



Australian Government

Australian Radiation Protection and Nuclear Safety Agency

**Regulatory Impact Statement
FINAL**

**National Directory for Radiation Protection
Edition 1.0**

Table of Contents

Background	3
<i>National Directory for Radiation Protection.....</i>	<i>3</i>
<i>National Competition Policy Review of Radiation Protection.....</i>	<i>4</i>
Statement of the Problem.....	5
Objective.....	5
Options.....	5
Impact Analysis.....	6
Affected Parties.....	6
Structure of the Directory and Relevance to Impact Analysis.....	7
Impacts of requirements in Part A of the Directory.....	8
<i>Objective of radiation protection legislation.....</i>	<i>8</i>
<i>Principles for regulatory frameworks.....</i>	<i>9</i>
<i>Powers and functions conferred by legislation.....</i>	<i>9</i>
<i>Advisory body.....</i>	<i>10</i>
<i>Review of legislation.....</i>	<i>10</i>
<i>Practices to which legislation applies.....</i>	<i>12</i>
<i>Categories of authorisation.....</i>	<i>13</i>
<i>Suspension or cancellation of a licence, registration or accreditation.....</i>	<i>13</i>
<i>Annual Reports.....</i>	<i>14</i>
Impacts of requirements in Part B of the Directory.....	14
<i>Exclusions.....</i>	<i>14</i>
<i>Exemptions.....</i>	<i>14</i>
<i>Mutual Recognition Principles.....</i>	<i>18</i>
<i>Competency Requirements.....</i>	<i>19</i>
<i>Services for rural and remote areas.....</i>	<i>20</i>
<i>Criteria for registration.....</i>	<i>20</i>
<i>Accreditation of third party service providers.....</i>	<i>22</i>
<i>National Adoption of Codes and Standards by direct referencing.....</i>	<i>22</i>
<i>National adoption of extracts of Codes and Standards.....</i>	<i>28</i>
<i>Adoption of National radiation incident reporting framework.....</i>	<i>28</i>
Consultation.....	31
Recommendations.....	33
National Competition Principles Statement.....	33
Implementation and Review.....	34
References.....	34

Background

- 1 In July 1998, the Australian Health Ministers' Conference endorsed the McNulty Report¹, which provided broad recommendations on a new 'model' radiation protection regulatory framework for Australia. As the report did not address legislative or administrative means for achieving national uniformity, Ministers asked that a panel, comprising representatives from the States, Territories and the Commonwealth, be formed to progress national uniformity. The National Uniformity Implementation Panel (Radiation Control) [NUIP(RC)] was formed in 1998, and subsequently became a working group of ARPANSA's Radiation Health Committee (RHC).
- 2 The NUIP(RC) found that national uniformity can be achieved with either template, mirror or complementary legislation but this would require jurisdictions to overhaul their existing legislative frameworks. National uniformity could also be progressed through non-legislative options, such as national standards and mutual recognition, which could facilitate uniformity without substantial legislative changes.
- 3 Two jurisdictions opposed the use of legislative methods for achieving national uniformity. Some other jurisdictions expressed reservations about the value of national legislation in radiation protection. As such, the NUIP(RC) recommended a non-legislative approach for the short to medium term and proposed the development of a national guidance document, the National Directory for Radiation Protection (the Directory) that could detail agreed principles, policies and practices for radiation protection and the safety of radioactive sources.
- 4 The Directory was envisaged by the NUIP(RC) to be a 'dynamic' document that would change over time as jurisdictions reached new agreements. All jurisdictions agreed to use the Directory to make changes to existing legislative frameworks to achieve a higher degree of national uniformity.

National Directory for Radiation Protection

- 5 The proposal for the Directory and a process for issues resolution received Ministerial approval at the Australian Health Ministers' Conference on 4 August 1999. Ministers affirmed the following approach:
 - (a) The development of a national guidance document called the *National Directory for Radiation Protection* to provide an overall agreed framework for ionizing and non-ionizing radiation safety, together with clear regulatory statements that can be adopted within existing Commonwealth and State/Territory legislative frameworks.
 - (b) The development and amendment of the Directory is to be managed by the RHC, with decisions on the contents of the Directory to be taken by the RHC via the approved process for issue resolution by a majority vote of 10 out of the 13 RHC members following full consultation with relevant stakeholders, including advisory councils in the jurisdictions.
 - (c) Final changes to the directory are to be approved by Australian Health Ministers' Conference, upon which, the provisions of the Directory and the regulatory elements of the Directory shall be adopted in each jurisdiction as soon as possible, using existing Commonwealth/State/Territory regulatory frameworks.
 - (d) Other agencies with a legislated responsibility for aspects of radiation safety (for example, mines, occupational health and safety and transport agencies in many jurisdictions), are to be actively involved in measures to progress national uniformity, including the development of the Directory.

¹ *Guidance for the Development of a Uniform National Framework for Radiation Protection*, by Dr J McNulty, ("The McNulty Report") October 1997

- (e) The adoption of uniform national regulatory controls (for example, through 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 planned national competition policy review of radiation protection.²

National Competition Policy Review of Radiation Protection Legislation

6 All jurisdictions, except Queensland³ participated in the review, which commenced on 8 August 2000. ARPANSA coordinated the review. On 30 May 2002, the Australian Health Ministers' Advisory Council (AHMAC) approved the recommendations and an Implementation Plan. The AHMC endorsed the recommendations and the Implementation Plan out-of-session in September 2002. Subsequently, all jurisdictions endorsed the report. The Office of Regulation Review accepted the analysis of the final report of the NCP Review as meeting COAG's regulatory impact statement requirements, commensurate with the likely impacts of the review's recommendations. The recommendations, several of which are relevant to the Directory, are as follows:

- (1) Jurisdictions are to ensure that the objectives of their radiation protection legislation include the goal of protecting the health and safety of people and the environment from the harmful effects of ionising and non-ionising radiation.
- (2) Jurisdictions are 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 are to include nationally consistent provisions in radiation protection legislation to protect people from the harmful effects of non-ionising radiation.
- (4) Jurisdictions are to retain the regulatory approach to achieve radiation protection objectives.
- (5) Jurisdictions are to consider using performance-based approaches where appropriate (that is, description of outcomes rather than the prescription of required action) based on risk management principles and all applicable quality and process standards. This is to be done in a nationally uniform manner within the framework of the National Directory for Radiation Protection.
- (6) Jurisdictions are to incorporate risk management principles in the National Directory for Radiation Protection.
- (7) Jurisdictions are 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 are to legislate to review their radiation protection legislation at intervals of no more than 10 years.
- (9) Jurisdictions are 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.

² The Final Report of the National Competition Policy Review of Radiation Protection Legislation (May 2001) recommended the continued development of the National Directory to achieve national uniformity in radiation protection frameworks across jurisdiction. Many other recommendations of the Review involve the use of the National Directory.

³ Queensland did not participate as it had completed a similar review for its regulations in 1999

- (12) The current systems of licensing and registration of operators, radiation equipment and radioactive substances are to be retained.
- (13) Jurisdictions are to review the need to license dentists as part of the development of the National Directory for Radiation Protection.
- (14) Jurisdictions are to retain the current prescriptive approach in their legislation, while making efforts to move towards a performance-based approach as required under Recommendation 5.
- (15) Jurisdictions are to take into account the needs of rural, remote and Aboriginal and Torres Strait Islander communities when formulating radiation protection policies.
- (16) Jurisdictions are 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 are 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 of the regulatory authorities that are of a public good nature.
- (19) Jurisdictions should agree on a nationally uniform system of classification for radiation incidents, accidents or emergencies and develop a cost-effective national system to collect and collate information and publish a national register for radiation incidents.

Statement of the Problem

- 7 The lack of national uniformity in radiation protection legislation adversely impacts on the effectiveness and efficiency of the administration of radiation protection legislation among jurisdictions. In particular, the lack of national uniformity in licensing, registration or exemption provisions for radioactive sources, radiation equipment and apparatus and occupational groups poses difficulties for users who have to comply with different requirements when operating across jurisdictions or when relocating from one jurisdiction to another. This could be expected to result in higher costs being passed on to those businesses which are the end users, and at the end of the day, to the community.
- 8 Some parts of the regulatory frameworks in individual jurisdictions in Australia are also out of step with the most up-to-date international guidelines aimed at protecting the health and safety of workers, the public and the environment.

Objective

- 9 To provide nationally uniform requirements in a cost effective manner for the protection of people and the environment against the harmful effects of ionizing and non-ionizing radiation.

Options

- 10 This regulatory impact statement will only examine the proposed contents of edition 1 of the Directory, with a view to examining its benefits and cost or other impacts on regulators, businesses and the community, and demonstrating that its benefits exceed its costs. The RIS does not consider other options for achieving uniformity, which had already been examined when the Ministers approved the development of the National Directory in August 1999.

Impact Analysis

Affected Parties

11 The main affected stakeholder groups are:

- (a) Regulatory agencies in each State and Territory and the Commonwealth.
- (b) People who make direct use of radiation in their employment (about 45,000) such as licensees and holders of registration for radioactive sources, radiation equipment and apparatus. 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.
- (c) People who do not directly use radioactive sources, radiation equipment or apparatus but who could be affected by the operation of such equipment in their workplace (about 100,000). The majority of these people are health workers.⁴ Other occupational categories which use radiation sources in their work, include people whose work is related to the following:
 - 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;
 - consumer products (for example, smoke detectors and thoriated gas mantles); and
 - scientific research and teaching.
- (d) The holders of registrations⁵ for a wide variety of medical and industrial equipment and material. 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. The following table⁶ provides the total number of licences and registrations⁷ issued by the various jurisdictions:

Jurisdiction	Total number of licences and registrations
Queensland	24535
New South Wales	17848
Victoria	10754
South Australia	6080
Western Australia	4093
Tasmania	1395
Australian Capital Territory	681

⁴ *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 formed under the ARPANS Act 1998, p. 3

⁵ The holder of a registration is often the owner of the apparatus, or the person responsible for its management. This is distinct from the operators listed in (b), although in small practices the holder of the registration may also be an operator and hold a licence for this purpose as well as the registration.

⁶ Source: *National Competition Policy Review of Radiation Protection Legislation – Final Report*, ARPANSA, May 2001, p.14, with figures from Queensland added.

⁷ Includes operator licences, equipment and substance registrations, management licences and registration of premises.

Northern Territory	478
Commonwealth	313
Total	66177

- (e) The public who may live or work in the vicinity of radiation installations, or be exposed to radiation as patients in medical procedures.

