficient means of service delivery.

## Section 5 – Benefits and Costs of the Restrictions

- Generalisation of risks could lead to over regulation for particular groups of people or equipment.
- Licensing and registration impose entry standards. However, unless adequately monitored, they do not necessarily ensure that the demonstrated standards are maintained throughout the life of the licence or registration.
- Some practitioners already have entry standards imposed by their professional bodies and organisations. They incur additional costs of licensing and registration, which are invariably passed onto consumers.
- Potential operators may be deterred from becoming service providers and this might restrict the choice of consumers.
- Governments incur costs to administer the licensing and registration systems and also to monitor and enforce compliance by practitioners and operators.

### *Necessity*

- It is not possible for a regulatory regime for radiation protection to operate effectively without licensing and registration as a gateway to minimise the risks that the misuse of radiation equipment and radioactive substances can cause to public health and safety or the environment. Agencies need to be able to filter out the unqualified or those with a history of non-compliance.

### Evaluation of category one restrictions

#### *Licensing and registration in general*

On balance the restrictions imposed by licensing and registration requirements are met without great expense or difficulty. The power to impose conditions on licences and registrations is necessary for authorities to exercise effective control. Where exemptions apply, these relate only to persons undergoing training or persons working under the supervision of a licensed person.

The precautionary approach to radiation control necessitates a regulatory approach. This implies that non-regulatory alternatives to licensing regimes are unsuitable. In fact, submissions to the Issues Paper overwhelmingly reject even the consideration of “negative licensing” or “self regulation” alternatives.

The licensing and registration provisions in the legislation provide a framework within which competition among firms can occur without adversely affecting public health and safety and the environment. They do not restrict competition, as there is no quota system.

In fact the restrictions imposed by certain professional bodies for the training and certification of their members are more onerous than the licensing requirements of radiation protection legislation, which are essentially to ensure that authorities have proper records and have control over persons with radiation safety responsibilities.

#### RECOMMENDATION 12

THE CURRENT SYSTEMS OF LICENSING AND REGISTRATION OF OPERATORS, RADIATION EQUIPMENT AND RADIOACTIVE SUBSTANCES ARE TO BE RETAINED.

## Section 5 – Benefits and Costs of the Restrictions

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### *National uniformity in licensing and registration requirements*

A major concern that shows up clearly in the submissions is the need for national uniformity in licensing and registration provisions and the granting of exemptions. This concern is justified. It is evident from the provisions that relate to licensing and registration that they are not written with the aim of achieving national uniformity. The Review Team noted that this issue would be addressed as part of the development of the National Directory for Radiation Protection.

### *Cardiologists*

Another issue that was raised by submissions to the Issues Paper was whether practising cardiologists ought to be licensed or restricted in the way they provided their services.

The issue was raised by a practising cardiologist from Victoria and the Cardiac Society of Australia and New Zealand (Victoria Division). They argued that cardiologists either do not need a licence to operate X-ray imaging equipment or even if they do, they should not be compelled to have a radiographer present at all times.

The Victorian Radiation Advisory Committee (RAC) recently considered the restrictions placed on cardiologists in that jurisdiction.<sup>46</sup> The RAC concluded that in the interest of the safety of patients a medical imaging technologist must be present during radioscopically guided cardiac procedures.

The RAC's view was that a medical imaging technologist can play an active role in controlling dose rates, frame rates, collimation, shielding, quality assurance tests, position of the image intensifier and the establishment of protocols to deliver the lowest radiation dose consistent with image quality.

The RAC also took into consideration the outcome of an action in a US court last year in which a 61-year old man suffered severe radiation burns after two complex angioplasty procedures of 5½ and 3½ hours respectively five months apart. The man was awarded US\$1 million in damages of which 90% was to be paid by the cardiologist.

While the Review Team acknowledges that incidents such as the one that was described above, are not common, it is also noteworthy that cardiac intervention procedures using X-ray imaging equipment is rapidly increasing.

Press reports after the case in the US was decided showed that many angioplasty patients who were interviewed did not even know that they will be exposed to radiation during the procedure. This is an example of a potential or actual market failure (See discussion on information asymmetry problems described in Section 4 above.)

The need to ensure the safety of cardiac patients from the hazards of excessive exposure to radiation during a cardiac procedure

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<sup>46</sup> Annual Report of the Victorian Radiation Advisory Committee, September 2000, p. 10.

necessitates strict controls to be imposed on cardiologists to ensure that all safety procedures are adhered to.

