



Code for Radiation Protection in Dental Exposure

Radiation Protection Series C-7



arpansa.gov.au FEB 2025

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.

Standards provide a national reference point for radiation protection and safety. They mainly provide quantitative requirements, such as exposure limits and key procedural guidance regarded as essential for best practice in radiation protection. They may be referenced by regulators, authorities, industry and other stakeholders in State, Territory or Commonwealth jurisdictions.

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.

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February 2025

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 February 2025.

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* (ARPANSA 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 dental diagnosis 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. Radiation protection of the patient, occupationally exposed staff and the general public are key requirements in the optimal use of ionising radiation in dental practice.

This Code for Radiation Protection in Dental Exposure sets out the 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 light of the previous Code of Practice for Radiation Protection in Dentistry (ARPANSA 2005) (RPS 10) and the current Code for Radiation Protection in Medical Exposure (2019) (ARPANSA 2019) (RPS C-5), having regard to the requirements relating to medical exposure described in the International Atomic Energy Agency's (IAEA) Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements (GSR) Part 3 (IAEA 2014).

This Code must, as relevant, be used in conjunction with the *Code for Radiation Protection in Planned Exposure Situations* (ARPANSA 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 Dentistry* (ARPANSA 2005) (RPS 10).

Following publication of this Code, it is intended that a revised Safety Guide will be developed in cooperation with participating professions, prior to its publication by ARPANSA.

Dr Gillian Hirth CEO of ARPANSA

12 Feb 2025

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1. Introduction

1.1 Citation

The formal citation for this Code is: *Code for Radiation Protection in Dental Exposure (2025)*. It may also be cited as the Dental Exposure Code (2025).

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* (ARPANSA 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 prescribed 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 **dental exposures**: including ionising radiation exposure received by patients as part of their own dental diagnosis (diagnostic 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 dental 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 (ARPANSA 2016) to ensure radiation protection for all aspects of the dental 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 Dentistry* (ARPANSA 2005) (RPS 10). It specifies Australia's arrangements for ensuring that the medical (and dental) exposure requirements of the IAEA General Safety Requirements (GSR) Part 3 (IAEA 2014) are achieved. The appendix lists the requirements cross-referenced to 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 dental exposures.

This Code is primarily directed to the **Responsible Person** of the **dental radiation facility** that conducts activities that result in dental exposure and sets out the measures that must be put in place for radiation

protection in dental exposure. Responsibilities are also assigned to the **radiological dental practitioner**, who has the overall responsibility for the conduct of a **radiological procedure** and the **operator**, who initiates a dental exposure.

1.4 Scope

This Code applies to all dental exposures involving ionising radiation¹ including exposure to patients, **carers and comforters**, and to volunteers in dental research. It applies to 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 dental radiation facility.

This Code does not apply to²:

- a. occupational exposure
- b. public exposure
- c. environmental exposure
- d. human exposure for any purpose other than:
 - i. dental diagnosis
 - ii. biomedical research
 - iii. health screening programs.

Dose limits³ do not apply to dental 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 interpretation given in this Code. Where the term 'radiation' is used, it means 'ionising radiation'.

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

A separate *Code for Radiation Protection in Medical Exposure (2019)* (RPS C-5) applies to the use of ionising radiation in medical settings. It is acknowledged that exposures of patients undertaken for dental purposes are sometimes undertaken in these settings. This Dental Exposure Code (2025) is consistent with the Medical Exposure Code (2019) in these circumstances. Appendix 2 lists related documents that address the areas not covered by this code and also lists relevant guidance related to this code.

² A separate *Code for Radiation Protection in Planned Exposure Situations (2020)* (RPS C-1 (Rev 1)) applies to the protection of occupationally exposed persons, the public and the environment from the harmful effects of ionising radiations in planned exposure situations.

³ However, in diagnostic radiological procedures, there are dose constraints and diagnostic reference levels (DRLs).

2. Radiation protection principles for dental exposures

2.1 Introduction

Protection during radiation exposures of patients in dentistry requires an approach that differs from radiation protection in other planned exposure situations. The exposure is intentional and must be appropriately justified. In dental diagnostic procedures radiation is used to generate images or information that guide diagnosis or treatment. Radiation protection in dental diagnostic procedures includes avoiding unnecessary exposures and maximising the benefit-risk ratio of justified exposures.

2.2 Principles for protection

The main principles for radiation protection in dentistry are **justification** and optimisation. In dental 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 dentistry.

- At the first level, the use of radiation in dentistry 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. periapical 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 will provide necessary information about the dental 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 dental exposures must be justified in advance, taking into account the specific objectives of the exposure and the characteristics of the dental condition of the individual involved.

2.2.2 Optimisation

Optimisation of protection is maximising the benefit-risk ratio of a dental 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. Special attention is required for exposures of paediatric patients, for individuals undergoing health screening, for volunteers in dental research and where an embryo or fetus 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 dental imaging. Their purpose is to raise awareness of patient doses and prompt dental radiation facilities administering doses greater than the reference levels to review procedures and revise or justify as appropriate.

3. Safety requirements for dental exposures

3.1 Control of dental exposures

Responsibilities specific to dental exposure

Responsible Person

- 3.1.1 The **Responsible Person** must ensure that no patient undergoes a dental exposure unless:
 - a. the dental exposure has been justified or requested by a radiological dental practitioner following communication⁴ with the **referrer** as appropriate, by giving consideration to the clinical indications, or it is part of an **approved health screening program**
 - b. a radiological dental practitioner is responsible for protection and safety in the planning and delivery of the dental exposure as specified in clause 3.1.4a
 - c. whenever clinically practicable, the patient or the patient's legal authorised representative is informed as appropriate of the expected benefits of the radiological procedure as well as the radiation risks, including risk to an embryo or fetus where appropriate
 - d. whenever clinically practicable, the patient or the patient's legal authorised representative consents to the procedure.
- 3.1.2 The Responsible Person must ensure that no individual receives a dental exposure as part of a program of research unless the exposure has been approved by a **Human Research Ethics Committee** as required in clause 3.2.6 and a radiological dental practitioner has assumed responsibility as specified in clause 3.1.4a. The Responsible Person must ensure that the requirements specified in clause 3.2.17 are fulfilled for the optimisation of protection and safety for persons subject to exposure as part of the program of research.
- 3.1.3 The Responsible Person must ensure that no individual receives a dental 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 3.2.16 are fulfilled for the optimisation of protection and safety for any radiological procedure in which an individual acts as a carer or comforter and that consent is given and documented.

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⁴ A written request with adequate clinical information on which to base a justification will usually meet the requirement for communication. However, contact information for the referrer must be provided to facilitate further communication, should it be required.

- 3.1.4 The Responsible Person must ensure that:
 - a. the radiological dental practitioner performing or authorising the radiological procedure is responsible for ensuring overall protection and safety for patients in the planning and delivery of the dental exposure, including the justification of the radiological procedure as required in clauses 3.1.7 and 3.2.1–3.2.6 and the optimisation of protection and safety, in collaboration with the **qualified expert**⁵ and the operator as required in clauses 3.2.7–3.2.17 and 3.3.2
 - b. radiological dental practitioners, operators, 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 area⁶
 - c. for diagnostic radiological procedures, the requirements of this Code for calibration, dosimetry and quality assurance, including the acceptance and commissioning of dental radiological equipment, as specified in clauses 3.2.11 3.2.15, are fulfilled by or under the supervision of, or with the documented advice of, a qualified expert, whose degree of involvement is determined by the relevant regulatory authority and by the complexity of the radiological procedures and the associated radiation risks
 - d. any delegation of duties by the Responsible Person or a radiological dental 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 authorised by the radiological dental practitioner.

Radiological dental practitioner

- 3.1.6 A radiological dental practitioner who authorises 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 3.1.7 and 3.2.1-3.2.6 and optimised in accordance with 3.2.7-3.2.17 and 3.3.1-3.3.2.
 - d. make information on the benefits and risks associated with the procedure available to the patient or the patient's legal authorised representative.
- 3.1.7 In determining the net benefit from a radiological procedure, the radiological dental 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

For the purposes of this Code, a medical physicist as defined in the *Code for Radiation Protection in Medical Exposure (2019)*, (RPS C-5) is a qualified expert.

⁶ As acknowledged and assessed by relevant professional and regulatory bodies.

- e. the pregnancy status of a patient of child-bearing capacity
- f. the efficacy, benefits and risks of available alternative techniques having the same objectives with less or no exposure to ionising radiation
- g. any available dental data and patient records relevant to the dental exposure.
- 3.1.8 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 dental practitioner must not undertake or authorise a radiological procedure unless a written request⁷ is provided that:
 - a. contains adequate patient identifying information
 - b. states the clinical question that the diagnostic procedure should try to answer
 - c. provides the referrer's contact details for consultative purposes.

If the radiological dental practitioner is also the referrer, then the information required in subclauses a – c above must be recorded in the relevant patient record.

Operator

- 3.1.9 The operator must be appropriately authorised by the relevant regulatory authority to administer ionising radiation to an individual for the type of dental diagnostic procedure.
- 3.1.10 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.
- 3.1.11 The operator must:
 - a. not expose a person to ionising radiation unless the procedure:
 - i. has been authorised by a radiological dental practitioner
 - ii. is in accordance with written protocols endorsed or established by:
 - the radiological dental practitioner or
 - 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.
- 3.1.12 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 requested procedure is to be performed on the patient.
- 3.1.13 Before conducting a radiological procedure on a patient of child-bearing capacity that is likely to result in a radiation dose to the uterus of 1 mSv or more, the operator must:

⁷ Requests, procedure prescriptions and specifications may be in hard copy or electronic form.

- a. seek confirmation from the radiological dental practitioner that the pregnancy status of the patient has been established, or
- b. in circumstances where a requested procedure is conducted in accordance with clause 3.1.11a(ii), take reasonable steps to establish the pregnancy status of the patient.
- 3.1.14 The operator must ensure that no person other than the patient is in the imaging area during a radiological procedure unless that person is required to be in attendance.
- 3.1.15 The operator of dental radiological equipment must ensure that no safety interlock devices are bypassed at any time during routine clinical use of the equipment.
- 3.1.16 The operator of dental 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 or diagnosis, report it to:
 - i. the Responsible Person
 - ii. the radiological dental practitioner.
- 3.1.17 The operator must report any unintended or accidental exposure to:
 - the Responsible Person in accordance with the procedures set out in the Radiation
 Management Plan
 - b. the radiological dental practitioner.

3.2 Radiation protection for dental exposure

Justification of dental exposure

- 3.2.1 The Responsible Person must have processes in place to ensure that dental exposures are justified by weighing the diagnostic benefits⁸ 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:
 - a. on an individual basis by the radiological dental practitioner, or
 - b. generically, via a written protocol authorised by a radiological dental practitioner for the procedure, or
 - c. 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 dental exposure for an individual patient is carried out by means of communication between the radiological dental practitioner and the referrer, as appropriate, with account taken, in particular for patients who are pregnant or paediatric, of:
 - a. the appropriateness of the request
 - b. the urgency of the radiological procedure
 - c. the characteristics of the dental exposure
 - d. the characteristics of the individual patient
 - e. relevant information from the patient's dental history, including previous radiological procedures.
- 3.2.4 The Responsible Person must have processes in place to ensure that relevant referral guidelines ⁹ endorsed by the relevant professional body or the relevant regulatory authority are taken into account for the justification of the diagnostic dental 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 dental exposure of volunteers as part of a program of biomedical research is conducted only if it has been approved by a Human Research Ethics

The diagnostic benefit that dental 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 healthcare. Similarly, the benefit for carers and comforters might be, for example, the successful performance of a diagnostic procedure on a child.

⁹ Professional bodies or health authorities within Australia may issue such guidelines from time to time.

Committee, in accordance with the requirements of the *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes* (ARPANSA 2005) (RPS 8) and its updates, and with the *National Statement on Ethical Conduct in Human Research* (NHMRC 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 3.2.17), and subject to applicable national or local regulations.

Optimisation of protection and safety

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

Design considerations

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

Operational considerations

- 3.2.9 The radiological dental practitioner must, for diagnostic radiological procedures, in collaboration with the operator and the qualified expert as appropriate, ensure that the following are used:
 - a. appropriate dental radiological equipment and software
 - b. appropriate techniques and parameters to deliver a dental 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.
- 3.2.10 The radiological dental practitioner must, in collaboration with the qualified expert or the operator, ensure that particular attention is given to the appropriateness of techniques and parameters in the optimisation process for:
 - a. paediatric patients subject to dental exposure
 - b. individuals subject to dental exposure as part of an approved health screening program
 - c. volunteers subject to dental exposure as part of a program of biomedical research
 - d. relatively high doses¹⁰ to the patient
 - e. exposure of an embryo or fetus, in particular for radiological procedures in which the uterus of a pregnant patient is exposed to the useful radiation beam or could otherwise receive a dose of 1 mSv or greater.

¹⁰ The term 'relatively high doses' is intended to apply in a given context. Depending on the context, the term 'relatively high doses' may also include doses from exposures in non-routine computed tomography procedures.

Calibration

- 3.2.11 In accordance with clause 3.1.4c, the Responsible Person must ensure that:
 - a. all sources giving rise to dental exposure are calibrated in terms of appropriate quantities using protocols endorsed by the relevant regulatory authority and 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. calibration of all reference equipment is traceable to relevant national standards.

Diagnostic reference levels

- 3.2.12 At the time of publication of this Code, no diagnostic reference levels (DRLs) have been published for dental radiological procedures in Australia. However, if a DRL is published for dental diagnostic procedures, 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 type of radiological procedure:
 - i. typical doses or administered activities for a representative sample of patients exceed the relevant diagnostic reference level, or
 - ii. exposures do not provide useful diagnostic information or do not yield the expected benefit to patients.

Quality assurance for dental exposures

- 3.2.13 The Responsible Person must ensure that a comprehensive program of quality assurance for dental exposures is established, performed, maintained and regularly reviewed, with the active participation of radiological dental practitioners, operators and qualified experts, 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.
- 3.2.14 The Responsible Person must ensure that programs of quality assurance for dental exposure include, as appropriate to the dental radiation facility:
 - a. measurements of the physical parameters of dental 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 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. maintaining records of relevant procedures and results, including documentation of work performed for repair, maintenance or modification
- e. 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.
- 3.2.15 The Responsible Person must ensure that regular reviews¹¹ are made of the program of quality assurance for dental 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.

Dose constraints

- 3.2.16 The Responsible Person must ensure that a dose constraint of 1 mSv per diagnostic radiological examination is used in the optimisation of protection and safety in any radiological procedure in which an individual acts as a carer or comforter.
- 3.2.17 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 3.2.6) 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 patients

- 3.3.1 For pregnant patients, standard dental diagnostic procedures using intra-oral, panoramic and cephalometric examinations can be undertaken. Exposures should follow best practice, avoiding the exposure of the patient's abdomen and using appropriate collimation. Exposures where the beam is directed towards the abdomen, such as the vertical occlusal projection, should be avoided.
- 3.3.2 The clinical need for a cone beam computed tomography exposure should consider the potential exposure to the patient's abdomen. Where practicable, the use of cone beam computed tomography should be delayed until after pregnancy. Where this is not practicable, the need for the shielding of the patient's abdomen should be considered and advice sought from a qualified expert.

^{&#}x27;regular review' means a systematic, documented evaluation against standards or requirements set by relevant professional bodies or the relevant regulatory authority.

3.4 Unintended and accidental dental exposure

Unintended and accidental dental exposure

- 3.4.1 The Responsible Person must ensure that all practicable measures are taken to minimise the likelihood of unintended or accidental dental exposures arising from flaws in design and operational failures of dental radiological equipment or facilities, from failures of and errors in software, or as a result of human error or the failure of processes.
- 3.4.2 The Responsible Person must ensure that unintended or accidental dental exposures are promptly investigated, including the following:
 - a. any diagnostic radiological procedure in which the wrong individual is subject to exposure or an individual receives the wrong exposure
 - b. any exposure for diagnostic purposes that is substantially greater than was intended
 - c. any inadvertent exposure of an embryo or fetus in the course of performing a radiological procedure
 - d. any failure of dental 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 dental exposure that is substantially different from what was intended
 - e. any other event specified by the relevant regulatory authority.
- 3.4.3 The Responsible Person must, with regard to any unintended or accidental dental exposures investigated as required in clause 3.4.2:
 - a. arrange for the calculation or estimation of the doses received
 - b. indicate the corrective actions required to prevent the recurrence of such an unintended or accidental dental 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 dental 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 dental practitioner informs the patient or the patient's legal authorised representative, and where appropriate the referrer, of the unintended or accidental dental 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 dental practitioners at the dental radiation facility, in collaboration with the operators and the qualified experts. 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 dental radiation facility.

Training

- 3.5.2 The Responsible Person must ensure that personnel (radiological dental practitioners, operators, qualified experts, and any other health professionals or approved personnel) with specific duties in relation to the radiation protection of patients:
 - a. meet the respective requirements for education, training and competence in radiation protection, in accordance with the requirements of the relevant regulatory authorities
 - b. are named in a list maintained up to date by the Responsible Person and referenced in the facility's Radiation Management Plan
 - c. 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 dental exposure has been carried out
 - b. optimisation of protection and safety for each dental exposure has been carried out.
- 3.5.4 The Responsible Person must maintain for a period of seven years, or as otherwise specified by regulatory authorities, and must make available, as required, the following records pertaining to:
 - a. personnel:
 - i. details of any delegation of responsibilities by the Responsible Person or a radiological dental practitioner (as required in clause 3.1.4d)
 - ii. training of personnel in radiation protection (as required in clause 3.5.2b)
 - b. calibration, dosimetry and quality assurance:
 - iii. results of calibrations and periodic checks of the relevant physical parameters and clinical protocols selected during treatment of patients
 - iv. dosimetry of patients
 - v. local assessments and reviews made with regard to diagnostic reference levels, as required in clause 3.2.12
 - vi. records associated with the quality assurance program, as required in clause 3.2.15
 - c. dental exposure:
 - vii. for dental diagnostic radiology, information necessary for retrospective assessment of doses, including the number of exposures
 - viii. exposure records for volunteers subject to dental exposure as part of a program of biomedical research
 - ix. reports on investigations of unintended and accidental dental exposures (as required in clause 3.4.3d).

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 3.5.5a addresses protection commensurate with the level of radiation risk that it seeks to mitigate for persons receiving a dental exposure
- c. the Radiation Management Plan prepared under clause 3.5.5a describes the management and reporting arrangements that enable the radiological dental practitioner, the operator, the qualified expert 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 dental exposure, as required in clause 3.5.3.

Schedule A Radiation Management Plan

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

- A.1 The Radiation Management Plan¹² must contain all of the necessary background and operational information for working with radiation, and must 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 dental exposures aspects of the Radiation Management Plan¹³ must include, where relevant to the dental radiation facility:
 - a. information about radiation protection principles applicable to dental exposure namely, justification and optimisation of protection and safety
 - b. the measures to control dental exposures resulting from the radiological procedures performed in the dental radiation facility
 - c. the measures to be applied to ensure that each dental exposure is justified
 - d. the measures to be applied to ensure that, for each dental exposure, protection and safety is optimised, including (as applicable):
 - i. choice of equipment
 - ii. selection and use of protocols for radiological procedures, including consideration of patient's age and pregnancy status
 - iii. observation of the patient throughout procedures where image quality could be affected by patient movement
 - iv. for dental radiation facilities performing diagnostic radiological procedures, procedures for performing local assessments and reviews of radiological procedures compared with national diagnostic reference levels
 - v. procedures for a program of quality assurance for dental exposures
 - vi. procedures for applying dose constraints with respect to carers and comforters
 - vii. 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 patient is or might be pregnant
 - g. the training, qualifications and competencies, roles and responsibilities of persons with responsibilities for patient radiation protection
 - h. the provision of information to and appropriate induction and on-going training for all persons with responsibilities for patient radiation protection
 - i. arrangements for obtaining expert advice in radiation protection

¹² The Radiation Management Plan may make reference to, and utilise, other documented safety procedures and work practices.

¹³ The Radiation Management Plan will also need to address the requirements of RPS C-1 in relation to public and occupational exposure

- j. an identification of potential failures of radiological dental equipment, failures or errors in software, or human errors, including an estimate of the extent of the consequences and in addition:
 - i. specification of preventive 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
- k. a list of actions necessary to manage an unintended or accidental dental exposure, including:
 - i. reporting of the event to the Responsible Person and the appropriate radiological dental practitioner
 - ii. investigation of the event
 - iii. determination of corrective actions required to prevent the recurrence of such an unintended or accidental dental exposure
 - iv. implementation of corrective actions
 - v. reporting (both internal and to the relevant regulatory authority)
 - vi. information to the referrer and patient
- I. arrangements for record keeping, including for records of personnel training in radiation protection, calibration, dosimetry, quality assurance and dental exposure
- m. arrangements for any other requirement that may have a bearing on radiation safety in dental exposures
- n. 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 dental 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 <u>IAEA website</u>.

RPS C-5	IAEA GSR Part 3	
Requirement	Clause(s)	Requirement
Responsibilities specific to dental exposure	3.1.1-3.1.19	Requirement 36
Justification of dental exposure	3.2.1-3.2.6	Requirement 37
Optimisation of protection and safety	3.2.7-3.2.18	Requirement 38
Pregnant patients	3.3.1	Requirement 39
Unintended and accidental dental exposure	3.4.1-3.4.3	Requirement 41
Reviews and records	3.5.1-3.5.6	Requirement 42

Appendix 2: Related codes and guidance

The following table lists related codes that address issues not covered in the scope of this *Dental Exposure Code*. Also listed are documents that give guidance on aspects of this Code.

Number	Title	Scope
RPS C-1	Code for Radiation Protection in Planned Exposure Situations (2016)	Requirements for general licensing and occupational exposure
RPS 8	Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005)	Requirements for approval of exposure of human research subjects
RPS 10	Code of Practice and Safety Guide for Radiation Protection in Dentistry (2005)	Previous requirements for dentistry (superseded)
RPS 14	Code for Radiation Protection in Medical Exposure (2019) (RPS C-5)	Requirements for medical facilities
RPS 14.1	Safety Guide for Radiation Protection in Diagnostic and Interventional Radiology (2008)	Guidance for diagnostic and interventional radiology

Glossary

Absorbed dose (D)

The fundamental dosimetric quantity *D*, defined as:

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

where

 $d\overline{\varepsilon}$ is the mean energy imparted by ionising radiation to matter in a volume element, and dm is the mass of matter in the volume element.

Approved health screening program

A program in which health tests or dental 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.

Dental exposure

lonising radiation exposure received by patients as part of their own dental diagnosis (diagnostic 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.

Dental radiation facility

A facility in which radiological procedures are performed.

Dental radiological equipment

Radiological equipment used in dental 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; to devices used in dental imaging to capture images, such as image intensifiers or flat panel detectors, and to other imaging systems such as dental cone beam computed tomography machines.

Diagnostic reference level (DRL)

Dose levels for dental 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.

Dosimetry

The measurement, calculation and assessment of ionising radiation doses absorbed by organs and tissues within the human body

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:

$$E = \sum_{\mathbf{T}} w_{\mathbf{T}} . H_{\mathbf{T}}$$

where

 H_T is the equivalent dose in tissue or organ T

 w_T is the tissue weighting factor for tissue or organ T.

From the definition of equivalent dose, it follows that:

$$E = \sum_{\mathbf{T}} w_{\mathbf{T}} \cdot \sum_{\mathbf{R}} w_{\mathbf{R}} \cdot D_{\mathbf{T},\mathbf{R}}$$

where

 w_R is the radiation weighting factor for radiation type R

 $D_{T,R}$ is the average absorbed dose in the tissue or organ T delivered by radiation type R.

Equivalent dose

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

$$H_{T,R} = w_R D_{T,R}$$

where

 $D_{T,R}$ is the absorbed dose delivered by radiation type R averaged over a tissue or organ T 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 by the relevant jurisdiction to practise a profession related to health (e.g. dentistry, medicine, podiatry, nursing, medical physics, medical radiation practice, radiopharmacy, occupational health).

Human Research Ethics Committee

A committee that advises an institution or organisation regarding ethical approval for research projects and 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.

Occupational exposure

Exposure of workers received in the course of their work.

Operator

A generic term for a person who is authorised by the relevant regulatory authority to use radiation sources for dental diagnostic imaging. Operators are usually dental practitioners or medical radiation practitioners, but could also be other persons authorised to use radiation sources for a particular purpose by the relevant regulatory authority, e.g. dental assistants.

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.

Public exposure

lonising radiation 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.

Qualified expert

An individual who, by virtue of certification by appropriate boards or societies, professional licence or academic qualifications and experience, is duly recognised as having expertise in a relevant field of specialisation, e.g. medical physics, radiation protection, occupational health, fire safety, quality management or any relevant engineering or safety specialty.

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 that spontaneously emits ionising radiation as a consequence of radioactive decay.

Radiological dental practitioner

A generic term for a health professional with education and training in the dental uses of radiation, who is competent to perform independently or to authorise radiological procedures in a given area of dentistry.

Radiological procedure

A 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.

Referrer

A health professional who, in accordance with the requirements of the relevant regulatory authority, may refer individuals to a radiological dental practitioner for dental 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

In relation to any radiation source, prescribed radiation facility or premises on which radiation sources are stored or used means the legal person¹⁴:

¹⁴ 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.

- 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.

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