Structure of the Directory and Relevance to Impact Analysis

- 12 The Directory is structured in three main parts, followed by Schedules and Annexes.
- Part A of the Directory sets out the General Principles that all jurisdictions should follow in establishing or modifying their regulatory frameworks. It is largely derived from international guidance, however there are some areas where regulatory impacts may occur and these have been analysed.
 - Part B of the Directory sets out the uniform regulatory elements that all jurisdictions will adopt under the 1999 agreement by Health Ministers. This is the main area of the Directory where regulatory impacts could occur in some jurisdictions, and is the main area subject to analysis in this regulatory impact statement.
 - Part C of the Directory sets out guidance for best practice. This material will assist regulators in adopting consistent approaches to radiation protection issues, but does not include regulatory material for adoption by jurisdictions, and therefore has no regulatory impact. This Part is not considered further in this regulatory impact statement.
 - Schedules to the Directory provide detailed material that supports the uniform regulatory elements in Part B of the Directory, and is therefore also for adoption by jurisdictions within their regulatory frameworks.
 - Annexes to the Directory provide additional material explaining the background to the provisions of the Directory. Annexes do not include regulatory material and are not considered further in this regulatory impact statement.
- 13 Edition 1 of the Directory deals with many of the 19 recommendations of the NCP Review of Radiation Protection Legislation. These 19 recommendations were distilled into 12 projects for implementation. Four of these projects were for individual jurisdictions to deal with, while 8 were national projects relevant to uniformity. Of these 8 projects, Edition 1 of the Directory implements the recommendations as outlined in the following table:

Project	Details	Progress and status with respect to Edition 1 of Directory
Fractionation	Dealing with duplication and discrepancies between radiation protection legislation and other industry specific legislation within a jurisdiction (eg, radiation safety, mining, occupational health & safety).	Report from NUIP(RC) expected in March 2004, for consideration in later editions of the Directory.
Regulatory Styles	Consideration of performance-based versus prescriptive approaches.	Consultant's Report received in early 2004, for consideration in later editions of the Directory.

Regulatory Impact Statement – Final
National Directory for Radiation Protection - Edition 1.0

Third-party certification	Developing a nationally consistent approach to third-party certification systems.	Consultant's report due in early 2004, for consideration in later editions of the Directory.
National Uniformity	Implementation of the National Directory.	Will be completed with promulgation of Edition 1.
Occupational licensing	Review of provisions for licensing occupational groups using radiation.	Several groups are included in Edition 1 of the Directory and further work will be undertaken by NUIP(RC) for later editions of the Directory.
Regional communities	Establishing principles to ensure policies address the needs of rural, remote and Aboriginal and Torres Strait Islander communities.	Provisions in edition 1 of the Directory address radiology services in rural and remote areas. A report from NUIP(RC) is expected in March 2004, to develop this issue further in later editions of the Directory.
Trans-boundary Issues	Examining overlap between jurisdictions, and mutual recognition issues.	Edition 1 addresses this matter by establishing competencies and criteria for uniform application. This will be developed further in later editions of the Directory, following an NUIP(RC) report in 2004.
National Incident Register	Developing a national system for incident reporting for radiation incidents.	A system for incident reporting is included in Edition 1 of the Directory.

- 14 As the Directory will be a dynamic document, updated regularly as new agreements are reached between jurisdictions, Edition 1 is not fully comprehensive. Throughout Edition 1 there are notes in italics, which indicate the further work to be undertaken and included in later editions of the Directory. It is recognised that the full benefits of uniformity will not accrue until all of the areas where there is a lack of uniformity of some substance have been addressed. In particular, a range of Codes and Standards will be incorporated in future editions as they are published, criteria for licensing for additional occupational groups, criteria for registration, security provisions for radioactive sources, provisions on accreditation of third party service providers, and additional guidance for best practice will be added. Each new edition of the Directory will be subject to regulatory impact assessment.

Impacts of requirements in Part A of the Directory

Objectives of radiation protection legislation

- 15 Section 2.1 requires every jurisdiction to ensure that the objectives of radiation protection legislation aim to achieve the “protection of the health and safety of people and the environment from the harmful effects of ionizing and non-ionizing radiation”. Having a consistent objective across jurisdictions ensures that jurisdictions’ efforts to promote uniformity in their legislative frameworks are not thwarted by the inability to cover a particular area. The comprehensiveness of an objective statement is important as other provisions in legislation and policy options for radiation safety administration will be judged against the objectives of the legislation. This requirement does not impose any compliance cost on industry and businesses, but does impose the cost of a

minor change to legislation in a few jurisdictions. It also implements Recommendation 1 of the final report of the NCP review of radiation protection legislation, which has been agreed to by jurisdictions and endorsed by the AHMC.

- 16 While having a broad objective of this type allows the implementation of further policy options and regulation not currently contemplated in some jurisdictions, all proposals for further regulation via the Directory would be accompanied by cost/benefit analysis demonstrating that its benefits outweigh its costs.

Principles for regulatory frameworks

- 17 The principles that underpin radiation safety requirements in the radiation protection legislation of all Australian jurisdictions are stated in section 2.2. These principles are established in international recommendations and guidelines adopted by authoritative bodies such as the International Commission on Radiological Protection (ICRP) and International Atomic Energy Agency (IAEA). The statement of these principles at the outset in the Directory ensures that these requirements are formalised in the Directory in order to underpin the regulatory framework in every jurisdiction. The principles do not add anything new, although there is an increased emphasis on the security of radioactive sources, arising from international efforts to reduce the risk of terrorists obtaining radioactive material. These principles are put into effect and impacts analysed in other areas of the Directory.

Powers and functions conferred by legislation

- 18 Section 2.3 requires jurisdictions to ensure that legislation establishes an “effectively independent” regulatory authority accountable to a Minister of the Crown and through that Minister to Parliament. This raises the question of the need for a regulatory approach to radiation protection. The NCP review considered radiation risks and potential or actual market failure in the context of the objectives of the legislation to protect the health and safety of people and the environment, information asymmetry problems, and Australia’s international obligations and concluded that there are net benefits from retaining a regulatory approach to radiation protection⁸. Under Recommendation 4 of the NCP review report jurisdictions are to retain the regulatory approach to achieve radiation protection objectives. This recommendation has been agreed to by jurisdictions and has been endorsed by the AHMC.
- 19 “Effectively independent” is derived from international specifications for regulatory authorities⁹ and means that the regulator should have independence from “...organisations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. This is so that regulatory judgements can be made, and enforcement actions taken, without pressure from interests that may conflict with safety.” In Australia’s case all of the radiation protection regulators are within Health portfolio structures or Environment Protection Authorities, so there would be no need to establish separate bureaucracies, or make any significant adjustment to meet this requirement. Similarly, there is no need to restructure mining or occupational health and safety regulators who have responsibility for aspects of radiation protection

⁸ See *National Competition Policy Review of Radiation Protection Legislation – Final Report*, ARPANSA, May 2001, pp 22-30. (Recommendation 4)

⁹ IAEA, *Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*, GS-R-1, 2000.

in some jurisdictions. Placing this requirement in the Directory purely guards against any future changes diminishing the independence of the regulatory authority.

- 20 Section 2.3 also lists the powers and functions that legislation must confer on an authority. Many of the powers and functions in this list already exist in jurisdictions' existing legislation and their inclusion in the Directory merely formalises the requirement. The listing of the powers and functions to be conferred by legislation is not likely to impose any significant administrative costs on regulators as only some of them would have to make very minor changes to their legislation. However, the list would benefit businesses using radiation as they could be assured that what is covered by legislation in one jurisdiction is also covered in another.
- 21 The main impact likely to arise in future from the powers listed under section 2.3, is the provision to regulate the categories of non-ionizing radiation specifically identified in Schedule 2 of the Directory. However, as no specific categories are included in Schedule 2 in edition 1.0 of the Directory, analysis of the impacts of regulating non-ionizing radiation will be undertaken on future editions of the Directory when specific categories of non-ionizing radiation have been identified. The need for regulatory control over areas such as the use of high-powered lasers, radiofrequency devices, ultraviolet radiation all need to be considered. Some jurisdictions regulate these areas already, while others do not.

Advisory body

- 22 Section 2.4 states that radiation protection legislation should make provision for the establishment of an advisory body to provide the regulatory agency and the relevant Minister with impartial policy advice in relation to radiation health matters such as the operation and application of the legislation. International guidance on national regulatory infrastructure for radiation protection recommends the use of advisory bodies to bring "broad perspectives to bear on the formulation of regulatory policy and regulations" and help to "assure that policies and regulations are clear, practical and complete". The guidance material also states that the use of advisory bodies "should result in regulations, which represent a good compromise between the needs of the regulated authority and the requirement for strict regulatory control¹⁰. This requirement does not impose compliance costs on industry. It is also a recommendation and not a mandatory requirement for regulators.
- 23 Northern Territory is the only jurisdiction not having a body of this type at present, although the roles and functions of bodies vary between jurisdictions, from a Council that is the regulatory body in WA, to Committees with an advisory role only, eg Victoria. As this is a recommendation only, individual jurisdictions can consider the costs and benefits of maintaining an advisory body in relation to their jurisdictions needs.

Review of legislation

- 24 Section 2.5 states that legislation must provide for the review of radiation protection legislation at intervals of not more than 10 years. This is to ensure that legislation is kept up-to-date. Although it does impose costs on regulators, such as the cost of

¹⁰ *Organisation and implementation of a national regulatory infrastructure governing protection against ionizing radiation and the safety of radiation sources: Interim report for comment*, IAEA-TECDOC-1067, February 1999, pp. 23-24.

undertaking a review, such costs are necessary for good regulatory practice. It imposes some cost on industry and the community in providing information and views as part of the review process, but benefits industry and the community by ensuring that legislation is kept up-to-date and relevant to their needs. It is in accordance with Recommendation 8 of the NCP review, which has been agreed to by jurisdictions and endorsed by AHMC in September 2002. A summary of the current principal radiation protection legislation in each jurisdiction appears in the table below [in some jurisdictions, there is additional legislation which covers some aspects of radiation protection (eg mining legislation, occupational health and safety legislation)].

State/Territory	Title of Act/Regulations
ACT	Radiation Act 1983 Radiation Regulations 2002
Commonwealth Commonwealth	Australian Radiation Protection and Nuclear Safety Act 1998 Australian Radiation Protection and Nuclear Safety Regulations 1999 Australian Radiation Protection and Nuclear Safety (Licence Charges) Act 1998 Australian Radiation Protection and Nuclear Safety Regulations (Licence Charges) 2000
New South Wales	Radiation Control Act 1990 Radiation Control Regulation 1993
Northern Territory	Radiation (Safety Control) Act 1978 ¹¹ Radiation (Safety Control) Regulations 1980
Queensland	Radiation Safety Act 1999 Radiation Safety Regulation 1999
South Australia	Radiation Protection and Control Act 1982 Ionizing Radiation Regulations 2000 Radiation Protection and Control (Transport of Radioactive Substances) Regulations 2003
Tasmania	Radiation Control Act 1977 Radiation Control Regulations 1994
Victoria	Health Act 1958 (as amended) Health (Radiation Safety) Regulations 1994
Western Australia	Radiation Safety Act 1975-1981 Radiation Safety (General) Regulations 1983-2003 Radiation Safety (Transport of Radioactive Substances) Regulations 2002 Radiation Safety (Qualifications) Regulations 1980-2000

25 It should be noted that NSW has already made changes to its Act and Regulations that require it to adopt the provisions of the Directory, when finalised.

