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Australian Radiation Protection and Nuclear Safety Agency

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Code for Radiation Protection in Medical Exposure

Radiation Protection Series C-5

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Radiation Protection Series

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) publishes Fundamentals, Codes and Guides in the Radiation Protection Series (RPS), which promote national policies and practices that protect human health and the environment from harmful effects of radiation. ARPANSA develops these publications jointly with state and territory regulators through the Radiation Health Committee (RHC), which oversees the preparation of draft policies and standards with the view of their uniform implementation in all Australian jurisdictions. Following agreement and, as relevant, approvals at the Ministerial level, the RHC recommends publication to the Radiation Health and Safety Advisory Council, which endorses documents and recommends their publication by the CEO of ARPANSA.

To the extent possible and relevant for Australian circumstances, the RPS publications give effect in Australia to international standards and guidance. The sources of such standards and guidance are varied and include the International Commission on Radiological Protection (ICRP); the International Commission on Non-Ionizing Radiation Protection (ICNIRP); the International Atomic Energy Agency (IAEA); and the World Health Organization (WHO).

Fundamentals set the fundamental principles for radiation protection and describe the fundamental radiation protection, safety and security objectives. They are written in an explanatory and non-regulatory style and describe the basic concepts and objectives of international best practice.

Codes are regulatory in style and may be referenced by regulations or conditions of licence. They contain either general safety or security requirements which may be applicable for all dealings with radiation, or practice-specific requirements. They provide overarching requirements and are expressed as 'must' statements which are to be satisfied to ensure an acceptable level of safety and/or security.

Guides provide recommendations and guidance on how to comply with the Codes or apply the principles of the Fundamentals. They are written in an explanatory and non-regulatory style and indicate the measures recommended to provide good practice. They are generally expressed as 'should' statements.

These three categories of publications are informed by public comment during drafting and are subject to a process of assessment of regulatory impact.

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This publication was prepared jointly with the *Radiation Health Committee*. The *Radiation Health and Safety Advisory Council* advised the CEO to adopt the Code.

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The mission of ARPANSA is to protect people and the environment from the harmful effects of radiation.

Published by the Chief Executive Officer of ARPANSA in MMM YYYY.

Acknowledgement of Country

ARPANSA proudly acknowledges Australia's Aboriginal and Torres Strait Islander community and their rich culture and pays respect to their Elders past and present. We acknowledge Aboriginal and Torres Strait Islander people as Australia's first peoples and as the Traditional Owners and custodians of the land and water on which we rely.

We recognise and value the ongoing contribution of Aboriginal and Torres Strait Islander people and communities to Australian life and how this enriches us. We embrace the spirit of reconciliation, working towards the equality of outcomes and ensuring an equal voice.

Foreword

The management of risks from ionising radiation requires actions that are based on fundamental principles of radiation protection, safety and security. The *Fundamentals for Protection Against Ionising Radiation (2014)* (RPS F-1) was published as part of ARPANSA's Radiation Protection Series (RPS) to provide an understanding of the effects of ionising radiation and associated risks for the health of humans and of the environment. RPS F-1 is the top tier document in the Australian national framework to manage risks from ionising radiation and explains how radiation protection, safety and security can work individually and collectively to manage such risks.

The use of ionising radiation in medical diagnosis and treatment continues to grow rapidly in Australia and worldwide. The exposure of a patient to radiation requires that the procedure be 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 a diagnostic procedure the radiation dose should be the minimum required to provide the diagnostic information. In therapy the prescribed radiation dose should be delivered to the target tissue whilst minimising 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 ionising radiation in medicine. A particular concern is the radiation protection of pregnant, or potentially pregnant, women and of children.

This *Code for Radiation Protection in Medical Exposure (201Y)* sets out the regulatory requirements in Australia for the protection of patients, their carers and comforters, and volunteers in biomedical research projects, in relation to their exposure to ionising radiation. The Radiation Health Committee (RHC) has developed this Code in the light of the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)* (RPS 14) but having regard to the requirements relating to medical exposure described in the Safety Requirements of the International Atomic Energy Agency (IAEA); *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements (GSR) Part 3* (IAEA 2014).

The Code must, as relevant, be used in conjunction with the *Code for Radiation Protection in Planned Exposure Situations (2016)* (RPS C-1), which sets out the requirements in Australia for the protection of occupationally exposed persons, the public, and the environment, in planned exposure situations.

This publication, together with RPS C-1, supersedes the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)* (RPS 14). This publication incorporates the salient aspects of the *Recommendations for the Discharge of Patients Undergoing Treatment with Radioactive Substances (2002)* (RPS 4) and, as a consequence, RPS 4 has been withdrawn.

At the time of publication of this document, it is intended that a revised Safety Guide providing information on best practice for radiation protection in radiotherapy, diagnostic and interventional radiology, and nuclear medicine will be developed. Until that time, the Safety Guides produced for use with RPS 14 can continue to be used to assist the implementation of this publication.

The Radiation Health Committee approved the final Code on XXXX and the Radiation Health and Safety Advisory Council advised me to adopt the Code at its meeting of XXXX.

Carl-Magnus Larsson
CEO of ARPANSA

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1. INTRODUCTION

1.1 Citation

This publication may be cited as the *Medical Exposure Code* (201Y).

1.2 Background

The International Commission on Radiological Protection (ICRP) published revised recommendations in 2007 (ICRP 2007) and the International Atomic Energy Agency (IAEA) published the *IAEA Safety Fundamentals* (IAEA 2006). Together with guidance on security developed by the IAEA in collaboration with its Member States, these documents have informed the development of Australia's *Fundamentals for Protection against Ionising Radiation* (2014) (the *Fundamentals*), which sets out the underlying principles that form the basis of the system of **radiation** protection used to manage risks from **ionising radiation** in Australia.

As stated in the *Fundamentals*, the objective of radiation protection, safety and security is to protect people and the environment from harmful effects of ionising radiation. This objective should be achieved without unduly limiting the operation of facilities or the conduct of activities that are **justified,** where the use of radiation results in net benefit despite also giving rise to radiation risks. The system of radiation protection aims to assess, manage and control **exposure** to radiation so that radiation risks, including risks of health effects and risks to the environment, are reduced to the extent reasonably achievable and, in the case of occupational and public exposure, radiation doses remain within limits.

The *Fundamentals* sets the overall strategy for Australia in relation to radiation protection; the high-level principles set out in the *Fundamentals* may be implemented through adoption of relevant Codes and Safety Guides. This Code applies to **medical exposures** including ionising radiation exposure received by patients as part of their own medical diagnosis (diagnostic exposure) or treatment (therapeutic exposure); by persons, other than those occupationally exposed, knowingly, while voluntarily helping in the support and comfort of patients; and by volunteers in a program of biomedical research involving their exposure. As medical exposures will always occur in a **planned exposure situation** and there will always be parallel considerations of occupational and public radiation protection and protection of the environment, this Code must always be used in conjunction with the *Code for Radiation Protection in Planned Exposure Situations* (2016) to ensure radiation protection for all aspects of medical uses of ionising radiation.

