Australian Government

Australian Radiation Protection and Nuclear Safety Agency

CODE OF PRACTICE

Radiation Protection in the use of Ionizing Radiation by Chiropractors

Radiation Protection Series Publication No.

Comment on the Regulatory Impact Statement and draft Code of Practice should be forwarded by 15 May 2009 to:

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(Electronic submissions preferred)

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

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Foreword

The justification for the use of X-rays for chiropractic procedures is controversial. Most regulatory authorities around the world have recognised that X-ray is part of chiropractic care and have authorised its use accordingly thus accepting the generic justification for its use. Having said that, the exposure of chiropractic clients to radiation still requires individual justification of the procedure in terms of good chiropractic practice and, where justified, optimisation of the radiation dose so that the client does not receive more than the dose necessary to achieve the objective of the exposure. The radiation dose should be the minimum required to provide the chiropractic information. Radiation protection of the client, occupationally exposed staff and the general public are key requirements in the optimal use of ionizing radiation in chiropractic. A particular concern is the radiation protection of pregnant, or potentially pregnant, women and of children.

This Code of Practice is a regulatory document and covers radiation protection in the use of ionizing radiation by chiropractors. It establishes the regulatory requirements for the use of ionizing radiation in chiropractic procedures for inclusion in the *National Directory for Radiation Protection* and adoption by Australian jurisdictions.

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 chiropractor (who justifies, optimises and authorises the exposure) and the operator (who administers the radiation to the client). It is recognised that in many cases, this may well be the same person. 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 outcomes are achieved for chiropractic clients who are administered ionizing radiation as part of their treatment.

The draft Code was released for a public consultation period from 6 March 2009 to 1 May 2009 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).* The working group reviewed all comments received and the Office of Best Practice Regulation cleared the final Regulatory Impact Statement on DD MMMM 2009. The Radiation Health Committee approved the final Code on DD-DD MMMM 2009 and the Radiation Health and Safety Advisory Council advised me to adopt the Code at its meeting of DD MMMM 2009.

PA Burns
Acting CEO of ARPANSA
DD MMMM 2009

1. Introduction

1.1 CITATION

This Code may be cited as the *Code of Practice for Radiation Protection in the use of Ionizing Radiation by Chiropractors (200X)*.

1.2 PURPOSE

This Code establishes:

(a) the regulatory requirements for the use of **ionizing radiation** by chiropractors that will, in the context of good practice, ensure that the risks associated with **radiation** exposure to:

(i) the client are optimised; and

(ii) 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 X-ray equipment or practice;
- the **chiropractor**, being the person responsible for the justification and optimisation of the procedure involving the exposure of the client to ionizing radiation, either for each individual client or by way of protocols specific for the procedure; and
- the **operator** who exposes the person to ionizing radiation, and

(e) the management and reporting of **radiation incidents**.

1.3 SCOPE

This Code of Practice applies to the following ionizing radiation exposures:

(a) the exposure of clients as part of their diagnosis;

(b) the **occupational exposure** of individuals; and

(c) the exposure of members of the public.

This Code is supplemented by a Safety Guides that address good practice in radiation protection in the use of ionizing radiation by chiropractors.

1.4 STRUCTURE

This Code of Practice sets out regulatory requirements to be met to achieve a satisfactory level of radiation protection. 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 by chiropractors within their jurisdiction. It should be noted that the provisions outlined in this Code are essentially the same as the radiographic

provisions contained in the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008).*

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

1.5 INTERPRETATION

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

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

2. Radiation Protection Principles

In this Code, the radiation protection principles of justification, optimisation and **dose** limitation are applied to the use of ionizing radiation by chiropractors.

2.1 JUSTIFICATION

The justification principle is common to all **practice**s involving 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*[1].

2.1.1 Before a procedure involving exposure of an individual to ionizing radiation is approved or commenced, the procedure must be justified for that individual[2].

2.2 OPTIMISATION

2.2.1 Radiation doses that arise from radiation exposures carried out by a chiropractor and that are 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 person for chiropractic purposes is:

(a) sufficient to enable the procedure to provide the required information; and

(b) not greater than is necessary to provide that information.

2.2.3 The amount of radiation administered to a pregnant client 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 applications of ionizing radiation must be managed in such a way that radiation doses to occupationally exposed persons 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 a person as part of their diagnosis.

