

# Code of Practice for Non-medical Irradiators

Draft for consultation

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# This consultation

This document sets out possible wording for a new code of practice to be issued under the Radiation Safety Act 2016 for the use of non-medical irradiators. Section 86(2) of the Act requires that anyone likely to be affected by the code is consulted before it is issued. The purpose of this document is to provide suggestions to assist in that consultation process.

The Introduction to the Code, Key roles, Definitions, equipment, testing and training sections set out the proposed wording for the new code. The Submission form contains specific questions that submitters may wish to answer. These questions are included for convenience only and submitters should feel free to provide any information they feel is relevant to the development of the code.

## Why are we consulting

In January 2017, ORS conducted a public consultation on a draft Code of Practice for Non-medical Uses of Ionising Radiation. The target audience for this consultation included all facilities using radiation or radioactive material for industrial, veterinary, agricultural, legal or security purposes. It also included facilities that use radiation or radioactive material for education, training or research, mining and procession of raw materials. The intention was to publish a single code for all non-medical activity categories supported by more detailed individual compliance guides, however, most of the audience preferred to have an individual code specific to each type of non-medical radiation use. Based on this feedback, ORS has drafted a separate code of practice for non-medical irradiators. During the drafting process, more detailed operational requirements were developed such as training, equipment and testing requirements. ORS would like invite feedback from the affected sectors on these requirements.

## How to provide feedback

You can provide feedback by:

- using our online tool at <https://consult.health.govt.nz/radiation-safety/code-of-practice-for-non-medical-irradiators-draft>.  
This is our preferred way to get feedback. Note, you can complete your submission over a number of sessions and save it as you go. If you select 'Save and come back later', you will be sent an email with a unique link that will let you return to edit and submit your response. This link can be shared with your colleagues if you require their contribution to, or review of, the submission. Once you have completed your submission, you will be sent a pdf copy for your records, or
- sending an electronic submission to [orsenquiries@health.govt.nz](mailto:orsenquiries@health.govt.nz) using the Consultation questions section of this consultation document.

The closing date for submissions is 8 November 2019.

# Introduction

## Purpose and commencement

This Code of Practice for Non-medical Irradiators ('the code') is issued by the Director for Radiation Safety ('the Director') under section 86 of the Radiation Safety Act 2016 ('the Act'). It provides operational details 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 a date to be determined following the consultation period.

## Scope

This code applies to activities associated with:

- self-shielded gamma irradiators
- panoramic wet source storage gamma irradiators
- electron beam irradiators.

The following irradiators are not included in the scope of the code:

- panoramic dry source storage gamma irradiators
- underwater gamma irradiators
- X-ray irradiators.

Activities can include manufacturing, possessing, controlling, managing, using, storing, importing, exporting, selling, supplying and disposing of radiation sources.

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

- safety of radioactive material in transport
- security of radioactive material in use, storage or transport.

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

## Contact

The Director's contact details are:

Office of Radiation Safety

PO Box 5013

Wellington 6140

Email: [orsenquiries@moh.govt.nz](mailto:orsenquiries@moh.govt.nz)

Fax: 04 496 2340

# Roles and responsibilities

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

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

**Managing entity** – the legal entity that manages or controls radiation sources and must, therefore, obtain a source licence as required by section 13(a) of the Act. Normally this is an incorporated company.

**Manufacturer/supplier** – the person or organisation that designs, manufactures, produces, constructs, assembles, installs, distributes, sells, exports or imports irradiators and radiation sources or develops software that could influence the delivery of exposures.

**Qualified expert** – an individual who is recognised as having expertise in a relevant field of specialisation such as the design of irradiators, radiation shielding calculations, and testing and maintenance of radiation survey meters.

**Radiation safety officer** – a person who is competent in radiation protection and safety who the managing entity designates to oversee the application of regulatory requirements for radiation protection and safety. This person should have seniority in the organisation and the authority to ensure that regulatory requirements are met.

