



Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**

National Directory for Radiation Protection - Edition 1.0

RADIATION PROTECTION SERIES No. 6

Radiation Protection Series

The *Radiation Protection Series* is published by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) to promote practices that protect human health and the environment from the possible harmful effects of radiation. ARPANSA is assisted in this task by its Radiation Health and Safety Advisory Council, which reviews the publication program for the *Series* and endorses documents for publication, and by its Radiation Health Committee, which oversees the preparation of draft documents and recommends publication.

There are four categories of publication in the *Series*:

Radiation Protection Standards set fundamental requirements for safety. They are prescriptive in style and may be referenced by regulatory instruments in State, Territory or Commonwealth jurisdictions. They may contain key procedural requirements regarded as essential for best international practice in radiation protection, and fundamental quantitative requirements, such as exposure limits.

Codes of Practice are also prescriptive in style and may be referenced by regulations or conditions of licence. They contain practice-specific requirements that must be satisfied to ensure an acceptable level of safety in dealings involving exposure to radiation. Requirements are expressed in 'must' statements.

Recommendations provide guidance on fundamental principles for radiation protection. They are written in an explanatory and non-regulatory style and describe the basic concepts and objectives of best international practice. Where there are related **Radiation Protection Standards** and **Codes of Practice**, they are based on the fundamental principles in the **Recommendations**.

Safety Guides provide practice-specific guidance on achieving the requirements set out in **Radiation Protection Standards** and **Codes of Practice**. They are non-prescriptive in style, but may recommend good practices. Guidance is expressed in 'should' statements, indicating that the measures recommended, or equivalent alternatives, are normally necessary in order to comply with the requirements of the **Radiation Protection Standards** and **Codes of Practice**.

In many cases, for practical convenience, prescriptive and guidance documents which are related to each other may be published together. Thus a **Code of Practice** and a corresponding **Safety Guide** may be published within a single set of covers.

All publications in the *Radiation Protection Series* are informed by public comment during drafting, and **Radiation Protection Standards** and **Codes of Practice**, which may serve a regulatory function, are subject to a process of regulatory review. Further information on these consultation processes may be obtained by contacting ARPANSA.



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Edition 1.0

Radiation Protection Series Publication No. 6

August 2004

Approved by the Radiation Health Committee on 20 May 2004

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Foreword

The purpose of the *National Directory for Radiation Protection* is to provide an agreed framework for radiation safety, including both ionizing and non-ionizing radiation, together with clear regulatory statements to be adopted by the Commonwealth, States and Territories.

The Australian Health Ministers' Conference endorsed the development of the *National Directory for Radiation Protection* in August 1999 as the means of achieving uniformity in radiation protection practices between jurisdictions. In particular, the Conference agreed that the *National Directory* would be prepared by the Radiation Health Committee for approval by the Conference, via a process for issues resolution which included meeting the Council of Australian Governments' (COAG) requirements for national standard setting. There would be full consultation with stakeholders in the development of the Directory.

The Australian Health Ministers' Conference (AHMC) agreed that upon consideration and approval of the provisions of the Directory, **the regulatory elements of the Directory shall be adopted in each jurisdiction as soon as possible, using existing Commonwealth/State/Territory regulatory frameworks.**

Ministers recognised that as a variety of agencies have a legislated responsibility for aspects of radiation safety (eg mines, occupational health and safety and transport agencies in many jurisdictions), these other agencies were to be involved actively in measures to progress national uniformity, including the development of the Directory.

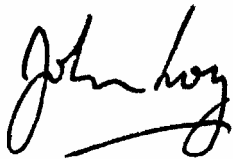
Subsequently, the development of the National Directory was supported by the recommendations of the National Competition Policy (NCP) Review of Radiation Protection Legislation (May 2001), which was endorsed by all participating jurisdictions. Queensland did not participate in the NCP Review, but endorsed the recommendations relating to uniformity.

This first edition of the *National Directory for Radiation Protection* was developed by a process designed to meet the COAG *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-setting Bodies* (Nov 1997). This included the development of a regulatory impact statement and appropriate consultation with stakeholders. Given that AHMC had already made a decision to develop the Directory, the regulatory impact statement analysed the impact of provisions of the Directory and not other regulatory options.

The National Directory was approved by the Radiation Health Committee out of session on 20 May 2004. It was subsequently endorsed by the Australian Health Ministers' Advisory Council for submission to Ministers, subject to a cost-benefit analysis sufficient to meet the subordinate legislation requirements of each jurisdiction being undertaken. Ministers endorsed the National Directory for Radiation Protection, edition 1, as the uniform national framework for radiation

protection at AHMC on 29 July 2004. Ministers noted that further cost-benefit analysis is being undertaken sufficient to meet the statutory requirements in each jurisdiction, and that edition 1 will not apply to mining and mineral processing industries.

Part A of the *National Directory for Radiation Protection* sets out the agreed overall framework for radiation protection in Australia. It is expected that jurisdictions will adopt these principles as reviews of legislation come forward. Part B of the Directory contains the uniform regulatory elements, which are to be adopted by each jurisdiction, within its particular regulatory framework. Part C of the Directory contains guidance that will assist regulators in adopting consistent approaches, but is not regulatory in nature.

A handwritten signature in black ink, appearing to read 'John Loy', with a stylized flourish at the end.

John Loy
CEO of ARPANSA

3 August 2004

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1. Introduction

1.1 Citation

This publication should be cited as the *National Directory for Radiation Protection, edition 1.0*.

1.2 Purpose

To provide an overall agreed framework for radiation safety, including both ionizing and non-ionizing radiation, together with clear regulatory statements to be adopted by the Commonwealth, States and Territories.

1.3 Scope

This Directory provides comprehensive resources to establish and maintain a uniform legislative framework for both ionizing and non-ionizing radiation protection in Australia. Although the Directory has been developed with the needs of radiation safety and protection agencies and regulators in mind, it is agreed that the Directory will also be used by all sectors involved in implementing radiation controls, including mining, mineral processing and occupational health and safety regulators. Edition 1 of the Directory will not be applied to the mining and mineral processing industries. A later edition of the Directory is proposed to be applied to these industries. That edition will include the Code of Practice for Radiation Protection and Radioactive Waste Management in Mining and Mineral Processing, and an accepted protocol for exemption processes.

1.4 Interpretation

The presence of the word 'must' in a section indicates that the requirement to which it refers is considered to be mandatory. The presence of the word 'should' in a section indicates a recommendation, that is, a requirement to be applied as far as is practicable to minimise risk¹. Sections containing the word 'should' summarise agreed best practice in relation to a particular matter at the time of publication.

There are a considerable number of terms that have technical or legal significance, and are central to the national radiation protection framework. The meanings of terms used in this Directory are those defined in the Glossary.

1.5 Structure

This Directory is structured in three Parts. Part A sets out the agreed overall framework for radiation protection in Australia. It is expected that jurisdictions will adopt these principles as reviews of legislation come forward.

¹ In accordance with *Recommendations for Limiting Exposure to Ionizing Radiation and National Standard for Limiting Occupational Exposure to Ionizing Radiation (1995)*, re-published as an ARPANSA/National Occupational Health and Safety Commission publication, Radiation Protection Series (RPS 1), CEO of ARPANSA, March 2002.

Part B of the Directory contains the uniform regulatory elements, which are to be adopted by each jurisdiction, within its particular regulatory framework.

Part C of the Directory contains guidance that will assist regulators in adopting consistent approaches, but is not regulatory in nature.

Schedules to the Directory provide additional detailed requirements that form an integral part of the uniform regulatory elements of the Directory.

Annexes to the Directory provide advisory material and background information on the provisions of the Directory.

Notes in italics throughout the Directory are included to assist in understanding the intended inclusions in future versions of the Directory. These notes do not form a part of the Directory.

PART A – General Principles

2. Regulatory frameworks

2.1 Objective of radiation protection legislation

Legislation must include the objective of protecting the health and safety of people and the environment from the harmful effects of ionizing and non-ionizing radiation.²

2.2 Principles for regulatory frameworks

A 'responsible person' is to be primarily responsible for radiation protection and safety. Nevertheless, regulators also need to establish and enforce standards through a system of regulation. Responsible persons are required to make notifications, or gain approvals and authorisations from regulators, before conducting a practice. These authorisations include registrations, licences and accreditations.

The regulatory frameworks in each Australian jurisdiction must follow the principles and requirements below³, to ensure that the objective of the legislation is met:

- (a) **Radiation protection principles** including justification of practices to ensure that benefits outweigh the detriment, limitation of radiation doses (see Schedule 1) to individuals from all practices, and optimisation of protection and safety so that individual doses, the number of people exposed and the likelihood of exposure are all kept as low as reasonably achievable, economic and social factors being taken into account.
- (b) **Management requirements** to provide for responsible persons to establish a safety culture, establish quality assurance programs, reduce the probability of human error leading to accidents, make appropriate training and information available to staff, allocate sufficient resources to enable safety and security of radiation sources over their lifetime (including disposal), and provide the qualified expertise necessary to observe the requirements.
- (c) **Technical requirements**, such as shielding design and interlocks as necessary, to ensure that radiation sources remain within control, and that they are secure from theft or damage. Defence-in-depth measures in facility design and operating procedures, which are intended to prevent accidents, to mitigate the consequences of accidents and to restore safety should an accident occur, must be established as required within this Directory. Further, good engineering practice is to be followed throughout the life (siting, design, construction, operation and decommissioning) of a facility.
- (d) **Processes for verification of safety and security**⁴, which involve safety assessments to identify and determine the magnitudes of radiation exposures during normal operation and accidents, and to assess the provisions for protection, safety and security. Procedures and equipment required for monitoring operations and verifying compliance with safety requirements and standards must be established and available. Appropriate records and reports must be maintained.

² In accordance with Recommendation 1 of the National Competition Policy (NCP) Review of Radiation Protection Legislation, May 2001

³ The principles for regulatory frameworks will require development of specific guidance on protection of non-human species, which will be included when international guidance on the issue becomes clear.

⁴ Australia has given a commitment to the Director General of the IAEA that it will work towards implementing the IAEA *Code of Conduct for the Safety and Security of Radioactive Sources* (2004).

- (e) **Risk management principles**, which include a broader evaluation of risk assessment and take into account not only scientific data, but also the social and economic considerations.
- (f) **Intervention actions** for accidental or abnormal exposure situations requiring protective action to reduce or avert radiation exposures, or their likelihood (see section 6).

2.3 Powers and functions conferred by legislation

Legislation must establish a regulatory authority [the Authority], which is effectively independent⁵, and accountable to a Minister of the Crown and through that Minister to the Parliament. Use of the term ‘the Authority’ throughout this Directory is not intended to preclude that a jurisdiction may choose to have more than one Authority to regulate different aspects of radiation protection. The legislation must prohibit any dealing with a radiation source without the appropriate authorisation. The administration of radiation control legislation in each jurisdiction must be the responsibility of the Authority. Legislation must bind the Crown and provide the following powers and functions to the Authority:

- (a) advise the Minister on radiation protection and nuclear safety matters;
- (b) set standards for radiation protection and the safety and security of radiation sources;
- (c) assess applications for authorisations against criteria specified in the Act or regulations;
- (d) grant, refuse, vary, revoke or suspend authorisations, and impose conditions on these;
- (e) grant exemptions from regulatory requirements and determine conditions for exemptions;
- (f) ensure a system of periodic inspections, documentation and reporting to verify compliance with regulatory requirements;
- (g) enforce compliance with regulatory requirements;
- (h) require safety assessments and environmental assessments where appropriate;
- (i) accredit persons or classes of persons to assess compliance with the requirements of the legislation, and set the conditions to which they should be subject;
- (j) control the categories of non-ionizing radiation apparatus specifically identified in Schedule 2 of this Directory;
- (k) maintain a register of radiation sources, including requirements for amendment of the register;
- (l) plan for, and give directions in the case of, a nuclear or radiological emergency;
- (m) require notification of radiation incidents to the Authority;
- (n) investigate radiation incidents, and provide reports to ARPANSA for inclusion in the Australian Radiation Incidents Register;
- (o) promote or conduct studies, investigations and research associated with radiation protection and nuclear safety, including public health and safety and environmental considerations; and
- (p) prepare an annual report for tabling before the Parliament⁶.

⁵ Effectively independent does not mean that the Authority needs to be a separate statutory authority, but that there should be arrangements to ensure that judgements may be made, and enforcement action taken, without undue pressure from interests that may compete with safety.

⁶ The annual report may form part of a broader Departmental annual report.

2.4 Advisory body

Legislation should provide for the establishment of an advisory body to provide the Authority and the Minister with policy and technical advice on radiation protection and nuclear safety matters.

