

Code of Practice Diagnostic and Interventional Radiology

Draft for consultation

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Introduction

Purpose

This Code of Practice for Diagnostic and Interventional Radiology (code) is issued by the Director for Radiation Safety (the Director) under section 86 of the Radiation Safety Act 2016 (the Act). Its purpose is to set out the technical requirements necessary to comply with the fundamental requirements in sections 9 to 12 of the Act. Appendix 5 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.

Scope

This code applies to all activities associated with radiological equipment used for radiographic, fluoroscopic or image-guided interventional procedures but excluding intra-oral and panoramic dental procedures. Activities can include the manufacture, possession, control, management, use, transport, storage, export, sale, supply and disposal 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.

Commencement

This code comes into force on 7 March 2017.

Exemptions

The Director may exempt a person from a provision in the code under section 86(3) of the Act if satisfied that:

- a) it is not practicable in the circumstances for the person to comply with the provision
- b) the fundamental requirement to which the provision relates will still be achieved (see Appendix 5 for details of the fundamental requirements of the Act to which clauses in the code relate).

Contact

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Roles and responsibilities

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

- Managing entity – the legal entity that manages or controls radiation sources. This could be, for example, a district health board, company, partnership, trust or individual person. The managing entity is responsible for setting up and implementing the technical and organisational requirements for the protection and safety of the practices and sources for which they hold a source licence.
- Manufacturer/supplier – the person who designs, manufactures, produces, constructs, assembles, installs, distributes, sells, exports or imports radiological equipment and develops software that could influence the delivery of the medical exposure.
- Medical physicist – an individual with specialist education and training in the concepts and techniques of applying physics in medicine who holds a use licence under section 21 of the Act in one or more of the specialties of medical physics.
- Practitioner – the individual who oversees, justifies and optimises radiological procedures. Clauses 6 and 22 apply if these functions are split between multiple practitioners. Depending on the activities they perform, a practitioner may also be classified as a radiation worker.
- Radiation worker – any individual who is subject to occupational exposure in the course of their work. Depending on the activities they perform, a radiation worker may also be classified as a practitioner.
- Servicing engineer – a person who has expertise in installing, servicing and maintaining X-ray equipment. Although this person's activities will normally require them to hold a user licence under the Act, such a licence is granted on the basis that the person can safely use the equipment. Their competence as a servicing engineer must be separately assessed by the managing entity.
- Ethics Committee – the committee that approves programmes of biomedical research, including, in particular, the justification of medical exposure of volunteers as part of that programme.

Definitions

Defined terms are identified in **bold** and have the following meanings.

Accident – any unintended event, including operating error, equipment fault or other mishap, the consequences or potential consequences of which are not negligible from the point of view of protection and safety, including (without limitation): exposure of the wrong individual, tissue or organ; substantially greater exposure than intended; inadvertent exposure of the embryo or foetus; severe radiation injuries involving ulceration and necrosis; and fault of **radiological equipment**, failure of software or system failure, or error, mishap or other unusual occurrence with the potential for subjecting a patient to a medical exposure that is substantially different from what was intended.

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, printers, image receptors, view boxes and equipment used for digital image display.

Comforter/carer – a person who voluntarily helps other than occupationally in the care, support and comfort of a patient undergoing a **radiological procedure**.

Controlled area – an area in which specific protection measures and safety provisions are or could be required for controlling exposures in normal working conditions, and preventing or limiting the extent of **potential exposures**.

Diagnostic reference level – **typical dose** for a specified **radiological procedure** established by the Director.

Dose limit – limits on **effective dose** and **equivalent dose** specified in Appendix 3.

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.

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

In-room protective device – device or equipment to reduce exposure to radiation but not worn on 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. Justifies, justified and justification have corresponding meanings.

Medical exposure – exposure to ionising radiation experienced by patients for the purposes of medical or dental diagnosis, by **comforters/carers** while providing care, support, or comfort to patients undergoing **radiological procedures**, and by volunteers in a programme of biomedical research.

Occupational exposure – exposure to ionising radiation experienced by **radiation workers** during the course of their work.

Optimise – reduce the magnitude of individual doses, the number of individuals exposed and the likelihood of exposure so that they are as low as reasonably achievable. Optimises, optimised and optimisation have corresponding meanings.

Personal protective equipment – equipment worn on the person to reduce exposure to radiation such as protective aprons, organ shields, protective eye-wear and protective gloves.

Potential exposure – prospectively considered exposure that is not certain to be delivered but that may result from 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.

Primary shielding – 2 mm lead equivalence.

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 experienced by a member of the public but excluding any **occupational exposure** or **medical exposure**.

Radiation worker – any individual who is exposed to radiation in the course of their work.

Radiological equipment – equipment used for the production of X-rays, including its associated software.

Radiological procedure – a procedure involving the use of **radiological equipment** for radiography, fluoroscopy or image-guided intervention but excluding intra-oral or panoramic dental procedures.

Secondary shielding – 1.5 mm lead equivalence in **X-ray rooms** where computed tomography equipment is performed, 18 mm gypsum plasterboard equivalence in all X-ray rooms where mammography or dual energy X-ray absorptiometry is performed and 1.0 mm lead equivalence for all other X-ray rooms.

Supervised area – an area other than a **controlled area** in which occupational exposure conditions need to be kept under review, even though specific protection measures or safety provisions are not normally needed.