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

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

# 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 that is important to the safe performance of **irradiations** such as radiation survey meters and radiation monitoring devices.

**Constraint** – a prospective and source-related value of individual dose (dose constraint) or of individual risk (risk constraint) that is used in **planned exposure situations** as a parameter for the **optimisation of protection and safety** for the source, and that serves as a boundary in defining the range of options in **optimisation**. Constraints for **occupational exposure** and **public exposure** are established or approved by the Director and, if established, are published in a compliance guide issued under this code.

**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**.

**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.

**Electron beam irradiator** – a self-contained, interlocked and integrally shielded irradiator that accelerates electrons within a vacuum system to directly irradiate products.

**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.

**Emergency equipment** – equipment other than the **irradiator** and **ancillary equipment** for use in an **emergency**.

**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 where an **irradiator** is 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** – the value of a quantity such as effective dose, intake or contamination per unit area or volume at or above which an investigation would be conducted.

**Irradiation** – the deliberate and direct exposure of products to radiation using an **irradiator**.

**Irradiator** – a self-contained unit or series of rooms in a **facility** that contains a radiation source for the purpose of directly irradiating products.

**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. '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 comforters/carers while caring for, supporting or comforting patients, 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.

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

**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, taking economic and social factors into account. 'Optimises', 'optimised' and 'optimisation' have corresponding meanings.

**Panoramic wet source storage irradiator** – an irradiator that includes a control room and a radiation room with a pool of water to fully shield radioactive sources when they are not in use.

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

**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 **irradiators**, including the means for achieving this, and the means for preventing **accidents** and for mitigating the consequences of **accidents** if they do occur.

**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.

**Radiation room** – the room in a **panoramic wet source storage irradiator** in which **irradiation** of products occurs and that has a pool of water to shield the radiation source when not in use.

**Reportable incident** – an **incident** resulting in a **dose limit** being exceeded or an **iradiator** that is lost, missing or beyond regulatory control.

**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**.

**Self-shielded gamma irradiator** – a self-contained, interlocked and integrally shielded irradiator unit with a radioactive source that emits gamma radiation.

**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:
  - (a) take prime responsibility for protection and safety
  - (b) establish a management system to enhance protection and safety that:
    - (i) effectively integrates protection and safety into the overall management system of the organisation
    - (ii) makes a commitment to protection and safety from the highest level of management at the facility, and by providing all required resources
    - (iii) promotes continuous improvement and a safety culture
    - (iv) appoints an in-house employee as a radiation safety officer to oversee the application of regulatory requirements
    - (v) delegates the planning and delivery of irradiations to an appropriately trained and qualified operator
    - (vi) consults with and engages the services of qualified experts and other interested parties as necessary to ensure that the requirements of this code are met
  - (c) for all delegations under sub-clauses 1(b)(iv) and 1(b)(v):
    - (i) ensure delegates are notified of their duties in relation to protection and safety and assume responsibility for performing them
    - (ii) fully document the delegations
  - (d) ensure that:
    - (i) all activities associated with irradiators are justified and optimised for protection and safety
    - (ii) dose limits for occupational and public exposure are not exceeded as a result of those activities
  - (e) notify the regulatory body of any proposed modifications of the irradiator or changes to key personnel.

# Safety assessment

2. The managing entity must conduct, document and keep up to date a comprehensive safety assessment to:
  - (a) identify the ways in which occupational and public exposures could be incurred, including consideration of:
    - (i) dose rates from both shielded and unshielded radiation sources
    - (ii) limits and technical conditions for operation of sources
    - (iii) ways in which external factors could affect protection and safety
    - (iv) ways in which operating errors and human factors could affect protection and safety
    - (v) evaluation and implications of any proposed modifications for protection and safety
  - (b) determine:
    - (i) the expected likelihood and magnitudes of exposures in normal operation and, to the extent reasonable and practicable, assess potential exposures of radiographers, other workers and the public, for a range of scenarios representing normal use and reasonably foreseeable incidents
    - (ii) ways in which structures, systems and components, as well as procedures relating to protection and safety, might fail or might otherwise lead to potential exposures, and the consequences of such failures
  - (c) assess the adequacy of provisions for protection and safety in respect of siting, design and operation.