2.5 Review of legislation

The legislation must be reviewed at intervals not exceeding ten years.⁷

2.6 Practices to which legislation applies

The practices to which the requirements of the legislation must apply include:

- (a) the manufacturing or possession of radiation sources;
- (b) the use of radiation or radioactive materials for any practice which involves or could involve exposure to radiation or radioactive materials, including medical (both diagnostic and therapeutic), dental, chiropractic, industrial, veterinary and agricultural purposes, in consumer products, education, training, research, or the servicing or maintenance of radiation apparatus or sealed source apparatus;
- (c) in relation to nuclear installations, and radiation facilities specifically identified in Schedule 3 of this Directory, the preparation of a site, possession or control, construction, operation, decommissioning or disposal of such an installation or facility;
- (d) practices involving exposure to natural sources specified by the Authority as requiring control;
- (e) practices dealing with radioactive material arising from exploration, mining, mineral processing or petroleum industries;
- (f) practices involving radioactive waste management and the disposal of radioactive material;
- (g) practices involving categories of non-ionizing radiation apparatus specifically identified in Schedule 2 of this Directory;
- (h) sale or transfer of responsibility of ionizing radiation sources and categories of non-ionizing radiation apparatus specified in this Directory;
- (i) transport of radioactive material; and
- (j) any other radiation-related practice specified by the Authority.

2.7 Categories of Authorisation

Legislation must provide for authorisations to regulate various dealings with radiation sources. The holding of the relevant authorisation will be a mandatory condition of engaging in a particular dealing, unless exemptions apply. The authorisation may be effected through a single authorisation covering various dealings or separate authorisations covering particular dealings, for example:

(a) Authorisation to possess

An authorisation to possess must be obtained by a responsible person who wishes to:

- possess a radiation source;
- otherwise be in control of a radiation source for a specified purpose; or
- be responsible for a practice.

⁷ This is in accordance with Recommendation 8 of the NCP Review of Radiation Protection Legislation, May 2001

(b) Authorisation to use

An authorisation to use must be obtained by any natural person who wishes to use a radiation source for a particular purpose, and who is not otherwise authorised to use the source under an authorisation for other dealings.

(c) Authorisation for other dealings

An Authorisation must be obtained by a responsible person for dealings such as preparation of a site, construction, possession or control, operation, decommissioning, and disposal of nuclear installations, and radiation facilities specifically identified in Schedule 3 of this Directory.

2.8 Refusal to grant an authorisation

An Authority must be able to refuse to grant an authorisation if:

- (a) the applicant is not a fit and proper person;
- (b) it is necessary to do so in the interests of public health and safety; or
- (c) the proposed use of radiation is inappropriate or unjustified.

2.9 Suspension, variation or cancellation of an authorisation

An Authority must be able to suspend, vary or cancel an authorisation if there is evidence to suggest that:

- (a) the authorisation was obtained improperly;
- (b) the holder of an authorisation has contravened a condition of the authorisation;
- (c) the holder of an authorisation has been convicted of an offence against the legislation, under which the authorisation was granted, or other relevant legislation;
- (d) unless the authorisation is suspended, varied or cancelled there would be a risk to the health and safety of people or to the environment;
- (e) unless the authorisation is suspended, varied or cancelled there would be security risk from access to the radioactive source;
- (f) the holder has ceased to hold a qualification or meet other criteria, which formed the basis on which the authorisation was granted;
- (g) the holder of an authorisation has consistently made decisions that compromised radiation safety; or
- (h) the holder of an accreditation has ceased working in a capacity for which accreditation is required.

Where an Authority makes a decision to suspend, vary or cancel an authorisation, it should advise all other relevant Authorities within and outside of its jurisdiction of that decision.

2.10 Annual reports

The Annual Report of an Authority is a necessary part of the accountability and transparency of its operations and should address the following key elements:

- (a) all activities and operations of the Authority for the year;
- (b) a summary of authorisations issued;
- (c) a summary of all radiation incidents investigated; and
- (d) a summary of prosecutions undertaken by the Authority.

PART B – Uniform Regulatory Elements

3. Scope of Regulation

3.1 Exclusions

The following exposures whose magnitude or likelihood is essentially not amenable to control through legislation are excluded from regulation:

- (a) K-40 in the body;
- (b) cosmic radiation at the surface of the earth; and
- (c) unmodified concentrations of radionuclides in most raw materials, unless otherwise specifically identified in this Directory.

3.2 Exemptions

3.2.1 The general criteria for granting an exemption are:

- (a) the health risks associated with the source, practice, or type of person using a source are sufficiently low as to be of no regulatory concern; and
- (b) radiation protection, including the cost of regulatory control, has been optimised⁸.

3.2.2 The criteria to exempt radioactive material⁹ or practices from notification, registration and licensing are:

- (a) The radioactive material has an activity concentration¹⁰ less than that prescribed in Schedule 4 or consists of or contains less than the activity prescribed in Schedule 4, or
- (b) the radioactive material has an activity concentration greater than that prescribed in Schedule 4 or consists of or contains greater than the activity prescribed in Schedule 4, but causes an annual effective dose to an individual member of the public of less than 10 μ Sv, and a collective effective dose to the critical group committed by one year of performance of the practice, as determined by the Authority, of less than 1 person.Sv, or
- (c) in the case of a mixture of radioactive materials, where each of the radioactive materials present does not exceed the individual activity or activity concentration, the mixture is defined as exempt if the sum of the fractions obtained by dividing the activity of each material present by the appropriate activity value from Schedule 4, or the sum of the fractions obtained by dividing the activity concentration of each material present by the appropriate activity concentration value from Schedule 4, does not exceed 1.
- (d) in the special case of exposure to naturally-occurring radon-222 in the workplace, the long-term average concentration of radon-222 is less than 1000 Bq/m³.

⁸ For ionizing radiation optimisation means, in relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received are all kept as low as reasonably achievable, economic and social factors being taken into account. For non-ionizing radiation, optimisation can be equated to cost-effectiveness.

⁹ The definition of radioactive material and the exemption levels for activity and activity concentration for particular radionuclides in this Directory are based on those of the International Atomic Energy Agency. The rationale for the definition and exemption levels is provided in Annex 2.

¹⁰ The 'activity concentration' of a radionuclide means the activity per unit mass of the material in which the radionuclide is essentially uniformly distributed. [A sealed source in a lead surround does not constitute being uniformly distributed].

- 3.2.3 The Authority may exempt material or practices that are not exempt under 3.2.2 above, subject to conditions that may be determined by the Authority¹¹, where an assessment for the optimisation of protection shows that exemption is the optimum option. When this provision is used, the Authority must notify the Radiation Health Committee (RHC) immediately after granting the exemption.
- 3.2.4 The Authority may declare material or practices otherwise exempt under 3.2.2 above to be subject to the legislation if an assessment of the magnitude of individual doses, the number of people exposed and the likelihood that potential exposures will actually occur justify the practice being subject to the legislation. When this provision is used, the Authority must notify the Radiation Health Committee immediately after making such a declaration.
- 3.2.5 Where the Authority has determined that regulatory controls will apply, the stringency of the regulatory measures should be proportionate to the degree of risk associated with the material.
- 3.2.6 A radiation generator or electronic tube, of a type approved by the Authority, must be exempted from notification, registration or licensing requirements, provided that:
- in normal operating conditions it does not cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding $1 \mu\text{Sv h}^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus;
 - the maximum energy of the radiation produced is no greater than 5 keV; or
 - the apparatus is listed in Schedule 5.

4. Authorisations

4.1 Authorisations to Possess

A responsible person seeking to possess or be in control of a radiation source for a specific purpose must hold an authorisation to possess, issued by the Authority.

Legislation in each jurisdiction places significant responsibilities and obligations on holders of such authorisations. Many of these responsibilities will be dealt with specifically on a practice type by practice type basis in Codes of Practice, however some requirements might be placed in future versions of this Directory if they are generally applicable or if they amend or over-ride instructions in Codes of Practice. These will be added as they are developed by the Radiation Health Committee.

Obligations on holders of such authorisations may include:

- ensuring a radiation protection plan for the practice is developed and implemented;*

¹¹ When an exemption is granted, the Authority should be able to impose appropriate conditions on the exemption, such as requirements for reporting and monitoring.

- *ensuring all radiation sources meet appropriate standards for safe use, that they are registered and that they have been assessed by an accredited person;*
- *ensuring all radiation sources are satisfactorily secured;*
- *ensuring all facilities in which radiation sources are used meet the appropriate radiation safety standards and that they are checked by an accredited person;*
- *ensuring all persons who use radiation sources are properly authorised to do so;*
- *ensuring appropriate safe handling and other safety equipment and clothing is provided to users of the sources and other persons as required, and is worn;*
- *ensuring they are advised by a competent radiation safety officer;*
- *if unsealed radioactive substances are involved in the practice, ensure that unsealed radioactive materials are disposed of in a way that is approved of by the Authority;*
- *ensuring that radiation doses arising from the radiation practice are kept below the limits and as low as reasonably achievable;*
- *providing personal radiation monitoring devices to relevant persons;*
- *keeping personal radiation monitoring records for persons exposed in the practice;*
- *ensuring radiation-related equipment is properly maintained;*
- *ensuring that the transport of radioactive material under the control of the responsible person is in accordance with the Code of Practice for the Safe Transport of Radioactive Material (2001); and*
- *notifying the Authority in the event of an incident.*

4.2 Requirements for authorising practices

Requirements applied to authorisations for practices by the Authority must include the set of requirements specified in Schedule 7 for the relevant categories.

The introduction of nationally uniform minimum set of requirements is an important element of uniformity. A minimum set of nationally agreed requirements is to be developed by the RHC to cover key practices. Once these 'model' requirements have been agreed nationally, the same practice carried out in different jurisdictions will be subject to the same requirements.

Model requirements covering practices including the following, will be developed and incorporated into a future version of this Directory in addition to those specified in Schedule 7:

Use for non-medical purposes;

Use for medical purposes (including radiology, radiography, restricted radiography in rural/remote areas, radiation oncology, cardiology, nuclear medicine, chiropractic, dentistry, and veterinary practice);

Use by installers/repairers;

Sale or transfer of responsibility of radiation sources;

Mining and mineral processing;

Disposal of radioactive materials;

Management of radioactive waste facilities; and

Possession and operation of radiation facilities.

4.3 Competency Requirements

The Mutual Recognition Act 1992 and the Trans-Tasman Mutual Recognition Act 1997 apply within Australia and have the effect of facilitating the recognition of equivalent occupations.

If a natural person in a jurisdiction meets the requirements as set out in Schedule 6 of this Directory, that person will, unless refused on the grounds specified in section 2.8 of this Directory, be granted authorisation to use the specified radiation source for the specified purposes in that jurisdiction.

The RHC will consider competency and/or pre-requisites for obtaining authorisation to use radiation sources for additional specified practices progressively over time and incorporate the agreed requirements in a future version of this Directory in Schedule 6.

The occupations and professions who may use a radiation source and whose members will typically be required to meet competency requirements include:

- *medical practitioners (including specialists);*
- *dental practitioners (including dental therapists and dental hygienists);*
- *veterinary surgeons;*
- *diagnostic radiographers;*
- *radiation therapists;*
- *nuclear medicine technologists;*
- *health & medical physicists;*
- *chiropractors;*
- *industrial radiographers;*
- *borehole loggers;*
- *radiation source testers; and*
- *persons servicing, installing, commissioning, maintaining, repairing, or manufacturing radiation sources.*

4.4 Security requirements

Any natural person or corporation making application for authorisation to deal with a radiation source must meet the security requirements as set out in Schedule 8 of this Directory.

4.5 Services for rural and remote areas

A natural person may be granted permission to undertake a restricted range of health-related diagnostic X-ray services without meeting the relevant competency requirements contained in Schedule 6 of this Directory only if:

- (a) the services are to be provided in an area recognised as an 'area of need' for particular services;
- (b) reasonable efforts have been made to attract an appropriately trained and accredited professional to the position;
- (c) the person has undertaken training accredited by the Authority for the purpose; and

- (d) appropriate conditions and restrictions are placed on the authorisation in regard to the services permitted to be provided.

4.6 Registrations

4.6.1 Requirement to Register

All apparatus, sources and premises in the categories specified in this Directory must be registered. The categories to which registration applies are:

- (a) sealed sources of radioactive materials, sealed source apparatus, radiation apparatus, non-ionizing radiation apparatus specified in this Directory, and the premises on which these radiation sources and apparatus are secured, stored, used or manufactured;
- (b) premises at which unsealed radioactive sources are stored or used; and
- (c) in the case of radiation sources that are intended for portable or field use, the sources and the principal place of storage.

