Code of Practice for Radiation Therapy

Draft for consultation

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# Introduction

## Purpose and commencement

This Code of Practice for Radiation Therapy (this code) will be issued by the Director for Radiation Safety (the Director) under section 86 of the Radiation Safety Act 2016 (the Act), when the Code comes into force. This code provides details necessary to comply with the fundamental requirements in sections 9–12 of the Act. It does not limit the general nature of those requirements. Appendix 1 cross-references those fundamental requirements with clauses in this code.

## Scope

This code applies to all facilities and activities relating to protection and safety in radiation therapy, including all related medical, occupational and public exposures. Activities include:

* producing, supplying and providing radioactive material and devices that contain radioactive material
* producing and supplying devices that generate radiation, including linear accelerators, cyclotrons and fixed and mobile radiography equipment
* using radiation or radioactive material for radiation therapy, which includes using associated equipment, software or devices where such use could affect exposure to radiation
* using radiation or radioactive material for medical purposes that involves education, training or research, including any activities relating to such use that involve or could involve exposure to radiation or exposure due to radioactive material.

This code excludes:

* protection and safety in non-medical uses of ionising radiation (dealt with in the *Code of Practice for Non-medical Uses of Ionising Radiation*)
* security of radiation sources in use and storage (dealt with in the *Code of Practice for Security of Radiation Sources*)
* safety and security of radiation sources in transport (dealt with in the *Code of Practice for Transport of Radiation Sources*).

Complying with this code does not necessarily mean that you have complied in related areas such as health practitioner clinical competence, occupational safety, hazards in the workplace and resource management.

## Contact

The Director’s contact details are:

|  |  |
| --- | --- |
| Office of Radiation SafetyPO Box 3877Christchurch 8140 | Phone: 03 974 2358Email: orsenquiries@moh.govt.nzwww.health.govt.nz/our-work/radiation-safety  |

# Roles and responsibilities

The following individuals and bodies have roles and responsibilities in relation to this code. The next section defines the other words given in bold.

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

**Managing entity** – the legal entity that manages or controls **radiation sources** and so must get a source licence, as section 13(a) of the Act states. A managing entity could be, for example, a district health board, company, partnership, trust or individual person.

**Medical physicist** – an individual with specialist education and training in the concepts and techniques of applying physics in medicine who is competent to practise independently in the radiation therapy specialty of medical physics.

**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 the managing entity appoints to oversee the application of regulatory requirements.

**Radiation practitioner** – a health practitioner with specialist education and training in radiation therapy who is competent to perform independently and oversee **radiation procedures** in a given specialty. Normally this will be an oncologist.

**Radiation therapist** – a **health practitioner** with specialist education and training in radiation therapy who is competent to perform **radiation procedures** on delegation from a radiation practitioner, in the radiation therapy specialty of medical radiation technology.

**Radiopharmacist** – a health practitioner with specialist education and training in radiopharmacy who is competent to prepare and dispense **radiopharmaceuticals** used for radionuclide therapy.

**Referring practitioner** – a health practitioner who the managing entity approves to refer individuals to a radiation practitioner for **medical exposure**.

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

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

**Supplier** – the person or organisation that designs, manufactures, produces, constructs, assembles, installs, distributes, sells, exports or imports **radiation sources** or develops software that could influence the delivery of **medical exposures.**

# Definitions

The **bold** defined terms on the left have the following meanings. Other **bold** terms indicate defined terms that this list also covers.

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

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

**Clearance level** – the level of activity and activity concentration for radioactive material set out in schedule 2 of the Act.

**Comforter/carer** – a person who voluntarily helps, without it being their occupation, in caring for, supporting and comforting a **patient** going through a **radiation 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 **optimising** **protection and safety** for the source, and that serves as a boundary in defining the range of options in **optimisation**. The Director establishes or approves constraints for **occupational exposure**, **public exposure** and **medical exposure** of **comforters/carers**. Compliance guides issued under this code then publish any constraints established. The ethics committee establishes or approves constraints for **medical exposure** of **volunteers** 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 or preventing the spread of contamination in normal working conditions, and preventing or limiting the likelihood and magnitude of **potential exposures**.

**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 makes prompt action essential, primarily to reduce actual or perceived hazards or harmful consequences for human health and safety, quality of life, property or the environment. Emergencies include **radiation emergencies** and conventional emergencies such as fires, release of hazardous chemicals, storms and earthquakes.

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

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

**Facility** – the location where **radiation equipment** and **ancillary equipment** are installed, used, handled or stored and **radiopharmaceuticals** are administered.

**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 that a health authority approves and justifies for populations who show no symptoms of disease.

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

**Individual monitoring** – **monitoring** using measurements by equipment worn by individuals, or measurements of monitoring quantities of **radioactive material** in or on, or taken into, the bodies of individuals, or monitoring quantities of **radioactive material** that individuals excrete from the body.

**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.

**Irradiating apparatus** – electrical equipment that generates ionising radiation as set out in section 5 of the Act.

**Justify** – establish that the expected benefits to individuals and to society from introducing or continuing a practice outweigh the harm (including the radiation detriment) resulting from the practice. For individual **radiation procedures**, justifying involves weighing expected benefits against the radiation detriment that might be caused, taking account of the benefits and risks of available alternative techniques that do not involve **medical exposure**. ‘Justifies’, ‘justified’, ‘justifying’ and ‘justification’ have corresponding meanings.

**Medical exposure** – exposure to ionising radiation of: **patients** for treatment; **comforters/carers** while caring for, supporting or comforting **patients** going through **radiation procedures**; and **volunteers** in a programme of medical research.

**Member of the public** – for purposes of **protection and safety**, any individual in the population except for individuals who experience **occupational exposure** or **medical exposure**.

**Monitoring** – measuring dose, dose rate or activity so that it is possible to assess or control exposure due to radiation or **radioactive material**, and to interpret the results.

**Occupational exposure** – exposure of **workers** to ionising radiation through the work they do.

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

**Optimise** – implement a level of **protection and safety** that keeps the size of individual doses, the number of individuals (**workers** and **members of the public**) who experience exposure and the likelihood of exposure as low as reasonably achievable, taking account of economic and social factors. For **medical exposures** of **patients**, optimising requires managing the radiation dose to the **patient** at a level that is appropriate for the medical purpose. ‘Optimises’, ‘optimised’, ‘optimising’ and ‘optimisation’ have corresponding meanings.

**Patient** – a person who experiences **medical exposure** for their own medical benefit.

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

**Potential exposure** – possible future exposure that may result from an anticipated operational occurrence or **accident** at a source or from an event or sequence of events that can potentially occur, including equipment faults and operating errors.

**Protection and safety** – the protection of people against exposure to ionising radiation or exposure due to **radioactive material** and the safety of **radiation sources**, including the means for achieving this, and the means for preventing **accidents** and for reducing 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 a hazard due to radiation exposure occurs or is perceived to occur.

**Radiation equipment** – equipment and its associated software used to perform **radiation procedures** that either deliver an exposure of an individual or directly control or influence the extent of such exposure.

**Radiation procedure** – a medical imaging procedure or therapeutic procedure that is intended to result in a **medical exposure** delivered by an **irradiating apparatus** or a device containing a **radioactive** **source** (whether sealed or unsealed), or by administering a **radiopharmaceutical** to a **patient**. This includes procedures in radiation therapy or a planning procedure.

**Radiation source** – anything that may cause radiation exposure, such as by emitting ionising radiation or by releasing radioactive substances or **radioactive material** that can be treated as a single entity for the purposes of **protection and safety**. This includes **radiation equipment** and **radioactive material** administered to or implanted in a patient.

**Radioactive material** – material that spontaneously emits ionising radiation.

**Radioactive source** – a **radiation source** that spontaneously emits ionising radiation.

**Radioactive waste** – radioactive material of no further use that contains, or is contaminated with, radionuclides at activity concentrations higher than **clearance levels**.

**Radiopharmaceutical** – a radioactive pharmaceutical preparation administered to a **patient** for therapeutic purposes.

**Reportable incident** – an **incident** that involves: (a) exceeding a **dose limit**; (b) losing a **radiation source**, or a **radiation source** that is missing or beyond regulatory control; or (c) administering a radiation dose to a **patient** that is significantly greater than intended.

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

**Source categorisation** – categorisation for **radioactive material** in line with Schedule II of the International Atomic Energy Agency’s publication *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards GSR Part 3.*

**Supervised area** – an area other than a **controlled area** for which occupational exposure conditions need to be kept under review, even though it does not normally need specific measures for **protection and safety**.

**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; use of the wrong radiopharmaceutical; use of a radiopharmaceutical with an activity, a dose or dose fractionation differing substantially from the values that the radiation practitioner prescribed; substantially greater exposure than intended; inadvertent exposure of the embryo or fetus; and fault of **radiation equipment**, failure of software or system failure, or error, mishap or other unusual occurrence with the potential to subject the **patient** to a **medical exposure** that is substantially different from what was intended.

**Volunteer** – an individual other than a **comforter/carer** who may experience **medical exposure** as part of a programme of medical research.

**Worker** – an individual who works, 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 seen as both an **employer** and a worker.

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

# Managing entity

## General

* + 1. The managing entity must:
			1. take overall responsibility for protection and safety, which it cannot delegate
			2. apply measures for protection and safety in a graded manner that is:
				1. appropriate for the radiation risks in the exposure situation
				2. adequate to ensure compliance with this code
			3. ensure that:
				1. no practice is undertaken unless it is justified
				2. protection and safety are optimised and documented
				3. occupational and public dose limits are not exceeded
			4. assess the likelihood and magnitude of potential exposures, their likely consequences and the number of individuals who they may affect
			5. conduct, document and keep up to date a safety assessment in any case where an exposure greater than 30 percent of a dose limit is possible
			6. conduct, document and keep up to date a radiation environmental impact assessment if radioactive material:
				1. is expected to be released to the environment in normal operations, or
				2. could be released to the environment in an accident
			7. establish a management system to enhance protection and safety by:
				1. effectively integrating protection and safety into the overall management system of the organisation
				2. making a commitment to protection and safety and providing all required resources
				3. promoting continuous improvement and a safety culture
			8. ensure infrastructural arrangements are in place for the interfaces between safety and security of radioactive sources.
		2. As part of meeting its responsibility in clause 1(a), the managing entity must:
			1. as necessary, consult with and engage the services of radiation practitioners, medical physicists, radiation therapists, qualified experts, workers and other interested parties
			2. delegate:
				1. the planning and delivering medical exposures, including compliance with clauses 20–23, to a radiation practitioner
				2. the installing and servicing of radiation equipment, including compliance with clause 28, to a servicing engineer
				3. other functions as appropriate, which may be to a radiation safety officer or someone else
			3. cooperate as necessary with employers in any case where workers are not employed by the managing entity
			4. for all delegations under clauses 2(b) and 23:
				1. ensure that delegates are notified of their duties in relation to protection and safety and that they take responsibility for performing them
				2. fully document the delegations.

## Facilities

* + 1. The managing entity must:
			1. provide facilities that are:
				1. sited, located, designed, manufactured, constructed, assembled, commissioned, operated, maintained and decommissioned with good engineering practice, minimising the need to rely on administrative controls and personal protective equipment for protection and safety
				2. shielded sufficiently to optimise protection and safety
			2. in consultation with a qualified expert, check and document the adequacy of the shielding required in clause 3(a)(ii)
			3. designate and delineate appropriate areas as controlled areas or supervised areas and periodically review those decisions
			4. prominently display signs:
				1. specifying the actual or potential presence of ionising radiation, using the symbol that the International Organization for Standardization recommends, at access points to controlled areas and supervised areas and at appropriate locations within controlled areas
				2. controlling access by members of the public to controlled areas and supervised areas
				3. in areas where patients may be (including waiting rooms and change cubicles), requiring patients who are to go through a radiation procedure to notify staff if they are or may be pregnant or, for procedures that involve administering radiopharmaceuticals, if they are breastfeeding.

## Radiation sources and equipment

* + 1. The managing entity must:
			1. provide, maintain, test and service radiation sources as necessary so that they:
				1. are appropriate for the radiation procedures to be performed
				2. remain capable of meeting their design requirements for protection and safety throughout their lifetime
			2. cooperate with suppliers to:
				1. ensure that the suppliers comply with clause 25
				2. ensure that radiation equipment is used only if it conforms to the applicable standards of the International Electrotechnical Commission and the International Organization for Standardization
				3. share information on use and operating experience that may be important for protection and safety
				4. apply the principles of optimisation in designing, planning, operating and decommissioning a source
				5. ensure, where practicable, that sealed sources are identifiable and traceable
			3. safely manage all radiation sources whether or not they are in use
			4. keep an accurate inventory of all radiation sources, including their:
				1. location and description
				2. activity and form if they are radioactive sources
				3. source categorisation if they are sealed sources
			5. keep 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
			6. maintain control of radiation sources to prevent loss or damage and to prevent any person from carrying out unauthorised activities, including by:
				1. periodically checking that the radiation sources are under control and in the locations recorded in the inventory maintained under clause 4(e)
				2. releasing them only to people who are authorised to assume management and control under the Act
			7. take immediate steps to regain control of any radiation sources that are abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation.
		2. In consultation with a medical physicist, the managing entity must ensure that:
			1. all sources leading to medical exposure are calibrated in terms of appropriate quantities, using internationally accepted protocols
			2. calibrations are carried out at the time of commissioning radiation equipment before it is used clinically, after any maintenance procedure that could affect the dosimetry and at intervals approved by the Director and published in safety guides issued under this code
			3. calibrations of radiation therapy units are subject to independent verification before they are used clinically
			4. calibrations of all dosimeters used for the calibration of sources are traceable to a standards dosimetry laboratory and performed by a calibration service that the Director has approved
			5. safely manage and dispose of radioactive waste, including by:
				1. keeping the activity and volume of waste generated to the minimum practicable
				2. separately processing radioactive waste of different types
				3. ensuring effective predisposal management and disposal of radioactive waste
				4. keeping an inventory of all radioactive waste that is generated, stored, transferred or disposed of
				5. developing and implementing a strategy for radioactive waste management, including gathering appropriate evidence that shows protection and safety are optimised.
		3. The managing entity must provide, maintain, test, calibrate and service equipment other than radiation equipment to a level that is sufficient to ensure it complies with this code. Such equipment includes equipment for personal protection, monitoring and measurement for compliance verification, accident verification, emergency response, and protection and safety of members of the public.

## Training and authorisation

* + 1. The managing entity must ensure that:
			1. all medical physicists and health practitioners with responsibilities for medical exposures are specialised in the appropriate area
			2. all people with responsibilities for protection and safety are:
				1. appropriately qualified, educated and trained in protection and safety so that they understand their duties and can perform them competently
				2. named in a current list with details of their specialisation, qualification, education and training
				3. authorised to assume their roles and responsibilities
			3. any external education or training service has been approved by the Director.

## Policies, procedures and local rules

* + 1. The managing entity must establish, implement and maintain policies and procedures to comply with this code. These include, without limitation, policies and procedures to:
			1. control access to areas where people can be exposed to radiation
			2. use constraints in optimising protection and safety
			3. control the discharge of radioactive material and restrict exposure due to contamination
			4. prevent accidents wherever possible and reduce the consequences of those accidents that do occur
			5. comply with operational limits and conditions relating to public exposure
			6. identify the pregnancy status of female patients of a reproductive age before performing any radiation procedure that could give a significant dose to the embryo or fetus
			7. establish whether a female patient is breastfeeding before performing any radiation procedure involving administering radiopharmaceuticals that could result in a breastfed infant receiving a significant dose
			8. comply with criteria and guidelines the Director issues under this code and publishes in compliance guides about releasing patients who have gone through therapeutic radiological procedures
			9. provide for protection and safety by applying preventive measures in the priority order of:
				1. engineered controls
				2. administrative controls
				3. personal protective equipment
			10. set investigation levels and establish procedures to follow if these levels are exceeded
			11. implement procedures for verification.
		2. The managing entity must maintain, publish and enforce written local rules that are necessary for protection and safety.

## Patient dosimetry

* + 1. The managing entity must, in consultation as appropriate with a medical physicist:
			1. perform and document dosimetry of patients to identify:
				1. absorbed doses to the planning target volume and relevant tissues as the radiation practitioner specifies for each patient treated with external beam therapy and/or brachytherapy
				2. typical absorbed doses to patients for therapeutic radiation procedures with unsealed radioactive material
			2. in order to satisfy the requirements in clause 10(a):
				1. follow internationally accepted protocols
				2. use only dosimeters with current calibrations traceable to a standards dosimetry laboratory and performed by a calibration service that the Director approves.

## Monitoring and measurement

* + 1. The managing entity must establish and maintain:
			1. a programme of continuous individual monitoring, whenever this is appropriate, adequate and feasible, that is sufficient to assess occupational exposures for workers who usually work in a controlled area or who may receive a dose above 30 percent of the dose limits
			2. a programme of workplace monitoring, under the supervision of a radiation safety officer or qualified expert, that is sufficient to:
				1. evaluate radiation conditions in all workplaces
				2. assess exposures in controlled areas and supervised areas that are not assessed under clause 11(a)
				3. review the classification of controlled areas and supervised areas
			3. a monitoring programme for all workers who could be subject to exposure due to contamination that is sufficient to:
				1. demonstrate the effectiveness of the measures for protection and safety
				2. assess intakes of radionuclides and committed effective doses
			4. programmes of source monitoring or environmental monitoring that are sufficient to assess public exposure and radioactivity in the environment coming from radiation sources for which the managing entity is responsible
			5. a capability that is sufficient to monitor unexpected increases in radiation levels or concentrations of radionuclides in the environment due to an incident attributed to a source or facility for which the managing entity is responsible
			6. other monitoring or measurement programmes that are necessary to verify compliance with this code.
		2. To satisfy the monitoring and measurement requirements in clause 11, the managing entity must:
			1. get approval from the Director for the monitoring or measurement programme
			2. use appropriate monitoring equipment
			3. for continuous individual monitoring under clause 10(a), use an external service or internal capability only if that service or capability:
				1. is approved by the Director
				2. returns results of monitoring to the managing entity within 20 working days of receiving all necessary raw information.
		3. The managing entity must:
			1. get all previous dose records in relation to workers
			2. keep records of all monitoring and verification of compliance, including records of:
				1. occupational exposure during and after the worker’s working life, at least until the former worker reaches or would have reached the age of 75 years, and for no less than 30 years after the worker has stopped the work in which they experienced occupational exposure
				2. estimated doses to members of the public
				3. the tests and calibrations carried out
			3. provide records of occupational exposure to:
				1. individual workers about their own exposure
				2. subsequent employers of workers, provided this meets confidentiality criteria
				3. the Director on request or if the managing entity can no longer keep records as required under clause 13(b)
			4. provide records of source monitoring and environmental monitoring to assess public exposure and radioactivity in the environment to:
				1. members of the public on request
				2. the Director on request
				3. the Director immediately any time that levels exceed operational limits and conditions, or when there is any significant increase in dose rate or concentration of radionuclides in the environment that the authorised practice could be responsible for.

## Incidents, accidents and emergencies

* + 1. The managing entity must:
			1. take all practicable steps to minimise the likelihood of accidents, including, in keeping with the likelihood and magnitude of potential exposures, a multilevel system of sequential, independent provisions for protection and safety
			2. take timely action to reduce the consequences of any accident that does occur and restore radiation sources to a safe condition
			3. promptly investigate any incident, including by:
				1. calculating or estimating doses a person has received and, if applicable, the dose distribution within them
				2. identifying corrective actions required to prevent such an incident from recurring
			4. implement all corrective actions identified in clause 14(c)(ii)
			5. keep a written record of the incident, including the:
				1. cause or suspected cause
				2. calculations made under clause 14(c)(i)
				3. corrective actions identified under clause 14(c)(ii)
				4. details of the implementation of corrective actions under clause 14(d)
			6. ensure that the referring practitioner and the patient (or the patient’s legal representative) are informed of any unintended medical exposure
			7. promptly notify the Director of any reportable incident.
		2. If the safety assessment required by clause 1(e) indicates that an emergency affecting either workers or members of the public is reasonably likely, the managing entity must prepare an emergency plan to protect people and the environment. This plan must include:
			1. arrangements for promptly identifying an emergency
			2. guidance to identify the correct level of emergency response
			3. arrangements for individual monitoring and area monitoring and for medical treatment
			4. arrangements for assessing and reducing any consequences of an emergency.

## Records

* + 1. The managing entity must keep, and make available as necessary, adequate records of:
			1. delegation of responsibilities of the managing entity and the radiation practitioner
			2. training
			3. results of calibrations and periodic checks of physical and clinical parameters selected during treatment of patients
			4. dosimetry of patients
			5. the quality assurance programme
			6. for external beam radiotherapy or brachytherapy, a description of the planning target volume, the absorbed dose to the centre of the planning target volume, and the maximum and minimum absorbed doses delivered to the planning target volume, or equivalent alternative information on absorbed doses to the planning target volume, and the absorbed doses to relevant tissues or organs as the radiation practitioner decides, and in addition, for external beam radiotherapy, the dose fractionation and the overall duration of treatment
			7. exposure records for volunteers who experience medical exposure as part of a programme of medical research
			8. reports on investigations of unintended and accidental medical exposures
			9. exemptions from this code granted under section 86(3) of the Act.

## Quality assurance

* + 1. With the active participation as appropriate of radiation practitioners, radiation therapists and medical physicists, the managing entity must establish a comprehensive programme of quality assurance for medical exposures. The programme must include:
			1. measuring the physical parameters of radiation equipment, including calibrating output in terms of appropriate quantities using internationally accepted protocols, with those measurements made:
				1. at the time the managing entity accepts and commissions the equipment, before practitioners use it clinically
				2. periodically after that first check
				3. after any major maintenance procedure that could affect protection and safety of patients
				4. after installing any new software or modifying any existing software that could affect the protection and safety of patients
			2. adopting internationally accepted tolerance limits for the physical parameters in clause 17(a), and implementing corrective actions if measured values fall outside those tolerance limits
			3. verifying the appropriateness of physical and clinical factors used in radiation procedures
			4. maintaining records of relevant procedures and results
			5. periodically checking the calibration and conditions of operation of dosimetry equipment and monitoring equipment.
		2. The managing entity must ensure that the programme of quality assurance for medical exposures has regular internal or external independent audits.
		3. The managing entity must ensure that radiation practitioners, in cooperation with radiation therapists and medical physicists, perform radiation reviews periodically to investigate and critically review the current practical application of the radiation protection principles of justifying and optimising radiation procedures

# Radiation practitioner

## Before a procedure

* + 1. Before starting a radiation procedure, the radiation practitioner must:
			1. take responsibility for overall protection and safety in planning and delivering the medical exposure
			2. get information on the clinical context for any procedure unless it is part of a health screening programme
			3. 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:
				1. the appropriateness of the request
				2. the urgency of the procedure
				3. the characteristics of the medical exposure
				4. the characteristics of the individual patient
				5. relevant information from the patient’s previous radiation procedures
				6. relevant national or international referral guidelines
			4. inform all individuals who may experience medical exposure, or their legal authorised representatives, of the expected benefits, risks and limitations of the procedure.

## Optimisation

* + 1. The radiation practitioner must, in consultation as appropriate with medical physicists, radiation therapists, radiopharmacists and radiochemists, optimise protection and safety for each medical exposure. To achieve this optimisation:
			1. for all therapeutic radiation procedures, they keep the exposure of volumes other than the planning target volume as low as reasonably achievable, consistent with the delivery of the prescribed dose to the planning target volume within required tolerances
			2. for therapeutic radiation procedures involving radiopharmaceuticals, they select and administer an appropriate radiopharmaceutical with an appropriate activity so that radioactivity is primarily localised in the organ(s) of interest, while radioactivity in the rest of the body is kept as low as reasonably achievable.
		2. The radiation practitioner must ensure that the optimisation process considers particular aspects of medical exposures for:
			1. paediatric patients who experience medical exposure
			2. individuals who experience medical exposure as part of a health screening programme
			3. volunteers who experience medical exposure as part of a programme of medical research
			4. exposure of the embryo or foetus, in particular for radiation procedures in which the abdomen or pelvis of a pregnant female patient is exposed to the useful radiation beam or could otherwise receive a significant dose
			5. exposure of a breastfed infant because a female patient has gone through a radiation procedure with radiopharmaceuticals.

## General

* + 1. The radiation practitioner may delegate functions but only to a person the managing entity has authorised. A written document must record that delegation in line with clause 2(d).

# Other parties

## Referring practitioner

* + 1. The referring practitioner must:
			1. provide sufficient information on the clinical context of the procedure in the referral
			2. cooperate with the radiation practitioner as part of the justification of the procedure in line with clause 20(c).

## Supplier

* + 1. The supplier of radiation sources must:
			1. supply well-designed, well-manufactured and well-constructed radiation sources that:
				1. provide for protection and safety in line with this code
				2. meet engineering, performance and functional specifications
				3. meet quality standards appropriate to the significance of systems and components, including software, for protection and safety
				4. provide clear displays, gauges and instructions on operating consoles
			2. test radiation sources to demonstrate that they comply with all relevant specifications
			3. provide information on how to properly install and use radiation sources and on associated radiation risks, including performance specifications, instructions for operating and maintenance, and instructions for protection and safety
			4. optimise the protection and safety that shielding and other protective devices provide
			5. supply all radiation equipment with all appropriate radiation protection tools as a default, rather than as optional extras
			6. ensure, where practicable, that radioactive sources or devices that contain radioactive sources are marked with the symbol that the International Organization for Standardization recommends
			7. cooperate with managing entities to ensure, where practicable, that sealed sources are identifiable and traceable.
		2. The supplier must:
			1. make suitable arrangements with managing entities to share information on use and operating experience that may be important for protection and safety
			2. cooperate with the managing entity as required by clause 4(b).

## Servicing engineer

* + 1. The servicing engineer must:
			1. install and service radiation equipment competently so that it complies with clause 4
			2. cooperate with the managing entity to ensure that radiation equipment cannot be used clinically while it is being installed or serviced
			3. after installing or servicing the equipment:
				1. collaborate with the managing entity and medical physicists to ensure necessary quality control tests are completed successfully
				2. provide immediate written confirmation to the managing entity when the equipment can be used clinically
				3. within 24 hours, 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-references 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) |  |
| 9(2) |  |
| 9(3) |  |
| 10(1) | *To be completed following*  |
| 10(2) | *consultation* |
| 10(3) |  |
| 11 |  |
| 12 |  |

# Consultation submission

|  |  |
| --- | --- |
| Your detailsThis submission was completed by: *(name)* |  |
| Address: *(street/box number)* |       |
|  *(town/city)* |       |
| Email: |       |
| Organisation *(if applicable)*: |       |
| Position *(if applicable)*: |       |

**Privacy**

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

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

[ ]  Do not publish this submission.

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

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

### Please return this form to:

Email: mailto:orsenquiries@moh.govt.nz (including ‘radiotherapy code’ in the subject line)

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

## Consultation questions

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

### Scope

1. The scope of the code relates to the use of radiation sources for the purpose of radiotherapy. Feedback on other medical codes has suggested that a more useful configuration would be a single medical code supported by compliance guides that elaborate on the requirements for each area of practice (in this case radiation therapy). Do you agree that a single code supported by a more detailed radiation therapy compliance guide is appropriate?

[ ]  Yes

[ ]  No

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

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### Roles and responsibilities

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

[ ]  Yes

[ ]  No

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

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### Definitions

3. Are the definitions appropriate and comprehensive?

[ ]  Yes

[ ]  No

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

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### Managing entity obligations

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

[ ]  Yes

[ ]  No

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

[ ]  Yes

[ ]  No

Please provide any comments below.

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### Radiation practitioner obligations

5. a. Are the subheadings within the ‘Radiation practitioner’ section appropriate?

[ ]  Yes

[ ]  No

b. Are there other changes you think are necessary to the obligations of the practitioner?

[ ]  Yes

[ ]  No

Please provide any comments below.

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### Other parties

6. a. Are there other parties who should have defined responsibilities?

[ ]  Yes

[ ]  No

b. Are there other changes you think are necessary to the obligations of other parties?

[ ]  Yes

[ ]  No

Please provide any comments below.

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### Additional comments

7 a. Was the information in this code appropriately presented?

[ ]  Yes

[ ]  No

b. Was the information in this code easy to find?

[ ]  Yes

[ ]  No

c. Are there any changes you would like to suggest?

[ ]  Yes

[ ]  No

d. Are there circumstances that are not included in this code but should be? If yes, please provide more details in the comments box below.

[ ]  Yes

[ ]  No

e. Is the information easily understood?

[ ]  Yes

[ ]  No

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

[ ]  Yes

[ ]  No

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

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