



**Australian Government**

**Australian Radiation Protection  
and Nuclear Safety Agency**

**CODE OF PRACTICE**

# **Radiation Protection in the Medical Applications of Ionizing Radiation**

**RADIATION PROTECTION SERIES No. 14**

## 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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Radiation Protection in the  
Medical Applications of Ionizing  
Radiation

Radiation Protection Series Publication No. 14

May 2008

This publication was approved by the Radiation Health Committee on 12-13 March 2008 and on 11 April 2008 the Radiation Health & Safety Advisory Council advised the CEO to adopt the Code of Practice.

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The mission of ARPANSA is to provide the scientific expertise and infrastructure necessary to support the objective of the ARPANS Act — to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation.

Published by the Chief Executive Officer of ARPANSA in May 2008.

## Foreword

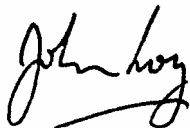
The use of ionizing radiation in medical diagnosis and treatment continues to grow rapidly in Australia and worldwide. The exposure of patients to radiation requires that the procedure is justified and optimised so that the radiation dose delivered to the patient is not greater than the dose necessary to achieve the clinical objective of the exposure. In the case of diagnostic procedures the radiation dose should be the minimum required to provide the diagnostic information and in therapy the prescribed radiation dose should be delivered to the target tissue with a minimum exposure of non-target tissue. Radiation protection of the patient, occupationally exposed staff and the general public are key requirements in the optimal use of ionizing radiation in medicine. A particular concern is the radiation protection of pregnant, or potentially pregnant, women and of children.

*This Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation* establishes the regulatory requirements for the use of ionizing radiation in medicine for inclusion in the *National Directory for Radiation Protection* and adoption by Australian jurisdictions. The Code is a regulatory document that covers the practices of radiotherapy, diagnostic and interventional radiology, and nuclear medicine. Three separate Safety Guides for radiation protection in radiotherapy, diagnostic and interventional radiology, and nuclear medicine inform best practice in each of these medical applications of ionizing radiation and provide useful radiation protection information to the medical community.

The Code is based on the radiation protection principles of justification, optimisation and limitation and to this end establishes the responsibilities of the Responsible Person (who may be a natural or legal person, and bears ultimate responsibility), the Radiation Medical Practitioner (who justifies, optimises and authorises the exposure) and the Operator (who administers the radiation to the patient). The Code also requires that a Qualified Expert is available for consultation and advice, and for calibration, dosimetry and quality assurance in radiation therapy. A central feature of the Code is the requirement that the Responsible Person ensures that a Radiation Management Plan is developed, implemented and regularly reviewed. The adoption of this Code should ensure that the best health outcomes are achieved for patients who are administered ionizing radiation in their medical diagnosis or treatment.

A draft of the Code was provided for initial comment from the medical radiation community in May 2007. This was followed by the formal public consultation period from 24 August 2007 to 26 October 2007, when the draft Code was released together with a draft Regulatory Impact Statement, as required under the *COAG Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies (June 2004)*. A one-day *National Conference on Radiation Protection in Medicine* was held during the public consultation period on 3 October 2007 both to explain the Code and Safety Guides to stakeholders and to allow for interactive

feedback and discussion. The working group reviewed all comments received and the Office of Best Practice Regulation cleared the final Regulatory Impact Statement on 18 February 2008. The Radiation Health Committee approved the final Code on 12-13 March 2008 and the Radiation Health and Safety Advisory Council advised me to adopt the Code at its meeting of 11 April 2008.

A handwritten signature in black ink, appearing to read "John Loy". The signature is fluid and cursive, with a long horizontal stroke at the end.

John Loy  
CEO of ARPANSA

**2 May 2008**

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*Note:* Technical terms which are described in the Glossary appear in **bold type** on their first occurrence in the text.

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# 1. Introduction

## 1.1 CITATION

This Code may be cited as the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)*.

## 1.2 PURPOSE

This Code establishes:

- (a) the regulatory requirements for the use of **ionizing radiation** in medicine that will, in the context of good practice, ensure that the risks associated with **radiation** exposure to the patient are optimised and those to staff and other persons are as low as reasonably achievable.
- (b) the radiation protection principles;
- (c) a requirement for the preparation of a comprehensive Radiation Management Plan addressing the radiation protection principles;
- (d) the specific roles and responsibilities of the following:
  - the **Responsible Person**, being the person who has the overall management responsibility of the **radioactive source**, **radiation-producing equipment** or medical practice;
  - the **radiation medical practitioner**, being the person responsible for the justification and optimisation of the procedure involving the exposure of the patient to ionizing radiation, either for each individual patient or by way of protocols specific for the procedure; and
  - the **operator** who exposes the patient to ionizing radiation, and
- (e) the management and reporting of **radiation incidents**.

## 1.3 SCOPE

This Code applies to the following ionizing radiation exposures in medicine:

- (a) the exposure of patients as part of their medical diagnosis or treatment;
- (b) the exposure of individuals as part of health screening programs;
- (c) the exposure of individuals participating in research programs<sup>2</sup>;
- (d) the exposure of individuals as part of medico-legal procedures;
- (e) the **occupational exposure** of individuals;

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<sup>1</sup> A separate Code of Practice for radiation protection in dentistry applies to the use of ionizing radiation in dentistry. A separate Code of Practice applying to the use of ionizing radiation by chiropractors is being planned.

<sup>2</sup> Specific requirements for research participants are given in the *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005)*, ARPANSA.

- (f) the exposure of **carers**; and
- (g) the exposure of members of the public arising from medical radiation-producing equipment and radioactive sources.

This Code is supplemented by three Safety Guides that address good practice in radiation protection in:

- (a) **diagnostic radiology and interventional radiology**;
- (b) **nuclear medicine**; and
- (c) **radiotherapy**.

#### **1.4 STRUCTURE**

This Code sets out regulatory requirements to be met to achieve a satisfactory level of radiation protection in medicine. It sets out material that will be adopted by State, Territory and Commonwealth Regulatory Authorities as part of their regulatory controls, and in conditions of **authorisation** associated with the use of ionizing radiation in medicine within their jurisdiction.

Schedules that set out additional information also form part of this Code.

#### **1.5 INTERPRETATION**

The presence of the word 'must' in a section indicates that the requirement to which it refers is mandatory.

The meanings of several terms used in this Code that have technical or legal significance, and are central to the national radiation protection framework, are defined in the Glossary.

## 2. Radiation Protection Principles

In this Code, the radiation protection principles of justification, optimisation and **dose** limitation are applied to radiation protection in medicine.

### 2.1 JUSTIFICATION

The justification principle is common to all **practices** that involve exposure to ionizing radiation. This principle can be stated as follows:

*No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes<sup>3</sup>.*

2.1.1 Before a medical procedure involving exposure of an individual to ionizing radiation is approved or commenced, the procedure must be justified for that individual<sup>4</sup>.

### 2.2 OPTIMISATION

2.2.1 Radiation doses that arise from medical radiation exposures and those received by the public and occupationally exposed persons must be kept as low as reasonably achievable, economic and social factors being taken into account.

