Te Kāwanatanga o Aotearoa
New Zealand Government

MANATŪ HAUORA
MINISTRY OF HEALTH

Code of Practice for Nuclear Medicine

ORS C2

2024

FOR PUBLIC CONSULTATION

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Contents

This consultation

This document sets out the revised Code of Practice for Nuclear Medicine: ORS C2 (revised C2). The Director for Radiation Safety (the Director) proposes to issue a further revised C2, with amendments and revocations, under **section 86** of the Radiation Safety Act 2016 (the Act). **Section 89(1)** of the Act allows the Director to amended or revoked a code of practice (code).

This revised C2 has been drafted following the review under **section 90(a)** of the Act, which requires the Director to review a code of practice once every five years.

Section 89(2) of the Act requires the Director to consult with any person who the Director reasonably considers is likely to be affected by a proposed amendment or revocation of a code. This consultation is under section 89(2) of the Act.

A submission form is included at the end of this document to help with this consultation process. The form is also available **online**. The form is intended as a guide only. You are welcome to submit any information that you consider to be relevant.

Your views matter

The current **Code of Practice for Nuclear Medicine: ORS C2** (current C2) came into force on 19 April 2019. Current C2 and any amendments made are **secondary legislation** under **sections 86(6)** and **89(4)** of the Act.

Current C2 applies to any person who 'deals with' a radiation source. The term 'deal with' is defined in **section 5** of the Act as: 'to manufacture, possess, control, manage, use, transport, store, export, import, sell, supply, or dispose of a radiation source; or to carry out any other activity or practice involving the radiation source'.

Those affected by the revised C2 include all regulated parties and other people and organisations with a professional interest in nuclear medicine.

The Ministry of Health – Manatū Hauora (the Ministry) will review all feedback received as part of this consultation and use it to inform amendments and revocations to the revised C2.

Summary of the proposed principal amendments in the revised C2

The Director's view is that the revised C2 represents an evolution in the framework established by the Act to protect the health and safety of people. The proposed changes are not expected to significantly increase the compliance burden on regulated parties.

The revised C2 has deletions, new clauses, replaced terms, changes to interpretations and rewordings. **Table 1** lists the principal proposed changes in the revised C2 and the main reasons for each change. Changes in the revised C2 compared with current C2 include the following.

- Amendments have been made to align with the recently reviewed Code of Practice for Diagnostic and Interventional Radiology: ORS C1. This includes the term 'the holder of a source licence', replacing the term 'managing entity'.
- The scope is narrowed by removing references to sealed radioactive material. The revised C2 applies only to unsealed radioactive material in nuclear medicine. Irradiating apparatus and sealed radioactive material are subject to other codes of practice.
- Clause 5(j) of the current C2, which applies to the disposal of radioactive material, has been rewritten as clause 6(j) and (k) in the revised C2. The reasons for this are discussed in **note 1** following Table 1 below.
- Clause 23 of the current C2, which applies to the release of patients following a therapeutic procedure, has been replaced by clause 21 'Discharge of a patient who has undergone therapy'. 'Appendix 3: Release of patients' has been deleted. The reasons for this are given in **note 2** following Table 1 below.
- Clause 24 'Referring practitioner' of current C2 has been deleted. The reasons for this are given in **note 3** following Table 1 below.

Table 1. Proposed amendments and deletions in the revised C2 and the main reasons for the changes

Section or clause	Principal amendments and deletions	Main reasons
Replacement of term 'delegate' used in current C2	The term 'delegate' used in the current C2 has been replaced in the revised C2 by the terms: 'duty' (clause 1(a)(v)), 'roles' (clauses 1(b) and 1(b)(i)), 'people' (clause 1(b)(ii)), 'roles and appointments' (clause 17(a)) and 'cooperate with and direct' (clause 22(b)).	Improved alignment with the Act.
Purpose and commencement	The phrase 'technical requirements necessary for a person who deals with' has replaced 'the operational information necessary'.	Improved alignment with the Act.
Scope	The phrase 'activities and practices' has replaced 'activities'.	Improved alignment with the Act.
	The revised C2 applies to activities and practices associated with the use of unsealed radioactive material in nuclear medicine. Activities and practices in nuclear medicine associated with irradiating apparatuses and sealed radioactive materials are subject to associated codes of practice. Consequently, clauses 5(c) and 5(d)(iv) have been deleted.	Clearer statement of requirements.
	The reference to 'deal with' has been expanded to fully include to all aspects given in the Act.	Improved alignment with the Act.
	A paragraph has been added stating that the fundamental requirements listed in the Act apply to every person who deals with a radiation source.	To avoid doubt.
	The term 'holder of a source licence' (HSL) has replaced the term 'managing entity'. The HSL is responsible at all times for managing and controlling each radiation source to which the licence applies.	Improved alignment with the Act. The HSL is a term used in **section 20** of the Act. This amendment has no effect on how the Director has identified responsibilities in the revised C2 compared with current C2.
Contact	This section has been deleted.	This information is most reliably accessed through the Ministry's web site.
Roles and responsibilities	The term 'Director for Radiation Safety' has been amended	Improved alignment with the Act.

Section or clause	Principal amendments and deletions	Main reasons
	The term 'health practitioner' has been added.	Improved alignment with the Act. Clearer statement of requirements.
	The term 'health professional' has been added.	Clearer statement of requirements.
	The term 'holder of a source licence' has been added. The interpretation of 'managing entity' has been deleted.	Improved alignment with the Act. Clearer statement of requirements.
	The term 'medical physics expert' (MPE) has replaced 'medical physicist'. The interpretation of an MPE includes an example of one mechanism for establishing the competence of an MPE.	Improved alignment with the term 'Qualified expert' used in the revised C2. Further recognises the role of an MPE in radiation protection of the patient.
	The term 'nuclear medicine technologist' has been deleted.	Clearer statement of requirements.
	The term 'user of unsealed radioactive material' has replaced 'operator'. **Section 21(3)** of the Act defines the meaning of 'use'.	Improved alignment with the Act. Clearer statement of requirements.
	An interpretation of the term 'person' has been added.	Clearer statement of requirements.
	The term 'radiation therapist' has been deleted.	Not used in the revised C2.
	The term 'radiopharmaceutical scientist' has been deleted.	Not used in the revised C2.
	The term 'health professional' has replaced 'health practitioner' in the interpretation of 'referring practitioner'.	A person other than a 'health practitioner' could legitimately request a radiological procedure.
	The term 'user of unsealed radioactive material' has been added.	Improved alignment with the Act. Clearer statement of requirements.
Interpretation Replaces 'definitions' (in the current C2)	The term 'interpretation' has replaced 'definitions' as the title of the section.	Improved alignment with the Act.
	The term 'absorbed dose' has been added.	Clearer statement of requirements.
	The term 'ambient dose equivalent' has been deleted.	Not used in the revised C2.
	The term 'area monitoring' has been added.	Clearer statement of requirements.

Section or clause	Principal amendments and deletions	Main reasons
	The terms 'baselines', 'remedial level' and 'suspension level' have been added. These additions support new clauses 18(d) and (e).	Clearer statement of requirements.
	The interpretation of 'committed equivalent dose' has been amended.	Clearer statement of requirements.
	The term 'constraint' has been amended. It no longer includes that the Director will establish or approve constraints.	The Director may establish a constraint for public exposure from sources in multiple places. If established, a constraint will be given in an associated compliance guide.
	The phrase 'diagnostic reference level' has been amended. It now includes the Director may establish national diagnostic reference levels. A new clause 10(d) requires the HSL to establish local diagnostic reference levels. The terms 'national diagnostic reference levels' and 'local diagnostic reference levels' have been added. Local diagnostic levels must be compared with national diagnostic levels where national diagnostic levels are available.	Clearer statement of requirements.
	The term 'place' has replaced 'facility'.	Improved alignment with the Act.
	The term 'health practitioner' is in the Roles and Responsibilities section of the revised C2.	Clearer statement of requirements.
	The term 'occupationally exposed person' has been deleted.	Term not used in the revised C2.
	The term 'overexposure of a person' has been added. This relates to the requirements for 'overexposure of a person' in **section 20(3)** of the Act.	Improved alignment with the Act. Clearer statement of requirements.
	The term 'planned exposure situation' has been amended.	Clearer statement of requirements.
	The term 'radioactive waste' has been added.	Improved alignment with the Act. Clearer statement of requirements.
	The term 'radiological equipment' has been added.	Clearer statement of requirements.

Section or clause	Principal amendments and deletions	Main reasons
	The term 'risk assessment' has replaced 'safety assessment'.	Clearer statement of requirements.
	The term 'underexposure of a patient' has been added.	Clearer statement of requirements.
	The term 'or volunteer' has been added to the interpretation of 'unintended medical exposure'.	Clearer statement of requirements.
General **Clause 1** (Clause 1 of the current C2)	A paragraph has been added associating clause 1 with the Act.	Improved alignment with the Act.
	Clause 1(a) has been deleted.	Improved alignment with the Act.
	The term 'procedures' has been included in clause 1(a)(iii).	Clearer statement of requirements.
	The term 'documenting the appointment' has been added to clause 1(a)(iv).	Clearer statement of requirements.
	Clause 1(a)(v) has replaced clause 1(b)(v).	Improved alignment with the Act. Clearer statement of requirements.
	Clause 1(b) has replaced clause 1(c).	Improved alignment with the Act. Clearer statement of requirements.
	Clauses 1(c) and (d) have replaced clause 1(d). A paragraph added in clause 1(d) associates the clause with the Act.	Improved alignment with the Act. Clearer statement of requirements.
	A new clause 1(e) requires the HSL to ensures that the referring practitioner provides necessary and sufficient information (also refer to clause 22(b)).	Clearer statement of requirements. Supports deletion of clause 24 'Referring practitioner' of current C2.
New clause 3	This new clause provides a requirement related to justification of occupational and public exposures.	Generally, occupational and public radiation exposure considerations in justification are not as prominent as the justification of a patient's radiological procedure. However, the HSL must still take account of the risk involved with occupational and public exposures.

Section or clause	Principal amendments and deletions	Main reasons
Risk assessment **Clause 4** Replaces 'risk assessment' (Clause 3 of the current C2)	The term 'risk' has replaced 'safety' in clause 3.	Clearer statement of requirements.
Places **Clause 5** Replaces 'facilities' (Clause 4 of the current C2)	The term 'places' has replaced 'facilities' in clause 4.	Improved alignment with the Act.
	The term 'background radiation interference with equipment' has been added to clause 5(a).	Clearer statement of requirements.
	Clauses 5(a), (c), (d) and (e) have replaced clauses 4(c) and (d). In clause 5(c)(ii) the requirement for an 'emergency shower' has been replaced by a requirement for 'where appropriate, a shower for the decontamination of a person contaminated with radioactive material'. Clause 5(e) has a requirement for radiation shielding to be approved by a MPE or another qualified expert.	Clearer statement of requirements.
	Clause 4(g) has been deleted. This requirement is in the interpretation of a 'controlled' and 'supervised area'.	Clearer statement of requirements.
	The term 'and others' has been added to clause 5(h)(ii).	Clearer statement of requirements.
	The term 'where needed' has replaced 'if long flush toilets are not used' in clause 5(h)(iv).	Clearer statement of requirements.
Unsealed radioactive material and equipment **Clause 6** (Clause 5 of the current C2)	The term 'unsealed radioactive material and equipment' has replaced 'radioactive sources and equipment 'as the title of the section'.	Clearer statement of requirements.
	Clause 5(c) has been deleted. Requirements applying to irradiating apparatuses are given in Code of Practice for Diagnostic and Interventional Radiology: ORS C1.	Clearer statement of requirements.
	Clause 5(d)(iv) has been deleted. Requirements applying to sealed radioactive sources are given in Code of Practice for Sealed Radioactive Material: ORS C12.	Clearer statement of requirements.

Section or clause	Principal amendments and deletions	Main reasons
	A new clause 6(e) has been added that requires the HSL to take corrective and preventive actions if a 'remedial level' or a 'suspension level' is exceeded.	Supports new 18(e) clause that require the HSL to identify and establish such values.
	Clauses 6(j) and 6(k) have replaced clause 5(j).	Refer to **note 1**.
Training and authorisation **Clause 7** (Clause 6 of the current C2)	A new clause 7(b) has replaced clause 6(b). Appendix 2 provides training requirements for a radiation safety officer. It also provides a syllabus to be used as the basis for other training. The HSL must establish training in consultation with a qualified expert.	Clearer statement of requirements. Training requirements for an authorisation under the Act are specified by the Director. These requirements can be obtained by application to the Director.
Policies, procedures and local rules **Clause 8** (Clause 7 of the current C2)	The term 'radioactive waste' has replaced 'discharge of waste material' in clause 8(c).	Clearer statement of requirements.
	Clause 7(l)(iii) and 'Appendix 3: Release of patients' have been deleted.	Refer to **note 2**.
Patient dosimetry **Clause 10** (Clause 9 of the current C2)	A requirement for the HSL to consult with a MPE has been added.	Clearer statement of requirements.
	The term 'common' has been deleted from clause 10(a).	Clearer statement of requirements.
	Clause 10(c) has replaced clause 9(b).	Clearer statement of requirements.
	A new clause 10(d) has a requirement for the HSL to establish, in consultation with an MPE, local diagnostic reference levels.	Clearer statement of requirements.
Monitoring and measurement **Clause 11** (Clause 10 of the current C2)	Clause 11(a) has requirements relating to a worker who occasionally works in a controlled area and may receive a significant dose. Clause 11(a) has replaced clause 10(a).	Clearer statement of requirements.
	The phrase 'and levels of radiation contamination' has been added to clause 11(b)(i).	Clearer statement of requirements.
	Clause 11(b)(ii) has replaced clause 10(b)(ii).	Clearer statement of requirements. Aligns clause 11(b) with clause 11(a).

Section or clause	Principal amendments and deletions	Main reasons
	Clause 10(b)(iii) has been deleted.	Clearer statement of requirements. Clause 5(g) requires the periodic review of designated areas.
	Clause 11(d) has replaced clause 10(d).	Clearer statement of requirements.
	Reference to '3 Bq/cm^{2}' has been removed from clause 11(f).	Clearer statement of requirements.
Clause 12 (Clause 11 of the current C2)	Clause 12(b) has replaced clause 11(b). Clause 12(b) has a new requirement that if an individual dose is likely to exceed three-tenths of a dose limit, the HSL must ensure that the provider of the dose monitor has a current accreditation to an appropriate standard.	Clearer statement of requirements. Application of a graded approach following **section 86(1)(b)** of the Act.
Clause 13 (Clause 12 of the current C2)	Clause 13(a) has replaced clause 12(a). The term 'to the extent practicable' has been added.	Clearer statement of requirement.
	Clause 13(c) has replaced clause 12(c). Clause 12(d) has been deleted.	Improved alignment with the Act. The Act includes powers for the Director to request information. In the case of an overexposure of a person, notification of the Director is referenced in clause 14 and 14(a). Other legislation requires information to be released on request from a member of the public.
Incidents, accidents and emergencies **Clause 14** (Clause 13 of the current C2)	Text has been added associating clause 14 to **section 20(3)** of the Act. This includes reference to 'overexposure of a person' as the term is applied in the Act.	Improved alignment with the Act. Clearer statement of requirement.
	A new clause 14(a) has been added. This requires the HSL to notify the Director as soon as practicable if an underexposure has occurred.	Clearer statement of requirement. This requirement relates to **section 9(1)** of the Act.
	Clause 13(g) has been deleted.	Improved alignment with the Act. **Section 20(3)(a)** of the Act provides a

Section or clause	Principal amendments and deletions	Main reasons
		requirement to notify the Director.
Records **New clause 16**	This new clause provides a requirement that relates to **section 35(1)(a)** of the Act and states a time that specified records must be kept.	Improved alignment with the Act. Clearer statement of requirement.
Clause 17 (Clause 15 of the current C2)	The term 'and make them available as necessary' has been deleted.	Improved alignment with the Act. **Section 35(1)(b)** of the Act includes a requirement to make records available.
	Clause 17(a) has replaced clause 15(a).	Clearer statement of requirement.
Quality assurance **Clause 18** (Clause 16 of the current C2)	Clause 18(a) has replaced clause 16(a). A requirement for approval by a qualified expert has been added.	Clearer statement of requirement.
	Clauses 18(d) and (e) have replaced clause 16(c).	Clearer statement of requirement.
	A new clause 18(f) requires values established in clauses 18(d) and (e) to have been reviewed and approved by an MPE.	Clearer statement of requirements.
	Clause 16(e) has been deleted. Clause 17(g) requires the HSL to maintain records of a quality assurance programme.	Clearer statement of requirement.
Clause 20 (Clause 18 of the current C2)	Clause 20(c)(iii) has been added.	Clearer statement of requirement.
Discharge of a patient who has undergone therapy **Clause 21** (Clause 23 of the current C2)	Clause 21 replaces clause 23 'release of patients'.	Clearer statement of requirement. Refer to **note 2**.
	The HSL is now responsible for ensuring the proper discharge of a patient who has undergone therapy. Clause 21(a) requires that a patient is not discharged without the approval of the radiation practitioner and clause 21(b) requires that advice from a medical physics expert be obtained where needed.	Improved alignment with the Act. Refer to **note 2**.
	The term 'carer and comforter' has been added. Clause 21(d) requires that a person acting as a 'carer and comforter' understand the radiation risks involved and agree to act as 'carer and comforter'.	Refer to **note 2**.

Section or clause	Principal amendments and deletions	Main reasons
	Clause 21(e) requires that, as far as practicable, a dose constraint of 5 mSv as a maximum be applied to an adult acting as a carer and comforter and the dose constraint be less than the public dose limit for children and casual visitors.	Refer to **note 2**.
	'Appendix 3: Release of Patients' has been deleted. Clause 21(f) requires that, as far as practicable, the patient is not discharged unless the activity of iodine-131 retained by that patient at the time of discharge is below 1.2 GBq.	Refer to **note 2**.
Radiation practitioner **Clause 22** (Clause 19 of the current C2)	Clause 22(a) has replaced clause 19(a).	Improved alignment with the Act. Clearer statement of requirement.
	Clause 22(b) has replaced clause 19(b).	Improved alignment with the Act. Clearer statement of requirement.
(Clause 23 of the current C2)	This is now clause 21.	Clearer statement of requirement.
(Clause 24 of the current C2)	Clause 24 'Referring practitioner' has been deleted.	Refer to **note 3**.
Manufacturer/supplier **Clause 26** (Clause 25 of the current C2)	Clause 26 has replaced clause 25.	Clearer statement of requirement.
Appendix 1: Cross-reference to Radiation Safety Act 2016	Left blank.	Feedback is requested on the usefulness of Appendix 1. Refer to question number 17 in the Submission form for revised C2 2024.
Appendix 2: Training requirements for radiation safety officers	'Appendix 2: Training requirements for radiation safety officers' has replaced 'Appendix 2: Training requirements'.	Clearer statement of requirement.
(Appendix 3 of the current C2)	Appendix 3 'release of patients' has been deleted.	Refer to **note 2**.

