Code of Practice for Sealed Radioactive Material

ORS C12

2020

Citation: Ministry of Health. 2020. *Code of Practice for Sealed Radioactive Material: ORS C12*. Wellington: Ministry of Health.

Published in July 2020 by the Ministry of Health
PO Box 5013, Wellington 6140, New Zealand

ISBN 978-1-99-002907-3 (online)
HP 7422



This document is available at health.govt.nz

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# Introduction

## Purpose and commencement

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

This code comes into force on 31 July 2020.

## Scope

This code applies to activities associated with sealed sources such as fixed and portable nuclear gauges and logging tools containing sealed sources used for non-medical purposes including research and education. Nuclear gauges can be used for purposes such as level indication and density, concentration and thickness measurement. Logging tools are used for well logging.

Activities can include the manufacture, possession, control, management, use, storage, import, export, sale, supply, and disposal of radioactive material and equipment.

The following issues are dealt with in separate codes of practice:

* safety of radioactive material in transport: ORS C6
* security of radioactive material in use, storage or transport: ORS C5.

Compliance with the code does not imply compliance in related areas such as occupational safety, hazards in the workplace and resource management.

## Contact

The Director’s contact details are:

|  |  |
| --- | --- |
| Office of Radiation SafetyPO Box 5013Wellington 6140 | Email: orsenquiries@health.govt.nzFax: 04 496 2340 |

# Roles and responsibilities

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

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

**Managing entity** – the legal entity that manages or controls sealed sources and must, therefore, obtain a source licence as required by section 13(a) of the Act.

**Manufacturer/supplier** – the person or organisation that designs, manufactures, produces, constructs, assembles, installs, distributes, sells, exports or imports sealed sources or ancillary equipment that could influence the successful outcome of a radiation procedure.

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

**Radiation safety officer** – a person competent in radiation protection and safety who the managing entity designates to oversee the application of regulatory requirements.

**Servicing engineer** – a person who has expertise in installing, servicing and maintaining sealed sources and devices.

# Definitions

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

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

**Ancillary equipment –** equipment other than **sealed sources**that has an impact on the successful outcome of a **radiation procedure**, such as radiation measurement equipment and local shielding.

**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**.

**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**.

**Device** – the instrument that contains **sealed sources** such as a nuclear gauge, logging tool assembly or storage container.

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

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

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

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

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

**Facility** – the location at which **radiation procedures** are performed and **sealed sources** are installed, used, handled or stored.

**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** – value of a quantity such as **effective dose** at or above which an investigation would be conducted.

**Justify** – determine that the expected benefits to individuals and society from introducing or continuing a practice outweigh the harm, including the radiation detriment, resulting from the practice. ‘Justifies’, ‘justified’ and ‘justification’ have corresponding meanings.

**Logging tool** – a device that contains one or more **sealed sources** for the purpose of **well logging**.

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

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

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

**Nuclear gauge** – a device that contains one or more **sealed sources** for purposes other than **well logging** such as a nuclear density meter or fixed industrial gauge.

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

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

**Optimise** – implement a level of **protection and safety** that results in the magnitude of individual doses, the number of individuals (**workers** and **members of the public**) subject to exposure and the likelihood of exposure being as low as reasonably achievable, taking economic and social factors into account. ‘Optimises’, ‘optimised’ and ‘optimisation’ have corresponding meanings.

**Personal protective equipment** – equipment worn on the person to reduce their exposure to radiation, such as a protective apron.

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

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

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

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

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

**Radiation procedure** – an activity or procedure involving the use of **sealed sources**.

**Reportable incident** – an **incident** resulting in (a) a **dose limit** to be exceeded or (b) **sealed sources** that are lost, missing or beyond regulatory control or (c) damage to the device shielding or sealed source.

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

**Sealed source** – any individual item that spontaneously emits ionising radiation and is permanently sealed in a capsule or closely bonded in solid form.

**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.

**Well logging** – the use of **sealed sources** for characterising and evaluating geological formations and borehole and well constructions.

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

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

# Managing entity

## General

* + - 1. The managing entity must:
				1. take prime responsibility for protection and safety
				2. establish a management system to enhance protection and safety that includes:

effectively integrating protection and safety into the overall management system of the organisation

making a commitment to protection and safety from the highest level of management at the facility, and by providing all required resources

promoting continuous improvement and a safety culture

appointing a radiation safety officer to oversee the application of regulatory requirements for radiation protection and safety

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

* + - * 1. for all appointments under subclause 1(b)(iv):

ensure appointees are notified of their duties in relation to protection and safety and assume responsibility for performing them

fully document the appointments in a letter setting out duties and countersigned by the appointee

* + - * 1. ensure that:

all activities associated with sealed sources are justified and optimised for protection and safety

occupational dose constraints are established and applied for each source or activity

dose limits for occupational and public exposure are not exceeded as a result of those activities.

* + - * 1. establish an annual review of the protection and safety management system to assess its effectiveness and to verify compliance with the requirements in this code.

## Safety assessment

* + - 1. The managing entity must conduct, document and keep up to date a safety assessment to:
				1. identify the ways in which occupational and public 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
				3. assess the adequacy of provisions for protection and safety in respect of siting, design and operation.

## Facilities

* + - 1. The managing entity must:
				1. provide facilities that are sited, located, designed, manufactured, constructed, assembled, shielded, commissioned, operated, maintained and decommissioned in accordance with good engineering practice, taking into account workload and minimising the need to rely on administrative controls and personal protective equipment for protection and safety
				2. designate and delineate appropriate storage and other areas as controlled areas or supervised areas and periodically review those designations and delineations
				3. restrict access as appropriate to controlled areas and supervised areas
				4. shield or manage all areas in which sealed sources that do not comply with subclause 4(a)(iv) will be used or stored so that:

no person can receive a dose exceeding 0.3 millisieverts (mSv) per year from occupying areas outside the use and storage areas for the sealed source

the instantaneous dose rate at any point outside the use and storage areas is less than 15 microsieverts (µSv) per hour

* + - * 1. verify and document the adequacy of shielding at commissioning and whenever circumstances change in ways that could increase the risks
				2. prominently display signs:

controlling access by members of the public to controlled areas and supervised areas

warning of the presence of radioactive material close to each fixed gauge containing a sealed source, in a position where it is prominently visible from all accessible positions.

## Sealed sources, devices and equipment

* + - 1. The managing entity must:
				1. provide, maintain, test and regularly service sealed sources, devices, personal protective equipment and ancillary equipment as necessary so that:

they are fit for their intended purpose

they fulfil their design requirements for protection and safety

they meet the requirements in Appendix 3

whenever sealed sources are used or stored in areas that are not shielded or managed in accordance with subclause 3(d), the sealed sources have sufficient shielding and interlocks so that no person can receive an effective dose exceeding 0.3 mSv per year, and the instantaneous dose rate in any occupied area is less than 15 µSv per hour

the protective value of personal protective equipment is clearly displayed on the equipment where applicable

* + - * 1. the protective value of personal protective equipment is clearly displayed on the equipment where applicable
				2. conduct leak tests of sealed sources to confirm that there is no leakage[[1]](#footnote-1) of radioactive material:

on installation if the manufacturer has not supplied a leak test certificate

every two years if the source is older than 10 years

immediately if the device has been damaged or there are other reasons to believe that it may be leaking

using an external service that maintains laboratory accreditation under ISO/IEC 17025 for ionising radiation dosimetry, or internal capability validated by a qualified expert

* + - * 1. prefer the use of fixed equipment over portable equipment whenever practicable and reasonable
				2. ensure that portable gauges are safely and securely stored when not in use, including that:

the source assembly is fully retracted and key locked into the shielded position

the gauge is not stored with explosives, or combustible, corrosive or oxidising chemicals

* + - * 1. provide, as appropriate:

personal protective equipment

equipment for individual monitoring and workplace monitoring

* + - * 1. maintain control of all sealed sources to prevent loss or damage and to prevent any person from carrying out unauthorised activities, including by:

maintaining an accurate inventory of all sealed sources including their location, description, activity, form and details of any device in which they are housed

periodically checking that sealed sources are under control and in the locations recorded in the inventory maintained under subclause 4(g)(i)

releasing sealed sources only to people who are authorised to assume management and control under the Act

* + - * 1. take immediate steps to regain control of any sealed source that is abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation
				2. ensure sealed sources that are no longer used are dealt with in one of these ways:

returned to the manufacturer

transferred to another authorised person or organisation within New Zealand

stored or disposed of in New Zealand as instructed by the Director.

## Training and authorisation

* + - 1. The managing entity must ensure that all people with responsibilities for protection and safety:
				1. are qualified, educated and trained in protection and safety so that they understand their duties and can perform them competently
				2. are suitably trained in accordance with the training requirements set out in Appendix 2, and receive regular refresher training
				3. are named in a current list with details of relevant qualifications, education and training
				4. are notified of their duties in relation to protection and safety
				5. are authorised to assume their roles and responsibilities.

## Restricted activities

* + - 1. The managing entity must not, without the prior written approval of the Director, allow:
				1. practices, except for justified practices involving medical exposure, that result in an increase in activity by deliberately adding radioactive material or by activation, in food, feed, beverages, cosmetics or any other commodity or product intended for a person to ingest, inhale or take in through the skin, or to be applied to them
				2. practices involving the frivolous use of radiation or radioactive material in commodities or in consumer products such as toys and personal jewellery or adornments, which result in an increase in activity by deliberately adding radioactive material or by activation
				3. human imaging using radiation that is:

performed as a form of art or for publicity purposes

performed for occupational, legal or health insurance purposes, and is undertaken without referring to clinical indication

used to detect concealed objects

* + - * 1. devices or manufactured items into which radionuclides have deliberately been incorporated or produced by activation, or that generate ionising radiation and that can be sold or made available to members of the public without special surveillance or regulatory control after sale to be made available to the public.

## Policies, procedures and local rules

* + - 1. The managing entity must establish, implement and maintain policies and procedures to meet the requirements of this code including, without limitation, policies and procedures:
				1. to control access to areas where people can be exposed to radiation
				2. to prevent people from being exposed to the primary radiation beam
				3. to prohibit the bypass of safety interlocks in normal operating conditions
				4. to set and apply dose constraints to optimise protection and safety
				5. to prevent accidents and mitigate the consequences of any that occur
				6. to report on and learn from accidents and other incidents
				7. to comply with operational limits and conditions relating to public exposure
				8. for staff who have indicated they may be pregnant, to minimise unnecessary exposure to the embryo or fetus
				9. to provide protection and safety by applying preventive measures in the following hierarchy:

engineered controls

administrative controls

personal protective equipment

* + - * 1. to set an investigation level and establish procedures to follow if such a level is exceeded
				2. to implement the annual review of the protection and safety management system.
			1. The managing entity must maintain, publish and enforce any written local rules that are necessary for protection and safety.

## Monitoring and measurement

* + - 1. The managing entity must establish and maintain:
				1. a programme of continuous individual monitoring whenever appropriate, adequate and feasible, which is sufficient to assess occupational exposures for workers who usually work in a controlled area or who may receive a dose exceeding 10 percent of the dose limits
				2. a programme of workplace monitoring that is sufficient to:

evaluate radiation conditions in all workplaces

assess exposures in controlled areas and supervised areas that are not assessed under subclause 9(a)

review the classification of controlled areas and supervised areas

* + - * 1. programmes of source monitoring or environmental monitoring that are sufficient to assess public exposure arising from radiation equipment under the responsibility of the managing entity
				2. a capability that is sufficient to monitor unexpected increases in radiation levels due to an incident attributed to a source or facility for which the managing entity is responsible
				3. a programme of monitoring for neutron generators that includes:

verification that the dose rate following termination of operation is below 1 μSv per hour at 10 centimetres from the target before it is handled

checking for surface contamination upon receipt and consignment, prior to repair, and at least annually

* + - * 1. other monitoring or measurement programmes as necessary to verify compliance with the requirements in this code.
			1. To satisfy the monitoring and measurement requirements in clause 9, the managing entity must:
				1. use appropriate monitoring equipment
				2. for continuous individual monitoring under subclause 9(a), use an external service that:

maintains laboratory accreditation under ISO/IEC 17025 for ionising radiation dosimetry; and

returns results to the managing entity within 20 working days of receiving all necessary raw information.

* + - 1. The managing entity must:
				1. take all reasonable steps to obtain previous dose records
				2. maintain records of all monitoring and verification of compliance, including:

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

records and estimated doses to members of the public

records of the tests and calibrations of radiation monitoring equipment carried out

* + - * 1. provide records of occupational exposure to:

individual workers in respect of their own exposure

subsequent employers of workers, subject to satisfying confidentiality criteria

the Director on request or if the managing entity is no longer able to maintain records as required under subclause 11(b)

* + - * 1. provide records of source monitoring and environmental monitoring to assess public exposure to:

members of the public on request

the Director on request

the Director immediately, if any levels exceed operational limits and conditions relating to public exposure or there is a significant increase in dose rate that could be attributed to the authorised practice.

## Incidents, accidents and emergencies

* + - 1. The managing entity 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. take timely action to mitigate the consequences of any accident that does occur and restore radiation equipment to a safe condition
				3. promptly investigate any incident, including by:

calculating or estimating doses a person has received and, if applicable, the dose distribution within them

identifying corrective actions required to prevent a recurrence

* + - * 1. implement all corrective actions identified in subclause 12(c)(ii)
				2. keep a written record of the incident, including the:

cause or suspected cause

calculations made under subclause 12(c)(i)

corrective actions identified under subclause 12(c)(ii)

details of the implementation of corrective actions under subclause 12(d)

* + - * 1. notify any reportable incident to the Director as soon as is practicable but not exceeding 48 hours.
			1. If the safety assessment required by clause 2 indicates a reasonable likelihood of an emergency affecting either workers or members of the public, the managing entity must prepare an emergency plan to protect people and the environment, which includes:
				1. arranging to promptly identify an emergency
				2. determining the correct level of emergency response
				3. providing individual monitoring and area monitoring and arranging for medical treatment
				4. arranging to assess and mitigate any consequences of an emergency
				5. conducting drills and/or emergency exercises at appropriate intervals, which include the involvement of external parties if they are part of the emergency plan.

## Records

* + - 1. The managing entity must maintain adequate records, retaining these records for not less than 10 years or as otherwise specified and make them available as necessary, including:
				1. the delegation of responsibilities of the managing entity
				2. the names of all people with responsibility for protection and safety, including details of their qualifications, education and training
				3. annual review of the protection and safety management system
				4. cradle-to-grave documentation for sealed sources including the manufacturer’s original documentation for not less than 10 years after sale, export or disposal
				5. a movement log for portable devices used in the field or that are sent away for service or calibration
				6. reports on investigations of unintended and accidental exposures
				7. non-routine releases of radioactive material to the environment
				8. exemptions from this code granted under section 86(3) of the Act.

# Other parties

## Radiation safety officer

* + - 1. The radiation safety officer must oversee the day-to-day implementation of regulatory requirements by the managing entity, including:
				1. maintaining sealed source inventory records
				2. inspecting and maintaining engineering controls, safety features and warning features
				3. overseeing access control for controlled areas
				4. establishing and periodically reviewing arrangements for personal dosimetry, including maintaining and reviewing occupational dose records
				5. performing routine operational checks of radiation survey meters and personal alarm monitors to ensure that the instruments are working properly
				6. ensuring that everyone with responsibilities for radiation protection and safety is suitably trained in the use of sealed sources and radiation protection, and that they receive regular refresher training
				7. ensuring that emergency plans are established and practised
				8. supervising workplace monitoring arrangements
				9. establishing, issuing and periodically reviewing local rules
				10. investigating higher-than-usual exposures and overexposures
				11. investigating and reporting incidents, including accidents.
			2. The radiation safety officer must work in close cooperation with qualified experts, if engaged, to ensure that all necessary duties and tasks are performed.

## Qualified expert

* + - 1. The qualified expert, if engaged, must work in close cooperation with the radiation safety officer to ensure that all necessary duties and tasks are performed.

## Manufacturer/supplier

* + - 1. The manufacturer/supplier of radiation sources, protective equipment and ancillary equipment must:
				1. supply well-designed, well-manufactured and well-constructed radiation sources and equipment that:

provide for protection and safety in line with the requirements of this code

meet engineering, performance and functional specifications

meet quality standards appropriate to the significance of systems and components, including software, for protection and safety

provide clear displays, gauges and instructions on operating consoles

* + - * 1. test radiation sources and equipment to demonstrate compliance with relevant specifications
				2. provide information on how to properly install and use radiation sources and equipment and on associated radiation risks, including performance specifications, instructions for operating and maintenance, and instructions for protection and safety
				3. optimise the protection provided by shielding and other protective equipment
				4. supply all radiation sources and equipment with all appropriate radiation protection tools as a default, rather than as optional extras.
			1. The manufacturer/supplier must:
				1. make suitable arrangements with managing entities to share information on use and operating experience that may be important for protection and safety
				2. cooperate with the managing entity for the purpose of meeting the requirements in clause 4.

## Servicing engineer

* + - 1. The servicing engineer must:
				1. install and service sealed sources and devices competently, so that they comply with the requirements in clause 4
				2. after installing or servicing the equipment, provide a written report to the managing entity verifying that the equipment complies with this code and describing:

the equipment fault (if any)

the tests and measurements carried out

the work done and any adjustments made, including parts replaced

any changes that may affect protection and safety.

# Appendix 1:Cross‑reference to Radiation Safety Act 2016

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

|  |  |
| --- | --- |
| **Section in Act** | **Clauses in code** |
| 9(1) | 1, 4–5 |
| 9(2) | 1-8, 12–15 |
| 9(3) | 1-8, 12–15 |
| 10(1) | 4, 7-8, 14–21 |
| 10(2) | 4, 12–13 |
| 10(3) | 4, 7-8, 14–21 |
| 11 | 3, 4 |
| 12 | 2–8, 12–14 |

# Appendix 2:Training requirements

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **User** | **Radiation safety officer** | **Servicing engineer** | **Qualified expert** |
| Nuclear structure and radioactivity | l | l | m | h |
| Radiological quantities and units | l | l | m | h |
| Physical characteristics of sealed sources | m | m | m | h |
| Fundamentals of radiation detection | m | m | h | h |
| Principle and process of justification | l | m | x | h |
| Fundamentals of radiobiology, biological effects of radiation | l | l | l | h |
| Risks of cancer and hereditary disease | l | l | l | h |
| Risks of deterministic effects | l | m | l | h |
| General principles of radiation protection, including optimisation | m | m | m | h |
| Operational radiation protection | m | h | m | h |
| Particular staff radiation protection aspects | m | h | m | h |
| Risks from fetal exposure | l | m | l | h |
| National regulations and international standards | m | h | h | h |

#### Level of knowledge

x – no requirement

l – low level of knowledge (general awareness and understanding of principles)

m – medium level of knowledge (basic understanding of the topic sufficient to influence practices undertaken)

h – high level of knowledge (detailed knowledge and understanding sufficient to be able to educate others)

#### Equivalence

Qualified expert: The training requirements for a qualified expert in this appendix are deemed to be satisfied by Australasian Radiation Protection Accreditation Board certification in radiation protection.

# Appendix 3:Sealed sources and devices

* + - 1. Devices are permanently and clearly marked with the:
				1. radiation trefoil
				2. word ‘RADIOACTIVE’ in letters not less than 10 millimetres in height
				3. chemical symbol(s) and mass number of the radionuclide(s) contained within
				4. activity of the source(s) on a stated date
				5. make, model and serial number of the device
				6. name of the manufacturer and/or distributor of the source
				7. maximum permitted activity, chemical symbol(s) and mass number of the radionuclide(s) for which the device is suitable if the device is designed to allow operators to perform a source change.
			2. Shutters and their operating mechanisms are only removable with tools.
1. Maximum permitted removable activity is 0.2 kilobecquerels. However, the presence of any measurable activity should be investigated, even if below the permitted activity. [↑](#footnote-ref-1)