# Irradiator

3. The managing entity must:
  - (a) provide facilities that are located, designed, manufactured, constructed, assembled, commissioned, operated, maintained and decommissioned through adopting good engineering practice, minimising the need to rely on administrative controls and personal protective equipment for protection and safety
  - (b) ensure that the irradiator requirements in Appendix 2 are satisfied
  - (c) ensure that construction and installation work does not compromise the safety of the facility

- (d) ensure that a qualified expert thoroughly and critically reviews the irradiator and any component part before it is commissioned to ensure that:
  - (i) safety features and warning signals and alarms have been properly installed and operate correctly
  - (ii) radiation protection for workers and members of the public and protection of the environment are adequate
- (e) designate and delineate as a controlled area:
  - (i) the irradiator
  - (ii) any other 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
- (f) periodically review the designations and delineations in clause 3(e)
- (g) shield the irradiator so that:
  - (i) no person can receive a dose exceeding 0.3 mSv per year from occupying areas outside the irradiator
  - (ii) the dose rate at any uncontrolled accessible point outside the irradiator is less than 15  $\mu$ Sv per hour
- (h) verify and document the adequacy of the shielding in controlled areas whenever circumstances change that could increase the risks
- (i) perform leak tests on sealed radioactive sources before their first use and every two years after than
- (j) prominently display signs:
  - (i) specifying the actual or potential presence of ionising radiation using the symbol recommended by the International Organization for Standardization at access points to controlled areas and supervised areas and at appropriate locations within controlled areas
  - (ii) controlling unauthorised access to controlled areas and supervised areas
- (k) formally decommission any irradiator if there are no plans to use it again in the foreseeable future, including by:
  - (i) conducting a comprehensive radiation survey to confirm that no radiation sources have been left on the site and that there is no contamination
  - (ii) preparing a final decommissioning report that includes the final radiation survey and details of the storage, transfer or disposal of the irradiator
  - (iii) submitting the final decommissioning report to the Office of Radiation Safety

- (l) ensure that ancillary equipment is provided, routinely inspected, maintained, tested, calibrated, serviced and safely managed so that the equipment:
  - (i) is appropriate for the procedures to be performed and enables those procedures to be carried out safely and effectively
  - (ii) remains capable of fulfilling its design requirements for protection and safety throughout its lifetime
  - (iii) is not modified without a prior assessment, reviewed by a qualified expert of the supplier, of the implications of the modification for the original design and the safety assessment
- (m) cooperate with manufacturers/suppliers to:
  - (i) share information on use and operating experience that may be important for protection and safety
  - (ii) apply the principles of optimisation in the design, planning, operation and decommissioning of a source
- (n) maintain an accurate inventory of all radiation sources, including their location and description
- (o) maintain a record of maintenance for the irradiator, which includes:
  - (i) a fault log and remedial actions taken (interim and subsequent repairs)
  - (ii) the results of testing before an item is reintroduced to use
  - (iii) any reports from servicing engineers.

## Training and authorisation

- 4. The managing entity must ensure that:
  - (a) all persons with responsibilities for protection and safety:
    - (i) are qualified, educated and trained in protection and safety so that they understand their duties and can perform them competently
    - (ii) satisfy the training requirements in Appendix 3
  - (b) all documents provided by the manufacturer, supplier or installer (including operating manuals, operating rules and procedures, and emergency procedures) are available in the local language and are understandable to the users.

