MINISTRY OF HEALTH
MANATŪ HAUORA

New Zealand Government

REVOKED Code of Practice for Diagnostic and Interventional Radiology

ORS C1

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Introduction

Purpose and commencement

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). It provides operational details necessary to comply with the fundamental requirements in sections 9 to 12 of the Act. Appendix 1 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 9 November 2018.

Scope

This code applies to all activities associated with:

- radiological equipment used for diagnostic radiology and image-guided interventional procedures
- radiological equipment used for diagnostic investigations of volunteers participating in programmes of medical research
- cone beam computed tomography equipment used for dental purposes.

Bone densitometry is included within the scope, but computed tomography equipment used solely for radiotherapy treatment planning or verification is excluded.

Activities can include manufacturing, possessing, controlling, managing, using, transporting, storing, importing, exporting, selling, supplying and disposing of equipment.

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.

Contact

The Director's contact details are:

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Roles and responsibilities

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

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

Ethics committee – the committee that approves programmes of medical research including the justification of medical exposure of volunteers.

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

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

Medical physicist – an individual with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practise independently in the diagnostic and interventional radiology specialty of medical physics and who provides specialist expertise for radiation protection of the patient.

Medical radiation technologist – a health practitioner with specialist education and training in medical radiation technology who is competent to perform radiological procedures on delegation from a radiation practitioner.

Operator – a medical radiation technologist or another person who is competent to perform radiological procedures on delegation from the radiation practitioner.

Qualified expert – an individual who is recognised as having expertise in a relevant field of specialisation such as medical physics or radiation safety.

Radiation safety officer – a person who is competent in radiation protection and safety, who is designated by the managing entity to oversee the application of regulatory requirements for occupational and public radiation protection and safety.

Radiation practitioner – a health practitioner with specialist education and training in the medical uses of radiation, who is competent to perform independently and oversee radiological procedures. This could include, for example, a radiologist, cardiologist, surgeon, general practitioner, chiropractor or, for cone beam computed tomography equipment, a dental practitioner.

Referring practitioner – a health practitioner who is approved by the managing entity to refer individuals to a radiation practitioner for medical exposure. Often this is a general practitioner who refers patients to a radiology department or practice.

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

Standards dosimetry laboratory – a laboratory that is certified or accredited to develop, maintain or improve primary or secondary standards for radiation dosimetry.

Definitions

Defined terms are identified in **bold** and 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**.

Ambient dose equivalent – the dose equivalent that would be produced by the corresponding aligned and expanded field in the International Commission of Radiation Units and Measurements ICRU sphere at a depth *d* on the radius vector opposing the direction of the aligned field.

Ancillary equipment – equipment other than **radiological equipment** or **protective equipment** that has an impact on the performance of a **radiological procedure** such as automatic film processors, printers, image receptors, view boxes, digital image displays, test and measurement equipment used to verify or calibrate radiological equipment.

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

Constraint – a prospective and source related value of individual dose (dose constraint) or of individual risk (risk constraint) that is used in **planned exposure situations** as a parameter for the **optimisation** of **protection and safety** for the source, and that serves as a boundary in defining the range of options in **optimisation**. Constraints for **occupational exposure**, **public exposure** and **medical exposure** of **comforter/carers** are established or approved by the Director and, if established, are published in a compliance guide issued under this code. Constraints for **medical exposure** of **volunteers** are established or approved by the ethics committee on a case by case basis as part of the proposal for medical research.

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

Diagnostic reference level – a level that is used to indicate whether, in routine conditions, the dose to the **patient** is unusually high or unusually low for that procedure. Diagnostic reference levels if any are established and published by the Director.

Dose limit – the value of **effective dose** or **equivalent dose** set out in Schedule 3 of the Act.

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

Emergency – any non-routine situation that necessitates prompt action, primarily to mitigate actual or perceived hazards or adverse consequences for human health and safety, quality of life, property or the environment. This includes **radiation emergencies** and conventional emergencies such as fires, release of hazardous chemicals, storms or earthquakes.

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

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

Facility – the location where **radiological equipment** 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 a health authority in conjunction with appropriate professional bodies.

In-room protective device – device or equipment to reduce exposure to radiation but not worn by a person, such as ceiling-suspended protective screens, protective lead curtains, mobile shields and disposable protective drapes.

Incident – any **accident** or other unintended event, including initiating events, accident precursors, near misses or other mishaps; or unauthorised acts, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of **protection and safety.**

Individual monitoring – **monitoring** using equipment worn by individuals.

Investigation level – value of a quantity such as effective dose, intake or contamination per unit area or volume at or above which an investigation would be conducted.

Justify – determine that the expected benefits to individuals and society from introducing or continuing a practice outweigh the harm, including the radiation detriment, resulting from the practice. In respect of individual **radiological procedures**, this involves the weighing of expected benefits against the radiation detriment that might be caused with account taken of the benefits and risks of available alternate techniques that do not involve **medical exposure**. 'Justifies', 'justified' and 'justification' have corresponding meanings.

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

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

Monitoring – the measurement of dose or dose rate to enable the assessment or control of exposure due to radiation, and the interpretation of the results.

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

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

Operational limits and conditions – limits and conditions that are established or approved by the Director and, if established, are published in compliance guides issued under this code.

Optimise – implement a level of **protection and safety** that results in the magnitude of individual doses, the number of individuals (**workers** and **members of the public**) subject to exposure and the likelihood of exposure being as low as reasonably achievable, economic and social factors being taken into account. For **medical exposures** of **patients** this requires the management of the radiation dose to the **patient** commensurate with the medical purpose. 'Optimises', 'optimised' and 'optimisation' have corresponding meanings.

Patient – a person who is subject to **medical exposure** for his or her own medical benefit.

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.

Planned exposure situation – situation of exposure that arises from the planned operation of **radiological equipment** or from a planned activity that results in an exposure due to **radiological equipment.**

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.

Primary shielding – 2 mm lead equivalence at 100 kVp.

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

Protection and safety – the protection of people against exposure to ionising radiation and the safety of **radiological equipment**, including the means for achieving this, and the means for preventing **accidents** and for mitigating the consequences of **accidents** if they do occur.

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

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

Radiological equipment – equipment and its associated software used to perform **radiological procedures** that either delivers an exposure of an individual or directly controls or influences the extent of such exposure.

Radiological procedure – a medical imaging procedure that is intended to result in a **medical exposure** delivered by **radiological equipment**. This includes procedures in diagnostic radiology, image-guided interventional procedures, other interventional procedure involving radiation or dental procedures involving cone beam computed tomography equipment.

Reportable incident – an **incident** resulting in (a) a **dose limit** being exceeded, (b) **radiological equipment** that is lost, missing or beyond regulatory control, or (c) a radiation dose to a **patient** exceeding two times the intended dose (for interventional radiology, radiographic and fluoroscopic procedures involving contrast agents and computed tomography examinations), twenty times the intended dose (for radiography of extremities, skull, dentition, shoulder, chest, elbow and knee), or ten times the intended dose (for mammography and all other radiographic examinations).

Safety assessment – assessment of all aspects of a practice that are relevant to **protection and safety** to determine the adequacy of provisions for **protection and safety**.

Secondary shielding – 1.5 mm lead equivalence at 120 kVp in areas where computed tomography equipment is performed, 18 mm gypsum plasterboard equivalence in all areas where mammography or dual-energy X-ray absorptiometry is performed and 1.0 mm lead equivalence for all other areas where **radiological procedures** are performed.

Supervised area – an area other than a **controlled area** for which occupational exposure conditions need to be kept under review, even though specific measures for **protection and safety** 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 other than a **comforter/carer** who may be subjected to **medical exposure** as part of a programme of medical research.

Unintended medical exposure – exposure of the wrong individual, tissue or organ; exposure that is substantially greater than intended; inadvertent exposure of the embryo or fetus; and failure of **radiological equipment**, failure of software or system failure, or error, mishap or other unusual occurrence with the potential for subjecting the **patient** to a **medical exposure** that is substantially different from what was intended.

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

Workplace monitoring – **monitoring** carried out in the working environment.

Managing entity

General

1. The managing entity must:
    a) take prime responsibility for protection and safety
    b) establish a management system to enhance protection and safety that includes:
        i) effectively integrating protection and safety into the overall management system of the organisation
        ii) making a commitment to protection and safety from the highest level of management at the facility, and by providing all required resources
        iii) promoting continuous improvement and a safety culture
        iv) appointing a radiation safety officer to oversee the application of regulatory requirements for occupational and public radiation protection and safety
        v) delegating the planning and delivery of medical exposures to a radiation practitioner
        vi) ensuring that requirements for medical imaging, calibration, dosimetry of patients, quality assurance and the commissioning and acceptance of radiological equipment are fulfilled by, or under the oversight of, or with the documented advice of a medical physicist whose degree of involvement is determined by the complexity of the radiological procedures and the associated radiation risks
        vii) consulting with and engaging the services of other experts and interested parties as necessary
    c) for all delegations under sub-clauses 1(b)(iv) and 1(b)(v):
        i) ensure delegates are notified of their duties in relation to protection and safety and assume responsibility for performing them
        ii) fully document the delegations
    d) ensure that:
        i) all activities associated with radiological equipment are justified and optimised for protection and safety
        ii) dose limits for occupational and public exposure are not exceeded as a result of those activities.

2. The managing entity must ensure that no practice or procedure is undertaken unless:

   a) it has been justified generically by a health authority

   b) it has been:

      i) justified specifically by a health authority in conjunction with appropriate professional bodies for procedures that are part of a health screening programme

      ii) approved by an ethics committee for medical exposures incurred as part of a programme of medical research

      iii) justified individually for the patient by a radiation practitioner in any other case.

Safety assessment

3. The managing entity must conduct, document and keep up to date a safety assessment to:

   a) identify the ways in which occupational, public and medical exposures could be incurred

   b) determine the expected likelihood and magnitudes of exposures in normal operation and, to the extent reasonable and practicable, assess potential exposures including the possibility of unintended or accidental medical exposures

   c) assess the adequacy of provisions for protection and safety in respect of siting, design and operation.

Facilities

4. The managing entity must:

   a) provide facilities that are located, designed, manufactured, constructed, assembled, commissioned, operated, maintained and decommissioned adopting good engineering practice, minimising the need to rely on administrative controls and personal protective equipment for protection and safety

   b) shield all areas in which radiological procedures are performed, so that protection and safety is optimised by satisfying either:

      i) the requirements for primary shielding in areas designed to be exposed to the primary radiation beam during normal use and the requirements for secondary shielding for all other doors, walls, ceilings, windows, floors and other material constructions, or

      ii) alternate requirements if they are approved and documented by a medical physicist or another qualified expert

c) in consultation with a medical physicist or another qualified expert, verify and document the adequacy of the shielding required in clause 4(b) whenever circumstances change that could increase the risks

d) designate and delineate appropriate areas as controlled areas or supervised areas and periodically review those designations and delineations

e) prominently display signs:

i) specifying the actual or potential presence of ionising radiation using the symbol recommended by the International Organization for Standardization at access points to controlled areas and supervised areas and at appropriate locations within controlled areas

ii) controlling access by members of the public to controlled areas and supervised areas

iii) in areas that patients may be (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.

Equipment

5. The managing entity must:

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

i) the equipment is appropriate for the radiological procedures to be performed

ii) the equipment remains capable of fulfilling its design requirements for protection and safety throughout its lifetime

b) ensure that:

i) the primary requirements in column 2 of Appendix 2 are satisfied

ii) all reasonable steps are taken to satisfy the secondary requirements in column 3 of Appendix 2

iii) the protective value of protective equipment is clearly displayed on the equipment

c) cooperate with manufacturer/suppliers to:

i) ensure that the requirements in sub-clauses 5(a) and 5(b) are met

ii) ensure that radiological equipment is used only if it conforms to the applicable standards of the International Electrotechnical Commission and the International Organization for Standardization

iii) share information on use and operating experience that may be important for protection and safety

iv) applying the principles of optimisation in the design, planning and operation and decommissioning of a source

d) safely manage all radiological equipment, whether or not the equipment is in use

e) maintain an accurate inventory of all radiological equipment, including its location and description

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

g) maintain control of radiological equipment to prevent loss or damage and to prevent any person from carrying out unauthorised activities including by:

   i) periodically checking that equipment is under control and in the locations recorded in the inventory maintained under clause 5(d)

   ii) releasing the equipment only to people who are authorised to assume management and control under the Act

h) take immediate steps to regain control of any radiological equipment that is abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation.

6. The managing entity must ensure that:

   a) all sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted protocols

   b) calibrations are carried out at the time of commissioning radiological equipment prior to clinical use, after any maintenance procedure that could affect the dosimetry, and at intervals approved by the Director and published in compliance guides issued under this code

   c) all dosimeters used for the calibration of sources are calibrated at least every two years and that such calibrations are traceable to a standards dosimetry laboratory.

7. The managing entity must provide, maintain, test, calibrate and service equipment, other than radiological equipment, sufficient to ensure compliance with this code including equipment for personal protection, monitoring and measurement for compliance verification, accident verification, emergency response, protection and safety of members of the public.

Training and authorisation

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

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

   b) satisfy the training requirements in Appendix 3

   c) are named in a current list with details of their specialisation, qualification, education and training

   d) are notified of their duties in relation to protection and safety

   e) are authorised to assume their roles and responsibilities.

Policies, procedures and local rules

9. The managing entity must establish, implement and maintain policies and procedures to meet the requirements of this code including, without limitation, policies and procedures to:

   a) control access to areas where people can be exposed to radiation

   b) use constraints to optimise protection and safety

   c) prevent accidents and mitigate the consequences of any that occur

   d) report on and learn from accidents and other incidents

   e) comply with operational limits and conditions relating to public exposure

   f) ascertain the pregnancy status of female patients of reproductive capacity before performing any radiological procedure that could result in a significant dose to the embryo or fetus

   g) provide protection and safety by applying preventive measures in the following hierarchy:

      i) engineered controls

      ii) administrative controls

      iii) personal protective equipment

   h) set investigation levels and establish procedures to follow if such a level is exceeded

   i) implement procedures for verification of compliance with this code

   j) periodically review the overall effectiveness of measures for protection and safety.

10. The managing entity must maintain, publish and enforce any written local rules that are necessary for protection and safety.

Patient dosimetry

11. The managing entity must:

    a) perform and document dosimetry of patients to determine typical doses to patients for:

        i) common diagnostic radiological procedures

        ii) image-guided interventional procedures where practicable

    b) in order to satisfy the requirements in clause 11(a):

        i) follow internationally accepted protocols, and

        ii) use only dosimeters with current calibrations traceable to a standards dosimetry laboratory.

Monitoring and measurement

12. The managing entity must establish and maintain:

    a) a programme of continuous individual monitoring whenever appropriate, adequate and feasible, which is sufficient to assess occupational exposures for workers who usually work in a controlled area or who may receive a dose exceeding 10 percent of the dose limits

    b) a programme of workplace monitoring that is sufficient to:

        i) evaluate radiation conditions in all workplaces

        ii) assess exposures in controlled areas and supervised areas that are not assessed under clause 12(a)

        iii) review the classification of controlled areas and supervised areas

    c) a monitoring programme for all workers who could be subject to exposure due to contamination, which is sufficient to:

        i) demonstrate the effectiveness of the measures for protection and safety

        ii) assess intakes of radionuclides and committed effective doses

    d) programmes of source monitoring or environmental monitoring that are sufficient to assess public exposure arising from radiological equipment under the responsibility of the managing entity

    e) a capability that is sufficient to monitor unexpected increases in radiation levels due to an incident attributed to a source or facility for which the managing entity is responsible

    f) other monitoring or measurement programmes as necessary to verify compliance with the requirements in this code.

13. In order to satisfy the monitoring and measurement requirements in clause 12 the managing entity must:

    a) use appropriate monitoring equipment

    b) for continuous individual monitoring under clause 12(a), use an external service or internal capability only if that service or capability:

        i) is approved by the Director

        ii) returns results to the managing entity within 20 working days of receiving all necessary raw information.

14. The managing entity must:

    a) obtain previous dose records

    b) maintain records of all monitoring and verification of compliance including:

        i) records of occupational exposure during and after the worker's working life, at least until the worker attains or would have attained the age of 75 years, and for not less than 30 years after ceasing work where the worker was subject to occupational exposure

        ii) records and estimated doses to members of the public

        iii) records of the tests and calibrations carried out

    c) provide records of occupational exposure to:

        i) individual workers in respect of their own exposure

        ii) subsequent employers of workers, subject to satisfying confidentiality criteria

        iii) the Director on request or, if the managing entity is no longer able to maintain records as required under clause 14(b)

    d) provide records of source monitoring and environmental monitoring to assess public exposure to:

        i) members of the public on request

        ii) the Director on request

        iii) the Director immediately, if any levels exceed operational limits and conditions relating to public exposure or there is a significant increase in dose rate that could be attributed to the authorised practice.

Incidents, accidents and emergencies

15. The managing entity must:

    a) take all practicable steps to minimise the likelihood of accidents including, a multilevel system of sequential, independent provisions for protection and safety, commensurate with the likelihood and magnitude of potential exposures

    b) take timely action to mitigate the consequences of any accident that does occur and restore radiological equipment to a safe condition

    c) promptly investigate any incident, 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

    d) implement all corrective actions identified in clause 15(c)(ii)

    e) keep a written record of the incident, including the:

        i) cause or suspected cause

        ii) calculations made under clause 15(c)(i)

        iii) corrective actions identified under clause 15(c)(ii)

        iv) details of the implementation of corrective actions under clause 15(d)

    f) ensure that the referring practitioner and the patient (or the patient's legal representative) are informed of any unintended medical exposure

    g) promptly notify any reportable incident to the Director.

16. If the safety assessment required by clause 3 indicates that there is a reasonable likelihood of an emergency affecting either workers or members of the public, the managing entity must prepare an emergency plan for the protection of people and the environment including:

    a) arrangements for promptly identifying an emergency

    b) determining the correct level of emergency response

    c) provision for individual monitoring, area monitoring and arrangements for medical treatment

    d) arrangements for assessing and mitigating any consequences of an emergency.

Records

17. The managing entity must maintain adequate records, and make them available as necessary, including:

    a) the delegation of responsibilities of the managing entity and the radiation practitioner

    b) the names of all people with responsibility for protection and safety, including details of their specialisation, qualifications, education and training

    c) results of calibrations and periodic checks of physical and clinical parameters selected during treatment of patients

    d) dosimetry of patients

    e) local assessments and reviews relating to diagnostic reference levels

    f) the quality assurance programme

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

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

    i) exposure records for volunteers subject to medical exposure as part of a programme of medical research

    j) reports on investigations of unintended and accidental medical exposures

    k) exemptions from this code granted under section 86(3) of the Act.

Quality assurance

18. The managing entity must establish a comprehensive quality assurance programme for medical exposures, including:

    a) measuring the physical parameters of radiological equipment, including calibrating output in terms of appropriate quantities using internationally accepted protocols, made:

        i) at the time it accepts and commissions the equipment, before practitioners use it clinically on patients

        ii) periodically after that first check

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

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

b) performing quality control tests on ancillary equipment and personal protective equipment

c) adopting internationally accepted tolerance limits for the physical parameters mentioned in sub-clauses 18(a) and 18(b), and implementing corrective actions if measured values fall outside those tolerance limits

d) verifying the appropriateness of physical and clinical factors used in radiological procedures

e) maintaining records of relevant procedures and results

f) periodically checking the calibration and conditions of operation of dosimetry equipment and monitoring equipment.

19. The managing entity must ensure that regular internal or external independent audits are made of the quality assurance programme for medical exposures.

20. The managing entity must ensure that:

a) radiation reviews are performed periodically by radiation practitioners in cooperation with medical radiation technologists and medical physicists, to investigate and critically review the current practical application of the radiation protection principles of justification and optimisation for radiological procedures

b) local assessments are made at regular intervals for those radiological procedures for which diagnostic reference levels have been established

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

i) exceed the relevant diagnostic reference level

ii) fall substantially below the diagnostic reference level, and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.

Radiation practitioner

General

21. The radiation practitioner:

    a) is responsible for overall protection and safety in the planning and delivery of the medical exposure

    b) may, in order to satisfy the responsibility in clause 21(a), delegate functions to a medical radiation technologist, medical physicist or otherwise[1]

    c) must inform in advance all individuals who may be subject to medical exposure (or their legal authorised representatives) of the expected benefits, risks and limitations of the procedure, as appropriate.

Justification

22. The radiation practitioner must:

    a) obtain information on the clinical context for any procedure unless it is part of a health screening programme

    b) for any procedure that is not part of a health screening programme, justify the medical exposure in consultation as appropriate with the referring practitioner taking into account, in particular for paediatric or possibly pregnant individuals:

        i) the appropriateness of the request

        ii) the urgency of the procedure

        iii) the characteristics of the medical exposure

        iv) the characteristics of the individual patient

        v) relevant information from the patient's previous radiological procedures

        vi) relevant national or international referral guidelines

    c) for any procedure to detect disease in an asymptomatic person that is not part of a health screening programme, justify the procedure specifically for the individual in accordance with any guidelines of relevant professional bodies or the health authority.

[1] The managing entity has obligations under clause 1 to ensure that these delegations are notified and documented and that delegates assume responsibility for the delegated functions.

Optimisation

23. The radiation practitioner must, in consultation as appropriate with medical physicists and operators, ensure that protection and safety is optimised for each medical exposure:

    a) for diagnostic radiological procedures and image-guided interventional procedures by:

        i) using appropriate radiological equipment

        ii) adopting techniques and parameters to deliver a medical exposure that is the minimum necessary to fulfil the clinical purpose of the radiological procedure, taking into account relevant norms of acceptable image quality and of relevant diagnostic reference levels

    b) by using constraints in any procedure in which an individual:

        i) acts as a comforter/carer

        ii) is subject to exposure as part of a programme of research.

24. The radiation practitioner must ensure that particular aspects of medical exposures are considered in the optimisation process for:

    a) paediatric patients

    b) individuals subject to medical exposure as part of a health screening programme

    c) volunteers subject to medical exposure as part of a programme of medical research

    d) procedures involving computed tomography

    e) exposure of the embryo or fetus, in particular, during radiological procedures in which the abdomen or pelvis of a pregnant patient is exposed to the useful radiation beam or could otherwise receive a significant dose.

Other parties

Referring practitioner

25. The referring practitioner must:

    a) provide sufficient information on the clinical context of the procedure in the referral

    b) cooperate with the radiation practitioner as part of the justification of the procedure in accordance with clause 22.

Manufacturer/supplier

26. 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

    b) test radiological equipment to demonstrate compliance with relevant specifications

    c) provide information on how to properly install and use radiological equipment and on associated radiation risks, including performance specifications, instructions for operating and maintenance, and instructions for protection and safety

    d) optimise the protection provided by shielding and other protective devices

    e) supply all radiological equipment with all appropriate radiation protection tools as a default, rather than as optional extras.

27. The manufacturer/supplier must:

    a) make suitable arrangements with managing entities to share information on use and operating experience that may be important for protection and safety

    b) cooperate with the managing entity as required by clause 5(c).

Servicing engineer

28. The servicing engineer must:

    a) install and service radiological equipment competently, so that it complies with the requirements in clause 5

    b) cooperate with the managing entity to ensure that radiological equipment cannot be used clinically while it is being installed or serviced

    c) after installing or servicing the equipment:

        i) collaborate with the managing entity and medical physicists to ensure necessary quality control tests are completed successfully

        ii) confirm that all radiation protection and safety features are in place and operating correctly before equipment is returned to clinical use

        iii) 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.

Appendix 1: 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 this code
9(1)	1, 8–9, 17, 21–22, 25
9(2)	1–4, 8–14, 17, 19–21, 23–24
9(3)	1, 8–9, 12, 17
10	5–7, 15–18, 26–28
11	5, 17
12	5, 17

Appendix 2: Equipment requirements

General radiography

Parameter	Requirement	
	Primary	Secondary
X-ray machine		
Minimum aluminium equivalent filtration in the incident primary X-ray beam	2.5 mm	3.5 mm
Maximum leakage radiation 1 metre from the focus, averaged over an area of 100 cm^2 at every rating specified by the manufacturer for that tube and housing	1 mGy/hr	100 µGy/hr
Focus-image receptor and focus-skin distances (FID, FSD)		
Means to indicate FID	Yes	
Maximum inaccuracy of indicated FID	10 mm	
Minimum standard FID: • chest radiography • other	 1.5 m 1 m	
Minimum focus to skin distance (FSD)	400 mm	500 mm
Collimation		
Capability to collimate the primary beam to the region of clinical interest	Yes	
X-ray detector completely intercepts the primary X-ray beam	Yes	
Maximum misalignment of each edge of the visually defined light field with the edge of the X-ray field at 1 metre focus to image receptor distance (FID)	15 mm	10 mm
Maximum misalignment of the centre and indicated centre of the light beam at 1 metre FID	15 mm	10 mm
Minimum illuminance of the light beam	100 lux	150 lux
Light field clearly visible in ambient illumination and the outer edges of the light field clearly shown and sharply defined	Yes	
Maximum inaccuracy of scale stating X-ray beam dimensions (where provided) at each FID	1.5%	1%
Automatic collimation allows for a field smaller than the whole image receptor	Yes	

Parameter	Requirement	
	Primary	Secondary
Exposure device		
Minimum exposure time:		
• single phase generator	20 ms	
• other	10 ms	
Maximum inaccuracy of actual time to set time	10%	5%
Maximum coefficient of variation of X-ray output from a series of at least five consecutive exposures	0.05	
Automatic exposure control (AEC) device		
Maximum AEC device response time with the appropriate chamber selected for the X-ray projection	10 ms	
Means to limit over-exposures to a maximum of 6 s or 600 mAs, whichever results in the smaller exposure	Yes	
(DR and CR) maximum variation of recorded receptor doses from the mean when patient thickness, kV and mA are varied over their normal clinical ranges for which the X-ray machine is used[2]	20%	10%
Maximum variation of receptor doses between left and right sensors	10%	5%
Maximum standard image receptor Air KERMA setting	5 µGy	3 µGy
X-ray tube output linearity		
Maximum deviation of output for any two mA, mAs or exposure time settings that do not differ by more than a factor of 4[3]	0.1	
X-ray tube voltage		
Maximum inaccuracy of measured tube voltage to the indicated value over the range of kV, time, current and mAs for which the machine is normally used	5%	
Grids		
Significant grid artefacts visible on the image	No	
Lamellae visible on moving grid image	No	
Dosimetry		
DAP meter provided		Yes
Maximum inaccuracy of displayed value to measured value of DAP meter (if provided)	20%	

[2] Recorded dose measured as raw mean pixel value, signal to noise ratio in the central area of the image or exposure index (all linearised to dose).

[3] Using the formula $|X_1 - X_2|/(X_1 + X_2)$ where X_1 and X_2 are the X-ray outputs at settings 1 and 2 respectively.

Digital radiography

Parameter	Requirement	
	Primary	Secondary
Exposure index (EI) display with each image	Yes	
EI conforms with IEC 62494-1		Yes
Maximum inaccuracy of EI calibration to measured dose	20%	10%
Minimum EI to detector dose linear correlation (r) across the clinical range to at least 20 µGy	0.95	0.99
Patient dose record accessible in DICOM image header	Yes	
Patient dose record accessible in PACS		Yes
Detector has high detective quantum efficiency for standard imaging setting and less than 5 µGy detector dose unless manufacturer justifies otherwise	Yes	
Images free of:		
• artefacts from ghosting of previous images	Yes	
• loss of visually detectable pixels	Yes	
• any artefact that could be reasonably misinterpreted as a clinical feature in a diagnostic image	Yes	
Images optimally recorded, processed, transferred and displayed to minimise the loss of clinically observable content	Yes	
Capability to display and provide appropriate measurement tools for corrected raw images (linear signal transfer properties) for quality control	Yes	
Capability to export corrected raw images (linear signal transfer properties) to an external device for quality control		Yes
Accessibility of bad pixel map of image	in service mode	to the user
Maximum deviation of dark noise from the manufacturer's specification	20%	10%
Maximum deviation from mean value in STP-corrected region of interest (ROI)	20%	10%
Maximum inaccuracy of distance measurements at a defined plane	4%	2%
Maximum AEC target dose for standard image resolution using manufacturer's phantom and setup conditions	5 µGy	3 µGy
Minimum limiting high contrast spatial resolution:		
• detector dose below 10 µGy	2.8 lp/mm	
• detector dose below 5 µGy	2.4 lp/mm	
DAP meter available		Yes
Maximum inaccuracy of displayed value to measured value of DAP meter (if provided)	20%	

Computed radiography

Parameter	Requirement	
	Primary	Secondary
X-ray dose to the image receptor indicated after each exposure	Yes	
EI conforms to IEC 62494-1		Yes
Maximum EI inaccuracy with respect to the image receptor air KERMA under exposure conditions in IEC 62494 or as specified by the manufacturer	20%	10%
Permanent record of EI maintained in the image file header in DICOM compliant format		Yes
Dark noise as specified by the manufacturer	Yes	
Images free of:		
• artefacts from ghosting of previous images	Yes	
• loss of visually detectable pixels	Yes	
• any artefact that could be reasonably misinterpreted as a clinical feature in a diagnostic image	Yes	
Maximum deviation from mean value in STP-corrected ROI	20%	10%
Maximum 'ghost image' factor	1%	
Minimum EI to detector dose linear correlation coefficient (r) across the clinical range up to at least 20 µGy	0.95	0.99
Maximum inaccuracy of distance measurements at a defined plane	4%	2%
Clinically significant blurring visible	No	
Minimum limiting high contrast spatial resolution:		
• detector dose below 10 µGy	2.8 lp/mm	
• detector dose below 5 µGy	2.4 lp/mm	

Computed tomography

Parameter	Requirement	
	Primary	Secondary
Maximum deviation of CTDI[4] from manufacturer's specification	20%	10%
Maximum deviation of the measured dose from the indicated dose parameters (DLP, $CTDI_{vol}$) for standard head and body exams	20%	10%
Maximum inaccuracy of geometric efficiency from manufacturer's specification	10%	5%
Warning at operator's console if geometric efficiency is less than 70%	Yes	
Maximum inaccuracy of CT number measured in a ROI in a water phantom	0 +/- 4	
Maximum deviation of image noise from manufacturer's specification	10%	5%
Maximum deviation of CT number from central value for water phantom up to 20 cm diameter	6 HU	4 HU
Maximum spatial resolution deviation from specification measured using the manufacturer's protocol	10%	
Maximum distance from the centre of the z-axis dose profile to the transverse laser	2 mm	
Maximum scan projection radiography (scout mode) deviation from specified distance	2 mm	
Maximum couch top index deviation from specified distance	2 mm	

[4] Measured free-in-air at the isocentre of the CT scanner.

Fluoroscopy and angiography

Parameter	Requirement	
	Primary	Secondary
Maximum fluoroscopic entrance surface dose rate at 30 cm from the detector cover:		
• normal mode	50 mGy/min	
• boost mode	100 mGy/min	
Maximum fluoroscopic image receptor entrance dose rate with 2.5 mm Cu in the X-ray beam at approximately 90 kV:		
• field size < 14 cm	120 µGy/min	
• 14 cm ≤ field size < 23 cm	90 µGy/min	
• field size ≥ 23 cm	60 µGy/min	
Maximum detector entrance dose (DSA):		
• ≤ 10 frames/s	10 µGy/frame	
• > 10 frames/s	1 µGy/frame	
Maximum detector entrance dose (cinefluorography):		
• field size < 17 cm	0.4 µGy/frame	0.2 µGy/frame
• field size ≥ 17 cm	0.2 µGy/frame	0.1 µGy/frame
Maximum patient entrance dose – acquisition:		
• DSA	2 mGy/frame	
• cardiac	0.2 mGy/frame	
Maximum inaccuracy of KAP or indicated patient entrance dose to measured dose	35%	20%
X-ray beam exceeds the actual field of view as seen on the display monitor	No	
Minimum fluoroscopy image resolution:		
• field size < 20 cm	1.2 lp/mm	
• 20 cm ≤ field size < 30 cm	1.0 lp/mm	
• field size ≥ 30 cm	0.8 lp/mm	
Minimum fluoroscopy image contrast with 1 mm Cu in the X-ray beam at 70 kV:		
• 10 mm diameter detail	5%	
• 1 mm diameter detail	15%	
Minimum FSD	350 mm	450 mm

Dental cone beam computed tomography

Parameter	Requirement	
	Primary	Secondary
Integrated dose indicator calibration (KAP meter accuracy) meets manufacturer's specification	Yes	
Dose meets manufacturer's specification	Yes	

Mammography

Parameter	Requirement	
	Primary	Secondary
Accessibility of dose information in DICOM record:		
• for CR systems		Yes
• for DR systems	Yes	
X-ray field extends beyond the image receptor at the chest wall edge, but does not project beyond the breast support by more than 2 mm	Yes	
Light field and the radiation field coincides within 1% of the FID at all edges		Yes
Maximum missing tissue at the chest wall edge:		
• in contact mode	5 mm	
• in magnification mode	7 mm	
Meet RANZCR recommendations for the specified SDNR	Yes	
Minimum SDNR ratios:		
• SDNR (2 cm PMMA)/SDNR (4 cm PMMA)	1.1	
• SDNR (6 cm PMMA)/SDNR (4 cm PMMA)	0.9	
Security cut-out mechanisms that terminate the exposure within 50 ms or within 5 mAs, or with an entrance absorbed dose for the ACR accreditation phantom of less than 0.44 mGy. Or, in absence of a security cut-out, a back-up timer that terminates exposure at <600 mAs	Yes	
Minimum ACR mammography accreditation phantom image quality visualisations:		
• 5 fibres, 3.5 speck groups, and 4 masses visualised	Yes	
• 5 fibres, 4 speck groups, and 4 masses visualised		Yes
Minimum ACR digital mammography phantom image quality visualisations: 4 fibres, 3 speck groups, and 3 masses visualised	Yes	

Parameter	Requirement	
	Primary	Secondary
Maximum inaccuracy of measured tube voltage to the indicated value	1 kV	
Maximum kV coefficient of variation from a series of at least 3 manually selected consecutive exposures	0.02	
The HVL within the following ranges: kV/100 + 0.03 ≤ HVL ≤ kV/100 + C Where: C = 0.12 mm Al for Mo/Mo = 0.19 mm Al for Mo/Rh = 0.22 mm Al for Rh/Rh = 0.23 mm Al for Rh/Ag = 0.30 mm Al for W/Rh	Yes	
Maximum exposure time (excluding scanning slot systems) for:		
• large focus, 6 cm PMMA	2.0 s	
• fine focus, 6 cm PMMA	3.5 s	
Maximum mean glandular dose for:		
• ACR mammography accreditation phantom	1.5 mGy	
• 2 cm PMMA	1.0 mGy	0.6 mGy
• 4 cm PMMA		1.5 mGy
• 6 cm PMMA	4.5 mGy	3.6 mGy
• 7 cm PMMA		5.1 mGy
Minimum coefficient of determination (R^2):		
• for DR systems MPV vs ESAK and SD^2 vs MPV	0.99	
• for CR systems EI linearised as specified by the plate manufacturer vs ESAK	0.99	
Minimum system resolution for large focus at 4 cm above the breast support	5 lp/mm	
Maximum inaccuracy of distance callipers ruler measurements in image to true dimension in plane specified by manufacturer	2%	
Images artefacts:		
• for DR systems: artefacts and dead pixels not apparent or not significant	Yes	
• for CR systems: jitter artefacts not apparent or not significant	Yes	
Maximum detector inhomogeneity:		
• in both contact and magnification modes, the maximum deviation of mean pixel value of any peripheral ROI less than 10% of mean pixel value for central ROI	Yes	
• the change of SNR with time less than 10%	Yes	
Maximum 'ghost image' factor	2%	
No ghost image if a lead block in the second image	Yes	

Parameter	Requirement	
	Primary	Secondary
CR uniformity of cassette/ image plate response:		
• maximum mAs and Air Kerma variation from the mean for all plates of one size.	5%	
• maximum mAs variation from the mean for plates of different sizes	20%	
Minimum resolution of reporting monitor	4.2 MP	
Minimum luminance of reporting monitor	450 cd/m^2	
Maximum ambient lighting illuminance	20 lux	
Minimum reporting monitor luminance ratio		350
Maximum monitor DICOM GSDF deviation	10%	
For TG18QC monitor test pattern:		
• absence of smearing artefact	Yes	
• ramps without contours	Yes	
• lines straight	Yes	
• boxes square	Yes	
• active display centred	Yes	
• borders complete	Yes	
• free from artefact	Yes	
• number of letters visible in the phrase 'QUALITY CONTROL' for the dark, mid-grey and light renditions >11	Yes	
For printer (hardcopy only):		
• maximum B+F deviation from baseline	0.03 OD	
• maximum B+F	0.25 OD	
• maximum Dmax deviation from baseline	0.10 OD	
• minimum Dmax	3.4 OD	
For TG18Qc image:		
• the number of letters visible in the phrase 'QUALITY CONTROL' for the dark, mid-gray and light renditions	11	
Maximum compression force allowable for:		
• power compression devices	200 N	
• other compression devices	300 N	
Power compression device capable of at least 150N	Yes	

Monitors and hardcopy devices

Parameter	Requirement	
	Primary	Secondary
Minimum luminance of reporting monitor	250 cd/m^2	350 cd/m^2
Minimum reporting monitor luminance ratio	250	350
Maximum monitor DICOM GSDF deviation	10%	5%
Minimum reporting monitor number of pixels: • CR/DR • CT/US	 2 MPx 3 MPx	
Minimum acquisition/QA/primary review monitors luminance	150 cd/m^2	200 cd/m^2
Minimum acquisition/QA/primary review monitors luminance ratio	100	150
Maximum acquisition/QA/primary review monitors DICOM GSDF deviation	20%	10%
For TG18QC monitor test pattern at least 10 low contrast letters in the phrase 'QUALITY CONTROL' visible in the dark, mid-grey and light rectangles, and SYMPTE 5% and 95% areas clearly visible	Yes	

Appendix 3: Training requirements

	Radiation practitioner			Operator		Other			
	DRS	IRC	OHP	MRT	OA	REF	MP	SIE	RSO
Atomic structure, x-ray production and interaction of radiation	m	l	l	m	l	x	h	m	l
Nuclear structure and radioactivity	m	l	x	m	x	x	h	m	l
Radiological quantities and units	m	m	m	m	l	l	h	m	l
Physical characteristic of x-ray machines	m	m	m	h	l	x	h	h	m
Fundamentals of radiation detection	m	l	l	h	x	x	h	h	m
Principle and process of justification	h	h	h	h	h	m	h	x	m
Fundamentals of radiobiology, biological effects of radiation	h	m	m	m	l	l	h	l	l
Risks of cancer and hereditary disease	h	m	m	h	l	m	h	l	l
Risks of deterministic effects	h	h	m	h	l	l	h	x	l
General principles of radiation protection including optimisation	h	h	m	h	m	l	h	m	h
Operational radiation protection	h	h	m	h	m	l	h	m	h
Particular patient radiation protection aspects	h	h	h	h	m	l	h	m	l
Particular staff radiation protection aspects	h	h	h	h	m	l	h	m	h
Typical doses from diagnostic c procedures	h	m	m	h	m	m	h	l	m
Risks from fetal exposure	h	l	m	h	l	l	h	l	l
Quality control and quality assurance	m	m	l	h	x	x	h	h	h
National regulations and international standards	m	m	m	m	l	l	h	h	h

Abbreviations used in this appendix

Parties

DRS – diagnostic radiology specialists
IRC – interventional radiologists and interventional cardiologists
OHP – other health practitioners taking responsibility for medical exposures
MRT – medical radiation technologists and others performing radiation procedures
OA – other health practitioners assisting in procedures
REF – health practitioners referring patients for medical exposure
MP – medical physicists
SIE – servicing and installation engineers
RSO – radiation safety officers

Level of knowledge

x – no requirement
l – low level of knowledge (general awareness and understanding of principles)
m – medium level of knowledge (basic understanding of the topic sufficient to influence practices undertaken)
h – high level of knowledge (detailed knowledge and understanding sufficient to be able to educate others)

Equivalences

The training requirements in this appendix are deemed to be satisfied as follows:

DRS	Health practitioners registered in the diagnostic and interventional radiology scope of practice by the Medical Council of New Zealand
IRC	Health practitioners registered in the diagnostic and interventional radiology scope of practice by the Medical Council of New Zealand
OHP	Health practitioners registered in the chiropractor scope of practice by the Chiropractic Board
OHP	Health practitioners registered in the general dental practice, special needs dental specialist, endodontic specialist, oral and maxillofacial surgery specialist, oral medicine specialist, oral pathology specialist, oral surgery specialist, orthodontic specialist, paediatric dentistry specialist, periodontic specialist, prosthodontic specialist, public health dentistry specialist or restorative dental specialist in respect of their use of cone beam computed tomography equipment
MRT	Health practitioners registered in the medical imaging technologist scope of practice by the Medical Radiation Technologists Board
MP	Persons previously recognised as qualified health physicists or who are registered in the radiology specialty of medical physics by the Australasian College of Physical Scientists and Engineers in Medicine