



Code of Practice for Dental Radiology ORS C4

For consultation

2023

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This consultation

This document sets out the revised Code of Practice for Dental Radiology ORS C4 (revised C4) that Manatū Hauora — the Ministry of Health (the Ministry) proposes to issue under the Radiation Safety Act 2016 (the Act). The revised C4 has been produced as part of a review that the Act requires.

Section 90(a) of the Act requires the Director for Radiation Safety (the Director) to review a code of practice every 5 years. Also, section 90(b) of the Act requires that the Director consult with any person who the Director reasonably considers is likely to be affected by the review.

At the end of the revised C4 is a submission form. People who wish to make a submission as part of the consultation can use it to help them complete their submission. The submission form is also available online. The submission form provides a guide only. You are free to submit any information that you consider to be relevant.

The revised C4 does not alter the scope of the current Code of Practice for Dental Radiology ORS C4 (C4). For this reason, this review does not address dealing with equipment capable of dental cone beam computed tomography. The Ministry will consult on this subject separately when it reviews the current Code of Practice for Diagnostic and Interventional Radiology ORS C1 later in 2023.

Your views matter:

C4 was effective as of 28 June 2018. It is secondary legislation made under the Act and applies to any person who deals with a radiation source. As interpreted in the Act, 'deal with' includes to control, manage, use, sell and supply a radiation source.

People affected by the review include all those who are required to comply with the revised C4 and other people and organisations with a professional interest in X-ray imaging in dentistry.

The Ministry will review all feedback received as part of the consultation and use it to inform the further revision of C4.

Summary of the significant proposals in the revised C4

The Ministry's view is that the proposed amendments to C4 will require minimal changes to protection and safety systems that are already in place to achieve compliance with C4.

The revised C4 includes new clauses, an additional appendix, some changes to interpretations and rewordings. Table 1 lists the most significant proposed amendments and the main reasons for those amendments.

Table 1: The most significant proposed amendments in the revised C4 and the main reasons for them

Amendment	Main reason(s)
The term 'holder of a source licence' replaces the term 'managing entity'.	'Holder of a source licence' is a term used in the Act. This change has no effect on how the revised C4 identifies the responsibilities compared with C4.
Clauses 1, 1(f), 7 and 8 now include explicit references to associated sections of the Act.	Clarifies how technical requirements in the revised C4 meet requirements in the Act.
Clause 1(b) has a new requirement for the 'holder of a source licence' to carry out a risk assessment.	Introduces an explicit requirement. C4 only implies the need for a risk assessment through the requirement in its clause 1(b). The revised C4 requires the 'holder of a source licence' to establish a management system. An assessment of radiation risks is required to do this. Because radiation safety management systems already exist, compliance with the new clause 1(b) in the revised C4 will not require regulated parties to make major adjustments. The proposed new clause 1(b) will align the revised C4 with other codes of practice.
Clause 1(c) has a new requirement for the 'holder of a source licence' to appoint a radiation safety officer (RSO). Clause 4(a)(i) has a new requirement that an RSO's training meets that specified in a new Appendix 2.	An RSO supports the management system for protection and safety. This is because the 'holder of a source licence' designates an RSO to oversee the application of regulatory requirements for radiation protection and safety. A health practitioner registered with the Dental Council in a vocational scope of practice that is set out in Schedule 3 of the Radiation Safety Regulations 2016 is recognised as having undergone training that meets the requirements of Appendix 2. Therefore, the appointment of such a person to be an RSO does not necessarily mean that the person must undergo additional training. The proposed new clause 1(c) will align the revised C4 with other codes of practice.