## Policies, procedures and local rules

5. The managing entity must establish, implement and maintain policies, procedures and local rules to meet the requirements of this code, including, without limitation, policies, procedures and local rules to:
  - (a) control access to areas where people can be exposed to radiation
  - (b) describe locations to be subject to workplace monitoring, the frequency of monitoring and the records to be kept
  - (c) use constraints to optimise protection and safety
  - (d) prevent accidents and emergencies and mitigate the consequences of any that occur
  - (e) report on and learn from accidents and other incidents
  - (f) comply with operational limits and conditions relating to public exposure
  - (g) provide protection and safety by applying preventive measures in the following hierarchy:
    - (i) engineered controls
    - (ii) administrative controls
    - (iii) personal protective equipment
  - (h) set investigation levels and establish procedures to follow if such levels are exceeded
  - (i) ensure that information on the safe use of equipment is provided to users
  - (j) implement procedures for verifying compliance with this code
  - (k) periodically review the overall effectiveness of measures for protection and safety.

## Monitoring and measurement

6. The managing entity must establish and maintain:
  - (a) a programme of continuous individual monitoring whenever appropriate, adequate and feasible, which is sufficient to assess occupational exposures for workers who usually work in a controlled area or who may receive a dose exceeding 10 percent of the dose limits
  - (b) a programme of workplace monitoring that is sufficient to:
    - (i) evaluate radiation conditions in all workplaces
    - (ii) assess exposures in controlled areas and supervised areas that are not assessed under clause 6(a)
    - (iii) review the classification of controlled areas and supervised areas

- (c) a monitoring programme for all workers who could be subject to exposure due to contamination, which is sufficient to:
    - (i) demonstrate the effectiveness of the measures for protection and safety
    - (ii) assess intakes of radionuclides and committed effective doses
  - (d) programmes of source monitoring or environmental monitoring that are sufficient to assess public exposure arising from the irradiator
  - (e) a capability that is sufficient to monitor unexpected increases in radiation levels due to an incident attributed to a source or facility for which the managing entity is responsible
  - (f) other monitoring or measurement programmes as necessary to verify compliance with the requirements in this code.
7. To satisfy the monitoring and measurement requirements in clause 6, the managing entity must:
- (a) use appropriate monitoring equipment
  - (b) for continuous individual monitoring under clause 6(a), use an external service or internal capability only if that service or capability:
    - (i) is approved by the Director
    - (ii) returns results to the managing entity within 20 working days of receiving all necessary raw information.
8. The managing entity must:
- (a) use best endeavours to obtain previous dose records for all workers
  - (b) maintain records of all monitoring and verification of compliance, including records of:
    - (i) occupational exposure during and after the worker's working life, at least until the worker attains or would have attained the age of 75 years, and for not less than 30 years after ceasing work where the worker was subject to occupational exposure
    - (ii) estimated doses to members of the public
    - (iii) the tests and calibrations carried out
  - (c) provide records of occupational exposure to:
    - (i) individual workers in respect of their own exposure
    - (ii) subsequent employers of workers, subject to satisfying confidentiality criteria
    - (iii) the Director on request or if the managing entity is no longer able to maintain records as required under clause 8(b)



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

## Incidents, accidents and emergencies

- 9. The managing entity must:
  - (a) take all practicable steps to minimise the likelihood of accidents, including by using a multilevel system of sequential, independent provisions for protection and safety, commensurate with the likelihood and magnitude of potential exposures
  - (b) take timely action to mitigate the consequences of any accident that does occur and restore the irradiator to a safe condition
  - (c) promptly investigate any incident, including by:
    - (i) calculating or estimating doses a person has received and, if applicable, the dose distribution within them
    - (ii) identifying corrective actions required to prevent a recurrence
  - (d) implement all corrective actions identified in clause 9(c)(ii)
  - (e) keep a written record of the incident, including of the:
    - (i) cause or suspected cause
    - (ii) calculations made under clause 9(c)(i)
    - (iii) corrective actions identified under clause 9(c)(ii)
    - (iv) details of the implementation of corrective actions under clause 9(d)
  - (f) promptly notify any reportable incident to the Director.
- 10. If the safety assessment required by clause 2 indicates that there is a reasonable likelihood of an emergency affecting either workers or members of the public, the managing entity must prepare and maintain an emergency plan for the protection of people and the environment, which includes:
  - (a) arrangements for promptly identifying an emergency
  - (b) determining the correct level of emergency response
  - (c) provision for individual monitoring, area monitoring and arrangements for medical treatment

- (d) arrangements for assessing and mitigating any consequences of an emergency.
11. The managing entity must:
- (a) conduct emergency exercises at appropriate intervals
  - (b) ensure that external parties know what is expected of them if they are part of the emergency plan.