The situation in the other participating jurisdictions is as follows:

- In SA, a cardiologist licensed to operate radiation equipment does not have to have a radiographer present during a procedure that involves radiation exposure to patients. However, many cardiologists have a radiographer present as not many cardiologists in South Australia are licensed to operate radiation equipment.
- In Tasmania, cardiologists who are licensed to operate radiation equipment do not require a radiographer to be present. However, no cardiologist in Tasmania is licensed to operate radiation equipment and as such cardiologists in Tasmania need to have a radiographer present during a procedure that involves radiation exposure to patients.
- In WA, all cardiologists must be licensed to operate radiation equipment and must also have a radiographer present during a procedure that involves radiation exposure to patients.
- In NSW cardiologists who use fluoroscopy equipment are required to be licensed and for certain procedures using high-dose rate fluoroscopy they are also required to have a radiographer present.
- In the ACT all cardiologists must be licensed to operate radiation equipment and must also have a radiographer present during a procedure that involves radiation exposure to patients.
- The NT does not have any cardiologist based in the Territory. Visiting cardiologists perform procedures that involve radiation exposure to patients in public hospitals. As such, a radiographer is invariably present during a cardiac procedure that involves radiation exposure to patients.

The Review Team was not able to find any evidence with which it could conclude that the radiation risks to cardiac patients are so low as to recommend a removal of the licensing of cardiologists or any other restriction imposed on their practice.

However, it is clear that there is merit in ensuring that licensing requirements and the need for a radiographer or medical imaging technologist to be present during a cardiac procedure involving radiation exposure to patients is applied in a nationally uniform manner. The Review Team notes that this will be done as part of the development of the National Directory for Radiation Protection.

### *Dentists*

The Australian Dental Association submitted that there is no need to licence dentists to perform dental radiography or require them to register their X-ray equipment. The ADA argued that routine exposure to dental radiography does not give rise to exposure levels of significant risk to the community.

The Review Team does not dispute the fact that radiation exposure during dental procedures constitutes a low level of exposure and consequently represent only a small risk to patients. It was concluded that a review should be undertaken to assess if there is a case to remove the requirement for dentists to be licensed to operate dental X-ray equipment.

## Section 5 – Benefits and Costs of the Restrictions

However, on the question of registering dental X-ray equipment, it must be noted that information in some annual reports of the authorities showed that registrations of dental X-ray machines had been revoked in the past due to poor service and maintenance of the equipment. The Review Team feels that registration of dental X-ray machines must be retained to enable authorities to ensure that registered equipment are being properly serviced and maintained.

### RECOMMENDATION 13

DENTISTS WILL CONTINUE TO BE LICENSED TO OPERATE RADIATION EQUIPMENT UNTIL THE NEED TO LICENSE DENTISTS IS REVIEWED AS PART OF THE DEVELOPMENT OF THE NATIONAL DIRECTORY FOR RADIATION PROTECTION.

#### *Nuclear medicine professionals*

The Australia and New Zealand Society of Nuclear Medicine (ANZSNM) Accreditation Board pointed out that inconsistencies among legislation across jurisdictions have led to some jurisdictions incorrectly treating a general qualification in medical imaging as sufficient for a person to undertake the duties of a Nuclear Medicine Technologist. The ANZSNM also argued that legislation must recognise the differences in the medical imaging professions (Nuclear Medicine Technologist, Diagnostic Radiographer and Radiation Therapist) and the need for appropriate qualifications for each of these categories.

The ANZSNM's argument is supported. The Review Team has not made a specific recommendation in this regard as it has been told that the discrepancies will be addressed in conjunction with the development of the National Directory for Radiation Protection.

## Category 2 - Strict and prescriptive standards

### Dose limits and maximum exposure levels:

#### *Impact*

- **MAJOR** – The regulatory approach is premised on strict adherence to prescribed dose limits and exposure levels. In principle, this is restrictive. In addition, risks that are overstated would adversely restrict persons and firms.

#### *Advantages*

- The prescribed limits and levels provide a quantifiable measure for users, and facilitate compliance.
- The limits/levels reflect international standards and recommendations enabling Australian agencies to reap the benefits of international research and development for radiation safety and protection.
- Consumers can assess the limits/levels against international benchmarks and feel confident that international benchmarks are being applied.
- Monitoring and compliance activities are made easier for agencies, which will have a firm measure of the dose limits and exposure levels.

## Section 5 – Benefits and Costs of the Restrictions

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### Disadvantages

- Risks may be overstated making compliance more expensive.
- Resources are required to review risk levels to ensure that limits/levels are not set at too high a level.
- A threshold level prescribed as the legally acceptable level, leaves little incentive for industry to ensure dose/exposure is the least possible

### Necessity

- The serious consequences of the risks of excessive dose or exposure to radiation justify the adoption of prescriptive rules as a precautionary approach to regulate radiation protection for public health and safety.

## Alteration, modification or change in information

### Impact

- MINOR – A regulatory regime involving licensing and registrations is meaningless if licensees and registration holders need not seek approval before modifying anything that is the subject of a licence or registration.

### Necessity

- The restriction is in principle only and does not adversely impact competition. It is necessary for the proper functioning of a licensing and registration scheme.