4.6.2 Criteria for registration allowing the use of radiation sources and premises

Registrations allowing the use of a radiation source or premises must only be issued when those criteria considered necessary for the safe operation and security of the radiation source or the premises and specified in Schedule 9 are met.

Standard criteria for industrial radiography radiation source and premises registrations are included in Schedule 9. Criteria for other radiation sources and premises will be developed and incorporated into future editions of this Directory in Schedule 9.

4.7 Accreditation of third party service providers

A future version of this Directory will specify in Schedule 10 nationally agreed categories of accreditations, standard requirements for accreditation, national accreditation processes and guidelines and functions suitable for outsourcing by an Authority. The Implementation Plan for the National Competition Policy Review of Radiation protection Legislation include a project on 3rd party certification, which is intended to provide an agreed set of regulatory functions that could be undertaken by accredited persons, and an agreed set of principles and guidelines for the development of accreditation standards and processes.

5. National Adoption of Codes and Standards

5.1 Adoption by direct referencing

Codes and Standards referenced in this Directory must be adopted by Authorities within their regulatory frameworks. This should be done preferably by direct reference to a Code or Standard in the regulations of an Authority, but may be achieved by using a Code or Standard as conditions of licence and/or

registration issued by an Authority. The referenced Codes and Standards are listed in Schedule 11.

The RHC will, progressively over time, agree on more Codes and Standards that must be adopted by jurisdictions and reference these Codes and Standards in Schedule 11 of future versions of this Directory as these Codes and Standards are promulgated under ARPANSA's Radiation Protection Series.

5.2 Adoption of extracts from Codes and Standards

Extracts from Codes of Practice or Standards specified in this Directory and detailed in Schedule 12 must be adopted by Authorities within their regulatory frameworks.

The RHC will, progressively over time, agree on extracts to be adopted by an Authority in its legislative framework and describe such agreed extracts in Schedule 12 of future versions of this Directory.

5.3 Adoption of national radiation incident reporting framework

An Authority must report radiation incidents of the types described in Schedule 13 to ARPANSA for inclusion in the Australian Radiation Incidents Register.

Required timelines for reporting particular incident types are to be included in Schedule 13.

PART C – Guidance for Best Practice

This section contains guidance to assist regulators. It will also, where appropriate, provide background information and rationale for provisions in other parts of this Directory. This section will be completed in a future version of this Directory.

6. Intervention in Radiological Emergencies and Chronic Exposure Situations

6.1 Basic Obligations

In order to reduce or avert exposures in intervention situations, protective actions or remedial actions must be undertaken whenever they are justified.

The form, scale, and duration of any such protective action or remedial action must be optimised so as to produce the maximum net benefit, understood in a broad sense, under the prevailing social and economic circumstances.

Responsible persons must be accountable for the development, maintenance and implementation of emergency plans and establishing remedial action plans for chronic radiation exposures.¹² Emergency plans should be consistent with the principles and requirements in the IAEA's *Preparedness and Response for a Nuclear or Radiological Emergency*, Safety Standards Series No. GS-R-2, 2002.

6.2 Application

Intervention actions (see section 2.2(f)) apply to emergency exposure situations requiring protective action to reduce or avert temporary radiation exposures, including:

- accidents and emergencies in which an emergency plan or emergency procedures have been activated; and
- any other temporary exposure situation identified by the Authority as warranting intervention.

Intervention actions also apply to chronic exposure situations requiring remedial action to reduce or avert chronic exposure, including:

- natural exposure, such as exposure to radon in buildings and workplaces;
- exposure to radioactive residues from past events, such as the radioactive contamination caused by accidents, after the situation requiring protective action has been terminated, as well as from the conduct of practices and the use of sources not under the system of notification, and authorization; and
- any other chronic exposure situation specified by the Authority as warranting intervention.

¹² In the case of intervention to reduce existing exposures, justification of protective or remedial actions is required, as is optimisation of the levels at which actions are implemented. However, dose limits (see Schedule 1), do not apply. Further, restrictions on the exposure of those taking part in the intervening action may need to be applied.

[Note: it is anticipated that the new ARPANSA intervention recommendations would be referenced in this section in an appropriate way when completed]

7. Patient Discharge Recommendations

The Authority should advise hospitals and clinics treating patients with radioactive substances to establish procedures for the discharge of patients consistent with the provisions of Radiation Protection Series (RPS) No. 4, *Recommendations for the Discharge of Patients Undergoing Treatment with Radioactive Substances* (ARPANSA 2002).

Schedule 1 – Dose Limits

(Refer section 2.2(a))

Application	Dose Limits ¹	
	Occupational	Public
Effective Dose	20 mSv per year, averaged over a period of 5 consecutive calendar years ²	1 mSv in a year ⁴
Annual equivalent dose:		
the lens of the eye	150 mSv	15 mSv
the skin ⁵	500 mSv	50 mSv
the hands and feet	500 mSv	-

- 1 The limits shall apply to the sum of the relevant doses from external exposure in the specified period and the 50-year committed dose (to age 70 years for children) from intakes in the same period.
- 2 With the further provision that the effective dose shall not exceed 50 mSv in any single year. In addition, when a pregnancy is declared by a female employee, the embryo or fetus should be afforded the same level of protection as required for members of the public.
- 3 (DELETED)
- 4 In special circumstances, a higher value of effective dose could be allowed in a single year, provided that the average over 5 years does not exceed 1 mSv per year.
- 5 The equivalent dose limit for the skin applies to the dose averaged over any 1 cm² area of skin, regardless of the total area exposed.

NOTE 1: The above dose limits table has been directly extracted from ARPANSA's *Recommendations for limiting exposure to ionizing radiation (1995)*, [republished as RPS 1 in 2002]. However, as the RHC now advises that the exceptional circumstances clause is not recommended for use in Australia, note 3 of the table in RPS 1 has been deleted from this Directory.

NOTE 2: Exposure to radiation from natural sources is generally excluded from occupational or public exposure, except when the exposure is a direct consequence of a practice or is specifically identified by the appropriate authority as requiring control through the implementation of a program of radiation protection. Medical exposure includes doses received by patients undergoing medical diagnosis or therapy, doses received by volunteers in medical research, and doses received knowingly and willingly by persons other than health care workers as a consequence of their proximity to an exposed patient. Dose limits do not apply to exposures from natural sources, except as described above, or to medical exposures.

Schedule 2 – Categories of Non-ionizing Radiation

(Refer sections 2.3(k) and 2.6(g))

The Radiation Health Committee will progressively add to this Schedule the categories of non-ionizing radiation that are agreed to need a regulatory approach.

Schedule 3 – Radiation facilities

(Refer sections 2.6(c) and 2.7(c))

The Radiation Health Committee will progressively add to this Schedule the radiation facilities that are agreed to require authorisation to prepare a site, construct, possess or control, operate, decommission or dispose of such an installation or facility.

For example, the types of facility that may be considered for inclusion in a future edition of this Directory are:

(a) a particle accelerator that has, or is capable of having, a beam energy greater than 1 MeV; or can produce neutrons;

(b) an irradiator that contains more than 10^{15} Bq of a radioactive material;

(c) an irradiator that contains more than 10^{13} Bq of a radioactive material and

(i) does not include shielding as an integral part of its construction; or

(ii) if it does include shielding as an integral part of its construction – the shielding does not prevent a person from being exposed to the source; or

(iii) if it does include shielding as an integral part of its construction – has a source that is not inside shielding during the operation of the irradiator.

(d) a facility used for the production, processing, use, storage, management or disposal of:

(i) sealed sources of radioactive materials of activity greater than 10^9 times the exemption limits;

(ii) unsealed sources of radioactive materials of activity greater than 10^6 times the exemption limits.

(e) a facility where:

(i) a mixture of radioactive materials is produced, used, stored, managed or disposed of using the facility; and

(ii) the activity of the mixture is greater than the applicable level, when determined as follows:

Step 1: Divide the activity of each radionuclide in the mixture by the exempt activity for that radionuclide.

Step 2: Add the fractions for each radionuclide. The activity of the mixture is greater than the applicable level if the result from step 2 is greater than 10^9 for sealed sources or 10^6 for unsealed sources.

Schedule 4 – Exemption Levels

(Refer section 3.2.2)

Exempt activity concentrations and exempt activities of radionuclides¹³

Nuclide	Activity concentration (Bq/g)	Activity (Bq)	Nuclide	Activity concentration (Bq/g)	Activity (Bq)
H-3 (tritiated compounds, including OBT)	1×10^6	1×10^9	Sc-48	1×10^1	1×10^5
H-3 (elemental)	1×10^6	1×10^9	V-48	1×10^1	1×10^5
Be-7	1×10^3	1×10^7	Cr-51	1×10^3	1×10^7
C-11	1×10^1	1×10^6	Mn-51	1×10^1	1×10^5
C-14	1×10^4	1×10^7	Mn-52	1×10^1	1×10^5
N-13	1×10^2	1×10^9	Mn-52m	1×10^1	1×10^5
O-15	1×10^2	1×10^9	Mn-53	1×10^4	1×10^9
F-18	1×10^1	1×10^6	Mn-54	1×10^1	1×10^6
Na-22	1×10^1	1×10^6	Mn-56	1×10^1	1×10^5
Na-24	1×10^1	1×10^5	Fe-52	1×10^1	1×10^6
Mg-28	1×10^1	1×10^5	Fe-55	1×10^4	1×10^6
Si-31	1×10^3	1×10^6	Fe-59	1×10^1	1×10^6
P-32	1×10^3	1×10^5	Co-55	1×10^1	1×10^6
P-33	1×10^5	1×10^8	Co-56	1×10^1	1×10^5
S-35	1×10^5	1×10^8	Co-57	1×10^2	1×10^6
Cl-36	1×10^4	1×10^6	Co-58	1×10^1	1×10^6
Cl-38	1×10^1	1×10^5	Co-58m	1×10^4	1×10^7
Ar-37	1×10^6	1×10^8	Co-60	1×10^1	1×10^5
Ar-41	1×10^2	1×10^9	Co-60m	1×10^3	1×10^6
K-40	1×10^2	1×10^6	Co-61	1×10^2	1×10^6
K-42	1×10^2	1×10^6	Co-62m	1×10^1	1×10^5
K-43	1×10^1	1×10^6	Ni-59	1×10^4	1×10^8
Ca-45	1×10^4	1×10^7	Ni-63	1×10^5	1×10^8
Ca-47	1×10^1	1×10^6	Ni-65	1×10^1	1×10^6
Sc-46	1×10^1	1×10^6	Cu-64	1×10^2	1×10^6
Sc-47	1×10^2	1×10^6	Cu-67	1×10^2	1×10^6
			Zn-65	1×10^1	1×10^6

¹³ This table is taken from the IAEA's *International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources*, Safety Series 115 [IAEA 1996], and is supplemented from NRPB Report R306, *Exempt Concentrations and Quantities for Radionuclides* not Included in the *European Basic Safety Standards Directive* [NRPB 1999].