Amendment	Main reason(s)
<p>Clauses 3(b) and 19(b) have new requirements relating to diagnostic reference levels.</p>	<p>Introduces an explicit requirement. C4 implies the application of diagnostic reference levels through the requirements in clauses 1(d)(i) and 14. Compliance with the new clauses will not require major adjustments as diagnostic reference levels should already be in place.</p> <p>The Ministry's Compliance Guide for Dental Radiology and Dental Cone Beam CT ORS C4 includes guidance on national diagnostic reference levels.</p>
<p>Clause 6(e) has a new requirement for the 'holder of a source licence' to ensure that occupational and public radiation exposures are justified.</p>	<p>This relates to the requirement of section 9(1) of the Act.</p>
<p>In the 'Intraoral' section of Appendix 1, Part 1, clause 5 the word 'permanent' is replaced with 'integral'.</p>	<p>Handheld portable units must have a backscatter shield. It must only be possible to remove the shield through a deliberate and a purposeful act.</p>
<p>Appendix 1, Part 2 includes the following additional text:</p> <p>'2. to the extent practicable, the use of E or F speed intraoral imaging films</p> <p>'3. to the extent practicable, the use of the fastest combination of film speed and cassette screens'.</p>	<p>These clauses support the optimisation process.</p> <p>D speed film is obsolete.</p> <p>The Compliance Guide for C4 addresses image receptor types in the section dedicated to this subject.</p>
<p>An explanation of the term 'person' has been added to the 'Roles and responsibilities' section.</p>	<p>Meaning is clearer.</p>
<p>Clause 1(a)(iii) replaces the word 'promoting' with 'procedures to promote'.</p>	<p>Meaning is clearer.</p>
<p>The revised C4 replaces 'delegating' with 'ensuring' (clauses 1(a)(iv) and 1(a)(v)), 'delegations' with 'roles' (clauses 1(d) and 1(d)(i)) and 'delegates' with 'people' (clause 1(d)(ii)).</p>	<p>Meaning is clearer.</p>
<p>Clause 5(c) replaces 'transfer patients to' with 'use'.</p>	<p>Meaning is clearer.</p>
<p>Clause 9(a) replaces 'take responsibility for' with 'direct'.</p>	<p>Meaning is clearer.</p>

How to provide feedback

All written submissions that fall within the scope of this consultation and are received before the closing date will be considered. The closing date for submissions is Friday 2 June 2023 at 16:00.

The preferred method of receiving submissions is by using our online consultation tool, Citizen Space: consult.health.govt.nz/radiation-safety/code-of-practice-for-dental-radiology

The Office of Radiation Safety (we) can also receive submissions by email, to:

ors.codes@health.govt.nz

Alternatively, submissions can be mailed to:
Radiation Safety Regulations Consultation
Ministry of Health
PO Box 5013
Wellington 6140

What happens after the consultation?

The Ministry (we) will analyse and respond to feedback. After analysing in-scope submissions, we will consider further drafting improvements of the revised C4.

The review will be completed before 28 June 2023.

Start of revised C4

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 specifies technical requirements necessary to comply with the fundamental requirements in sections 9 to 12 of the Act. Appendix 3 of this code 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 a date to be advised <when available>.

Scope

This code applies to all activities and practices associated with radiological equipment used for intraoral, 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 or practices can include manufacturing, possessing, controlling, managing, using, transporting, storing, exporting, importing, selling, supplying or disposing of a radiation source.

Compliance with this 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.

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 be, 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 — a committee that approves programmes of biomedical research, including, in particular, the justification of medical exposure of volunteers.

Holder of a source licence — has the managing given to it in the Act.

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 a medical exposure.

Person — a person is as defined in the Legislation Act 2019 and includes a corporation sole, a body corporate and an unincorporated body, unless the context otherwise requires.

Radiation safety officer — a person who is competent in radiation protection and safety and is designated by the holder of a source licence to oversee the application of regulatory requirements for radiation protection and safety.

Referring practitioner — a health practitioner who is approved by the holder of a source licence to refer individuals to a dental practitioner for a medical exposure.

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

Interpretation

The 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.

Carer and comforter — 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 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. National diagnostic reference levels, if established, will be published for the purpose of comparison in a compliance guide issued under this code.

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

In-room protective device — device or equipment to reduce a person's exposure to radiation that is not worn by the person, 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 **carers and comforters** while caring for, supporting or comforting patients undergoing **radiological procedures**, and by **volunteers** in a programme of biomedical 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.

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, taking economic and social factors into account. For **medical exposures** of patients, this process involves managing the radiation dose to the patient commensurate with the medical purpose. 'Optimised' and 'optimisation' have corresponding meanings.