## Storage and disposal

### Impact

- MAJOR – These provisions, being prescriptive and requiring the maintenance of records, may increase compliance costs for firms.

### Advantages

- Although relatively uncommon, there have been instances in Australia of radioactive substances having turned up in public places without explanation. Strict prescriptive rules on storage and disposal provide certainty in the manner in which persons may store or dispose of radiation equipment and radioactive substances.
- Members of the public would feel confident that persons or firms dealing with radioactive substances cannot cut costs by the disposal of radioactive substances without approval or without proper records on the manner in which the disposal had been done.
- Uncontrolled storage or disposal would create externalities that impose costs (clean-up, health etc) if radioactive substances are stored or disposed in a manner that is dangerous to public health and safety and the environment.
- Enables authorities to conduct inspections to ensure that storage and disposal are being done in accordance with approved safety standards.

### Disadvantages

- Persons and firms will incur costs to comply with record keeping and approval requirements. Government agencies would also incur costs to administer the provisions and enforce compliance.

## Section 5 – Benefits and Costs of the Restrictions

### Necessity

- The storage and disposal of radioactive substances and radiation equipment, is critical to public safety and health. Provisions controlling these activities are essential to achieve the objectives of radiation protection legislation.

### Transport

#### Impact

- **MAJOR** – The potential hazards inherent in the transportation of radioactive material has a major impact on public health and safety. There are strict guidelines on transportation activities under the Code of Practice for the Safe Transport of Radioactive Substances 1990, which has been adopted by all jurisdictions. The requirements include standards on packaging, documentation and labelling and the training of transport workers. These requirements involve compliance costs.

#### Advantages

- Prescribing the requirements in a nationally accepted Code enables a common standard to be applied by all jurisdictions. This is useful as transport necessarily involves cross-border activities.
- The public can feel confident that there are strict standards for every activity in the transport chain that pose risks to public health and safety and the environment.
- Persons and firms involved in the use of radioactive substances are able to access a nationally accepted Code that comprehensively covers all aspects of safety in the transport of radioactive substances.

#### Disadvantages

- Prescriptive standards on packaging, documentation, labelling and other activities for the safe transport of radioactive substances necessarily involve compliance costs for firms.
- Governments incur administrative costs for enforcement activities.

#### Necessity

- The transport of radioactive substances is potentially a hazardous activity. If unregulated, it could lead to externalities that could risk public health and safety and the environment. As such, there is a compelling need for legislative intervention.

### Powers of inspection in routine situations and powers to deal with dangerous situations

#### Impact

- **MAJOR** – Enforcing compliance of a regulatory regime through inspectors and authorised officers necessarily involves costs to governments.

#### Advantages

- Governments can ensure that licensees and registration holders continue to comply with provisions in the Acts and regulations and any special condition in licences and registration certificates.
- The powers, which, in emergency situations, can be exercised without a warrant, ensure that public health and safety is protected from unscrupulous operators using unsafe practices.

## Section 5 – Benefits and Costs of the Restrictions

- The extensive powers given to inspectors or authorised officers enable governments to collect evidence for the successful prosecution of offenders. This provides added safeguards to public health and safety.
- The powers to make directions to ensure licensees or registration certificate holders take certain actions or refrain from acting in a certain way is critical to ensure that any harm to public health and safety is minimised or avoided.

### Disadvantages

- Governments have to fund the employment and training of a network of inspectors and authorised officers and this may be more expensive than a competitive system involving audits and reports by certified third parties.

### Necessity

- The breach of any safety regulation that may adversely affect public health and safety through harmful levels of radiation is serious and justifies inspections undertaken through government agency officers.

## Rules and guidelines for radiation workers

### Impact

- MINOR – The provisions in this regard aim to ensure that radiation workers take all necessary precautions to protect their health and safety.

### Necessity

- This involves costs but the provisions impose do not impact adversely on competition and are in the interests of the safety of radiation workers.

## Evaluation of Category 2 restrictions

The Review Team feels the retention of all the provisions under the category of “Strict and Prescriptive Standards” has a net public benefit. Nevertheless, there is a strong case for authorities to review these prescriptive rules to ensure that they are legislated and applied in a nationally uniform manner. The Review Team notes that the issue of national uniformity will be addressed as part of the development of the National Directory for Radiation Protection.

As strict prescriptive rules in the legislation are those that have the most impact on public safety, there is merit in considering a strategy to ensure that the public and consumers, in particular those in rural, remote and indigenous communities, fully appreciate the dangers of radiation and the safeguards in place to protect them.

### RECOMMENDATION 14

JURISDICTIONS TO RETAIN THE PRESCRIPTIVE APPROACH IN THEIR LEGISLATION.

### RECOMMENDATION 15

JURISDICTIONS TO TAKE INTO ACCOUNT THE NEEDS OF RURAL, REMOTE AND INDIGENOUS COMMUNITIES WHEN FORMULATING RADIATION PROTECTION POLICIES.