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1 ICRP 60 (1991), paragraph 112.

2 Justification may take into account a generic justification applicable to a well established procedure as defined through the relevant professional bodies.

3. Responsibilities

3.1 THE 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 a chiropractor 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.

Justification of a radiation procedure

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

(a) it has been justified on an individual basis by a chiropractor in accordance with clause 3.2.2 depending on the nature of the procedure and the client;

(b) it has been approved for each individual by a chiropractor; and

(c) where a procedure may result in a radiation dose of more than 1 mSv to an embryo or fetus, the chiropractor has taken reasonable steps to determine the pregnancy status of the client.

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

3.1.3 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.

3.1.4 The Responsible Person must ensure that the X-ray 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 for occupationally exposed persons and members of the public are not exceeded.

3.1.5 The Responsible Person must have systems in place to ensure that each client is correctly identified for the intended radiation procedure.

3.1.6 The Responsible Person must ensure that, for each X-ray procedure, a record is kept of:

(a) sufficient information on the procedure that would allow the radiation dose to the client to be estimated; or

(b) the radiation dose administered to the client.

3.1.7 The Responsible Person must establish a program to ensure that radiation doses administered to a person for chiropractic purposes are:

(a) periodically compared with **diagnostic reference levels (DRLs)** for radiographic 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

3.1.8 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) a record is kept of the radiation doses received by each occupationally exposed person in accordance with the requirements of RPS1; and

(c) work practices are investigated and reviewed if an occupationally exposed person receives effective doses in excess of the dose constraints acceptable to the relevant regulatory authority.

3.1.9 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

3.1.10 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 an X-ray unit that is, or may be, lost or stolen, immediately report the event to the relevant regulatory authority.

3.1.11 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 the recurrence of the radiation incident investigated in 3.1.10(a) is minimised.

Accountability for X-ray equipment

3.1.12 The Responsible Person must be able to account for all X-ray equipment within the Responsible Person's control at all times.

Inadvertent irradiation of an embryo or fetus

3.1.13 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.

Training

3.1.14 The Responsible Person must ensure that all individuals who may be occupationally exposed to ionizing radiation have training[3] or instruction that relates to:

(a) the type of work being undertaken;

(b) the X-ray equipment, and related ancillary equipment, that the individual may be required to use;

(c) any potential radiation hazards associated with the practice; and

(d) the means of protection and minimisation of unwanted radiation exposure.

Radiation shielding

3.1.15 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 X-ray equipment; and

(ii) where shielding modifications are made subsequent to commissioning.

Warning notices

3.1.16 The Responsible Person must ensure that:

(a) illustrated notices requesting that the client inform staff before the radiation procedure if she may be pregnant are prominently displayed within the facility; and

(b) each access point into a radiation area has a visible warning sign or device to indicate that the room contains an X-ray unit.

[3] Specific competency requirements are established in the *National Directory for Radiation Protection*.

X-ray equipment

3.1.17 The Responsible Person must ensure that all X-ray procedures are performed using equipment that has been designed for the intended purpose.

3.1.18 The Responsible Person must advise the relevant regulatory authority of the receipt or disposal of any X-ray equipment.

Quality Assurance Program

3.1.19 The Responsible Person must ensure that a comprehensive equipment Quality Assurance program is established, performed, maintained and regularly reviewed at any site where X-ray equipment is used.

3.1.20 The Responsible Person must ensure that the results of each Quality Assurance program and their outcomes are clearly documented.

Expert advice

3.1.21 The Responsible Person must ensure that a **qualified expert** is available:

(a) for consultation on optimisation, dosimetry and quality assurance; and

(b) to give advice on matters relating to radiation protection.

Equipment repair, maintenance or modification

3.1.22 The Responsible Person must, following any repair, maintenance or modification on X-ray equipment that could affect radiation safety, ensure that:

(a) the operation of the equipment is re-assessed so that the radiation safety of clients, staff and the public is maintained; and

(b) a radiation survey is carried out by a qualified expert.

3.1.23 The Responsible Person must ensure that a written record is kept detailing the work performed on X-ray equipment following any repair, maintenance or modification on that equipment.

3.1.24 Where the Responsible Person is informed that a fault that could compromise safety or diagnosis has been identified in X-ray equipment 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.

3.2 CHIROPRACTOR

Authorisation for a radiation procedure

3.2.1 A chiropractor who approves a procedure involving the exposure of a person 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:

(i) justified in accordance with 3.2.2; and

(ii) optimised in accordance with 3.2.5.

Justification of a radiation procedure

3.2.2 In determining the net benefit from a radiation procedure, the chiropractor must take into account:

(a) the specific objectives of the procedure;

(b) the characteristics of the individual involved;

(c) the total potential benefits, including the direct health benefits to the person and, where relevant, the benefits to society in general;

(d) the individual detriment to the client that may result from the procedure;

(e) the pregnancy status of a female client of child bearing capacity;

(f) the efficacy, benefits and risk of available alternate techniques having the same objectives with less or no exposure to ionizing radiation; and

(g) any data and records relevant to the radiation exposure.

Approval of a radiation procedure

3.2.3 The chiropractor must not undertake or approve a procedure involving exposure to ionizing radiation unless a written referral[4] is provided that:

(a) contains adequate client identifying information;

(b) states the clinical question that the procedure should try to answer; and

(c) provides the referrer's contact details for consultative purposes.

3.2.4 In approving a procedure involving exposure to ionizing radiation, the chiropractor must specify the procedure to be performed.

Optimisation of protection

3.2.5 The chiropractor must ensure that the radiation dose arising from an X-ray procedure is optimised.

Potentially pregnant or pregnant clients

3.2.6 Where a radiation procedure is likely to result in a radiation dose of more than 1 mSv to an embryo or fetus, the chiropractor must ensure that reasonable steps are taken immediately before the commencement of the procedure to establish whether the client is pregnant.

[4] This referral may be in hard-copy or electronic form.

3.2.7 The chiropractor must comply with the requirements of Schedule B for females for whom pregnancy has been established.

3.3 OPERATOR

Authorisation for a procedure

3.3.1 Only a person who is appropriately authorised by the relevant regulatory authority 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 radiation procedure

3.3.4 The operator must:

(a) not expose a person to ionizing radiation unless the procedure has been approved by a chiropractor;

(b) follow the established protocol for the procedure;

(c) ensure that the protection of the client is optimised within the scope of the parameters under the control of the operator; and

(d) ensure that the radiation exposure of persons other than the client is minimised.

Identification of a client

3.3.5 Immediately before conducting a radiation procedure on a person, the operator must:

(a) take reasonable steps to ensure that the person is correctly identified; and

(b) ensure that the prescribed procedure is to be performed on the person.

Potentially pregnant or pregnant clients

3.3.6 Before conducting a procedure on a female client 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 seek confirmation from the chiropractor that the pregnancy status of the client has been established.

Control of exposure to persons other than the client

3.3.7 The operator must ensure that no person is in the X-ray room during a radiation exposure of a client unless that person is required to be in attendance.

Equipment fault or error

3.3.8 The operator of X-ray equipment 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 safety, diagnosis or treatment, report it to:

(i) the Responsible Person; and

(ii) the chiropractor.

Radiation incidents

3.3.9 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 chiropractor.

Schedule A

Radiation Management Plan

A1 Preparation of the Radiation Management Plan

A1.1 The Radiation Management Plan[5] must address the following:

(a) work practices and protocols for all procedures involving exposure to ionizing radiation, including those:

(i) to ensure that the prescribed radiation procedure is performed on the correct person;

(ii) for optimising the protection of the client consistent with section 2 of this Code; and

(iii) observation[6] of the client by the operator throughout procedures where the dosimetry or image quality could be affected by client movement;

(b) construction and shielding of the 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) the training, qualifications and supervision of the staff of the facility and their roles and responsibilities;

(f) the licensing requirements of the radiation regulatory authority;

(g) personal radiation monitoring requirements for persons involved in the use of radiation;

(h) personal protective equipment to be worn by persons involved in the use of radiation;

(i) actions necessary to manage a radiation incident, including reporting (both internal and to the radiation regulatory authority) and investigation of the radiation incident;

(j) procedures for the reporting of faults in X-ray equipment that could compromise safety or diagnosis;

(k) emergency procedures in response to radiation incidents;

(l) 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,

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5 The Radiation Management Plan may make reference to, and utilise, other documented safety procedures and work practices.