Nuclide	Activity concentration (Bq/g)	Activity (Bq)	Nuclide	Activity concentration (Bq/g)	Activity (Bq)
Zn-69	1×10^4	1×10^6	Y-90	1×10^3	1×10^5
Zn-69m	1×10^2	1×10^6	Y-91	1×10^3	1×10^6
Ga-67	1×10^2	1×10^6	Y-91m	1×10^2	1×10^6
Ga-72	1×10^1	1×10^5	Y-92	1×10^2	1×10^5
Ge-68	1×10^1	1×10^5	Y-93	1×10^2	1×10^5
Ge-71	1×10^4	1×10^8	Zr-93 ^a	1×10^3	1×10^7
As-73	1×10^3	1×10^7	Zr-95	1×10^1	1×10^6
As-74	1×10^1	1×10^6	Zr-97 ^a	1×10^1	1×10^5
As-76	1×10^2	1×10^5	Nb-93m	1×10^4	1×10^7
As-77	1×10^3	1×10^6	Nb-94	1×10^1	1×10^6
Se-73	1×10^1	1×10^6	Nb-95	1×10^1	1×10^6
Se-75	1×10^2	1×10^6	Nb-97	1×10^1	1×10^6
Br-75	1×10^1	1×10^6	Nb-98	1×10^1	1×10^5
Br-76	1×10^1	1×10^5	Mo-90	1×10^1	1×10^6
Br-82	1×10^1	1×10^6	Mo-93	1×10^3	1×10^8
Kr-74	1×10^2	1×10^9	Mo-99	1×10^2	1×10^6
Kr-76	1×10^2	1×10^9	Mo-101	1×10^1	1×10^6
Kr-77	1×10^2	1×10^9	Tc-95m	1×10^1	1×10^6
Kr-79	1×10^3	1×10^5	Tc-96	1×10^1	1×10^6
Kr-81	1×10^4	1×10^7	Tc-96m	1×10^3	1×10^7
Kr-83m	1×10^5	1×10^{12}	Tc-97	1×10^3	1×10^8
Kr-85	1×10^5	1×10^4	Tc-97m	1×10^3	1×10^7
Kr-85m	1×10^3	1×10^{10}	Tc-99	1×10^4	1×10^7
Kr-87	1×10^2	1×10^9	Tc-99m	1×10^2	1×10^7
Kr-88	1×10^2	1×10^9	Ru-97	1×10^2	1×10^7
Rb-81	1×10^1	1×10^6	Ru-103	1×10^2	1×10^6
Rb-86	1×10^2	1×10^5	Ru-105	1×10^1	1×10^6
Sr-85	1×10^2	1×10^6	Ru-106 ^a	1×10^2	1×10^5
Sr-85m	1×10^2	1×10^7	Rh-103m	1×10^4	1×10^8
Sr-87m	1×10^2	1×10^6	Rh-105	1×10^2	1×10^7
Sr-89	1×10^3	1×10^6	Pd-103	1×10^3	1×10^8
Sr-90 ^a	1×10^2	1×10^4	Pd-109	1×10^3	1×10^6
Sr-91	1×10^1	1×10^5	Ag-105	1×10^2	1×10^6
Sr-92	1×10^1	1×10^6	Ag-108m	1×10^1	1×10^6
Y-88	1×10^1	1×10^6	Ag-110m	1×10^1	1×10^6

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SCHEDULE 4 – EXEMPTION LEVELS**

Nuclide	Activity concentration (Bq/g)	Activity (Bq)	Nuclide	Activity concentration (Bq/g)	Activity (Bq)
Ag-111	1×10^3	1×10^6	I-133	1×10^1	1×10^6
Cd-109	1×10^4	1×10^6	I-134	1×10^1	1×10^5
Cd-115	1×10^2	1×10^6	I-135	1×10^1	1×10^6
Cd-115m	1×10^3	1×10^6	Xe-131m	1×10^4	1×10^4
In-111	1×10^2	1×10^6	Xe-133	1×10^3	1×10^4
In-113m	1×10^2	1×10^6	Xe-135	1×10^3	1×10^{10}
In-114m	1×10^2	1×10^6	Cs-129	1×10^2	1×10^5
In-115m	1×10^2	1×10^6	Cs-131	1×10^3	1×10^6
Sn-113	1×10^3	1×10^7	Cs-132	1×10^1	1×10^5
Sn-117m	1×10^2	1×10^6	Cs-134m	1×10^3	1×10^5
Sn-121	1×10^5	1×10^7	Cs-134	1×10^1	1×10^4
Sn-125	1×10^2	1×10^5	Cs-135	1×10^4	1×10^7
Sb-122	1×10^2	1×10^4	Cs-136	1×10^1	1×10^5
Sb-124	1×10^1	1×10^6	Cs-137 ^a	1×10^1	1×10^4
Sb-125	1×10^2	1×10^6	Cs-138	1×10^1	1×10^4
Te-123m	1×10^2	1×10^7	Ba-131	1×10^2	1×10^6
Te-125m	1×10^3	1×10^7	Ba-133	1×10^2	1×10^6
Te-127	1×10^3	1×10^6	Ba-140 ^a	1×10^1	1×10^5
Te-127m	1×10^3	1×10^7	La-140	1×10^1	1×10^5
Te-129	1×10^2	1×10^6	Ce-139	1×10^2	1×10^6
Te-129m	1×10^3	1×10^6	Ce-141	1×10^2	1×10^7
Te-131	1×10^2	1×10^5	Ce-143	1×10^2	1×10^6
Te-131m	1×10^1	1×10^6	Ce-144 ^a	1×10^2	1×10^5
Te-132	1×10^2	1×10^7	Pr-142	1×10^2	1×10^5
Te-133	1×10^1	1×10^5	Pr-143	1×10^4	1×10^6
Te-133m	1×10^1	1×10^5	Nd-147	1×10^2	1×10^6
Te-134	1×10^1	1×10^6	Nd-149	1×10^2	1×10^6
I-123	1×10^2	1×10^7	Pm-147	1×10^4	1×10^7
I-124	1×10^1	1×10^6	Pm-149	1×10^3	1×10^6
I-125	1×10^3	1×10^6	Sm-147	1×10^1	1×10^4
I-126	1×10^2	1×10^6	Sm-151	1×10^4	1×10^8
I-129	1×10^2	1×10^5	Sm-153	1×10^2	1×10^6
I-130	1×10^1	1×10^6	Eu-152	1×10^1	1×10^6
I-131	1×10^2	1×10^6	Eu-152m	1×10^2	1×10^6
I-132	1×10^1	1×10^5	Eu-154	1×10^1	1×10^6

Nuclide	Activity concentration (Bq/g)	Activity (Bq)	Nuclide	Activity concentration (Bq/g)	Activity (Bq)
Eu-155	1×10^2	1×10^7	Au-198	1×10^2	1×10^6
Gd-153	1×10^2	1×10^7	Au-199	1×10^2	1×10^6
Gd-159	1×10^3	1×10^6	Hg-195m	1×10^2	1×10^6
Tb-160	1×10^1	1×10^6	Hg-197	1×10^2	1×10^7
Dy-165	1×10^3	1×10^6	Hg-197m	1×10^2	1×10^6
Dy-166	1×10^3	1×10^6	Hg-203	1×10^2	1×10^5
Ho-166	1×10^3	1×10^5	Tl-200	1×10^1	1×10^6
Ho-166m	1×10^1	1×10^6	Tl-201	1×10^2	1×10^6
Er-161	1×10^1	1×10^6	Tl-202	1×10^2	1×10^6
Er-169	1×10^4	1×10^7	Tl-204	1×10^4	1×10^4
Er-171	1×10^2	1×10^6	Pb-203	1×10^2	1×10^6
Tm-170	1×10^3	1×10^6	Pb-210 ^a	1×10^1	1×10^4
Tm-171	1×10^4	1×10^8	Pb-212 ^a	1×10^1	1×10^5
Yb-169	1×10^2	1×10^7	Bi-206	1×10^1	1×10^5
Yb-175	1×10^3	1×10^7	Bi-207	1×10^1	1×10^6
Lu-177	1×10^3	1×10^7	Bi-210	1×10^3	1×10^6
Hf-181	1×10^1	1×10^6	Bi-212 ^a	1×10^1	1×10^5
Ta-182	1×10^1	1×10^4	Bi-213	1×10^2	1×10^6
W-181	1×10^3	1×10^7	Po-203	1×10^1	1×10^6
W-185	1×10^4	1×10^7	Po-205	1×10^1	1×10^6
W-187	1×10^2	1×10^6	Po-207	1×10^1	1×10^6
W-188	1×10^2	1×10^5	Po-210	1×10^1	1×10^4
Re-186	1×10^3	1×10^6	At-211	1×10^3	1×10^7
Re-188	1×10^2	1×10^5	Rn-220 ^a	1×10^4	1×10^7
Os-185	1×10^1	1×10^6	Rn-222 ^a	1×10^1	1×10^8
Os-191	1×10^2	1×10^7	Ra-223 ^a	1×10^2	1×10^5
Os-191m	1×10^3	1×10^7	Ra-224 ^a	1×10^1	1×10^5
Os-193	1×10^2	1×10^6	Ra-225	1×10^2	1×10^5
Ir-190	1×10^1	1×10^6	Ra-226 ^a	1×10^1	1×10^4
Ir-192	1×10^1	1×10^4	Ra-227	1×10^2	1×10^6
Ir-194	1×10^2	1×10^5	Ra-228 ^a	1×10^1	1×10^5
Pt-191	1×10^2	1×10^6	Ac-225	1×10^1	1×10^4
Pt-193m	1×10^3	1×10^7	Ac-227	1×10^{-1}	1×10^3
Pt-197	1×10^3	1×10^6	Ac-228	1×10^1	1×10^6
Pt-197m	1×10^2	1×10^6	Th-226 ^a	1×10^3	1×10^7

Nuclide	Activity concentration (Bq/g)	Activity (Bq)	Nuclide	Activity concentration (Bq/g)	Activity (Bq)
Th-227	1×10^1	1×10^4	Pu-242	1×10^0	1×10^4
Th-228 ^a	1×10^0	1×10^4	Pu-243	1×10^3	1×10^7
Th-229 ^a	1×10^0	1×10^3	Pu-244	1×10^0	1×10^4
Th-230	1×10^0	1×10^4	Am-241	1×10^0	1×10^4
Th-231	1×10^3	1×10^7	Am-242	1×10^3	1×10^6
Th-nat	1×10^0	1×10^3	Am-242m ^a	1×10^0	1×10^4
(incl Th-232)			Am-243 ^a	1×10^0	1×10^3
Th-234 ^a	1×10^3	1×10^5	Cm-242	1×10^2	1×10^5
Pa-230	1×10^1	1×10^6	Cm-243	1×10^0	1×10^4
Pa-231	1×10^0	1×10^3	Cm-244	1×10^1	1×10^4
Pa-233	1×10^2	1×10^7	Cm-245	1×10^0	1×10^3
U-230 ^a	1×10^1	1×10^5	Cm-246	1×10^0	1×10^3
U-231	1×10^2	1×10^7	Cm-247	1×10^0	1×10^4
U-232 ^a	1×10^0	1×10^3	Cm-248	1×10^0	1×10^3
U-233	1×10^1	1×10^4	Bk-249	1×10^3	1×10^6
U-234	1×10^1	1×10^4	Cf-246	1×10^3	1×10^6
U-235 ^a	1×10^1	1×10^4	Cf-248	1×10^1	1×10^4
U-236	1×10^1	1×10^4	Cf-249	1×10^0	1×10^3
U-237	1×10^2	1×10^6	Cf-250	1×10^1	1×10^4
U-238 ^a	1×10^1	1×10^4	Cf-251	1×10^0	1×10^3
U-nat	1×10^0	1×10^3	Cf-252	1×10^1	1×10^4
U-239	1×10^2	1×10^6	Cf-253	1×10^2	1×10^5
U-240	1×10^3	1×10^7	Cf-254	1×10^0	1×10^3
U-240 ^a	1×10^1	1×10^6	Es-253	1×10^2	1×10^5
Np-237 ^a	1×10^0	1×10^3	Es-254	1×10^1	1×10^4
Np-239	1×10^2	1×10^7	Es-254m	1×10^2	1×10^6
Np-240	1×10^1	1×10^6	Fm-254	1×10^4	1×10^7
Pu-234	1×10^2	1×10^7	Fm-255	1×10^3	1×10^6
Pu-235	1×10^2	1×10^7	Alpha-emitting radionuclide not mentioned in this Table	1×10^0	1×10^3
Pu-236	1×10^1	1×10^4	Radionuclide that is not alpha-emitting and not mentioned in this Table	1×10^1	1×10^4
Pu-237	1×10^3	1×10^7			
Pu-238	1×10^0	1×10^4			
Pu-239	1×10^0	1×10^4			
Pu-240	1×10^0	1×10^3			
Pu-241	1×10^2	1×10^5			

^a The exemption levels given in this Schedule for the following radionuclides are for the parent nuclides, which are assumed to be in secular equilibrium with the progeny listed below:

Sr-80	Rb-80
Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Ag-108m	Ag-108
Cs-137	Ba-137m
Ce-134	La-134
Ce-144	Pr-144
Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat(incl Th-232)	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
U-240	Np-240m
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

NOTE 1: The limits in relation to U(nat) and Th(nat) are to be applied in terms of the parent radionuclides ie. U-238 and Th-232 respectively.

Schedule 5 – Exempt radiation generating apparatus and electron tubes

(Refer section 3.2.6(c))

The apparatus listed in this Schedule are exempt from notification, registration and licensing requirements.

- (a) television receivers
- (b) visual display units
- (c) cold cathode gas discharge tubes
- (d) electron microscopes

Schedule 6 – Competency Requirements for Authorisation to Use Radiation Sources for Specified Practices

(Refer sections 4.3 and 4.5)

This schedule specifies the agreed competencies and/or pre-requisites for obtaining authorisations to use radiation sources for specified practices.