Typical dose – the median or average of the doses for a representative sample of relatively standard-sized patients, at clinically acceptable image quality.

Volunteer – an individual who is subject to medical exposure as part of a programme of biomedical research.

X-ray room – any room used principally for the purpose of undertaking **radiological procedures**.

Managing entity

General

1. The managing entity must:
 - (a) assume overall responsibility for protection and safety at the facility
 - (b) ensure that any delegation of the responsibility in clause 1(a) is fully documented and the delegate is authorised, capable and resourced sufficiently to carry out those delegations
 - (c) establish a management system that enhances protection and safety by:
 - (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
 - (d) ensure that:
 - (i) all activities associated with radiological equipment are justified and optimised
 - (ii) dose limits are not exceeded as a result of those activities.

Facilities

2. The managing entity must:
 - (a) provide facilities that are sited, located, designed, manufactured, constructed, assembled, commissioned, operated, maintained and decommissioned in accordance with good engineering practice, minimising the need to rely on administrative controls and personal protective equipment for protection and safety
 - (b) shield all X-ray rooms by either:
 - (i) satisfying the requirements for primary shielding in all areas that can be exposed to the primary radiation beam and the requirements for secondary shielding for all other doors, walls, ceilings, floors and other material constructions in the room, or
 - (ii) in consultation with a medical physicist, ensuring that expected doses to any person are as low as reasonably achievable
 - (c) ensure that no access door can be exposed to the primary X-ray beam
 - (d) in consultation with a medical physicist, verify and document the adequacy of the structural shielding of new facilities before clinical use, when the intended use of a room changes, radiological equipment is upgraded, underlying procedures or patient workload changes, or surrounding room occupancy is altered

- (e) designate and physically delineate:
 - (i) as controlled areas, all X-ray rooms
 - (ii) as controlled areas, any other areas if specific protection measures and safety provisions are or could be required for controlling exposures in normal working conditions, and preventing or limiting the extent of potential exposures
 - (iii) as supervised areas, any areas not already designated as controlled areas if occupational exposure conditions need to be kept under review, even though specific protection measures or safety provisions are not normally needed
- (f) erect and maintain prominently displayed signs in appropriate languages and/or warning lights:
 - (i) prohibiting unauthorised entry to controlled areas and supervised areas
 - (ii) warning of the possibility of X-ray exposures at all points of uncontrolled access to controlled areas and supervised areas
 - (iii) in areas that patients may be in (including waiting rooms and change cubicles), requiring patients who are to undergo a radiological procedure to notify staff if they are or may be pregnant
- (g) provide an operator console for X-ray rooms that:
 - (i) is shielded so that no further protection is required for the operator
 - (ii) enables the operator to clearly observe and communicate with the patient at all times during the radiological procedure
 - (iii) provides the same level of protection in the viewing window as is provided for the rest of the console
- (h) provide for the proper display and interpretation of radiographs and, if film radiography is performed, for the proper processing of films.

Equipment

3. The managing entity must, in consultation with a medical physicist:
 - (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
 - (b) ensure that:
 - (i) radiological equipment satisfies the requirements in Appendix 1
 - (ii) radiological equipment obtained after the date of commencement of this code also satisfies the requirements in Appendix 2
 - (iii) protective equipment retains its shielding integrity
 - (iv) the protective value of protective equipment is clearly displayed on the equipment
 - (c) take all reasonable steps to prevent damage or unauthorised access to, or loss of radiological equipment

- (d) relinquish management and control of radiological equipment only to people who are authorised to assume management and control under the Radiation Safety Act 2016.

Radiological procedures

- 4. The managing entity must prevent radiological procedures for any purpose other than medical diagnosis or biomedical research.
- 5. For each radiological procedure, the managing entity must ensure that:
 - (a) a practitioner is appointed to take overall responsibility for protection and safety
 - (b) a practitioner justifies and optimises the procedure
 - (c) any practitioners performing functions under clause 5(a) and (b) are:
 - (i) appropriately specialised and qualified and have continuing education and training to competently perform those functions
 - (ii) authorised by the managing entity in respect of the specific radiological equipment to be used
 - (iii) permitted to perform those functions under the Health Practitioners Competence Assurance Act 2003 and licensed as necessary under the Radiation Safety Act 2016.
- 6. If the performance of functions under clause 5(a) and (b) involves more than one practitioner for a single radiation procedure, the managing entity must assign roles and issue communication protocols to ensure that:
 - (a) all practitioner obligations in clauses 21–31 are fully assigned
 - (b) each practitioner understands which of those obligations they are required to perform.

Occupational and public dose monitoring

- 7. The managing entity must assess occupational and public exposures in consultation with a medical physicist:
 - (a) for occupational exposures, either:
 - (i) by continuously monitoring individual occupational exposures to all radiation workers who usually work in controlled areas or who may receive a dose exceeding 10 percent of the dose limits, or
 - (ii) if individual monitoring under clause 7(a)(i) is inappropriate, inadequate or not feasible, under a programme of workplace monitoring
 - (b) for public exposures, by establishing and implementing a monitoring programme.
- 8. The managing entity must:
 - (a) set investigation levels for occupational doses
 - (b) investigate doses that exceed those investigation levels

- (c) provide radiation workers with access to records of their occupational exposure under clause 7(a)(i) or the results of the workplace monitoring programme under clause 7(a)(ii).
 - (d) maintain records of all monitoring for 10 years
 - (e) promptly notify the Director if a dose limit is exceeded.
9. To satisfy the monitoring requirement in clause 7, the managing entity must only use an external service or internal capability if that service or capability:
- (a) returns results of monitoring to the managing entity within 20 working days of receiving all necessary raw information
 - (b) is capable of assessing personal dose equivalent at a depth appropriate to the application, $H_p(d)$ for individual monitoring and ambient dose equivalent, $H^*(10)$ for area monitoring
 - (c) is otherwise approved by the Director.

