MINISTRY OF HEALTH
MANATŪ HAUORA

New Zealand Government

Code of Practice for Irradiating Apparatus

ORS C10

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Introduction

Purpose and commencement

This Code of Practice for Irradiating Apparatus ('code') is issued by the Director for Radiation Safety ('the Director') under section 86 of the Radiation 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 all activities associated with fixed and mobile irradiating apparatus used for non-medical purposes such as analysis of structures; identification and quantification of elements in materials; inspection of bags, mail, containers and other items; and inspection of food items for foreign objects.

The use of irradiating apparatus for medical, veterinary, industrial radiography, irradiation, or electron beam welding purposes is dealt with in separate codes of practice.

Activities can include the manufacture, possession, control, management, use, storage, import, export, sale, supply and disposal of irradiating apparatus.

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, electrical safety, hazards in the workplace and resource management.

Contact

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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 irradiating apparatus 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 items of irradiating apparatus 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 irradiating apparatus.

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 **irradiating apparatus** 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**. 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 – 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**.

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 items of **irradiating apparatus** are installed, used, handled or stored.

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

Irradiating apparatus – electrical equipment that:

(a) is designed to generate ionising radiation such as X-rays, neutrons, electrons or other charged particles, or

(b) produces ionising radiation as a byproduct:

  (i) resulting in a dose equivalent rate of or exceeding 1 microsievert (μSv) per hour at a point 0.1 metres from any accessible surface, and

  (ii) that has a maximum energy of or exceeding 5 kiloelectronvolts.

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.

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.

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 **irradiating apparatus** or from a planned activity that results in an exposure due to **irradiating apparatus.**

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 **irradiating apparatus**, including the means for achieving this, and the means for preventing **accidents** and the mitigation of consequences of **accidents** if they do occur.

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

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 – a procedure involving the use of **irradiating apparatus**.

Reportable incident – an **incident** resulting in (a) a **dose limit** being exceeded or (b) **irradiating apparatus** 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**.

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.

Worker – an individual who works, whether full time, part time or temporarily, for the managing entity and who has recognised rights and duties in relation to occupational radiation protection. 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 includes:

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

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

      (iii) promoting continuous improvement and a safety culture

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

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

   (c) for all appointments under subclause 1(b)(iv):

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

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

   (d) ensure that:

      (i) all activities associated with irradiating apparatus are justified and optimised for protection and safety

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

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

   (e) 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

2. The managing entity must conduct, document and keep up to date a safety assessment to:

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

(b) determine the expected likelihood and magnitudes of exposures in normal operation and, to the extent reasonable and practicable, assess potential exposures

(c) assess the adequacy of provisions for protection and safety in respect of siting, design and operation.

Facilities

3. The managing entity must:

(a) 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

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

(c) restrict access as appropriate to controlled areas and supervised areas

(d) provide suitable means for exit so that any person inadvertently remaining in a room containing irradiating apparatus can promptly exit the area

(e) shield or manage all areas in which irradiating apparatus that does not comply with subclause 4(a)(iv) will be used or stored so that:

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

(ii) the dose rate at any point outside the use and storage areas is less than 10 μSv per hour

(f) verify and document the adequacy of shielding at commissioning and whenever circumstances change in ways that could increase the risks

(g) 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 access by members of the public to controlled areas and supervised areas.

Equipment

4. The managing entity must:

   (a) provide, maintain, test and regularly service each item of irradiating apparatus, protective equipment and ancillary equipment so that:

      (i) it is fit for its intended purpose

      (ii) it fulfils its design requirements for protection and safety

      (iii) irradiating apparatus meets the requirements in Appendix 3

      (iv) whenever irradiating apparatus is used or stored in areas that are not shielded or managed in accordance with subclause 3(e), the apparatus has sufficient shielding and interlocks so that no person can receive an effective dose exceeding 0.3 mSv per year and the dose rate in any occupied area is less than 10 µSv per hour

      (v) the protective value of protective equipment is clearly displayed on the equipment where applicable

      (vi) the removal of any interlocked shielding component prevents X-ray generation, and the replacement of such a component does not allow X-ray generation until the equipment operation is reset

   (b) prefer the use of fixed equipment over portable handheld equipment whenever practicable and reasonable

   (c) provide, as appropriate:

      (i) protective equipment

      (ii) equipment for individual monitoring and workplace monitoring

   (d) maintain control of all items of irradiating apparatus to prevent loss or damage and to prevent any person from carrying out unauthorised activities, including by:

      (i) maintaining an accurate inventory of all items of irradiating apparatus, including their location and description

      (ii) periodically checking that items of irradiating apparatus are under control and in the locations recorded in the inventory maintained under subclause 4(d)(i)

      (iii) releasing irradiating apparatus only to people who are authorised to assume management and control under the Act

   (e) take immediate steps to regain control of any item of irradiating apparatus that is abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation.

   (f) dispose of irradiating apparatus[1] only if:

      (i) it is rendered impracticable to restore the unit to a condition where it is capable of producing radiation such as by puncturing the glass tube within the X-ray head or destroying vital components

[1] Any radioactive material, eg, activated components from accelerators, must be disposed of in accordance with the *Code of Practice for Unsealed Radioactive Material: ORS C11*.

(ii) radiation signs such as trefoils are removed or obscured.

Training and authorisation

5. The managing entity must ensure that all people with responsibilities for protection and safety:

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

   (b) are suitably trained according to the training requirements set out in Appendix 2, and receive regular refresher training

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

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

   (e) are authorised to assume their roles and responsibilities.

Restricted activities

6. The managing entity must not, without the prior written approval of the Director, allow irradiating apparatus to be used for human imaging:

   (a) as a form of art or for publicity purposes

   (b) for occupational, legal or health insurance purposes, and undertaken without referring to clinical indication

   (c) to detect concealed objects.

Policies, procedures and local rules

7. The managing entity must establish, implement and maintain policies and procedures to meet the requirements of this code including, without limitation, policies and procedures:

   (a) to control access to areas where people can be exposed to radiation

   (b) to prevent people from being exposed to the primary radiation beam

   (c) to prohibit the bypass of safety interlocks in normal operating conditions

   (d) to use constraints to optimise protection and safety

   (e) to prevent accidents and mitigate the consequences of any that occur

   (f) to report on and learn from accidents and other incidents

   (g) to comply with operational limits and conditions relating to public exposure

(h) for staff who have indicated they may be pregnant to minimise unnecessary exposure to the embryo or fetus

(i) to provide protection and safety by applying preventive measures in the following hierarchy:

(i) engineered controls

(ii) administrative controls

(iii) personal protective equipment

(j) to set an investigation level and establish procedures to follow if such a level is exceeded

(k) to implement the annual review of the protection and safety management system.

8. The managing entity must maintain, publish and enforce any written local rules that are necessary for protection and safety.

Monitoring and measurement

9. 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 subclause 9(a)

(iii) review the classification of controlled areas and supervised areas

(c) 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

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

10. To satisfy the monitoring and measurement requirements in clause 9, the managing entity must:

    (a) use appropriate monitoring equipment[2]

    (b) for continuous individual monitoring under subclause 9(a), use an external service that:

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

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

11. The managing entity must:

    (a) take all reasonable steps to obtain previous dose records

    (b) maintain records of all monitoring and verification of compliance, including:

        (i) records of occupational exposure during and after the worker's working life, at least until the worker 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) records and estimated doses to members of the public

        (iii) records of the tests and calibrations of radiation monitoring equipment 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 subclause 11(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.

[2] Care should be taken to select the correct monitoring equipment for pulsed radiation fields, eg, an ionisation chamber based survey meter.

Incidents, accidents and emergencies

12. 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 radiation equipment 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 subclause 12(c)(ii)

    (e) keep a written record of the incident, including the:

        (i) cause or suspected cause

        (ii) calculations made under subclause 12(c)(i)

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

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

    (f) notify any reportable incident to the Director as soon as is practicable but not exceeding 48 hours.

13. 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:

    (a) arranging to promptly identify an emergency

    (b) determining the correct level of emergency response

    (c) providing individual monitoring and area monitoring and arranging for medical treatment

    (d) arranging to assess and mitigate any consequences of an emergency

    (e) conducting drills and/or emergency exercises at appropriate intervals, including the involvement of external parties if they are part of the emergency plan.

Records

14. The managing entity must maintain adequate records, retain records for not less than 10 years or as otherwise specified, and make them available as necessary, including:

    (a) the delegation of responsibilities of the managing entity

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

    (c) annual review of the protection and safety management system

    (d) cradle-to-grave records for sealed sources including the manufacturer's original documentation for not less than 10 years after sale, export or disposal

    (e) reports on investigations of unintended and accidental exposures

    (f) exemptions from this code granted under section 86(3) of the Act.

Other parties

Radiation safety officer

15. The radiation safety officer must oversee the day-to-day implementation of regulatory requirements by the managing entity, including:

    (a) maintaining radiation 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 maintaining and reviewing occupational dose records

    (e) performing routine operational checks of radiation survey meters and personal alarm monitors to ensure that the instruments are working properly

    (f) ensuring that everyone with responsibilities for radiation protection and safety is suitably trained in the use of irradiating apparatus and radiation protection, and that they receive regular refresher training

    (g) ensuring that emergency plans are established and practised

    (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.

16. 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

17. 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

18. The manufacturer/supplier of radiation sources, protective equipment and ancillary equipment must:

(a) supply well-designed, well-manufactured and well-constructed radiation sources and equipment 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 radiation sources and equipment to demonstrate compliance with relevant specifications

(c) 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

(d) optimise the protection provided by shielding and other protective equipment

(e) supply all radiation sources and equipment with all appropriate radiation protection tools as a default, rather than as optional extras.

19. 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 for the purpose of meeting the requirements in clause 4.

Servicing engineer

20. The servicing engineer must:

(a) install and service irradiating apparatus competently, so that it complies with the requirements in clause 4

(b) after installing or servicing the equipment, provide a written report to the managing entity verifying that the equipment complies with this code and describing:

(i) the equipment fault (if any)

(ii) the tests and measurements carried out

(iii) the work done and any adjustments made, including parts replaced

(iv) 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)	1–2, 5–8, 16–18
9(2)	1–5, 7–11, 14–18
9(3)	1–5, 7–11, 16–18
10(1)	4, 7–8, 14–21
10(2)	4, 12–13
10(3)	4, 7–8, 14–21
11	4
12	4

Appendix 2: Training requirements

	User	Radiation safety officer	Servicing engineer	Qualified expert
Atomic structure, X-ray production and interaction of radiation	l	l	m	h
Nuclear structure and radioactivity	x	x	m	h
Radiological quantities and units	l	l	m	h
Physical characteristics of irradiating apparatus	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 fatal exposure	l	m	l	h
Quality control and quality assurance	l	m	h	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: Equipment requirements

General requirements

- An illuminated warning sign visible from all possible operator positions is:
  - activated when the radiation beam is on
  - interlocked with the generator so that failure of the lamp will terminate the production of radiation.
- A durable and legible label is affixed showing the equipment model and serial number.
- Signage or labelling is affixed warning of the possible presence of radiation.
- The dose rate due to leakage and scatter radiation must be as low as reasonably achievable and must not exceed 25 µSv per hour at any accessible surface on the equipment when the irradiating apparatus is operated at any of the permitted ratings specified by the manufacturer.
- Access is key-operated or password-protected to prevent unauthorised operation.

X-ray analysis equipment

In addition to the general requirements above:

- it is not possible to remove shutters and their operating mechanisms without the use of tools
- in normal operating conditions:
  - it is not possible for any workers operating the equipment to be exposed to the primary radiation beam, or
  - a local rule is established and enforced to prevent any such exposure
- for X-ray diffraction equipment:
  - each independently operated shutter has a distinct warning light, and is interlocked so that it cannot open unless diffraction equipment, which will completely intercept the primary beam, is in position at the beam port
  - for all equipment that allows routing changing of samples in the path of the primary X-ray beam, the sample position is not accessible when the beam is on
- for handheld XRF equipment, either:
  - a proximity sensor prevents X-rays from being generated without a sample held against the aperture, or
  - where this is not practicable, a low-count (backscatter) interlock is fitted.[3]

[3] Ideally, both safety systems should be fitted.

X-ray inspection equipment

In addition to the general requirements above:

- the radiation beam can be precisely collimated
- interlocked systems can prevent inadvertent exposures, if applicable
- pre-set technique factors are available for each mode of operation
- emergency stop buttons are available, if applicable.