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

Personal protective equipment — equipment a person wears to reduce their exposure to radiation, such as protective aprons, organ shields, protective eyewear 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, if accidents do occur, the mitigation of their consequences.

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

Radiological procedure — a procedure involving the use of **radiological equipment** for intraoral, panoramic and cephalometric dental procedures.

Risk assessment — the overall process of systematically identifying, estimating, analysing and evaluating risk for the purpose of informing priorities, developing or comparing courses of action, and informing decision-making.

Unintended medical exposure — exposure of the wrong individual, tissue or organ; exposure that is substantially greater than intended; inadvertent exposure of an embryo or foetus; 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** or a **volunteer** in biomedical research 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 biomedical research.

Worker — an individual who works, full time, part time or temporarily, for the holder of a source licence 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.

Holder of a source licence

General

1. Section 20(1) of the Act provides that 'The holder of a source licence is responsible at all times for the management and control of each radiation source to which the licence applies.' The holder of a source licence must therefore take prime responsibility for protection and safety of each radiation source. The holder of a source licence must:
 - (a) establish a management system to enhance protection and safety, which 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) establishing procedures to promote continuous improvement and a safety culture
 - (iv) ensuring that a dental practitioner has the role of planning and delivering medical exposures
 - (v) ensuring that an appointed radiation safety officer or other suitably qualified people have the role of carrying out other tasks as appropriate
 - (vi) consulting with and engaging the services of experts and other interested parties as necessary
 - (vii) maintaining and enforcing procedures and local rules as appropriate
 - (b) carry out and maintain a risk assessment for a radiation source and all aspects of a practice that are relevant to protection and safety. The risk assessment is for the purpose of ensuring the adequacy of the protection and safety provisions
 - (c) appoint a radiation safety officer who has the training required in clause 4(a)
 - (d) for all roles under clause sub-clauses (iv) and (v) of 1(a):
 - (i) fully document the roles
 - (ii) ensure that people are notified of their duties in relation to protection and safety and that they carry out those roles

- (e) ensure that all activities associated with radiological equipment are justified and optimised for protection and safety
- (f) in line with section 9(3) of the Act, which provides that 'A person who deals with a radiation source must ensure that any ionising radiation exposure that results from a planned operation or activity does not exceed the applicable dose limits set out in Schedule 3', be conversant with the requirements set out in Schedule 3 of the Act and ensure that any radiation exposure that results from planned operations or activities does not exceed applicable dose limits.

Facilities

- 2. The holder of a source licence 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 minimise the need to rely on administrative controls and personal protective equipment for protection and safety
 - (ii) enable the person conducting a radiological procedure that uses fixed units to perform duties either (A) further than 2 metres from the X-ray tube head and the patient or (B) behind shielding equivalent to at least 18-millimetre gypsum plasterboard
 - (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) if cephalometry is performed with an image receptor that does not fully intercept the primary X-ray beam, are shielded 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 holder of a source licence 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 of this code
 - (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, and generating diagnostic reference levels on all of the following occasions:
 - (i) at the time of commissioning equipment and before using it clinically
 - (ii) periodically after that commission, but at least every 3 years
 - (iii) after any maintenance that could affect protection and safety
 - (iv) after installing any new software or modifying any existing software that could affect protection and safety
 - (c) maintain a record of maintenance for each item of radiological equipment, including a log of faults and remedial actions taken (interim and subsequent repairs), the results of testing before reintroducing an item 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 Act
 - (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 holder of a source licence 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. This includes ensuring that a radiation safety officer has training that meets that specified

in Appendix 2 of this code. A health practitioner registered with the Dental Council in a vocational scope of practice that is set out in Schedule 3 of the Radiation Safety Regulations 2016 does not necessarily need to undergo additional training to satisfy the requirements of this clause

- (b) named in a current list with details of their qualifications, education and training
- (c) authorised to assume their roles and responsibilities.