## Records

12. The managing entity must maintain adequate records, and make them available as necessary, including records of:
- (a) the management structure as it relates to radiation safety
  - (b) the delegation of responsibilities of the managing entity and the radiation practitioner
  - (c) the names of all people with responsibility for protection and safety, including details of their qualifications, education and training
  - (d) the design and shielding of the irradiator
  - (e) the quality assurance programme
  - (f) information necessary for the retrospective assessment of doses
  - (g) reports on investigations of unintended and accidental medical exposures
  - (h) exemptions from this code granted under section 86(3) of the Act.

## Quality assurance

13. The managing entity must establish a comprehensive quality assurance programme, which covers:
- (a) maintaining the irradiator
  - (b) carrying out the tests in Appendix 4 for panoramic wet source storage irradiators
  - (c) ensuring that the irradiator is not used until repairs are made if any of the tests required in clause 13(b) indicate a fault or if safety interlocks do not function properly
  - (d) testing and maintaining exposure bays and storage rooms to ensure the requirements in this code are satisfied, including requirements for appropriate safety systems and warning systems
  - (e) maintaining records of relevant procedures and results.

# Other parties

## Radiation safety officer

14. The radiation safety officer must oversee the managing entity's day-to-day implementation of regulatory requirements, including by:
  - (a) maintaining source inventory records
  - (b) inspecting and maintaining engineering controls, safety features and warning features
  - (c) overseeing access control for controlled areas
  - (d) establishing and periodically reviewing arrangements for personal dosimetry, including maintenance and review of occupational dose records
  - (e) performing routine operational checks of radiation survey meters and personal alarm monitors, in collaboration with the operators, to ensure that the instruments are working properly
  - (f) ensuring that everyone with responsibilities for protection and safety is suitably trained in the use of equipment and radiation protection, and that they receive regular refresher training
  - (g) ensuring that emergency plans are established and that they are practised regularly
  - (h) supervising workplace monitoring arrangements
  - (i) establishing, issuing and periodically reviewing local rules
  - (j) investigating higher-than-usual exposures and overexposures
  - (k) investigating and reporting incidents, including accidents.
15. The radiation safety officer must work in close cooperation with qualified experts, if appointed, to ensure that all necessary duties and tasks are performed.

## Qualified expert

16. The qualified expert, if appointed, must work in close cooperation with the radiation safety officer to ensure that all necessary duties and tasks are performed.

# Manufacturer/supplier

17. The manufacturer/supplier of irradiators must:
- (a) supply well-designed, well-manufactured and well-constructed irradiators that:
    - (i) provide for protection and safety in line with the requirements of this code
    - (ii) meet engineering, performance and functional specifications
    - (iii) meet quality standards appropriate to the significance of systems and components, including software, for protection and safety
    - (iv) provide clear displays, gauges and instructions on operating consoles
  - (b) test irradiators to demonstrate compliance with relevant specifications
  - (c) provide information on how to properly install and use irradiators and on associated radiation risks, including performance specifications, instructions for operating and maintenance, and instructions for protection and safety
  - (d) optimise the protection provided by shielding and other protective devices
  - (e) supply all irradiators with all appropriate radiation protection tools as a default, rather than as optional extras
  - (f) maintain records of sealed sources provided, including records of:
    - (i) model number, serial number or identification number of the radioactive source, the radionuclide contained, the source activity and the date to which the stated source activity relates
    - (ii) ISO Standard 2919 source certificate
    - (iii) leak test certificate
    - (iv) contamination test certificate.
18. The manufacturer/supplier must:
- (a) make suitable arrangements with managing entities to share information on use and operating experience that may be important for protection and safety
  - (b) cooperate with the managing entity in accordance with clause 3(l).

# Servicing engineer

19. The servicing engineer must:
- (a) install and service the irradiator competently, so that it complies with the requirements in clause 3
  - (b) cooperate with the managing entity to ensure that irradiators cannot be used while it is being installed or serviced
  - (c) after installing or servicing the irradiator:
    - (i) collaborate with the managing entity to ensure necessary quality control tests are completed successfully
    - (ii) confirm that all radiation protection and safety features are in place and operating correctly before returning the irradiator to use
    - (iii) provide a written report to the managing entity describing the fault (if any), the work done, parts replaced, adjustments made and 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 this code
9(1)	1, 4–5
9(2)	1–8, 12–15
9(3)	1–8, 12–15
10	2–15, 17–19
11	3, 14
12	2–8, 12–15

# Appendix 2:

## Irradiator requirements

### Self-shielded gamma irradiators and electron beam irradiators

#### Shielding

- The irradiator unit is shielded to ensure that radiation exposure of workers and members of the public is limited to optimised levels and within dose constraints.
- No changes are made to shielding without the regulatory body's approval.

#### Access

- Access controls enable the managing entity to restrict the use of the irradiator to authorised personnel only.

#### Safety systems and devices

- Systems and devices combine to provide protection in depth so that if one system fails, a second or third system can be relied on to provide the intended protection.
- Redundancy and diversity are built into each system to reduce the risk of failure.
- Systems and devices are independent so that a fault of the irradiator does not impair the safety system that is intended to mitigate the fault.
- Systems always fail to safety.

# Panoramic wet source storage gamma irradiators

## Equipment

- All equipment inside the radiation room, including the wiring, electrical equipment, notices and lighting, is selected to minimise failure due to prolonged exposure to radiation.

## Product positioning and movement

- Any malfunction of the product conveyor mechanism automatically causes the source rack to return to its fully shielded position.
- A timer is provided to monitor the movement of the product past the source rack.
- If the product ever fails to move as expected:
  - the source rack automatically returns to its fully shielded position
  - the product positioning system stops
  - visible and audible signals are triggered to alert the operator to the malfunction.

## Shielding

- All rooms are shielded to ensure that radiation exposure of workers and members of the public is limited to optimised levels and within dose constraints.
- No changes are made to shielding without the regulatory body's approval.

## Access

- A series of sequential safety interlocks and controls is integrated into the master control system to ensure that:
  - nobody can gain access to the radiation room while the source is in the exposed position
  - any attempt to pre-empt the controls or to apply them out of sequence will automatically prevent the intended operation
  - violation or malfunction of the system will cause the irradiation to be automatically terminated and will trigger visible and audible alarms.
- Additional and independent backup controls are at all points of entry to the radiation room to detect entry of personnel while the source rack is in the unshielded position so that any detection of personnel entry when radiation levels are high will cause the irradiation to be automatically terminated and will trigger visible and audible alarms.



## Monitoring system

- A monitoring system measures the ambient radiation level in the radiation room to provide independent verification when the source rack has been returned to its shielded position.
- The system:
  - is interlocked with the personnel access door to prevent access to the radiation room when radiation levels are above a preset level, or the system malfunctions or is switched off
  - triggers visible and audible alarms if the radiation level exceeds the preset level.

## Control console

- A single multipurpose key:
  - can be used to operate the irradiator in normal use and to gain access to the radiation room
  - is attached to a portable radiation survey meter by a chain or cable that is long enough to allow easy operation of all key switches.
- A clearly labelled emergency stop device is provided for preventing, quickly interrupting or aborting irradiator operations and returning the source rack to its shielded position.
- Capability to disable the means of producing radiation while servicing operations are being carried out.

## Radiation room

- A safety delay timer inside the radiation room:
  - is set off to begin the irradiator start up procedure
  - automatically triggers visible and audible alarms to alert personnel in the radiation room that start up processes have begun and to allow them sufficient time to leave the area
  - is integrated with the control system so that operation of the radiation source cannot be initiated unless the start up sequence has been completed within the preset time and the control console indicates that it is safe to start the irradiator.
- An emergency stop device is in the radiation room for promptly aborting irradiator operations and returning the source rack to its fully shielded position.
- The emergency stop device:
  - is clearly labelled and readily accessible to personnel in the radiation room
  - can trigger a visible or audible alarm outside the radiation room.
- A means is provided for anyone inadvertently shut inside the radiation room to exit at any time.

## Seismic event warning

- Instrumentation is provided to warn that a seismic event has occurred and to return the source rack to its shielded position.

## Notices and symbols

- Radiation symbols and other notices, warning of the presence of radioactive material, are placed at entrances to the radiation room and next to the source rack.
- A supplementary radiation symbol (ISO 21482) is also placed in close proximity to the source to inform members of the public that the source poses a significant danger to them.

## Irradiation status indicators

- An irradiation status indicator is clearly visible at the control console and at each personnel and product entrance and exit port to show when the source rack is in:
  - shielded position
  - irradiation position
  - transit between its shielded and irradiation positions.

## Audible signals

- Each audible signal used in the control system is distinct and loud enough to immediately gain the attention of people in the area.

## Labelling and posting

- Indicators and visual signals are clearly labelled to identify the conditions that can set them off.
- A copy of the source licence issued under the Radiation Safety Act 2016 and emergency contact information are posted in clearly visible locations in the facility.

## Radioactive source and source rack

- The source is housed in an outer capsule that does not corrode due to its storage in the storage pool.
- Radioactive material is substantially insoluble in water.
- The sealed source is firmly fixed within its source holder and source rack so that it cannot be readily dislodged.

## Water pool

- Automatic water-level control is provided to maintain water at a level that provides adequate shielding.
- The storage pool is cleaned periodically to remove any foreign matter that has accumulated at the bottom.
- A fixed radiation monitor is located on the water treatment system to detect any contamination that occurs if a radioactive source leaks.
- The fixed radiation monitor triggers visible and audible alarms if radiation levels are too low or too high.
- The storage pool is:
  - watertight and retains water under all reasonably foreseeable circumstances
  - made of corrosion-resistant materials
  - equipped with a water condition system capable of keeping the water clear and at a level of conductivity not more than 1,000  $\mu\text{S}/\text{m}$  for routine operation and not more than 2,000  $\mu\text{S}/\text{m}$  for temporary excursions not exceeding 90 days.

## Fire protection

- A fire protection system is provided in the radiation room.

## Power failure

- The source rack is automatically returned to its shielded position if electrical power fails for longer than 10 seconds.

# Appendix 3:

## Training requirements

	IOP	RSO
<b>Fundamental concepts and measurements</b>		
Basic radiation concepts	m	h
Radiation quantities and units	m	h
Radiation detection instruments	h	h
Biological effects of radiation	m	m
<b>Principles of radiation protection</b>		
Justification, optimisation and limitation	m	h
Regulatory requirements	m	h
Designation of controlled areas and supervised areas	m	h
Dose limits and investigation levels	m	h
<b>Practical radiation protection</b>		
Design, operation and preventive maintenance of the irradiator	m	h
Written procedures for routine and emergency operation of the irradiator	m	h
Dose rates at all areas around the irradiator	h	h
Maintenance of required operation logs and records	m	h
Organisation structure and delegations of authority for irradiator operation	m	h
Local rules	m	h
Emergency plans, preparedness and response	m	h
End-of-life considerations for radiation sources	m	h
Accidents and other incidents	m	h
Emergency preparedness and response	m	h

# Abbreviations used in this appendix

ALARA = as low as reasonably achievable

## Parties

IOP = irradiator operator

RSO = radiation safety officer

## Level of knowledge

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)

# Appendix 4:

## Testing requirements

This appendix sets out the testing requirements to be completed for panoramic wet source storage gamma irradiators.

### Weekly tests

- Check radiation levels at the deioniser filter and resin beds using a survey meter.
- Check the water deioniser system for correct operation.
- Check that the access control system, the emergency stop device in the radiation room and the system for the detection of entry by personnel are functioning.

### Monthly tests

- Check that the radiation monitor in the radiation room is functioning properly.
- Check that access to the radiation room is prevented when the radiation room monitor alarm sounds upon exposing the monitor probe to a check source.
- Test that the product exit radiation monitor is functioning properly.
- Check that the continuous radiation monitoring device on the circulation system for the storage pool water is functioning correctly.
- Test irradiator shutdown controls during operation where possible.
- Test the source rack hoist mechanism, the ventilation system and any similar hardware that contributes to the safe operation of the irradiator, and the product positioning mechanism.
- Check that other main items of equipment associated with the means of producing radiation function properly and show no signs of excessive wear or potential failure.
- Check that all product containers are undamaged and in good condition.
- Check for correct functioning of the emergency stop device on the control console and at any other locations.
- Check all visual warning signals and alarms for correct operation.
- Check control indicator lights to ensure that they illuminate.
- Attempt to operate the irradiator after deliberately violating the approved start up procedure, to ensure that the safety interlocks and sequential controls are functioning correctly.

- Verify that the uninterruptible power supply is functioning properly and is capable of providing adequate electrical power to allow safe shutdown of the irradiator.
- Verify that heat detectors and smoke detectors are operating properly.
- Verify that safety interlocks associated with removable shield plugs in the radiation room are operating properly.
- Evaluate the amount of water added to the source storage pool to determine whether the amount of make-up water added is abnormal.
- Verify that posted notices and symbols are still present, legible and clearly visible.
- Check that the access control system, the emergency stop device in the radiation room and the system for the detection of entry by personnel are functioning.
- Test the safety delay timer by setting off the timer, waiting until the time limit has expired and then attempting start up to verify that the system cannot be started.

# Submission form

## Your details

This submission was completed by: *(name)* \_\_\_\_\_  
Address: *(street/box number)* \_\_\_\_\_  
*(town/city)* \_\_\_\_\_  
Email: \_\_\_\_\_  
Organisation *(if applicable)*: \_\_\_\_\_  
Position *(if applicable)*: \_\_\_\_\_

## Additional information

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

New Zealand     Australia     Other *(please specify)*: \_\_\_\_\_

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

Servicing engineer                       Organisation that uses/stores material  
 Radiation security officer               Other *(please specify)*: \_\_\_\_\_

## Privacy

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

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

Do not publish this submission.

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

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

## Please return this form:

By email to: orsenquiries@health.govt.nz (including 'irradiators code' in the subject line)

By post to: Office of Radiation Safety, PO Box 5013, Wellington 6140.



# Consultation questions

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

## Scope

1. Do you agree that the scope of this code is appropriate?

Yes

No

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

## Roles and responsibilities

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

Yes

No

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

## Definitions

3. Are the definitions appropriate and comprehensive?

Yes

No

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

## Managing entity obligations

4. a. Are the subheadings within the 'Managing entity' section appropriate?
- Yes
- No
- b. Are there other changes you think are necessary to the obligations of the managing entity?
- Yes
- No
- c. Please provide any comments below.

## Other parties

5. a. Are there other parties who should have defined responsibilities?
- Yes
- No
- b. Are there other changes you think are necessary to the obligations of other parties?
- Yes
- No
- c. Please provide any comments below.

## Appendix 2: Irradiators requirements

6. a. Is the information in this appendix appropriate and comprehensive?
- Yes
- No
- b. Please provide any comments below.

## Appendix 3: Training requirements

7. a. Is the information in this appendix appropriate and comprehensive?
- Yes
- No
- b. Please provide any comments below.

## Appendix 4: Testing requirements

8. Was the information in this code appropriately presented?
- Yes
- No

## Additional comments

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

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

Yes

No

g. Please provide any comments related to your answers to 9(a)–(f) below.