Accident prevention and mitigation

10. The managing entity must:
- (a) take all practicable steps, including defence in depth, to minimise the likelihood of accidents
 - (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 received by, and if applicable the dose distribution within, any person
 - (ii) determining corrective actions required to prevent a recurrence
 - (d) implement all corrective actions identified in clause 10(c)(ii)
 - (e) keep a written record of the accident, including the:
 - (i) cause
 - (ii) calculations made under clause 10(c)(i)
 - (iii) corrective actions identified under clause 10(c)(ii)
 - (iv) details of the implementation of corrective actions under clause 10(d)
 - (f) promptly notify the Director if the accident results in a significant unintended or accidental exposure.

Calibration and dosimetry

11. The managing entity must ensure that all dosimeters used for dosimetry of patients and for the measurement of the physical parameters of radiological equipment are calibrated at least every two years and that such calibrations are traceable to a standards dosimetry laboratory.
12. The managing entity must ensure that dosimetry of patients is performed and documented by or under the supervision of a medical physicist using calibrated dosimeters and

following internationally accepted or nationally accepted protocols, including dosimetry to determine typical doses to patients for:

- (a) diagnostic procedures that are commonly performed
- (b) broad types of image-guided interventional procedures that are commonly performed.

Quality assurance

13. With the active participation of medical physicists and practitioners, the managing entity must establish a comprehensive programme of quality assurance commensurate with the risks, including:
 - (a) measurements of the physical parameters of radiological equipment made by, or under the supervision of, a medical physicist:
 - (i) at the time of acceptance and commissioning of the equipment prior to its clinical use on patients
 - (ii) periodically thereafter
 - (iii) after any major maintenance procedure that could affect protection and safety of patients
 - (iv) after any installation of new software or modification of existing software that could affect the protection and safety of patients
 - (b) quality control tests on other equipment, devices or facilities that have an impact on the successful outcome of the radiological procedure
 - (c) the establishment of tolerance limits for the physical parameters mentioned in clauses 13(a) and (b), and the implementation of corrective actions if measured values fall outside those tolerance limits
 - (d) verification of the appropriate physical and clinical factors used in radiological procedures
 - (e) periodic repeat and reject analysis
 - (f) routine maintenance of radiological equipment and other equipment
 - (g) periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment
 - (h) regular review of the results of patient dosimetry surveys, including by:
 - (i) comparing them with diagnostic reference levels
 - (ii) implementing corrective actions (including a review of imaging procedures) if typical actual doses exceed the diagnostic reference levels, or if typical doses fall substantially below those levels and the exposures do not yield the expected medical benefits
 - (i) regular internal or external independent audits are made of the programme of quality assurance for medical exposures.

Local rules and protocols

14. The managing entity must maintain and publish written protocols:

- (a) to establish appropriate communication between individuals involved in the referral of patients and the justification and authorisation of procedures to ensure that the benefits of those procedures exceed the detriment
- (b) to correctly identify patients and the procedures they are to undergo
- (c) to ensure the timely reporting of incidents
- (d) to report equipment faults
- (e) to minimise unnecessary irradiation of embryo/foetus
- (f) for operating parameters specific for each piece of radiological equipment to be used for common diagnostic radiological procedures, including size-specific written protocols for children
- (g) for possibly pregnant staff
- (h) for all quality control tests, including frequency and tolerance limits
- (i) for monitoring of staff doses and investigation of doses that exceed investigation levels
- (j) for the conduct and frequency of the independent audit required by clause 13
- (k) for the conduct and frequency of the radiological review required by clause 17
- (l) to ensure staff use protective equipment when structural shielding and administrative controls alone cannot afford the required level of occupational radiation protection.

Records

15. The managing entity must maintain adequate records of:
- (a) shielding in X-ray rooms, including the medical physicist's report on the adequacy of that shielding
 - (b) an accurate inventory of all radiological equipment, including:
 - (i) its location
 - (ii) details and unique identifying information
 - (iii) a record of maintenance for each item, including a fault log and remedial actions taken (interim and subsequent repairs), and the results of testing before an item is reintroduced to clinical use
 - (iv) reports from service engineers
 - (c) reports from workers identifying circumstances that could affect compliance
 - (d) the results of the quality assurance programme
 - (e) the radiation safety plan
 - (f) medical exposure as follows:
 - (i) for diagnostic radiology, information necessary for retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures

- (ii) for image-guided interventional procedures, information necessary for retrospective assessment of doses, including the duration of the fluoroscopic component and the number of images acquired
- (iii) exposure records for volunteers subject to medical exposure as part of a programme of biomedical research
- (iv) reports on investigations of unintended and accidental medical exposures
- (g) occupational dose monitoring programme
- (h) public dose monitoring programme
- (i) decisions regarding protection and safety
- (j) exemptions from this code granted under section 86(3) of the Act.

Radiation safety plan

16. The managing entity must prepare and maintain a radiation safety plan that:
 - (a) shows how the requirements of the Act and this code will be complied with
 - (b) clearly defines the roles and responsibilities of staff, including a well-defined reporting structure
 - (c) records training details for all practitioners and radiation workers
 - (d) sets out local rules and protocols
 - (e) contains records or references records required in this code
 - (f) satisfies the safety assessment requirements in Appendix 4 in any case where computed tomography equipment is used.
17. The managing entity must periodically perform a radiological review, including a review and update of the radiation safety plan and an investigation and critical review of the current practical application of the radiation protection principles of justification and optimisation.
18. The radiological review must take into account:
 - (a) the outcome of the previous radiological review
 - (b) the report of the independent audit of the quality assurance programme
 - (c) lessons learnt from past accidents and incidents
 - (d) results of updated safety assessments
 - (e) reviews of supervised areas as required by clause 2(e)(iii)
 - (f) results of occupational dose monitoring programme.
19. In respect of any activities involving the use of radiological equipment for computed tomography, the managing entity must:
 - (a) conduct and document a safety assessment that satisfies the requirements in Appendix 4
 - (b) review and, if appropriate, update the safety assessment to ensure the technical specifications or conditions of use continue to be met when:

- (i) significant modifications to the facility or to its operating procedures or maintenance procedures are envisaged
- (ii) significant changes occur on the site that could affect the safety of the facility or of activities on the site
- (iii) information on operating experience, or information about accidents and other incidents that could result in exposures, indicates that the current assessment might be invalid
- (iv) any significant changes in activities are envisaged
- (v) any relevant changes in guidelines or standards have been made or are envisaged.

Training

20. The managing entity must:

- (a) ensure that all practitioners and radiation workers:
 - (i) are appropriately specialised and qualified and have continuing education and training so that they can perform their duties competently
 - (ii) receive adequate information on health risks due to occupational exposure in normal operation, anticipated operational occurrences and accident conditions
 - (iii) understand their roles, responsibilities and functions as they relate to protection and safety
- (b) provide workers who could be involved in an emergency with appropriate information and instruction/training and periodic retraining for protection and safety
- (c) communicate decisions regarding protection and safety
- (d) provide radiation workers who may enter controlled areas or supervised areas, or who may undertake emergency duties, with appropriate information on risk to the embryo/foetus due to exposure of a pregnant woman, and on the importance of advising the managing entity if the worker thinks she may be pregnant.

Practitioner

General

21. The practitioner must:
- (a) assume overall responsibility for protection and safety related to radiological procedures
 - (b) comply with local rules and protocols issued by the managing entity
 - (c) report any faults or other irregularities to the managing entity using the protocol issued by the managing entity
 - (d) only use radiological equipment that is fit for its purpose, the most appropriate available and designed for its purpose
 - (e) stop using equipment if there is a fault that adversely affects protection and safety
 - (f) report accidents to the managing entity using the protocol issued by the managing entity
 - (g) maintain appropriate patient details and medical records for radiological procedures, which are adequate to allow the patient dose to be retrospectively assessed if required.

Multiple practitioners

22. If the oversight, justification and optimisation of a radiological procedure involve more than one practitioner, then each practitioner must:
- (a) carry out the responsibilities assigned to them under clause 6
 - (b) comply with protocols issued by the managing entity under clause 6.

Justification

23. If a radiological procedure involves the possibility of a significant dose to an embryo/foetus of a woman of childbearing age, the practitioner must make reasonable inquiries into the possibility of pregnancy.
24. Before starting a radiological procedure, the practitioner must determine that the expected benefits to the individual and to society outweigh the harm (including radiation detriment). They must take into account, in particular for patients who are paediatric, asymptomatic or possibly pregnant:
- (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
25. Clause 24 does not apply to radiological procedures justified by the Ethics Committee as part of an approved health screening programme.
26. If the procedure involves an asymptomatic individual for early detection of disease (but not as part of an approved health screening programme), the practitioner must inform the patient in advance of the expected benefits, risks and limitations of the procedure.
27. The practitioner must ensure that no person incurs a medical exposure as a carer or comforter unless they have received, and have indicated they understand, relevant information on the radiation risks.

Reducing radiation doses to patients

28. The practitioner must keep doses arising from medical exposure as low as reasonably achievable 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 collimation of the beam (radiography, mammography, fluoroscopy and image-guided interventional procedures) or by choosing appropriate scan parameters (computed tomography)
 - (d) shielding radiosensitive organs that may be exposed when appropriate
 - (e) minimising the need for repeat procedures
 - (f) adopting equipment settings and features issued for the procedure by the managing entity or, if no such factors have been issued, applying settings and features that keep the dose to the patient as low as reasonably achievable consistent with obtaining the desired diagnostic information for which the procedure was undertaken
 - (g) applying the following dose constraints:
 - (i) 5 millisieverts (mSv) per event for adult comforters and carers
 - (ii) 1 mSv per event for child or pregnant comforters and carers
 - (iii) such level as may be set by the Ethics Committee for volunteers.