6 Observation may be by indirect means such as video surveillance.

(m) mechanisms for implementation of the Radiation Management Plan;

(n) mechanisms for, and frequency of, review of the Radiation Management Plan;

(o) arrangements for obtaining expert advice in radiation protection; and

(p) 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.

Schedule B

Protection of an Embryo or Fetus

B1 Protocol if a client is pregnant

B1.1 A procedure on a pregnant client that may result in a radiation dose of more than 1 mSv to an embryo or fetus must:

(c) be justified on an individual basis; and

(d) include an assessment of the risks to:

(i) the embryo or fetus from the radiation exposure; and

(ii) the client if the procedure is not performed.

B1.2 Where it is decided that a 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:

(e) the referrer; and

(f) the pregnant person,

before the procedure is carried out.

B1.3 Before approving a radiation procedure for a pregnant client 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 (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.

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 reference level (DRL) for exposure

dose levels for X-ray exposures applied to groups of standard-sized clients or standard phantoms for common types of chiropractic examinations and broadly defined types of equipment. These levels are expected not to be 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 **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 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, J kg^{-1}, with the special name sievert (Sv).

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.

Occupational exposure

exposure of a person to radiation which occurs in the course of that person's work and which is not excluded exposure[7].

Operator

any natural person who is authorised by the relevant regulatory authority to administer radiation to a person.

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

[7] 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[8].

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.

Referrer

a registered medical practitioner, dentist or other health professional who is entitled to refer individuals to a chiropractor who will be responsible for the overall conduct of the procedure involving the exposure of the person 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 to 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[9]:

(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.

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8 Competency requirements for a qualified expert will be listed in future editions of the *National Directory for Radiation Protection.*

9 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.

X-ray equipment

any equipment that produces ionizing radiation when energised.

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 Tel: (02) 9541 8333 Miranda NSW 1490 Fax: (02) 9541 8314 Email: info@arpansa.gov.au
New South Wales	Manager Hazardous Materials and Radiation Section Department of Environment and Climate Change PO Box A290 Tel: (02) 9995 5000 Sydney South NSW 1232 Fax: (02) 9995 6603 Email: radiation@environment.nsw.gov.au
Queensland	Director, Radiation Health Unit Department of Health 450 Gregory Terrace Tel: (07) 3406 8000 Fortitude Valley QLD 4006 Fax: (07) 3406 8030 Email: radiation_health@health.qld.gov.au
South Australia	Director, Radiation Protection Division Environment Protection Authority PO Box 721 Tel: (08) 8130 0700 Kent Town SA 5071 Fax: (08) 8130 0777 Email: radiationprotection@epa.sa.gov.au
Tasmania	Senior Health Physicist Health Physics Branch Department of Health and Human Services GPO Box 125B Tel: (03) 6222 7256 Hobart TAS 7001 Fax: (03) 6222 7257 Email: health.physics@dhhs.tas.gov.au
Victoria	Team Leader, Radiation Safety Department of Human Services GPO Box 4057 Tel: 1300 767 469 Melbourne VIC 3001 Fax: 1300 769 274 Email: radiation.safety@dhs.vic.gov.au
Western Australia	Secretary, Radiological Council Locked Bag 2006 PO Tel: (08) 9346 2260 Nedlands WA 6009 Fax: (08) 9381 1423 Email: radiation.health@health.wa.gov.au
Australian Capital Territory	Director Health Protection Service ACT Health Locked Bag 5 Tel: (02) 6205 1700 Weston Creek ACT 2611 Fax: (02) 6205 1705 Email: hps@act.gov.au
Northern Territory	Manager Radiation Protection Radiation Protection Section Department of Health and Families GPO Box 40596 Tel: (08) 8922 7152 Casuarina NT 0811 Fax: (08) 8922 7334 Email: envirohealth@nt.gov.au

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). 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[10] 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 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

[10] The sievert (Sv) is a unit of measurement of radiation dose (see ARPANSA's *Recommendations for limiting exposure to ionizing radiation (2002)*).

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[11], 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)

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[12] 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*

[11] The *Australian Radiation Protection and Nuclear Safety Act (1998)*

[12] The gray (Gy) is a unit of radiation dose. For X-rays and gamma radiation, it is essentially equivalent to the sievert.

(1995) and *National standard for limiting occupational exposure to ionizing radiation (both republished 2002).*

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