¹¹ In NT a new Bill proposed to update the Act is scheduled to be put before Parliament during 2004.
January 2005

Practices to which legislation applies

- 26 Under section 2.6, legislation must apply to a defined set of practices. Having already established the need for jurisdictions to ensure that there is legislation in place to control radiation practices; this section establishes a list of radiation practices to which the legislation must apply. Prescribing this list in the Directory ensures that the legislation of all jurisdictions covers a certain minimum set of practices. When implemented by all jurisdictions, this will ensure a high degree of uniformity.
- 27 In considering the costs and benefits of the set of practices specified in the Directory, the practices that fall within current legislative requirements of all jurisdictions must be compared with those in the Directory.
- 28 The following table analyses the impacts of provisions (a) – (j) of section 2.6, based on advice of the current requirements of all jurisdictions.

Provision in section 2.6	Impacts
(a) manufacturing or possession of radiation sources	All jurisdictions already have such a provision, so there is no impact.
(b) use of radiation or radioactive material for medical, dental, industrial, veterinary or agricultural purposes, in consumer products, education, training, research, or any practice which involves or could involve exposure to radiation or radioactive materials	All jurisdictions have requirements covering the practices specified; hence there would be no impact.
(c) preparation of a site for construction operation, modification, decommissioning or release from regulatory control of nuclear installations, and radiation facilities specifically identified in this Directory	Some jurisdictions do not have explicit provisions of this sort. Both Vic and NSW have legislation prohibiting certain nuclear installations. Introduction of a requirement of this type has the benefit of ensuring that there is thorough assessment of proposals for major facilities at all stages of development. In view of the small number of such facilities in Australia, it would have limited impact on the jurisdictions needing to make adjustments to their present requirements (ACT, Vic). NT is already proposing to include such a requirement in the revision of its Act.
(d) practices involving exposure to natural sources specified by the Authority as requiring control	NSW and ACT do not have explicit provisions of this type, however as no practices have been specified, the impacts cannot be analysed. It is anticipated that such practices would be identified in future editions of this Directory and any impacts would be analysed at the time these practices are proposed.
(e) practices dealing with radioactive material arising from exploration, mining, mineral processing or petroleum industries	Only ACT does not have such provisions, as they are not relevant to that jurisdiction. Hence there would be no impact.
(f) practices involving radioactive waste management and the disposal of radioactive material	All jurisdictions already have such a provision, so there is no impact
(g) practices involving categories of non-ionizing radiation apparatus specifically identified in this Directory	Currently, no non-ionizing radiation practices have been specified in Schedule 2 of the Directory. The impacts of this provision will be analysed in future editions of the Directory when practices are identified in Schedule 2.
(h) sale or transfer of responsibility of ionizing radiation sources and categories of non-ionizing radiation apparatus specified in this Directory	All jurisdictions have provisions for ionizing radiation, but not all jurisdictions have provisions for non-ionizing radiation. Hence there is no impact for ionizing radiation, and the impact for non-ionizing radiation will be analysed when specific categories are identified in future editions of the Directory.
(i) transport of radioactive material	All jurisdictions already have such a provision, so there is no impact.
(j) any other practices specified by the Authority	This general provision allows the regulator to ensure that any new (or previously unidentified) practices using radiation can be brought under regulatory control without delay. It is expected that such actions would only be taken where the public health benefit clearly outweighs any costs, and as jurisdictions already have powers to control practices leading to radiation exposure, the impact is likely to be low. While this provision has potential to lead to non-uniformity, the flexibility is necessary, and it is intended that actions under this provision would be considered at the national level for

	inclusion in future editions of the Directory, and subject to regulatory impact assessment as part of that process.
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- 29 As can be seen from the table above, the costs involved for regulators are minimal as many regulators already cover most, if not all, of these practices and any required amendment to legislation will be small. Introduction of these provisions in the Directory will also benefit other stakeholders as someone who is operating across jurisdictions will have a reasonable amount of certainty on the practices that are likely to be covered by legislation in another jurisdiction. Similarly, overseas companies doing business in Australia will benefit as practices in all jurisdictions will be similarly regulated. Less effort will therefore be required to determine what is necessary to comply.

Categories of authorisation

- 30 Section 2.7 describes the types of authorisations for which the legislation must provide. An authorisation to possess must be obtained by any natural person or corporation to possess, be in control of a radiation source, or be responsible for a practice. An authorisation to use must be obtained by any natural person who wishes to use a radiation source for particular purpose, and who is not otherwise covered under an authorisation to deal. An authorisation must also be obtained for any other dealing with a radiation apparatus or radioactive source, for example siting, design, construction, installation, operation, maintenance, modification, decommissioning, release for unrestricted access, and disposal of nuclear installations and radiation facilities.
- 31 The necessity for this section flows from the need to have a regulatory regime that provides for the issuing of authorisations. Again, a clear definition of the types of authorisations that legislation must provide for assists regulators and streamlines the regulatory requirements for potential applicants.
- 32 While there are a number of categories of authorisation in the Directory, the categories requiring individual authorisation are limited to those uses of radiation where regulatory experience and/or the recommendations in international guidelines show it to be necessary for an adequate level of protection of public health and safety. There are a range of uses of ionizing radiation where individual authorisation is not required (eg radiation gauges in industry). The level of authorisation required in particular situations is subject to review as part of the process of developing the Directory.
- 33 The impact of this provision describing the types of authorisation is minimal given that in each jurisdiction there are licensing systems of similar type already operating. The impacts of the provisions relating to the different categories are discussed later in this statement under headings on authorisation, licensing and registration.

Suspension or cancellation of an authorisation

- 34 Section 2.8 requires all jurisdictions to suspend or cancel an authorisation in certain circumstances. Again, the listing of these circumstances ensures the uniform application of this power by all jurisdictions. The requirement is not new and formalises existing legislated arrangements in the Directory to ensure uniformity. It does not impose additional compliance costs and benefits the community by ensuring that radiation practices are conducted safely and in accordance with legislative provisions, radiation protection standards or licence conditions.

Annual Reports

- 35 Section 2.9 indicates the typical provisions that should be included in an Annual Report of the Authority. As it is a statement of principle that aims to achieve some consistency in reporting between Authorities, and as the information proposed is readily available in all jurisdictions, it has minimal impact on regulators. It does not require any new information from industry and hence has no impact on industry.

Impacts of requirements in Part B of the Directory

Exclusions

- 36 Any exposure whose magnitude or likelihood is essentially not amenable to control through legislation (eg cosmic radiation at the surface of the Earth) must be excluded from the operation of the legislation. Section 3.1 lists those radiation exposures that are to be excluded from legislation. This is in accordance with international guidelines¹² and there is no adverse impact on regulators or other stakeholders. Additional exclusions for exposures not amenable to control may be added to the list in future editions of the Directory.

Exemptions

- 37 Regulatory frameworks in all jurisdictions define a radioactive material, sometimes generally and sometimes with an activity concentration prescribed in regulation, and separately list exemption levels based on an activity in the regulations. The table below summarises the definitions of radioactive material.

State/Territory	Radioactive Material Definition in Act	Single Activity/Activity Concentration Limit for Radionuclides in Regulations
ACT	General Definition	4 kBq
Commonwealth (ARPANSA)	Not defined	No ¹³
New South Wales	>Prescribed Amount (specific activity) AND >prescribed activity in regulations	100 Bq/g
Northern Territory	General Definition	10 µCi (370 kBq)
Queensland	General definition	No ¹³
South Australia	General Definition	35 kBq/kg
Tasmania	General Definition	31 Bq/kg
Victoria	>Prescribed amount OR >Prescribed circumstances	30 Bq/g
Western Australia	General Definition	30 kBq/kg

¹² *Organisation and implementation of a national regulatory infrastructure governing protection against ionizing radiation and the safety of radiation sources: Interim report for comment, IAEA-TECDOC-1067, February 1999, p.8.*

¹³ Regulations include an exemption list with a separate activity and activity concentration for each radionuclide.

- 38 The approach to definition of radioactive material and exemption limits in international recommendations is to define radioactive material generally and to list individual exemptions for each radionuclide, rather than have a single limit applying to all radionuclides as a number of jurisdictions have at present.
- 39 Section 3.2 of the Directory provides for exemptions from licensing, registration, approvals or other authorisation provisions in legislation. The general criteria for granting an exemption is stated in section 3.2.1 of the Directory, and is based on internationally accepted principles¹⁴. The exemption levels for activity and activity concentration for particular radionuclides as provided for in section 3.2.2 (and Schedule 3) of the Directory are also based on internationally accepted principles¹⁵.
- 40 Despite this approach, the exemption limits have still been the subject of considerable comment, particularly in relation to the exemption limits for natural materials. The discussion draft of the Directory included a provision applying the factor of 10 allowance used in the Transport Code¹⁶ for natural materials. One view expressed was that this provision would allow situations where large quantities of natural radioactive materials could cause significant doses to workers and the public if the factor of 10 remained. An opposing view that the international system led to exemption levels that were too low for natural materials was also expressed in comment. As a result the factor of 10 was removed from the Directory and the exemption levels in Schedule 11 reflect those agreed internationally.
- 41 In Australia, the exemption levels adopted by jurisdictions in regulation vary considerably, reflecting the different approaches to exemption taken at the times the regulations were developed. Some of these approaches rely on radiation protection philosophy and methodology that dates back many years and is no longer consistent with current philosophy and practice.
- 42 The Directory includes exemption levels for over 300 radionuclides along with two “catch-all” clauses for unlisted radionuclides, so it is not practical to attempt to identify the impact of the change in level for each radionuclide over all 9 jurisdictions; however an analysis for some commonly used radionuclides follows.
- 43 A comparison of the exemption limits used by Australian jurisdictions with the international limits published by the International Atomic Energy Agency and those proposed for the Directory for some of the most commonly used radionuclides appears in the table below.