### Category 3 - Restrictions on advertising and promotional activities.

#### Impact

- **MINOR** – Only one of the eight participating jurisdictions (WA) has a provision that restricts advertising and promotional activities and the impact of the restriction on the economy as a whole is not serious enough for a detailed analysis of this restriction.

#### Advantages/Disadvantages

- There is no justification for any provision to restrict the public from knowing that a person or organisation is fit to hold a licence or registration to use or deal with radiation equipment or radioactive substances.
- Licensing and registration provisions are there to overcome the problem of information asymmetry. As such, it does not make sense to prohibit a person from publicising the fact that the person has been properly licensed or registered by the competent authority.

#### RECOMMENDATION 16

JURISDICTIONS TO REMOVE ANY PROVISION THAT RESTRICTS ANY LICENSEE, HOLDER OF AN EXEMPTION OR REGISTRATION FROM REFERRING TO THAT FACT IN ANY ADVERTISING OR PROMOTIONAL MATERIAL.

### Category 4 - Compliance costs

#### Licences and registrations costs and cost recovery issues

#### Impact

- **MAJOR** – Businesses and individuals are required to pay for the issue (and renewal) of licences and registration certificates. The fact that licences and registrations have to be paid for in each jurisdiction implies additional costs for businesses that operate in more than one jurisdiction.

#### Advantages

- Only qualified persons will be allowed to use or deal with radiation equipment and radioactive substances. Specific risks to public safety can be treated with licence or registration conditions.
- Increased certainty of the quality of goods and services boosts public confidence. Consumers will be assured that providers of goods and services have been subject to stringent checks before they were licensed or registered.
- The threat of revocation of licence or other penalties ensures that licensees and holders of registration are motivated to maintain safety standards.
- The record of licensees and registration holders would enable proper audits and safety checks to be done by inspectors to ensure the continued safety of people and the environment.
- The risk of illness, fatality or injury is reduced.

## Section 5 – Benefits and Costs of the Restrictions

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### Disadvantages

- Applications for licences and registrations involve costs in the form of application and renewal fees. Applicants need to demonstrate that the proposed activities will benefit the public and are not harmful to public health and safety and this involves time and resources.
- The separate licensing and registration regimes in each jurisdiction impose further costs as individuals and firms operating across borders will have to pay for separate licences in each State or Territory.

### Necessity

- Having reached the conclusion that radiation protection requires a regulatory approach, the non-regulatory alternatives, such as, negative licensing or self-regulation, are not feasible or desirable.
- For radiation protection to work within a regulatory environment there is a need for users to be licensed and radiation equipment, radioactive substances and premises of unsealed radioactive substances to be registered.

## Duty to inform

### Impact

- MINOR – An employer or licensee is obliged to ensure that radiation workers are kept fully informed of all possible hazards, safety arrangements, working rules, instructions and the name of the Radiation Safety Officer.

### Necessity

- It is an integral part of fostering a “safety culture” and is a major plank in the achievement of the objectives of radiation protection legislation.

## Duty to ensure compliance

### Impact

- MINOR – Employers are required to take all reasonable care to ensure that every employee or person under his or her control complies with all regulatory requirements.

### Necessity

- This provision falls squarely within the ambit of the precautionary principle. It ensures that employers exercise their duty of care. Any restriction that this requirement imposes is in principle only and would not adversely affect competition by imposing significant compliance costs.

## Safety manuals and safe working rules

### Impact

- MINOR – Employers are required to not just prepare a safety manual but also, in some cases, use prescribed guidelines to prepare them and submit copies for approval.

### Necessity

- This is restrictive in principle only as it is necessary to ensure that legislation, regulations and standards are translated into practical instructions for radiation workers.

### Personal and area monitoring and the record and maintenance of monitoring devices

#### Impact

- MINOR – Employers are required to ensure that relevant employees are issued with personal radiation monitoring devices. They are also required to install devices to monitor certain premises.

#### Necessity

- Such provisions impose compliance costs. However, they are necessary and unavoidable costs of radiation protection and do not restrict competition. Instead they benefit radiation workers.

### Dose or exposure in excess of prescribed limits

#### Impact

- MINOR – An employer, licensee, or employee is obliged to take all reasonable steps to ensure that any worker or person does not receive a radiation dose or is not exposed to radiation levels in excess of prescribed limits.

#### Necessity

- It is based on the principle of fostering a “safety culture”. It entrenches the principle of “duty of care” in legislation and yields a net benefit to the health and safety of radiation workers and other users of radiation equipment or radioactive substances.

### Keeping of records

#### Impact

- MINOR – This involves the keeping of proper records of all radiation equipment and sealed and unsealed radioactive substances and the use to which they have been put and any change in that use.

#### Necessity

- The provisions are critical to radiation safety. The costs that such requirements impose are part and parcel of fostering a safety management culture and do not deter or restrict competition.

### Personal exposure record

#### Impact

- MINOR – Employers are required to ensure that their employees’ personal exposure records are maintained and handed over to appropriate persons.

#### Necessity

- This obligation is a logical extension to the need to provide monitoring devices. It ensures employers exercise their duty of care. The restriction does not adversely affect competition or impose excessive costs.

## Section 5 – Benefits and Costs of the Restrictions

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### Faults or defects

#### Impact

- MINOR – Any fault or defect that an employer or licensee detects in radiation equipment or apparatus has to be investigated and repaired.

#### Necessity

- It is not restrictive, as it does not impose any unnecessary compliance cost. It is of benefit to the public and radiation workers as it ensures that equipment and apparatus are regularly checked and maintained.

### Physical security, display of warning signs and certificates

#### Impact

- MINOR – This is to prevent the theft of radiation equipment or radioactive substances or to prevent access of unauthorised persons to premises in which ionising radiation may be present.

#### Necessity

- It ensures that persons who do not appreciate the dangers of radiation are kept out of premises or areas where they should not be. It ensures the safety of persons and as such is deemed to be of public benefit.

### Fire, loss or theft

#### Impact

- MINOR –The duty to report any fire, theft or loss of radiation equipment and radioactive substances is an important obligation and involves only minor compliance costs.

#### Necessity

- The duty to ensure that any fire, loss or theft of radioactive substances or radiation equipment is reported and directions are complied with is necessary to achieve the objectives of radiation protection legislation. It is critical to protect the public against externalities caused by the theft or loss of radiation equipment and radioactive substances.

### Radiation incidents, accidents or emergencies and the decontamination or acquisition of premises

#### Impact

- MINOR –The obligations placed on authorities, firms and organisations to deal with such radiation incidents or emergencies involve costs.

#### Necessity

- The serious consequences of radiation emergencies require authorities to have the power to acquire and decontaminate premises or serve directions on licensees or registration holders.

### Medical examinations

#### Impact

- MINOR – Medical examinations are an integral part of ensuring the health and safety of radiation workers in the event of a radiation accident or incident.

#### Necessity

- Unless regulated, it would be difficult to ensure that radiation workers do not compromise their own health by not attending medical examinations when there is a need to do so. The regulations also enable authorities to specify the type of medical examination that is required for particular types of exposure. The restriction does not adversely affect competition and is in the interest of employers and radiation workers.

### Actual or risk of exposure in excess of prescribed limits

#### Impact

- MINOR – These provisions enable an authority to stop a radiation worker from performing any further work involving radiation exposure if the worker has been or could be exposed to excessive radiation.

#### Necessity

- The provision protects workers from unscrupulous employers who may continue to expose workers to excessive radiation. It is in the interest of the health and safety of radiation workers and ought to be retained.

### Radiation safety officers and committees

#### Impact

- MINOR– The regulations are very prescriptive in specifying the requirements for the appointment of a radiation safety officer or committee. Several requirements are imposed on employers or licensees as well as the radiation safety officers and committees.

#### Necessity

- Radiation Safety Officers or Committees perform a very important function in the area of safety compliance and training programs. They are also useful contact points for regulatory authorities.
- Legislation on the appointment and functions of Radiation Safety Officers or Committees is considered to be in the public benefit. They are in line with general OH&S standards and are critical to radiation protection in view of the risks involved

### Liability

#### Impact

- MINOR – Employers are forced to employ due diligence or they may find themselves strictly liable for the actions of their employees.

#### Necessity

- This is an extension of the principle of “duty of care” and does not adversely affect competition. Such provisions are of public benefit as they force employers to consider the consequences of their employees’ breaches.

### Offences by corporations

#### Impact

- MINOR – The ability of the law to enforce compliance by the threat of personal sanctions is necessary to ensure that an offender does not hide behind the corporate veil. Individuals run corporations. For the purposes of the law a corporation has a legal personality, but for purposes of radiation protection effective compliance can only be achieved if the threat of sanction is also directed at the individuals who run the corporations.

#### Necessity

- Such provisions are not deemed to be unduly restrictive. It benefits the public by ensuring that offenders are adequately dealt with. The sanctions also provide incentive to officers of corporations to ensure that they and their employees conform to regulations and licence conditions.

### Increased penalty for causing serious harm

#### Impact

- MINOR – Legislation prescribes penalties and sanctions for the breach of conditions in licences and registration certificates, including the revocation of a licence. Increased penalties can be imposed for knowingly causing serious harm.

#### Necessity

- Effective deterrence and enforcement of regulatory controls require stiff sanctions for serious offences. This restriction does not adversely affect competition. It is a legitimate intervention to minimise or avoid the harm that can be caused by externalities. It is of public benefit.

