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Code of Practice for Dental Radiology

ORS C4

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Introduction

Purpose and commencement

This Code of Practice for Dental Radiology (this code) is issued by the Director for Radiation Safety (the Director) under section 86 of the Radiation Safety Act 2016 (the Act). It provides details necessary to comply with the fundamental requirements in sections 9 to 12 of the Act. Appendix 2 sets out cross-references between clauses in this code and those fundamental requirements. The requirements in this code do not limit the general nature of the fundamental requirements.

This code comes into force on 28 June 2018.

Scope

This code applies to all activities associated with radiological equipment used for intra-oral, panoramic and cephalometric dental procedures. Activities associated with cone beam computed tomography equipment are dealt with in *ORS C1: Code of Practice for Diagnostic and Interventional Radiology*. Activities can include manufacturing, possessing, controlling, managing, using, transporting, storing, exporting, selling, supplying and disposing of equipment.

Compliance with the code does not imply compliance in related areas such as health practitioner clinical competence, occupational safety, hazards in the workplace, resource management and transport of hazardous substances.

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Roles and responsibilities

The following individuals and bodies have roles and responsibilities in relation to this code.

Dental practitioner – a health practitioner with education and training in the dental uses of radiation who is competent to perform independently and oversee dental radiological procedures. This could include, for example, a dentist, dental specialist, dental therapist, dental hygienist or orthodontic auxiliary.

Director for Radiation Safety – the individual appointed under section 76 of the Act to perform functions and duties and exercise powers set out in the Act including the power to issue this code.

Ethics Committee – the committee that approves programmes of medical research, including, in particular, the justification of medical exposure of volunteers.

Managing entity – the legal entity that manages or controls radiation sources and must therefore obtain a source licence as required by section 13(a) of the Act. This could be, for example, a district health board, company, partnership, trust or individual person.

Manufacturer/supplier – the person who designs, manufactures, produces, constructs, assembles, installs, distributes, sells, exports or imports radiological equipment or develops software that could influence the delivery of the medical exposure.

Referring practitioner – a health practitioner who is approved by the managing entity to refer individuals to a dental practitioner for medical exposure.

Servicing engineer – a person who has expertise in installing, servicing and maintaining radiological equipment.

Definitions

The defined terms given in **bold** have the following meanings.

Accident – any **unintended medical exposure** or other unintended event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible from the point of view of **protection and safety**.

Ancillary equipment – equipment other than **radiological equipment** or **protective equipment** that has an impact on the successful outcome of a **radiological procedure** such as automatic film processors, image receptors, view boxes and equipment used for digital image display.

Comforter/carer – a person who voluntarily helps other than occupationally in caring for, supporting and comforting a patient undergoing a **radiological procedure**.

Diagnostic reference level – a level established by the Director that is used to indicate whether, in routine conditions, the dose to the patient in a specified radiological procedure is unusually high or unusually low for that procedure. Diagnostic reference levels, if established, will be published in a compliance guide issued under this code.

Dose limits – limits on **effective dose** and **equivalent dose** specified in Schedule 2 of the Act.

Effective dose – the tissue-weighted sum of **equivalent doses** in all specified tissues and organs of the body.

Equivalent dose – the radiation-weighted dose in a tissue or organ of the body.

Emergency – any non-routine situation or event that necessitates prompt action, primarily to mitigate a hazard or adverse consequences for human life, health, property or the environment. This includes nuclear and radiological emergencies and conventional emergencies such as fires, release of hazardous chemicals, storms or earthquakes. This also includes situations for which prompt action is warranted to mitigate the effects of a perceived hazard.

Employer – the legal entity that employs **workers**. A self-employed person is regarded as being both an employer and a **worker**.

Facility – the location where **radiological** and **ancillary equipment** is installed, used, handled or stored.

Health practitioner – an individual who is, or is deemed to be, registered with an authority as a practitioner of a particular health profession under the Health Practitioners Competence Assurance Act 2003.

Health screening program – a program for asymptomatic populations that is approved and justified by the Ministry of Health in conjunction with appropriate professional bodies (also called an authorised screening program).

In-room protective device – device or equipment to reduce a person's exposure to radiation but the person does not wear it, such as ceiling-suspended protective screens, protective lead curtains, mobile shields and disposable protective drapes.

Justify – determine that the expected benefits to individuals and to society from a radiological procedure outweigh the harm resulting from that procedure. 'Justified', and 'justification' have corresponding meanings.