Note 1

Clauses 6(j) and 6(k) are on the disposal of radioactive waste. Clause 6(j)(i) has a new requirement for the HSL to dispose of radioactive waste following a waste management plan that ensures radiation protection and safety. This requirement aligns

with clause 8(c) of the revised C2 and Appendix 3 of Code of Practice for Unsealed Radioactive Material: ORS C11. Records of disposals are required by clause 17(k) of the revised C2.

Clause 6(j)(ii) has a new requirement that disposal limits must be within any limits given on a source licence. The Director may apply such limits as a condition on a source licence under **section 19(2)** of the Act.

Clause 6(k) has options for disposal of radioactive waste that is not a sealed radioactive source. A radionuclide generator is not considered to be a sealed radioactive source. Storage for decay should continue until radiation levels measured are at or near to background levels given the short half-lives of the radionuclides involved.

Note 2

Clause 21 is for the 'Discharge of a patient who has undergone therapy'. Assigning the responsibility for the discharge of a patient to the HSL better aligns the revised C2 with **section 20(1)** of the Act. This states that 'The holder of a source licence is responsible at all times for the management and control of each radiation source to which the licence applies.'

The dose constraint of an effective dose of 5 mSv for an adult carer and comforter who is not a casual visitor is based on guidance from the International Atomic Energy Agency (IAEA).[1] The activity values in Appendix 2 of current C2 are based on the maximally exposed individual not being likely to exceed an effective dose of 5 mSv. Appendix 3 of current C2 has been deleted in the revised C2. This allows individual circumstances to be fully considered. For instance, in the case of a parent attending a sick child or an adult over 60 years old who has agreed to act as a carer or comforter.

In addition to the effective dose constraint requirement of 5 mSv, the HSL must ensure that the activity of iodine-131 retained by the patient when the patient is discharged is below 1.2 giga-becquerel (GBq). This recognises that the use of iodine-131 is likely to result in the highest exposures to carers and comforters and to the public.

Note 3

Clause 24 'Referring practitioner' of current C2 has been deleted. Following section 5 of the Act, the Director has determined that making a request to the holder of a source licence for a radiological procedure does not constitute 'dealing with' a radiation source. This is because requesting a radiological examination does not constitute an activity or practice involving a radiation source such as management, control or use.

The requirements in clause 24 of current C2 have been translated as follows.

- Clause 1(e) requires the HSL to ensure that necessary and sufficient clinical information is provided to the radiation practitioner. This information is supplied by the referring practitioner.
- Clause 22(b) requires that the radiation practitioner cooperate with a referring practitioner.

[1] **IAEA. 2009. Release of patients after radionuclide therapy, *Safety Reports Series No. 63*. Vienna: International Atomic Energy Agency (IAEA).**

How to provide feedback

All written submissions that fall within the scope of this consultation and are received before the closing date for the consultation will be considered. The closing time and date for submissions is 11.00pm on Monday 15 April 2024.

The preferred and most convenient method of providing submissions is by using the **Ministry's online consultation tool, Citizen Space.**

The Director can also receive submissions by email, to:
ors.codes@health.govt.nz

Alternatively, submissions can be mailed to:
Office of Radiation Safety C2
Ministry of Health
PO Box 5013
Wellington 6140.

What happens after the consultation?

The Ministry will analyse and respond to feedback. After analysing in-scope submissions, the Ministry will consider further drafting improvements of the revised C2.

Start of revised C2

Introduction

Purpose and commencement

This Code of Practice for Nuclear Medicine: ORS C2 (this code) is issued by the Director for Radiation Safety (the Director) under **section 86** of the Radiation Safety Act 2016 (the Act). This code provides technical requirements necessary for a person who deals with a radiation source 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 the fundamental requirements. The requirements in this code do not limit the general nature of the fundamental requirements.

This code comes into force on <date to added when code is issued>.

Scope

This code applies to activities and practices associated with:

- unsealed radioactive material
- nuclear medicine, that is, the use of unsealed radionuclides in medicine for diagnosis, staging of disease, therapy and monitoring the response of a disease process. This includes but is not limited to the use of unsealed radioactive material in imaging, in vivo diagnostics and as tracers.

Activities and practices in nuclear medicine associated with irradiating apparatus are subject to Code of Practice for Interventional and Diagnostic Radiology: ORS C1.

Activities and practices in nuclear medicine associated with sealed radioactive material are subject to Code of Practice for Sealed Radioactive Material: ORS C12.

The phrase 'deal with' includes to manufacture, possess, control, manage, use, transport, store, export, import, sell, supply or dispose of a radiation source.

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

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

Roles and responsibilities

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

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

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

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

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

Holder of a source licence: used in **section 20** of the Act to describe the person who is responsible at all times for the management and control of each radiation source to which the licence applies.

Manufacturer/supplier: the person or organisation who designs, manufactures, produces, constructs, assembles, installs, distributes, sells, exports or imports radiopharmaceuticals that this code applies to.

Medical physics expert: an individual with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practise independently in one or more of the subfields (specialties) of medical physics. Specialties must be nuclear medicine or radiation therapy for this code. A medical physics expert is a **qualified expert** and provides specialist expertise with respect to radiation protection of the patient. The competence of a medical physics expert is generally established through a recognised formal mechanism of registration. An example is the mechanism provided by the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM).

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

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 holder of a source licence to oversee the application of regulatory requirements for occupational and public radiation **protection and safety**.

Referring practitioner: a **health professional** who is approved by the holder of a source licence to refer individuals to a radiation practitioner for medical exposure. Often this will be a general practitioner.

User of unsealed radioactive material: a natural person authorised through the Act for the **use of unsealed radioactive material**. Authorisations through the Act include through the granting of a use licence to a person. Also, the Act provides specified situations where a use licence is not required, for instance, under **Schedule 3** of the Radiation Safety Regulations 2016. Schedule 3 includes that a use licence under the Act is not required for a certain person to use unsealed radioactive material for medical diagnostic purposes, such as a health practitioner who is, or is deemed to be, registered with the New Zealand Medical Radiation Technologists Board in the scope of practice of nuclear medicine technologist and who holds a current practicing certificate.

Interpretation

Interpreted terms are identified in **bold**.

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

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

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

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

Ancillary equipment: equipment other than **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 and radiation measurement equipment that this code applies to.

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

Baselines: levels related to safety and performance that represent expected performance and provide references for quality control. The levels are established at commissioning and during routine testing based on standards and guidance.

Carer and comforter: a person who voluntarily (rather than occupationally) helps in caring for, supporting and comforting a **patient** undergoing a radiological procedure.

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 over a specified time. Where the time is not specified, for an adult this is the 50-year period following the intake. For a child, this is the time it takes the child reach the age of 70 years, that is, 70 years minus the child's age in years (for example, 60 years for a 10-year-old child).

Constraint: a prospective and source-related value of individual dose (dose constraint) or of individual risk (risk constraint) that is used in **planned exposure situations** as a parameter for optimising **protection and safety** and that serves as a boundary in defining the range of options in **optimisation**. Constraints for **medical exposure** of

volunteers are established or approved by the ethics committee on a case-by-case basis as part of the proposal for medical research.

Controlled area: 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 low for that procedure. The Director may publish **national diagnostic reference levels** for comparison with **diagnostic reference levels**.

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.

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 (for example, shields for bench tops, vials, syringes, activity meters) and for the preparation of radiopharmaceuticals; tools for the remote handling of radioactive material, including tongues and forceps; containers for transporting 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: to determine that the expected benefits to individuals and society from introducing or continuing a practice outweigh the harm, including the radiation detriment, resulting from the practice. In respect of individual **radiation procedures**, this involves weighing expected benefits against the radiation detriment that might be caused, taking account of the benefits and risks of available alternate techniques that do not involve **medical exposure**. 'Justifies', 'justified' and 'justification' have corresponding meanings.

Local diagnostic reference level: a **diagnostic reference level** for a health care facility that is based on a representative distribution of the appropriate diagnostic reference level quantities and is related to the use of specified activities of radionuclides in that facility. Local diagnostic levels must be compared with national diagnostic levels where national diagnostic levels are available.

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

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

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

National diagnostic reference levels: values of **diagnostic reference levels** based on data from a representative sample of health care facilities. The Director will publish national diagnostic reference levels.

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

Optimise: implementing 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 the 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 patient's radiation dose to be commensurate with the medical purpose. 'Optimises', 'optimised' and 'optimisation' have corresponding meanings.

Overexposure of a person:

a) when a **dose limit** has been exceeded

b) where a **patient** had been administered the incorrect radiopharmaceutical, regardless of dose

c) where a person has received a dose and no dose was intended

d) for nuclear medicine imaging: when the total **effective dose** to a **patient** (including any intended and necessary repeat components) is:

    i) 10 or more times greater than the intended dose if the intended dose was below 2.5 mSv

ii) 25 mSv or above if the intended dose was between 2.5 mSv and 10 mSv

iii) 2.5 or more times greater than the intended dose if the intended dose was more than 10 mSv

e) for nuclear medicine therapy:

i) if the delivered activity is more than 20% of the prescribed activity for selective internal radiation therapy

ii) if the delivered activity is more than 10% of the prescribed activity for all other therapies not included under e(i).

Patient: a person who is subject to **medical exposure** for their 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.

Place: as defined in **section 5** of the Act: 'includes any dwelling, premises, vehicle, ship, craft, or aircraft; and a building or a structure; and part of a place'.

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

Potential exposure: possible future exposure that may result from an anticipated operational occurrence or **accident** at a source or due to an event or sequence of events that could be expected to occur, 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 equipment**.

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 equipment: equipment and the associated software used to allow, perform or control a **radiation procedure**.

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 that this code applies.

Radioactive waste: radioactive material for which no further use is foreseen that contains, or is contaminated with, radionuclides at activity levels greater than the acceptable activity levels listed in **Schedule 2** of the Act.

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

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

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

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

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.

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

Typical dose: the median or average of the dose or activity for a representative sample of relatively standard-sized patients at clinically acceptable outcomes or meeting the required imaging standard.

Underexposure of a patient: when, for nuclear medicine therapy:

a) the delivered activity is less than 20% of the prescribed activity for selective internal radiation therapy

b) the delivered activity is less than 10% of the prescribed activity for all other therapies not covered in (a).

Unintended medical exposure: exposure of the wrong individual, tissue or organ during a diagnostic or a therapeutic **radiation procedure**; for a therapeutic radiation procedure use of the wrong **radiopharmaceutical** or 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. Also, inadvertent exposure of an

embryo or fetus, and any diagnostic exposure substantially greater than was intended. And finally, any **radioactive sources** or **ancillary equipment** fault, system or software failure or error, mishap or other unusual occurrence with the potential to subject the **patient** or **volunteer** to a **medical exposure** that is substantially different from what was intended.

Use of unsealed radioactive material: as specified in **section 21(3)** of the Act.

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

Worker: an individual who works, whether full time, part time or temporarily, for the holder of a source licence and who has recognised rights and duties in relation to occupational radiation protection.

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

The holder of a source licence

General

1. **Section 20(1)** of the Act states that 'The holder of a source licence is responsible at all times for the management and control of each radiation source to which the licence applies.' The holder of a source licence must therefore take responsibility for the protection and safety of each radiation source. The holder of a source licence must:

    a) establish a management system to enhance protection and safety that includes:

        i) effectively integrating protection and safety into an organisation's overall management system

        ii) making a commitment to protection and safety from the highest level of management and by providing all required resources

        iii) procedures to promote continuous improvement and a safety culture

        iv) documenting the appointment of a radiation safety officer to oversee the application of regulatory requirements for occupational and public radiation protection and safety

        v) ensuring that a radiation practitioner has the duty to plan and justify medical exposures

        vi) ensuring that requirements for medical imaging, calibration, dosimetry of patients, quality assurance and the commissioning and acceptance of radiation equipment are fulfilled under the oversight of or with the documented advice of a medical physics expert whose degree of involvement is determined by the complexity of the radiation procedures and the associated radiation risks

        vii) consulting with and engaging the services of experts and interested parties as necessary

    b) for all roles with duties in relation to protection and safety:

        i) fully document the roles

        ii) ensure people are notified of their duties and assume responsibility for performing those duties

    c) ensure that all activities associated with radiation sources are justified and optimised for protection and safety

    d) in line with **section 9(3)** of the Act, which states that 'a person who deals with a radiation source must ensure that any ionising radiation exposure that results from a planned operation or activity does not exceed the applicable

dose limits set out in Schedule 3', be conversant with the requirements set out in **Schedule 3** of the Act and ensure that any radiation exposure that results from planned operations or activities does not exceed applicable dose limits

e) ensure that necessary and sufficient information on the clinical context of a procedure is provided by the referring practitioner to the radiation practitioner.

2. The holder of a source licence must ensure that no practice or procedure is undertaken unless:

   a) it has been justified generically by a health authority

   b) it has been:

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

      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.

3. The holder of a source licence must ensure that, for occupational and public exposures, the radiological procedure is expected to give benefits to the individuals who undergo the procedure and to society that outweigh the harm resulting from the procedure. This must be done in consultation with the radiation practitioner.

Risk assessment

4. The holder of a source licence must conduct, document and keep up to date a risk assessment to:

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

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

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

Places

5. The holder of a source licence must:

   a) provide places that are located, designed, manufactured, constructed, assembled, commissioned, operated, maintained and decommissioned in

accordance with good engineering practice, using appropriate radiation shielding where needed; taking into account workload, patient flow and background radiation interference with equipment, 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, radioactive waste storage and predisposal processing

c) provide a suitable radiopharmacy that has:

   i) hand washing facilities that can be operated without the operator using their hands

   ii) where appropriate, a shower for decontaminating a person contaminated with radioactive material

   iii) eyewash facilities

d) ensure that an appropriate ventilation system is provided wherever unsealed radioactive materials that include radioactive aerosols or gases are handled

e) ensure that radiation shielding that forms part of the structure of places where nuclear medicine procedures are performed, such as walls, doors and windows, or that is used to provide shielding around radiation sources is approved to be adequate for protection, safety and operational needs, such as low background levels, by a medical physics expert or another qualified expert

f) in consultation with a medical physics expert or other qualified expert, verify and document the adequacy of shielding required in clause 5(e) whenever circumstances change that could increase the levels of risks

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

h) prominently display signs:

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

   ii) controlling access by members of the public and others 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 wash their hands and, where needed, 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,

rooms designated for patients undergoing radiopharmaceutical therapy, toilets used by patients following the administration of radiopharmaceuticals and transitional areas between the radiopharmacy and radiopharmaceutical administration area

j) provide for the proper display and interpretation of patient images.

Unsealed radioactive material and equipment

6. The holder of a source licence must:

a) ensure that radiopharmaceuticals are:

i) fit for their intended purpose

ii) measured to determine activity at the time of dispensing and, if appropriate, decay corrected to the time of administration

b) ensure that the measurement required in clause 6(a)(ii) is carried out using a calibrated dosemeter traceable to a standards dosimetry laboratory

c) provide, maintain, test and regularly service protective equipment and ancillary equipment so that:

i) it is fit for its intended purpose, including that it fulfils its design requirements for protection and safety

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

d) 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 two years

e) ensure that, as soon as practicable, corrective and preventive actions are taken if the values in clause 18(e) are exceeded

f) provide, as appropriate, at entrances to controlled areas:

i) personal protective equipment

ii) equipment for individual and workplace monitoring

iii) equipment to monitor contamination of skin and clothing

g) provide, as appropriate, kits for dealing with spills, including items such as:

i) protective clothing, such as 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, sponges 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 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 6(h)(i)

iii) releasing radioactive sources only to authorised persons

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) following a waste management plan to ensure radiation protection and safety

ii) within any limits imposed on the holder of a source licence as a condition on the source licence

k) subject to other regulatory requirements that apply, dispose of radioactive waste that is:

i) a gas into the atmosphere

ii) from patient excretions and is aqueous waste to a sewage system

iii) a liquid radioactive waste that is not from patient excretions into a sewage system, following appropriate storage for decay[2]

iv) an item contaminated with radioactive material into landfill, avoiding recycling streams and following appropriate storage for decay[2] or by transfer for disposal to an appropriate facility, such as organic solvents, following appropriate storage for decay[2] or by returning it to the vendor, such as for a technetium generator.

Training and authorisation

7. The holder of a source licence must ensure that all people with responsibilities for protection and safety:

[2] Storage for decay of short-lived radionuclides will generally reduce measured levels of radiation to background or near background radiation levels.

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

b) have training that:

   i) is regularly updated

   ii) satisfies the requirements in Appendix 2 if a person is appointed as a radiation safety officer

   iii) takes account of the training specified in Appendix 2 and has been established in consultation with a qualified expert

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

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

e) are authorised to assume their roles and responsibilities.

Policies, procedures and local rules

8. The holder of a source licence must establish, implement and maintain policies and procedures to meet the requirements of this code, including, without limitation, policies and procedures:

   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 and disposal of radioactive waste

   d) for routine radiopharmaceutical preparations and dispensing procedures

   e) specifying what radiation procedures can involve a carer and comforter

   f) to prevent accidents and mitigate the consequences of any accidents 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 being pregnant

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

   k) to ascertain the breastfeeding status of 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 fetus

      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 when the patient has died after being administered a radiopharmaceutical

m) to provide protection and safety by applying preventive measures in the hierarchies of:

   i) engineered controls

   ii) administrative controls

   iii) personal protective equipment

n) to set investigation levels and establish procedures to follow if such levels are exceeded

o) to implement procedures for verifying compliance with this code

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

9. The holder of a source licence must maintain, publish and enforce any written local rules that are necessary for protection and safety.

Patient dosimetry

10. The holder of a source licence in consultation with a medical physics expert must:

    a) determine typical patient doses for diagnostic nuclear medicine procedures

    b) determine typical patient absorbed doses for therapeutic radiation procedures

    c) satisfy the requirements in clause 10(a) and (b) by following internationally accepted protocols using, where appropriate, dosemeters with current calibrations traceable to a standards dosimetry laboratory

    d) establish, for optimisation purposes, local diagnostic reference levels.

Monitoring and measurement

11. The holder of a source licence must establish and maintain:

    a) individual monitoring where appropriate, adequate and feasible for any worker who usually works, or occasionally works in a controlled area and may receive a significant dose from occupational exposure, such as exceeding an investigation level

    b) programmes of workplace monitoring that are sufficient to:

       i) evaluate radiation dose conditions in all workplaces and levels of radioactive contamination

       ii) assess the occupational exposure of a worker in cases where individual monitoring of the worker is inappropriate, inadequate or not feasible

    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 protection and safety measures

ii) assess intakes of radionuclides and, if significant, calculate the committed effective doses

d) programmes of area monitoring that are sufficient to assess public exposure arising from nuclear medicine procedures

e) a capability that is sufficient to monitor unexpected increases in radiation levels due to an incident attributed to a source or place for which the holder of a source licence is responsible

f) a programme to monitor areas after radiopharmaceuticals have been used to ensure all contaminated articles have been appropriately disposed of and surface contamination levels are assessed to be within safe levels

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

12. To satisfy the monitoring and measurement requirements in clause 11 the holder of a source licence must:

    a) use appropriate equipment

    b) where a worker may receive a radiation dose exceeding three-tenths of a dose limit, ensure that individual monitoring of the worker is continuous and, to the extent practicable, is carried out using an external provider or internal capability that has a current accreditation to an appropriate standard, such as General Requirements for the Competence of Testing and Calibration Laboratories (ISO/IEC 17025:2017).