S 6.1 - Use of X-ray equipment by chiropractors for plain film diagnostic radiography of the spine and pelvis¹⁴

Must provide evidence of the following:

- current registration as a chiropractor in the relevant jurisdiction; and one of the following:
 - graduates in Chiropractic from RMIT University, Bundoora, Victoria (or forerunner Phillip Institute of Technology)
 - graduates in chiropractic from Macquarie University, NSW (or forerunner Sydney College of Chiropractic, Ashfield, Sydney, NSW since 30 Nov 1983)
 - For overseas trained chiropractors, one of the following:
 - satisfactory assessment by RMIT University or Macquarie University
 - individual Assessment by the relevant State/Territory Authority against a protocol agreed by the Radiation Health Committee

S 6.2 - Use of intra-oral X-ray equipment by dentists for radiography of teeth and facial bones¹⁵

Must provide evidence of the following:

- current registration by the relevant Dental Board

S 6.3 - Use of intra-oral X-ray equipment by dental hygienists for dental radiography¹⁶

Must provide evidence of the following:

- current registration as a dental hygienist by the relevant Dental Board; and one of the following:
 - Diploma of Dental Hygiene from Oral Health Centre of WA or Torrens Valley College of TAFE (Gilles Plains SA)
 - for overseas trained dental hygienists, satisfactory assessment from Oral Health Centre of WA or Torrens Valley College of TAFE (Gilles Plains SA)

S 6.4 - Use of intra-oral X-ray equipment by dental therapists for dental radiography

Must provide evidence of the following:

- current registration as a dental therapist by the relevant Dental Board, and satisfactory assessment at course in dental therapy accredited by the Authority.

S 6.5 - Use of X-ray equipment by diagnostic radiographers for diagnostic radiography

Must provide evidence of one of the following:

¹⁴ Nationally agreed requirements for radiography of extremities will be included in a later edition of the Directory.

¹⁵ Nationally agreed requirements for OPG, and for radiography of hand & wrist for bone age, will be included in a later edition of the Directory.

¹⁶ Nationally agreed requirements for dental assistants will be considered for inclusion in a future edition of the Directory.

- Australian Institute of Radiography (AIR) Statement of Accreditation (AIR Statement of Accreditation)
- Certificate of Competence issued by the Conjoint Board of the Royal Australasian College of Radiologists (RACR) and the AIR
- Diploma of Qualification issued by the Conjoint Board of the RACR and the AIR
- 1984 Assoc. Diploma in Diagnostic Radiography Graduates from Sydney TAFE

Persons undertaking the Professional Development Year (PDY) at an accredited institution or practice must provide evidence of the following to obtain a restricted authorisation:

- AIR Provisional Statement of Accreditation

S 6.6 - Use of radiation equipment by radiation therapists for radiation therapy

Must provide evidence of one of the following:

- AIR Statement of Accreditation in therapeutic radiography (AIR Statement of Accreditation)
- Certificate of Competence in therapeutic radiography issued by the Conjoint Board of the RACR and the AIR
- Diploma of Qualification in therapeutic radiography issued by the Conjoint Board of the RACR and the AIR

Persons undertaking the Professional Development Year (PDY) at an accredited institution or practice must provide evidence of the following to obtain a restricted authorisation:

- AIR Provisional Statement of Accreditation

S 6.7 - Use of radioactive materials by nuclear medicine technologists for nuclear medicine purposes

Must provide evidence of the following:

- Statement of Accreditation by ANZSNM

Persons undertaking the Professional Development Year (PDY) at an accredited institution or practice must provide evidence of the following to obtain a restricted authorisation:

- Provisional Statement of Accreditation from Australian and New Zealand Society of Nuclear Medicine (ANZSNM)

S 6.8 - Use of radiation sources by veterinary surgeons for veterinary purposes

Must provide evidence of the following:

- diagnostic X-ray equipment use for small animal radiography¹⁷
 - current registration by the relevant Veterinary Board
- sealed radioactive source use:
 - current registration by the relevant Veterinary Board, and satisfactory completion of an accredited examination on the principles and practices of radiation protection in the proposed use of radioactive materials
- unsealed radioactive source use:
 - current registration by the relevant Veterinary Board, and satisfactory completion of an accredited examination on the principles and practices of radiation protection in the proposed use of radioactive materials.

¹⁷ Requirements for large animal radiography and therapy use of X-ray equipment will be considered in a future edition of the Directory.

Schedule 7 – Requirements for Licensing Specific Practices

(Refer section 4.2)

S 7.1 Requirements for Bore Hole Logging or Well Logging

1. The licence must include a purpose statement that restricts the licensee to the use of radioactive sources or radiation apparatus registered for use in bore hole logging or well logging only.
2. The licence must require the licensee to comply with the *ARPANSA/NOHSC Standard for limiting occupational exposure to ionizing radiation RPS1 (2002)*.
3. The licence must require the licensee to comply with the *Code of practice for the safe use of sealed radioactive sources in borehole logging (1989) [RHS 28]*.
4. The licence must require the licensee to ensure the direct supervision of any field site while radioactive sources or radiation apparatus are in use, to ensure that unauthorised persons do not enter the site.

S 7.2 Requirements for Industrial Radiography

1. The licence must include a purpose statement that restricts the licensee to the use of radioactive sources or radiation apparatus registered for use in industrial radiography only.
2. The licence must require the licensee to comply with the *ARPANSA/NOHSC Standard for limiting occupational exposure to ionizing radiation RPS1 (2002)*.
3. The licence must require the licensee to ensure that all practices involving industrial radiography ionizing radiation sources are conducted in compliance with the *Code of practice for the safe use of industrial radiography equipment (1989) [RHS 31]*.
4. The licence must require the licensee to undertake continuous and immediate personal supervision of any assistant using industrial radiography apparatus.
5. The licence must prohibit the licensee from using industrial radiography ionizing radiation apparatus or sealed source apparatus if the working conditions are likely to render radiation-warning devices ineffective.
6. The licence must require the licensee to ensure that a beam stop is used when performing warm up operations on industrial radiography X-ray apparatus or when energising the X-ray tube for any purpose other than the production of a radiographic image.
7. The licence must require the licensee to use collimating devices on industrial radiography ionizing radiation apparatus or sealed source apparatus where practicable.
8. The licence must require the licensee to ensure that:
 - (a) unless otherwise approved in writing by the Authority, the source is disposed of by returning it to the supplier at the end of its useful life;

- (b) where a radioactive source is being used for industrial radiography at an area other than the place where it is usually stored, diagrams or photographs with dimensions and identifying features of the source and the steps to be taken by any person finding such a source are immediately available at the area where the source is being used.

Schedule 8 – Nationally Agreed Security Requirements for persons applying for authorisation to possess, store or use a radiation source

(Refer section 4.4)

A future version of this Directory will specify in this Schedule the agreed security requirements for persons to be authorised to possess, store or use radiation sources of specified categories.

Schedule 9 – Criteria for Registration allowing the Use of Radiation Sources and Premises

(Refer section 4.6.2)

S 9.1 Registration criteria for Industrial Radiography Sealed Sources and Premises

1. All source capsules used for industrial radiography must:
 - (a) be designed and constructed to so that any radioactive material must remain effectively enclosed within the capsule during normal use and accident conditions;
 - (b) for the purposes of section (a), a capsule complies if it meets the requirements of ISO 2919:1999 (E), as expressed in table 4 of that Standard;
 - (c) have current special form certification;
2. All source containers used for industrial radiography, other than those for X-ray crawler control sources, must:
 - (a) comply with the *Code of Practice for the Safe Use of Industrial Radiography Equipment* (1989) [RHS 31]; and
 - (b) have current Type B(U) certification, the requirements for which are specified in the *Code of Practice for the Transport of Radioactive Material* (2001) [RPS2], or be transported in the relevant approved overpack.
3. The premises constituting the principal place of storage of sources used for industrial radiography must comply with the *Code of Practice for the Safe Use of Industrial Radiography Equipment* (1989) [RHS 31].

Schedule 10 – Minimum Set of Nationally Agreed Accreditation Requirements for Third-Party Service Providers

(Refer section 4.7)

A future version of this Directory will specify in this Schedule categories of accreditations, standard requirements for accreditation and personnel security checks, national accreditation processes and guidelines and functions suitable for outsourcing by an Authority to a third-party service provider.

Schedule 11 – National Adoption of Referenced Codes of Practice and Standards

(Refer section 5.1)

The following Codes of Practice and Standards are referenced and must be adopted by all jurisdictions within their respective regulatory frameworks:

RPS 1 Recommendations and National Standard	<i>Recommendations for Limiting Exposure to Ionizing Radiation (1995) and National Standard for Limiting Occupational Exposure to Ionizing Radiation (1995)</i> , NOHSC/ARPANSA, republished in March 2002.
RPS 2 Code of Practice	<i>Safe Transport of Radioactive Material</i> , ARPANSA, September 2001
RPS 3 Radiation Protection Standard	Maximum Exposure Levels to Radiofrequency Fields – 3 kHz to 300 GHz, ARPANSA, May 2002.

NOTES:

Codes of Practice and Standards previously published by the NHMRC in its the Radiation Health Series (RHS) publications have been handed over to ARPANSA for review and re-publication in ARPANSA's Radiation Protection Series (RPS). The RHC will progressively review RHS publications and promulgate the new publications in the RPS series.

Many Codes and Standards in the RHS series have been adopted by one or more Australian jurisdictions either in their regulations or as conditions of licence. The status of the RHS documents and other standards in the various jurisdictions is tabulated in Annex 3.

Schedule 12 – National adoption of extracts from Codes of Practice and Standards

(Refer section 5.2)

The RHC will, progressively over time, agree on extracts that must be adopted by an Authority in its legislative framework and include such agreed extracts in future versions of this Directory.

Schedule 13 – National incident reporting framework

(Refer section 5.3)

This Schedule specifies the types of incidents that must be reported to ARPANSA for compilation in the Australian Radiation Incidents Register (ARIR).

S. 13.1 DEFINITIONS

Radiation Incident

Any unintended or ill-advised event when using ionizing radiation apparatus, specified types of non-ionizing radiation apparatus or radioactive substances, which results in, or has the potential to result in, an exposure to radiation to any person or the environment, outside the range of that normally expected for a particular practice, including events resulting from operator error, equipment failure, or the failure of management systems that warranted investigation.

S. 13.2 TYPES OF INCIDENT TO BE REPORTED TO THE ARIR

Radiation incidents of the following types must be reported to ARPANSA for inclusion in the Register. In some cases judgements will need to be made by the Authority in regard to whether an incident is too minor for reporting to the Register.

1. Incidents that cause or may lead to radiation injuries or radiation doses exceeding the annual dose limits to workers or members of the public

Note that situations where radiation injuries or high doses [exceeding 0.25 Sv whole body, 0.75 Gy organ dose, 2-3 Gy skin dose] occur must be reported to the ARIR as soon as possible, and within 24 hours. ARPANSA will report incidents exceeding these doses to the IAEA for inclusion on their severe incidents database.

2. Medical exposure of patients

- (a)* When during the administration of a radioactive substance for diagnostic purposes, the activity of the substance administered exceeds the activity prescribed in the hospital/practice standard protocol for that test by 50% or more;
- (b)* When during the administration of a radioactive substance for therapeutic purposes, the activity administered differs from that prescribed by 15% or more;
- (c)* When during administration of a therapeutic dose of radiation from a radiation apparatus or a sealed radioactive source, the dose delivered differs from the total prescribed treatment dose by more than 10%;
- (d)* Any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong radiopharmaceutical;
- (e)* Any diagnostic procedure other than as prescribed by the medical practitioner;
- (f)* Any diagnostic procedure resulting in an observable acute radiation effect.

3. Lost or Stolen Radioactive Sources or Radiation Apparatus

4. Transport of Radioactive Material

- (a)* Where a package is damaged during freight handling or transport;
- (b)* Where a package is transported without the required documentation, placarding or labelling.

5. Unintentional or Unauthorised Discharges of Radioactive Materials into the Environment¹⁸

Reporting is required when the unintentional or unauthorised activity discharged exceeds 100 times the exemption limit for that radionuclide specified in Schedule 3 of this Directory.

6. Damage to, or Malfunctioning of, a Radiation Apparatus or Sealed Source Apparatus

Reporting is required where the damage or malfunction could in any way affect the radiation safety of the apparatus, including issues such as shielding integrity or causing increased radiation levels.

7. Contamination with, or Dispersal of, a Radioactive Material

Reporting is required where a surface, substance or material is contaminated by a radioactive substance resulting from the spillage of more than 100 times the exempt activity of that substance specified in Schedule 3 of this Directory.

8. Out of Control Source of Radiation

Reporting is required for situations where a radiation source is out of control. Out of control means, for example, that the source is not safely secured or shielded, or contamination is not confined.

9. Non-ionizing Radiation

Reporting is required for occurrences where there is actual injury, or the potential for injury, as a result of operator error, damage or malfunction of equipment, or failure of management systems, for the types of non-ionizing radiation equipment specified below:

- (i) lasers;
- (ii) radiofrequency generating equipment;
- (iii) man-made sources of ultraviolet radiation;
- (iv) magnetic resonance imaging machines.

