

Code of Practice for Nuclear Medicine

ORS C2

2019

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Introduction

Purpose and commencement

This Code of Practice for Nuclear Medicine (code) is issued by the Director for Radiation Safety (the Director) under section 86 of the Radiation Safety Act 2016 (the Act). It provides the operational information necessary to comply with the fundamental requirements in sections 9 to 12 of the Act. Appendix 1 sets out cross-references between clauses in this code and those fundamental requirements. The requirements in this code do not limit the general nature of the fundamental requirements.

This code comes into force on 29 April 2019.

Scope

This code applies to all activities associated with the administration of unsealed radiopharmaceuticals to patients to diagnose or treat disease, or for clinical or pre-clinical research. This includes, but is not limited to, the practices of nuclear medicine, positron emission tomography, in vivo diagnostics and sentinel node biopsy procedures that use radiopharmaceuticals. The use of a cyclotron to manufacture radiopharmaceuticals is dealt with in a separate code. Activities can include the manufacture, dispensing, possession, control, management, use, administration, storage, import, export, sale, supply, discharge and disposal of radioactive material and equipment.

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

Contact

The Director's contact details are:

Office of Radiation Safety
PO Box 5013
Wellington 6140

Email: orsenquiries@moh.govt.nz
Fax: 04 496 2340

Roles and responsibilities

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

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

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

Managing entity – the legal entity that manages or controls radiation sources and must, therefore, obtain a source licence as required by section 13(a) of the Act. This could be, for example, a district health board, or an independent company providing nuclear medicine services.

Manufacturer/supplier – the person or organisation who designs, manufactures, produces, constructs, assembles, installs, distributes, sells, exports or imports radiopharmaceuticals, sealed source used for calibration and quality control tests or ancillary equipment that could influence the delivery of the medical exposure.

Medical physicist – an individual with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practise independently in the nuclear medicine or radiation oncology specialties of medical physics and who provides specialist expertise for radiation protection of the patient.

Nuclear medicine technologist – a health practitioner with specialist education and training in nuclear medicine technology who is competent to perform **radiation procedures** on delegation from the radiation practitioner.

Operator – a nuclear medicine technologist, radiation therapist or other health practitioner who is competent to perform radiation procedures on delegation from the radiation practitioner.

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

Radiation practitioner – a health practitioner with specialist education and training in the medical uses of radiation who is competent to perform independently and oversee radiation procedures. This could include, for example, a nuclear medicine specialist, radiologist, endocrinologist, cardiologist, or radiation oncologist.

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

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

Radiopharmaceutical scientist – an individual with specialist education and training in pharmacy, chemistry or science who is competent to prepare and dispense radiopharmaceuticals used for the purposes of medical diagnosis and radionuclide therapy.

Referring practitioner – a health practitioner who is approved by the managing entity to refer individuals to a radiation practitioner for medical exposure.

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

Definitions

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

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

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

Ancillary equipment – equipment other than **protective equipment** that has an impact on the successful outcome of a **radiation procedure** such as SPECT-CT scanners, PET-CT scanners, digital image displays, test objects, liquid scintillation counters, well counters, dose calibrators, activity meters, radiation measurement equipment and sealed sources used for calibration and quality control tests.

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

Committed effective dose – the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the **committed equivalent doses** to those organs or tissues.

Committed equivalent dose – the **equivalent dose** to organs or tissues of reference that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

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

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

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

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

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

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

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

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

Facility – the location at which nuclear medicine **radiation procedures** are performed and radiopharmaceuticals and ancillary equipment are installed, used, handled or stored. This could for example be a department within a hospital or a stand-alone facility providing nuclear medicine services.

Health practitioner – an individual who is, or is deemed to be, registered with an authority as a practitioner of a particular health profession under the Health Practitioners Competence Assurance Act 2003.

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

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.

In-room protective equipment – equipment used to reduce exposure to radiation but not worn on the person, such as shields for bench tops, vials, syringes, activity meters, and for the preparation of radiopharmaceuticals; tools for the remote handling of radioactive material, including tongs and forceps; containers for transport of radioactive waste and sources; and fume hoods

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

Justify – determine that the expected benefits to individuals and society from introducing or continuing a practice outweigh the harm, including the radiation detriment, resulting from the practice. In respect of individual **radiation procedures**, this involves the weighing of expected benefits against the radiation detriment that might be caused with account taken of the benefits and risks of available alternate

techniques that do not involve **medical exposure**. 'Justifies', 'justified' and 'justification' have corresponding meanings.