### Recovery of costs and restoration of damaged property

#### Impact

- MINOR – The power to recover the costs of dealing with dangerous situations or breaches of regulation or licence conditions is in line with the “polluter pays” principle.

#### Necessity

- Society should not bear the burden of externalities. This provision is a legitimate legislative intervention to deal with externalities. The restriction is considered to be of public benefit.

### Evaluation of Category 4 restrictions

#### *Compliance costs and cost recovery issues*

Submissions on the issue of compliance costs generally pointed to the fact that compliance costs were not unnecessary and were not excessive. The Australian Nursing Federation (Victorian Branch) pointed out that the safety issues involved outweigh the “relatively negligible costs” of registration and licensing. Dr Gerald Laurence of South Australia submitted that compliance costs are not excessive and are not necessarily avoided in a non-regulatory climate where indirect costs will have to be borne for prudential reasons.

The Review Team concurs that compliance costs incurred to comply with the legislation are not significant and are necessary for the achievement of radiation protection objectives, which are primarily to protect public health and safety and the environment.

The issue of licensees and registration holders having to pay for licences or registrations in every jurisdiction in which they may operate remains of concern. From the discussion in Section 4, it is evident that the current approach to national uniformity (through the National Directory for Radiation Protection) necessitates the maintenance of the existing system of separate licensing and registration regimes in each jurisdiction.

Nevertheless, the mechanism to deal with at least part of the problem is available through the National Directory effort. The National Directory will contain guidelines for achieving uniformity in licensing and registration requirements and procedures. When these provisions are fully adopted consumers and businesses will benefit from uniform requirements and procedures across the jurisdictions.

The Review Team feels that jurisdictions could reach an agreement that obliges a jurisdiction to grant a licence or registration upon demonstration that an inter-State/Territory applicant is the holder of an existing valid licence or registration issued by a competent authority in another jurisdiction. The agreement could be incorporated into the National Directory as an administrative protocol.

#### RECOMMENDATION 17

JURISDICTIONS TO INCORPORATE AN ADMINISTRATIVE PROTOCOL IN THE NATIONAL DIRECTORY FOR RADIATION PROTECTION FOR THE APPLICATION OF MUTUAL RECOGNITION PRINCIPLES TO THE GRANT OF LICENCES AND REGISTRATIONS TO INTER-STATE/TERRITORY APPLICANTS.

On the question of cost recovery there was, on balance, support for the “user pays” principle to ensure that authorities recover the costs of their regulatory oversight functions. However, some activities, such as, public education, emergency action, research and development and maintenance of statutory committees and councils are public goods

## Section 5 – Benefits and Costs of the Restrictions

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that need to be funded by tax payers and authorities should continue to fund these activities.

### RECOMMENDATION 18

JURISDICTIONS SHOULD RECOVER THE COST OF THEIR REGULATORY OVERSIGHT FROM LICENCE AND REGISTRATION FEES EXCEPT FOR ACTIVITIES THAT ARE OF A PUBLIC GOOD NATURE.

#### *National register of radiation incidents*

Efforts to compile a national register of radiation incidents have been ongoing since 1971. However, the task has not been easy, as reporting from the States and Territories has been inconsistent. Differing definitions among jurisdictions on what is a radiation “incident”, “accident” or “emergency” has not helped the effort.

Recently ARPANSA created a computerised database of incidents based on the information reported by States and Territories. The Review Team understands that efforts are already underway to develop procedures for the re-development of the national register. This includes plans to develop common reporting forms with uniform criteria and definitions and a program to generate reports from the database to publish a periodic national register of radiation incidents.

The Review Team stresses that a comprehensive national register of radiation incidents would not only assist in the training of radiation workers but also constitute a useful database for the review of the effectiveness and efficiency radiation protection legislation.

### RECOMMENDATION 19

JURISDICTIONS SHOULD AGREE ON NATIONALLY UNIFORM DEFINITIONS FOR RADIATION INCIDENTS, ACCIDENTS OR EMERGENCIES AND DEVELOP A NATIONAL SYSTEM TO COLLECT AND COLLATE INFORMATION AND PUBLISH A NATIONAL REGISTER FOR RADIATION INCIDENTS.

## SECTION 6 – CONSULTATION

Consultation is mandatory under the guidelines for NCP reviews published by all jurisdictions and the National Competition Council. In addition, COAG's *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies* require extensive consultation with stakeholders

The Steering Committee decided that consultation was necessary if the recommendations of the NCP review are to be credible and meaningful. Accordingly, the Committee decided to publish an Issues Paper for public comment before analysing the legislation to assess its impact on competition.

The Steering Committee acknowledged that it was important to outline only the issues in the Issues Paper without canvassing specific reform options at that stage. This was to avoid any misunderstanding that the Steering Committee had pre-determined views. Discussion papers, albeit controversial, produced by the National Competition Council on the reform of professions in general and health care professionals in particular, were included as attachments to the Issues Paper to encourage debate.