Comparison of Directory Exemption Levels with current jurisdiction levels and IAEA exemption levels											
(MBq)											
	Directory	IAEA	ACT	NSW	NT	QLD	SA	TAS ¹⁷	VIC	WA	CWLTH
Cobalt-60	0.1	0.1	0.04	0.4	0.37	0.1	0.05	0.0029	0.04	0.04	0.1
Caesium-137	0.01	0.01	0.04	0.4	0.37	0.01	0.05	0.00077	0.4	0.4	0.01

¹⁴ IAEA Safety Series No. 89 (1988)

¹⁵ IAEA Safety Series 115, Schedule 1, Table I-1.

¹⁶ *Code of Practice for the Safe Transport of Radioactive Material*, 2001.

¹⁷ The Tasmanian levels are based on 1/2000th of the most restrictive Annual Limit on Intake (ALI) for that radionuclide. As ALI based on ingestion/inhalation pathways only, the limits are very restrictive when compared with systems that take into account a range of exposure scenarios.

Regulatory Impact Statement – Final
National Directory for Radiation Protection - Edition 1.0

Iodine-131	1	1	0.04	0.4	0.37	0.1	0.05	0.00045	0.04	0.04	1
Americium-241	0.01	0.01	0.004	0.04	0.037	0.01	0.005	0.00005	0.004	0.004	0.01
Technetium-99m	10	10	4	40	Not listed	10	5	0.45455	4	4	10
Strontium-90	0.01	0.01	0.04	0.4	0.37	0.01	0.05	0.00036	0.004	0.004	0.01
Thallium-204	0.01	0.01	0.04	0.4	3.7	0.01	0.05	0.00775	0.4	0.4	0.01
Krypton-85	0.01	0.01	4	40	Not listed	0.01	5	0.000039	4	4	0.01
Thorium (nat.)	0.001	0.001	4	40	Not listed	0.001	5	Not listed ¹⁸	4	4	0.001
Uranium (nat.)	0.001	0.001	4	40	Not listed	0.001	5	Not listed ¹⁹	4	4	0.001
Iridium-192	0.01	0.01	0.04	0.4	0.37	0.01	0.05	0.00714	0.4	0.4	0.01
Radium-226	0.01	0.01	0.004	0.04	0.037	0.01	0.005	0.00004	0.0004	0.0004	0.01
Tritium	1000	1000	4	40	37	10	5	0.23809	40	40	1000
Phosphorus-32	0.1	0.1	0.4	4	3.7	0.1	0.5	0.00417	0.4	0.4	0.1

- 44 Clearly, the fact that jurisdictional exemption levels vary so much will have a current impact on industry, which needs to know whether a particular radionuclide is regulated in each jurisdiction.
- 45 If the levels in the Directory are adopted, it can be seen from the table that exemption levels for some radionuclides will rise in some jurisdictions and fall in others.
- 46 Industry, particularly industry that operates across several jurisdictions, will benefit from the clarity of having a single national set of exemption levels specified in the Directory. Compliance costs are likely to be reduced as industry will not need to spend resources to determine whether a source or practice is exempt in each jurisdiction. Industry will have greater confidence in a system which gives clarity and consistency about what is regulated and what is exempt across Australia.
- 47 A single system of exemptions will also have benefits in the import/export trade area. Suppliers of sources or equipment containing sources will know the exemption requirements for all of Australia instead of needing to determine the level in each jurisdiction.
- 48 A uniform system of exemptions will also benefit regulators, as industry will not enter a jurisdiction anticipating that their practices are subject to an exemption that may have applied in another jurisdiction, and fail to comply with requirements as a result.
- 49 The exemption levels specified in Schedule 3 of the Directory are derived from the IAEA International Basic Safety Standards, for which there is an established rationale based on restriction of doses to 10 μ Sv per year. A range of scenarios is examined and the exemption limit is derived from the most restrictive scenario leading to a 10 μ Sv dose. While there is some criticism of this approach as being too restrictive for natural radionuclides, the derivation of the exemption has a rationale that can be reviewed and assessed, and no better approach is available. Industry is likely to have less confidence

¹⁸ The Tasmanian regulations exempt a natural material with concentration less than 31 Bq/g, but do not have an activity limit. The limit for Th-232 is 0.00000025 MBq.

¹⁹ The Tasmanian regulations exempt a natural material with concentration less than 31 Bq/g, but do not have an activity limit. The limit for U-238 is 0.0000014 MBq.

in a system for which there is no clear radiation protection rationale, so while the IAEA limits have some criticism, they are still widely used throughout the world.

- 50 The Directory also includes provision for exemptions to be granted in specific cases (see section 3.2.2(e)) where an optimisation process shows that exemption is the best option, so in any cases where the application of the international exemption levels has an unintended impact there is still provision for an exemption to be applied by the Authority and the Radiation Health Committee to be notified so that the exemption can be considered nationally.
- 51 As can be seen from the previous table, the exemption levels for natural materials (eg Th (nat.) and U (nat.)) will be reduced considerably in some jurisdictions. For commodities and practices containing small quantities of these materials, exemption may still be considered as in paragraph 40 above, however the possibility of these materials existing in bulk quantities or widespread practices still requires control.
- 52 The following table summarises the likely impacts of adopting the exemption levels in the Directory for some commonly used radionuclides. In summary, in many cases the activity of radionuclides in use greatly exceeds the exemption levels currently in use or proposed in the Directory. Hence the changes in exemption levels have little impact in most cases. Comment on the impact in specific cases is made in the table.

Radionuclide	Increase or decrease from current exemption levels	Comment on Impact
Cobalt-60	Increase for ACT, SA, Tas, Vic, WA Decrease for NSW, NT No change for Qld, Cwlth	Little impact as the differences are small for all jurisdictions except Tas, and most cobalt-60 sources in use are of activity much higher than the exemption levels (eg industrial radiography, industrial gauges)
Caesium-137	Increase for Tas Decrease for ACT, NSW, NT, SA, VIC, WA No change for Qld, Cwlth	The levels for NSW, NT, Vic, WA will decrease by more than a factor of 10, and the Tas limit will increase considerably, however there are limited numbers of caesium-137 sources in this range (perhaps some calibration sources)
Iodine-131	Increase for ACT, NSW, NT, SA, Qld, Tas, Vic, WA No change for Cwlth	The levels for ACT, SA, Qld, Vic, WA will increase by a factor of 10 or more, however, I-131 is predominantly used as an unsealed source for medical treatments and in laboratories at activities significantly greater than the Directory exemption limit, so in practice this change will have little impact.
Americium-241	Increase for ACT, SA, Vic, WA, Tas Decrease for NSW, NT No change for Qld, Cwlth	The levels for all jurisdictions except Tasmania are within a factor of 5 of the limit in the Directory. There are some sources, eg domestic smoke detectors, which have americium-241 sources slightly above the exemption level. Specific exemption for the use of these detectors applies in most jurisdictions already and a national provision can be considered for a future edition of the Directory, hence there will be little impact.
Technetium-99m	Increase for ACT, SA, Tas, Vic, WA Decrease for NSW No change for Qld, Cwlth	All jurisdictions except Tasmania have a limit within a factor of 4 of the Directory limit. Technetium-99m is a medical radionuclide of short half-life, and is used for patient diagnosis in quantities exceeding the Directory exemption limit. This change would have little impact.
Strontium-90	Increase for Tas, Vic, WA Decrease for ACT, NSW, NT, SA No change for Qld, Cwlth	NSW and NT exemption limits will reduce by a factor of about 40, ACT and SA will reduce by a factor of 5, while Vic and WA limits will increase by a factor of 2.5, Tas by 25 and Cwlth and Qld remain the same. While these differences are numerically significant, in practice most strontium-90 sources are in industrial or medical sources of activity greater than 40 MBq, although NSW and NT may need to regulate some calibration sources that are below their current exemption limits.
Thallium-204	Decrease for ACT, NSW, NT, SA, Vic, WA No change for Qld, Cwlth	The NT exemption limit would reduce by a factor of 400, Vic, NSW and WA by a factor of 40, SA and ACT by a factor of about 5, while Tas would increase slightly and Cwlth and Qld would remain the same. While these differences are numerically significant, in practice thallium-204 sources are used in industrial sources of activity greater than 40MBq, so this change would have no impact.
Krypton-85	Decrease for ACT, NSW, SA, Vic, WA No change for Qld, Cwlth	The NSW exemption limit would reduce by a factor of 4000, ACT, SA Vic and WA by 400, Tas would increase by a factor of 250, Qld and Cwlth remain the same and NT has no listed exemption. Krypton-85 is gaseous, but is usually used in an encapsulated form in industrial gauges of activity greater than 400MBq, so in practice there is no likely impact.
Thorium (nat.)	Decrease for ACT, NSW, SA, Vic, WA No change for Qld, Cwlth	The NSW exemption limit would decrease by a factor of 40,000. ACT, SA, Vic and WA by about 4000, Cwlth and Qld remain the same and NT and Tas have no listed exemption limit. See discussion on natural material exemption limits in paragraphs 37 & 46-48.

Regulatory Impact Statement – Final
National Directory for Radiation Protection - Edition 1.0

Uranium (nat.)	Decrease for ACT, NSW, SA, Vic, WA No change for Qld, Cwlth	The NSW exemption limit would decrease by a factor of 40,000. ACT, SA, Vic and WA by about 4000, Tas would increase by a factor of 4, Cwlth and Qld remain the same and NT has no listed exemption limit. See discussion on natural material exemption limits in paragraphs 37 & 46-48.
Iridium-192	Increase for Tas Decrease for ACT, NSW, NT, SA, Vic, WA No change for Qld, Cwlth	The NSW, NT, Vic and WA limits would decrease by a factor of 40, ACT and SA by about 5, Tas would increase slightly and Qld and Cwlth would remain the same. Iridium-192 is primarily used in industrial radiography sources at activities more than 1 million times greater than the Directory exemption limit. In practice, there is no impact.
Radium-226	Increase for ACT, SA, Tas, Vic, WA Decrease for NSW, NT No change for Qld, Cwlth	The NSW and NT exemption limits would decrease by a factor of 4, Tas would increase by a factor of 250, Vic and WA by 25, ACT and SA by about 2, Qld and Cwlth would remain the same. As radium is no longer used for medical or many industrial purposes, the exemption limit is mainly relevant to obsolete sources in storage, and to some sites contaminated by past practices. A consistent national approach would be of benefit to regulators and the community.
Tritium	Increase for ACT, NSW, NT, SA, Qld, Tas, Vic, WA No change for Cwlth	The increases range from a factor of 4000 (Tas) to 25 (NSW, NT, Vic and WA). The limit for the Cwlth remains the same. While Qld adjusted the IAEA level down by a factor of 100 on the basis that organically-bound tritium had not been considered, later information from NRPB ²⁰ indicates that it was considered and no adjustment is necessary. Tritium is mainly used in unsealed form at different activity levels and the effect of the change is that some sources will no longer require regulation.
Phosphorus-32	Increase Tas Decrease for ACT, NSW, NT, SA, Vic, WA No change for Qld, Cwlth	NSW and NT would reduce by a factor of 40, ACT, SA by 5, Vic and WA by 4, Tas would increase by 25, Qld and Cwlth remain the same. Phosphorus-32 is used primarily in medicine in activities of 150 MBq or greater and in laboratories at activities greater than 10 MBq. Hence the change has no impact.