Medical exposure – exposure to ionising radiation experienced by patients for the purpose of dental diagnosis, by **comforters/carers** while caring for, supporting or comforting patients undergoing **radiological procedures**, and by volunteers in a programme of medical research.

Member of the public – for purposes of protection and safety, any individual in the population except when subject to **occupational exposure** or **medical exposure**.

Occupational exposure – exposure of **workers** incurred in the course of their work.

Occupationally exposed person – any person who is subject to **occupational exposure**.

Optimise – the process of determining what level of protection and safety would result in the magnitude of individual doses, the number of individuals (**workers** and **members of the public**) subject to exposure and the likelihood of exposure being as low as reasonably achievable, economic and social factors being taken into account. For medical exposures of patients this is the management of the radiation dose to the patient commensurate with the medical purpose. 'Optimised' and 'optimisation' have corresponding meanings.

Patient – an individual who is subject to medical exposure as the recipient of a radiological procedure except as part of a programme of medical research.

Personal protective equipment – equipment a person wears to reduce their exposure to radiation, such as protective aprons, organ shields, protective eye-wear and protective gloves.

Potential exposure –possible future exposure that may result from an anticipated operational occurrence or accident at a source or due to an event or sequence of events of a probabilistic nature, including equipment faults and operating errors.

Protection and safety – the protection of people against exposure to ionising radiation, the safety of radiation sources, the prevention of accidents and the mitigation of consequences of accidents if they do occur.

Protective equipment – **personal protective equipment** and **in-room protective devices**.

Public exposure – exposure to ionising radiation that a member of the public experiences, but excluding any **occupational exposure** or **medical exposure**.

Radiological emergency – an emergency in which there is, or is perceived to be, a hazard due to radiation exposure.

Radiological equipment – equipment, including its associated software, used to produce X-rays.

Radiological procedure – a procedure involving the use of **radiological equipment** for intra-oral, panoramic and cephalometric dental procedures.

Unintended medical exposure - exposure of the wrong individual, tissue or organ; exposure that is substantially greater than intended; inadvertent exposure of the embryo or fetus; and failure of **radiological equipment**, failure of software or system failure, or 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.

Volunteer – an individual who may be subjected to medical exposure as part of a programme of medical research.

Worker – an individual who works, whether full time, part time or temporarily for the managing entity or another **employer** and who has recognised rights and duties in relation to occupational radiation protection. A self-employed person is regarded as being both an **employer** and a worker.

Managing entity

General

1. The managing entity must:
   (a) take prime responsibility for protection and safety
   (b) establish a management system to enhance protection and safety that includes:
      (i) effectively integrating protection and safety into the overall management system of the organisation
      (ii) making a commitment to protection and safety from the highest level of management at the facility, including by providing all required resources
      (iii) promoting continuous improvement and a safety culture
      (iv) delegating the planning and delivery of medical exposures to a dental practitioner
      (v) delegating other tasks as appropriate whether to radiation safety officers or other suitably qualified people
      (vi) consulting with an engaging the services of experts and other interested parties as necessary
      (vii) maintaining and enforcing local rules as appropriate
   (c) for all delegations under sub-clauses 1(b)(iv) and 1(b)(v):
      (i) ensure delegates are notified of their duties in relation to protection and safety and assume responsibility for performing them
      (ii) fully document the delegations
   (d) ensure that:
      (i) all activities associated with radiological equipment are justified and optimised for protection and safety
      (ii) dose limits for occupational and public exposure are not exceeded as a result of those activities.

Facilities

2. The managing entity must:
   (a) provide facilities that:
      (i) are sited, located, designed, manufactured, constructed, assembled, commissioned, operated, maintained and decommissioned in accordance with good engineering practice, and minimising the need to rely on administrative controls and personal protective equipment for protection and safety

(ii) enable the person conducting a radiological procedure using fixed units to perform duties (a) further than 2 metres from the X-ray tube head and the patient or (b) behind shielding of at least 18-millimetre gypsum plasterboard equivalence

(iii) enable the person conducting a radiological procedure to clearly observe and communicate with the patient at all times during the radiological procedure

(iv) provide ways for properly displaying and interpreting radiographs and, if film radiography is performed, for properly processing films

(v) are shielded, if cephalometry is performed with equipment that does not fully intercept the primary X-ray beam, with at least 2-millimetre lead equivalence to intercept the beam before it reaches regularly occupied areas to which the dental practitioner does not control access