The Issues Paper was advertised nationally in *The Australian* on 16 October 2000 and *The Weekend Australian* on 21 October 2000. A dedicated web page for the NCP Review was created in the ARPANSA homepage and the Issues Paper was made available from this site in Rich Text, MS Word and PDF formats.

The Issues Paper was also sent by email to the following organisations, and, where applicable, to their State/Territory branches or divisions:

- Association of Professional Engineers, Scientists and Managers, Australia (APESMA)
- Australasian Association of Educators in Medical Radiation Sciences
- Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM)
- Australia and New Zealand Association of Physicians in Nuclear Medicine. (ANZAPNM)
- Australian Academy of Science (AAS)
- Australian Academy of Technological Sciences and Engineering (ATSE)
- Australian and New Zealand Society of Nuclear Medicine (ANZSNM)
- Australian Dental Association (ADA)
- Australian Dental Therapists' Association (ADTA)
- Australian Institute of Non-Destructive Testing (AINDT)
- Australian Institute of Physics (AIP)
- Australian Institute of Radiography (AIR)
- Australian Medical Association (AMA)
- Australian Nursing Federation (ANF)
- Australian Physiological and Pharmacological Society (APPS)

- Australian Radiation Protection Society Inc (ARPS)
- Australian Veterinary Association (AVA)
- Australian X-ray Analytical Association (AXAA)
- Cardiac Society of Australia and New Zealand (CSANZ)
- Chiropractors' Association of Australia (National) Limited (CAA)
- Dental Hygienists' Association of Australia (DHAA)
- enHealth Council
- Federation of Australian Scientific and Technological Societies (FASTS)
- Health Insurance Commission (HIC)
- Interventional Radiological Society of Australasia (IRSA)
- National Occupational Health and Safety Commission (NOHSC)
- Royal Australasian College of Dental Surgeons (RACDS)
- Royal Australasian College of Physicians (RACP)
- Royal Australasian College of Surgeons (RACS)
- Royal Australian and New Zealand College of Radiologists (RANZCR)
- Royal Australian Chemical Institute (RACI)
- Royal Australian College of General Practitioners (RACGP)
- Society of Crystallographers in Australia and New Zealand (SCANZ)

Many respondents obtained the Issues Paper by downloading it from the NCP Review website. However, some others requested the Issues Paper to be sent to them. They are:

- Cellsites International
- Medical Applications Pty Ltd
- Australian Nuclear Science and Technology Organisation (ANSTO)
- Andersen Legal
- Jim Brough (Tour Guide – Lucas Heights area)
- Medical Association for Prevention of War
- Chiropractors' Association, Tasmania Branch

A total of thirty (30) submissions were received. Some respondents directly addressed questions posed in the Issues Paper. Some others provided a more general commentary and addressed only specific questions posed in the Issues Paper.

Some submissions were on competition policy in general but outside the scope of this review. These included submissions on ANSTO's services, ARPANSA's GST exempt status (which is currently under review by the Treasurer) and Medicare rebate provisions. These are important issues in themselves. However, they are not related to the NCP review of the legislation listed in the Terms of Reference.

Submissions were also received on whether ARPANSA should also be a service provider. Under Section 15(1)(d) of the ARPANSA Act 1998, one of the functions of the CEO of ARPANSA is "to provide services relating to radiation protection, nuclear safety and medical exposures to radiation". Under Section 15(2) of the Act the CEO must take all reasonable steps to avoid any conflict of interest between the CEO's regulatory functions and the CEO's other functions.

The submissions that proposed that a regulator should not also provide services argued their case by stating that this is unfair competition. Except for those who raised the issue of ARPANSA's GST exempt status, no one provided any evidence to show that the CEO had exercised his functions in breach of Section 15(2).

ARPANSA's GST exempt status could arguably to place it at an advantage. However, it is not the ARPANS Act that confers that advantage. It was a decision by the Treasury. As such, the issue does not fall within the terms of reference of this review which is an NCP review of the stated legislation.

In any case, ARPANSA's GST exempt status is currently under review and is expected to be removed.

Except for two submissions for which permission was not obtained from their originators to make them public, all other submissions have been reproduced at **Attachment 3**, with some minor editorial and style changes to streamline headings, sub-headings and bullet-points. All relevant submissions have been considered. Below is a summary of the submissions on the main issues:

### Objectives of the legislation

- All respondents supported the way in which the legislation stated the objectives, that is, to protect the health and safety of people and the environment. There was no adverse comment on the manner in which the objectives were addressed by the provisions in the legislation or the way in which the jurisdictions were achieving these objectives.
- However, respondents highlighted the inconsistencies among jurisdictions in the way in which they phrased their objectives in the legislation. Respondents stressed the need for objectives to be written into the legislation rather than having to decipher them from other related documents.
- Respondents did not want radiation protection objectives being addressed by other related legislation (such as OH&S Acts) and stressed the need for specific legislation on radiation protection.
- Respondents also encouraged the Review Team to consider market failure and economic problems in the context of the objectives, which have as their paramount aim, the protection of the health and safety of people and the environment from the harmful effects of radiation.