- 53 In addition to the consideration of which sources require regulation of their possession and use, the exemption limits also have an impact in relation to the level at which obsolete sources can be released from regulatory control. If a lower exemption limit is introduced, a longer period of storage to allow for decay will be required before a source no longer needs to be controlled. Where the half-life of the source is short this has little impact, however for long half-life sources there may be an impact of additional costs to store unwanted sources. Given the current international emphasis on security of sources^{21,22}, the benefit of ensuring that all sources are safely and securely stored until decayed to exempt activity levels outweighs any such cost that may be incurred.
- 54 Given that the table above demonstrates that for common radionuclides the exemption levels in some cases rise and in others fall, the duration of storage required will fall for some radionuclides and rise for others. Where the exemption level rises, there would be no impact, other than a reduction in storage costs in some cases. Where the exemption level falls, sources would need to be stored longer if there was no disposal option immediately available. As the main impact is to extend the period of storage in a few cases (in many situations sources are returned to the supplier when obsolete not stored to decay), rather than to require new storage facilities, the cost to industry is not expected to be significant, and is also offset by the reduced storage time required for other radionuclides.

Licences to Possess

- 55 Section 4.1 of the Directory requires that persons seeking to possess or be in control of a radiation source hold a licence to possess. Existing legislation in all jurisdictions

²⁰ Mobbs SF and Harvey MP, NRPB-R306, *Exempt Concentrations and Quantities for Radionuclides not included in the European Basic Safety Standards Directive*, National Radiological Protection Board, UK, April 1999.

²¹ IAEA, *Revised Code of Conduct for the Safety and Security of Radioactive Sources*, Sep 2003

²² IAEA, TECDOC 1355, *Security of Radioactive Sources, Interim Guidance for Comment*, June 2003

places significant responsibilities and obligations on persons responsible for radiation sources, and while the terminology for the particular authorisation varies between jurisdictions, the regulatory requirements are similar, and hence the impact of this provision is not significant.

Mutual Recognition Principles

- 56 Section 4.2.1 notes that the Mutual Recognition Act 1992 and the Trans-Tasman Mutual Recognition Act 1997 apply in Australia and have the effect of facilitating the recognition of equivalent occupations.
- 57 Nonetheless, differences of view have arisen from time to time as to what competencies are required to establish equivalent occupations with regard to the ability to use radiation. Section 4.2.1 is intended to overcome this problem by establishing uniform competencies for the range of relevant occupations.
- 58 This approach has been adopted rather than follow the recommendation of the NCP Review to establish a protocol for mutual recognition, as national agreement on competencies and licence pre-requisites will resolve the core issue and obviate the need for a protocol. The introduction of a national agreement on competencies and licence pre-requisites is not expected to involve significant additional costs for either licensees or regulators compared to the adoption of a protocol. It is expected that jurisdictions would apply the agreed competencies prospectively, hence licences issued in a particular jurisdiction would not need to be re-issued, nor new applications made. Regulators would have a minimal cost to adjust to the new agreed competencies. Those groups not covered by the harmonisation under this edition of the Directory will be subject to existing arrangements in their jurisdiction, including the application of the Mutual Recognition Act as it is implemented in that jurisdiction.

Competency Requirements

- 59 Under the heading of Licences to Use, Section 4.2.1 establishes the need to meet competency requirements or pre-requisites to obtain authorisation to use radiation sources for specified practices. This requirement will benefit users and industry by enabling them to know exactly the requirements to obtain authorisation in every jurisdiction. The costs for regulators are minimal as many of the regulators already have such requirements in their regulatory framework. Users also will not have any significant change to compliance costs as all jurisdictions have similar requirements for the practices specified in edition 1.0 of the Directory in Schedule 4. Schedule 4 currently includes the nationally agreed competency requirements for:
- Use of X-ray equipment by chiropractors for chiropractic radiography;
 - Use of X-ray equipment by dentists for dental radiography;
 - Use of intra-oral X-ray equipment by dental hygienists for dental radiography;
 - Use of intra-oral X-ray equipment by dental therapists for dental radiography;
 - Use of medical X-ray equipment by diagnostic radiographers for diagnostic radiography;
 - Use of medical radiation equipment by radiation therapists for radiation therapy;
 - Use of radioactive materials by nuclear medicine technologists for nuclear medicine purposes; and

- Use of radiation sources by veterinary surgeons for veterinary purposes

This Schedule will in future cover competencies and pre-requisites for licensing of all identified radiation protection and radiation health occupational categories and professions, where it is deemed that individual licensing is necessary to ensure public health and safety.

- 60 Jurisdictions would need to consider how existing licences would be affected, however it is not expected that licences issued in a particular jurisdiction would need to be re-issued, or new applications made. The advantages of moving from jurisdiction to jurisdiction without the need for re-assessment will therefore apply prospectively. The Directory also does not provide for national licensing, so radiation users would still need to hold the relevant licence in each jurisdiction in which they operate, as is the case at present.
- 61 The implementation of the requirement in Section 4.2.1 will not impose any additional costs on regulators. Instead, regulators and businesses would both benefit from reduced costs as regulators will not need to re-assess an applicant's existing valid licence or registration from another jurisdiction, and businesses will not have to spend resources in demonstrating fitness for a licence or registration in each jurisdiction in which they operate.

Services for rural and remote areas

- 62 The requirements of Section 4.2.4 will ensure that in a limited range of circumstances a person could be granted permission to undertake a restricted range of health-related radiological services without holding the professional qualifications contained in Section 4.2.1 of the Directory.
- 63 The section enables nationally uniform criteria to enhance radiation health services in rural and remote areas where there is often insufficient work to employ a trained and accredited professional (eg diagnostic radiographer), or a lack of professionals willing to work in rural and remote areas.
- 64 Only ACT has no existing provisions for this purpose, as for geographical reasons the provisions are not relevant.
- 65 Because there are already provisions of this type in all jurisdictions except ACT, the requirements do not impose additional costs to regulators. The requirements also benefit the community by ensuring that basic health-related diagnostic radiological services are available to the community in rural and remote areas. The requirements enable this to be done in a manner consistent with appropriate standards of radiation protection.

Criteria for registration

- 66 Section 4.3 requires the registration of radiation sources and premises where these sources will be stored or used. This requirement in the Directory ensures that uniform requirements will apply in all jurisdictions, ensuring that businesses or individuals moving sources across jurisdictions are subject to the same requirements. The Directory does not change the current situation where businesses using sources or apparatus in different jurisdictions would require registration in each jurisdiction in which the source or apparatus is operated.
- 67 Although not all jurisdictions currently require registration of sources or premises (see table below), the uniform implementation of this requirement is expected to result in a

net benefit for businesses operating across jurisdictions and also improve the regulatory control of sources and premises where sources are stored or used. This is discussed further in the following paragraphs.

Jurisdiction	Details of source/apparatus registration	Details of premises registration
ACT	Registers individual sources and apparatus.	Does not register premises on their own although licensing provisions do cover premises indirectly, by referring to them.
Commonwealth	Sources and apparatus must be covered under a licence for the facility or controlled person.	Each facility dealing with radioactive sources/apparatus must be licensed.
NSW	After July 2004, the following items will require individual registration: diagnostic imaging apparatus (current); fixed radiation gauges (current); radiotherapy apparatus (as of 1 Feb 2004); portable radioactive sources (gauges) (as of 1 July 2004).	It is anticipated that the registration of premises will commence on 1 July 2004
NT	Does not register individual sources on its own but register them as part of licences issued to source owners. Registers individual apparatus	Does not register premises on their own although licensing provisions do cover premises indirectly, by referring to them.
Qld	Each sealed radioactive source (above the exemption limit) and irradiating apparatus must be individually registered.	Premises where radiation sources are stored or used must be registered including, for mobile sources, the principal place of storage.
SA	Each sealed radioactive source (above the exemption limit) and irradiating apparatus must be individually registered.	Premises where unsealed radioactive substances are used or stored must be registered.
Tas	Sources and apparatus must be covered under a licence for the practice, and are individually identified on the licence.	Accommodation and premises where radioactive material or electronic products are stored (and used) must be approved.
Vic	Each sealed radioactive source apparatus (above the exemption limit) and irradiating apparatus must be individually registered.	The principal location of storage/use of each source/apparatus must be notified to the regulator as part of the registration process. Laboratories using unsealed radioactive sources must be licensed.
WA	Each sealed radioactive source (above the exemption limit), irradiating apparatus and prescribed electronic products must be individually registered.	Each premises where sealed sources, unsealed sources, apparatus or prescribed electronic products are used/stored/manufactured must be registered. Premises where unsealed sources are used/manufactured have limits on the maximum activity for each radionuclide placed on the registration.

68 The requirement to register radioactive sources is consistent with provisions of the IAEA's *Revised Code of Conduct for the Safety and Security of Radioactive Sources*

- (2003). This Code establishes requirements to reduce the risk of unauthorised acquisition of radioactive sources by terrorists and includes provisions for national registers of radioactive sources. IAEA has encouraged all member states to write to the Director-General of IAEA giving a commitment to implementing the Code and to encourage other countries to do so.
- 69 Currently all jurisdictions have requirements for registration of radiation apparatus²³ or have equivalent provisions through their licence systems, however not all have provisions to register non-ionizing radiation apparatus. The impact of registration of non-ionizing radiation apparatus will be analysed when specific categories of apparatus are identified for registration in a future edition of the Directory.
- 70 In the case of registration of premises, all jurisdictions either have such provisions, have plans to introduce such provisions or have equivalent requirements through licensing, or through equipment registration provisions. While the principal place of storage of mobile sources is not registered in all jurisdictions, it is listed on the registration of the source. For jurisdictions that need to introduce registration of premises there would be some cost to radiation users to comply. The cost of compliance would be small given that the most costly aspects of compliance (eg some or all of shielding, interlocking, ventilation such as fume cupboards, and security provisions may be relevant) are already implemented under various existing mechanisms.
- 71 Section 4.3.2 (and Schedule 7) specifies uniform criteria for registration. Currently only criteria for industrial radiography sealed sources and premises are specified. As these are based on a Code²⁴ that has been in use (effectively as a mandatory requirement, usually applied via licence or registration conditions) in all jurisdictions and followed by the industry, the criteria should impose little impact or compliance cost. Criteria for other categories will be added to this Schedule and analysed in future editions of the Directory.

Accreditation of third party service providers

- 72 Third party accreditation for specified functions is provided for in the Directory, along with requirements, processes and guidelines for accreditation. The provision will enable independent private sector organisations or individuals accredited by the regulator to undertake a range of compliance and regulatory activities on its behalf (eg testing of medical X-ray equipment to meet performance standards).
- 73 No specific proposals on third party accreditation are put forward in Edition 1.0 of the Directory. An analysis of the impact of this section will be undertaken when specific proposals on third party accreditation are put forward in future editions of the Directory.

National Adoption of Codes and Standards by direct referencing

- 74 Codes of practice and Standards prescribed under Section 5.1 must be adopted by regulators within their regulatory frameworks. This should be done by direct reference to a Code or Standard in regulations, but may be achieved by using a Code or Standard as mandatory conditions of licence and/or registrations issued by an Authority. It should be done in a manner consistent with COAG *Principles and Guidelines for*

²³ NSW is still in the process of implementing requirements for some categories of equipment.

²⁴ NHMRC *Code of Practice for the Safe Use of Industrial Radiography Equipment*, RHS 31, (1989)

National Standard Setting and Regulatory Action by Ministerial Councils and Standard-setting bodies (Nov 1997), such that if a Code or Standard was amended, the new edition would be subject to further regulatory impact assessment prior to its adoption in the Directory.

- 75 The prescribed Codes and Standards are listed in Schedule 9 of the Directory. These are RPS1, RPS2 and RPS3. In 2002, the Office of Regulation Review (ORR) exempted RPS1²⁵ from the requirements of a regulatory impact statement as there were no changes in the dose limits and RPS 1 was merely a re-publication of an existing set of recommendations and a national standard. However, as the forerunner of RPS1 had never been subject to an RIS process, an assessment of the main provisions is included in this RIS.
- 76 All jurisdictions were requested to advise whether the requirements in their current legislation covered the main elements of RPS1 to assist in determining whether adoption of RPS1 in the Directory would have an impact in any jurisdiction. The results of this are summarised in the table below.

RPS1 adoption	Impact of adoption
Direct adoption of all of RPS1 by regulation or licence conditions	The Cwlth adopts RPS1 in regulation and Victoria adopts it by licence conditions, and NT is in the process of amending its Act to be consistent with RPS1, so there would be no impact in those jurisdictions of adopting RPS1 in the Directory. NSW also adopts RPS1 in the licence conditions of some licensees. The impact of adopting RPS1 is assessed on the basis of considering the individual provisions below.
Adoption of requirements equivalent to RPS1	Impact of adopting requirement
Occupational Dose limits	All jurisdictions except NT adopt dose limits based on those in RPS1, and NT is in the process of amending its Act, so adoption of the RPS1 dose limits would have no impact.
Public dose limits	All jurisdictions except NT adopt dose limits based on those in RPS1, and NT is in the process of amending its Act, so adoption of the RPS1 dose limits would have no impact.

²⁵ *Recommendations for Limiting Exposure to Ionizing Radiation* (1995) and *National Standard for Limiting Occupational Exposure to Ionizing Radiation* (1995), NOHSC/ARPANSA, republished in March 2002)

Regulatory Impact Statement – Final
National Directory for Radiation Protection - Edition 1.0

Radon-222 action level in dwelling	Cwlth, Vic and WA adopt this level and hence there would be no impact in those jurisdictions. In SA the level is applied to conditions on licences to mine or mill radioactive ores. In other jurisdictions the impact is also likely to be small in that a national survey ²⁶ of radon levels in homes in 1993 showed that very few homes in Australia exceed this action level.
Radon-222 action level in workplace	Cwlth, Vic and WA adopt this level and hence there would be no impact in those jurisdictions. In SA the level is applied to conditions on licences to mine or mill radioactive ores. In other jurisdictions, the impact is also likely to be small in that a national survey ²⁷ of radon levels in homes in 1993 showed that very few homes in Australia exceed this action level, and it could therefore be inferred that very few workplaces would exceed the action level for workplaces. Exceptions to this would be in mines, where radon levels are kept low by ventilation, and in tourist caves, where surveys of radon levels ²⁸ have been undertaken, and in some instances work practices for tour guides modified.
Guidance level for patient dose in mammography	ACT, Qld, NT and WA do not adopt this guidance level. SA use it in their recommendations. Given that mammography doses are regularly measured, that similar guidance levels are established by the RANZCR and the Breastscreen program, and the guidance level is in effect a target rather than a limit, it is not anticipated that there would be any impact of adoption of this provision.
Dose constraint for volunteers in medical research using ionizing radiation	NSW, NT, SA and WA do not adopt this provision; however NSW, SA and WA have similar dose constraints based on a 1984 NHMRC statement ²⁹ . NT has not had research of this type so a limit has not been relevant. Tas does not have an explicit provision, but would use the RPS1 requirement should research of this type be proposed. Adoption of the RPS1 constraint allows more flexibility to researchers while maintaining radiation protection standards for volunteers.
EMPLOYER DUTIES Implement a radiation protection program, such that the employer ensures that:	ACT, NSW, NT, SA, Vic and WA do not explicitly require a radiation protection program, but many of the provisions of this RPS1 requirement are implemented within their regulatory frameworks as explained in the following paragraphs.
(a) workplace and procedures are designed to keep doses as low as reasonably achievable (ALARA)	Only NSW and NT do not explicitly require ALARA, however it is implicit in other requirements, and is mentioned as an object of the Act in NSW, so there would be little impact from implementing this requirement.
(b) all necessary approvals and authorisations are obtained from the Authority	All jurisdictions except NSW require this already within their regulations, and even though not explicit in NSW it is an implicit requirement of every regulatory system, so there would be no impact.
(c) appoint a Radiation Safety Officer as required by the Authority	Only NSW does not explicitly require an RSO to be appointed, however, the NSW Advisory Council has a specific function to advise the EPA of facilities that need an RSO to be appointed, so that RSO's can be appointed required by the Director-General of the Authority.

²⁶ Langroo MK, Wise KN, Duggleby JC & Kotler LH. *A nation-wide survey of radon and gamma-ray radiation levels in Australian homes*, Technical Report TR090, Australian Radiation Laboratory, 1990

²⁷ Langroo MK, Wise KN, Duggleby JC & Kotler LH. *A nation-wide survey of radon and gamma-ray radiation levels in Australian homes*, Technical Report TR090, Australian Radiation Laboratory, 1990

²⁸ Solomon SB, Langroo R, Pegg JR, Lyons GR & James JM. *Occupational Exposure to Radon in Australian Tourist Caves*, Technical Report TR119, Australian Radiation Laboratory, 1996.

²⁹ RHS 12, *Administration of ionizing radiation to human subjects in medical research*, NHMRC, 1984.

Regulatory Impact Statement – Final
National Directory for Radiation Protection - Edition 1.0

	Hence this provision has little impact.
(d) provide for consultation with employees who may be exposed to ionizing radiation.	All jurisdictions except NT require this already within their regulations, and NT is in the process of amending its Act, so there would be no impact.
(e) provide information, induction and on-going training for employees	NSW is the only jurisdiction that does not have explicit requirements of this type, however it is a general provision of occupational health and safety legislation, and hence would be expected to have little impact.
(f) ensure that a plan for the control of exposure to radiation is developed, approved, implemented and regularly reviewed, the workforce being consulted in planning and review process	NSW is the only jurisdiction that does not have explicit requirements of this type; however control of exposure is implicit in other requirements, so there would be little impact from implementing this requirement.
(g) ensure resources for implementing the plan are provided	ACT, NSW, and NT do not explicitly require this, however adequate resources to implement are implicit in a requirement to control exposures.
(h) ensure that a plan for monitoring exposure and assessing doses to radiation is developed, approved, implemented and regularly reviewed	All jurisdictions require monitoring and assessment of doses, so implementing this requirement would create no impact.
(i) ensure exposures are kept as low as reasonably achievable	NSW, and NT do not have any explicit requirement, however it is implicit in other requirements, and is an object of the NSW Act, so there would be little impact from implementing this requirement.
(j) not employ persons under the age of 16 under conditions where they are directly involved in work with ionizing radiation	ACT, SA, NSW and NT do not have this requirement. However, employment of persons under 16 years old in radiation work has not been a known issue, hence implementation of this requirement purely formalises existing situations and would therefore have no impact.
(k) demonstrate that doses comply with the limits	All jurisdictions require that compliance with dose limits be demonstrated, so adoption of this requirement would have no impact.
(l) demonstrate that where a dose constraint is used, that the level of protection is compatible with that constraint	NT and NSW do not have this requirement, but NT is in the process of adopting a new Act consistent with RPS1. Also demonstration that protection is consistent with a dose constraint is implicit in the use of a dose constraint; hence this requirement would have little impact.
(m) ensure that where a pregnancy is declared, that the level of protection is equivalent to the public limit	NT does not have this requirement, but is in the process of adopting a new Act consistent with RPS1; hence this requirement would have no impact.
(n) investigate and rectify problems reported by employees	All jurisdictions have a requirement of this type, so adoption of this requirement would have no impact.
(o) ensure that a plan for dealing with incidents, accidents and emergencies involving exposure to radiation is developed, approved, implemented and regularly reviewed	All jurisdictions except NSW have a requirement of this type, so adoption of this requirement would have only have impact in NSW. The cost of developing and implementing such a plan would vary with the type of industry and complexity of the radiation practice, however the benefits of having a plan in place should an incident occur could be significant and would be expected to outweigh the costs.
(p) inform Authority of incidents, accidents ,and steps taken	All jurisdictions have a requirement of this type, so adoption of this requirement would have no impact.
(q) keep exposure records	All jurisdictions have a requirement of this type, so adoption of this requirement would have no impact.
(r) provide copies of employee dose records on request and on termination of	All jurisdictions have a requirement of this type, so adoption of this requirement would have no impact.

Regulatory Impact Statement – Final
National Directory for Radiation Protection - Edition 1.0

employment	
(s) provide periodic reports to the Authority as required evaluating the performance of the radiation protection program	Qld, NSW and WA do not have an explicit requirement of this type; however it could be implemented through licence conditions (NSW has done this for one installation), or as in Qld through the provisions of radiation protection plans. It would involve some cost for companies required to report, but would provide the benefit of ensuring that radiation protection programs were evaluated regularly so that levels of safety for employees and the public were maintained.
Provisions for employers to seek exemptions for any of the above where they are not all appropriate in a particular case.	ACT and Tas do not provide for exemptions from the above requirements. Provision of the capacity to exempt in appropriate cases would allow flexibility and tailoring of the requirements to meet individual situations. This would provide a benefit to industry, but would have a small cost for those jurisdictions needing to make a minor change to implement it.
EMPLOYEE DUTIES To the extent that they are capable, comply with all reasonable measures to control and assess exposure to radiation in the workplace, including:	ACT, NSW, WA, Tas and SA have no explicit requirement for employees to meet the obligations of section 6.1 of RPS1; however comparable obligations are imposed on employees as described in the following paragraphs. The requirements are also standard requirements in occupational health and safety legislation, even if they are not explicitly stated in the radiation protection legislation.
(a) follow the radiation protection practices specified in the plan for control of exposure	All jurisdictions except Tas and NSW have a requirement of this type. While Tas does not have an explicit requirement, these matters are standard requirements in occupational health and safety legislation that apply anyway, and in Tas would be expected to be addressed in the working rules adopted by licence holders. Hence, there is no overall impact in adopting this provision.
(b) comply with legitimate instructions of employer, RSO or their agents	All jurisdictions except Tas and NSW have requirements of this type. While Tas and NSW do not have explicit requirements, these matters are standard requirements in occupational health and safety legislation that apply anyway, and in Tas would be expected to be addressed in the working rules adopted by licence holders. Adoption of this provision would therefore have no impact.
(c) participate in training as required	All jurisdictions except Tas, NSW and ACT have requirements of this type. While Tas, NSW and ACT do not have explicit requirements, these matters are standard requirements in occupational health and safety legislation that apply anyway, and in Tas would be expected to be addressed in the working rules adopted by licence holders. Adoption of this provision would therefore have no impact.
(d) make proper use of training to ensure their health and safety and that of others	All jurisdictions except Tas, NSW and ACT have requirements of this type. While Tas, NSW and ACT do not have explicit requirements, these matters are standard requirements in occupational health and safety legislation that apply anyway, and in Tas would be expected to be addressed in the working rules adopted by licence holders. Adoption of this provision would therefore have no impact.
(e) make proper use of protective and monitoring equipment	While NSW and Tas do not have explicit requirements, these matters are standard requirements in occupational health and safety legislation that apply anyway, and in Tas would be expected to be addressed in the working rules adopted by licence holders.

(f) upon employment, provide details of prior radiation exposure	Vic, Qld, NSW, Tas and NT do not have requirement of this type. SA does not require the employee to provide these records, but requires it of the previous employer. While Tas does not have explicit requirements, these matters would be expected to be addressed in the working rules adopted by licence holders. The cost of implementing this requirement would be minimal as these records are already required to be kept by employers and are therefore available for this purpose. The benefit would be to ensure that an ongoing record of an employee's cumulative occupational exposure of is maintained.
(g) report matters that may compromise radiation safety	ACT, NT, Tas and NSW do not have requirements of this type. However this is a standard requirement in occupational health and safety legislation that applies anyway, and in Tas would be expected to be addressed in the working rules adopted by licence holders.

- 77 As explained in the table, development of a radiation protection program and radiation emergency plan are not explicit requirements in NSW in particular. While expectation that such plans will be developed is implicit in other existing NSW requirements, the following comments relate to the costs of such programs and plans. An example of a radiation protection plan is costed in the Consultation RIS for the Portable Density/Moisture Gauge Code (PDMG Code) (<http://www.arpansa.gov.au/dr-gauges.htm>) as ranging from \$352 to \$1320. As the variation between types of industry using radiation varies considerably, the complexity of a plan would range from the trivial (where cost would be lower than for the PDMG Code, to the complex, for large industries, where the cost would be considerably greater. However, given that larger operations normally already have such plans and programs in place, and that generic guidance on radiation protection plans and programs is already available for smaller operators, it is expected that the typical average cost of producing a plan would be less than described in the PDMG Code RIS. Radiation Emergency Plans would typically be a component of a radiation protection program or plan and are not considered separately.
- 78 While the discussion in the table above largely concentrates on possible cost impacts of adopting RPS1 in the Directory, the benefits can be described in an overall context as being consistent with international best practice (as RPS1 is derived from the recommendations of the ICRP³⁰), the cost reductions that would flow from having a uniform Standard which would be applied in all jurisdictions, and industry and radiation users having easy access (via printed or electronic publication) to the national occupational standard and the recommendations on which it is based, thereby improving familiarity and understanding of radiation protection philosophy and requirements.
- 79 Overall, it can be seen from the discussion in the table above that with the exception of the Northern Territory, which (until its new Act is promulgated) is using dose limits inconsistent with international guidance and the requirements in RPS1, and NSW in regard to radiation protection plans, regulatory frameworks in Australia either adopt the RPS1 National Standard or similar provisions. Hence, adopting RPS1 in the National Directory will mostly have the effect of formalising national agreement on a range of provisions that are already largely implemented across Australia.

³⁰ ICRP Publication 60, *1990 Recommendations of the International Commission on Radiological Protection*, Annals of the ICRP, vol 21, no 1-3, ICRP, 1991.

- 80 An issue that could be relevant if RPS1 and other national publications are not adopted is that of liability in the event of an incident where Standards have not been followed. While this cannot be costed it would be of concern to radiation users.
- 81 An RIS on RPS2³¹ was approved by the ORR in mid-2001, and an RIS on RPS3³² was approved in 2002. Both are available via the ARPANSA web site at www.arpansa.gov.au.
- 82 The prescription of codes and standards in the Directory for adoption by jurisdictions underpins the central role of the Directory as a document that will ensure uniform adoption of codes and standards. Currently jurisdictions have selectively adopted codes or standards promulgated under the Radiation Health Series and other standards (see Annex 3 of the Directory for a listing). This has led to a situation where a particular standard may be adopted and be in force in one jurisdiction but not another. When jurisdictions agreed in 1999 to the using the Directory as a means to achieve national uniformity, jurisdictions agreed that they will adopt all codes and standards prescribed in the Directory either directly in regulations or as licence conditions.
- 83 The provision in Section 5.1 ensures uniformity for many practices using radiation through national adoption of Codes and Standards. It imposes some costs on regulators as they would have to adopt Codes and Standards prescribed in the Directory within their regulatory frameworks, but the benefits of uniformity that accrues to regulators, businesses and the community outweigh these costs, as is demonstrated in the regulatory impact statements on RPS2 and RPS3 and the analysis of RPS1 in this regulatory impact statement. Future Codes and Standards will also need to undergo a regulatory impact assessment in line with the COAG *Principles and Guidelines for National Standard setting and Regulatory Action by Ministerial Councils and Standard-setting bodies* (Nov 1997) prior to their publication and adoption into the Directory. Hence the impact of including this provision in the Directory will in effect be analysed separately in regulatory impact statements for each new Code or Standard.

National adoption of extracts of Codes and Standards

- 84 No specific extracts are proposed for adoption in Edition 1.0 of the Directory. The impacts of this section will be analysed when particular proposals are put forward in future editions of the Directory.

Adoption of national radiation incident reporting framework

- 85 A system for reporting of radiation incidents to a national register has existed since the 1970's. Over time there has been a need to update the types of incidents required to be reported, for example to be consistent with international reporting requirements. All jurisdictions currently have requirements for radiation users to report radiation incidents to the regulator (as in RPS 1 clause 5(p)), however reporting to the national register by regulators has not always been consistent and has been hampered in some cases by differences in current regulatory reporting requirements. The adoption of the national incident reporting framework proposed in Schedule 11 of the Directory is expected to have an impact only on regulators and other stakeholders, where they are required to report incidents of a type not previously required in that jurisdiction. Some

³¹ *Code of Practice for the Safe Transport of Radioactive Material*, ARPANSA, September 2001

³² *Radiation Protection Standard for Maximum Exposure Levels to Radiofrequency Fields – 3kHz to 300GHz*, May 2002.

adjustment to reporting requirements, to be consistent with the types of incidents specified in Schedule 11, may need to be undertaken in some jurisdictions.

86 The benefits of a national system of incident reporting outweigh the one-off cost of reviewing reporting requirements in some jurisdictions as:

- Only small numbers of incidents are reported each year, typically less than ten in larger jurisdictions,
- All jurisdictions have reporting requirements in their legislation similar to the provisions of Schedule 11, and thereby already have the information for most if not all of the types of incidents required to be reported. As such, there is no need for regulators to establish new or different systems for reporting of radiation incidents, and consequently no costs to implement such a system,
- All jurisdictions have been reporting most incidents to the national register on a voluntary basis, and placing this obligation in the Directory will ensure that all relevant incidents are reported so that maximum value can be obtained for regulators and radiation users from analysis and publication of reports on incidents,
- Information can be published from a nationally coordinated reporting system to help radiation users identify potential problems and reduce the possibility of similar incidents in future.

87 Similarly, the costs to radiation users would be small given that:

- Reporting requirements for most of the incident types already exist in most jurisdictions, and
- The number of incidents for an individual user company is likely to be extremely small.

However, the user would benefit from access to national information on radiation incidents which may be of considerable assistance in preventing similar incidents from occurring.

Cost-Benefit Analysis

88 Following NSW EPA's submission requesting more quantitative cost benefit analysis in the RIS, all jurisdictions agreed to a process of obtaining a cost-benefit analysis on a range of Codes and Regulatory Impact Statements currently in preparation. The National Directory was agreed by the Radiation Health Committee and was submitted to AHMAC and AHMC for endorsement. Both AHMAC (10 June 2004) and AHMC (29 July 2004) endorsed the Directory subject to further cost-benefit analysis, sufficient to meet the requirements of all jurisdictions, being undertaken. Allen Consulting was contracted to prepare an additional cost-benefit analysis (The Allen Consulting Group, 2004) – see copy of report attached.

89 The Allen Consulting Report compared the cost and benefits of the National Directory as follows:

“In drawing any definitive conclusion as to the costs and benefits of the National Directory it should be noted that it is generally easier to quantify costs of safety-related regulations because these are crystallised as actual expenditures, whereas the health benefits are less easily quantified because these tend to be avoided costs (such as avoided incidents, illnesses, or cancers). Keeping this in mind, The Allen Consulting Group believes that on balance it would appear that the benefits are likely to more than exceed the costs. Table 4.1 provides summary of this assessment.

TABLE 4.1 - SUMMARY OF COASTS AND BENEFITS COMPARED

Category	Discussion
Costs — Administration	
Amending legislation	The cost to all jurisdictions could range between \$400 000 and \$4 million but this is a one-off cost and is not usually costed in regulatory impact statements.
Advisory body	May require Northern Territory to incur costs of around \$10 000 to \$20 000 p.a. plus establishment costs.
Exemptions	May add up to \$15 000 p.a. to New South Wales' administration costs but this will be charged to registrants.
Criteria for registration	May add \$26 000 to Australian Capital Territory's administration costs and \$6 000 to Northern Territory's administration costs but this will be charged to registrants.
Radiation Safety Officers	Will not add to administration costs, although if New South Wales requires licensing then this will result in some administrative costs but these are not attributable to the National Directory.
Incident reporting	This may increase the number of incidents that are reported by four to eight per year but the cost is considered negligible.
Costs — Compliance	
Criteria for registration	This may increase the costs to users who have to fill in forms to register premises that previously were not registered. The marginal cost of this is believed to be negligible though.
Exemptions	May result in some additional storage and disposal costs but these are expected to be low.
Radiation Safety Officers	May add between zero and \$1.2 million p.a. in New South Wales, depending on the requirements for radiation safety officers and the degree to which training is already undertaken
Benefits — Health and Safety	Total health and safety benefits are likely to range between \$856 000 and \$5.73 million p.a.
Benefits — National Uniformity	
For government	There are potential efficiency savings for government, although these need to be balanced against the resource costs of facilitating the agreement of nine jurisdictions.
For industry	There are potential savings for industry, particularly for those industries or professionals who work across multiple jurisdictions and for small business that will no longer need to keep track of multiple regulatory requirements.
For the broader community	The National Directory should allow for better and more coordinated promotion of radiation protection arrangements, thus addressing public expectations about radiation risks.
Net Impact	Overall, there is likely to be a net benefit for Australia from adopting the National Directory. The net present value of this benefit ranges between \$3.2 million p.a. and \$56.1 million p.a. (this Net Present Value estimation is explained on the next page)

While table 4.1 provides a holistic view of both the quantifiable and non-quantifiable costs and benefits, it is useful to look specifically at the quantifiable net impact. Conscious of the uncertainty of the estimates provided earlier, an upper and lower estimate are provided:

- the lower bound net present value estimation is based on comparing the lower bound benefit — estimated to be \$856 000 per year — with the upper bound costs — estimated to be \$5.3 million in the first year and \$50 000 in subsequent years. This lower bound provides a worst-case scenario where by the maximum costs are compared to the lowest expected benefits. By discounting these impacts over twenty years at a discount rate of 8 per cent provides a net present value estimate of \$3.2 million;³³ and
- the upper bound net present value estimate is based on comparing the upper bound benefits — estimated to be \$5.73 million per year — with the lower bound costs — estimated to be \$500 000 in the first year and \$50 000 in subsequent years. This upper bound provides the most optimistic estimate of net benefits with the maximum benefits and the lowest expected costs. Again using a discount rate of 8 per cent this provides a net present value estimate of \$56.1 million.

Thus, the impact of the National Directory's introduction is likely to provide a net benefit of somewhere between \$3.2 and \$56 million in net present value terms.

While this analysis provides an estimate of the expected benefits, it is highly dependant on the realisation of improved health and safety outcomes. The overall results should therefore be interpreted more as an indication that it is quite likely that the introduction of the National Directory will result in a net benefit for Australia rather than as a definitive estimate of the actual net benefit. Nevertheless, the fact that some benefits have not been quantified and that the majority of the costs are one-off implementation costs, it is reasonable to recommend that the National Directory should be implemented.”

Consultation

- 90 The draft edition 1 of the National Directory was produced after extensive consultation with the regulatory agencies in all jurisdictions, through the NUIP(RC) and other relevant Commonwealth departments, such as the Department of Transport and Regional Services. Radiation Councils or Advisory Councils in many jurisdictions were also consulted on the intent and content of the Directory during the focused consultation meetings conducted during the NCP Review in 2001. Consultation with State and Territory radiation protection regulators and other government agencies that have a role in aspects of radiation protection (eg mining and occupational health and safety) took place in February 2002.
- 91 A draft edition of the Directory was released as a Discussion document for public comment in December 2002/January 2003. Twenty-seven submissions were received. The most substantive comments on the draft related to exemption limits, particularly

³³ A discount rate of 8 per cent is used in this analysis in accordance with advice from the Office of Regulation Review. While the Office of Regulation Review indicates that there is some debate as to the most appropriate discount rate — or cost of capital for government — 8 per cent is broadly consistent with the approach outlined in Department of Finance 1991, *Handbook of Cost Benefit Analysis*, AGPS, Canberra. For completeness sake, sensitivity analysis was undertaken on the discount rate. This analysis highlighted that with a 5 per cent discount rate the NPV ranged from between \$5.3 million and \$72 million and with a 10 per cent discount rate the NPV ranged between \$2.19 million and \$48.4 million.

those for natural radioactive materials. Analysis of the issues raised is included in the impact analysis in this RIS.

92 The draft Directory was advertised in The Australian on 5 March 2004 for a period of public comment until 2 April 2004. Copies of the proposed Directory were also available on the ARPANSA web site at www.arpansa.gov.au. A range of organisations including the following were advised of the availability of the proposed Directory and this Regulatory Impact Statement and their comments were requested:

- Radiation Regulatory Authorities (incl OHS and Mining) in all jurisdictions
- Professional societies and associations (RANZCR, ACPSEM, ARPS, ANZSNM, ANZAPNM, RACP, AINDT, AIR, AXAA, Chiropractors Association of Australia, Australian Diagnostic Imaging Association, Australian Veterinary Association, SCANZ, AMA, ADA, RACDS, Aust. Academy of Technological Sciences and Engineering, CSANZ, Dental Hygienists Assoc. of Aust, Aust. Academy of Science, FASTS, Interventional Radiological Society of Australasia, AIP, RACGP, APPS, RACS, ARPAB, RACCS, Aust. Osteopathic Assoc, HURSOG NSW, RANZCO)
- ARPANSA Council and Committee members
- Radiation Councils and Advisory Councils in all jurisdictions
- 27 submitters of comment on the Discussion Draft edition of the Directory
- Industry and employee bodies for relevant industries (AMC, ACTU, ANF, SAMFS, APPEA, Aust Assoc of Private Radiation Oncology Practices, APESMA, Chamber of Minerals & Energy WA, Aust Assoc of Educators in Medical Radiation Science, LHMU, RACI, AMTA, Aust. Dental Industry Assoc)
- Chairs of ARPANSA Codes and Standards working groups
- Commonwealth, State and Territory Government Departments, Agencies & Committees (NOHSC, DEST, ANSTO, DITR, NSW Cabinet Office, NSW EPA, NSW Dept of Health, NSW Workcover, Office of the Supervising Scientist, National Public Health Partnership, EnHealth Council, Workplace Services SA, CSIRO, DHA, HIC, COAG CRR Secretariat, Legislation Reform Working Group)
- Other (Medical Practitioners for Prevention of War, Northern Land Council, Individual medical physicists and medical specialists, Universities, IFAP WA, Roger Alsop Consulting, Dr D Higson, Mr R Robotham)
- Industry (Steritech, Medical Applications, Iluka Resources, Newcrest Mining, Jacobs Medical, Cable Sands, Philips Analytical, Aduchem, Esso, ERA Ranger, WMC Olympic Dam, Australian Radiation Services, Allen Consulting Group, Radiation Safety Services WA, M Carter & Assoc, Radiation-Wise, Bensons Radiology, Dr Jones & Partners SA, Toshiba, Heathgate Resources, Southern Cross Resources, PMCI)

93 The consultation process resulted in 26 submissions commenting on the National Directory and the regulatory impact statement. There was considerable comment on the need to improve uniformity and supportive of the Directory process. There was general comment on how gaps in Edition 1 would be addressed, or calling for additional material in Edition 1. Responses to the submissions make it clear that Edition 1 incorporates that which has been agreed at present, and future editions of the Directory will address those additional issues. The submissions identified concerns within the mining industry about the exemption levels and application of the Directory to their industry. As a consequence, the Directory will not be applied to the mining and mineral processing issues until:

- there has been further consultation,
- the Code of Practice on Radiation Protection and Radioactive Waste Management in Mining and Mineral Processing, currently being drafted, is

- complete, and
 - there is an accepted protocol for consideration of exemption from the requirements of the Directory.
- 94 Some jurisdictions, notably NSW, indicated that the level of quantitative assessment undertaken in the consultation Regulatory Impact Statement (cleared by the Office of Regulatory Review) was insufficient to meet their requirements for sub-ordinate legislation. As a result, further quantitative analysis was commenced.
- 95 AHMAC and AHMC also required additional cost-benefit analysis to be undertaken.

Conclusion and Recommendations

- 96 While the National Directory was published following the conditional endorsement of AHMC (29 July 2004), its adoption by all jurisdictions was subject to additional cost-benefit analysis, sufficient to meet the needs of all jurisdictions, being undertaken.
- 97 The Allen Consulting cost-benefit analysis, prepared for that purpose, has been completed and provided to all jurisdictions, and all jurisdictions have confirmed that it meets their requirements in terms of the level of analysis undertaken.
- 98 The Allen Consulting Group cost-benefit analysis concludes that
- “..the impact of the National Directory’s introduction is likely to provide a net benefit of somewhere between \$3.2 and \$56 million in net present value terms.
- While this analysis provides an estimate of the expected benefits, it is highly dependant on the realisation of improved health and safety outcomes. The overall results should therefore be interpreted more as an indication that it is quite likely that the introduction of the National Directory will result in a net benefit for Australia rather than as a definitive estimate of the actual net benefit. Nevertheless, the fact that some benefits have not been quantified and that the majority of the costs are one-off implementation costs, it is reasonable to recommend that the National Directory should be implemented.”
- 99 As all jurisdictions have confirmed that the cost-benefit analysis is sufficient to meet their needs, it is recommended that AHMAC and AHMC be requested to confirm that the additional cost-benefit analysis requested has been satisfactorily completed and to endorse the National Directory for adoption by all jurisdictions.

National Competition Policy Statement

- 100 Under the NCP agreements, there is a need for every regulatory proposal to satisfy the two- fold test of whether (1) the benefits of the restrictions in the proposal outweigh the costs and (2) whether the restrictions are necessary to achieve the objective/s of the proposal.
- 101 The requirements in edition 1 of the National Directory contain many restrictions. However, all these restrictions were considered in the NCP review of radiation protection legislation and edition 1 of the Directory is consistent with the recommendations of the NCP review, which were endorsed by the AHMC in September 2002, and subsequently by all participating jurisdictions, with Queensland endorsing the recommendations relating to uniformity, even though it did not participate in the review.

Implementation and Review

- 102 The Directory will be reviewed by the Radiation Health Committee within 3 years of its commencement to evaluate its effectiveness and efficiency.
- 103 The Radiation Health Committee will be developing the Directory as a dynamic document that will be amended as new agreements are reached between jurisdictions to create further editions of the Directory. Further editions of the Directory will also require a regulatory impact assessment of new provisions not already assessed in this regulatory impact statement. Further editions of the Directory also require AHMAC and AHMC endorsement before being put into effect.
- 104 The Directory will also be reviewed by the Radiation Health Committee at appropriate intervals to ensure that it remains consistent with international radiation protection practice.

References

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