Reducing occupational radiation doses

29. The practitioner must keep doses arising from occupational exposure as low as reasonably achievable by:
- (a) if the radiological procedure is to take place outside an existing controlled area, designating and physically delineating a temporary controlled area
 - (b) restricting access to the controlled area (whether declared under clause 2(e) or under clause 29(a)) to only those who need to be present

- (c) for those radiological procedures where staff do not need to be in the controlled area during an exposure, requiring all attending staff to position themselves in the appropriately shielded areas
- (d) using comforters/carers in preference to radiation workers if a patient needs to be held or comforted during a radiological procedure
- (e) ensuring no radiation worker is exposed to the primary radiation beam
- (f) using protective equipment in any case where shielding in a controlled area is insufficient to keep doses arising from occupational exposure as low as reasonably achievable
- (g) maintaining barriers and shielded doors in a closed or protected position during exposures.

Reducing radiation doses to the public

- 30. The practitioner must keep doses arising from public exposure as low as reasonably achievable by:
 - (a) preventing access to controlled areas by members of the public during a radiological procedure unless their presence is necessary as a comforter/carer.

Other parties

Manufacturer/supplier

31. The manufacturer/supplier of radiological equipment must:
- (a) supply well-designed, -manufactured and -constructed radiological equipment that:
 - (i) provides for protection and safety in accordance 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 the proper installation and use of 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.
32. 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.

Radiation worker

33. All radiation workers must:
- (a) follow any applicable rules and procedures for protection and safety
 - (b) properly use monitoring equipment and protective equipment
 - (c) cooperate with the managing entity over protection and safety
 - (d) provide information to the managing entity about protection and safety
 - (e) abstain from any wilful action contravening this code
 - (f) accept information, instruction and training in protection and safety
 - (g) report circumstances that could adversely affect protection and safety.

Servicing engineer

34. The servicing engineer must:

- (a) install and service radiological equipment competently so that it complies with the requirements in clause 3
- (b) cooperate with the managing entity to ensure that radiological equipment cannot be used clinically while it is being installed or serviced
- (c) on completion of installation or servicing and before any clinical use of the equipment:
 - (i) provide a written report to the managing entity describing the equipment fault (if any), the work done, parts replaced, adjustments made and any changes that may affect protection and safety
 - (ii) collaborate with the managing entity and medical physicists to ensure necessary quality control tests are completed successfully.

Appendix 1: Equipment

General radiography

These requirements apply to all radiological equipment used in diagnostic radiology and image-guided interventional procedures. This radiological equipment requires:

1. total filtration in the incident primary X-ray beam greater than 2.5 mm aluminium equivalence
2. 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
3. misalignment of each edge of the visually defined light field with the respective edge of the X-ray field less than 1.5 percent of the focus to image distance (FID)
4. centre of the X-ray beam and indicated centre of the light beam less than 1.5 percent of the FID
5. minimum luminance of the light field greater than 100 lux
6. X-ray beam collimated to either a rectangular cross-section congruent with that of the image receptor being used, or a circular cross-section that inscribes the X-ray image detector being used
7. centre of the X-ray beam and indicated centre of the light beam accurate to within 1.5 percent of the distance from the focus to the point on the illuminated surface at which it appears
8. scale stating the X-ray beam dimensions at each focus-image receptor distance to within 1.5 percent of actual dimensions
9. misalignment of the edges of the X-ray field with the image receptor less than 2 percent of the FID
10. automatic collimation allowing fields smaller than the whole image receptor
11. X-ray beam outside the active area of the image receptor less than 2 percent of the FID
12. for fixed X-ray equipment, means to indicate distances from the focus to the receptor accurate to within 10 mm
13. for mobile and portable X-ray equipment, retractable tape mounted on the X-ray tube head assembly to measure the distance from the focus to the end of the extended tape is indicated to within 10 mm
14. focus-skin distance (FSD) not less than 400 mm
15. exposure device with timer capable of exposure times of less than 20 milliseconds
16. exposure device providing actual time within 10 percent of the set time when the set time is 0.2 seconds or greater with a difference in successive exposures less than 10 percent
17. minimum response time of the automatic exposure control device (AEC) with the appropriate chamber selected for the X-ray projection less than 10 milliseconds for multi-phase, medium and high frequency X-ray machines
18. AEC installed which can be set to terminate the exposure after a time no greater than 6 seconds, or after an exposure of no more than 600 milliamperere second (mAs), whichever is the lesser

19. for digital radiography and computerised radiography, an AEC device to control exposures such that the recorded receptor dose varies within 20 percent when the patient thickness, peak kilovoltage peak (kVp) and milliamperage (mA) are varied over their normal clinical ranges for which the X-ray machine is used
20. X-ray tube output within the range 25–80 microgray (μGy) per mAs at 80 kV and total filtration of 2.5 mm Aluminium
21. X-ray tube output coefficient of variation less than 0.1 for 5 or more consecutive exposures at the same setting
22. X-ray tube output linear within 10 percent between two mA, mAs or exposure time settings that do not differ by more than a factor of 4
23. X-ray tube voltage within 5 percent of the indicated value over the range of kilovoltage (kV), time, current and mAs settings for which the X-ray machine is normally used.

Digital radiography

These requirements apply if the radiological equipment is digital. This radiological equipment requires:

1. exposure index calibration correct and reproducible to an accuracy within 20 percent
2. exposure index correlation to detector dose within 5 percent across the clinical range to at least 20 μGy
3. images free from artefacts from ghosting of previous images, loss of visually detectable pixels or any artefact that could be reasonably misinterpreted as a clinical feature
4. digital image optimally recorded, processed, transferred and displayed to minimise the loss of clinically observable content
5. deviation from mean signal transfer property-corrected region of interest of less than 20 percent gross non-uniformity
6. automatic exposure control target dose less than 5 μGy for standard image resolution using manufacturer's phantom and setup conditions
7. spatial resolution more than 2.4 lp/mm for up to 5 μGy and more than 2.8 lp/mm for up to 10 μGy .

Computed radiography

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

1. an indication of the X-ray dose to the image receptor after each exposure
2. exposure index accurate to within 20 percent of the image receptor kinetic energy released per unit mass in air (air kerma) under expected exposure conditions
3. standard image receptor air kerma greater than 8 μGy
4. images free from artefacts from ghosting of previous images, loss of visually detectable pixels or any artefact that could be reasonably misinterpreted as a clinical feature
5. exposure index correlation to detector dose within 5 percent across the clinical range to at least 20 μGy
6. scaling error less than 4 percent

7. spatial resolution more than 2.4 lp/mm for up to 5 μ Gy and more than 2.8 lp/mm for up to 10 μ Gy.

Computed tomography

These requirements apply to all radiological equipment used for computed tomography (CT). This radiological equipment requires:

1. deviation of CT dose index free-in-air less than 20 percent from manufacturer's specification
2. accuracy of CT dose index free-in-air less than 20 percent of indicated dose
3. measured geometric efficiency within 10 percent of the manufacturer's specification
4. display on operator's console if the geometric efficiency is less than 70 percent of manufacturer's specification
5. CT number of water in region of interest between minus 4 and 4
6. deviation of noise within 10 percent of the specified value
7. deviation of CT number from central value less than 6 hounsfield units for a water phantom up to 20 cm in diameter
8. centre of z-axis dose profiles less than 2 mm from the transverse laser
9. spatial resolution less than 10 percent deviation from manufacturer's specification.

Fluoroscopy and angiography

These requirements apply to all radiological equipment used for fluoroscopy and angiography. This radiological equipment requires:

1. maximum entrance surface dose rate not exceeding 50 mGy per minute or 100 mGy per minute in high dose rate mode
2. fluoroscopic image receptor entrance dose rate not greater than 120 μ Gy per minute (less than 14 cm field size), 90 μ Gy per minute (14 to 23 cm field size) and 60 μ Gy per minute (greater than 23 cm field size) when 2.5 mm copper is added to the beam and the measurements are made at approximately 90 kVp
3. maximum dose per frame at the image intensifier input face less than 0.2 μ Gy (field size not less than 17 cm) or 0.4 μ Gy (field size less than 17 cm)
4. displayed air kerma area product or patient dose accurate to within 35 percent of measured values
5. matching of radiation field area within 20 percent of displayed field area
6. fluoroscopic contrast sensitivity at 70 kVp within 5 percent (or a 10 mm detail) and 15 percent (for a 1 mm detail)
7. minimum FSD greater than 350 mm.

Mammography

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

1. kVp accurate and reproducible to within 1 kV from the indicated kV.

Appendix 2: New equipment

General

These requirements apply to all radiological equipment used in diagnostic radiology and image-guided interventional procedures. This radiological equipment requires:

1. means to detect immediately any malfunction of a single component of the system that may lead to an inadvertent under-exposure or over-exposure of the patient or exposure of staff so that the risk of any unintended or accidental medical exposure is minimised
2. means to minimise the frequency of human error and its impact on the delivery of unintended or accidental medical exposure
3. hardware and software controls that minimise the likelihood of unintended or accidental medical exposures
4. 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
5. radiation beam control mechanisms, including devices that indicate clearly (visually and/or audibly) and in a fail-safe manner when the beam is 'on'
6. X-ray tubes with inherent and added filtration adequate to remove low-energy components of the X-ray beam, which do not provide diagnostic information
7. collimating devices to define the radiation beam; in the case of a light beam diaphragm, the light field should align with the radiation field
8. with the exception of mammography and computed tomography equipment, diagnostic and interventional X-ray equipment that is fitted with continuously adjustable beam collimating devices. Such devices allow the operator to limit the area being imaged to the size of the selected image receptor or the region of interest, whichever is the smaller
9. when preset protocols are provided, technique factors that are readily accessible and modifiable by adequately trained personnel
10. design of the X-ray tube to keep radiation leakage as low as reasonably achievable and not exceeding 1 mGy in an hour measured at 1 metre from the focal spot.

Radiography

These requirements apply, in addition to the general equipment requirements, to all radiological equipment used in radiography. This radiological equipment must:

1. provide devices that automatically terminate the irradiation after a preset time, tube current–exposure time product, or dose to the automatic exposure control (AEC) detector, or when the 'dead man' hand switch is released
2. incorporate AEC systems in radiographic units where practicable. Such AEC systems must be able to compensate for energy dependence, patient thickness and dose rate, for the expected range of clinical imaging conditions, and must be suited to the type of image receptor being used, whether film/screen or digital

3. include indications or displays of the air kerma product and/or incident air kerma for all new equipment commissioned after the date of commencement of this code.

Computed tomography

These requirements apply, in addition to the general equipment requirements, to all radiological equipment used for computed tomography (CT). This radiological equipment requires:

1. console display of all CT parameters that directly influence the image acquisition (these may be displayed over a number of screens)
2. console display of estimated volume CT air kerma index and CT air kerma-length product for the procedure or image acquisition
3. operator alert if exposure factors are set too high (usually expressed in terms of the volume CT air kerma index and/or the CT air kerma-length product)
4. means for dose modulation (rotational and z-axis), and means for selection of noise index or equivalent
5. a comprehensive range of beam widths and pitches and other ancillary devices, eg, dynamic collimation, to keep ‘over ranging’ in CT as low as reasonably achievable by facilitating the appropriate choice of beam width and pitch to limit patient dose while maintaining diagnostic image quality
6. reconstruction algorithms that result in dose reduction without compromising image quality, such as iterative reconstruction algorithms
7. a range of selectable tube potentials, tube current–exposure time products, and filters to facilitate the optimisation of protocols, especially for children.

Mammography

These requirements apply, in addition to the general equipment requirements, to all radiological equipment used for mammography. This radiological equipment requires:

1. various anode and filter combinations
2. compression and immobilisation capabilities
3. magnification views
4. display on the console of a dose index, for example, incident air kerma or mean glandular dose
5. an image receptor or image receptors to accommodate all breast sizes.

Fluoroscopy

These requirements apply, in addition to the general equipment requirements, to all radiological equipment used for fluoroscopy. This radiological equipment requires:

1. a device that energises the X-ray tube only when continuously depressed (such as an exposure footswitch or ‘dead man’ switch)
2. indications or display (both at the control console and on monitors) of the elapsed time, air kerma area product, and cumulative reference air kerma
3. automatic brightness control (ABC) or automatic dose rate control (ADRC)

4. pulsed fluoroscopy and pulsed image acquisition modes
5. the capture and display of the last acquired frame ('last image hold')
6. interlocks that prevent inadvertent energising of the X-ray beam when the image detector is removed from the imaging chain
7. the capability to deactivate the exposure footswitch between cases
8. a timer and an alarm that sounds at the end of a preset interval (typically 5 minutes).

The following additional requirements apply if the radiological equipment is used for image-guided interventional procedures. This radiological equipment requires:

9. X-ray tubes that have high heat capacities to enable operation at high tube currents and short times
10. a radiation generator with capability of at least 80 kilowatts (kW) of power
11. a radiation generator with a large dynamic range of tube current and tube potential (to minimise the pulse width necessary to accommodate differences in patient attenuation)
12. for paediatric work:
 - (a) a radiation generator that supports an X-ray tube with a minimum of three focal spots
 - (b) an anti-scatter grid that is removable
 - (c) an image acquisition frame rate that extends up to at least 60 frames per second for small children
13. a real-time display of air kerma area product and cumulative reference air kerma
14. imaging detectors that allow different fields of view (magnification) to improve spatial resolution
15. automatic collimation
16. dual-shape collimators incorporating both circular and elliptical shutters to be used to modify the field for collimation along cardiac contours
17. system-specific variable filtration in the X-ray beam that is applied according to patient attenuation (often as part of the ADRC system)
18. selectable dose per pulse and selectable number of pulses per second
19. wedge filters that move automatically into the field of view to attenuate the beam in areas where there is no tissue and thus no need for imaging
20. possibly, means for manipulation of diaphragms while in 'last image hold'
21. the option of the automatic display of the last acquired image run
22. display and recording in a dose report in digital format of the following parameters:
 - (a) reference air kerma rate
 - (b) cumulative reference air kerma
 - (c) cumulative air kerma area product
 - (d) cumulative time of fluoroscopy
 - (e) cumulative number of image acquisitions (acquisition runs and frames per run)
 - (f) integrated reference air kerma

23. option for digital subtraction angiography
24. ‘road mapping’ (a technique used for navigation of the catheter or wire in endovascular procedures).

Digital

These requirements apply in addition to any other equipment requirements if the radiological equipment is digital. This radiological equipment requires:

1. real-time dose display and end-of-case dose report (radiation dose structured report (RDSR), DICOM object), including export of dose metrics for the purpose of DRLs and individual patient dose calculation
2. connectivity to RIS/PACS.

Paediatric

These requirements apply in addition to any other equipment requirements if the radiological equipment is used for performing diagnostic and interventional radiology procedures on children. This radiological equipment requires:

1. capability of very short exposure times for radiography
2. specifically designed AEC systems
3. ‘paediatric modes’ for the automatic brightness and/or dose rate control systems in fluoroscopy and image-guided interventional procedures
4. paediatric protocols for CT.

Appendix 3: Dose limits

Occupational exposure

1. For occupational exposure of workers over 18 years of age, the dose limits for ionising radiation are:
 - (a) an effective dose of 20 millisieverts (mSv) per year averaged over 5 consecutive years (100 mSv in 5 years) and of 50 mSv in any single year, or
 - (b) an equivalent dose to the lens of the eye of 20 mSv per year averaged over 5 consecutive years (100 mSv in 5 years) and of 50 mSv in any single year, or
 - (c) an equivalent dose to the extremities (hands and feet) or the skin of 500 mSv in a year.
2. For occupational exposure of people aged 16–18 years who are being trained for employment involving radiation, and for exposure of students aged 16–18 years who use ionising radiation sources in the course of their studies, the dose limits are:
 - (a) an effective dose of 6 mSv in a year, or
 - (b) an equivalent dose to the lens of the eye of 20 mSv in a year, or
 - (c) an equivalent dose to the extremities (hands and feet) or the skin of 150 mSv in a year.

Public exposure

3. For public exposure, including exposure of an embryo or a foetus in a female worker, the dose limits for ionising radiation are:
 - (a) an effective dose of 1 mSv in a year, or
 - (b) an equivalent dose to the lens of the eye of 15 mSv in a year, or
 - (c) an equivalent dose to the skin of 50 mSv in a year.
4. For public exposure, the effective dose may be higher than 1 mSv in a year, if so specified in regulations, provided that the average dose over 5 consecutive years does not exceed 1 mSv per year.

Appendix 4:

Safety assessments

Safety assessments must consider the following aspects:

- possible radiation risks – maximum possible radiological consequences of anticipated operational occurrences or with accidents in which no account was taken of the safety systems or protective measures in place to prevent these
- safety functions – functions necessary to be performed for the facility or activity to prevent or mitigate radiological consequences of normal operation, anticipated operational occurrences and accident conditions
- site characteristics – natural and human-induced external events in the region that have the potential to affect the safety of facilities and activities
- provisions for radiation protection – assessment of whether adequate measures are in place to control the radiation exposure of workers and members of the public within relevant dose limits and whether protection is optimised
- engineering aspects – assessment of whether a facility or activity uses, to the extent practicable, structures, systems and components of robust and proven design
- human factors – assessment of whether personnel competencies, associated training programmes and the specified minimum staffing levels for maintaining safety are adequate
- long-term safety – ensure that the safety assessment covers all stages in the lifetime of the facility or activity in which radiation risks are possible.

Appendix 5: Cross-reference to Radiation Safety Act 2016

As required by section 87(1) of the 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, 4–5, 21–27
9(2)	1–3, 5–9, 11–22, 28–31, 33
9(3)	1, 3, 7–9, 11–22, 28–31, 33
10(1)	3, 13–22, 31–34
10(2)	6–10, 20, 33
10(3)	3, 13–20, 31–34
11	3
12	3

Submission form

Your details

This submission was completed by: (name) _____

Address: (street/box number) _____

(town/city) _____

Email: _____

Organisation (if applicable): _____

Position (if applicable): _____

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: (tick all that apply)

<input type="checkbox"/> District health board	<input type="checkbox"/> Private health provider
<input type="checkbox"/> Professional body	<input type="checkbox"/> Other institution, eg, university
<input type="checkbox"/> Health practitioner	<input type="checkbox"/> Member of the public
<input type="checkbox"/> Other (please specify): _____	

Privacy

We may publish submissions on the Ministry's website. If you are submitting as an individual, we will automatically 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. If you want your personal details removed from your submission, please tick this box:

☐ Remove my personal details from responses to Official Information Act requests.

Please return this form to:

Email: <mailto:orsenquiries@moh.govt.nz> (including 'radiology code' in the subject line)

or post: Office of Radiation Safety, PO Box 3877, Christchurch 8140

Consultation questions

The Office of Radiation Safety is seeking comments on the following.

Scope

1. The scope of the code relates to the use of X-rays for diagnostic and interventional radiology but excluding intra-oral and panoramic dental procedures, which will be the subject of a separate code (note this means that the dental use of cone beam CT is therefore included in this code). Is this appropriate?

☐ Yes

☐ No

If no, please provide alternative suggestions for the scope of this code.

Roles and responsibilities

2. Are the roles and responsibilities of key parties adequately described?

☐ Yes

☐ No

If no, please provide details of parties that should/should not be included and any changes that should be made to the descriptions.

Definitions

3. Are the definitions appropriate and comprehensive?

☐ Yes

☐ No

If no, please provide suggestions for any new terms to be defined or changes to existing definitions.

Managing entity obligations

4. a. Are the subheadings within the 'Managing entity' section appropriate?

☐ Yes

☐ No

- b. Are there other changes you think are necessary to the obligations of the managing entity?

☐ Yes

☐ No

Please provide any comments below.

Practitioner obligations

5. a. Are the subheadings within the 'Practitioner' section appropriate?
- ☐ Yes
- ☐ No
- b. Are there other changes you think are necessary to the obligations of the practitioner?
- ☐ Yes
- ☐ No

Please provide any comments below.

Other parties

6. a. Are there other parties who should have defined responsibilities?
- ☐ Yes
- ☐ No
- b. Are there other changes you think are necessary to the obligations of other parties?
- ☐ Yes
- ☐ No

Please provide any comments below.

Additional comments

7. a. Was the information in this code appropriately presented?
- ☐ Yes
- ☐ No
- b. Was the information in this code easy to find?
- ☐ Yes
- ☐ No
- c. Are there any changes you would like to suggest?
- ☐ Yes
- ☐ No
- d. Are there circumstances that are not included in this code but should be? If yes, please provide more details in the comments box below.
- ☐ Yes
- ☐ No
- e. Is the information easily understood?
- ☐ Yes
- ☐ No

f. Is there any other information or subject that should be included in this code?

☐ Yes

☐ No

Please provide any comments related to your answers to 7(a)–(f) below.

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