

# **Code of Practice for Nuclear Medicine**

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**Draft for consultation**

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# Contents

<b>Introduction</b>	<b>1</b>
Purpose	1
Scope	1
Commencement	1
Exemptions	1
Contact	1
<b>Roles and responsibilities</b>	<b>2</b>
<b>Definitions</b>	<b>3</b>
<b>Managing entity</b>	<b>6</b>
General	6
Facilities	7
Equipment and radiopharmaceuticals	8
Radiological procedures	9
Training	10
Occupational and public dose monitoring	11
Accident prevention and mitigation	12
Calibration and dosimetry	13
Quality assurance for medical exposures	13
Local rules and protocols	14
Records	15
<b>Radiological practitioner</b>	<b>16</b>
General	16
Justification	16
Optimisation of protection and safety	17
<b>Other parties</b>	<b>19</b>
Referring practitioner	19
Manufacturer/supplier	19
Workers	19
Servicing engineer	20
<b>Appendices</b>	
Appendix 1: Dose limits	21
Appendix 2: Safety assessments	22
Appendix 3: Cross-reference to Radiation Safety Act 2016	23
<b>Consultation submission</b>	<b>25</b>
Consultation questions	26



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# Introduction

## Purpose

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). Its purpose is to set out the technical requirements necessary to comply with the fundamental requirements in sections 9 to 12 of the Act. Appendix 3 sets out cross-references between clauses in this code and those fundamental requirements. The requirements in this code do not limit the general nature of the fundamental requirements.

## Scope

This code applies to all activities associated with the administration of unsealed radiopharmaceuticals to patients to diagnose or treat disease, or for clinical or pre-clinical research. 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, transport, storage, 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.

## Commencement

This code comes into force on 7 March 2017.

## Exemptions

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

1. it is not practicable in the circumstances for the person to comply with the provision
2. compliance with the fundamental requirement to which the provision relates can be achieved in another way (see Appendix 4 for the fundamental requirements of the Act to which clauses in the code relate).

## Contact

The Director's contact details are:

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# Roles and responsibilities

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

**Ethics Committee** – the committee that approves programmes of biomedical research, including, in particular, the justification of medical exposure of volunteers as part of that programme.

**Managing entity** – the legal entity that manages or controls radiation sources. This could be, for example, a district health board, or an independent company providing nuclear medicine services. The managing entity is responsible for setting up and implementing the technical and organisational requirements for the protection and safety of the practices and sources for which they hold a source licence.

**Manufacturer/supplier** – the person who (1) manufactures, produces, distributes, sells, exports or imports radiopharmaceuticals, and/or (2) designs, manufactures, produces, constructs, assembles, installs, distributes, sells, exports or imports radiological equipment or ancillary equipment that generates ionising radiation and develops software that could influence the delivery of the medical exposure.

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

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

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

**Radiological 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 in a given specialty. This could include, for example, a nuclear medicine specialist, radiologist, cardiologist, or radiation oncologist.

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

**Servicing engineer** – a person who has expertise in installing, servicing and maintaining radiological equipment. Although this person's activities will normally require them to hold a user licence under the Act, such a licence is granted on the basis that the person can safely use the equipment. Their competence as a servicing engineer must be separately assessed by the managing entity.

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# Definitions

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

**Accident** – any 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. In the case of **medical exposures** these include exposure of the wrong individual, tissue or organ arising from diagnostic **radiological procedures**; any therapeutic **radiological 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 **radiological 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 **radiological equipment**, failure of software or system failure, or error, mishap or other unusual occurrence with the potential for subjecting the **patient** to a **medical exposure** that is substantially different from what was intended.

**Ancillary equipment** – equipment other than **radiological equipment** or **protective equipment** that has an impact on the successful outcome of a **radiological procedure** such as equipment used for digital image display, test objects, liquid scintillation counters, well counters, activity meters, 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 **radiological procedure**.

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

**Diagnostic reference level** – a level established by the Director following consultation that is used to indicate whether, in routine conditions, the dose to the patient or the amount of radiopharmaceuticals administered in a specified **radiological procedure** is unusually high or unusually low for that procedure.

**Dose limit** – limits on **effective dose** and **equivalent dose** specified in Appendix 1.

**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 radiological emergencies and conventional emergencies such as fires, release of hazardous chemicals, storms or earthquakes.

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

**Facility** – the location at which nuclear medicine **radiological procedures** are performed. 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.

**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

**Justify** – determine that the expected benefits to individuals and to society from a radiological procedure outweigh the harm resulting from that procedure. Justifies, justified and justification have corresponding meanings.

**Medical exposure** – exposure to ionising radiation experienced by patients for the purposes of medical diagnosis, by **comforters and carers** while providing care, support, or comfort to patients undergoing **radiological 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**.

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

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

**Optimise** – the process of determining what level of protection and safety would result 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 is 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 as the recipient of a radiological procedure except as part of a programme of biomedical research.

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

**Potential exposure** – prospectively considered exposure that is not certain to be delivered but that may result from anticipated operational occurrence or accident at a source or due to an event or sequence of events of a probabilistic nature, including equipment faults and operating errors.

**Protection and safety** – the protection of people against exposure to ionising radiation, the safety of radiation sources, the prevention of accidents and the mitigation of consequences of accidents if they do occur.

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

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

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

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

**Radiological equipment** – equipment used to generate ionising radiation (including computed tomography equipment used as part of hybrid imaging systems) and to detect ionising radiation (including probes, gamma cameras and positron emission tomography scanners) and its associated software.

**Radiological procedure** – a procedure involving the use of **radiological equipment** or the administration of **radiopharmaceuticals** for medical diagnosis, therapy or research.

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

**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.

**Volunteer** – an individual who may be subjected to medical exposure as part of a programme of biomedical research.

**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.

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# Managing entity

## General

1. The managing entity must:
  - (a) assume prime responsibility for protection and safety, which cannot be delegated
  - (b) ensure that any delegation of tasks relating to the responsibility in clause 1(a) is fully documented and the delegate is authorised, capable and resourced sufficiently to carry out those delegations
  - (c) establish a management system that enhances protection and safety by:
    - (i) effectively integrating protection and safety into the overall management system of the organisation
    - (ii) making a commitment to protection and safety from the highest level of management at the facility, including by providing all required resources
    - (iii) promoting continuous improvement and a safety culture
  - (d) ensure that:
    - (i) all activities associated with radiological equipment and 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:
  - (a) conduct and document a safety assessment that satisfies the requirements in Appendix 2
  - (b) review and, if appropriate, update the safety assessment to ensure the technical specifications or conditions of use continue to be met when:
    - (i) significant modifications to the facility or to its operating procedures or maintenance procedures are envisaged
    - (ii) significant changes occur on the site that could affect the safety of the facility or of activities on the site
    - (iii) information on operating experience, or information about accidents and other incidents that could result in exposures, indicates that the current assessment might be invalid
    - (iv) any significant changes in activities are envisaged
    - (v) any relevant changes in guidelines or standards have been made or are envisaged.

# Facilities

## 3. The managing entity must:

- (a) in consultation with a medical physicist, provide facilities that:
  - (i) 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
  - (ii) contain 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.
  - (iii) have taps and soap dispenser 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
- (b) in consultation with a medical physicist or qualified expert in radiation protection, shield the facility with structural and ancillary protective barriers as appropriate, to ensure that expected doses to any person are as low as reasonably achievable and that rooms housing sensitive instruments maintain a sufficiently low background to avoid interference
- (c) verify and document the adequacy of structural and ancillary protective barriers of new facilities before clinical use, when the intended use of a room changes, radionuclides or activities handled change, radiological equipment is upgraded, underlying procedures or patient workload changes, or surrounding room occupancy is altered
- (d) designate and physically delineate:
  - (i) as controlled areas, all rooms for the preparation, injection, storage and decay of radiopharmaceuticals; imaging rooms with radiopharmaceutical dispensing equipment; waiting rooms dedicated to patients who have been injected with radiopharmaceuticals; rooms for patients undergoing radiopharmaceutical therapy; and rooms with hybrid equipment that generates X-rays
  - (ii) as controlled areas, any other areas if specific protection measures and safety provisions are or could be required for controlling exposures in normal working conditions, and preventing or limiting the extent of potential exposures
  - (iii) as supervised areas, any areas not already designated as controlled areas if occupational exposure conditions need to be kept under review, even though specific protection measures or safety provisions are not normally needed
- (e) erect and maintain prominently displayed signs in appropriate languages and/or warning lights:
  - (i) prohibiting unauthorised entry to controlled areas and supervised areas
  - (ii) warning of the possibility of exposure to radiation at all points of uncontrolled access to controlled areas and supervised areas

- (iii) in areas that patients may be in (including waiting rooms and change cubicles), requiring patients who are to undergo a radiological procedure to notify staff if they are or may be pregnant or if they are breastfeeding
- (iv) in rooms designated for patients undergoing radiopharmaceutical therapy, requesting patients to flush the toilet at least twice and to wash their hands
- (f) ensure that floors, walls and other surfaces in areas where radiopharmaceuticals are used or stored and in rooms designated for patients undergoing radiopharmaceutical therapy are covered with smooth, continuous non-absorbent materials that can be easily cleaned and decontaminated.
- (g) provide an operator console for rooms where radiological equipment is used that:
  - (i) is shielded so that no further protection is required for the operator
  - (ii) enables the operator to clearly observe and communicate with the patient at all times during the radiological procedure
  - (iii) provides the same level of protection in the viewing window as is provided for the rest of the console
- (h) provide for the proper display and interpretation of images in a room specifically designed for that purpose.

## Equipment and radiopharmaceuticals

4. The managing entity must:
  - (a) provide, maintain, test and regularly service radiological equipment, protective equipment and ancillary equipment, in consultation with a medical physicist so that it:
    - (i) is fit for its intended purpose
    - (ii) fulfils its design requirements for protection and safety
  - (b) ensure, in consultation with a medical physicist that:
    - (i) radiological equipment that generates X-rays satisfies the radiological equipment requirements in clause 3 of *ORS C1: Code of practice for diagnostic and interventional radiology*
    - (ii) radiopharmaceuticals, whether manufactured onsite or obtained from an external supplier, are manufactured in accordance with good manufacturing practice and are fit for their intended purpose
    - (iii) protective equipment retains its shielding integrity
    - (iv) the protective value of protective equipment is clearly displayed on the equipment
    - (v) sealed sources are subject to leak tests before their first use and every two years after that
  - (c) maintain an accurate inventory of all radiological equipment, including its location, details and unique identifying information
  - (d) maintain a record of maintenance for each item of radiological equipment, 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

- (e) take all reasonable steps to prevent damage or unauthorised access to, or loss of radiological equipment or radioactive sources
- (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 overshoes and gloves
  - (ii) decontamination materials for the affected areas, including absorbent materials for wiping up spills
  - (iii) decontamination materials for people
  - (iv) warning notices and barrier tape
  - (v) portable monitoring equipment
  - (vi) bags for waste, together with tape, labels and pencils
- (h) transfer management and control of radiopharmaceuticals and radiological equipment or ancillary equipment that generates ionising radiation only to people who are authorised to assume management and control under the Radiation Safety Act 2016.

## **Radiological procedures**

5. The managing entity must prevent radiological procedures for any purpose other than medical diagnosis or medical therapy.
6. For each radiological procedure the managing entity must ensure that:
  - (a) a radiological practitioner takes overall responsibility for protection and safety including justification and optimisation of protection and safety
  - (b) any delegation of a radiological practitioner responsibility is documented
  - (c) sufficient personnel are available to successfully perform the procedure
  - (d) all people performing functions are:
    - (i) authorised by the managing entity for the specific radiological equipment to be used
    - (ii) permitted to perform those functions under the Health Practitioners Competence Assurance Act 2003
    - (iii) licensed as necessary under the Radiation Safety Act 2016
  - (e) patients are subject to medical exposure only if:
    - (i) the procedure has been requested by a referring practitioner and information on the clinical context has been provided, or it is part of a health screening programme
    - (ii) the procedure has been justified by the radiological practitioner in consultation as appropriate with the referring practitioner, or it is part of a health screening programme

- (iii) the patient or the patient's legal representative has been informed of the expected diagnostic benefits as well as the risks
  - (f) volunteers are subject to medical exposure only if:
    - (i) the medical exposure has been approved by an ethics committee
    - (ii) dose constraints and other conditions imposed by the ethics committee are satisfied
  - (g) comforters and carers are subject to medical exposure only if they have received, and indicated an understanding of, relevant information on radiation protection and on the radiation risks.
7. The managing entity must, at the time of discharge, ensure the patient or the legal guardian of the patient is provided with written instructions on how to keep doses to members of the public and comforter/carers as low as reasonably achievable.
8. The managing entity must ensure that:
- (a) radiological reviews are performed periodically by radiological practitioners in cooperation with nuclear medicine technologists and medical physicists to investigate and critically review the current practical application of the radiation protection principles of justification and optimisation for radiological procedures
  - (b) local assessments are made at regular intervals not exceeding three years 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 diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.

## **Training**

9. The managing entity must:
- (a) ensure that all people with responsibilities for protection and safety:
    - (i) are appropriately specialised and qualified and have continuing education and training so that they can perform their duties competently, including responsibilities for radiation protection of patients
    - (ii) receive adequate information on health risks due to occupational exposure in normal operation, anticipated operational occurrences and accident conditions
    - (iii) understand their roles, responsibilities and functions as they relate to protection and safety
  - (b) provide workers who could be involved in an emergency with appropriate information and instruction/training and periodic retraining for protection and safety
  - (c) communicate decisions to workers regarding protection and safety

- (d) provide workers who may enter controlled areas or supervised areas, or who may undertake emergency duties, with appropriate information on risk to the embryo or foetus due to exposure of a pregnant woman, and on the importance of advising the managing entity if the worker thinks she may be pregnant.

## Occupational and public dose monitoring

10. The managing entity must monitor and assess occupational exposures in consultation with a medical physicist:
  - (a) by continuous individual monitoring of personal dose equivalent at a depth appropriate to the application,  $H_p(d)$ , for any worker who usually works in controlled areas or may receive a dose exceeding 10 percent of the dose limits
  - (b) by identifying workers at risk of surface or internal contamination, through monitoring of hands after protective gloves have been removed, and monitoring the thyroid to assess the uptake of radioiodine and calculating the committed effective dose as part of the worker's total effective dose
  - (c) if individual monitoring under clause 10(a)(i) is inappropriate, inadequate or not feasible, by assessing ambient dose equivalent,  $H^*(10)$  through the programme of workplace monitoring.
11. The managing entity must conduct workplace monitoring in consultation with a medical physicist by:
  - (a) systematically monitoring external radiation and surface contamination of laboratories and all areas in which radiopharmaceuticals are used or stored including:
    - (i) all working surfaces, tools, equipment, floors, and any items removed from these areas
    - (ii) workstations, ventilation systems and drain systems during maintenance
    - (iii) protective and personal clothing when leaving a controlled area
    - (iv) clothing, bedding and utensils used by radiopharmaceutical therapy patients
  - (b) periodic monitoring of external radiation and surface contamination in controlled and supervised areas
  - (c) surveying external dose rate and removable surface contamination of packages containing radioactive material if they are damaged on arrival.
12. The managing entity must monitor and assess public exposures arising from the facility to ensure such exposures do not exceed the dose limits and keep records for not less than 10 years.
13. The managing entity must:
  - (a) ensure individual dosimeters are only worn in the facility for which they were issued
  - (b) set investigation levels for occupational doses and workplace monitoring
  - (c) investigate doses that exceed those investigation levels
  - (d) provide workers with access to records of their occupational exposure under clause 10(a)(i) or the results of the workplace monitoring programme under clause 10(a)(iii)

- (e) maintain records of occupational exposure during and after the worker's working life, at least until the former worker attains or would have attained the age of 75 years, and for not less than 30 years after cessation of work in which the worker was subject to occupational exposure
  - (f) provide the records referred to in clause 13(e) to the Director if the managing entity is no longer able to maintain the records
  - (g) promptly notify the Director if a dose limit is exceeded.
14. To satisfy the monitoring requirement in clause 10, the managing entity must only use an external service or internal capability if that service or capability:
- (a) is approved by the Director
  - (b) returns results of monitoring to the managing entity within 20 working days of receiving all necessary raw information.

## **Accident prevention and mitigation**

15. The managing entity must:
- (a) take all practicable steps, including defence in depth, to minimise the likelihood of accidents
  - (b) take timely action to mitigate the consequences of any accident that does occur
  - (c) promptly investigate any accident including by:
    - (i) calculating or estimating doses received by, and if applicable the dose distribution within, any person
    - (ii) determining corrective actions required to prevent a recurrence
  - (d) implement all corrective actions identified in clause 15(c)(ii)
  - (e) keep a written record of the accident, including the:
    - (i) cause
    - (ii) calculations made under clause 15(c)(i)
    - (iii) corrective actions identified under clause 15(c)(ii)
    - (iv) details of the implementation of corrective actions under clause 15(d)
  - (f) promptly notify the Director if the accident results in a significant unintended or accidental exposure including, but not limited to:
    - (i) any diagnostic radiological procedure with a dose 10 times the intended dose, or in the case of hybrid imaging, twice the intended dose
    - (ii) any treatment with a dose deviating more than 10 percent from the intended dose, or that could lead to unduly severe secondary effects
    - (iii) exposure or a dose where none was intended
    - (iv) any inadvertent exposure of an embryo or foetus during a radiological procedure
    - (v) any accident caused by equipment failure.

# Calibration and dosimetry

16. With the active participation of medical physicists, the managing entity must ensure that:
  - (a) all sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted protocols
  - (b) calibrations are carried out at the time of commissioning radiological equipment prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals of no more than two years
  - (c) unsealed sources for nuclear medicine procedures are calibrated at the time of administration and are also checked for radioactive impurities when these may be present
  - (d) calibrations of all dosimeters used for dosimetry of patients and for the calibration of sources are traceable to a standards dosimetry laboratory and are conducted using calibrated reference sources that cover the energy range used in clinical practice at intervals not exceeding two years
  - (e) calibrations of survey meters and contamination monitors used for workplace monitoring are in appropriate operational quantities, traceable to a standards dosimetry laboratory, and conducted at intervals not exceeding two years.
17. The managing entity must ensure that dosimetry of patients is performed and documented by or under the supervision of a medical physicist using calibrated dosimeters and following internationally accepted protocols, including dosimetry to determine:
  - (a) typical doses to patients for diagnostic radiological procedures that are commonly performed
  - (b) typical absorbed doses to patients for therapeutic radiological procedures.

# Quality assurance for medical exposures

18. With the active participation of radiological practitioners, nuclear medicine technologists and medical physicists, the managing entity must establish a comprehensive programme of quality assurance for medical exposures commensurate with the risks, including:
  - (a) measurements of the physical parameters of radiological equipment, including calibration of output in terms of appropriate quantities using internationally accepted protocols, made:
    - (i) at the time of acceptance and commissioning of the equipment prior to its clinical use on patients
    - (ii) periodically thereafter
    - (iii) after any major maintenance procedure that could affect protection and safety of patients
    - (iv) after any installation of new software or modification of existing software that could affect the protection and safety of patients
  - (b) the adoption of internationally accepted tolerance limits for the physical parameters mentioned in clause 18(a), and the implementation of corrective actions if measured values fall outside those tolerance limits

- (c) verification of the appropriate physical and clinical factors used in radiological procedures
  - (d) maintaining records of relevant procedures and results
  - (e) periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment.
19. The managing entity must ensure that regular internal or external independent audits are made of the programme of quality assurance for medical exposures.

## **Local rules and protocols**

20. The managing entity must maintain and publish written protocols in consultation with radiological practitioners, nuclear medicine technologists and medical physicists:
- (a) to establish appropriate communication between individuals involved in the referral of patients and the justification and authorisation of procedures to ensure that the benefits of those procedures exceed the detriment
  - (b) to correctly identify patients and the procedures they are to undergo
  - (c) to ensure the timely reporting of incidents
  - (d) to report equipment faults
  - (e) to minimise unnecessary exposure to:
    - (i) the embryo or foetus
    - (ii) infants breastfeeding from a patient who has been administered a radiopharmaceutical
    - (iii) any person who may need to handle the body of a patient who dies after they were administered a radiopharmaceutical
  - (f) for receiving shipments of radioactive material
  - (g) for routine dispensing procedures
  - (h) for routine radiopharmaceutical preparations
  - (i) for each diagnostic and therapeutic procedure
  - (j) to minimise exposure from external radiation and contamination and spread of contamination
  - (k) for the release of patients who have undergone therapeutic radiological procedures
  - (l) for operating parameters specific for each piece of radiological equipment to be used for common diagnostic radiological procedures, including size-specific written protocols for children
  - (m) to ascertain the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or foetus so that this information can be considered in the justification of the radiological procedure and the optimisation of protection and safety
  - (n) for possibly pregnant staff
  - (o) for all quality control tests, including frequency and tolerance limits

- (p) for monitoring of staff doses and investigation of doses that exceed investigation levels
- (q) for the conduct and frequency of the independent audit required by clause 19
- (r) for the conduct and frequency of the radiological review required by clause 8(a)
- (s) for the use of protective equipment when structural shielding and administrative controls alone cannot afford the required level of occupational radiation protection
- (t) for the management of radioactive waste and discharges of radioactive material
- (u) for the transport of radioactive material
- (v) detailing arrangements for events considered in the safety assessment such as damage to a radionuclide generator or a medical emergency involving a patient who has received therapeutic radiopharmaceuticals.

## Records

21. The managing entity must maintain adequate records of:
- (a) delegation of tasks by the managing entity (clause 1(a)) and the radiological practitioner (clause 6(b))
  - (b) training (clause 9)
  - (c) results of calibrations and periodic checks of physical and clinical parameters (clause 16)
  - (d) dosimetry of patients (clause 17)
  - (e) radiological reviews (clause 8(a))
  - (f) local assessments and reviews relating to diagnostic reference levels (clause 8(b) and (c))
  - (g) the quality assurance programme (clauses 18 and 19)
  - (h) the types of radiopharmaceutical administered and their activity (clause 27(c))
  - (i) exposure of volunteers (clause 6(f))
  - (j) investigations of unintended or accidental medical exposures (clause 15)
  - (k) shielding in the facility, including the medical physicist's report on the adequacy of that shielding (clause 3)
  - (l) inventory and maintenance of radiological equipment and sources (clause 4)
  - (m) inventory of all radioactive waste that is generated, stored, transferred or disposed of (clause 31(c))
  - (n) exemptions from this code granted under section 86(3) of the Act.

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# Radiological practitioner

## General

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

## Justification

23. Before starting a radiological procedure, the radiological practitioner must in consultation as appropriate with the referring practitioner, justify the medical exposure taking into account, in particular for paediatric, breast-feeding or possibly pregnant patients:
- (a) the appropriateness of the request
  - (b) the urgency of the radiological procedure
  - (c) the characteristics of the medical exposure
  - (d) the characteristics of the individual patient
  - (e) relevant information from the patient's previous radiological procedures and clinical history
  - (f) relevant national or international referral guidelines
24. Clause 23 does not apply to radiological procedures justified by the Ethics Committee as part of an approved health screening programme.
25. If the procedure involves an asymptomatic individual for early detection of disease (but not as part of an approved health screening programme), the radiological practitioner must:
- (a) justify the procedure specifically for that individual:
    - (i) in consultation with the referring practitioner
    - (ii) in accordance with relevant guidelines

- (b) inform the patient in advance of the expected benefits, risks and limitations of the procedure.
26. For any radiological procedure involving a comforter/carer, the practitioner must:
- (a) make reasonable enquiries to find out whether the comforter/carer is pregnant and prevent any person who is or may be pregnant from fulfilling this role
  - (b) fully inform the comforter/carer of the radiation risks and check that they understand
  - (c) ensure no part of the comforter/carer is exposed to the primary radiation beam
  - (d) ensure that the comforter/carer wears a lead apron.

## **Optimisation of protection and safety**

27. The radiological practitioner must in consultation as appropriate with medical physicists and operators ensure that operational aspects of optimisation of protection and safety for patients undergoing radiological procedures are implemented by:
- (a) correctly identifying the patient and the procedure
  - (b) for diagnostic radiological procedures, adopting techniques and parameters, including equipment settings and features issued for the procedure by the managing entity or, if no such factors have been issued, applying techniques and parameters that keep the dose to the patient as low as reasonably achievable consistent with obtaining the desired clinical outcome for which the procedure was undertaken.
  - (c) for therapeutic radiological procedures, 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) minimising the need for repeat procedures
28. The radiological practitioner must ensure that particular aspects of the optimisation of protection and safety for patients undergoing radiological procedures are considered for:
- (a) paediatric patients subject to medical exposure
  - (b) individuals subject to medical exposure as part of an approved health screening programme
  - (c) volunteers subject to medical exposure as part of a programme of biomedical research
  - (d) therapeutic radiological procedures
  - (e) exposure of the embryo or foetus, in particular for radiological 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.
29. The radiological practitioner must keep doses arising from occupational exposure as low as reasonably achievable, including by:
- (a) if the radiological procedure is to take place outside an existing controlled area, designating and physically delineating a temporary controlled area

- (b) restricting access to the controlled area (whether declared under clause 3(d) or under clause 29(a)) to only those who need to be present
  - (c) for those radiological procedures where staff do not need to be in the controlled area during an exposure, requiring all attending staff to position themselves in the appropriately shielded areas
  - (d) using comforters/carers in preference to workers if a patient needs to be held or comforted during a radiological procedure
  - (e) ensuring no worker is exposed to the primary radiation beam
  - (f) using protective equipment in any case where shielding in a controlled area is insufficient to keep doses arising from occupational exposure as low as reasonably achievable
  - (g) maintaining barriers and shielded doors in a closed or protected position during exposures
  - (h) ensuring that all persons involved in the performance of image guided interventional procedures follow the local rules and protocols established by the managing entity for minimising occupational exposure arising from these procedures.
30. The radiological practitioner must keep doses arising from public exposure as low as reasonably achievable by:
- (a) preventing access to controlled areas by members of the public during a radiological procedure unless their presence is necessary as a comforter or carer
  - (b) advising patients who have been administered radiopharmaceuticals about, as appropriate:
    - (i) measures to help eliminate residual radioactivity
    - (ii) restrictions on breastfeeding and physical contact with members of the public, especially those with increased radiosensitivity.
31. The radiological practitioner must, in consultation with medical physicists, ensure that operational aspects of optimisation of protection and safety are implemented by:
- (a) ensuring the release of each patient who has undergone a therapeutic radiological procedure will not result in doses to members of the public in excess of public dose limits
  - (b) applying dose constraints for comforter and carers and for volunteers of:
    - (i) 5 millisieverts (mSv) per event for adult comforter/carers
    - (ii) 1 mSv per event for child or pregnant comforters/carers
    - (iii) such level as may be set by the Ethics Committee for volunteers
  - (c) disposing of radioactive waste by:
    - (i) storage for decay, segregating radioactive waste based on the physical half-life of radionuclides and storing it for sufficient time to meet the criteria for clearance in Schedule 2 of the Act before disposing of it as non-radioactive waste, or
    - (ii) returning to the manufacturer, or
    - (iii) for excreta of therapy patients, through a continuously flowing sewerage system, or
    - (iv) in a manner approved by the Director.

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# Other parties

## Referring practitioner

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

## Manufacturer/supplier

33. The manufacturer/supplier of radiological equipment must:
- (a) supply well-designed, -manufactured and -constructed radiological equipment that:
    - (i) provides for protection and safety in accordance with the requirements of this code
    - (ii) meets engineering, performance and functional specifications
    - (iii) meets quality standards appropriate to the significance of systems and components, including software, for protection and safety
    - (iv) provides clear displays, gauges and instructions on operating consoles in appropriate languages
  - (b) provide information in appropriate languages on the proper installation and use of the radiological equipment and on its associated radiation risks, including performance specifications, instructions for operating and maintenance, and instructions for protection and safety
  - (c) supply all radiological equipment with all appropriate radiation protection tools as a default, rather than as optional extras
  - (d) supply radiopharmaceuticals that are manufactured in accordance with good manufacturing practice and fit for their intended purpose.
34. 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.

## Workers

35. All workers must:
- (a) comply with this code and any local rules and protocols issued by the managing entity under clause 20
  - (b) properly use monitoring equipment and protective equipment
  - (c) cooperate with the managing entity over protection and safety, and programmes for workers' health surveillance and programmes for dose assessment

- (d) provide information to the managing entity on their past and present work that is relevant for ensuring effective and comprehensive protection and safety for themselves and others
- (e) accept information, instruction and training in protection and safety to enable them to comply with this code
- (f) report circumstances that could adversely affect protection and safety to the managing entity.

## **Servicing engineer**

36. The servicing engineer must:

- (a) install and service radiological equipment competently so that it complies with the requirements in clause 4
- (b) cooperate with the managing entity to ensure that radiological equipment cannot be used clinically while it is being installed or serviced
- (c) ensure that all dosimeters used for dosimetry of patients and to measure the physical parameters of radiological equipment are calibrated at least every two years and that such calibrations are traceable to a standards dosimetry laboratory
- (d) after installing or servicing the equipment and before the equipment is used clinically, provide a written report to the managing entity:
  - (i) clearly identifying the equipment
  - (ii) describing the equipment fault (if any), the work done, parts replaced, adjustments made and any changes that may affect protection and safety
  - (iii) certifying that all radiation protection and safety features are in place and operating correctly
- (e) collaborate with the managing entity and medical physicists to ensure necessary quality control tests are completed successfully.

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# Appendix 1: Dose limits

## Occupational exposure

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

## Public exposure

3. For public exposure, including exposure of an embryo or a foetus in a female worker, the dose limits for ionising radiation are:
  - (a) an effective dose of 1 mSv in a year, or
  - (b) an equivalent dose to the lens of the eye of 15 mSv in a year, or
  - (c) an equivalent dose to the skin of 50 mSv in a year.

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# Appendix 2:

## Safety assessments

Safety assessments must consider the following aspects:

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

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# Appendix 3: 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)	1–2, 5–6, 8–9, 16–26, 32, 35
9(2)	1–4, 7–11, 13–14, 16–22, 27–31, 35
9(3)	1–3, 6, 8–14, 18–21, 35
10(1)	1–2, 4, 6, 8–9, 18–22, 33–36
10(2)	1–4, 6, 8–11, 13–16, 18–22, 35
10(3)	1–2, 4, 6, 8–9, 18–22, 33–36
11	2–4, 8–9, 18–21, 35
12	2–4, 8–9, 18–21, 35



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# Consultation submission

## Your details

This submission was completed by: (name) \_\_\_\_\_

Address: (street/box number) \_\_\_\_\_

(town/city) \_\_\_\_\_

Email: \_\_\_\_\_

Organisation (if applicable): \_\_\_\_\_

Position (if applicable): \_\_\_\_\_

## Additional information

I am, or I represent an organisation that is, based in:

New Zealand     Australia     Other (please specify):

I am, or I represent, a: (tick all that apply)

District health board                       Private health provider  
 Professional body                               Other institution, eg, university  
 Health practitioner                            Member of the public  
 Other (please specify):

## Privacy

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

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

Do not publish this submission.

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

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

## Please return this form to:

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

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

# Consultation questions

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

## Scope

1. The scope of the code relates to the use of unsealed radioactive material for the purpose of nuclear medicine. Is it appropriate to have a separate code for this?

Yes

No

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

## Roles and responsibilities

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

Yes

No

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

## Definitions

3. Are the definitions appropriate and comprehensive?

Yes

No

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

## Managing entity obligations

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

Yes

No

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

Yes

No

Please provide any comments below.

## Radiological practitioner obligations

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

Please provide any comments below.

## Other parties

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

Please provide any comments below.

## Additional comments

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

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

Yes

No

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