



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 (this code) is issued by the Director for Radiation Safety (the Director) under section 86 of the Radiation Safety Act 2016 (the Act). This code provides the technical requirements for a person who deals with a radiation source to comply with the fundamental requirements in sections 9 to 12 of the Act. The requirements in this code do not limit the general nature of the fundamental requirements.

This code comes into force on 1 December 2024.

This code replaces the Code of Practice for Diagnostic and Interventional Radiology which was issued on 9 November 2018 and revoked on 1 December 2024.

Scope

This code applies to activities and practices 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 radiology.

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

To 'deal with', in relation to a radiation source, means to manufacture, possess, control, manage, use, transport, store, export, import, sell, supply or dispose of a radiation source.

This code does not absolve the holder of a source licence from the obligation to comply with the fundamental requirements in sections 9 to 12 of the Act, which apply to every person who deals with a radiation source.

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

Interpretation

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

Absorbed dose — the fundamental dosimetric quantity D , defined as:

$$D = \frac{d\bar{\epsilon}}{dm}$$

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

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

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

Area monitoring — a form of **workplace monitoring** in which an area is monitored by taking measurements at one or more different points in that area.

Baselines — levels related to safety and performance of **radiological, protective** and **ancillary equipment** that represent expected performance and provide references for quality control. The levels are established at commissioning and during routine testing based on standards and guidance.

Carer and comforter — a person who voluntarily (rather than occupationally) helps 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 **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** in a specified radiological procedure is unusually high or unusually low for that procedure.

Director for Radiation Safety — a person appointed under section 76 of the Act to carry out the functions and duties and exercise the powers conferred or imposed by the Act, including the power to issue this code.

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 **absorbed dose** in a tissue or organ of the body.

Ethics committee — the committee that approves programmes of medical research, including the justification of medical exposure of **volunteers**.

Health practitioner — defined in regulation 3 of the Radiation Safety Regulations 2016 as having ‘the same meaning as in section 5(1) of the Health Practitioners Competence Assurance Act 2003’: that is, a person who is, or is deemed to be, registered with an authority as a practitioner of a particular health profession.

Health professional — a person who is, or is deemed to be, registered with an authority to perform services that fall within the description of a health profession.

Health screening programme — a programme for asymptomatic populations that is approved and justified by a health authority in conjunction with appropriate professional bodies.

Holder of a source licence — as in section 20 of the Act, the person responsible at all times for the management and control of each radiation source to which the licence applies.

In-room protective device — a 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 — the value of a quantity such as **effective dose** at or above which an investigation would be conducted.

Justify — to 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 alternative techniques that do not involve **medical exposure**. The words 'justifies', 'justified' and 'justification' have corresponding meanings.

Local diagnostic reference level — a diagnostic reference level for a health care facility based on a representative distribution of the appropriate diagnostic reference level quantity and related to the use of specified irradiating apparatus in that facility. A local diagnostic reference level can be compared to a **national diagnostic reference level**.

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

Medical physics expert — an individual with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practise independently in one or more of the subfields (specialties) of medical physics. For the purposes of this code, **medical physics expert** means a medical physics expert with a speciality in diagnostic radiology. A medical physics expert is a **qualified expert** and provides specialist expertise with respect to radiation protection of the patient. The competence of a medical physics expert is generally established through a recognised formal mechanism of registration. An example is the mechanism provided by the Australasian College of Physical Scientists and Engineers in Medicine.

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.

National diagnostic reference level — a **diagnostic reference level based** on data from a representative sample of health care facilities. **National diagnostic reference levels**, if established, will be published by the **Director for Radiation Safety**.

Occupational exposure — as set out in section 5 of the Act, exposure to ionising radiation experienced by **workers** during the course of their work.

Operational limits and conditions — limits and conditions that are established or approved by the **Director for Radiation Safety** and, if established, published in compliance guides issued under this code.

Optimise — to 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, after taking economic and social factors into account. For **medical exposures** of **patients** this requires the management of the radiation dose to the **patient** commensurate with the medical purpose. The words 'optimises', 'optimised' and 'optimisation' have corresponding meanings.

Overexposure of a person — when:

- a) a **dose limit** has been exceeded
- b) there is an unpredicted or unintended observable deterministic effect, such as skin erythema
- c) a person has received a dose and no dose was intended
- d) the total **effective dose** to a **patient** (this includes any intended and necessary repeat components) is:
 - i) 10 times or more greater than the intended dose if the intended dose was below 2.5 mSv; or
 - ii) 25 mSv or above if the intended dose was between 2.5 mSv and 10 mSv; or
 - iii) 2.5 times or more greater than the intended dose if the intended dose was more than 10 mSv.

Patient — a person who is subject to **medical exposure** for their own medical benefit.

Person — includes a corporation sole, a body corporate and an unincorporated body (as defined in section 13 of the Legislation Act 2019), unless the context otherwise requires.

Personal protective equipment — equipment a person wears to reduce exposure to radiation, such as protective aprons, organ shields, protective eyewear and protective gloves.

Place — as in section 5 of the Act, any dwelling, premises, vehicle, ship, craft or aircraft; a building or a structure; or part of a place.

Planned exposure situation — a 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.

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.

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

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

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

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

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, chiropractor or, for cone beam computed tomography equipment, a dental practitioner.

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

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 procedures involving radiation and dental procedures involving cone beam computed tomography equipment.

Referring practitioner — a **health professional** who is approved by the holder of a source licence 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.

Remedial level — a reference value that if exceeded indicates that the performance of **radiological, protective** or **ancillary equipment** is sufficiently close to satisfactory performance that it will not reduce clinical effectiveness, or **protection and safety**, but action taken as soon as practicable is required to restore the equipment to satisfactory performance. Where needed, a level is established relative to a **baseline**.

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

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.

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.

Suspension level — a reference value that if exceeded indicates that the performance of **radiological, protective or ancillary equipment** requires that the equipment be taken out of service until it is restored to satisfactory performance or until it is reviewed in a risk assessment. Following a risk assessment, the suspended equipment potentially could be used in defined and limited circumstances. Where needed a level is established relative to a **baseline**. Values are generally based on standards and guidance.

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

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; failure of **radiological equipment**, software or systems; or error, mishap or other unusual occurrence with the potential for subjecting a **patient** or **volunteer** to a **medical exposure** that is substantially different from what was intended.

Use of irradiating apparatus — has the meaning given in section 21(3) of the Act.

User of irradiating apparatus — a natural person authorised through the Act for the **use of irradiating apparatus** to perform radiological procedures. Authorisations through the Act include through the granting of a use licence to a person. Also, the Act provides specified situations where a use licence is not required. For instance, Schedule 3 of the Radiation Safety Regulations 2016 specifies that a use licence under the Act is not required for a health practitioner using irradiating apparatus for medical diagnostic purposes if that practitioner is, or is deemed to be, registered with the:

- Medical Council of New Zealand in the scope of practice of diagnostic and interventional radiology, and holds a current practicing certificate; or
- Medical Radiation Technologists Board in the scope of practice of medical imaging technologist and holds a current practicing certificate.

Volunteer — an individual other than a **carer and comforter** who may be subjected to **medical exposure** as part of a programme of medical or dental research.

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

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

The holder of a source licence

General

1. Section 20(1) of the Act provides that 'The holder of a source licence is responsible at all times for the management and control of each radiation source to which the licence applies.' The holder of a source licence must therefore take prime responsibility for protection and safety of each radiation source. The holder of a source licence must:
 - a) establish a management system to enhance protection and safety 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, and providing all required resources
 - iii) implementing procedures to promote continuous improvement and a safety culture
 - iv) documenting the appointment of a radiation safety officer to oversee the application of regulatory requirements for occupational and public radiation protection and safety
 - v) ensuring that a radiation practitioner has the duty to plan and justify medical exposures
 - 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 physics expert, 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 experts and interested parties as necessary
 - b) for all roles with duties in relation to protection and safety:
 - i) fully document the roles
 - ii) ensure people are notified of their duties and assume responsibility for performing them
 - c) ensure that all activities associated with radiological equipment are justified and optimised for protection and safety
 - d) apply the requirements set out in Schedule 3 of the Act to ensure that any radiation exposure that results from planned operations or activities does

not exceed applicable dose limits. This sub-clause relates to the requirements of section 9(3) of the Act, which states that 'a person who deals with a radiation source must ensure that any ionising radiation exposure that results from a planned operation or activity does not exceed the applicable dose limits set out in Schedule 3'.

- e) ensure that sufficient information on the clinical context of a procedure is provided by the referring practitioner to the radiation practitioner.
2. The holder of a source licence 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; or
 - ii) approved by an ethics committee for medical exposures incurred as part of a programme of medical research; or
 - iii) justified individually for the patient by a radiation practitioner in any other case.
3. The holder of a source licence must ensure that for occupational and public exposures, the radiological procedure is expected to give benefits to the individuals who undergo the procedure and to society that outweigh the harm resulting from the procedure. This must be done in consultation with the radiation practitioner.

Risk assessment

4. The holder of a source licence must conduct, document and keep up to date a risk 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 the siting, design and operation of irradiating apparatus.

Places

5. The holder of a source licence must:
- a) provide places 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, and that utilise appropriate radiation shielding where needed
- b) ensure that radiation shielding that forms part of the structure of places in which radiological procedures are performed, such as walls, doors and windows, is approved to be adequate for protection and safety by a medical physics expert or another qualified expert
 - c) in consultation with a medical physics expert or another qualified expert, verify and document the adequacy of the shielding required in clause 5(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

6. The holder of a source licence must:
- a) provide, maintain, test and service radiological equipment, protective equipment and ancillary equipment to ensure 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 operational lifetime
 - b) ensure that as soon as practicable corrective and preventive actions are taken if the values established in clause 20(a)(ix) are exceeded
 - c) ensure that the protective value of protective equipment is clearly displayed on the equipment
 - d) cooperate with manufacturer/suppliers to:
 - i) ensure that the requirements in clauses 6(a)(i) and (ii) 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) apply the principles of optimisation in the design, planning, operation and decommissioning of a source
 - e) safely manage all radiological equipment, whether or not the equipment is in use
 - f) maintain an accurate inventory of all radiological equipment, including its location and description
 - g) maintain a record of maintenance for each item, including a fault log and corrective and preventive actions taken (interim and subsequent repairs), the results of testing before an item is reintroduced to clinical use and any reports from servicing engineers
 - h) 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 6(f)
 - ii) releasing the equipment only to people who are authorised to assume management and control under the Act
 - i) take immediate steps to regain control of any radiological equipment that is abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation.
7. The holder of a source licence 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.
8. The holder of a source licence 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, and the protection and safety of members of the public.

Training and authorisation

9. The holder of a source licence must ensure that all people with roles 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) have training that:
 - i) is regularly updated
 - ii) satisfies the requirements in Appendix 1 if a person is appointed as a radiation safety officer, or
 - iii) takes account of the training in Appendix 1 and is established in consultation with a qualified expert
 - 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 perform their roles and responsibilities.

Policies, procedures and local rules

10. The holder of a source licence 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 patients of reproductive capacity before performing any radiological procedure that could result in a significant dose to an embryo or fetus
 - g) ensure correct patient identification, including the use of independent methods of confirming the identity of a patient
 - h) describe how dosimeters used for individual monitoring are managed, distributed and stored
 - i) ensure that any person who may potentially be occupationally exposed
 - i) as far as practicable, does not act as a carer and comforter
 - ii) is made aware of the means of informing the holder of a source licence of a pregnancy
 - j) ensure that an individual intending to act as a carer and comforter is correctly informed about radiation protection and the radiation risks

- involved, that the information provided is understood by the individual and that the individual agrees to act as a carer and comforter
- k) provide protection and safety by applying preventive measures in the following hierarchy:
 - i) engineered controls
 - ii) administrative controls
 - iii) personal protective equipment
 - l) set investigation levels and establish procedures to follow if such a level is exceeded
 - m) implement procedures for verification of compliance with this code
 - n) periodically review the overall effectiveness of measures for protection and safety.
11. The holder of a source licence must maintain, publish and enforce any written local rules that are necessary for protection and safety.

Patient dosimetry

12. The holder of a source licence must:
- a) in consultation with a medical physics expert 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) to satisfy the requirements in clause 12(a):
 - i) follow internationally accepted protocols
 - ii) use only dosimeters with current calibrations traceable to a standards dosimetry laboratory
 - c) establish for the purposes of optimisation local diagnostic reference levels in consultation with a medical physics expert.

Monitoring and measurement

13. The holder of a source licence must establish and maintain:
- a) for any worker who usually works in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure, such as exceeding an investigation level, individual monitoring where appropriate, adequate and feasible
 - b) programmes of workplace monitoring that are sufficient to:
 - i) evaluate radiation conditions in all workplaces

- ii) assess the occupational exposure of a worker in cases where individual monitoring of the worker is inappropriate, inadequate or not feasible
 - c) programmes of area monitoring that are sufficient to assess public exposure arising from radiological equipment under the responsibility of the holder of a source licence
 - d) a capability that is sufficient to monitor unexpected increases in radiation levels due to an incident attributed to a radiation source for which the holder of a source licence is responsible
 - e) other monitoring or measurement programmes as necessary to verify compliance with the requirements in this code.
14. To satisfy the monitoring and measurement requirements in clause 13, the holder of a source licence must:
- a) use appropriate equipment
 - b) where a worker receives a radiation dose exceeding three-tenths of a dose limit, ensure that individual monitoring of the worker is continuous and, to the extent practicable, is carried out using an external provider or internal capability that has a current accreditation to an appropriate standard, such as the International Organization for Standardization's General Requirements for the Competence of Testing and Calibration Laboratories (ISO/IEC 17025:2017).
15. The holder of a source licence must:
- a) to the extent practicable, obtain previous dose records of workers for the purposes of individual monitoring
 - b) maintain records of all monitoring and verification of compliance, including:
 - i) records of occupational exposure during and after each 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 the worker ceases 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) to the extent practicable, provide records of occupational exposure to:
 - i) individual workers in respect of their own exposure
 - ii) current and subsequent employers of workers, subject to satisfying regulatory requirements applying to confidentiality and data security and protection.

Incidents, accidents and emergencies

16. Section 20(3) of the Act sets out what the holder of a source licence must do if they believe an incident has occurred that has resulted in an overexposure of a person to radiation. Section 20(3)(a) requires that 'If the holder of a source licence believes that an incident has occurred that has resulted in unintended loss or release of radiation, or overexposure of a person to radiation, the holder must notify the Director as soon as practicable'. Overexposure of a person has the interpretation given in this code. As well as complying with these requirements, the holder of a source licence must:
 - a) take all practicable steps to minimise the likelihood of accidents by implementing a multilevel system of sequential, independent provisions for protection and safety that is commensurate with the likelihood and magnitude of potential exposures
 - b) as soon as practicable, restore radiological equipment to a safe condition
 - c) promptly investigate any incident, including by:
 - i) calculating or estimating the doses a person has received
 - ii) identifying actions required to prevent a recurrence of the incident
 - d) implement all actions identified in clause 16(c)(ii)
 - e) keep a written record of the incident, noting the:
 - i) cause or suspected cause
 - ii) calculations made under clause 16(c)(i)
 - iii) actions identified under clause 16(c)(ii)
 - iv) details of the corrective actions implemented under clause 16(d)
 - f) ensure that the referring practitioner and the patient (or the patient's legal representative) are informed of any unintended medical exposure.
17. If the risk assessment required by clause 4 indicates that there is a reasonable likelihood of an emergency affecting either workers or members of the public, the holder of a source licence must prepare an emergency plan for the protection of people and the environment, which specifies:
 - a) arrangements for promptly identifying an emergency
 - b) a method for determining the correct level of emergency response
 - c) provision for individual monitoring and area monitoring and arrangements for medical treatment
 - d) arrangements for assessing and mitigating the consequences of an emergency.

Records

18. Section 35(1)(a) of the Act provides that 'A person who has management or control of a radiation source must keep records that contain sufficient information to enable the Director to ascertain whether the person is complying with the radiation safety requirements'. To meet this requirement, the holder of a source licence must maintain records that verify compliance with this code and retain those records for not less than 10 years. These records are not patient or occupational health and safety records where other legislation applies. Clause 15(b)(i) sets out the requirements that apply to occupational exposure.
19. The holder of a source licence must maintain records that set out:
 - a) the roles and appointments of individuals made by the holder of a source licence
 - 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 and the associated medical physics expert approvals required by clause 20(b)
 - 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) relevant procedures and results
 - l) exemptions from this code granted under section 86(3) of the Act.

Quality assurance

20. The holder of a source licence must establish a comprehensive quality assurance programme for medical exposures which must:
 - a) measure and assess the physical parameters of radiological equipment for the purpose of quality control, including:
 - i) at the time of commissioning the equipment, before equipment is put into clinical use

- ii) periodically following commissioning
 - iii) after any major maintenance procedure that could affect protection and safety
 - iv) after installing any new software or modifying any existing software that could affect protection and safety
 - v) calibrating outputs in terms of appropriate quantities using internationally accepted protocols
 - vi) performing tests on ancillary equipment and personal protective equipment
 - vii) periodically checking the calibration and conditions of operation of dosimetry equipment and monitoring equipment
 - viii) for the purposes of identifying and setting of baselines
 - ix) for the purposes of assessing safety and performance against remedial and suspension levels that have been set based on national and international norms and operational experience
- b) ensure that methods used and values established in clauses 20(a)(viii) and (ix) have been reviewed and approved by a medical physicist expert
 - c) verify the appropriateness of physical and clinical factors used in radiological procedures.
21. The holder of a source licence must ensure that regular internal or external independent audits are made of the quality assurance programme for medical exposures.
22. The holder of a source licence must ensure that:
- a) radiation reviews are performed periodically by radiation practitioners in cooperation with users of irradiating apparatus and medical physics experts 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; or
 - ii) fall substantially below the relevant diagnostic reference level
 - iii) do not provide useful diagnostic information
 - iv) do not yield the expected medical benefit to the patient.

Radiation practitioner

General

23. The radiation practitioner:
- a) is responsible for the planning and delivery of a medical exposure
 - b) to satisfy the responsibility in clause 23(a), must cooperate with a referring practitioner, and as needed cooperate with and direct a user of irradiating apparatus, medical physics expert or others
 - 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

24. 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.

Optimisation

25. The radiation practitioner must, in consultation as appropriate with a medical physics expert and the user of irradiating apparatus, 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 carer and comforter
 - ii) is subject to exposure as part of a programme of research.
26. 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 an 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

Manufacturer/supplier

27. 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 national and international 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.
28. The manufacturer/supplier must:
- a) make suitable arrangements with the holders of source licences to share information on use and operating experience that may be important for protection and safety
 - b) cooperate with the holder of a source licence as required by clause 6(d).

Servicing engineer

29. The servicing engineer must:
- a) install and service radiological equipment competently, so that it complies with the requirements in clause 6
 - b) cooperate with the holder of a source licence 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 holder of a source licence and medical physics experts 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 holder of a source licence describing the equipment fault (if any), work done, parts replaced, adjustments made and any changes that may affect protection and safety.

Appendix 1:

Training requirements for radiation safety officers

The following table sets out the levels of knowledge a radiation safety officer must have on specified topics. In the 'Level of knowledge' column '1' indicates a general awareness and understanding of the topic and '2' indicates an ability to use radiation safety knowledge to assess situations, predict outcomes and apply plans or actions based on those assessments and predictions.

Topic area	Level of knowledge
X-ray production, interaction and detection	
X-ray production and interaction of X-rays with matter (to include attenuation and scatter)	1
Methods of detecting X-rays	1
Radiation effects, risks, dose units and typical doses	
Biological effects of radiation	1
Risks of stochastic effects (including from fetal and paediatric exposures)	2
Causes and consequences of deterministic effects (also referred to as harmful tissue reactions)	2
Risk and benefits of radiation exposures	2
Radiation dose quantities and units (absorbed dose, equivalent dose, effective dose, and operational quantities such as kerma-area product)	2
Factors affecting radiation dose	2
Typical doses from diagnostic and interventional radiology procedures (including diagnostic reference levels)	2
Protection of people and the safety of irradiating apparatus used in radiology	
Physical considerations of radiation exposure (eg, tissue and organ doses)	2
Time, distance and shielding	2
Specific hazards, including factors affecting radiation doses	2
Regulatory requirements	
Authorisations and compliance with the 'radiation safety requirements' under the Radiation Safety Act 2016	2
Radiation protection of patients, carers and comforters, and volunteers in biomedical research	2
Radiation protection of workers and the public (including dose limits and individual dose monitoring for the assessment of occupational exposure)	2
Quality control and quality assurance	2