Radiological procedures

- 5. The holder of a source licence must prevent:
 - (a) anyone from conducting radiological procedures for any purpose other than dental diagnosis
 - (b) radiological equipment designed for intraoral procedures from being used for cephalometry
 - (c) the use of handheld portable radiological equipment without a stand unless it is impractical or medically unacceptable to use a fixed or mobile unit.
- 6. For each radiological procedure, the holder of a source licence must ensure that:
 - (a) sufficient personnel are available to successfully perform the procedure
 - (b) patients are subject to a 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 programme
 - (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 programme
 - (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) carers and comforters are subject to medical exposure only if they have received, and indicated they understand, relevant information on radiation protection and on the radiation risks
 - (e) for occupational and public exposures, the radiological procedure is expected to give benefits to the individuals who undergo the procedure and

to society that outweigh the harm resulting from the procedure. This must be done in consultation with the dental practitioner.

Accident prevention and mitigation

7. Section 20(3) of the Act provides requirements that apply if the holder of a source licence believes an incident has occurred that has resulted in a person's overexposure to radiation. As well as complying with those requirements, the holder of a source licence 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(c)(iii)
 - (e) promptly notify the Director if the accident either:
 - (i) results in a significant unintended or accidental exposure, or
 - (ii) is caused by equipment failure.

Records

8. Section 35(1) of the Act provides that 'A person who has management or control of a radiation source must — (a) keep records that contain sufficient information to enable the Director to ascertain whether the person is complying with the radiation safety requirements'. To meet this requirement, records that verify compliance with this code must be maintained for 6 years.

Dental practitioner

General

9. The dental practitioner must:
 - (a) direct 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 holder of a source licence
 - (e) comply with local rules and protocols
 - (f) report accidents to the holder of a source licence.

Justification

10. Before starting a radiological procedure, the dental practitioner must, in consultation as appropriate with the referring practitioner, justify the medical exposure for the individual involved considering, 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 for that individual in accordance with guidelines of relevant professional bodies
 - (b) in advance of the procedure, inform the individual or the individual's legal guardian of the expected benefits, risks and limitations of the procedure.

13. For any radiological procedure involving a carer and comforter, the dental practitioner must:
 - (a) fully inform the carer and comforter of the radiation risks and check that they understand
 - (b) ensure no part of the carer and comforter is exposed to the primary X-ray beam
 - (c) ensure that a carer and comforter 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. This includes:
 - (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 intraoral 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 holder of a source licence has set or, if the holder of a source licence 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 that the procedure was undertaken to obtain
 - (f) optimising the processing and display of images.
15. The dental practitioner must keep doses arising from occupational exposure as low as reasonably achievable. This includes:
 - (a) establishing a controlled area no 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 a carer or comforter in preference to a worker 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 intraoral radiological equipment) or image receptor during the exposure

- (f) using protective equipment if a worker must be within 2 metres of 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 controlled areas during a radiological procedure unless they need to be present as a carer and comforter.

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 the holder of the source licence 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, and compare diagnostic reference levels with national levels, if any, or appropriate international levels
 - (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 2 years and that such calibrations are traceable to a standards dosimetry laboratory
- (e) cooperate with the holder of a source licence to ensure that radiological equipment cannot be used clinically while it is being installed or serviced
- (f) collaborate with the holder of a source licence 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 holder of a source licence that:
 - (i) clearly identifies the equipment
 - (ii) describes the equipment fault (if any), the work done, parts replaced, adjustments made and any changes that may affect protection and safety
 - (iii) certifies that the radiological equipment complies with the relevant requirements in clause 3
 - (iv) for installation of new equipment, certifies that the installation enables the facilities to comply with clause 2(a)
 - (v) certifies 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 intraoral, 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 2 exposure time settings that do not differ by more than a factor of 4, with peak kilovoltage and milliamperage kept constant.

Intraoral

These requirements apply to all radiological equipment used in intraoral 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 centimetres 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 intraoral 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, an integral backscatter shield protecting the operator's entire body
6. for handheld portable units, a durable 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 spot so that it is possible to radiograph dentition of sizes typical of both children and adults
3. the ability to limit 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

These 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. to the extent practicable, the use of E or F speed intraoral imaging films
3. to the extent practicable, the use of the fastest combination of film speed and cassette screens
4. intensifying screens, digital receptors and cassettes that are maintained in clean condition, free of blemishes and monitored by regular quality control checks
5. for digital imaging, a means of displaying images at a diagnostic quality, including the ability to display them at a relevant resolution and contrast.

Appendix 2:

Requirements for a person to be adequately trained for the role of radiation safety officer

Training syllabus for a radiation safety officer in dental radiology

Subject area	Level of knowledge required
X-ray production, interaction and detection	
X-ray production and interaction of X-rays with matter (to include attenuation and scatter)	1
Methods of detecting X-rays	1
Radiation effects, risks, dose units and typical doses	
Biological effects of radiation	1
Risks of stochastic effects (including from foetal and paediatric exposures)	2
Risks of deterministic effects	1
Risk and benefits of radiation exposures	2
Radiation quantities and units (absorbed dose, dose equivalent and effective dose)	2
Factors affecting radiation dose	1
Typical doses from dental diagnostic procedures (including diagnostic reference levels)	2
Safety of irradiating apparatus used in dental radiology and protection	
Physical characteristics	2
Time, distance and shielding	2
Specific hazards including factors affecting radiation doses (where applicable to include handheld portable irradiating apparatus for intraoral dental radiological procedure)	2
Regulatory requirements	
The radiation safety requirements in the Radiation Safety Act 2016	2

Subject area	Level of knowledge required
Radiation protection of patients, carers and comforters, and volunteers in biomedical research	2
Radiation protection of workers and the public (including individual dose monitoring for the assessment of occupational exposure)	2
Quality control and quality assurance applied to dental radiology	2

Key

- 1 General awareness and understanding
- 2 Working knowledge. Understanding of principles and ability to interpret and apply knowledge in different situations

Appendix 3:

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 this 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

End of revised C4

Submission form

1 Your details

This submission was completed by: *(name)* _____

Address: *(street/box number)* _____

(town/city and postcode) _____

Email: _____

Organisation (if applicable): _____

Position (if applicable): _____

2 Additional Information

I am, or I represent an organisation that is, based in:

New Zealand:

Australia:

Other (please specify): _____

I am or I represent:

A health practitioner:

A servicing engineer:

A qualified expert other than a servicing engineer:

An organisation involved with dental radiology:

Other (please specify):

3 Privacy statement

We may publish submissions on the Ministry's website. If you are submitting as an individual, we will remove your personal details and any identifiable information.

If you do not want your submission published on the Ministry's website, please tick this box:

Do not publish this submission

Your submission will be subject to requests made under the Official Information Act 1982. If you want your personal details removed from your submission, please tick this box:

Remove my personal details from responses to Official Information Act 1982 requests

Please return this form:

By email to: ors.codes@health.govt.nz

4 Consultation questions

We are specifically seeking feedback and comments on the following:

1. Roles and responsibilities

Do you agree that the 'holder of a source licence' is the appropriate term to apply to the legal person (individual or organisation) responsible for managing and controlling the irradiating apparatus that is in the scope of the revised Code of Practice for Dental Radiology ORS C4 (revised C4)?

Yes

No

If no, please provide information to support your view and/or an alternative proposal:

2. New provision

Do you agree that it is warranted to include an explicit requirement in the revised C4 to undertake a risk assessment, which brings the revised C4 into line with other codes of practice issued under the Radiation Safety Act 2016 (other codes)?

Yes

No

If no, please provide information to support your view and/or an alternative proposal:

3. New provision

Do you agree that it is warranted to include an explicit requirement in the revised C4 to appoint a radiation safety officer, which brings the revised C4 into line with other codes?

Yes

No

If no, please provide information to support your view and/or an alternative proposal:

4. Are there other changes you think are necessary to the obligations of the 'holder of a source licence' in the revised C4?

Yes

No

Comments:

5. Are there changes you think are necessary to the obligations of 'other parties' in the revised C4?

Yes

No

Comments:

6. 'Appendix 2: Requirements for a person to be adequately trained for the role of radiation safety officer'

Are the training requirements in Appendix 2 appropriate and comprehensive?

Yes

No

Comments:

7. Are there any other changes you would like to suggest to the revised C4 or comments that you would like to make?

Yes

No

Suggestions and comments: