Code of Practice for Diagnostic and Interventional Radiology

ORS C1

For consultation

2023

Citation: Ministry of Health. 2023. *Code of Practice for Diagnostic and Interventional Radiology: ORS C1: For consultation*. Wellington: Ministry of Health.

Published in September 2023 by the Ministry of Health  
PO Box 5013, Wellington 6140, New Zealand

ISBN 978-1-991075-55-0 (online)  
HP 8828



This document is available at health.govt.nz

|  |  |
| --- | --- |
| **CCBY** | This work is licensed under the Creative Commons Attribution 4.0 International licence. In essence, you are free to: share ie, copy and redistribute the material in any medium or format; adapt ie, remix, transform and build upon the material. You must give appropriate credit, provide a link to the licence and indicate if changes were made. |

Contents

[This consultation iv](#_Toc144957752)

[Summary of the proposed principal amendments in the revised C1 v](#_Toc144957753)

[How to provide feedback xiii](#_Toc144957754)

[What happens after the consultation? xiii](#_Toc144957755)

[Introduction 1](#_Toc144957756)

[Purpose and commencement 1](#_Toc144957757)

[Scope 1](#_Toc144957758)

[Roles and responsibilities 2](#_Toc144957759)

[Interpretations 4](#_Toc144957760)

[The holder of a source licence 9](#_Toc144957761)

[General 9](#_Toc144957762)

[Risk assessment 10](#_Toc144957763)

[Places 10](#_Toc144957764)

[Equipment 11](#_Toc144957765)

[Training and authorisation 13](#_Toc144957766)

[Policies, procedures and local rules 13](#_Toc144957767)

[Patient dosimetry 14](#_Toc144957768)

[Monitoring and measurement 14](#_Toc144957769)

[Incidents, accidents and emergencies 15](#_Toc144957770)

[Records 16](#_Toc144957771)

[Quality assurance 17](#_Toc144957772)

[Radiation practitioner 19](#_Toc144957773)

[General 19](#_Toc144957774)

[Justification 19](#_Toc144957775)

[Optimisation 20](#_Toc144957776)

[Other parties 21](#_Toc144957777)

[Manufacturer/supplier 21](#_Toc144957778)

[Servicing engineer 21](#_Toc144957779)

[Appendix 1: General cross-references to the Radiation Safety Act 2016 23](#_Toc144957780)

[Appendix 2: Training requirements for radiation safety officers 24](#_Toc144957781)

[Submission form for revised C1 2023 26](#_Toc144957782)

# This consultation

This document sets out the revised Code of Practice for Diagnostic and Interventional Radiology ORS C1 (revised C1). The Director for Radiation Safety (the Director) proposes to issue an amended revised C1 under [section 86](https://www.legislation.govt.nz/act/public/2016/0006/latest/DLM6339744.html) of the Radiation Safety Act 2016 (the Act).

The amended revised C1 has been produced as part of a review that [section 90](https://www.legislation.govt.nz/act/public/2016/0006/latest/DLM6560514.html) of the Act requires. Section 90(a) of the Act requires the Director to review a code of practice every five years.

Section 90(b) of the Act requires that the Director consult with any person who the Director reasonably considers is likely to be affected by the review. To this end a submission form has been appended at the end of this document. The form is also available online [here](https://consult.health.govt.nz/radiation-safety/code-practice-diagnostic-interventional-radiology). The form is intended as a guide only. You are free to submit any information that you consider to be relevant.

### Your views matter

The current [Code of Practice for Diagnostic and Interventional Radiology ORS C1](https://www.health.govt.nz/publication/code-practice-diagnostic-and-interventional-radiology) (C1) came into force on 9 November 2018. C1 (and any amendments made) is a [secondary legislation](https://www.legislation.govt.nz/act/public/2019/0058/latest/DLM7298133.html#DLM7298133) under [section 86(6)](https://www.legislation.govt.nz/act/public/2016/0006/latest/DLM6339744.html) of the Act and applies to any person who ‘deals with’ a radiation source. The term ‘deal with’ is defined in [section 5](https://www.legislation.govt.nz/act/public/2016/0006/latest/DLM6339526.html) of the Act and includes ‘to manufacture, possess, control, manage, use, transport, store, export, import, sell, supply, or dispose of a radiation source’. Also, ‘deal with’ is interpreted to mean ‘to carry out any other activity or practice involving the radiation source’.

Those affected by the revised C1 include all regulated parties, and other people and organisations with a professional interest in diagnostic and interventional radiology or dental radiology.

Manatū Hauora | the Ministry of Health (the Ministry) will review all feedback received as part of the consultation and use it to inform the amendment of the revised C1.

## Summary of the proposed principal amendments in the revised C1

The Director’s view is that the revised C1 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 C1 has deletions, new clauses, replaced terms, changes to interpretations, and rewordings.

* Appendix 2 ‘Equipment requirements’ of C1 has been deleted. The main reason for this change is because Appendix 2 of C1 has contestable conditions and includes subjective tests that without clinical and technical interpretation may be unnecessarily stringent.
* New clauses require the holder of a source licence to establish reference values that are approved by a medical physics expert.
* There are new requirements for the holder of a source licence to establish local diagnostic reference levels (clause 12(c)), for a qualified expert to approve radiation shielding that is part of the structure (eg, walls, doors and windows) of a place (clause 5(b)), and for the provider of certain individual issue dosemeters to be accredited (clause 14(b)).
* Appendix 3 ‘Training requirements’ of C1 has been amended. The revised training requirements are for a radiation safety officer. Also, the training requirements provide a basis for devising training for other roles.
* **Table 1** lists the principal proposed changes in the revised C1 and motivations for the change. **Note 1** provides reasons for the deletion of Appendix 2 of C1 and **Note 2** provides reasons for the deletion of clause 25 ‘Referring practitioner’ of C1.

Table 1. Principal proposed amendments and Deletions in the revised C1 and the main motivation(s) for the changes

| **Section or clause** | **Principal amendments and deletions** | **Main motivation(s)** |
| --- | --- | --- |
| **Various** | The term ‘delegate’ used in C1 has been replaced by ‘duty’ (clause 1(b)(v) of C1), ‘roles’ (clause 1(c) of C1), ‘people’ (clause 1(c)(i) of C1), ‘roles’ (clause 1(c)(ii) of C1), ‘roles’ (clause 17(a) of C1), ‘cooperate with and direct’ (clause 21(b) of C1). | Improved alignment with the Act. |
| **Purpose and commencement** | ‘technical requirements’ has replaced ‘operational details’. | Improved alignment with the Act. |
| ‘for a person who deals with’ has been added. | Improved alignment with the Act. |
| **Scope** | ‘activities and practices’ has replaced ‘activities’. | Improved alignment with the Act. |
| What ‘deal with’ includes has been added. | Improved alignment with the Act. |
| Paragraph added stating that the fundamental requirements listed in the Act apply to every person who deals with a radiation source. | For the avoidance of doubt. |
| The ‘holder of a source licence’ (HSL) has replaced ‘managing entity’.  The HSL is a term used in [section 20](https://www.legislation.govt.nz/act/public/2016/0006/latest/DLM6339637.html) of the Act.  The HSL is responsible at all times for the management and control of each radiation source to which the licence applies. | Improved alignment with the Act.  This amendment has no effect on how the Director has identified responsibilities in the revised C1 compared with C1. |
| **Roles and responsibilities** | ‘Director for Radiation Safety’ has been amended. | Improved alignment with the Act. |
| ‘Health practitioner’ has been added. | Improved alignment with the Act.  Clearer statement of requirements. |
| ‘Health professional’ has been added. | Clearer statement of requirements. |
| An interpretation of ‘holder of a source licence’ has been added.  Interpretation of ‘managing entity’ in C1 has been deleted. | Improved alignment with the Act.  Clearer statement of requirements. |
| What a ‘person’ includes has been added. | Clearer statement of requirements. |
| ‘Medical physics expert’ (MPE) has replaced ‘Medical physicist’.  The interpretation of an MPE includes an example of one mechanism of establishing the competence of an MPE. | ‘Medical physics expert’ better aligns with the term ‘Qualified expert’ used in the revised C1.  Further recognises the role of an MPE in radiation protection of the patient. |
| ‘Medical radiation technologist’ has been deleted. | Clearer statement of requirements. |
| ‘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. |
| ‘General practitioner’ has been deleted from the examples In ‘Radiation practitioner’. This is because a general practitioner does not usually act as a ‘radiation practitioner’. | Clearer statement of requirements. |
| ‘User of irradiating apparatus’ has replaced ‘Operator’. Includes use has the meaning given in section 21(3) of the Act.’ | Improved alignment with the Act. |
| **Interpretations** Replaces ‘definitions’ used in C1 | ‘Interpretations’ has replaced ‘definitions’ as the title of the section. | Improved alignment with the Act. |
| ‘Absorbed dose’ has been added. | Clearer statement of requirements. |
| ‘Area monitoring’ has been added. | Clearer statement of requirements. |
| ‘Baselines’, ‘Remedial level’, and ‘Suspension level’ have been added. These additions support new clauses 20(a)(viii) and (ix), and 20(b). | Clearer statement of requirements. |
| ‘Constraint’ has been amended. This 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 would be given in a compliance guide. |
| ‘Diagnostic reference level’ has been amended. This now includes the Director may establish national diagnostic reference levels. A new clause 12(c) requires that the HSL establish local diagnostic reference levels. | Clearer statement of requirements. |
| ‘Investigation level’ has been amended. It no longer refers to intake or contamination. | Outside of the scope of the revised C1. |
| Interpretation of an ‘Overexposure of a person’ has been added. Relates to overexposure of a person in section 20(3) of the Act. | Improved alignment with the Act.  Clearer statement of requirements. |
| ‘Place’ has replaced ‘Facility’. | Improved alignment with the Act. |
| ‘Primary shielding’ and ‘Secondary shielding’ have been deleted. Clause 5(b) requires that the HSL consults a qualified expert. | Terms not used in the revised C1. |
| ‘Occupationally exposed person’ has been deleted. | Term not used. |
| ‘Risk assessment’ has replaced ‘Safety assessment’. | Clearer statement of requirements. |
| ‘or volunteer’ has been added to the interpretation of ‘Unintended medical exposure’. | Clearer statement of requirements. |
| **Clause 1**  **General**  (Clause 1 of C1) | Paragraph added associating clause 1 with the Act.  Clause 1(a) of C1 has been deleted. | Improved alignment with the Act. |
| ‘procedures’ has been included in clause 1(a)(iii). | Clearer statement of requirements. |
| ‘documenting’ has been added to clause 1(iv). | Clearer statement of requirements. |
| Clause 1(b) has replaced clause 1(c) of C1. | Improved alignment with the Act.  Clearer statement of requirements. |
| Clauses 1(c) and (d) have replaced clause 1(d) of C1.  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 that the HSL ensures that the referring practitioner provides necessary information. | Clearer statement of requirements.  Supports deletion of clause 25 ‘Referring practitioner’ of C1. |
| **General**  **New clause 3** | 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, account is still required to be taken by the HSL of the risk involved with occupational and public exposures. |
| **Places**  **Clause 5**  Replaces ‘Facilities’ used in C1  (Clause 4 of C1) | ‘Places’ has replaced ‘Facilities’ as title of section. | Improved alignment with the Act. |
| Clause 5(b) has replaced clause 4(b) of C1. Clause 5(b) is a new requirement for the HSL to ensure that all radiation shielding installed as part of the structure of a place (eg, walls, doors and windows) is approved by an MPE or another qualified expert. | Clearer statement of requirements. |
| **Equipment**  **Clause 6**  (Clause 5 of C1) | A new clause 6(b) requires that if a ‘remedial level’ or a ‘suspension level’ is exceeded, the HSL must take corrective and preventive actions. | Clearer statement of requirements.  Supports new clauses 20(a)(viii) and (ix), which require the HSL to identify and establish such values. |
| In clause 6(g), ‘corrective and preventive’’ has replaced ‘remedial’ of clause 5(f) of C1. | Clearer statement of requirements. |
| Clauses 5(b)(i) and (ii) of C1 have been deleted. | This is because Appendix 2 of C1: equipment requirements has been deleted. Refer to **Note 1**. |
| **Training and authorisation**  **Clause 9**  (Clause 8 of C1) | ‘roles’ has replaced ‘responsibilities’ in clause 8 of C1. | Clearer statement of requirements. |
| A new clause 9(b) has been added. Appendix 2 provides training requirements for a radiation safety officer. It also provides a syllabus to be used as the basis for other training.  Clause 8(b) of C1 has been deleted. | 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 10**  (Clause 9 of C1) | New clauses 10(g), (h), (i) and (j) have been added. | Clearer statement of requirements. |
| **Patient dosimetry**  **Clause 12**  (Clause 11 of C1) | Clause 12(a) has a requirement for the HSL to consult with an MPE. | Clearer statement of requirements. |
| A new clause 12(c) 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 13**  (Clause 12 of C1) | Clause 13(a) has replaced clause 12(a) of C1. This has requirements relating to a worker who occasionally works in a controlled area and may receive a significant dose. | Clearer statement of requirements. |
| A new clause 13(b)(ii) has replaced clause 12(b)(ii) of C1 | Clearer statement of requirements. |
| Clause 12(c) of C1 has been deleted. | Outside of the scope of the revised C1. |
| In clause 13(d) ‘radiation source’ has replaced ‘source or a facility’ of clause 12(e) of C1. | Clearer statement of requirements. |
| **Clause 14**  (Clause 13 of C1) | Clause 14(b) has replaced clause 13(b) of C1. This 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)](https://www.legislation.govt.nz/act/public/2016/0006/latest/DLM6339744.html) of the Act. |
| **Clause 15**  (Clause 14 of C1) | Clause 15(a) has replaced clause 14(a) of C1. ‘To the extent practicable’ has been added. | Clearer statement of requirement. |
| Clause 14(d) of C1 has been deleted. | Improved alignment with the Act. Powers for the Director to request information are provided in the Act.  In the case of an overexposure of a person, notification of the Director is referenced in clause 16.  Other legislation requires information to be released on request from a member of the public. |
| **Incidents, accidents and emergencies**  **Clause 16**  (Clause 15 of C1) | Additional text added associating clause 16 to section 20(3) of the Act. Includes reference to ‘overexposure of a person’ as the term is applied in the Act. | Improved alignment with the Act.  Clearer statement of requirement. |
| Clause 16(b) has replaced clause 15(b) of C1. | Improved alignment with the Act. |
| Clause 16(c) has replaced clause 15(c). | Clearer statement of requirement. |
| **Records**  **New clause 18** | Provides a requirement that relates to [section 35(1)(a)](https://www.legislation.govt.nz/act/public/2016/0006/latest/DLM6339662.html) of the Act and states a time that specified records must be kept. | Improved alignment with the Act.  Clearer statement of requirement. |
| **Clause 19**  (Clause 17 of C1) | Clause 19(a) has replaced clause 17(a) of C1. | Clearer statement of requirement. |
| Clause 19(f) has replaced clause 17(f) of C1. Records of approvals by an MPE required in clause 20(b) have been added. | Clearer statement of requirement. |
| Clause 19(K) has replaced clause 18(e) of C1. | Clearer statement of requirement. |
| **Quality assurance**  **Clause 20**  (Clause 18 of C1) | Clauses 20(a)(viii) and (ix) have replaced clause 18(c) of C1. | Clearer statement of requirements. |
| A new clause 20(b) requires that values established in clauses 20(a)(viii) and (ix) have been reviewed and approved by an MPE. | Clearer statement of requirements. |
| Clause 20(a) has replaced clause 18(a) of C1.  Clause 20(v) has ‘including calibrating output in terms of appropriate quantities using internationally accepted protocols’, which is part of clause 18(a) of C1. | Clearer statement of requirement. |
| Clause 20(a)(ii) has replaced clause 18(a)(ii) of C1. | Clearer statement of requirement. |
| Clause 19(K) has replaced clause 18(e) of C1. | Clearer statement of requirement. |
| Clauses 20(a)(vi) and (vii) have replaced clauses 18(b) and (f) of C1. | Clearer statement of requirement. |
| Clause 20(c) has replaced 18(d) of C1. | Clearer statement of requirement. |
| **General**  **Clause 23**  (Clause 21 of C1) | Clause 23(a) has replaced clause 21(a) of C1. | Improved alignment with the Act.  Clearer statement of requirement. |
| Clause 23(b) has replaced clause 21(b) of C1. Clause 23(b) is a requirement. | Improved alignment with the Act.  Clearer statement of requirement. |
| **Clause 25 of C1** | Clause 25 of C1‘Referring practitioner’ has been deleted. | Refer to **Note 2**. |

**Note 1:** Deletion of Appendix 2: Equipment requirements of C1.

Appendix 2 of C1 has subjective tests and contestable conditions that without clinical and technical interpretation may be unnecessarily stringent.