(b) verify and document the adequacy of the structural shielding of new facilities before they are used clinically, when the intended use of a room changes, radiological equipment is upgraded, underlying procedures or patient workload changes, or surrounding room occupancy is altered

Equipment

3. The managing entity must:

(a) provide, maintain, test and regularly service radiological equipment, protective equipment and ancillary equipment so that it:

(i) is fit for its intended purpose

(ii) fulfils its design requirements for protection and safety and optimisation

(iii) meets the requirements in Appendix 1

(b) ensure that a servicing engineer measures the physical parameters of radiological equipment, including calibration of output in terms of appropriate quantities using internationally accepted protocols:

(i) at the time it accepts and commissions the equipment and before it is used clinically

(ii) periodically after that first check, but at least every three years

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

(iv) after installing any new software or modifying any existing software that could affect the protection and safety of patients

(c) maintain a record of maintenance for each item of radiological equipment, including a fault log and remedial actions taken (interim and subsequent repairs), the results of testing before an item is reintroduced to clinical use, and any reports from servicing engineers

(d) maintain an accurate inventory of all radiological equipment, including its location, details and unique identifying information

(e) take all reasonable steps to prevent damage or unauthorised access to, or loss of radiological equipment

(f) transfer management and control of radiological equipment only to people who are authorised to assume management and control under the Radiation Safety Act 2016

(g) dispose of radiological equipment only if:

(i) the equipment has been rendered permanently inoperative

(ii) all radiation warning signs have been removed.

Training and Authorisation

4. The managing entity must ensure that all persons with responsibilities for protection and safety are:

(a) qualified, educated and trained in protection and safety so that they understand their duties and can perform them competently

(b) named in a current list with details of their qualification, education and training

(c) authorised to assume their roles and responsibilities.

Radiological procedures

5. The managing entity must prevent:

(a) anyone from conducting radiological procedures for any purpose other than dental diagnosis

(b) radiological equipment designed for intra-oral procedures from being used for cephalometry

(c) the use of handheld portable radiological equipment unless it is impractical or medically unacceptable to transfer patients to a fixed or mobile unit.

6. For each radiological procedure, the managing entity must ensure that:

(a) sufficient personnel are available to successfully perform the procedure

(b) patients are subject to medical exposure only if:

(i) the procedure has been requested by a referring practitioner and information on the clinical context has been provided, or it is part of a health screening program

(ii) the procedure has been justified by the dental practitioner in consultation as appropriate with the referring practitioner, or it is part of a health screening program

(iii) the patient or the patient's legal representative has been informed of the expected diagnostic benefits as well as the risks

(c) volunteers are subject to medical exposure only if:

(i) the medical exposure has been approved by an ethics committee

(ii) dose constraints and other conditions imposed by the ethics committee are satisfied

(d) comforters and carers are subject to medical exposure only if they have received, and indicated an understanding of, relevant information on radiation protection and on the radiation risks.

Accident prevention and mitigation

7. The managing entity must:
   (a) take all practicable steps to minimise the likelihood of accidents including, commensurate with the likelihood and magnitude of potential exposures, a multilevel system of sequential, independent provisions for protection and safety
   (b) take timely action to mitigate the consequences of any accident that does occur
   (c) promptly investigate any accident, including by:
      (i) calculating or estimating doses a person has received and, if applicable, the dose distribution within them
      (ii) identifying corrective actions required to prevent a recurrence
      (iii) implement all corrective actions identified in clause 7(c)(ii)
   (d) keep a written record of the accident, including the:
      (i) cause
      (ii) calculations made under clause 7(c)(i)
      (iii) corrective actions identified under clause 7(c)(ii)
      (iv) details of the implementation of corrective actions under clause 7(d)
   (e) promptly notify the Director if the accident:
      (i) results in a significant unintended or accidental exposure, or
      (ii) is caused by equipment failure.

Records

8. The managing entity must maintain records for six years that are sufficient to verify compliance with this code.

Dental practitioner

General

9. The dental practitioner must:
   (a) take responsibility for the planning and delivery of medical exposures
   (b) only use radiological equipment that is fit for its purpose, the most appropriate available and designed for its purpose
   (c) stop using equipment if it has a fault that reduces protection and safety
   (d) report any faults or other irregularities to the managing entity using the protocol that the managing entity sets
   (e) comply with local rules and protocols that the managing entity sets
   (f) report accidents to the managing entity using the protocol that the managing entity sets.