### National uniformity

- Respondents strongly supported the need for national uniformity. Some respondents preferred a national system with one Act that was "mirrored" by all jurisdictions. Nevertheless, most respondents maintained the need for jurisdictions to administer their own licensing and registrations systems even if a national Act was adopted. The general feeling was that jurisdictions are better equipped to effectively monitor compliance and respond to emergencies and crisis situations.
- Although there was overwhelming support for national uniformity, respondents also cautioned against the "lowest common denominator" approach. The general view was that standards might be raised but not lowered to achieve national uniformity.

## Regulation of the occupations

- All the submissions strongly supported the need to regulate occupational groups, medical practitioners and other professionals involved in the use of radioactive substances or radiation apparatus. The general view was that the current system is satisfactory and there is no need for a major overhaul.
- However, some groups, submitted that there was no need to license their professions as their professional training and registration schemes provide adequate control mechanisms for the safe use and handling of radioactive substances and radiation apparatus.
- There were strong views in favour of uniformity and consistency in the manner in which professions involved in the use of radioactive substances and radiation apparatus are classified, licensed or exempted from licensing.

## Restrictions in the legislation

- Respondents strongly felt that restrictions in the legislation should generally be maintained and not even be subjected to a competition policy review. The controls in the legislation were upheld as major planks in public health and occupational safety programs. The general view was that free market forces in the area of radiation protection would inevitably lower standards.
- There were unequivocal calls for no relaxation to current restrictions to the entry of persons or firms or the conduct of their activities, even if better information was made available to consumers to enable them to make informed choices. Instead suggestions were made for the strict enforcement of certain provisions related to storage and disposal and emergency situations, including better communication of such provisions to rural, remote and indigenous communities.
- Respondents did not just want the restrictions to be maintained and strictly enforced. They also wanted restrictions to be applied in a nationally consistent manner attracting higher fiscal penalties, for a wider range of breaches.
- Views on compliance costs were mixed. Many submissions did not even raise the issue of compliance costs. When they did so, they concluded that compliance costs were justified to support government involvement in the regulation of radiation safety. Comparisons were also made to the fact that costs (insurance, etc) cannot be avoided even in a deregulated environment.
- Only a small minority of respondents suggested that compliance costs are excessive. Suggestions were also received on the manner in which compliance costs can be reduced. One suggestion was for accredited commercial service contractors (instead of regulators) to certify equipment.

## Regulatory infrastructure

- There were some calls for the effective separation of regulatory activities from service delivery. The argument was that as many radiation protection services, such as calibration facilities and radiation consultancy, have become increasingly commercialised, a regulator should not also provide services (as ARPANSA does) as this may unfairly advantage the regulator.
- There were some calls for ARPANSA to be a national regulatory body charged with monitoring and compliance audit functions nationally, instead of only over Commonwealth entities.
- There was strong support for prescriptive regulations. Even those who supported performance-based legislation did not detract from the need for prescriptive rules on matters such as dose limits and exposure levels.
- However, in some cases, there was resistance to prescriptive standards that generalised risks, and as such, apparently imposed more onerous

requirements then would otherwise be required. For example, dentists argued that the risk posed by their x-ray equipment is so low that there is no need to register this equipment or license the dentists who use it. There was also resistance to prescriptive controls that imposed rules for such matters as “fixtures, fittings and finishing” in laboratories using unsealed radioactive sources.

- All submissions that addressed the issue of negative licensing or self-regulation were strongly opposed to them. On the contrary there was support for the extension of regulation to certain hazardous non-ionising radiation as well, such as the use of Class 4 lasers. Even where there was some form of limited self-regulation in certain professions, the call was for the maintenance of regulated dose limits and exposure levels.

### Standards and codes of practice

- There was overwhelming support for the need to produce national standards and codes of practice that are referenced uniformly in the Acts or regulations of all jurisdictions. There was also strong support for the adherence to international standards and a centralised system for the development and maintenance (using latest electronic methods) of standards and codes of practice.
- There was support for uniform definitions, in particular of, radiation terms and radiation incidents and emergencies. There were also calls for an effective national incident monitoring system. One submission sought changes to the way in which risks from excessive doses or exposure are operationally defined in legislation.

### Cost recovery

- Responses on this issue were mixed. Some submissions called for full cost recovery. Some others urged partial cost recovery, with Governments continuing to fund activities such as emergency response and public education.
- One submission sought substantial fines for non-compliance and minimal cost recovery for administrative activities. However, there was also an opposing view that cost recovery through only substantial fines for non-compliance might leave Governments without funds for their regulatory role if and when licensees achieve full compliance.