Also, the range of equipment in radiology is diverse and is subject to continual improvement. This means that performance criteria require regular review and necessary updating.

Standards, and guidance produced by professional bodies that are intended to be interpreted by clinical staff with the support of an MPE are the appropriate means of applying equipment-related safety and performance requirements. Providers of guidance include the International Atomic Energy Agency, the Royal Australian and New Zealand College of Radiologists and other professional bodies. Clauses 20(viii) and (ix) has been added to the revised C1 requiring that the HSL establish such values. Clause 20(b) requires that these values are reviewed and approved by an MPE.

**Note 2:** Deletion of clause 25 ‘Referring practitioner’ of C1.

Following section 5 of the Act, the Director has determined that making a request to the HSL 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 and use.

The requirements in clause 25 of C1 have been translated into:

* Clause 1(e). This requires the HSL to ensure necessary clinical information is provided to the radiation practitioner. This information is supplied by the referring practitioner.
* Clause 23(b). This requires that the radiation practitioner cooperates with a referring practitioner.

## How to provide feedback

All written submissions that fall within the scope of this consultation and are received before the closing date will be considered. The closing date for submissions is Thursday 5 October 2023 at 16:00.

The preferred and most convenient method of providing submissions is by using the Ministry’s online consultation tool, Citizen Space [here](https://consult.health.govt.nz/radiation-safety/code-practice-diagnostic-interventional-radiology/).

The Ministry’s Office of Radiation Safety can also receive submissions by email, to:

[ors.codes@health.govt.nz](mailto:ors.codes@health.govt.nz)

Alternatively, submissions can be mailed to:

Office of Radiation Safety C1

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 C1.

The statutorily required review of C1 will be completed following public consultation and before 9 November 2023.

### Start of revised C1

# Introduction

## Purpose and commencement

This Code of Practice for Diagnostic and Interventional Radiology (this code) is issued by the Director for Radiation Safety (the Director) under section 86 of the Radiation Safety Act 2016 (the Act). This code provides 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 those fundamental requirements. The requirements in this code do not limit the general nature of the fundamental requirements.

This code comes into force on a date to be advised.

## Scope

This code applies to activities and practices associated with:

* radiological equipment used for diagnostic radiology and image-guided interventional procedures
* radiological equipment used for diagnostic investigations of volunteers participating in programmes of medical research
* cone beam computed tomography equipment used for dental radiology.

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

‘Deal with’, in relation to a radiation source, 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’s clinical competence, occupational safety, hazards in the workplace, resource management and transport of hazardous substances.

# Roles and responsibilities

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

**Director for Radiation Safety** — is a person appointed under section 76 of the Act and who has the power to issue this code.

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

**Health practitioner** — is defined in 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** — is used in section 20 of the Act for the person responsible at all times for the management and control of each radiation source to which the licence applies.

**Manufacturer/supplier** — the person or organisation that designs, manufactures, produces, constructs, assembles, installs, distributes, sells, exports, or imports radiologicalequipmentor develops software that could influence the delivery of medical exposures.

**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. A specialty must be radiology 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.

**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 radiological procedures. This could include, for example, a radiologist, cardiologist, surgeon, chiropractor or, for cone beam computed tomography equipment, a dental practitioner.

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

**Referring practitioner** — a **health professional** who is approved by the holder of a source licence to refer individuals to a radiation practitioner for medical exposure. Often this is a general practitioner who refers patients to a radiology department or practice.

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

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

**User of irradiating apparatus** —a person authorised through the Act to use irradiating apparatus to perform radiological procedures, such as a medical radiation technologist who is, or is deemed to be, registered with the Medical Radiation Technologists Board in an appropriate scope. Use has the meaning given in section 21(3) of the Act.

# Interpretations

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

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

where is the mean energy imparted by ionising radiation to matter in a volume element and is the mass of matter in the volume element.

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

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

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

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

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

**Constraint** — a prospective and source related value of individual dose (dose constraint) or of individual risk (risk constraint) that is used in **planned exposure situations** as a parameter for the **optimisation** of **protection and safety** for the source, and that serves as a boundary in defining the range of options in **optimisation**. Constraints for **medical exposure** of **volunteers** are established or approved by the ethics committee on a case-by-case basis as part of the proposal for medical research.

**Controlled area** —a defined area in which specific measures for **protection and safety** are or could be required for controlling exposures in normal working conditions and preventing or limiting the likelihood and magnitude of **potential exposures**.

**Diagnostic reference level** —a level that is used to indicate whether, in routine conditions, the dose to the **patient** in a specified radiological procedure is unusually high or unusually low for that procedure. National diagnostic reference levels, if established, will be published by the Director.

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

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

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

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

**Equivalent dose** — the radiation-weighted **absorbed 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.

**In-room protective device** — a device or equipment to reduce exposure to radiation but not worn by a person, such as ceiling-suspended protective screens, protective lead curtains, mobile shields and disposable protective drapes.

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

**Individual monitoring** — **monitoring** using equipment worn by individuals.

**Investigation level** — the value of a quantity such as **effective dose** at or above which an investigation would be conducted.

**Justify** — to determine that the expected benefits to individuals and society from introducing or continuing a practice outweigh the harm, including the radiation detriment, resulting from the practice. In respect of individual **radiological procedures**,this involves the weighing of expected benefits against the radiation detriment that might be caused with account taken of the benefits and risks of available alternative techniques that do not involve **medical exposure**. The words ‘Justifies’, ‘justified’ and ‘justification’ have corresponding meanings.

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

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

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

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

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

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

**Overexposure of a person** — is when

* 1. a **dose limit** has been exceeded
  2. there is an unpredicted or unintended observable deterministic effect such as skin erythema
  3. where a person has received a dose and no dose was intended
  4. when the total **effective dose** to a **patient** (this includes any intended and necessary repeat components) is:
     1. 10 times or more greater than the intended dose if the intended dose was below 2.5 mSv; or
     2. 25 mSv or above if the intended dose was between 2.5 mSv and 10 mSv; or
     3. 2.5 times or more greater than the intended dose if the intended dose was more than 10 mSv.

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

**Personal protective equipment** —equipment worn on the person to reduce exposure to radiation, such as protective aprons, organ shields, protective eyewear and protective gloves.

**Place** — has the meaning given to it in section 5 of the Act. This includes any dwelling, premises, vehicle, ship, craft, or aircraft; a building or a structure; part of a place.

**Planned exposure situation** —a situation of exposure that arises from the planned operation of **radiological equipment** or from a planned activity that results in an exposure due to **radiological equipment.**

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

**Protection and safety** —the protection of people against exposure to ionising radiation, and the safety of **radiological equipment**, including the means for achieving this, and the means for preventing **accidents** and for mitigating the consequences of **accidents** if they do occur.

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

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

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

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

**Radiological procedure** —a medical imaging procedure that is intended to result in a **medical exposure** delivered by **radiological equipment**. This includes procedures in diagnostic radiology, image-guided interventional procedures, other interventional procedure involving radiation, or dental procedures involving cone beam computed tomography equipment.

**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** for which occupational exposure conditions need to be kept under review, even though specific measures for **protection and safety** are not normally needed.

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

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

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

**Unintended medical exposure** — exposure of the wrong individual, tissue or organ; exposure that is substantially greater than intended; inadvertent exposure of the embryo or fetus; and failure of **radiological equipment**, failure of software or system failure, or error, mishap or other unusual occurrence with the potential for subjecting the **patient** or **volunteer** to a **medical exposure** that is substantially different from what was intended.

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

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

# The holder of a source licence

## General

1. Section 20(1) of the Act provides that ‘The holder of a source licence is responsible at all times for the management and control of each radiation source to which the licence applies.’ The holder of a source licence must therefore take prime responsibility for protection and safety of each radiation source. The holder of a source licence must:
   1. establish a management system to enhance protection and safety that includes:
      1. effectively integrating protection and safety into the overall management system of the organisation
      2. making a commitment to protection and safety from the highest level of management, and by providing all required resources
      3. procedures to promote continuous improvement and a safety culture
      4. documenting the appointment of a radiation safety officer to oversee the application of regulatory requirements for occupational and public radiation protection and safety
      5. ensuring that a radiation practitioner has the duty to plan and justify medical exposures
      6. ensuring that requirements for medical imaging, calibration, dosimetry of patients, quality assurance and the commissioning and acceptance of radiological equipment are fulfilled by, or under the oversight of, or with the documented advice of, a medical physics expert, whose degree of involvement is determined by the complexity of the radiological procedures and the associated radiation risks
      7. consulting with and engaging the services of other experts and interested parties as necessary
   2. for all roles with duties in relation to protection and safety:
      1. fully document the roles
      2. ensure people are notified of their duties and assume responsibility for performing them
   3. ensure that all activities associated with radiological equipment are justified and optimised for protection and safety
   4. in line with section 9(3) of the Act, which provides 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
   5. ensure that sufficient information on the clinical context of a procedure is provided by the referring practitioner to the radiation practitioner.
2. The holder of a source licence must ensure that no practice or procedure is undertaken unless:
   1. it has been justified generically by a health authority
   2. it has been:
      1. justified specifically by a health authority in conjunction with appropriate professional bodies for procedures that are part of a health screening programme; or
      2. approved by an ethics committee for medical exposures incurred as part of a programme of medical research; or
      3. 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

1. The holder of a source licence must conduct, document and keep up to date a risk assessment to:
   1. identify the ways in which occupational, public and medical exposures could be incurred
   2. 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
   3. assess the adequacy of provisions for protection and safety in respect of siting, design and operation.

## Places

1. The holder of a source licence must:
   1. provide places that are located, designed, manufactured, constructed, assembled, commissioned, operated, maintained and decommissioned adopting good engineering practice, minimising the need to rely on administrative controls and personal protective equipment for protection and safety
   2. ensure that radiation shielding that forms part of the structure of places in which radiological procedures are performed, such as walls, doors, and windows, is approved to be adequate for protection and safety by a medical physics expert or another qualified expert
   3. in consultation with a medical physics expert or another qualified expert, verify and document the adequacy of the shielding required in clause 5(b) whenever circumstances change that could increase the risks
   4. designate and delineate appropriate areas as controlled areas or supervised areas and periodically review those designations and delineations
   5. prominently display signs:
      1. specifying the actual or potential presence of ionising radiation using the symbol recommended by the International Organization for Standardization at access points to controlled areas and supervised areas and at appropriate locations within controlled areas
      2. controlling access by members of the public to controlled areas and supervised areas
      3. in areas that patients may be (including waiting rooms and change cubicles), requiring patients who are to undergo a radiological procedure to notify staff if they are or may be pregnant.

## Equipment

1. The holder of a source licence must:
   1. provide, maintain, test and service radiological equipment, protective equipment and ancillary equipment to ensure that:
      1. the equipment is appropriate for the radiological procedures to be performed
      2. the equipment remains capable of fulfilling its design requirements for protection and safety throughout its operational lifetime
   2. ensure that as soon as practicable corrective and preventive actions are taken if the values established in clause 20(a)(ix) are exceeded
   3. ensure that the protective value of protective equipment is clearly displayed on the equipment
   4. cooperate with manufacturer/suppliers to:
      1. ensure that the requirements in clauses 6(a)(i) and (ii) are met
      2. ensure that radiological equipment is used only if it conforms to the applicable standards of the International Electrotechnical Commission and the International Organization for Standardization
      3. share information on use and operating experience that may be important for protection and safety
      4. apply the principles of optimisation in the design, planning, operation and decommissioning of a source
   5. safely manage all radiological equipment, whether or not the equipment is in use
   6. maintain an accurate inventory of all radiological equipment, including its location and description
   7. maintain a record of maintenance for each item, including a fault log and corrective and preventive actions taken (interim and subsequent repairs), the results of testing before an item is reintroduced to clinical use, and any reports from servicing engineers
   8. maintain control of radiological equipment to prevent loss or damage and to prevent any person from carrying out unauthorised activities, including by:
      1. periodically checking that equipment is under control and in the locations recorded in the inventory maintained under clause 6(f)
      2. releasing the equipment only to people who are authorised to assume management and control under the Act
   9. take immediate steps to regain control of any radiological equipment that is abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation.
2. The holder of a source licence must ensure that:
   1. all sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted protocols
   2. calibrations are carried out at the time of commissioning radiological equipment prior to clinical use, after any maintenance procedure that could affect the dosimetry, and at intervals approved by the Director and published in compliance guides issued under this code
   3. all dosimeters used for the calibration of sources are calibrated at least every two years and that such calibrations are traceable to a standards dosimetry laboratory.
3. The holder of a source licence must provide, maintain, test, calibrate and service equipment, other than radiological equipment, sufficient to ensure compliance with this code, including equipment for personal protection, monitoring and measurement for compliance verification, accident verification, emergency response, and protection and safety of members of the public.

## Training and authorisation

1. The holder of a source licence must ensure that all persons with roles for protection and safety:
   1. are specialised, qualified, educated and trained in protection and safety so that they understand their duties and can perform them competently
   2. have training:
      1. that is regularly updated
      2. that satisfies the requirements in Appendix 2 if a person is appointed as a radiation safety officer, or
      3. that takes account of the training in Appendix 2 and is established in consultation with a qualified expert
   3. are named in a current list with details of their specialisation, qualification, education and training
   4. are notified of their duties in relation to protection and safety
   5. are authorised to assume their roles and responsibilities.

## Policies, procedures and local rules

1. The holder of a source licence must establish, implement and maintain policies and procedures to meet the requirements of this code, including, without limitation, policies and procedures to:
   1. control access to areas where people can be exposed to radiation
   2. use constraints to optimise protection and safety
   3. prevent accidents and mitigate the consequences of any that occur
   4. report on and learn from accidents and other incidents
   5. comply with operational limits and conditions relating to public exposure
   6. ascertain the pregnancy status of patients of reproductive capacity before performing any radiological procedure that could result in a significant dose to an embryo or fetus
   7. ensure correct patient identification, including the use of independent methods of confirming the identity of a patient
   8. describe how dosemeters used for individual monitoring are managed, distributed and stored
   9. ensure that any person who may potentially be occupationally exposed
      1. as far as practicable, does not act as a carer and comforter
      2. is made aware of the means of informing the holder of a source licence of a pregnancy
   10. ensure that an individual intending to act as a carer and comforter is correctly informed about radiation protection and the radiation risks involved, and that the information provided is understood by the individual and that the individual agrees to act as a carer and comforter
   11. provide protection and safety by applying preventive measures in the following hierarchy:
       1. engineered controls
       2. administrative controls
       3. personal protective equipment
   12. set investigation levels and establish procedures to follow if such a level is exceeded
   13. implement procedures for verification of compliance with this code
   14. periodically review the overall effectiveness of measures for protection and safety.
2. The holder of a source licence must maintain, publish and enforce any written local rules that are necessary for protection and safety.

## Patient dosimetry

1. The holder of a source licence must:
   1. in consultation with a medical physics expert perform and document dosimetry of patients to determine typical doses to patients for:
      1. common diagnostic radiological procedures
      2. image-guided interventional procedures where practicable
   2. to satisfy the requirements in clause 12(a):
      1. follow internationally accepted protocols, and
      2. use only dosimeters with current calibrations traceable to a standards dosimetry laboratory
   3. establish for the purposes of optimisation local diagnostic reference levels in consultation with a medical physics expert.