This Code builds upon and supersedes the foundation set by Australia's implementation of the Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008) (RPS 14). It specifies Australia's arrangements for ensuring that the requirements of the IAEA GSR Part 3 for medical exposure are achieved. The appendix lists the requirements cross-referenced to GSR Part 3. GSR Part 3 is published on the IAEA website.

1.3 Purpose

The purpose of this document is to set out the requirements in Australia for the protection of persons receiving medical exposures.

This Code is primarily directed to the **Responsible Person** of the **medical radiation facility** that conducts activities that result in medical exposure and sets out the measures that must be put in place for radiation protection in medical exposure. Responsibilities are also assigned to the **radiological medical practitioner**

who has the overall responsibility for the conduct of a radiological procedure and the **operator** who initiates a medical exposure.

1.4 Scope

This Code applies to all medical exposures involving ionising radiation[1] including exposure to **carers and comforters** and to volunteers in medical research, and also including intended, unintended and accidental exposures.

The requirements of this Code should be applied using a **graded approach** and interpreted accordingly. A Responsible Person also needs to comply with any requirements specified by the relevant regulatory authority. Not all requirements specified in this Code are relevant for every medical radiation facility.

This Code does not apply to:

(a) **occupational exposure**

(b) **public exposure**, except in the context of the release of a patient after radionuclide diagnosis or treatment

(c) environmental exposure

(d) human exposure for any purpose other than:

  (i) medical diagnosis

  (ii) medical treatment

  (iii) biomedical research

  (iv) health screening programs.

Dose limits[2] do not apply to medical exposures.

1.5 Interpretation

In this Code, unless the contrary intention appears, a reference to a Clause is a reference to the relevant Clause of this Code; and a reference to a Schedule, or part thereof, is a reference to the relevant Schedule, or part thereof, of this Code.

Each of the terms in bold type on first use has the meaning given in the Glossary together with any amplification given in this Code. In particular, the term 'radiation' means 'ionising radiation', as defined in the Glossary.

The presence of the term 'must' when it appears in this Code indicates that the requirement to which it refers is mandatory.

[1] A separate Code of Practice (RPS 10) applies to the use of ionising radiation in dentistry and a separate Code of Practice (RPS 19) applies to the use of ionising radiation by chiropractors.

[2] However, in diagnostic radiological procedures there are dose constraints and Diagnostic Reference Levels (DRLs).

2. Radiation Protection Principles for Medical Exposures

2.1 Introduction

Radiation exposures of patients in medicine require an approach that differs from radiological protection in other planned exposure situations. The exposure is intentional and must be appropriately justified. In radiation therapy, the biological effects of high-dose radiation (e.g. cell killing) are used for the benefit of the patient to treat cancer and other diseases. In diagnostic and interventional procedures radiation is used to generate images or information that guide diagnosis or treatment. Radiation protection in diagnostic and interventional procedures includes avoiding unnecessary exposures and maximising the benefit-risk ratio of justified exposures, while in radiation therapy the goal is delivery of the required dose to the volume to be treated, avoiding unnecessary exposure of healthy tissues.

2.2 Principles for Protection

The main principles of radiation protection in medicine are justification and optimisation. In medical exposures, the level of the radiation exposure (the dose) should be commensurate with the clinical objective.

2.2.1 Justification

The principle of justification applies at three levels to the use of radiation in medicine.

- At the first level, the use of radiation in medicine is accepted as doing more good than harm to patients.
- At the second level, a specified procedure and objective is defined and justified (e.g. chest radiographs for patients showing relevant symptoms, or a group of individuals at risk of a condition that can be detected and treated). The aim of this generic justification is to judge whether the radiological procedure will usually improve diagnosis or treatment or will provide necessary information about the medical condition of the exposed individuals.
- At the third level, the particular application must be judged to do more good than harm to a specific patient.

All individual medical exposures must be justified in advance, taking into account the specific objectives of the exposure and the characteristics of the medical condition of the individual involved.

2.2.2 Optimisation

Optimisation of protection is maximising the benefit-risk ratio of a medical exposure for that patient. Radiation exposure must be minimised yet still sufficient to fulfil the clinical objective of the procedure, with account taken of relevant norms of acceptable image quality or therapeutic efficacy. Special attention is required for exposures of paediatric patients, for individuals undergoing health screening, for volunteers in medical research and where a foetus or breast-fed infant may receive an incidental exposure.

Diagnostic reference levels (DRLs), which give an indication of levels of doses to patients for common procedures, are one method that can be used as an optimisation tool in medical imaging. Their purpose is to raise awareness of patient doses and prompt medical radiation facilities at which doses are greater than the reference levels to review procedures and revise as appropriate.

3. Safety Requirements for Medical Exposures

3.1 Control of medical exposures

Responsibilities specific to medical exposure

Responsible Person

3.1.1 The **Responsible Person** must ensure that no patient undergoes a medical exposure unless:

(a) it is a **radiological procedure** that has been requested by a **referrer** and information on the clinical context has been provided, or it is part of an **approved health screening program**

(b) the medical exposure has been justified by means of communication between the **radiological medical practitioner** and the referrer, as appropriate, or it is part of an approved health screening program

(c) a radiological medical practitioner is responsible for protection and safety in the planning and delivery of the medical exposure as specified in clause 3.1.4(a)

(d) the patient or the patient's legal authorised representative has been informed as appropriate (and, in the case of diagnostic procedures, where practical and when requested by the patient) of the expected benefits of the radiological procedure as well as the radiation risks, including risk to a foetus where appropriate.

3.1.2 The Responsible Person must ensure that no individual receives a medical exposure as part of a program of research unless the exposure has been approved by a **human research ethics committee** as required in clause 3.2.7 and a radiological medical practitioner has assumed responsibility as specified in clause 3.1.4(a). The Responsible Person must ensure that the requirements specified in clause 3.2.21 are fulfilled for the optimisation of protection and safety for persons subject to exposure as part of a program of research.

3.1.3 The Responsible Person must ensure that no individual receives a medical exposure as a carer or comforter unless he or she has received, and has indicated an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure. The Responsible Person must ensure that the requirements specified in clause 3.2.20 are fulfilled for the optimisation of protection and safety for any radiological procedure in which an individual acts as a carer or comforter.

3.1.4 The Responsible Person must ensure that:

(a) the radiological medical practitioner performing or authorising the radiological procedure is responsible for ensuring overall protection and safety for patients in the planning and delivery of the medical exposure, including the justification of the radiological procedure as required in clauses 3.1.9 and 3.2.1–3.2.7 and the optimisation of protection and safety, in collaboration with the **medical physicist** and the **medical radiation technologist** as required in clauses 3.2.8–3.2.21 and 3.3.1–3.3.4

(b) radiological medical practitioners, medical physicists, medical radiation technologists and other **health professionals** with specific duties in relation to protection and safety for patients in a given radiological procedure are adequately trained in the appropriate area

(c) for therapeutic radiological procedures, the requirements of this Code for calibration, dosimetry and quality assurance, including the acceptance and commissioning of **medical radiological equipment**, as specified in clauses 3.2.14, 3.2.15(c), 3.2.15(d), 3.2.17, and 3.2.18, are fulfilled by or under the supervision of a medical physicist

(d) for diagnostic radiological procedures and image guided interventional procedures, the requirements of this Code for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in clauses 3.2.14, 3.2.15(a), 3.2.15(b), 3.2.15(d), 3.2.16, 3.2.17, and 3.2.18, are fulfilled by or under the supervision of or with the documented advice of a medical physicist, whose degree of involvement is determined by the relevant regulatory authority and by the complexity of the radiological procedures and the associated radiation risks

(e) any delegation of responsibilities by the Responsible Person or a radiological medical practitioner is documented.

3.1.5 The Responsible Person must have processes in place to ensure that a patient is correctly identified for the intended radiological procedure and the procedure has been approved.

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

3.1.7 The Responsible Person must have processes in place to ensure that in the event of the death of a patient within the medical radiation facility 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

(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.

Radiological Medical Practitioner

3.1.8 A radiological medical practitioner who approves a radiological procedure must:

(a) be appropriately authorised by the relevant regulatory authority

(b) comply with the relevant provisions of the Radiation Management Plan, except where good professional practice would dictate otherwise for a particular circumstance

(c) ensure that the radiation exposures are justified in accordance with 3.1.9 and 3.2.1-3.2.7 and optimised in accordance with 3.2.8-3.2.21 and 3.3.1-3.3.4

(d) provide information on the benefits and risks associated with the procedure to the patient or the patient's legal authorised representative.

3.1.9 In determining the net benefit from a radiological procedure, the radiological 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 a female patient to be administered a radiopharmaceutical if there is the potential for a radiation dose of 1 mSv or more to a breast-fed child

(g) the efficacy, benefits and risks of available alternative techniques having the same objectives with less or no exposure to ionising radiation

(h) any medical data and patient records relevant to the medical exposure.

3.1.10 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 radiological medical practitioner must not undertake or approve a radiological procedure unless a written referral[3] 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

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

If the radiological medical practitioner is also the referrer then the information in (a) – (c) above must be recorded in the relevant patient record.

3.1.11 In approving a radiological procedure, the radiological medical practitioner must, for:

(a) a therapeutic procedure, before the first treatment delivery:

(i) provide a written prescription[3] for the procedure

(ii) approve the treatment plan

(b) a diagnostic nuclear medicine procedure:

(i) provide a written prescription[3] for the procedure

(ii) specify the procedure, or

(iii) have provided generic written guidelines for the procedure

(c) a diagnostic or interventional radiology procedure:

(i) specify in writing[3] the procedure to be performed, or

(ii) have provided generic written guidelines for the procedure.

[3] Referrals, procedure prescriptions and specifications may be in hard copy or electronic form.

3.1.12 Where a radiological procedure is likely to result in a radiation dose of more than 1 mSv to the abdomen of a patient of childbearing capacity, the radiological medical practitioner must ensure that:

(a) reasonable steps are taken immediately before the commencement of the procedure to establish whether the patient is pregnant

(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.

3.1.13 Where a radiological procedure is to be conducted on a pregnant patient that is likely to result in a radiation dose of 1 mSv or more to an embryo or foetus, the radiological medical practitioner must:

(a) justify the procedure for that individual patient

(b) include an assessment of the risks to:

(i) the embryo or foetus from the radiation exposure

(ii) the patient if the procedure is not performed

(c) before the procedure is carried out, fully explain the risks to the referrer and the pregnant patient or the patient's legal authorised representative

(d) estimate and record the expected radiation dose to the embryo or foetus.

3.1.14 The radiological 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.

3.1.15 The radiological 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.

3.1.16 The radiological medical practitioner must, following an interventional radiological procedure where there is a possibility of radiation induced deterministic effects, liaise with the referrer to ensure follow-up of the patient.

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

Operator

3.1.18 The operator must be appropriately authorised by the relevant regulatory authority to administer ionising radiation to an individual for diagnostic or interventional radiology, nuclear medicine or radiotherapy.

3.1.19 The operator must comply with the relevant provisions of the Radiation Management Plan, except where good professional practice would dictate otherwise for a particular circumstance.

3.1.20 The operator must:

(a) not expose a person to ionising radiation unless the procedure:

(i) has been approved by a radiological medical practitioner, or

(ii) is in accordance with written protocols established by:

a. the radiological medical practitioner, or

b. an acknowledged professional college or authority

(b) follow the established protocol for the procedure

(c) ensure that 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

(e) in the case of a therapeutic radiological procedure, ensure that:

(i) the radiation treatment plan has been approved by the radiological medical practitioner

(ii) the radiation dose to the patient is delivered in accordance with the radiation treatment plan

(iii) there is continuous oversight of the operating parameters of medical radiological equipment during the radiation dose delivery

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

3.1.21 Immediately before conducting a radiological procedure on a patient, the operator must:

(a) take reasonable steps to ensure that the patient is correctly identified

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

3.1.22 Before conducting a radiological procedure on a female patient of child-bearing capacity that is likely to result in a radiation dose to an embryo or foetus of 1 mSv or more, the operator must:

(a) seek confirmation from the radiological 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 3.1.20(a)(ii), take reasonable steps to establish the pregnancy status of the patient.

3.1.23 The operator must ensure that no person is in the imaging, administration or treatment area during a radiological procedure unless that person is required to be in attendance.

3.1.24 The operator of equipment that delivers radiotherapy, other than via administered radiopharmaceuticals, must:

(a) ensure that no-one other than the patient receiving the treatment is in the room during the exposure unless the circumstances are specified in the Radiation Management Plan

(b) ensure that visual surveillance of the treatment room is maintained during the exposure

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

3.1.25 The operator of medical radiological equipment must ensure that no safety interlock devices are bypassed at any time during routine clinical use of the equipment.

3.1.26 The operator of medical radiological equipment, 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

(c) where the fault could compromise patient safety, diagnosis or treatment, report it to:

(i) the Responsible Person

(ii) the radiological medical practitioner.

3.1.27 The operator must report any unintended or accidental exposure to:

(a) the Responsible Person in accordance with the procedures set out in the Radiation Management Plan

(b) the radiological medical practitioner.

3.2 Radiation Protection for medical exposure

Justification of medical exposure

3.2.1 The Responsible Person must have processes in place to ensure that medical exposures are justified by weighing the diagnostic or therapeutic benefits[4] that they are expected to yield against the radiation detriment that they might cause, with account taken of the benefits and the risks of available alternative techniques that involve less or no radiation exposure.

3.2.2 The Responsible Person must have processes in place to ensure that no radiological procedure is carried out unless it has been justified, either:

(a) generically or on an individual basis by the radiological medical practitioner, depending on the nature of the procedure and the patient, or

(b) generically by an acknowledged professional college or authority.

3.2.3 The Responsible Person must have processes in place to ensure that the justification of medical exposure for an individual patient is carried out by means of communication between the radiological medical practitioner and the referrer, as appropriate, with account taken, in particular for patients who are pregnant or breast-feeding or are paediatric, of:

(a) the appropriateness of the request

(b) the urgency of the radiological procedure

(c) the characteristics of the medical exposure

(d) the characteristics of the individual patient

(e) relevant information from the patient's medical history, including previous radiological procedures.

[4] The diagnostic or therapeutic benefit that medical exposures are expected to yield may not necessarily be to the person exposed. For patients, this is clearly the case, but for exposures in biomedical research the benefit is expected to be for biomedical sciences and for future health care. Similarly, the benefit for carers and comforters might be, for example, the successful performance of a diagnostic procedure on a child.

3.2.4 The Responsible Person must have processes in place to ensure that relevant national[5] or international referral guidelines and any requirements of the relevant regulatory authority are taken into account for the justification of the diagnostic medical exposure of an individual patient in a radiological procedure.

3.2.5 The Responsible Person must ensure that no radiological procedures are performed as part of a health screening program for asymptomatic populations, unless the procedures have been justified by the health authority in conjunction with appropriate professional bodies and approved by the relevant regulatory authority, as appropriate.

3.2.6 The Responsible Person must ensure that any radiological procedure on an asymptomatic individual that is intended to be performed for the early detection of disease, but not as part of an approved health screening program, is specifically justified for that individual by the radiological medical practitioner and the referrer, in accordance with the guidelines of relevant professional bodies or the health authority. As part of this process, the individual must be informed in advance of the expected benefits, risks and limitations of the radiological procedure.

3.2.7 The Responsible Person must ensure that medical exposure of volunteers as part of a program of biomedical research is conducted only if it has been approved by a human research ethics committee, in accordance with the requirements of the *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes* (RPS 8), and with the *National Statement on Ethical Conduct in Human Research (2007)* and its updates, and the radiological procedure is conducted in accordance with any conditions of that approval including any dose constraints that may be specified (as required for implementation in clause 3.2.21), and subject to applicable national or local regulations.

Optimisation of protection and safety

3.2.8 The Responsible Person, in collaboration with the radiological medical practitioners, must ensure that protection and safety is optimised for each medical exposure.

Design considerations

3.2.9 The Responsible Person, in collaboration with suppliers, must ensure that medical radiological equipment and software that could influence the delivery of medical exposure are used only if they conform to the applicable standards of the International Electrotechnical Commission and the International Organization for Standardization or to standards adopted by the relevant regulatory authority.

[5] Professional bodies or health authorities within Australia may issue such guidelines from time to time.

Operational considerations

3.2.10 The radiological medical practitioner must, for diagnostic radiological procedures and image guided interventional procedures, in collaboration with, as appropriate, the medical radiation technologist and/or the medical physicist, and if appropriate with the **radiopharmaceutical scientist**, ensure that the following are used:

(a) appropriate medical radiological equipment and software, and, for nuclear medicine, appropriate radiopharmaceuticals

(b) appropriate techniques and parameters to deliver a medical exposure of the patient that minimises the dose to fulfil the clinical purpose of the radiological procedure, with account taken of relevant norms of acceptable image quality established by relevant professional bodies and of relevant diagnostic reference levels where available.

3.2.11 The radiological medical practitioner must, for therapeutic radiological procedures, in collaboration with the medical physicist and/or the medical radiation technologist, ensure that for each patient the exposure of volumes other than the **planning target volume** is kept as low as reasonably achievable consistent with delivery of the prescribed dose to the planning target volume within the required tolerances.

3.2.12 The radiological medical practitioner must, for therapeutic radiological procedures in which radiopharmaceuticals are administered, in collaboration with the medical physicist and/or the medical radiation technologist, and if appropriate with the radiopharmaceutical scientist, ensure that for each patient the appropriate radiopharmaceutical with the appropriate activity is selected and administered, so that the radioactivity is primarily localised in the organ(s) of interest, while the radioactivity in the rest of the body is kept as low as reasonably achievable.

3.2.13 The radiological medical practitioner must ensure that particular attention is given to the appropriateness of techniques and parameters in the optimisation process for:

(a) paediatric patients subject to medical exposure

(b) individuals subject to medical exposure as part of an approved health screening program

(c) volunteers subject to medical exposure as part of a program of biomedical research

(d) relatively high doses[6] to the patient

(e) exposure of the embryo or foetus, in particular for radiological procedures in which the abdomen or pelvis of the pregnant female patient is exposed to the useful radiation beam or could otherwise receive a dose of 1 mSv or greater

(f) exposure of a breastfed infant, or a significant dose to the breasts of a lactating patient, as a result of a radiological procedure involving radiopharmaceuticals.

[6] The term 'relatively high dose' is intended to apply in a given context. Clearly, doses from therapeutic radiological procedures are included in 'relatively high doses', as are image guided interventional procedures. In medical imaging, 'relatively high doses' would include doses from exposures in certain computed tomographic procedures and in nuclear medicine with higher activities.

Calibration

3.2.14 In accordance with clause 3.1.4(c) and (d), the Responsible Person must ensure that:

(a) all sources giving rise to medical exposure are calibrated in terms of appropriate quantities using protocols endorsed by the relevant regulatory authority or professional bodies

(b) calibrations relevant to the intended clinical use are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry, and at intervals approved by the relevant regulatory authority

(c) calibrations of brachytherapy units are subject to verification prior to clinical use by a medical physicist using equipment where neither the medical physicist nor the equipment was associated with the initial calibration

(d) calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a **standards dosimetry laboratory**

(e) calibration of all reference equipment is traceable to relevant national standards.

Dosimetry of patients

3.2.15 The Responsible Person must ensure that dosimetry of patients is performed and documented, using calibrated dosimeters and following internationally accepted or nationally accepted protocols, including dosimetry to determine the following:

(a) for diagnostic radiological procedures, typical doses to patients for common procedures

(b) for image guided interventional procedures, typical doses to patients

(c) for radiotherapy procedures, **absorbed doses** to the planning target volume for each patient treated with external beam therapy and/or brachytherapy and absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner

(d) for therapeutic or diagnostic nuclear medicine procedures, the radiopharmaceutical and the confirmed[7] activity delivered.

Diagnostic reference levels

3.2.16 The Responsible Person must establish a program to ensure that:

(a) radiation doses administered to patients for diagnostic purposes are compared with diagnostic reference levels (DRLs) at least annually for those radiological procedures for which DRLs have been established in Australia

(b) a review is conducted to determine whether the optimisation of protection and safety for patients is adequate, or whether corrective action is required, if, for a given radiological procedure:

(i) typical doses or activities exceed the relevant diagnostic reference level, or

(ii) exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.

[7] '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.

Quality assurance for medical exposures

3.2.17 The Responsible Person must ensure that a comprehensive program of quality assurance for medical exposures is established, performed, maintained and regularly reviewed, with the active participation of radiological medical practitioners, medical radiation technologists and, where relevant, medical physicists and radiopharmaceutical scientists, and in conjunction with other health professionals as appropriate. Principles established by relevant professional bodies and requirements of the relevant regulatory authority must be taken into account.

3.2.18 The Responsible Person must ensure that programs of quality assurance for medical exposure include, as appropriate to the medical radiation facility:

(a) measurements of the physical parameters of medical radiological equipment conducted:

(i) at the time of acceptance and commissioning of the equipment prior to its clinical use on patients

(ii) periodically thereafter, according to national protocols and as required by the relevant regulatory authority

(iii) after any major maintenance procedure that could affect protection and safety of patients

(iv) after any installation of new software or modification of existing software that could affect protection and safety of patients

(b) implementation of corrective actions if measured values of the physical parameters mentioned in (a) above are outside established tolerance limits

(c) verification that appropriate physical parameters and clinical protocols are used in radiological procedures

(d) independent[8] verification of calibrations of external beam radiation therapy units, including reference dose verification, non-reference dose verification, and end-to-end dose delivery verification:

(i) at the time of acceptance and commissioning of the equipment prior to its clinical use on patients

(ii) periodically thereafter, at intervals specified by professional bodies and as required by the relevant regulatory authority

(iii) after any major maintenance procedure or software upgrade that could affect protection and safety of patients

(e) maintaining records of relevant procedures and results, including documentation of work performed for repair, maintenance or modification

(f) periodic checks of the calibration and conditions of operation of dosimetry equipment, reference equipment and monitoring equipment. These must be traceable to relevant national standards.

3.2.19 The Responsible Person must ensure that regular and independent audits are made of the program of quality assurance for medical exposures and that their frequency is in accordance with the complexity and associated risks of the radiological procedures being performed and any requirements of the relevant regulatory authority.

[8] 'Independent' means performed by a non-affiliated national or international service.

Dose constraints

3.2.20 The Responsible Person must ensure that a dose constraint of 5 mSv per radiological examination or treatment episode is used in the optimisation of protection and safety in any radiological procedure in which an individual acts as a carer or comforter.

3.2.21 The Responsible Person must ensure that dose constraints specified or approved by a human research ethics committee on a case by case basis as part of a proposal for biomedical research (clause 3.2.7) are considered in the optimisation of protection and safety for persons subject to exposure as part of a program of biomedical research.

3.3 Additional requirements with respect to specific patients

Pregnant or breast feeding patients

3.3.1 The Responsible Person must ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding.

3.3.2 The Responsible Person must ensure that illustrated signs in appropriate languages are placed in public places within the facility, waiting rooms for patients, cubicles and other prominent places, and that other means of communication are also used as appropriate[9], to request female patients who are to undergo a radiological procedure to notify the radiological medical practitioner, operator or other personnel in the event that:

(a) she is or might be pregnant

(b) she is breast-feeding and the scheduled radiological procedure includes the administration of a radiopharmaceutical.

3.3.3 The Responsible Person must ensure that there are procedures in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a dose of 1 mSv or greater to the embryo or foetus, so that this information can be considered in the justification for the radiological procedure (clauses 3.1.9, 3.2.1 and 3.2.3) and in the optimisation of protection and safety (clause 3.2.13).

3.3.4 The Responsible Person must ensure that there are procedures in place to establish the breast feeding status of a female patient before the performance of any radiological procedure involving the administration of a radiopharmaceutical that could result in a dose of 1 mSv or greater to a breastfed infant, or significant dose to the breasts of a lactating female patient, so that this information can be considered in the justification for the radiological procedure (clauses 3.1.9, 3.2.1 and 3.2.3) and in the optimisation of protection and safety (clause 3.2.13).

[9] 'Other means of communication' include explicitly asking female patients whether they are or might be pregnant or whether they are breast-feeding.

Release of patients after radionuclide therapy

3.3.5 The Responsible Person must ensure that there are arrangements in place to ensure compliance with the dose limit for members of the public and a dose constraint of 5 mSv per treatment episode for carers and comforters before a patient is released following radionuclide therapy.

3.3.6 The radiological medical practitioner must ensure that no patient who has undergone a therapeutic radiological procedure with a sealed source or an **unsealed source** is discharged from a medical radiation facility until it has been established that:

(a) the activity of radionuclides in the patient is such that doses that could be received by members of the public and carers and comforters would be in compliance with the requirements in clause 3.3.5

(b) the patient or the legal guardian of the patient is provided with:

(i) written instructions for keeping doses to persons in contact with or in the vicinity of the patient as low as reasonably achievable and for avoiding the spread of contamination

(ii) information on the radiation risks to the patient and to other persons who may be in the vicinity of the patient

(iii) written instructions outlining any radiation safety requirements following the death of the patient.

3.4 Unintended and accidental medical exposure

Unintended and accidental medical exposure

3.4.1 The Responsible Person must ensure that all practicable measures are taken to minimise the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error.

3.4.2 The Responsible Person must ensure that unintended or accidental medical exposures are promptly investigated, including the following:

(a) any medical treatment delivered to the wrong individual or to the wrong tissue or organ of the patient, or using the wrong radiopharmaceutical, or with an activity, a dose or dose fractionation differing substantially[10] from (over or under) the values prescribed by the radiological medical practitioner, or that could lead to unacceptably severe secondary effects

(b) any diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or the wrong tissue or organ of the patient is subject to exposure

(c) any exposure for diagnostic purposes that is substantially greater than was intended

(d) any exposure arising from an image guided interventional procedure that is substantially greater than was intended

(e) any inadvertent exposure of the embryo or foetus in the course of performing a radiological procedure

[10] 'Substantially' means outside the range normally expected for the particular procedure.

(f) any failure of medical radiological equipment, failure of software or system failure, or accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended

(g) any other event specified by the relevant regulatory authority.

3.4.3 The Responsible Person must, with regard to any unintended or accidental medical exposures investigated as required in clause 3.4.2:

(a) arrange for the calculation or estimation by a medical physicist of the doses received and the dose distribution within the patient

(b) indicate the corrective actions required to prevent the recurrence of such an unintended or accidental medical exposure

(c) implement all the corrective actions that are under their own responsibility

(d) produce and keep a written record of the investigation that states the cause of the unintended or accidental medical exposure and includes as relevant the information specified in (a)–(c) above, and any other information as required by the relevant regulatory authority; and submit a copy of this written record, to the relevant regulatory authority, as required

(e) ensure that the radiological medical practitioner informs the patient or the patient's legal authorised representative, and where appropriate the referrer, of the unintended or accidental medical exposure.

3.5 Plans, training and record keeping

Reviews and records

3.5.1 The Responsible Person must ensure that radiological reviews are performed periodically by the radiological medical practitioners at the medical radiation facility, in collaboration with the medical radiation technologists and where relevant the medical physicists. The radiological review must include an investigation and critical review of the current practical application of the radiation protection principles of justification and optimisation for the radiological procedures that are performed in the medical radiation facility.

Training

3.5.2 The Responsible Person must ensure that personnel (radiological medical practitioners, medical radiation technologists, medical physicists, and any other health professionals or approved personnel with specific duties in relation to the radiation protection of patients):

(a) are specialised[11] in the appropriate area[12]

(b) meet the respective requirements for education, training and competence in radiation protection, in accordance with the requirements of the relevant regulatory authorities

[11] 'Specialised' means specialised as acknowledged by the relevant professional body, health authority or appropriate organisation.

[12] 'The appropriate area' means, in the first instance, diagnostic radiology, image guided interventional procedures, radiation therapy or nuclear medicine (diagnostic radiological procedures, therapeutic radiological procedures or both). The area of specialisation may be narrower, however, in particular with regard to the radiological medical practitioner. Examples include cardiologists, urologists or neurologists.

(c) are named in the facility's Radiation Management Plan in a list maintained up to date by the Responsible Person

(d) where required, hold an applicable use licence or permit under the legislation of the relevant regulatory authority.

Record keeping

3.5.3 The Responsible Person must keep sufficient evidence to be able to demonstrate, at any time, that:

(a) justification of each medical exposure has been carried out

(b) optimisation of protection and safety for each medical exposure has been carried out.

3.5.4 The Responsible Person must maintain for a period of 7 years, or as otherwise specified by regulatory authorities, and must make available, as required, the following records pertaining to medical exposure:

(a) personnel:

(i) details of any delegation of responsibilities by the Responsible Person or a radiological medical practitioner (as required in clause 3.1.4(e))

(ii) training of personnel in radiation protection (as required in clause 3.5.2(b))

(b) calibration, dosimetry and quality assurance:

(i) results of calibrations and periodic checks of the relevant physical parameters and clinical protocols selected during treatment of patients

(ii) dosimetry of patients, as required in clause 3.2.15

(iii) local assessments and reviews made with regard to diagnostic reference levels, as required in clause 3.2.16

(iv) records associated with the quality assurance program, as required in clause 3.2.18

(c) medical exposure:

(i) For diagnostic radiology, information necessary for retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures

(ii) For image guided interventional procedures, information necessary for retrospective assessment of doses, including the duration of the fluoroscopic component and the number of images acquired

(iii) For nuclear medicine, the types of radiopharmaceutical administered and their activity

(iv) For external beam radiation therapy or brachytherapy

- a description of the planning target volume
- the absorbed dose to the centre of the planning target volume
- the maximum and minimum absorbed doses delivered to the planning target volume, or equivalent alternative information on absorbed doses to the planning target volume
- the absorbed doses to relevant tissues or organs as specified by the radiological medical practitioner
- for external beam radiation therapy, the dose fractionation and the overall treatment time

(v) exposure records for volunteers subject to medical exposure as part of a program of biomedical research

(vi) reports on investigations of unintended and accidental medical exposures (as required in clause 3.4.3(d)).

Radiation Management Plan

3.5.5 The Responsible Person must ensure that:

(a) the Radiation Management Plan incorporates the components listed in Schedule A of this Code

(b) the Radiation Management Plan prepared under clause 3.5.5(a) addresses protection commensurate with the level of radiation risk that it seeks to mitigate for persons receiving a medical exposure

(c) the Radiation Management Plan prepared under clause 3.5.5(a) describes the management and reporting arrangements that enable the radiological medical practitioner, the medical radiation technologist, the medical physicist and any other health professional with responsibilities for patient radiation protection to discharge their obligations under this Code.

Implementation of the Radiation Management Plan

3.5.6 The Responsible Person must ensure implementation of the Radiation Management Plan. The Responsible Person must:

(a) have access to qualified expert advice sufficient to develop and implement the Radiation Management Plan

(b) document the induction and training programs specific to patient radiation protection conducted in accordance with the Radiation Management Plan and record participation

(c) ensure that all persons affected by the Radiation Management Plan have access to, follow, and comply with the Radiation Management Plan

(d) ensure that all necessary resources for implementing the Radiation Management Plan are provided

(e) when any person reports a matter that may compromise patient radiation protection, ensure that appropriate action is taken to investigate and, if necessary, rectify the matter

(f) keep records relating to radiation protection in medical exposure, as required in clause 3.5.3.

Schedule A Radiation Management Plan

Preparation of additional components to the Radiation Management Plan, pertaining to medical exposure

A.1 The Radiation Management Plan[13] must contain all the necessary background and operational information for working with radiation, and be kept up-to-date. It is the first point of reference for staff, and provides supervisors with all necessary policies and procedures. The plan must be commensurate with the radiation sources that are associated with the particular facility. The medical exposures aspects of the Radiation Management Plan[14] must include, where relevant to the medical radiation facility:

(a) information about radiation protection principles applicable to medical exposure – namely, justification and optimisation of protection and safety

(b) the measures to control medical exposures resulting from the radiological procedures performed in the medical radiation facility

(c) the measures to be applied to ensure that each medical exposure is justified

(d) the measures to be applied to ensure that for each medical exposure protection and safety is optimised, including (as applicable):

(i) choice of equipment, and choice of radiopharmaceutical

(ii) selection and use of protocols for radiological procedures, including consideration of patient's age and, for female patients, pregnancy and breast-feeding status

(iii) proper planning and delivery of radiotherapy doses

(iv) preparation and dispensing of radiopharmaceuticals

(v) observation of the patient throughout procedures where the dosimetry or image quality could be affected by patient movement

(vi) procedures and protocols for calibration of sources and dosimeters

(vii) procedures and protocols for dosimetry of patients

(viii) for medical radiation facilities performing diagnostic radiological procedures, procedures for performing local assessments and reviews of radiological procedures compared with national diagnostic reference levels

(ix) procedures for a program of quality assurance for medical exposures

(x) procedures for applying dose constraints with respect to carers and comforters

(xi) procedures for applying dose constraints set by human research ethics committees for persons subject to exposure as part of a program of biomedical research

(e) the measures to ensure that a patient for a radiological procedure is correctly identified before the procedure is performed, the radiological procedure is the correct one and the correct side and site have been confirmed.

(f) the measures to be applied to ensure appropriate radiation protection in cases where a female patient is or might be pregnant

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

[14] The Radiation Management Plan will also need to address the requirements of RPS C-1 in relation to public and occupational exposure

(g) the measures to be applied to ensure appropriate radiation protection in cases where a female patient is breast-feeding

(h) the measures to be applied to ensure appropriate radiation protection for members of the public and for carers and comforters before a patient is released following radionuclide therapy

(i) the training, qualifications and competencies, roles and responsibilities of persons with responsibilities for patient radiation protection

(j) the provision of information to and appropriate induction and on-going training for all persons with responsibilities for patient radiation protection

(k) arrangements for obtaining expert advice in radiation protection

(l) an identification of potential failures of radiological medical equipment, potential failures or errors in software or potential human errors, including an estimate of the extent of the consequences and in addition:

  (i) specification of preventative measures

  (ii) procedures for handling such events and corrective actions

  (iii) procedures for the reporting of any fault with a radiation source that could compromise safety

(m) a list of actions necessary to manage an unintended or accidental medical exposure, including:

  (i) reporting of the event to the Responsible Person and the appropriate radiological medical practitioner

  (ii) investigation of the event

  (iii) determination of corrective actions required to prevent the recurrence of such an unintended or accidental medical exposure

  (iv) implementation of corrective actions

  (v) reporting (both internal and to the relevant regulatory authority)

  (vi) information to the referrer and patient

(n) arrangements for record keeping, including for records of personnel training in radiation protection, calibration, dosimetry, quality assurance, and medical exposure

(o) arrangements for any other requirement that may have a bearing on radiation safety in medical exposures

(p) mechanisms for, and frequency of, review of the Radiation Management Plan.

A.2 Where other documented safety procedures and work practices that exist within the medical radiation facility are referred to or used:

(a) the Responsible Person must have authority over the safety procedures and work practices referred to

(b) the safety procedures and work practices referred to must not be modified without consideration of the effect on the Radiation Management Plan.

Appendix 1: Derivation of clauses from GSR Part 3 requirements

The following table cross-references each clause in Section 3 of this Code to the relevant requirement in the Trusted International Standard, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards - General Safety Requirements, IAEA Safety Standards Series GSR Part 3 (IAEA 2014). GSR Part 3 is published on the IAEA website.

RPS C-5		IAEA GSR Part 3
Guidance	**Clause(s)**	**Requirement**
Responsibilities specific to medical exposure	3.1.1-3.1.27	Requirement 36
Justification of medical exposure	3.2.1-3.2.7	Requirement 37
Optimisation of protection and safety	3.2.8-3.2.21	Requirement 38
Pregnant or breast feeding patients	3.3.1-3.3.4	Requirement 39
Release of patients after radionuclide therapy	3.3.5-3.3.6	Requirement 40
Unintended and accidental medical exposure	3.4.1-3.4.3	Requirement 41
Reviews and records	3.5.1-3.5.6	Requirement 42

Glossary

Absorbed dose, *D*

The fundamental dosimetric quantity *D*, defined as:

$$D = \frac{\mathrm{d}\bar{\varepsilon}}{\mathrm{d}m}$$

where $\mathrm{d}\bar{\varepsilon}$ is the mean energy imparted by ionising radiation to matter in a volume element, and d*m* is the mass of matter in the volume element.

Approved health screening program

A program in which health tests or medical examinations are performed for the purpose of early detection of disease and which has been justified by the health authority in conjunction with appropriate professional bodies and approved by the relevant regulatory authority, as appropriate. It may refer to a test that is offered to all individuals in a target group, defined by age or occupation, as part of an organised program.

Carers and comforters

Persons who willingly and voluntarily help (other than in their occupation) in the care, support and comfort of patients undergoing radiological procedures for medical diagnosis or in the course of their medical treatment.

Diagnostic Reference Level (DRL)

Dose levels for medical exposures in radiological procedures, or levels of activity in the case of radiopharmaceuticals, applied to groups of standard-sized patients 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 in consultation with 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**, **effective dose** or organ dose, as indicated by the context.

Dose constraint

A prospective and source related value of individual dose that is used in planned exposure situations as a parameter for the optimisation of protection and safety for the source, and that serves as a boundary in defining the range of options in optimisation.

For medical exposure, the dose constraint is a source related value used in optimising the protection of carers and comforters of patients undergoing radiological procedures, and the protection of volunteers subject to exposure as part of a program of biomedical research.

Dose limit

The value of the effective dose or the equivalent dose to individuals in planned exposure situations that is not to be exceeded.

Effective dose, *E*

The quantity *E*, defined as a summation of the tissue or organ equivalent doses, each multiplied by the appropriate tissue weighting factor:

$$E = \sum_{\mathrm{T}} w_{\mathrm{T}} \,.\, H_{\mathrm{T}}$$

where H_{T} is the equivalent dose in tissue or organ T, and
w_{T} is the tissue weighting factor for tissue or organ T.

From the definition of equivalent dose, it follows that:

$$E = \sum_{\mathrm{T}} w_{\mathrm{T}} \,.\, \sum_{\mathrm{R}} w_{\mathrm{R}} \,.\, D_{\mathrm{T,R}}$$

where w_{R} is the radiation weighting factor for radiation type R, and
$D_{\mathrm{T,R}}$ is the average absorbed dose in the tissue or organ T delivered by radiation type R.

Equivalent dose

The quantity $H_{\mathrm{T,R}}$, defined as:

$$H_{T,R} = W_R \, D_{T,R}$$

where $D_{\mathrm{T,R}}$ is the absorbed dose delivered by radiation type R averaged over a tissue or organ T, and
w_{R} is the radiation weighting factor for radiation type R.

When the radiation field is composed of different radiation types with different values of w_{R}, the equivalent dose is:

$$H_{\mathrm{T}} = \sum_{\mathrm{R}} w_{\mathrm{R}} \,.\, D_{\mathrm{T,R}}$$

Exposure

The state or condition of being subject to irradiation.

Graded approach

An application of safety requirements that is commensurate with the characteristics of the facilities and activities or the source and with the magnitude and likelihood of the exposures.

Health authority

A governmental authority (at the national, state or local level) that is responsible for policies and interventions, including the development of standards and the provision of guidance, for maintaining or improving human health, and that has the legal power of enforcing such policies and interventions.

Health professional

An individual who has been formally recognised through appropriate national procedures to practice a profession related to health (e.g. medicine, podiatry, nursing, medical physics, medical radiation technology, radiopharmacy, occupational health).

Human research ethics committee

A committee which advises an institution or organisation regarding ethical approval for research projects which is constituted in accordance with, and acting in compliance with, the *National Statement on Ethical Conduct in Research Involving Humans* (NHMRC 2007), as amended from time to time.

Ionising radiation

For the purposes of radiation protection, radiation capable of producing ion pairs in biological material(s).

Justification

For a planned exposure situation, the process of determining whether a practice is, overall, beneficial; i.e. whether the expected benefits to individuals and to society from introducing or continuing the practice outweigh the harm (including radiation detriment) resulting from the practice.

Medical exposure

Ionising radiation exposure received by patients as part of their own medical diagnosis (diagnostic exposure) or treatment (therapeutic exposure); by persons, other than those occupationally exposed, knowingly, while voluntarily helping in the support and comfort of patients; and by volunteers in a program of biomedical research involving their exposure.

Medical physicist

A health professional with education and training in the concepts and techniques of applying physics in medicine and competent to practice independently in one or more of the sub-fields of medical physics or a person who 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.

Medical radiation facility

A facility in which radiological procedures are performed.

Medical radiation technologist

A health professional, with education and training in medical radiation technology, competent to perform radiological procedures, on authorisation from the radiological medical practitioner, in one or more of the specialties of medical radiation technology.

Medical radiological equipment

Radiological equipment used in medical radiation facilities to perform radiological procedures that either delivers an exposure of an individual or directly controls or influences the extent of such exposure. The term applies to irradiating apparatus, such as X ray machines or medical linear accelerators; to devices containing sealed sources, such as ^{60}Co teletherapy units; to devices used in medical imaging to capture images, such as gamma cameras, image intensifiers or flat panel detectors, and to hybrid systems such as positron emission tomography–computed tomography scanners.

Occupational exposure

Exposure of workers received in the course of their work.

Operator

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

Planned exposure situation

The situation of exposure that arises from the planned operation of a radiation source or from a planned activity that results in an exposure due to a radiation source.

Planning target volume

A geometrical concept used in radiation therapy planning which considers geometrical uncertainties due to patient setup and organ motion. Involves addition of a margin to the tumour volume to account for variation in size and shape of tissues, and variation in beam geometry.

Public exposure

Exposure received by members of the public due to sources in planned exposure situations, emergency exposure situations and existing exposure situations, excluding any occupational exposure or medical exposure.

Radiation

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

Radiation source

Anything that may cause radiation exposure — such as by emitting ionising radiation or by releasing radioactive substances or radioactive material — and can be treated as a single entity for purposes of protection and safety.

Radioactive material

Material which spontaneously emits ionising radiation as a consequence of radioactive decay.

Radiological medical practitioner

A health professional with education and training in the medical uses of radiation, who is competent to perform independently or to authorise radiological procedures in a given specialty.

Radiological procedure

A medical procedure that involves ionising radiation — such as a procedure in diagnostic radiology, nuclear medicine or radiation therapy, or a planning procedure, image guided interventional procedure or other interventional procedure involving radiation — delivered by irradiating apparatus, a device containing a sealed source or an unsealed source, or by means of a radiopharmaceutical administered to a patient.

Radiopharmaceutical scientist

A specialist with education and training in chemistry, pharmacy or science, who is involved in the design, manufacture and analysis of radiopharmaceuticals, and is suitably experienced and competent to produce radio-labelled compounds or to prepare and dispense radiopharmaceuticals used for the purposes of medical diagnosis and radionuclide therapy.

Referrer

A health professional who, in accordance with national requirements, or the requirements of the relevant regulatory authority, may refer individuals to a radiological medical practitioner for medical exposure.

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 ionising radiation. A list of relevant regulatory authorities in Australia can be found on ARPANSA's website at www.arpansa.gov.au/Regulation/Regulators.

Responsible person[15]

In relation to any radiation source, prescribed radiation facility or premises on which radiation sources are stored or used means the legal person:

(a) having overall management responsibility including responsibility for the security and maintenance of the radiation source, facility or premises

(b) having overall control over who may use the radiation source, facility or premises

(c) in whose name the radiation source, facility or premises would be registered if this is required.

Sealed source

A radioactive source in which the radioactive material is permanently sealed in a capsule or closely bonded and in a solid form. The capsule or material of a sealed source must be strong enough to maintain leak-tightness under the conditions of use and wear for which the source was designed and also under foreseeable mishaps.

Standards dosimetry laboratory

A laboratory, designated by the relevant national authority, that possesses certification or accreditation necessary for the purpose of developing, maintaining or improving primary or secondary standards for radiation dosimetry.

Unsealed source

A radioactive source in which the radioactive material is neither permanently sealed in a capsule nor closely bonded and in a solid form.

[15] A legal person can be a natural person, a body corporate, a partnership, a Person Conducting a Business or Undertaking (PCBU), or any other entity recognised as a 'legal person', who is conducting a business or undertaking that uses radiation and requires an authorisation under appropriate legislation.

References

Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) 2014. *Fundamentals for Protection Against Ionising Radiation*. Radiation Protection Series F-1. [https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/fundamentals/rpsf-1]

Australia Radiation Protection and Nuclear Safety Agency (ARPANSA) 2014. *National Directory for Radiation Protection, June 2017.* Radiation Protection Series No.6. [https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/national-directory-for-radiation-protection]

Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) 2016. *Radiation Protection in Planned Exposure Situations*. Radiation Protection Series C-1. [https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/codes-and-standards/rpsc-1]

Department of Health, Western Australia 2018. *Diagnostic Imaging Pathways*. [http://www.imagingpathways.health.wa.gov.au/]

European Atomic Energy Community, Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Organization, International Maritime Organization, OECD Nuclear Energy Agency, Pan American Health Organization, United Nations Environment Program, World Health Organization, *Fundamental Safety Principles*, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006). [https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1273_web.pdf]

European Commission, Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Organization, OECD Nuclear Energy Agency, Pan American Health Organization, United Nations Environment Program, World Health Organization (2014). *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*, IAEA Safety Series No. GSR Part 3, IAEA, Vienna (2014). [http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf]

International Commission on Radiological Protection (2007). The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. [http://www.icrp.org/publication.asp?id=ICRP Publication 103]

International Commission on Radiological Protection (ICRP) 1991. *Radiological Protection in Biomedical Research*, ICRP Publication 62, Pergamon Press, Oxford and New York (1991). [http://www.icrp.org/publication.asp?id=ICRP Publication 60]

National Health and Medical Research Council (NHMRC) 2007 – *National Statement on Ethical Conduct in Human Research (2007)* (National Statement (2007, and updates – latest May 2015) [https://www.nhmrc.gov.au/guidelines-publications/e72]

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