2.2.2 Equipment and methods must be selected to ensure that radiation administered to a patient for:

- (a) diagnostic purposes, including interventional radiology, is:
  - (i) sufficient to enable the procedure to provide the required information; and
  - (ii) not greater than is necessary to provide that information,
- (b) therapeutic purposes:
  - (i) is consistent with the intended radiotherapeutic purpose of the exposure; and
  - (ii) will achieve the required dose(s) to the target tissue(s).

2.2.3 The amount of radiation administered to a pregnant patient must be such that the radiation dose to the embryo or fetus is minimised within the parameters of the procedure.

### 2.3 DOSE LIMITS

2.3.1 All medical applications of ionizing radiation must be managed in such a way that radiation doses to occupationally exposed persons

<sup>3</sup> ICRP 60 (1991), paragraph 112.

<sup>4</sup> Justification may take into account a generic justification applicable to a well established procedure as defined through the relevant professional bodies.

and members of the public do not exceed the dose limits specified in **RPS1**.

- 2.3.2 Dose limits do not apply to the exposure of patients as part of their diagnosis or treatment.

## **3. Responsibilities**

### **3.1 RESPONSIBLE PERSON**

#### **Radiation Management Plan**

3.1.1 The Responsible Person must ensure that:

- (a) a Radiation Management Plan that incorporates the components listed in section A1 of Schedule A of this Code is developed, documented, resourced, implemented and regularly reviewed;
- (b) the Radiation Management Plan prepared under 3.1.1(a) describes the management and reporting arrangements that enable the radiation medical practitioner and the operator to discharge their obligations under this Code; and
- (c) all persons affected by the Radiation Management Plan follow and comply with the Radiation Management Plan.

3.1.2 Where radioactive waste is generated by the practice, the Responsible Person must ensure that the Radiation Management Plan includes a section on Radioactive Waste Management that incorporates the components listed in section A2 of Schedule A of this Code.

#### **Justification of a medical radiation procedure**

3.1.3 The Responsible Person must have protocols in place to ensure that no radiation procedure is carried out unless:

- (a) it has been justified, either:
  - (i) generically or on an individual basis by the radiation medical practitioner, in accordance with clause 3.2.2 depending on the nature of the procedure and the patient; or
  - (ii) generically by an acknowledged professional college or authority;
- (b) it has been approved for each individual by:
  - (i) the radiation medical practitioner; or
  - (ii) the operator in accordance with written guidelines established by:
    - a. the radiation medical practitioner; or
    - b. an acknowledged professional college or authority;
- (c) where a medical procedure may result in a radiation dose of more than 1 mSv to an embryo or fetus, the radiation medical practitioner has taken reasonable steps to determine the pregnancy status of the patient; and

- (d) where a radiopharmaceutical is to be administered, the breast-feeding status of that patient has been established if there is the potential for a radiation dose of more than 1 mSv to a breast-fed child.

### Optimisation of protection, limitation of radiation doses and recording of radiation doses

- 3.1.4 The Responsible Person must ensure that radiation doses to occupationally exposed persons and members of the public:
  - (a) do not exceed the dose limits specified in RPS1; and
  - (b) are kept as low as reasonably achievable, economic and social factors being taken into account.
- 3.1.5 The Responsible Person must ensure that the medical facility is designed, constructed, shielded, used, and maintained so that the:
  - (a) **dose constraints** acceptable to the **relevant regulatory authority** are applied; and
  - (b) dose limits to occupationally exposed persons and members of the public are not exceeded.
- 3.1.6 The Responsible Person must have systems in place to ensure that a patient is correctly identified for the intended medical radiation procedure.
- 3.1.7 The Responsible Person must ensure that a record is kept of:
  - (a) for a type of diagnostic radiology procedure:
    - (i) sufficient information on the procedure or exposure parameters<sup>5</sup> that would allow the radiation dose to a patient to be estimated; or
    - (ii) the radiation dose administered to the patient;
  - (b) for a nuclear medicine procedure, the radionuclide, radiopharmaceutical form and confirmed<sup>6</sup> activity administered to the patient;
  - (c) for a radioactive source implant or applicator:
    - (i) the radionuclide;
    - (ii) chemical and physical form;
    - (iii) confirmed activity or dose administered to the patient; and
    - (iv) the duration of the implant; or

<sup>5</sup> Typically, this means that the practice keeps information that identifies for each type of examination, the standard protocol and the standard exposure factors.

<sup>6</sup> 'confirmed' means that the radionuclide, form and activity for a diagnostic procedure are verified by at least one trained and qualified staff member and for a therapeutic procedure, a second such person witnesses and verifies the measurement of the dispensed activity.

- (d) for external beam radiotherapy, intra-operative radiotherapy or remote afterloading brachytherapy:
  - (i) the radiation dose administered to the patient; and
  - (ii) the technique parameters used.

3.1.8 The Responsible Person must establish a program to ensure that radiation doses administered to a patient for diagnostic purposes are:

- (a) periodically compared with **diagnostic reference levels (DRLs)** for diagnostic procedures for which DRLs have been established in Australia; and
- (b) if DRLs are consistently exceeded, reviewed to determine whether radiation protection has been optimised.

### Occupational radiation exposures

3.1.9 The Responsible Person must ensure that:

- (a) a **personal radiation monitoring device** supplied by a Personal Radiation Monitoring Service, approved in accordance with the criteria specified in the *National Directory for Radiation Protection*, is provided to each occupationally exposed person who is likely to be exposed to ionizing radiation in excess of 1 mSv in any one year;
- (b) for each occupationally exposed person who is likely to be exposed to internal **radioactive material** resulting in an **effective dose** in excess of 1 mSv in any one year, internal radiation dose assessments and biological monitoring are carried out as detailed in the *National Directory for Radiation Protection*;
- (c) a record is kept of the radiation doses received by each occupationally exposed person in accordance with the requirements of RPS1; and
- (d) work practices are investigated and reviewed if an occupationally exposed person receives an effective dose in excess of the dose constraints acceptable to the relevant regulatory authority.

3.1.10 When an occupationally exposed female declares that she is pregnant, the Responsible Person must, if necessary, adapt the working conditions of the pregnant female so as to ensure that the embryo or fetus is afforded the same level of protection as that of a member of the public, as specified in RPS1.

### Radiation incident

3.1.11 In the event of a **radiation incident**, the Responsible Person must:

- (a) ensure that the radiation incident is investigated;

- (b) submit a written report of a **reportable radiation incident**, including the preventative action to avoid a recurrence, to the **relevant regulatory authority** within 7 days; and
- (c) in the case of a radiation-producing equipment or a radioactive source that is, or may be, lost or stolen, immediately report the event to the relevant regulatory authority.

3.1.12 The Responsible Person must ensure that:

- (a) an internal report on each radiation incident is written and kept in the institution's radiation incident report register; and
- (b) measures are implemented so that the possibility of a recurrence of the radiation incident investigated in 3.1.11(a) is minimised.

#### **Accountability for radiation-producing equipment and radioactive sources**

3.1.13 The Responsible Person must, at all times, be able to account for all radiation-producing equipment and radioactive sources within the Responsible Person's control.

#### **Inadvertent irradiation of an embryo or fetus**

3.1.14 The Responsible Person must ensure that where an embryo or fetus inadvertently receives a radiation dose of more than 1 mSv:

- (a) protocols are in place to address the situation; and
- (b) the relevant requirements of Schedule B are met.

#### **Deterministic effects from interventional radiology**

3.1.15 The Responsible Person must ensure that, following an interventional radiological procedure where there is a possibility of radiation induced **deterministic effects**, there are protocols in place for the radiation medical practitioner to liaise with the **referrer** to ensure follow-up of the patient.

#### **Training**

3.1.16 The Responsible Person must ensure that all individuals who may be occupationally exposed to ionizing radiation have training<sup>7</sup> or instruction that relates to:

- (a) the type of work being undertaken;
- (b) the radiation-producing equipment or radioactive source, and related ancillary equipment, that the individual may be required to use;

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<sup>7</sup> Specific competency requirements are established in the *National Directory for Radiation Protection*.

- (c) any potential radiation hazards associated with the practice; and
- (d) the means of protection and minimisation of unwanted radiation exposure.

### **Radiation shielding**

3.1.17 The Responsible Person must ensure that radiation shielding:

- (a) meets the requirements of the Radiation Management Plan; and
- (b) is documented:
  - (i) as part of the commissioning procedure of the radiation-producing equipment or radioactive source; and
  - (ii) where shielding modifications are made subsequent to commissioning.

### **Warning notices**

3.1.18 The Responsible Person must ensure that:

- (a) illustrated notices requesting that the patient informs staff before the radiation procedure if she may be pregnant are prominently displayed within the facility;
- (b) illustrated notices requesting that the patient informs staff before the administration of a radiopharmaceutical if she is breast-feeding are prominently displayed in the waiting rooms and administration rooms;
- (c) each access point into a radiation area has a visible warning sign or device to indicate that the room contains an ionizing radiation hazard;
- (d) an illuminated radiation warning sign displaying the illuminated words 'IONIZING RADIATION – DO NOT ENTER' (or equivalent) is positioned directly adjacent to any entry point of any room that houses:
  - (i) fixed radiation-producing equipment used for external beam radiotherapy, fluoroscopy or computed tomography; or
  - (ii) remote afterloading brachytherapy equipment; and
- (e) the illuminated sign required in (d) is illuminated immediately:
  - (i) as the radiation-producing equipment is placed in the preparation mode prior to exposure and continues to illuminate during the exposure; or
  - (ii) as the radioactive source is driven out of its shielded housing and continues to illuminate until the source has been returned to the shielded position.

## Radiation-producing equipment and radioactive sources

- 3.1.19 The Responsible Person must ensure that all diagnostic and therapeutic procedures are performed using equipment that has been designed for the intended purpose.
- 3.1.20 The Responsible Person must:
- (a) ensure that a Radiation Source Register is maintained and updated with information relating to:
    - (i) the acquisition, movement, replacement or disposal of all radiation-producing equipment or **sealed radioactive sources**; and
    - (ii) the maximum activity of each unsealed radionuclide that the medical facility has been authorised to possess;
  - (b) advise the relevant regulatory authority of the receipt or disposal of any:
    - (i) radiation-producing equipment; or
    - (ii) sealed radioactive source (unless given a generic approval in accordance with an authorisation issued by the relevant regulatory authority).

## Quality Assurance Program

- 3.1.21 The Responsible Person must ensure that a comprehensive equipment Quality Assurance program is established, performed, maintained and regularly reviewed at any site where radiation-producing equipment or radioactive sources are used.
- 3.1.22 The Responsible Person must ensure that a Quality Assurance program for all dosimetry and associated measuring instruments is implemented and regularly reviewed to ensure their continued accuracy.
- 3.1.23 The Responsible Person must ensure that the results of each Quality Assurance program and their outcomes are clearly documented.

## Expert advice

- 3.1.24 The Responsible Person must ensure that:
- (a) a **qualified expert** is available:
    - (i) for consultation on optimisation, dosimetry and quality assurance; and
    - (ii) to give advice on matters relating to radiation protection in **medical exposure**, and
  - (b) for radiotherapy, the calibration, dosimetry and quality assurance requirements of this Code are conducted by, or under the supervision of, a qualified expert.

## **Equipment calibration – Radiotherapy**

3.1.25 The Responsible Person must ensure that:

- (a) all radiation-producing therapy equipment and remote afterloading brachytherapy equipment is calibrated for the proposed clinical techniques by a qualified expert at the time of acceptance following installation;
- (b) before release for clinical use, all radiation-producing therapy equipment and remote afterloading brachytherapy equipment is subjected to an independent<sup>8</sup> series of calibration tests for the proposed clinical techniques that confirm that the conditions under which it was calibrated produce acceptable clinical accuracy of dose output;
- (c) clinical use of radiation-producing therapy equipment and remote afterloading brachytherapy equipment is restricted to those techniques for which the equipment has been calibrated and independently checked as described in (a) and (b);
- (d) each of the clinically-used treatment beams for radiation-producing therapy equipment and all clinical parameters for equipment containing radioactive sources (in relation to both planning and treatment delivery) are checked and recalibrated by a qualified expert at intervals specified in national or international protocols; and
- (e) all calibrations of reference and radiation-measuring equipment are traceable to relevant national standards.

## **Radiotherapy treatment planning**

3.1.26 The Responsible Person must ensure that all dosimetry data used for treatment planning:

- (a) are clearly documented; and
- (b) have a reference trace to the original data source.

3.1.27 The Responsible Person must ensure that:

- (a) the treatment planning procedures are followed;
- (b) all treatment planning equipment is tested;
- (c) the basic data for each available treatment planning computer program are verified by a qualified expert:
  - (i) on initial acceptance; and
  - (ii) after any change or upgrade; and
- (d) patient-specific independent calculations of monitor units or treatment time are performed for radiotherapy.

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<sup>8</sup> 'Independent' means by a qualified expert using equipment where neither the expert nor the equipment was associated with the initial calibration.

### **Equipment repair, maintenance or modification**

- 3.1.28 The Responsible Person must, following any repair, maintenance or modification on radiation-producing equipment, or equipment containing radioactive source(s), that could affect radiation safety, ensure that:
- (a) the operation of the equipment is re-assessed so that the radiation safety of patients, staff and the public is maintained; and
  - (b) a radiation survey is carried out by a qualified expert.
- 3.1.29 The Responsible Person must ensure that, following any repair, maintenance or modification on radiation-producing therapy equipment, including source changes, that could alter the dose output, the equipment is calibrated by a qualified expert before it is returned to clinical use.
- 3.1.30 The Responsible Person must ensure that a written record is kept detailing the work performed on radiation-producing equipment or equipment containing radioactive source(s) following any repair, maintenance or modification on that equipment.
- 3.1.31 Where the Responsible Person is informed that a fault that could compromise patient safety, diagnosis or treatment has been identified in radiation-producing equipment or equipment containing radioactive source(s), and where the fault could be one which might be present in other similar equipment, the Responsible Person must:
- (a) report the details of the fault to the relevant regulatory authority; and
  - (b) ensure that a record is maintained of:
    - (i) such faults; and
    - (ii) the necessary corrective maintenance performed.

### **Death of a patient**

- 3.1.32 The Responsible Person must have systems in place to ensure that in the event of the death of a patient with radioactive material above the relevant activity exemption level *in situ*:
- (a) exposure to radiation of any person handling the body is minimised;
  - (b) each temporarily implanted sealed source or radioactive applicator is removed;
  - (c) consideration is given as to whether a permanent radioactive implant or tissue containing unsealed radioactive material is to be excised;

- (d) the level of activity of a permanent implant or unsealed radioactive material remaining in the body is calculated and documented; and
- (e) where a permanent implant or unsealed radioactive material remains in the body, written instructions regarding handling and safety are provided to each person who handles the body.

### **3.2 RADIATION MEDICAL PRACTITIONER**

#### **Authorisation for a medical radiation procedure**

- 3.2.1 A radiation medical practitioner who approves a procedure involving the exposure of a patient to ionizing radiation must:
- (a) be appropriately authorised by the relevant regulatory authority;
  - (b) comply with the relevant provisions of the Radiation Management Plan; and
  - (c) ensure that the radiation exposures are justified in accordance with 3.2.2 and optimised in accordance with 3.2.5.

#### **Justification of a medical radiation procedure**

- 3.2.2 In determining the net benefit from a medical radiation procedure, the radiation medical practitioner must take into account:
- (a) the specific objectives of the procedure;
  - (b) the characteristics of the individual patient involved;
  - (c) the total potential clinical benefits, including the direct health benefits to the patient and, where relevant, the benefits to society in general;
  - (d) the individual **detriment** to the patient that may result from the procedure;
  - (e) the pregnancy status of a female patient of child bearing capacity;
  - (f) the breast-feeding status of the female patient to be administered a radiopharmaceutical if there is the potential for a radiation dose of more than 1 mSv to a breast-fed child;
  - (g) the efficacy, benefits and risk of available alternate techniques having the same objectives with less or no exposure to ionizing radiation; and
  - (h) any medical data and patient records relevant to the medical exposure.

#### **Approval of a medical radiation procedure**

- 3.2.3 Other than for a patient involved in an approved health screening program, an individual involved in an approved research project, or a

patient undergoing an emergency radiology procedure, the radiation medical practitioner must not undertake or approve a procedure involving exposure to ionizing radiation unless a written referral<sup>9</sup> is provided that:

- (a) contains adequate patient identifying information;
- (b) states the:
  - (i) clinical question that the diagnostic procedure should try to answer; or
  - (ii) clinical condition that the therapeutic treatment is seeking to treat, and
- (c) provides the referrer's contact details for consultative purposes.

3.2.4 In approving a procedure involving exposure to ionizing radiation, the radiation medical practitioner must, for:

- (a) a therapeutic procedure, before the first treatment delivery:
  - (i) provide a written prescription for the procedure; and
  - (ii) approve the treatment plan;
- (b) a diagnostic nuclear medicine procedure:
  - (i) provide a written prescription for the procedure;
  - (ii) specify the procedure; or
  - (iii) have provided generic written guidelines for the procedure, or
- (c) a diagnostic or interventional radiology procedure:
  - (i) specify the procedure to be performed; or
  - (ii) have provided generic written guidelines for the procedure.

### **Optimisation of protection**

3.2.5 The radiation medical practitioner must ensure that the radiation dose arising from a diagnostic procedure is optimised.

### **Provision of advice to patients and carers**

3.2.6 In the case of a patient discharged while undergoing treatment with an implanted radioactive implant, attachment or with a therapeutic quantity of radiopharmaceutical, the radiation medical practitioner must ensure that the patient, carer or the patient's legal guardian is provided with written information and instructions that address:

- (a) the risks associated with ionizing radiation exposure to carers and other persons;

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<sup>9</sup> This referral may be in hard copy or electronic form.

- (b) how to restrict exposures to carers and other persons that could result from proximity to the patient, if relevant;
- (c) storage or disposal of any dislodged radioactive sources, if relevant; and
- (d) prevention of contamination, if relevant;

before the patient leaves the place where the radiation procedure took place.

### **Potentially pregnant or pregnant patients**

3.2.7 Where a radiation procedure is likely to result in a radiation dose of more than 1 mSv to an embryo or fetus, the radiation medical practitioner must ensure that:

- (a) reasonable steps are taken immediately before the commencement of the procedure to establish whether the patient is pregnant; and
- (b) for a therapeutic nuclear medicine administration, the pregnancy status of a patient of childbearing capacity is established with a definitive biochemical test within 24 hours before the commencement of the treatment.

3.2.8 The radiation medical practitioner must comply with the requirements of Schedule B for females for whom pregnancy has been established.

### **Patient who is breast-feeding or caring for a child**

3.2.9 The radiation medical practitioner must, when a radiopharmaceutical is administered to a patient who is breast-feeding a child, take reasonable measures to ensure that any exposure of the breast-fed child is eliminated or minimised.

3.2.10 The radiation medical practitioner must, when a therapeutic radiopharmaceutical is administered to a patient who is providing close care of a child, take reasonable steps to ensure that any exposure of the child is eliminated or minimised.

### **High Dose Rate brachytherapy**

3.2.11 The radiation medical practitioner must be immediately available in person while a radioactive source is within the patient, for all High Dose Rate brachytherapy procedures where medical assistance could be required to remove a source-containing applicator from the patient in the event of an emergency.

### **3.3 OPERATOR**

#### **Authorisation for a medical procedure**

3.3.1 Only a person who is appropriately authorised by the relevant regulatory authority to administer ionizing radiation to an individual for diagnostic or interventional radiology, nuclear medicine or radiotherapy may administer ionizing radiation to an individual.

#### **General requirements for an operator**

3.3.2 The operator must comply with the relevant provisions of the Radiation Management Plan.

3.3.3 The operator must wear:

- (a) all personal protective equipment provided by the Responsible Person where applicable to the procedure; and
- (b) a personal radiation monitoring device where provided by the Responsible Person.

#### **Delivery of a medical radiation procedure**

3.3.4 The operator must:

- (a) not expose a person to ionizing radiation unless the procedure has been approved or prescribed:
  - (i) by a radiation medical practitioner; or
  - (ii) in accordance with written protocols established by:
    - a. the radiation medical practitioner; or
    - b. an acknowledged professional college or authority,
- (b) follow the established protocol for the procedure;
- (c) ensure that the protection of the patient is optimised within the scope of the parameters under the control of the operator;
- (d) ensure that the radiation exposure of persons other than the patient is minimised; and
- (e) in the case of radiotherapy, ensure that:
  - (i) the radiation treatment plan has been approved by the radiation medical practitioner;
  - (ii) the radiation dose to the patient is delivered in accordance with the radiation treatment plan;
  - (iii) there is a continuous oversight of the operating parameters of radiation-producing equipment during the radiation dose delivery; and

- (iv) the exposure from radiation-producing equipment is immediately terminated if there is any concern that the equipment will not deliver the correct patient radiation dose.

### **Identification of a patient**

- 3.3.5 Immediately before conducting a radiation procedure on a patient, the operator must:
- (a) take reasonable steps to ensure that the patient is correctly identified; and
  - (b) ensure that the prescribed procedure is to be performed on the patient.

### **Potentially pregnant or pregnant patients**

- 3.3.6 Before conducting a procedure on a female patient of child-bearing capacity that is likely to result in a radiation dose to an embryo or fetus of more than 1 mSv, the operator must:
- (a) seek confirmation from the radiation medical practitioner that the pregnancy status of the patient has been established; or
  - (b) in circumstances where an approved procedure is conducted in accordance with clause 3.3.4(a)(ii):
    - (i) take reasonable steps to establish the pregnancy status of the patient; and
    - (ii) take into account the requirements of Schedule B for a female patient in whom pregnancy cannot be excluded.

### **Control of exposure to persons other than the patient**

- 3.3.7 The operator must ensure that no person is in the imaging, administration or treatment area during a radiation exposure or the administration of a radioactive source to a patient unless that person is required to be in attendance.
- 3.3.8 The operator of equipment that delivers external beam radiotherapy, intra-operative radiotherapy or High Dose Rate brachytherapy must:
- (a) ensure that no-one other than the patient receiving the treatment is in the room during the time that the equipment is emitting radiation or the radioactive source is exposed unless the circumstances are specified in the Radiation Management Plan;
  - (b) ensure that visual surveillance of the treatment room is maintained for the time that:
    - (i) the radiation-producing equipment is delivering the exposure; or
    - (ii) the radioactive source is exposed; and

- (c) immediately terminate the exposure if any person other than the patient might be accidentally exposed.

**Equipment**

3.3.9 The operator of radiation-producing equipment or equipment containing radioactive source(s) must ensure that no safety interlock devices are bypassed at any time during routine clinical use of the equipment.

**Equipment fault or error**

3.3.10 The operator of medical radiation-producing equipment, equipment containing radioactive sources or other associated apparatus, who experiences any fault or error of equipment or system, or unusual operating behaviour must:

- (a) immediately cease using the equipment or apparatus until the fault, error or unusual operating behaviour is rectified;
- (b) record the details of the fault, error or unusual operating behaviour; and
- (c) where the fault could compromise patient safety, diagnosis or treatment, report it to:
  - (i) the Responsible Person; and
  - (ii) the radiation medical practitioner.

**Radiation incidents**

3.3.11 The operator must report any radiation incident within 24 hours to:

- (a) the Responsible Person in accordance with the procedures set out in the Radiation Management Plan; and
- (b) the radiation medical practitioner.

## **Schedule A**

### **Radiation Management Plan**

#### **A1 PREPARATION OF THE RADIATION MANAGEMENT PLAN**

A1.1 The Radiation Management Plan<sup>10</sup> must address the following:

- (a) work practices and protocols for all procedures involving medical exposure to ionizing radiation, including those:
  - (i) to ensure that the prescribed radiation procedure is performed on the correct patient;
  - (ii) for the proper planning and delivery of radiotherapy doses;
  - (iii) for preparation and dispensing of radiopharmaceuticals;
  - (iv) for optimising the protection of the patient consistent with section 2 of this Code; and
  - (v) for observation<sup>11</sup> of the patient by the operator throughout procedures where the dosimetry or image quality could be affected by patient movement;
- (b) construction and shielding of the medical facility or premises so that dose constraints acceptable to the relevant regulatory authority are applied for occupationally exposed persons and members of the public;
- (c) the action to be taken if the radiation doses to occupationally exposed persons or members of the public are found to exceed the dose constraints;
- (d) optimisation of the shielding so that external radiation exposure rates are kept as low as reasonably achievable, economic and social factors being taken into account;
- (e) arrangements for appropriate isolation of hospital in-patients undergoing treatment with sealed or unsealed radioactive sources;
- (f) the training, qualifications and supervision of the staff of the medical facility and their roles and responsibilities;
- (g) the licensing requirements of the radiation regulatory authority;
- (h) personal radiation monitoring requirements for persons involved in the use of radiation;
- (i) personal protective equipment to be worn by persons involved in the use of radiation;
- (j) actions necessary to manage a radiation incident, including reporting (both internal and to the radiation regulatory authority) and investigation of the radiation incident;

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<sup>10</sup> The Radiation Management Plan may make reference to, and utilise, other documented safety procedures and work practices.

<sup>11</sup> Observation may be by indirect means such as video surveillance.

- (k) procedures for the reporting of faults in radiation-producing equipment or radioactive sources that could compromise patient safety, diagnosis or treatment;
- (l) emergency procedures in response to radiation incidents;
- (m) a Quality Assurance program that includes planned and systematic actions necessary to provide adequate confidence that a structure, system, component or procedure will:
  - (i) perform satisfactorily and safely;
  - (ii) comply with agreed standards; and
  - (iii) include quality control procedures, with particular emphasis on the optimisation of radiation protection,
- (n) arrangements for the storage of radioactive material;
- (o) arrangements for the transport of radioactive material;
- (p) arrangements for radioactive waste management, if relevant;
- (q) mechanisms for implementation of the Radiation Management Plan;
- (r) mechanisms for, and frequency of, review of the Radiation Management Plan;
- (s) arrangements for obtaining expert advice in radiation protection; and
- (t) any other requirement that may have a bearing on radiation safety.

- A1.2 Where other documented safety procedures and work practices that exist within the organisation are referred to or used:
- (a) the Responsible Person must have authority over the safety procedures and work practices referred to; and
  - (b) the safety procedures and work practices referred to must not be modified without consideration of the effect on the Radiation Management Plan.

## **A2 REQUIREMENTS FOR RADIOACTIVE WASTE MANAGEMENT**

- A2.1 A Radiation Management Plan that includes Radioactive Waste Management must address the following:
- (a) mixed waste hazards<sup>12</sup>;
  - (b) the necessary equipment and instructions for the safe handling and disposal of all radioactive waste in accordance with any authorisation issued by the relevant regulatory authority;
  - (c) procedures to ensure that all persons involved in the handling of radioactive waste receive, understand and comply with the radioactive waste management requirements;
  - (d) the storage of all radioactive waste in adequately shielded containers or in a secure shielded room, as appropriate to the nature of the waste, so as to ensure no member of the public receives an effective dose greater than the relevant limit specified in RPS1;

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<sup>12</sup> The radioactive waste may also be flammable, toxic, infectious or putrescible material.

- (e) procedures to ensure that all radioactive waste leaving the facility, either as gaseous or liquid effluent discharged to the environment or sewerage system, does so within the relevant requirements specified in the *National Directory of Radiation Protection*; and
- (f) notification to the relevant regulatory authority of any radiation incident which has, or may have, resulted, or may result in:
  - (i) a discharge of effluent in excess of the relevant discharge limit;  
or
  - (ii) spillage of radioactive waste during transport.

## **Schedule B**

### **Protection of an Embryo or Fetus**

#### **B1 PROTOCOL IF A PATIENT IS PREGNANT**

- B1.1 A procedure on a pregnant patient that may result in a radiation dose of more than 1 mSv to an embryo or fetus must:
- (a) be justified on an individual basis; and
  - (b) include an assessment of the risks to:
    - (i) the embryo or fetus from the radiation exposure; and
    - (ii) the patient if the procedure is not performed.
- B1.2 Where it is decided that a medical radiation procedure that may result in a radiation dose of more than 1 mSv to the embryo or fetus is necessary or advisable for a woman who is pregnant, the risks must be fully explained to:
- (a) the referrer; and
  - (b) the pregnant patient,
- before the procedure is carried out.
- B1.3 Before approving a radiation procedure for a pregnant patient that may result in a radiation dose of more than 1 mSv to an embryo or fetus, an estimate of the expected radiation dose to the embryo or fetus must be made and recorded.

## Glossary

### Absorbed dose

the energy absorbed per unit mass by matter from ionizing radiation which impinges upon it.

Absorbed dose,  $D$ , is defined by the expression:

$$D = \frac{dE}{dm}$$

where  $dE$  is the mean energy imparted by ionizing radiation to matter of mass  $dm$ .

The unit of absorbed dose is joule per kilogram ( $\text{J kg}^{-1}$ ), with the special name gray (Gy).

### Authorisation

a written permission granted by the relevant regulatory authority to perform specified practices. The form of an authorisation can include a licence, registration, or accreditation.

### Carer

a person who voluntarily, willingly and knowingly assists or helps in the care, support or comfort of patients undergoing a diagnostic or therapeutic medical radiation procedure.

### Deterministic effect

an effect, such as partial loss of function of an organ or tissue, caused by radiation and manifest only above some threshold of dose, the severity of the effect depending upon the dose received.

### Detriment

a measure, or measures, of harm caused by exposure to radiation and usually taken to mean health detriment; it has no single definition, but can be taken to be an attribute or a collection of attributes which measure harm, such as attributable probability of death and reduction of life expectancy.

### Diagnostic radiology

the use of X-rays to diagnose disease or injury, or provide imaging information for medical purposes.

### Diagnostic reference level (DRL) for medical exposure

dose levels for medical exposures in medical radiodiagnostic practices, or levels of activity in the case of radiopharmaceuticals, applied to groups of standard-sized patients or standard phantoms for common types of diagnostic examination and broadly defined types of equipment. These levels are expected not to be consistently exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied. DRLs will be set by relevant professional bodies and published by ARPANSA or the relevant regulatory authority from time to time.

## Dose

a generic term that may mean **absorbed dose**, **equivalent dose** or effective dose depending on context.

### Dose constraint

a prospective restriction on anticipated dose, primarily intended to be used to discard undesirable options in an optimisation calculation.

In occupational exposure, a dose constraint may be used to restrict the options considered in the design of the working environment for a particular category of employee.

In medical exposure, a dose constraint for volunteers in medical research may be used to restrict the options considered in the design of an experimental protocol.

In **public exposure**, a dose constraint may be used to restrict the exposure of the critical group from a particular source of radiation.

### Effective dose

a measure of dose which takes into account both the type of radiation involved and the radiological sensitivities of the organs and tissues irradiated.

Effective dose,  $E$ , is the sum of weighted equivalent doses in all organs and tissues of the body. It is given by the expression:

$$E = \sum_T w_T H_T$$

where  $H_T$  is the equivalent dose in organ or tissue  $T$  and  
 $w_T$  is the tissue weighting factor for that organ or tissue.

The unit of effective dose is  $\text{J kg}^{-1}$ , with the special name sievert (Sv).

### Equivalent dose

a measure of dose in organs and tissues which takes into account the type of radiation involved.

Equivalent dose,  $H$ , is a weighted dose in an organ or tissue, with the radiation weighting factor(s) determined by the type and energy of the radiation to which the organ or tissue is exposed. The equivalent dose  $H_T$  in organ or tissue  $T$  is given by the expression:

$$H_T = \sum_R w_R D_{T,R}$$

where  $D_{T,R}$  is the absorbed dose averaged over the organ or tissue  $T$  due to radiation  $R$  and  
 $w_R$  is the radiation weighting factor for that radiation.

The unit of equivalent dose is the same as for absorbed dose,  $\text{J kg}^{-1}$ , with the special name sievert (Sv).

### **Interventional radiology**

procedures comprising guided therapeutic and diagnostic interventions, by percutaneous or other access, usually performed under local anaesthesia or sedation, with fluoroscopic or computed tomographic imaging used to localise, in conjunction with a surgical procedure, the lesion/treatment site, monitor the surgical procedure, or control and document the therapy or diagnosis.

### **Ionizing radiation**

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

### **Medical exposure**

exposure of a person to radiation received as a patient undergoing medical diagnosis or therapy, or as a volunteer in medical research, or non-occupational exposure received as a consequence of assisting an exposed patient.

### **Nuclear medicine**

the use of **unsealed radioactive sources** for diagnostic imaging, physiological testing and therapy.

### **Occupational exposure**

exposure of a person to radiation which occurs in the course of that person's work and which is not excluded exposure<sup>13</sup>.

### **Operator**

any natural person who is authorised by the relevant regulatory authority to administer radiation to a patient for radiology, nuclear medicine or radiotherapy.

### **Personal radiation monitoring device**

a device designed to be worn by a person to monitor the radiation dose received by the person.

### **Practice**

a type of human activity; in a radiological context, a human activity which may result in exposure to ionizing radiation and to which a system of radiation protection applies.

### **Public exposure**

exposure of a person, or persons, to radiation which is neither occupational nor medical exposure.

### **Qualified expert**

a person who:

- (a) is qualified in the application of the physics of therapeutic or diagnostic uses of ionizing radiation; and

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<sup>13</sup> Excluded exposure means the component of exposure that arises from natural background radiation.

- (b) has been recognised by the relevant regulatory authority as being able to perform the dosimetric calculations, radiation measurements and monitoring relevant to the person's area of expertise<sup>14</sup>.

**Radiation**

electromagnetic waves or quanta, and atomic or sub-atomic particles, propagated through space or through a material medium.

**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.

**Radiation medical practitioner**

the practitioner responsible for the overall conduct of the procedure involving the exposure of the patient to ionizing radiation. In nuclear medicine, this person will normally be a nuclear medicine specialist, in radiation oncology, this person will normally be a radiation oncologist and in diagnostic or interventional radiology, this person will usually be a radiologist, but might also be, for example, a cardiologist or, for limited procedures, a general practitioner.

**Radiation-producing equipment**

any equipment that produces ionizing radiation when energised.

**Radioactive material**

material which spontaneously emits ionizing radiation as a consequence of radioactive decay.

**Radioactive source**

any radioactive material that is either a sealed radioactive source or an unsealed radioactive source.

**Radiotherapy**

the therapeutic use of ionizing radiation from radiation-producing equipment and sealed radioactive sources to treat disease.

**Referrer**

a registered medical practitioner, dentist or other health professional who is entitled to refer individuals to the radiation medical practitioner who will be responsible for the overall conduct of the procedure involving the exposure of the patient to ionizing radiation.

**Relevant regulatory authority**

the radiation protection authority or authorities designated, or otherwise recognised, for regulatory purposes in connection with protection and safety relating

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<sup>14</sup> Competency requirements for a qualified expert will be listed in future editions of the *National Directory for Radiation Protection*.

to medical applications of ionizing radiation. A list of relevant regulatory authorities in Australia is included in Annex 1 of this Code.

### **Reportable radiation incident**

a radiation incident as defined in Schedule 13 of the *National Directory for Radiation Protection*.

### **Responsible Person**

in relation to any radioactive source, radiation-producing equipment, prescribed radiation facility or premises on which radioactive sources are stored or used means the legal person<sup>15</sup>:

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

### **RPS1**

the *Recommendations for Limiting Exposure to Ionizing Radiation (1995)*, and *National Occupational Health and Safety Commission National Standard for Limiting Occupational Exposure to Ionizing Radiation*, Radiation Protection Series No. 1, republished 2002, ARPANSA, Yallambie.

### **Sealed radioactive source**

a radioactive substance bonded within metals or sealed in a capsule or other container in such a way as to:

- (a) minimise the possibility of escape or dispersion of the radioactive substance; and
- (b) allow the emission of ionizing radiation for use as required.

### **Unsealed radioactive source**

a radioactive source that is not a sealed radioactive source.

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<sup>15</sup> A legal person can be a natural person, a body corporate, a partnership or any other entity recognised as a 'legal person' by the legislation in the jurisdiction.

## Annex 1

### Regulatory Authorities

Where advice or assistance is required from the relevant regulatory authority, it may be obtained from the following officers:

COMMONWEALTH, STATE / TERRITORY	CONTACT
Commonwealth	Chief Executive Officer ARPANSA PO Box 655 Miranda NSW 1490 Email: <a href="mailto:info@arpansa.gov.au">info@arpansa.gov.au</a> Tel: (02) 9541 8333 Fax: (02) 9541 8314
Australian Capital Territory	Manager Radiation Safety Radiation Safety Section ACT Health Locked Bag 5 Weston Creek ACT 2611 Email: <a href="mailto:radiation.safety@act.gov.au">radiation.safety@act.gov.au</a> Tel: (02) 6207 6946 Fax: (02) 6207 6966
New South Wales	Manager Hazardous Materials and Radiation Section Department of Environment and Climate Change PO Box A290 Sydney South NSW 1232 Email: <a href="mailto:radiation@environment.nsw.gov.au">radiation@environment.nsw.gov.au</a> Tel: (02) 9995 5000 Fax: (02) 9995 6603
Northern Territory	Manager Radiation Protection Radiation Protection Section Department of Health and Community Services GPO Box 40596 Casuarina NT 0811 Email: <a href="mailto:envirohealth@nt.gov.au">envirohealth@nt.gov.au</a> Tel: (08) 8922 7152 Fax: (08) 8922 7334
Queensland	Director, Radiation Health Unit Department of Health 450 Gregory Terrace Fortitude Valley QLD 4006 Email: <a href="mailto:radiation_health@health.qld.gov.au">radiation_health@health.qld.gov.au</a> Tel: (07) 3406 8000 Fax: (07) 3406 8030
South Australia	Director, Radiation Protection Division Environment Protection Authority PO Box 721 Kent Town SA 5071 Email: <a href="mailto:radiationprotection@epa.sa.gov.au">radiationprotection@epa.sa.gov.au</a> Tel: (08) 8130 0700 Fax: (08) 8124 4671
Tasmania	Senior Health Physicist Health Physics Unit Department of Health and Human Services GPO Box 125B Hobart TAS 7001 Email: <a href="mailto:health.physics@dhhs.tas.gov.au">health.physics@dhhs.tas.gov.au</a> Tel: (03) 6222 7256 Fax: (03) 6222 7257
Victoria	Team Leader Radiation Safety Department of Human Services GPO Box 4057 Melbourne VIC 3001 Email: <a href="mailto:radiation.safety@dhs.vic.gov.au">radiation.safety@dhs.vic.gov.au</a> Tel: 1300 767 469 Fax: 1300 769 274
Western Australia	Secretary, Radiological Council Locked Bag 2006 PO Nedlands WA 6009 Email: <a href="mailto:radiation.health@health.wa.gov.au">radiation.health@health.wa.gov.au</a> Tel: (08) 9346 2260 Fax: (08) 9381 1423

**Please note:** This table was correct at the time of printing but is subject to change from time to time. For the most up-to-date list, the reader is advised to consult the ARPANSA web site ([www.arpansa.gov.au](http://www.arpansa.gov.au)). For after hours emergencies only, the police will provide the appropriate emergency contact number.

## Annex 2

### Health Effects of Ionizing Radiation and Standards for Control of Exposure

It is well known that high doses of ionizing radiation can cause harm, but there is continuing scientific uncertainty about effects at low doses. At levels of dose routinely encountered by members of the public and occupationally exposed persons, there is little or no epidemiological evidence of health effects. Radiation protection standards recognise that it is not possible to eliminate all radiation exposure, but they do provide for a system of control to avoid unnecessary exposure and to keep doses in the low dose range.

Extreme doses of radiation to the whole body (around 10 sievert<sup>16</sup> and above), received in a short period, cause so much damage to internal organs and tissues of the body that vital systems cease to function and death may result within days or weeks. Very high doses (between about 1 sievert and 10 sievert), received in a short period, kill large numbers of cells, which can impair the function of vital organs and systems. Acute health effects, such as nausea, vomiting, skin and deep tissue burns, and impairment of the body's ability to fight infection may result within hours, days or weeks. The extent of the damage increases with dose. However, 'deterministic' effects such as these are not observed at doses below certain thresholds. By limiting doses to levels below the thresholds, deterministic effects can be prevented entirely.

Doses below the thresholds for deterministic effects may cause cellular damage, but this does not necessarily lead to harm to the individual: the effects are probabilistic or 'stochastic' in nature. It is known that doses above about 100 millisievert, received in a short period, lead to an increased risk of developing cancer later in life. There is good epidemiological evidence – especially from studies of the survivors of the atomic bombings – that, for several types of cancer, the risk increases roughly linearly with dose, and that the risk factor averaged over all ages and cancer types is about 1 in 100 for every 100 millisievert of dose (i.e. 1 in 10 000 per millisievert).

At doses below about 100 millisievert, the evidence of harm is not clear-cut. While some studies indicate evidence of radiation-induced effects, epidemiological research has been unable to establish unequivocally that there are effects of statistical significance at doses below a few tens of millisieverts. Nevertheless, given that no threshold for stochastic effects has been demonstrated, and in order to be cautious in establishing health standards, the proportionality between risk and dose observed at higher doses is presumed to continue through all lower levels of dose to zero. This is called the linear, no-threshold (LNT) hypothesis and it is made for radiation protection purposes only.

There is evidence that a dose accumulated over a long period carries less risk than the same dose received over a short period. Except for accidents and medical exposures, doses are not normally received over short periods, so that it is appropriate in determining standards for the control of exposure to use a risk factor that takes this into account. While not well quantified, a reduction of the high-dose risk factor by a factor of two has been adopted internationally, so that for radiation

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<sup>16</sup> The sievert (Sv) is a unit of measurement of radiation dose (see ARPANSA's *Recommendations for limiting exposure to ionizing radiation (2002)*).

protection purposes the risk of radiation-induced fatal cancer (the risk factor) is taken to be about 1 in 20 000 per millisievert of dose for the population as a whole.

If the LNT hypothesis is correct, any dose carries some risk. Therefore, measures for control of exposure for stochastic effects seek to avoid all reasonably avoidable risk. This is called optimising protection. However, risk in this sense may often be assessed in terms of risk to a population, and may not ensure sufficient protection of the individual. Consequently, the optimisation approach is underpinned by applying dose limits that restrict the risk to individuals to an acceptable level. The fundamental regulatory philosophy is expressed in three principles, based on the recommendations of the International Commission on Radiological Protection (ICRP), which may be summarised as follows:

*Justification:* human activities that cause exposure to radiation may be permitted only if they do more good than harm;

*Optimisation of protection:* exposure to radiation from justified activities should be kept as low as reasonably achievable, social and economic factors being taken into account; and

*Limitation of individual dose:* doses must not exceed the prescribed dose limits.

Determining what is an acceptable risk for regulatory purposes is a complex value judgement. The ICRP reviewed a number of factors in developing its recommendations, which have in general been internationally endorsed, including by the World Health Organization, the International Labour Organisation and the International Atomic Energy Agency. Australia's Radiation Health Committee, now established under the ARPANS Act<sup>17</sup>, has recommended that the international standards be adopted in Australia. The recommended dose limits are summarised as follows:

**Limit on effective dose\***

	For occupational exposure	For members of the public
To limit individual risk	20 mSv per year, averaged over 5 years*	1 mSv in a year*

\*for details, see ARPANSA's *Recommendations for limiting exposure to ionizing radiation (2002)*

In most situations, the requirements for limiting individual risk ensure that doses are below deterministic thresholds, but for cases where this does not apply, the recommended limits are as follows:

**Annual limit on equivalent dose\***

	For occupational exposure	For members of the public
To prevent deterministic effects		
in the lens of the eye	150 mSv	15 mSv
in the skin	500 mSv	50 mSv
in the hands and feet	500 mSv	—

\*for details, see ARPANSA's *Recommendations for limiting exposure to ionizing radiation (2002)*

<sup>17</sup> The Australian Radiation Protection and Nuclear Safety Act (1998)

In the case of occupational exposure during pregnancy, the general principle is that the embryo or fetus should be afforded the same level of protection as is required for a member of the public. For medical workers, the ICRP recommends that there should be a reasonable assurance that fetal dose can be kept below 1 mGy<sup>18</sup> during the course of the pregnancy. This guidance may be generalised to cover all occupationally exposed pregnant workers by keeping the fetal dose below 1 mSv. A full explanation of radiation protection principles and of the recommended standards for Australia is given in ARPANSA/NOHSC Radiation Protection Series No. 1: *Recommendations for limiting exposure to ionizing radiation (1995)* and *National standard for limiting occupational exposure to ionizing radiation (both republished 2002)*.

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<sup>18</sup> The gray (Gy) is a unit of radiation dose. For X-rays and gamma radiation, it is essentially equivalent to the sievert.

## Annex 3

### ARPANSA Radiation Protection Series Publications

ARPANSA has taken over responsibility for the administration of the former NHMRC Radiation Health Series of publications and for the codes developed under the *Environment Protection (Nuclear Codes) Act 1978*. The publications are being progressively reviewed and republished as part of the *Radiation Protection Series*. All of the Nuclear Codes have now been republished in the Radiation Protection Series.

All publications listed below are available in electronic format, and can be downloaded free of charge by visiting ARPANSA's website at [www.arpansa.gov.au/Publications/codes/index.cfm](http://www.arpansa.gov.au/Publications/codes/index.cfm).

Radiation Protection Series publications are available for purchase directly from ARPANSA. Further information can be obtained by telephoning ARPANSA on 1800 022 333 (freecall within Australia) or (03) 9433 2211.

#### RADIATION PROTECTION SERIES

- RPS 1. Recommendations for Limiting Exposure to Ionizing Radiation (1995) and National Standard for Limiting Occupational Exposure to Ionizing Radiation (republished 2002)
- RPS 2. Code of Practice for the Safe Transport of Radioactive Material (2008)
- RPS 3. Radiation Protection Standard for Maximum Exposure Levels to Radiofrequency Fields – 3 kHz to 300 GHz (2002)
- RPS 4. Recommendations on the Discharge of Patients undergoing Treatment with Radioactive Substances (2002)
- RPS 5. Code of Practice and Safety Guide for Portable Density/Moisture Gauges Containing Radioactive Sources (2004)
- RPS 6. National Directory for Radiation Protection, Edition 1.0 (2004)
- RPS 7. Recommendations for Intervention in Emergency Situations Involving Radiation Exposure (2004)
- RPS 8. Code of Practice for the Exposure of Humans to Ionizing Radiation for Medical Research Purposes (2005)
- RPS 9. Code of Practice and Safety Guide for Radiation Protection and Radioactive Waste Management in Mining and Mineral Processing (2005)
- RPS 10. Code of Practice and Safety Guide for Radiation Protection in Dentistry (2005)
- RPS 11. Code of Practice for the Security of Radioactive Sources (2007)
- RPS 12. Radiation Protection Standard for Occupational Exposure to Ultraviolet Radiation (2006)
- RPS 13. Code of Practice and Safety Guide for Safe Use of Fixed Radiation Gauges (2007)
- RPS 14. Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)

Those publications from the NHMRC Radiation Health Series that are still current are:

### **RADIATION HEALTH SERIES**

- RHS 3. Code of practice for the safe use of ionizing radiation in veterinary radiology: Parts 1 and 2 (1982)
- RHS 8. Code of nursing practice for staff exposed to ionizing radiation (1984)
- RHS 9. Code of practice for protection against ionizing radiation emitted from X-ray analysis equipment (1984)
- RHS 10. Code of practice for safe use of ionizing radiation in veterinary radiology: part 3-radiotherapy (1984)
- RHS 13. Code of practice for the disposal of radioactive wastes by the user (1985)
- RHS 14. Recommendations for minimising radiological hazards to patients (1985)
- RHS 15. Code of practice for the safe use of microwave diathermy units (1985)
- RHS 16. Code of practice for the safe use of short wave (radiofrequency) diathermy units (1985)
- RHS 18. Code of practice for the safe handling of corpses containing radioactive materials (1986)
- RHS 19. Code of practice for the safe use of ionizing radiation in secondary schools (1986)
- 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)
- RHS 22. Statement on enclosed X-ray equipment for special applications (1987)
- RHS 23. Code of practice for the control and safe handling of radioactive sources used for therapeutic purposes (1988)
- RHS 24. Code of practice for the design and safe operation of non-medical irradiation facilities (1988)
- RHS 25. Recommendations for ionization chamber smoke detectors for commercial and industrial fire protection systems (1988)
- RHS 28. Code of practice for the safe use of sealed radioactive sources in borehole logging (1989)
- RHS 30. Interim guidelines on limits of exposure to 50/60Hz electric and magnetic fields (1989)
- RHS 31. Code of practice for the safe use of industrial radiography equipment (1989)
- RHS 34. Safety guidelines for magnetic resonance diagnostic facilities (1991)
- RHS 35. Code of practice for the near-surface disposal of radioactive waste in Australia (1992)
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