## Monitoring and measurement

1. The holder of a source licence must establish and maintain:
   1. for any worker who usually works in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure, such as exceeding an investigation level, individual monitoring where appropriate, adequate and feasible.
   2. programmes of workplace monitoring that are sufficient to:
      1. evaluate radiation conditions in all workplaces
      2. assess the occupational exposure of a worker in cases where individual monitoring of the worker is inappropriate, inadequate or not feasible
   3. programmes of area monitoring that are sufficient to assess public exposure arising from radiological equipment under the responsibility of the holder of a source licence
   4. a capability that is sufficient to monitor unexpected increases in radiation levels due to an incident attributed to a radiation source for which the holder of a source licence is responsible
   5. other monitoring or measurement programmes as necessary to verify compliance with the requirements in this code.
2. To satisfy the monitoring and measurement requirements in clause 13 the holder of a source licence must:
   1. use appropriate equipment
   2. 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).
3. The holder of a source licence must:
   1. to the extent practicable, obtain previous dose records of individual monitoring
   2. maintain records of all monitoring and verification of compliance, including:
      1. records of occupational exposure during and after the worker’s working life, at least until the worker attains or would have attained the age of 75 years, and for not less than 30 years after ceasing work where the worker was subject to occupational exposure
      2. records and estimated doses to members of the public
      3. records of the tests and calibrations carried out
   3. provide records of occupational exposure to:
      1. individual workers in respect of their own exposure
      2. subsequent employers of workers, subject to satisfying confidentiality or other associated regulatory criteria.

## Incidents, accidents and emergencies

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

## Records

1. 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 15(b)(i) has requirements that apply to occupational exposure.
2. The holder of a source licence must maintain records that include:
   1. the roles and appointments of individuals made by the holder of a source licence
   2. the names of all people with responsibility for protection and safety, including details of their specialisation, qualifications, education and training
   3. results of calibrations and periodic checks of physical and clinical parameters selected during treatment of patients
   4. dosimetry of patients
   5. local assessments and reviews relating to diagnostic reference levels
   6. the quality assurance programme and the associated medical physics expert approvals required by clause 20(b)
   7. information necessary for the retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures, for diagnostic radiology
   8. information necessary for the retrospective assessment of doses, including the duration of the fluoroscopic component and the number of images acquired, for image-guided interventional procedures
   9. exposure records for volunteers subject to medical exposure as part of a programme of medical research
   10. reports on investigations of unintended and accidental medical exposures
   11. relevant procedures and results
   12. exemptions from this code granted under section 86(3) of the Act.

## Quality assurance

1. The holder of a source licence must establish a comprehensive quality assuranceprogramme for medical exposures. This must:
   1. measure and assess the physical parameters of radiological equipment for the purpose of quality control, including:
      1. at the time of commissioning the equipment, before equipment is put into clinical use
      2. periodically following commissioning
      3. after any major maintenance procedure that could affect protection and safety
      4. after installing any new software or modifying any existing software that could affect protection and safety
      5. calibrating outputs in terms of appropriate quantities using internationally accepted protocols
      6. performing tests on ancillary equipment and personal protective equipment
      7. periodically checking the calibration and conditions of operation of dosimetry equipment and monitoring equipment
      8. for the purposes of identifying and setting of baselines
      9. 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
   2. ensure that methods used, and values established in clauses 20(a)(viii) and (ix) have been reviewed and approved by a medical physicist expert
   3. verify the appropriateness of physical and clinical factors used in radiological procedures.
2. The holder of a source licence must ensure that regular internal or external independent audits are made of the quality assurance programme for medical exposures.
3. The holder of a source licence must ensure that:
   1. radiation reviews are performed periodically by radiation practitioners in cooperation with users of irradiating apparatus and medical physics experts to investigate and critically review the current practical application of the radiation protection principles of justification and optimisation for radiological procedures
   2. local assessments are made at regular intervals for those radiological procedures for which diagnostic reference levels have been established
   3. 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:
      1. exceed the relevant diagnostic reference level; or
      2. fall substantially below the relevant diagnostic reference level
      3. do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.

# Radiation practitioner

## General

1. The radiation practitioner:
   1. is responsible for the planning and delivery of a medical exposure
   2. to satisfy the responsibility in clause 23(a), must cooperate with a referring practitioner, and as needed cooperate with and direct a user of irradiating apparatus, medical physics expert or otherwise
   3. 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

1. The radiation practitioner must:
   1. obtain information on the clinical context for any procedure unless it is part of a health screening programme
   2. for any procedure that is not part of a health screening programme, justify the medical exposure in consultation as appropriate with the referring practitioner taking into account, in particular for paediatric or possibly pregnant individuals:
      1. the appropriateness of the request
      2. the urgency of the procedure
      3. the characteristics of the medical exposure
      4. the characteristics of the individual patient
      5. relevant information from the patient’s previous radiological procedures
      6. relevant national or international referral guidelines
   3. 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

1. The radiation practitioner must, in consultation as appropriate with a medical physics expert and the user of irradiating apparatus, ensure that protection and safety is optimised for each medical exposure:
   1. for diagnostic radiological procedures and image-guided interventional procedures by:
      1. using appropriate radiological equipment
      2. adopting techniques and parameters to deliver a medical exposure that is the minimum necessary to fulfil the clinical purpose of the radiological procedure, taking into account relevant norms of acceptable image quality and of relevant diagnostic reference levels
   2. by using constraints in any procedure in which an individual:
      1. acts as a carer and comforter
      2. is subject to exposure as part of a programme of research.
2. The radiation practitioner must ensure that particular aspects of medical exposures are considered in the optimisation process for:
   1. paediatric patients
   2. individuals subject to medical exposure as part of a health screening programme
   3. volunteers subject to medical exposure as part of a programme of medical research
   4. procedures involving computed tomography
   5. exposure of the embryo or fetus; in particular, during radiological procedures in which the abdomen or pelvis of a pregnant patient is exposed to the useful radiation beam or could otherwise receive a significant dose.

# Other parties

## Manufacturer/supplier

1. The manufacturer/supplier of radiological equipment must:
   1. supply well-designed, well-manufactured and well-constructed radiological equipment that:
      1. provides for protection and safety in line with the requirements of this code
      2. meets engineering, performance and functional specifications
      3. meets quality standards appropriate to the significance of systems and components, including software, for protection and safety
      4. provides clear displays, gauges and instructions on operating consoles
   2. test radiological equipment to demonstrate compliance with relevant specifications
   3. provide information on how to properly install and use radiological equipment and on associated radiation risks, including performance specifications, instructions for operating and maintenance, and instructions for protection and safety
   4. optimise the protection provided by shielding and other protective devices
   5. supply all radiological equipment with all appropriate radiation protection tools as a default, rather than as optional extras.
2. The manufacturer/supplier must:
   1. make suitable arrangements with the holders of source licences to share information on use and operating experience that may be important for protection and safety
   2. cooperate with the holder of a source licence as required by clause 6(d).

## Servicing engineer

1. The servicing engineer must:
   1. install and service radiological equipment competently, so that it complies with the requirements in clause 6
   2. cooperate with the holder of a source licence to ensure that radiological equipment cannot be used clinically while it is being installed or serviced
   3. after installing or servicing the equipment:
      1. collaborate with the holder of a source licence and medical physics experts to ensure necessary quality control tests are completed successfully
      2. confirm that all radiation protection and safety features are in place and operating correctly before equipment is returned to clinical use
      3. provide a written report to the holder of a source licence describing the equipment fault (if any), the work done, parts replaced, adjustments made and any changes that may affect protection and safety.

# Appendix 1: General cross-references to the Radiation Safety Act 2016

As required by section 86(1) of the Radiation Safety Act 2016, clauses in this code apply to the fundamental requirements in sections 9–12 of the Act as follows:

|  |  |
| --- | --- |
| **Section in Act** | **Clauses in this code** |
| 9(1) | 1, 9–10, 18–19, 23–24 |
| 9(2) | 1–5, 9–15, 18, 21–23, 25–26 |
| 9(3) | 1, 9–10, 13, 18–19 |
| 10 | 6–8, 16–20, 27–29 |
| 11 | 6, 18–19 |
| 12 | 6, 18–19 |

# Appendix 2: Training requirements for radiation safety officers

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

**Key for level of knowledge:**

1 General awareness and understanding.

2 Working knowledge. Ability to interpret and apply knowledge in different situations.

### End of revised C1

Submission form for revised C1 2023

### 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 diagnostic and interventional radiology, or dental radiology | |
|  | Other (please specify): |  |

### Privacy statement

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](mailto:ors.codes@health.govt.nz)

By post to: Office of Radiation Safety C1  
Ministry of Health  
PO Box 5013  
Wellington 6140

### Consultation questions

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

* + - 1. Is the title of the revised C1 clear and accurate (eg, should it include dental radiology using cone beam computed tomography)?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

Comments:

|  |
| --- |
|  |

* + - 1. Is the proposed interpretation of ‘medical physics expert’ appropriate?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

Comments:

|  |
| --- |
|  |

* + - 1. Is the proposed interpretation of an ‘overexposure of a person’ appropriate and comprehensive?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

Comments:

|  |
| --- |
|  |

* + - 1. Is the proposed interpretation of ‘user of irradiating apparatus’ appropriate?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

Comments:

|  |
| --- |
|  |

* + - 1. In the proposed interpretation of ‘referring practitioner’, ‘health professional’ has replaced ‘health practitioner’. Is this an appropriate change?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

Comments:

|  |
| --- |
|  |

* + - 1. Is the proposed requirement for the holder of a source licence (HSL) to ensure that radiation shielding incorporated in the structure of a place is approved by a medical physics expert or another qualified expert justified to ensure protection and safety?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

Comments:

|  |
| --- |
|  |

* + - 1. Is the proposed requirement that the HSL 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:

|  |
| --- |
|  |

* + - 1. Is the proposed requirement that the HSL must retain records that verify compliance and are not patient or occupational health records where other legislation applies for not less than 10 years appropriate?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

Comments:

|  |
| --- |
|  |

* + - 1. Is it appropriate for clause 25 (‘Referring practitioner’) of the current Code of Practice for Diagnostic and Interventional Radiology ORS C1 to be deleted?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

Comments:

|  |
| --- |
|  |

* + - 1. Is it appropriate for Appendix 2 of the current Code of Practice for Diagnostic and Interventional Radiology ORS C1 to be deleted?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

Comments:

|  |
| --- |
|  |

* + - 1. 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:

|  |
| --- |
|  |

* + - 1. Clause 20(a)(ii) of the revised C1 requires that quality control testing is carried out periodically following commissioning. Is it appropriate that such testing should be carried out at least once every year (this is not in the revised C1)?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

Comments:

|  |
| --- |
|  |

* + - 1. Do the training requirements in Appendix 2 of the revised C1 provide an adequate core of knowledge for those who have roles for protection and safety that are specified by the HSL?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

Comments:

|  |
| --- |
|  |

* + - 1. Are the training requirements in Appendix 2 of the revised C1 appropriate and comprehensive for the training of a radiation safety officer?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

Comments:

|  |
| --- |
|  |

* + - 1. Are there changes you think are necessary to the obligations of the HSL in the revised C1?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

Comments:

|  |
| --- |
|  |

* + - 1. Are there changes you think are necessary to the obligations of other parties in the revised C1?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

Comments:

|  |
| --- |
|  |

* + - 1. Are there any other changes you would like to suggest to the revised C1 or comments that you would like to make?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

Comments:

|  |
| --- |
|  |