10. Nuclear Incidents

Reporting is required for events such as criticality incidents or events related to the safety of a nuclear reactor.

11. Other incidents that the Authority considers warrant reporting

This could include near-miss situations that should serve as a warning to other users. It could also include situations where radiation monitors at the entrance of scrap metal processing factories and landfill sites are triggered.

¹⁸ This provision does not apply to mining. Reporting levels for mining incidents will be considered in a future edition of the Directory

Annex 1 – Process for Resolving a National Approach to Various Radiation Protection Issues¹⁹

Introduction

This paper describes a process for resolving the various issues which will arise as national uniformity of radiation protection frameworks is progressed. The shorthand reference to this process will be the 'process for issue resolution'.

Over time, a broad range of issues will be resolved through use of the process for issue resolution. In some cases, the outcome will be new national standards or codes of practice. As such, the process for issue resolution will need to mirror, as closely as possible, the existing processes for national standards setting which were prescribed by the Council of Australian Governments in the publication *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies* (the COAG Principles and Guidelines). That document effectively sets out the requirements for impact assessment where new regulation is proposed, including the steps to preparing a regulatory impact statement (RIS).

The approach to progressing national uniformity which has been agreed at officer level centres on the Radiation Health Committee (RHC), established under the Commonwealth's *Australian Radiation Protection and Nuclear Safety Act 1998* and serviced by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), developing a National Directory for Radiation Protection. The process for issue resolution, comprising research, consultation, and implementation, will need to be followed for each matter which will appear in the National Directory. Once the RHC has completed its deliberations on a particular issue, the proposed provisions will be submitted direct to Health Ministers (through AHMAC) for approval.

It is also expected that, where the process for issue resolution has been followed in resolving a particular issue, there will be a reduced need for individual jurisdictions to complete their own comprehensive regulation impact assessment prior to implementing agreed provisions of the National Directory. For example, comprehensive consultations will occur at the national level as provisions are being developed, perhaps requiring only a limited supplementary process in States and Territories. To achieve this aim, however, the process will need to meet not only the requirements laid down by the Council of Australian Governments' 'Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies', but also regulation review requirements of all States and Territories. The process will be developed further until this objective has been achieved.

Once the contents of the initial draft National Directory are resolved through use of the process for issue resolution, the draft National Directory will be used as a resource guiding all States, Territories and the Commonwealth to undertake nationally uniform legislative changes.

The National Directory will also change over time as further agreements are reached by the members of the RHC, and as additional scientific and other research becomes available about the health effects of radiation.

¹⁹ This Annex is a copy of the paper submitted to the 4 August 1999 Australian Health Ministers' Conference, and formed part of the Ministerial agreement to develop the National Directory for Radiation Protection.

General description of the process for issue resolution

The various elements of the process for issue resolution are discussed below. Naturally, the process is intended to be flexible and it is expected that some of these steps may be dispensed with, or combined, in any particular case. Likewise, timeframes for completion of the process will depend on the complexity of the particular issue at hand.

The key objectives of the process for issue resolution are to ensure that:

- a range of options is considered;
- comprehensive consultation is undertaken, and the results are recorded and considered; and
- there are visible ‘signposts’ which indicate how a particular decision was reached.

It is worth noting that the COAG Principles and Guidelines outline various techniques which may be used as part of an RIS framework. Some of the available techniques include cost effectiveness analysis and risk assessment. The particular issue at hand will largely determine which of these techniques is most appropriate.

Issue identification

The process for issue resolution is initiated when an issue is brought to the attention of the RHC of ARPANSA. Some understanding will need to be developed between jurisdictions to ensure that the RHC is given an opportunity to discuss issues which have a national dimension. If possible, unilateral action by any jurisdiction where that action will detract from uniformity should be avoided.

An issue may be raised by a range of interested parties, including:

- the CEO of ARPANSA;
- a member of the RHC;
- a member of the Radiation Health and Safety Advisory Council (RHSAC) of ARPANSA; or
- an outside stakeholder such as another State or Commonwealth agency (eg Workcover) or a professional peak organisation, for example the Australian Institute of Non-Destructive Testing [in this case the approach would be made in writing to the CEO].

Regulations under the ARPANS Act will prescribe in general terms the roles and functions of the RHSAC and various Committees. However, it is anticipated that these arrangements will give the RHC some discretion to decide how a particular issue should be dealt with. The options here may include:

- direct resolution of an issue by the RHC;
- a recommendation to the RHSAC that it address a particular issue;
- the co-operative resolution of an issue through discussions and correspondence with outside agencies and other stakeholders [co-ordinated by the CEO];
- combining the ‘new’ issue with other issues already being discussed; or
- a decision that an issue raised does not require further investigation.

Several broad types of issues for resolution may be identified at this point. Many issues will be primarily ‘scientific’ in nature, such as the definition of a radioactive substance or the content of a Code of Practice. Other issues will be primarily ‘regulatory’ in nature, such as reaching an agreed position on how a particular occupation or

professional group should be regulated across all jurisdictions, or creating a policy for the use of accredited private sector inspectors/auditors (and the criteria for their accreditation). Both types of issues are likely to require impact assessment.

As a matter of policy, the issue to be resolved should be identified in a broad sense. This will allow a range of perspectives to be considered as part of the process for issue resolution. This in turn will help to ensure that the best decision is made. An example would be ‘Ensure radiographic services in remote areas are operated to a high radiation safety standard.’

Working group

Once the RHC has resolved to take action, a Working Group will be formed to oversee the process for issue resolution.

Composition of the Working Group will depend on the issue at hand. It will always comprise one or more members of the RHC, and will include other members as required. These other members may be representatives of stakeholders such as industry, professional groups or academic institutions. They may also be nominees of other Commonwealth or State/Territory agencies such as WorkSafe Australia.

While the formation of each Working Group will be issue-specific, it is anticipated that the resolution of each issue will generally require both scientific and legal/policy expertise. The members of each Working Group will be selected with this in mind. Other sources of available expertise will include members of the ARPANSA Secretariat and ARPANSA scientific, technical, policy and legal staff, as well as contractors.

At the outset, the Working Group will agree a workplan for completing a response to the particular issue. In deciding a workplan, it may be most appropriate for the Working Group to refer to the various techniques for impact assessment set out in the COAG Principles and Guidelines. In all cases, the workplan will include a deadline.

Development of a preferred position

The Working Group will undertake research on the issue for resolution, including examining work done previously in Australia and overseas. The Secretariat will provide assistance in this area. Working Group members will also discuss the issue with other RHC members.

As the process for issue resolution progresses, the Working Group will develop a ‘preferred position’. That position should, where possible, be the outcome of consideration of a range of options. The process of looking at the relative impacts of different options to achieve the objective will allow the Working Group to identify the one with the greatest net benefit.

The development of a preferred position should take account of the ‘features of good regulation’ as identified in the COAG Principles and Guidelines. These include:

- provisions should entail the minimum necessary regulation to achieve the objectives;
- provisions should minimise, as much as possible, the financial impact of administration and enforcement on government and the affected sectors of the community;
- provisions should be performance based, that is they should focus on outcomes rather than inputs; and
- provisions should be drafted in ‘plain language’ so that their intent is clear.

The preferred position should be reached by consensus within the group.

Once developed and agreed, a ‘preferred option’ may be compared with the status quo, and other possible options, to provide some assessment of the impact of the proposed changes, including costs and benefits. This will ensure that the preferred position is the one with the greatest net benefit.

Consideration should also be given to what final form the provision should take. The majority of processes for issue resolution will conclude with an entry into the National Directory. However, beyond that point, a new Code of Practice may be required, or an amendment to an existing Code or Standard.

The development of a preferred position will also include consultation with the full RHC to ensure that the Committee is comfortable with the direction being taken by the Working Group.

Consultation

The consultation process undertaken by the Working Group will conform to the COAG Principles and Guidelines. Interested parties should be given a firm proposal to consider. This means that the preferred position should be developed to a point where the impacts are clear before consultation begins.

The level of consultation will correspond to the particular issue being discussed and, at the least, will include those most likely to be affected by regulations (eg business organisations and professional bodies). In most cases, however, it will comprise full consultation with relevant stakeholders, including radiological advisory councils in most States and Territories.

Effective consultation at the national level will indicate the level of support for the proposal. In most cases, it will also provide valuable feedback on the costs and benefits of a proposed regulation.

The outcome of all consultations will be recorded by the Working Group and members of the Secretariat. At the conclusion of the process for issue resolution, details of the stakeholders consulted and their views on the preferred option (and other options) will be included in the final report.

Nationally agreed position

A nationally agreed position will be created when, following the consultation phase, the Working Group reports back to the whole RHC. This will take the form of a final written report.

Another important element in developing the nationally agreed position will be the technical advice provided by all members of the RHC in relation to implementation issues.

Once the Working Party’s written report has been received, the RHC will provide that report to the CEO of ARPANSA and request that the Standards Development and Committee Support Section of ARPANSA prepare the necessary papers for consideration by Health Ministers (through AHMAC).

At this stage, the RHC may also recommend to the CEO that consideration be given to further action on the matter. For example, the RHC may recommend that work begin on a new Code of Practice or that an existing Code be revised.

Approval

Once the report has been provided to ARPANSA, the nationally agreed position will be considered to be a draft entry in the National Directory. It will remain a draft pending formal approval by Health Ministers.

Since AHMAC and Health Ministers meet only twice a year, they will be advised on several issues at each meeting. Those briefings will comprise detailed information on 'complex' issues, for example those connected with the professions, and shorter summaries of agreements on more 'routine' matters such as new definitions. Other business related to the Directory may be completed on an out-of-session basis.

Once approved by Health Ministers, the provision will become a 'final' entry in the National Directory and will be used by jurisdictions undertaking legislative changes. It may also be further developed to become a new Code of Practice, or a Standard, or a Guidance Note.

Implementation

After Health Ministers have approved the agreed position, the provision will be available to guide legislative amendments in each jurisdiction.

Other details of the implementation process, including the degree of flexibility available to jurisdictions in implementing provisions of the National Directory, may be a matter for negotiations between the Commonwealth and the States and Territories.

Annex 2 – Derivation of Exemption Levels for Regulatory Purposes

Introduction

The definition of radioactive material and the levels used to define exemption from regulatory control in legislation and regulations throughout Australia vary considerably between jurisdictions. These differences have been historical in origin as regulations have changed at different times and local issues such as mining in some jurisdictions have also influenced the definitions used. In some cases legislation has defined what is radioactive and in other jurisdictions the definition has been in terms of what is exempt from legislation. The differences between definitions can cause difficulties where a material defined as radioactive in one jurisdiction is unregulated in another. There have also been changes in radiation protection philosophy and practice introduced following the publishing of International Commission on Radiological Protection publication 60. These have included the adoption of Australian ARPANSA/NOHSC recommendations and National Standard, revised ICRP kinetic and dosimetric model of the respiratory tract, new dose coefficients for workers using this model (ICRP 68), and revised IAEA Basic Safety Standards which include a new system for exempting radioactive materials from regulatory control. The IAEA has also recently revised its transport regulations and adopted the dose criteria used in the Basic Safety Standards.

Consequently a need for a uniform definition of radioactive material and exemption limits for regulatory purposes has been identified and this guideline has been developed for this purpose.

Principles & Methods

In order to develop a uniform Australian approach to the definition of radioactive material a review was undertaken of existing approaches both in Australia and overseas. As a result a generalised definition of radioactive material has been adopted in conjunction with exemption levels based on IAEA Safety Series No. 115. IAEA adopts a system of activity and activity concentration levels for each radionuclide rather than a single overall figure. The IAEA approach has also been adopted by the European Communities.

IAEA established general principles for exemption from regulatory control in Safety Series No. 89 (1988). Broadly, they are:

- (a) the radiation risks to individuals should be sufficiently low as to be of no regulatory concern;
- (b) radiation protection, including the cost of regulatory control, must be optimised.

The individual risk is addressed by defining a level of dose that can be regarded as 'trivial'. Two approaches were adopted in Safety Series No. 89. A level of risk (and the corresponding dose) was chosen that could be considered to be of no significance to individuals. Exposure to natural background radiation was used as a reference level, as it is both normal and unavoidable.

Safety Series No. 89 concluded that for the purposes of exemption from regulations, a level of dose of some tens of μSv in a year could reasonably be regarded as trivial. Since an individual may be exposed to radiation from several exempt sources, it is necessary to ensure that the total dose from exempt sources does not exceed the trivial dose level. Accordingly, it was recommended that the critical group dose from any one exempt source should be of the order of 10 μSv per year. This level was used in the IAEA International Basic Safety Standards and has been adopted in this guideline.

The IAEA International Basic Safety Standards calculated individual exemption levels for 299 radionuclides, of which 103 were found to have current or conceivable uses. Six physical forms were considered to cover the existing range of use: gas/vapour, liquid/solution, dispersible solid (eg powder), non-dispersible solid, thin film/foil, and sealed source/capsule. The exemption level given for each radionuclide was that for the most restrictive form. Short-lived radionuclide daughters were included with the parent where they would be expected to be in equilibrium over the period of use and/or disposal. Two extra cases were considered: naturally occurring materials where all radionuclides in (i) ^{238}U and (ii) ^{232}Th decay chains would be in equilibrium.

The IAEA exemption levels were derived using a methodology given in the EC report Radiological Protection 65 and resulted from taking the most limiting case for potential exposure from workplace and public exposure scenarios. Three basic scenarios were considered: normal use, accidental exposure and disposal. Each results in doses from one or more of three exposure pathways: ingestion, inhalation and external exposure. A total dose for each scenario was calculated by summing across the pathways. Since it is unlikely that an individual will be significantly exposed via more than one pathway at any time, this is clearly a conservative assumption. The scenarios and pathways used are listed in Table I.

There were no scenarios covering accidents in the workplace used in calculating exempt concentrations; it was considered that the scenarios developed for normal use and the associated dose criterion, $10 \mu\text{Sv y}^{-1}$, ensured an adequate level of protection in the case of possible accidents. The methodology is further outlined in the block diagrams, Figures 1,2 & 3.

There is one other issue with the application of the exemption values: the quantity of material involved. The radionuclide-specific concentration levels for exemption were calculated on the basis of small to moderate amounts of materials. This is mainly an issue in the external exposure scenario that assumes a source size of 1 m^3 . Clearly, if a larger volume of radioactive material was assumed, doses higher than $10 \mu\text{Sv y}^{-1}$ would be estimated. However, it is difficult to envisage circumstances where doses could be higher than 1 mSv y^{-1} from material containing radionuclides at the exempt concentration level.

Thus, the radionuclide-specific levels are such that:

- (i) the maximum effective dose to an individual using radionuclides, or to an individual subsequently exposed as a result of, or as a consequence of, disposal following use, will be $10 \mu\text{Sv y}^{-1}$ or less under plausible normal circumstances;
- (ii) effective doses from accidents, misuse, or unexpected situations should not be higher than the dose limit for members of the public, and
- (iii) skin doses should not exceed 50 mSv y^{-1} .

Nevertheless, the International Basic Safety Standards do note that exemption of bulk amounts of materials with activity concentrations lower than the exemption levels may require further consideration by the appropriate authority.

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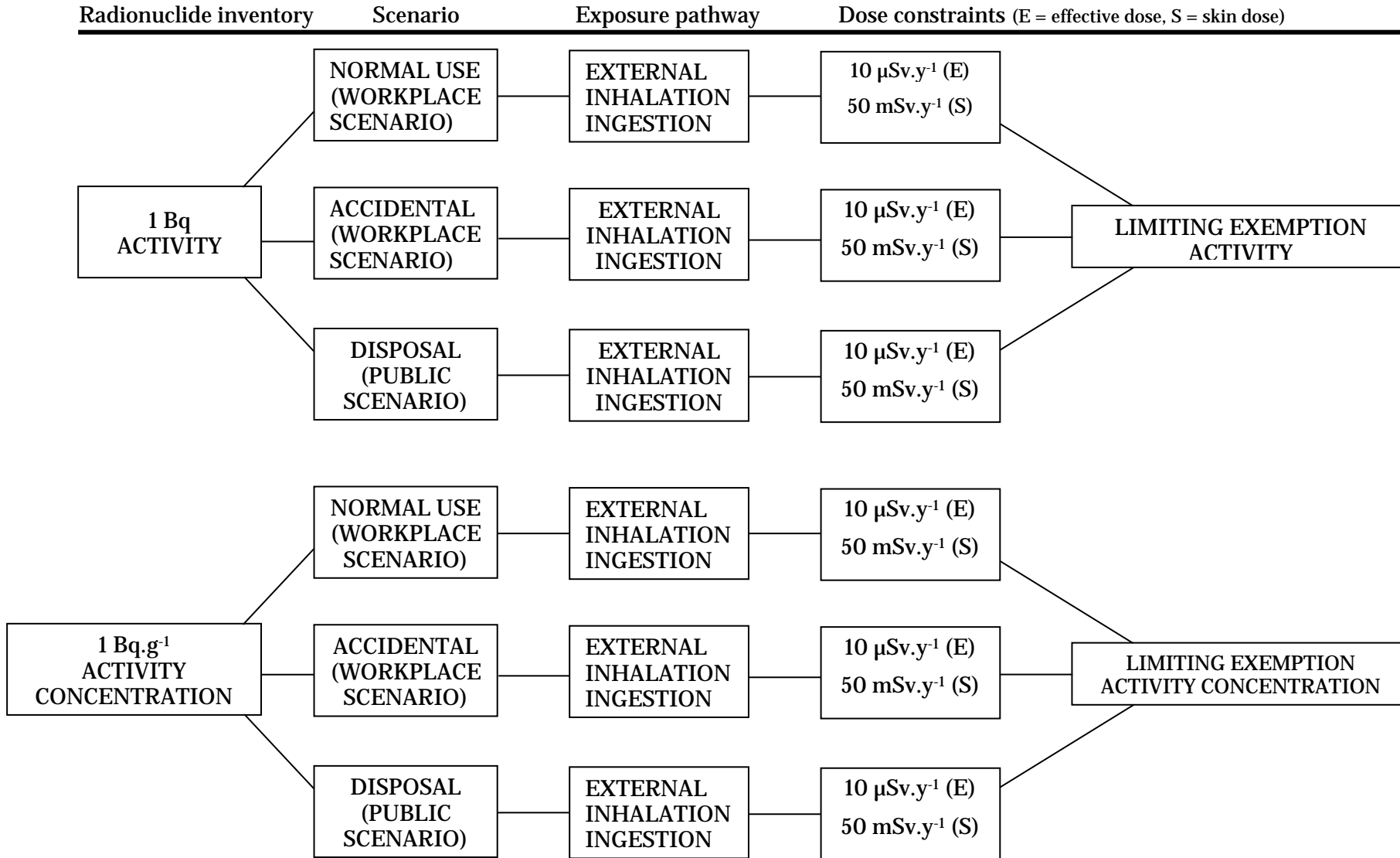
Official Journal of the European Communities, L159, Volume 39, 29 June 1996, Council Directive 96/29/EURATOM of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.

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 as Radiation Protection Series (RPS) 1.

TABLE I: LIST OF EXPOSURE SCENARIOS AND PATHWAYS CONSIDERED IN CALCULATIONS OF DOSES FOR EXEMPTION IN THE BASIC SAFETY STANDARDS.

A	ACTIVITY CONCENTRATION
A1	<p>Normal use (workplace) scenario</p> <ul style="list-style-type: none"> External exposure from a 1 m³ source External exposure from a gas bottle External exposure from handling a source Ingestion from contaminated hands Inhalation of Dusts
A2	<p>Accidental (workplace) scenario:</p> <ul style="list-style-type: none"> This is covered by Normal use (workplace) scenario
A3	<p>Disposal (public) scenario</p> <ul style="list-style-type: none"> External exposure from a landfill site Inhalation of dust from a landfill site Ingestion of object from a landfill site
B	ACTIVITIES/QUANTITIES
B1	<p>Normal use (workplace) scenario:</p> <ul style="list-style-type: none"> External exposure from a point source External exposure from handling a source
B2	<p>Accidental (workplace) scenario:</p> <ul style="list-style-type: none"> Spillage: External exposure from contaminated surface Spillage: External exposure from contaminated hands Spillage: External exposure from contaminated face Spillage: Ingestion from hands Spillage: Inhalation of resuspended activity Spillage: External dose from aerosol or dust cloud Fire: Contamination of skin Fire: External from combustion products Fire: Inhalation of dust or volatiles
B3	<p>Disposal (public) scenario</p> <ul style="list-style-type: none"> External exposure from a landfill site Inhalation from a landfill site External exposure to skin from handling an object from a landfill site Ingestion of an object from a landfill site

Figure 1: Block diagram illustrating method for calculating exempt activities and activity concentrations



ANNEX 2 – DERIVATION OF EXEMPTION LEVELS FOR REGULATORY PURPOSES

Figure 2: Block diagram showing workplace and public scenarios used to calculate doses for unit activity of 1 Bq

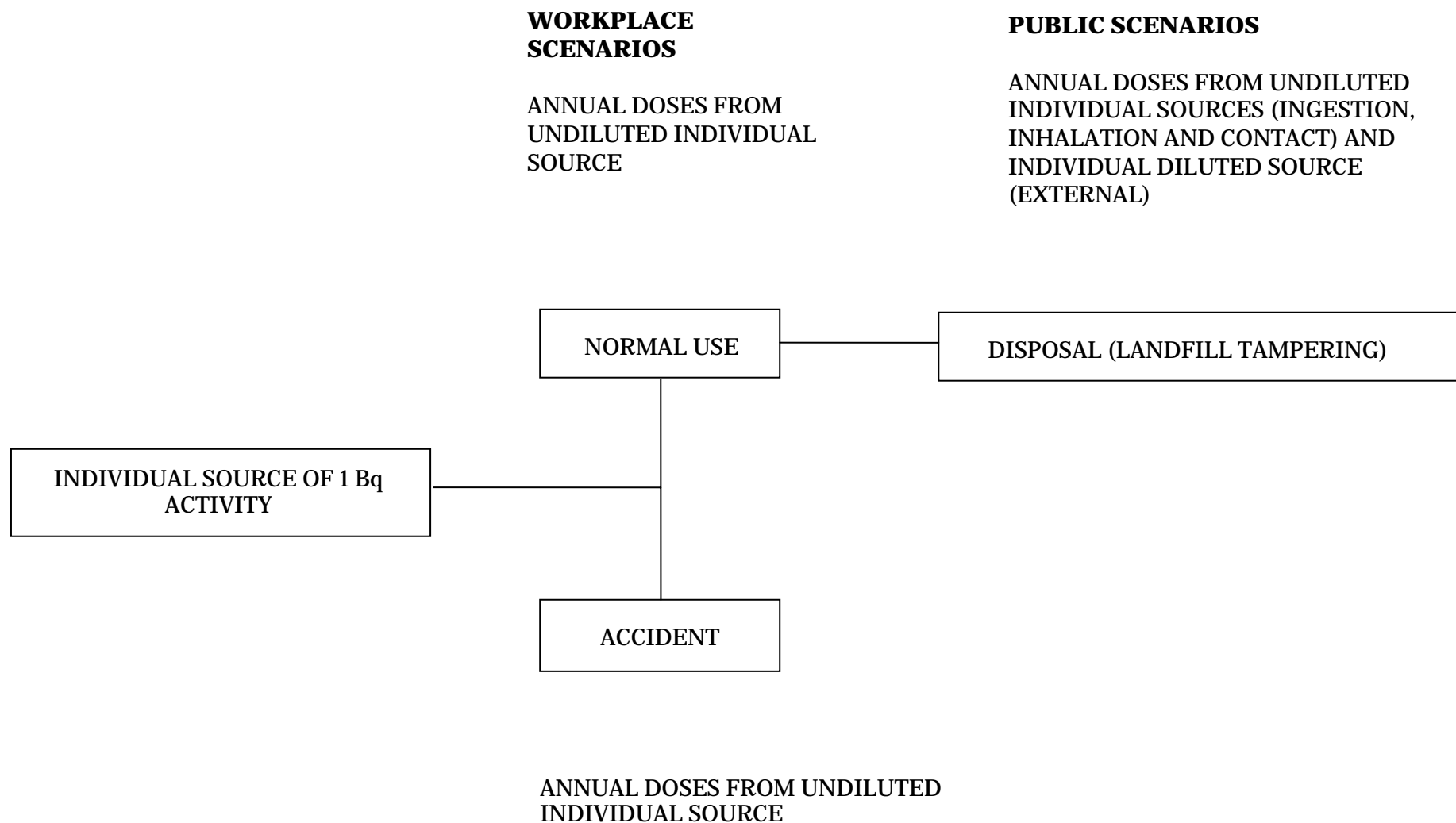


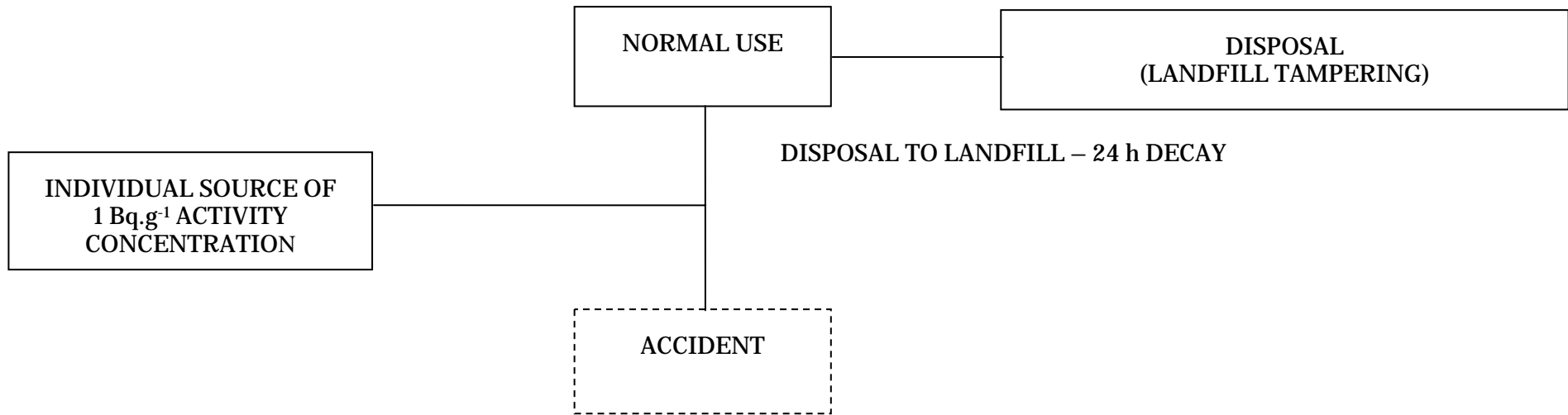
Figure 3. Block diagram showing workplace and public scenarios used to calculate doses for unit activity concentration of 1 Bq.g⁻¹.

WORKPLACE SCENARIOS

ANNUAL DOSES FROM
UNDILUTED INDIVIDUAL
SOURCE

PUBLIC SCENARIOS

ANNUAL DOSES FROM UNDILUTED
INDIVIDUAL SOURCES (INGESTION),
AND INDIVIDUAL DILUTED SOURCE
(EXTERNAL, INHALATION)



Annex 3 – Current status of Radiation Health Series documents and other standards in jurisdictions

	Adopted in regulations	Adopted as requirements, licence or registration conditions
RHS 2 - Code of Practice for the Design of Laboratories using Radioactive Substances for Medical Purposes (1980)		Vic
RHS 3 - Code of Practice for the Safe Use of Ionizing Radiation in Veterinary Radiology		NSW, Vic, Tas, NT, SA, Qld, WA, ARPANSA
RHS 4 - Code of Practice for the Safe Use of Radiation Gauges (1982)	SA, WA	NSW, Vic, Tas, Qld NT, ARPANSA
RHS 5 - Recommendations Relating to the Discharge of Patients Undergoing Treatment with Radioactive Substances		Vic, Tas, NT
RHS 8 - Code of Nursing Practice for Staff Exposed to Ionizing Radiation (1984)		Tas, NT
RHS 9 - Code of Practice for Protection Against Ionizing Radiation Emitted from X-ray Analysis Equipment (1984)	WA	NSW, Vic, Tas, Qld, NT, ARPANSA
RHS 10 - Code of Practice for Safe Use of Ionizing Radiation in Veterinary Radiology: part 3 - Radiotherapy		NSW, Vic, ARPANSA
RHS 11 - Code of Practice for the Safe Use of Soil Density and Moisture Gauges Containing Radioactive Sources (1984)		NSW, Vic, Tas, NT, Qld, WA, ARPANSA
RHS 12 - Administration of Ionizing Radiation to Human Subjects in Medical Research (1984)	NSW	Vic, Tas, NT, Qld, SA(exemptions adopted through Govt. Gazette)
RHS 13 - Code of Practice for the Disposal of Radioactive Wastes by the User (1985)	Tas, ARPANSA	Vic, NT, SA
RHS 14 - Recommendations for Minimising Radiological Hazards to Patients (1985)		Tas, Qld
RHS 15 - Code of Practice for the Safe Use of Microwave Diathermy Units (1985)		ARPANSA
RHS 16 - Code of Practice for the Safe Use of Shortwave (Radiofrequency) Diathermy Units (1985)		ARPANSA

	Adopted in regulations	Adopted as requirements, Licence or registration conditions
RHS 18 - Code of Practice for the Safe Handling of Corpses Containing Radioactive Materials (1986)		Tas
RHS 19 - Code of Practice for the Safe Use of Ionizing Radiation in Secondary Schools (1986)	SA, Tas	NSW, NT, WA
RHS 20 - Code of Practice for Radiation Protection in Dentistry (1987)		NSW, Vic, SA, Qld, Tas, ARPANSA
RHS 21 - Revised Statement on Cabinet X-ray Equipment for Examination of Letters, Packages, Baggage, Freight and Other Articles for Security, Quality Control and Other Purposes (1987)	SA, WA	Vic, NT, Qld, Tas, ARPANSA
RHS 22 - Statement on Enclosed X-ray Equipment for Special Applications (1987)	WA	Vic, NT, Qld, ARPANSA
RHS 23 - Code of Practice for the Control and Safe Handling of Radioactive Sources Used for Therapeutic Purposes (1988)		Vic, NT, Tas
RHS 24 - Code of Practice for the Design of and Safe Operation of Non-medical Irradiation Facilities (1988)		Vic, Qld, ARPANSA
RHS 25 - Recommendations for Ionization Chamber Smoke Detectors for Commercial and Industrial Fire Protection Systems (1988)		Vic
RHS 28 - Code of Practice for the Safe Use of Sealed Radioactive Sources in Borehole Logging		NSW, Vic, NT, WA, Tas, Qld ARPANSA
RHS 29 - Occupational Standard for Exposure to Ultraviolet Radiation (1989)	WA, ARPANSA	
RHS 30 - Interim Guidelines on Limits of Exposure to 50/60 Hz Electric and Magnetic Fields (1989)	WA, ARPANSA	
RHS 31 - Code of Practice for the Safe Use of Industrial Radiography Equipment (1989)	WA, SA	NSW, Vic, NT, Qld Tas, ARPANSA
RHS 34 - Safety guidelines for magnetic resonance diagnostic facilities (1991)		Tas
RHS 35 - Code of Practice for the Near-Surface Disposal of Radioactive Waste in Australia (1992)	WA, ARPANSA	
RHS 37 - Code of Practice for the Safe Use of Lasers in the Entertainment Industry (1995)		Tas, WA
RHS 39 - Recommendations for Limiting Exposure to Ionizing Radiation (1995) and National Standard for Limiting Occupational Exposure to Ionizing Radiation (1995) (see Note 2 below)	ARPANSA, Comcare, Qld (Act is based on RHS 39), SA (defns refer to RHS 39 defns)	Tas, SA (in Mining licences)

	Adopted in regulations	Adopted as requirements, Licence or registration conditions
Code of Practice on Radiation Protection in the Mining and Milling of Radioactive Ores (1987)	WA	Vic, NT, SA
Code of Practice on the Management of Radioactive Wastes from the Mining and Milling of Radioactive Ores (1982)		Vic, NT, SA
AS 2772.1 (1990) Radiofrequency Maximum Exposure Levels - 100kHz to 300 GHz	Comcare, WA	
AS 2772.2 Radiofrequency Radiation Principles and methods of measurement - 100kHz to 300 GHz		Comcare
RPS 3 - Radiation protection Standard for Maximum Exposure Levels to Radiofrequency Fields 3 kHz – 300 GHz (2002)	ARPANSA	
AS 2211 (1991) Laser Safety	Comcare, WA	Tas
AS/NZS 2211 Pts 1-2 (1997) Code of Practice for Laser Safety	Qld (use classification system for regulating Class 4 medical lasers), ARPANSA	Comcare
AS/NZS 2243 Pts 1-10 Safety in Laboratories		Comcare
AS/NZS 2243 Pt 4 Safety in Laboratories		NSW
AS 1188 (1990) Radio Transmitters and Similar Equipment - Safe Practices	Comcare	
AS 2397 Guide to the Safe Use of Lasers in the Construction industry	Comcare	
Guidance Note for the Protection of Workers from the Ultraviolet Radiation in Sunlight [NOHSC:3012(1991)]		Comcare

NOTE 1 All RHS documents will be reviewed and progressively re-published under ARPANSA's Radiation Protection Series but not all of them will be re-published as Codes of Practice or Standards, with some of them being re-written as guidance notes in this Directory.

NOTE 2 This has been re-published as RPS 1 and has been adopted in Schedule 11 of this Directory.

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- International Atomic Energy Agency 2002, Preparedness and Response for a Nuclear or Radiological Emergency, Safety Standards Series No. GS-R-2, IAEA, Vienna.
- International Organisation for Standardisation 1980, *Sealed Radioactive Sources – Classification*, ISO 2919.
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Glossary

Accreditation means an authorisation by the Authority for a person to provide any of the specified radiation protection services identified in this Directory.

Accessible surface means that surface of the apparatus to which human access is possible without the use of tools or without penetration of any radiation shield.

Authorisation means a written permission granted by the Authority for an operating organisation to perform specified practices. The form of an authorisation can include a licence, registration, or accreditation.

Dealing includes to use, manufacture, store, transport, sell, possess, install, operate, maintain, repair, or dispose of, a radiation source.

Defence-in-Depth means the application of more than a single protective measure for a given safety objective such that the objective is achieved even if one or more of the protective measures fails.

Intervention means an action intended to reduce or avert exposure or the likelihood of exposure to sources which are not part of a controlled practice or which are out of control as a consequence of an accident or other event.

Ionizing radiation is defined as meaning electromagnetic or particulate radiation capable of producing ions directly or indirectly, but does not include electromagnetic radiation of a wavelength greater than 100 nanometres.

Ionizing radiation apparatus is defined as an apparatus that produces ionizing radiation when energised, or when assembled or repaired is capable of doing so when energised (e.g. a diagnostic x-ray machine or an industrial radiography x-ray machine).

Legislation refers to Acts and Regulations covering radiation protection, which are in place in Australian jurisdictions.

Licence means an authorisation granted by the Authority allowing a person to carry out a practice involving radiation.

Non-ionizing radiation is defined as meaning electromagnetic radiation of a wavelength greater than 100 nanometres.

Non-ionizing radiation apparatus is defined as an apparatus of a prescribed type that when energised produces non-ionizing radiation, or when assembled or repaired is capable of doing so (e.g. laser surgery equipment).

Notification means a document submitted to the Authority to notify an intention to carry out a practice or any other dealing described in this Directory.

Nuclear Installation²⁰ means a nuclear fuel fabrication plant, nuclear reactor (including critical and sub-critical assemblies), research reactor, nuclear power plant, spent fuel storage facility, enrichment plant or reprocessing facility.

Person in this Directory includes a natural person and corporation.

Practice means any human activity that introduces additional sources or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed to radiation.

Radiation is defined as meaning electromagnetic waves or quanta and/or sub-atomic particles, propagated through space or through a material medium.

²⁰ Certain types of nuclear installation may be prohibited in Australian jurisdictions by government policy or other legislation.

Radiation apparatus means an ionizing radiation apparatus or a non-ionizing radiation apparatus.

Radiation source²¹ means anything that may emit ionizing radiation, or an apparatus specified in Schedule 2 that emits non-ionizing radiation.

Radioactive material²² means any material that emits ionizing radiation spontaneously.

Registration means an authorisation by the Authority for a radiation apparatus or sealed source apparatus, or for a premises in which radiation sources are used.

Responsible person in relation to any radioactive source, ionizing or non-ionizing radiation apparatus, nuclear installation, prescribed radiation facility or premises on which unsealed radioactive sources are stored or used means the person:

- (a) having overall management responsibility including responsibility for the security and maintenance of the source, apparatus, installation or facility;
- (b) having overall control over who may use the source or apparatus, installation or facility; and
- (c) in whose name the source, apparatus, installation or facility, would be registered if this is required.

Sealed source is defined as radioactive material that is permanently sealed in a capsule or closely bound and in solid form.

Sealed source apparatus is defined as an apparatus that produces ionizing radiation by virtue of the fact that it contains radioactive material in the form of a sealed source.

[NOTE: Many additional terms require definition and a more detailed glossary will be published in a later version of the Directory.]

²¹ For regulatory purposes, subject to the exemption and exclusion provisions of this Directory

²² For regulatory purposes, subject to the exemption and exclusion provisions of this Directory

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