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

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

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

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

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

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

Patient – an individual who is subject to **medical exposure** for his or her own medical benefit. A patient may also be a **volunteer** for the purpose of this code.

Personal protective equipment – equipment worn on the person to reduce their exposure to radiation such as protective aprons, or to prevent the transfer of contamination such as laboratory gowns, waterproof gloves, and overshoes.

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

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

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

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

Public exposure – exposure to ionising radiation experienced by a **member of the public** but excluding any **occupational exposure** or **medical exposure**.

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

Radiation procedure – a procedure involving the administration of **radiopharmaceuticals** for medical diagnosis, therapy or research.

Radioactive source – source that spontaneously emits ionising radiation including a **radiopharmaceutical** or a sealed source used for calibration and quality control tests.

Radiopharmaceutical – compound labelled with a **radioactive source** for administration to patients.

Reportable incident – an **incident** resulting in (a) a **dose limit** being exceeded, (b) **radioactive sources** that are lost, missing or beyond regulatory control, or (c) a radiation dose to a **patient** that exceeds 1.5 times the intended dose (when the intended effective dose exceeds 5 mSv), 2 times the intended dose (when the intended effective dose exceeds 0.5 mSv but is less than or equal to 5 mSv), or 20 times the intended dose (when the intended dose is less than or equal to 0.5 mSv).

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

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

Typical dose – the median or average of the dose or activity 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 arising from diagnostic **radiation procedures**; any therapeutic **radiation procedure** delivered to the wrong individual or to the wrong tissue or organ of the patient, or using the wrong **radiopharmaceutical**, or with an activity or a dose differing substantially from (over or under) the values prescribed by the **radiation practitioner**, or that could lead to unduly severe secondary effects; any diagnostic exposure substantially greater than was intended; inadvertent exposure of the embryo or fetus; and fault of **radiation sources** or **ancillary equipment**, failure of software or system failure, or error, mishap or other unusual occurrence with the potential for subjecting the **patient** to a **medical exposure** that is substantially different from what was intended.

Volunteer – an individual other than a **comforter/carer** who may be subjected to medical exposure as part of a programme of biomedical research. A **volunteer** may also be a patient for the purpose of this code.

Worker – an individual who works, whether full time, part time or temporarily for the managing entity and who has recognised rights and duties in relation to occupational radiation protection.

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

Managing entity

General

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

2. The managing entity must ensure that no practice or procedure is undertaken unless:
 - a. it has been justified generically by a health authority
 - b. it has been:
 - i. justified specifically by a health authority in conjunction with appropriate professional bodies for procedures that are part of a health screening programme
 - ii. approved by an ethics committee for medical exposures incurred as part of a programme of medical research
 - iii. justified individually for the patient by a radiation practitioner in any other case.

Safety assessment

3. The managing entity must conduct, document and keep up to date a safety assessment to:
 - a. identify the ways in which occupational, public and medical exposures could be incurred
 - b. determine the expected likelihood and magnitudes of exposures in normal operation and, to the extent reasonable and practicable, assess potential exposures including the possibility of unintended or accidental medical exposures
 - c. assess the adequacy of provisions for protection and safety in respect of siting, design and operation.

Facilities

4. The managing entity must:
 - a. provide facilities that are sited, located, designed, manufactured, constructed, assembled, commissioned, operated, maintained and decommissioned in accordance with good engineering practice, taking into account workload and patient flow, and minimising the need to rely on administrative controls and personal protective equipment for protection and safety
 - b. provide suitable areas for source storage and radiopharmaceutical preparation, radiopharmaceutical administration to patients, uptake rooms, in vivo imaging, in vitro sample measurement, waiting areas, changing areas, dedicated toilets for patients, personal contamination monitoring, decontamination, and radioactive waste storage and predisposal processing

- c. provide taps and soap dispensers that are operable without direct hand contact, an emergency shower, and an eyewash in areas where radiopharmaceuticals are handled, and have an appropriate ventilation system in areas where radioactive aerosols or gases are produced or handled
- d. shield the facility to ensure that expected doses to any person are as low as reasonably achievable and that rooms housing sensitive instruments maintain a sufficiently low levels of background radiation to avoid interference
- e. in consultation with a medical physicist or other qualified expert, verify and document the adequacy of shielding required in clause 4(d) whenever circumstances change that could increase the risks
- f. designate and delineate appropriate areas as controlled areas or supervised areas and periodically review those designations and delineations
- g. restrict access as appropriate to controlled areas and supervised areas
- h. 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 in (including waiting rooms and change cubicles), requiring patients who are to undergo a radiation procedure to notify staff if they are or may be pregnant or if they are breastfeeding
 - iv. in rooms designated for patients undergoing radiopharmaceutical therapy, requesting patients to wash their hands and, if long flush toilets are not used, flush the toilet at least twice
- i. ensure that floors, walls and other surfaces are covered with smooth, continuous non-absorbent materials that can be easily cleaned and decontaminated in areas where radiopharmaceuticals are used or stored, in rooms designated for patients undergoing radiopharmaceutical therapy, in toilets used by patients following the administration of radiopharmaceuticals and in transitional areas between the radiopharmacy and radiopharmaceutical administration area.
- j. provide for the proper display and interpretation of images.

Radioactive sources and equipment

5. The managing entity must:
 - a. ensure that radiopharmaceuticals are:
 - i. fit for their intended purpose
 - ii. measured at the time of dispensing and, if appropriate, decay corrected to the time of administration
 - b. ensure that the measurement required in clause 5(a)(ii) is carried out using a calibrated dosimeter traceable to a standards dosimetry laboratory
 - c. ensure that equipment that generates X-rays in hybrid procedures such as PET-CT satisfies the requirements in clause 5 of *ORS C1: Code of practice for diagnostic and interventional radiology*
 - d. provide, maintain, test and regularly service protective equipment and ancillary equipment so that:
 - i. it is fit for its intended purpose
 - ii. it fulfils its design requirements for protection and safety
 - iii. the protective value of protective equipment is clearly displayed on the equipment
 - iv. sealed sources are subject to leak tests before their first use and every two years after that
 - e. ensure that dose calibrators used to measure the activity of gamma-emitting radionuclides administered to humans have:
 - i. an accuracy within 10% over the range of activities usually used
 - ii. a repeatability and linearity within 5% over the range of activities usually used
 - iii. a calibration traceable to a national standard of radioactivity at least every 2 years
 - f. provide, as appropriate, at entrances to controlled areas:
 - i. personal protective equipment
 - ii. equipment for individual monitoring and workplace monitoring
 - iii. equipment to monitor contamination of skin and clothing
 - g. provide, as appropriate, kits available for dealing with spills, including items such as:
 - i. protective clothing, for example gowns, disposable overshoes and impermeable gloves
 - ii. decontamination materials for the affected areas, including absorbent materials for wiping up spills, for example buckets, brushes, towels or absorbent pads, forceps or tongs, and decontaminating agents
 - iii. decontamination materials for people, for example mild soap or chelating detergent, sponge and iodide or iodate tablets if appropriate

- iv. warning notices and barrier tape
- v. portable monitoring equipment
- vi. bags for waste, together with tape, labels and pencils
- h. maintain control of radioactive sources to prevent loss or damage and to prevent any person from carrying out unauthorised activities including by:
 - i. maintaining an accurate inventory of all radioactive sources, including their location, description, activity and form
 - ii. periodically checking that radioactive sources are under control and in the locations recorded in the inventory maintained under clause 5(h)(i)
 - iii. releasing radioactive sources only to people who are authorised to assume management and control under the Act
- i. take immediate steps to regain control of any radioactive sources that are abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation.
- j. dispose of radioactive waste:
 - i. as non-radioactive waste after storing it for sufficient time to meet the criteria for clearance in Schedule 2 of the Act, or
 - ii. by returning it to the manufacturer, or
 - iii. for excreta of patients and general liquid waste, through a continuously flowing sewerage system, or by dilution prior to entering the sewerage system
 - iv. in any other manner approved by the Director.

Training and authorisation

6. The managing entity must ensure that all persons with responsibilities for protection and safety:
 - a. are specialised, qualified, educated and trained in protection and safety so that they understand their duties and can perform them competently
 - b. satisfy the training requirements in Appendix 3
 - c. are named in a current list with details of their specialisation, qualification, education and training
 - d. are notified of their duties in relation to protection and safety
 - e. are authorised to assume their roles and responsibilities.

Policies, procedures and local rules

7. The managing entity must establish, implement and maintain policies and procedures to meet the requirements of this code including, without limitation, policies and procedures:
 - a. to control access to areas where people can be exposed to radiation
 - b. to use constraints to optimise protection and safety
 - c. for the management of radioactive waste and discharges of radioactive material
 - d. for routine radiopharmaceutical preparations and dispensing procedures
 - e. specifying what radiation procedures can involve a comforter/carer
 - f. to prevent accidents and mitigate the consequences of any that occur
 - g. to report on and learn from accidents and other incidents
 - h. to comply with operational limits and conditions relating to public exposure
 - i. for staff who have indicated the possibility of pregnancy
 - j. to ascertain the pregnancy status of female patients of reproductive capacity before performing any radiation procedure that could result in a significant dose to the embryo or fetus
 - k. ascertain the breast feeding status of female patients before performing any radiation procedure that could result in a significant dose to a breastfeeding infant
 - l. to minimise unnecessary exposure to:
 - i. the embryo or foetus
 - ii. infants breastfeeding from a patient who has been administered a radiopharmaceutical
 - iii. any person who may come into close proximity of a patient who has been administered a radiopharmaceutical by adopting the release guidelines in Appendix 3
 - iv. any person who may need to handle the body of a patient who dies after they were administered a radiopharmaceutical
 - m. provide protection and safety by applying preventive measures in the following hierarchy:
 - i. engineered controls
 - ii. administrative controls
 - iii. personal protective equipment

- n. set investigation levels and establish procedures to follow if such a level is exceeded
 - o. implement procedures for verification of compliance with this code
 - p. periodically review the overall effectiveness of measures for protection and safety.
8. The managing entity must maintain, publish and enforce any written local rules that are necessary for protection and safety.

Patient dosimetry

9. The managing entity must:
- a. determine typical doses to patients for common diagnostic radiation procedures and typical absorbed doses to patients for therapeutic radiation procedures
 - b. in order to satisfy the requirements in clause 9(a):
 - i. follow internationally accepted protocols, and
 - ii. use only dosimeters with current calibrations traceable to a standards dosimetry laboratory.

Monitoring and measurement

10. The managing entity must establish and maintain:
- a. a programme of continuous individual monitoring whenever appropriate, adequate and feasible, which is sufficient to assess occupational exposures for workers who usually work in a controlled area or who may receive a dose exceeding 10 percent of the dose limits
 - b. a programme of workplace monitoring that is sufficient to:
 - i. evaluate radiation conditions in all workplaces
 - ii. assess exposures in controlled areas and supervised areas that are not assessed under clause 10(a)
 - iii. review the classification of controlled areas and supervised areas
 - c. a monitoring programme for all workers who could be subject to exposure due to contamination, which is sufficient to:
 - i. demonstrate the effectiveness of the measures for protection and safety
 - ii. assess intakes of radionuclides and if significant calculating the committed effective doses

- d. programmes of source monitoring or environmental monitoring that are sufficient to assess public exposure arising from radiation equipment under the responsibility of the managing entity
 - e. a capability that is sufficient to monitor unexpected increases in radiation levels due to an incident attributed to a source or facility for which the managing entity is responsible
 - f. a programme to monitor areas after radiopharmaceuticals have been used to ensure that all contaminated articles have been appropriately disposed of and that surface contamination levels are less than 3 Bq/cm²
 - g. other monitoring or measurement programmes as necessary to verify compliance with the requirements in this code.
11. In order to satisfy the monitoring and measurement requirements in clause 10 the managing entity must:
- a. use appropriate monitoring equipment
 - b. for continuous individual monitoring under clause 10(a), use an external service or internal capability only if that service or capability:
 - i. is approved by the Director
 - ii. returns results to the managing entity within 20 working days of receiving all necessary raw information.
12. The managing entity must:
- a. obtain previous dose records
 - b. maintain records of all monitoring and verification of compliance including:
 - i. records of occupational exposure during and after the worker's working life, at least until the worker attains or would have attained the age of 75 years, and for not less than 30 years after ceasing work where the worker was subject to occupational exposure
 - ii. records and estimated doses to members of the public
 - iii. records of the tests and calibrations carried out
 - c. provide records of occupational exposure to:
 - i. individual workers in respect of their own exposure
 - ii. subsequent employers of workers, subject to satisfying confidentiality criteria
 - iii. the Director on request or, if the managing entity is no longer able to maintain records as required under clause 12(b)

- d. provide records of source monitoring and environmental monitoring to assess public exposure to:
 - i. members of the public on request
 - ii. the Director on request
 - iii. the Director immediately, if any levels exceed operational limits and conditions relating to public exposure or there is a significant increase in dose rate that could be attributed to the authorised practice.

Incidents, accidents and emergencies

- 13. The managing entity must:
 - a. take all practicable steps to minimise the likelihood of accidents including, a multilevel system of sequential, independent provisions for protection and safety, commensurate with the likelihood and magnitude of potential exposures
 - b. take timely action to mitigate the consequences of any accident that does occur and restore radiation equipment to a safe condition
 - c. promptly investigate any incident, including by:
 - i. calculating or estimating doses a person has received and, if applicable, the dose distribution within them
 - ii. identifying corrective actions required to prevent a recurrence
 - d. implement all corrective actions identified in clause 13(c)(ii)
 - e. keep a written record of the incident, including the:
 - i. cause or suspected cause
 - ii. calculations made under clause 13(c)(i)
 - iii. corrective actions identified under clause 13(c)(ii)
 - iv. details of the implementation of corrective actions under clause 13(d)
 - f. ensure that the referring practitioner and the patient (or the patient's legal representative) are informed of any unintended medical exposure
 - g. promptly notify any reportable incident to the Director.
- 14. If the safety assessment required by clause 3 indicates that there is a reasonable likelihood of an emergency affecting either workers or members of the public,

the managing entity must prepare an emergency plan for the protection of people and the environment including:

- a. arrangements for promptly identifying an emergency
- b. determining the correct level of emergency response
- c. provision for individual monitoring, area monitoring and arrangements for medical treatment
- d. arrangements for assessing and mitigating any consequences of an emergency.

Records

15. The managing entity must maintain adequate records, and make them available as necessary, including:
 - a. the delegation of responsibilities of the managing entity and the radiation practitioner
 - b. the names of all people with responsibility for protection and safety, including details of their specialisation, qualifications, education and training
 - c. results of calibrations and periodic checks of physical and clinical parameters selected during treatment of patients
 - d. dosimetry of patients
 - e. local assessments and reviews relating to diagnostic reference levels
 - f. the types of radiopharmaceutical administered and their activity
 - g. the quality assurance programme
 - h. information necessary:
 - i. for the retrospective assessment of doses
 - ii. to enable the traceability of radiopharmaceutical preparations if they fail
 - 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. radioactive waste that is generated, stored, transferred or disposed of
 - l. exemptions from this code granted under section 86(3) of the Act.

Quality assurance

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

- a. measuring the physical parameters of radiation equipment, including calibrating output in terms of appropriate quantities using protocols established by the American College of Radiology, Australian and New Zealand Society of Nuclear Medicine or that are otherwise internationally accepted, made:
 - i. at the time it accepts and commissions the equipment, before practitioners use it clinically on patients
 - ii. periodically after that first check
 - iii. after any major maintenance procedure that could affect the protection and safety of patients
 - iv. after installing any new software or modifying any existing software that could affect the protection and safety of patients
 - b. performing quality control tests on ancillary equipment and personal protective equipment
 - c. adopting internationally accepted tolerance limits established by the American College of Radiology, Australian and New Zealand Society of Nuclear Medicine or that are otherwise internationally accepted for the physical parameters mentioned in sub-clause 16(a), and implementing corrective actions if measured values fall outside those tolerance limits
 - d. verifying the appropriateness of physical and clinical factors used in radiation procedures
 - e. maintaining records of relevant procedures and results
 - f. periodically checking the calibration and conditions of operation of dosimetry equipment and monitoring equipment.
17. The managing entity must ensure that regular internal or external independent audits are made of the quality assurance programme for medical exposures.
18. The managing entity must ensure that:
- a. radiation reviews are performed periodically by radiation practitioners in cooperation with medical radiation technologists and medical physicists, to investigate and critically review the current practical application of the radiation protection principles of justification and optimisation for radiation procedures
 - b. local assessments are made at regular intervals for those radiation 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 radiation procedure, typical doses or activities:
 - i. exceed the relevant diagnostic reference level
 - ii. fall substantially below the diagnostic reference level, and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.

Radiation practitioner

General

19. The radiation practitioner:
- a. is responsible for overall protection and safety in the planning and delivery of the medical exposure
 - b. may, in order to satisfy the responsibility in clause 19(a), delegate functions to a nuclear medicine technologist, radiation therapist, medical physicist or otherwise¹
 - 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

20. 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, breast-feeding 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 radiation procedures
 - vi. relevant national or international referral guidelines
 - c. for any procedure to detect disease in an asymptomatic person that is not part of a health screening programme, justify the procedure specifically for the individual in accordance with any guidelines of relevant professional bodies or the health authority.

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

Optimisation of protection and safety

21. The radiation practitioner must, in consultation as appropriate with medical physicists and operators, ensure that protection and safety is optimised for each medical exposure:
 - a. by using appropriate pharmaceuticals
 - b. for diagnostic radiation procedures by adopting techniques and parameters to deliver a medical exposure that is the minimum necessary to fulfil the clinical purpose of the radiation procedure, taking into account relevant norms of acceptable image quality and of relevant diagnostic reference levels
 - c. for therapeutic radiation procedures by selecting and administering the appropriate activity for each patient, so that the radioactivity is primarily localised in the organ(s) of interest, while the radioactivity in the rest of the body is kept as low as reasonably achievable
 - d. by using constraints in any procedure in which an individual:
 - i. acts as a comforter/carer
 - ii. is subject to exposure as part of a programme of research
 - e. by minimising the need for repeat procedures
 - f. by maximising the image quality per administered activity.
22. 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. therapeutic radiation procedures
 - e. exposure of the embryo or fetus, in particular, during radiation procedures in which the abdomen or pelvis of a pregnant patient is exposed to the useful radiation beam, for radiopharmaceuticals that would cross the placenta or accumulate in a material bladder or could otherwise receive a significant dose
 - f. exposure of a breast-fed infant as a result of a female patient having undergone a radiation procedure with radiopharmaceuticals.

Release of Patients

23. The radiation practitioner must ensure that no patient who has undergone a therapeutic radiation procedure is discharged from the facility until:
 - a. either:
 - i. the activity of radionuclides in the patient and the dose rate at 1 metre from the patient are less than the levels set out in Appendix 3, or
 - ii. the radiation practitioner or a medical physicist has approved the discharge
 - b. the patient or the legal guardian of the patient is provided with:
 - i. written instructions for keeping doses to persons in contact with or in the vicinity of the patient as low as reasonably achievable and for avoiding the spread of contamination
 - ii. information on the radiation risks.

Other parties

Referring practitioner

24. The referring practitioner must:
 - a. provide sufficient information on the clinical context of the procedure in the referral
 - b. cooperate with the radiation practitioner as part of the justification of the procedure.

Manufacturer/supplier

25. The manufacturer/supplier must:
 - a. supply well-designed, well-manufactured and well-constructed ancillary equipment and protective equipment that provides for protection and safety in accordance with the requirements of this code
 - b. supply radiopharmaceuticals that are manufactured in accordance with good manufacturing practice and fit for their intended purpose.
26. The manufacturer/supplier must make suitable arrangements with managing entities to share information on use and operating experience that may be important for protection and safety.

Appendix 1: Cross-reference to Radiation Safety Act 2016

As required by section 87(1) of the Radiation Safety Act 2016 clauses in this code apply to the fundamental requirements in sections 9–12 of the Act as follows:

Section in Act	Clauses in code
9(1)	1–3, 5–8, 19, 20, 24
9(2)	1, 3–19, 20–23
9(3)	1, 3–8, 10–18
10(1)	1, 3–8, 15–18, 25–26
10(2)	13–14
10(3)	1, 3–8, 15–18, 25–26
11	4–5
12	3–8, 13–18

Appendix 2:

Training requirements

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

Abbreviations used in this appendix

Parties

NM	nuclear medicine specialist
MDN	other medical specialists using nuclear medicine
NMT	nuclear medicine technologist
RT	radiation therapist
REF	health practitioner referring patients for medical exposure
MP	medical physicist
RSO	radiation safety officer

Level of knowledge

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

Equivalences

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

MDN	Health practitioners registered in the radiation oncology scope of practice by the Medical Council of New Zealand
NMT	Health practitioners registered in the nuclear medicine technologist scope of practice by the Medical Radiation Technologists Board
RT	Health practitioners registered in the radiation therapist scope of practice by the Medical Radiation Technologists Board
MP	Persons who are registered in the nuclear medicine or radiation oncology specialties of medical physics by the Australasian College of Physical Scientists and Engineers in Medicine

Appendix 3:

Release of Patients

Radionuclide	Activity (GBq)	Dose rate at 1 m (mSv/h)
Au-198	3.5	0.21
Ga-67	8.7	0.18
I-123	6.0	0.26
I-131	1.2	0.07
In-111	2.4	0.2
P-32	*	*
Re-186	28	0.15
Re-188	29	0.20
Sm-153	5–26	0.06–0.3
Sr-89	*	
Tc-99m	28	0.58
Tl-201	16	0.19
Y-90	*	
Yb-169	0.37	0.02

* No value given because of minimal exposures to the public.