Justification

10. Before starting a radiological procedure, the dental practitioner must in consultation as appropriate with the referring practitioner, justify the medical exposure taking into account, in particular for paediatric or possibly pregnant patients:
   (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 previous radiological procedures and clinical history
   (f) relevant national or international referral guidelines.

11. Clause 10 does not apply to radiological procedures that an Ethics Committee has justified or that are part of an approved health screening programme.

12. If the procedure involves an asymptomatic individual for early detection of disease (but not as part of an approved health screening programme), the dental practitioner must, in addition to satisfying the justification requirements above:
   (a) justify the procedure specifically for that individual:
      (i) in consultation with the referring practitioner if any
      (ii) in accordance with guidelines of relevant professional bodies
   (b) inform the patient or the patient's legal guardian in advance of the expected benefits, risks and limitations of the procedure.

13. For any radiological procedure involving a comforter/carer, the dental practitioner must:
    (a) fully inform the comforter/carer of the radiation risks and check that they understand
    (b) ensure no part of the comforter/carer is exposed to the primary X-ray beam
    (c) ensure that the comforter/carer wears a lead apron.

Optimisation of protection and safety

14. The dental practitioner must ensure that operational aspects of optimisation of protection and safety for patients undergoing radiological procedures are implemented including by:
    (a) selecting radiological equipment that is fit for its purpose, the most appropriate available and designed for its purpose
    (b) correctly identifying the patient and the procedure
    (c) strictly limiting patient exposure to the area of clinical interest by collimating the beam and, for intra-oral radiography, by positioning the end of the cone as close as possible to the patient's skin, and shielding radiosensitive organs that may be exposed when appropriate
    (d) minimising the need for repeat procedures
    (e) adopting equipment settings and features for the procedure that the managing entity has set or, if the managing entity has set no such requirements, applying settings and features that keep the dose to the patient as low as reasonably achievable to get the desired diagnostic information for which the procedure was undertaken
    (f) optimised processing and displaying of images.

15. The dental practitioner must keep doses arising from occupational exposure as low as reasonably achievable, including by:
    (a) establishing a controlled area not less than 2 metres from the patient and the tube head during radiological procedures involving fixed units
    (b) restricting access to the controlled area to only those who need to be there
    (c) using comforters/carers in preference to workers if a patient needs to be held or comforted during a radiological procedure
    (d) ensuring no worker is exposed to the primary radiation beam
    (e) ensuring no worker holds the tube head (except for procedures using handheld intra-oral radiological equipment) or image receptor during the exposure
    (f) using protective equipment if a worker must be within 2 meters from the patient and is not adequately shielded by a barrier
    (g) maintaining barriers and shielded doors in a closed or protected position during exposures.

16. The dental practitioner must keep doses arising from public exposure as low as reasonably achievable by preventing members of the public from entering to controlled areas during a radiological procedure unless they need to be present as a comforter/carer.

Other parties

Manufacturer/supplier

17. The manufacturer/supplier of radiological equipment must:
    (a) supply well-designed, well-manufactured and well-constructed radiological equipment that:
        (i) provides for protection and safety in line with the requirements of this code
        (ii) meets engineering, performance and functional specifications
        (iii) meets quality standards appropriate to the significance of systems and components, including software, for protection and safety
        (iv) provides clear displays, gauges and instructions on operating consoles in appropriate languages
    (b) provide information in appropriate languages on how to properly install and use the radiological equipment and on its associated radiation risks, including performance specifications, instructions for operating and maintenance, and instructions for protection and safety
    (c) supply all radiological equipment with all appropriate radiation protection tools as a default, rather than as optional extras.

18. The manufacturer/supplier must make suitable arrangements with managing entities to share information on use and operating experience that may be important for protection and safety.

Servicing engineer

19. The servicing engineer must:
    (a) install and service radiological equipment competently so that it complies with the requirements in clause 3
    (b) for newly installed, serviced or modified radiological equipment ensure that the setting of the image receptor sensitivity matches the sensitivity of the image receptor being used
    (c) ensure that radiological equipment fitted with an object programmed exposure control is adjusted to match the speed of the image receptor in use
    (d) ensure that all dosimeters used for dosimetry of patients and to measure the physical parameters of radiological equipment are calibrated at least every two years and that such calibrations are traceable to a standards dosimetry laboratory
    (e) cooperate with the managing entity to ensure that radiological equipment cannot be used clinically while it is being installed or serviced

(f) collaborate with the managing entity after installation or servicing to ensure necessary quality control tests are completed successfully and confirming that all radiation protection and safety features are in place and operating correctly before equipment is returned to clinical use

(g) after installing or servicing equipment provide a written report to the managing entity:

  (i) clearly identifying the equipment

  (ii) describing the equipment fault (if any), the work done, parts replaced, adjustments made and any changes that may affect protection and safety

  (iii) certifying that the radiological equipment complies with the relevant requirements in clause 3

  (iv) for installation of new equipment, certifying that the installation enables the facilities to comply with clause 2(a)

  (v) certifying that all radiation protection and safety features are in place and operating correctly.

Appendix 1: Equipment

Part 1: Radiological equipment

General

These requirements apply to all radiological equipment used for intra-oral, panoramic and cephalometric dental radiography. This radiological equipment requires:

1. hardware and software controls that minimise the likelihood of unintended or accidental medical exposures
2. devices that automatically terminate the irradiation after a pre-set time, tube current–exposure time product, or dose to the automatic exposure control detector, or when the 'dead man' hand switch is released
3. radiation beam control mechanisms, including devices that indicate clearly (visually and/or audibly) and in a fail-safe manner when the beam is 'on'
4. when pre-set protocols are provided, technique factors that adequately trained personnel can readily access and modify
5. operating parameters for radiation generators, such as the generating tube potential, filtration, focal spot position and size, source-image receptor distance, field size indication and either tube current and time or their product, that are clearly and accurately shown
6. total filtration in the incident primary X-ray beam greater than 1.5-millimetre aluminium equivalence for equipment designed to be operated at tube potentials up to and including 70 peak kilovoltage (kVp), and greater than 2.5-millimetre aluminium equivalence above 70 kVp
7. leakage radiation at 1 metre from the focus less than 1 milligray per hour at every rating specified by the manufacturer for that tube in that housing
8. X-ray tube output coefficient of variation less than 0.1 for 5 or more consecutive exposures at the same setting
9. for radiological equipment where the exposure time is selected, X-ray tube output linear within 10 percent between two exposure time settings that do not differ by more than a factor of 4, with peak kilovoltage and milliamperage kept constant.

Intra-oral

These requirements apply to all radiological equipment used in intra-oral radiography. This radiological equipment requires:

1. a minimum tube potential of 60 kVp
2. radiation output sufficient to obtain radiographs with exposure times of 1 second or less
3. an open-ended collimator providing a focus to skin distance of at least 20 cm and a field size at the collimator end of no more than 4 centimetres by 5 centimetres if rectangular, or 6 centimetres in diameter if cylindrical
4. for fixed intra-oral units, manoeuvrability at short focal distances around the head of the patient, and the tube head supported so that it remains stationary when positioned for radiography
5. for handheld portable units, a permanent backscatter shield protecting the operator's entire body
6. for handheld portable units, a permanent label in a prominent position with wording to the following effect: 'Danger – equipment produces X-rays when energised'.

Cephalometric

These requirements apply to all radiological equipment used for cephalometric. This radiological equipment requires:

1. devices to precisely align the patient, image receptor and X-ray field
2. limitation of field size to the dimensions of the image receptor
3. field size at each focus to image distance for which it is used to be marked on the housing.

Panoramic

These requirements apply to all radiological equipment used for panoramic radiography. This radiological equipment requires:

1. a permanent primary barrier equivalent to 2 millimetres of lead or more
2. provisions to vary the size of the focal trough so that it is possible to radiograph dentition of sizes typical of both children and adults
3. ability to limit of the field size to:
   (a) the dimensions of the receptor slit (if present) and the image receptor
   (b) the area required for diagnosis, by means of programmed field size trimming and 'child-imaging mode'.

Part 2: Ancillary equipment

There requirements apply to all ancillary equipment used for dental radiography. This ancillary equipment requires:

1. digital images that are free of artefacts produced from ghosting of previous images or the loss of visually detectable pixels or any artefact that could be reasonably misinterpreted as a clinical feature
2. intensifying screens, digital receptors and cassettes that are maintained in clean condition, free of blemishes and monitored by regular quality assurance checks
3. for digital imaging a means to displaying images of diagnostic quality including the ability to display at a relevant resolution and contrast.

Appendix 2: Cross-reference to Radiation Safety Act 2016

Clauses in this code apply to the fundamental requirements in sections 9–12 of the Act as follows.

Section in Act	Clauses in code
9(1)	1, 4–6, 10-11
9(2)	1–4, 6, 9-16
9(3)	1–4, 6, 9-16
10	1, 3, 17-19
11	3
12	3