13. The holder of a source licence must:

    a) to the extent practicable, obtain previous dose records of individual monitoring

    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 reaches, or would have reached, the age of 75 years and for not less than 30 years after the worker ceased work, where the worker was subject to occupational exposure

        ii) records and estimated doses to members of the public

        iii) records of the tests and calibrations carried out.

    c) to the extent practicable, provide records of occupational exposure to:

        i) individual workers in respect of their own exposure

        ii) current and subsequent employers of workers, subject to satisfying regulatory requirements about privacy, confidentiality and data security and protection.

Incidents, accidents and emergencies

14. **Section 20(3)** of the Act sets out what the holder of a source licence must do if they holder of a source licence believe an incident has occurred that has resulted in overexposure of a person to radiation. The holder of a source licence 'must notify the Director as soon as practicable'. 'Overexposure of a person' has the interpretation given in this code. As well as complying with these requirements, the holder of a source licence must:

    a) notify the Director as soon as practicable if the holder of a source licence believes an underexposure in nuclear medicine therapy has occurred

    b) take all practical 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

    c) take timely action to mitigate the consequences of any accident that occurs and restore radiation equipment to a safe condition

    d) promptly investigate any incident, including by:

        i) calculating or estimating doses an individual has received and, if applicable, the dose distribution within that the individual person

        ii) identifying actions required to prevent a recurrence

    e) implement all corrective actions identified in clause 14(c)

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

        i) cause or suspected cause

        ii) calculations made under clause 14(d)(i)

        iii) corrective actions identified under clause 14(d)(ii)

        iv) details of the implementation of corrective actions under clause 14(e)

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

15. If the risk assessment required by clause 4 indicates that there is a reasonable likelihood of an emergency affecting either workers or members of the public, the holder of a source licence must prepare an emergency plan for protecting people and the environment, including:

    a) making arrangements for promptly identifying an emergency

    b) determining the correct level of emergency response

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

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

Records

16. **Section 35(1)(a)** of the Act provides that 'a person who has management or control of a radiation source must keep records that contain sufficient information to enable the Director to ascertain whether the person is complying with the radiation safety requirements'. To meet this requirement, records that verify compliance and are not patient or occupational health records where other legislation applies must be maintained for not less than 10 years. Clause 13(b)(i) has requirements that apply to occupational exposure.

17. The holder of a source licence must maintain records, that include

    a) the roles and appointments of individuals made by the holder of a source licence

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

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

    d) dosimetry of patients

    e) local assessments and reviews relating to diagnostic reference levels

    f) the 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 radiopharmaceutical preparations to be traced

    i) exposure of volunteers who are subject to medical exposure as part of a programme of medical research

    j) 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

18. The holder of a source licence must establish a comprehensive quality assurance programme for medical exposures, including:

    a) measuring and assessing the physical parameters of radiation equipment for the purpose of quality control, including calibrating output in terms of appropriate quantities using protocols established by professional, national and international bodies and approved by a medical physics expert, and made:

        i) at the time of commissioning the equipment before that equipment is put to clinical use

ii) periodically following commissioning

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

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

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

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

d) for the purposes of identifying and setting of baselines

e) for the purposes of assessing safety and performance against remedial and suspension levels that have been set based on national and international norms and operational experience

f) ensuring the methods used and the values established in clauses 18(d) and (e) have been reviewed and approved by a medical physics expert

g) verifying the appropriateness of physical and clinical factors used in radiation procedures

19. The holder of a source licence must ensure the quality assurance programme for medical exposures is subject to regular internal or external independent audits.

20. The holder of a source licence must ensure:

a) radiation reviews are performed periodically by radiation practitioners, in cooperation with the user of radiation sources and medical physic experts, 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 radiation procedures where diagnostic reference levels have been established

c) a review is conducted to determine whether the optimisation of protection and safety of patients is adequate or 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

iii) do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.

Discharge of a patient who has undergone therapy

21. The holder of a source licence must ensure a patient who has undergone a therapeutic radiation procedure is not discharged to be an outpatient without:
    a) the approval of the radiation practitioner
    b) advice from a medical physics expert, when needed
    c) the discharged patient or the legal guardian of the patient having been correctly informed in writing and understanding the precautions needed to:
        i) restrict the exposure of people the patient may come into contact with
        ii) protect nursing infants and a fetus from radiation exposures
        iii) avoid the spread of radiation contamination and precautions needed for the disposal of contaminated items
    d) ensuring that an individual intending to act as a carer and comforter has been correctly informed in writing about radiation protection and the radiation risks involved and the information provided is in a form that can reasonably be understood by the individual and the person agrees to act as a carer and comforter
    e) as far as practicable, ensuring the dose constraint applied to a carer and comforter is the minimum achievable and is within an effective dose of 5 mSv per treatment episode for an adult who is not a casual visitor and less than the public dose limit for others
    f) as far as practicable, ensuring the activity of iodine-131 retained by a patient when the patient is discharged is below 1.2 giga-becquerel (GBq).

Radiation practitioner

General

22. The radiation practitioner:

    a) is responsible for planning and delivering a medical exposure

    b) to satisfy the responsibility described in clause 22(a), must cooperate with a referring practitioner and, as needed, cooperate with and direct a user of unsealed radioactive material, medical physics expert or others

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

Justification

23. The radiation practitioner must:

    a) obtain information on the clinical context for any procedure unless that procedure 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 paediatric, breastfeeding 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 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.

Optimisation

24. The radiation practitioner must, in consultation as appropriate with a medical physics expert and the user of unsealed radioactive material, ensure that protection and safety is optimised for each medical exposure:

a) by using appropriate radiopharmaceuticals

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 relevant diagnostic reference levels

c) for therapeutic radiation procedures, by selecting and accurately 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 carer and comforter

   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.

25. 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 an embryo or fetus, in particular, for radiopharmaceuticals that would cross the placenta, accumulate in a bladder or could otherwise result in a significant dose

f) exposure of a breastfeeding infant as a result of a patient having undergone a radiation procedure with radiopharmaceuticals.

Other parties

Manufacturer/supplier

26. The manufacturer/supplier must provide:

    a) well-designed radiation and protective equipment that provides for protection and safety in accordance with the requirements of this code and appropriate national and international standards

    b) radiopharmaceuticals that are manufactured in accordance with good manufacturing practice and fit for their intended purpose.

27. The manufacturer/supplier must make suitable arrangements with the holder of a source licence 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 (left blank intentionally)
9(1)	
9(2)	
9(3)	
10	
11	
12	

Appendix 2: Training requirements for radiation safety officers

Topic area	Level of knowledge required
Radioactive materials	
Atomic and nuclear structure, radioactivity and radioactive decay	1
Interaction of ionising radiation with matter	1
Radiation detection	1
Radiation effects, risks, dose units, typical doses and activities	
Biological effects of radiation	1
Risks of stochastic effects (including from fetal and paediatric exposures)	2
Causes and consequences of deterministic effects (also referred to as harmful tissue reactions)	2
Risk and benefits of radiation exposures	2
Radiation dose quantities and units (absorbed dose, equivalent dose, effective dose and operational quantities)	2
Factors affecting radiation dose	2
Typical doses from nuclear medicine procedures and activities used for nuclear medicine procedures (including diagnostic reference levels)	2
Protecting of people and the safety of radioactive material used in nuclear medicine	
Physical considerations of radiation exposure (for example, tissue and organ doses)	2
Time, distance and shielding	2
Precautions required for handling radioactive material (to include spills)	2
Specific hazards, including factors affecting radiation doses from internal and external radiation exposure	2
Regulatory requirements	
Authorisations and compliance with the 'radiation safety requirements' under the Radiation Safety Act 2016	2

Topic area	Level of knowledge required
Radiation protection of patients, carers and comforters, and volunteers in biomedical research	2
Radiation protection of workers and the public (including dose limits and individual dose monitoring for the assessment of occupational exposure)	2
Quality control and quality assurance	2

Key for level of knowledge

1. General awareness and understanding
2. Ability to interpret and apply working knowledge in different situations

Submission form for revised C2 2024

Your details

This submission was completed by: *(name)* _____

Address: *(street/box number)* _____

(town/city and postcode) _____

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 health practitioner

☐ a servicing engineer

☐ a medical radiation technologist

☐ a medical physics expert

☐ a qualified expert other than a servicing engineer, medical radiation technologist or a medical physics expert

☐ a supplier of radiological equipment

☐ an organisation involved with nuclear medicine

☐ other (please specify): _____

Privacy statement

The Ministry of Health – Manatū Hauora (the Ministry) may publish submissions on the Ministry's website. If you are submitting as an individual, the Ministry will 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 1982**. If you want your personal details removed from your submission, please tick this box:

☐ Remove my personal details from responses to Official Information Act 1982 requests.

Please return this form:
By email to: **ors.codes@health.govt.nz**
By post to: Office of Radiation Safety C2
Ministry of Health
PO Box 5013
Wellington 6140

Consultation questions

The Director for Radiation Safety (the Director) is specifically seeking feedback and comments on the following:

1. Is restricting the scope of the revised C2 to unsealed radioactive material appropriate?
   ☐ Yes
   ☐ No

   Comments:

2. Is describing nuclear medicine as 'the use of unsealed radionuclides in medicine for diagnosis, staging of disease, therapy and monitoring the response of a disease process. This includes but is not limited to the use of unsealed radioactive material in imaging, in vivo diagnostics, and as tracers' accurate?
   ☐ Yes
   ☐ No

   Comments:

3. Is the proposed interpretation of ‘medical physics expert’ appropriate?

☐ Yes

☐ No

Comments:

4. Is the proposed interpretation of an ‘overexposure of a person’ appropriate and complete?

☐ Yes

☐ No

Comments:

5. Is interpretation of ‘radioactive waste’ appropriate?

☐ Yes

☐ No

Comments:

6. In the proposed interpretation of 'referring practitioner', 'health professional' has replaced 'health practitioner'. Is this an appropriate change?

☐ Yes
☐ No

Comments:

7. Is the proposed interpretation of an 'underexposure of a person' appropriate and complete, and is the requirement to notify the Director appropriate?

☐ Yes
☐ No

Comments:

8. Is the proposed interpretation of a 'user of unsealed radioactive material' appropriate and comprehensive?

☐ Yes
☐ No

Comments:

9. Is the replacement of the requirement in clause 5(c)(ii) for an 'emergency shower' by a requirement for 'where appropriate, a shower for the decontamination of a person contaminated with radioactive material' appropriate?

☐ Yes

☐ No

Comments:

10. Is the requirement in clause 5(e) for radiation shielding to be approved by a medical physics expert or another qualified expert appropriate?

☐ Yes
☐ No

Comments:

11. Are the requirements in clause 6(j) and 6(k) of the revised C2 for the disposal of radioactive waste, such as potentially limits being added to source licences, appropriate and adequate?

☐ Yes
☐ No

Comments:

12. '3 Bq/cm$^{2'}$ is referenced in clause 10(f) of the current C2. Is the removal of the reference from clause 11(f) of revised C2 appropriate?

☐ Yes
☐ No

Comments:

13. Is the proposed requirement in clause 12(b) of the revised C2 that the holder of a source licence must use an accredited provider to provide a dose monitor to be used by an individual who is likely to exceed three-tenths of a dose limit justified to ensure protection and safety?

☐ Yes
☐ No

Comments:

14. Is it appropriate for baselines and suspension and remedial levels to be approved by a medical physics expert and for such values to be based on the values provided in standards and in guidance produced by professional bodies?

☐ Yes
☐ No

Comments:

15. In clause 21 of the revised C2, is the title 'Discharge of a patient who has undergone therapy' appropriate and are the requirements, including use of the description 'not discharged to be an outpatient', adequate and appropriate?

☐ Yes
☐ No

Comments:

16. Is it appropriate to delete clause 24 ('Referring practitioner') of the current C2?

☐ Yes
☐ No

Comments:

17. Would the inclusion in a revised C2 of a completed 'Appendix 1: Cross-reference to Radiation Safety Act 2016' be useful?

☐ Yes
☐ No

Comments:

18. Is it appropriate to replace 'Appendix 2: Training requirements' (as in the current C2) with 'Appendix 2: Training requirements for radiation safety officers'?

☐ Yes
☐ No

Comments:

19. Are the training requirements in Appendix 2 of the revised C2 appropriate and comprehensive for training a radiation safety officer?

☐ Yes
☐ No

Comments:

20. Do the training requirements in Appendix 2 of the revised C2 provide an adequate core of knowledge for those who have roles for protection and safety that are specified by the holder of a source licence?

☐ Yes
☐ No

Comments:

21. Are there any other changes you would like to suggest to the revised C2 or comments that you would like to make?

☐ Yes
☐ No

Comments: