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**CODE OF SAFE PRACTICE FOR THE USE OF
SEALED RADIOACTIVE MATERIALS FOR
BRACHYTHERAPY**

**National Radiation Laboratory
Ministry of Health
PO Box 25-099
Christchurch
New Zealand**

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1 INTRODUCTION

1.1 Purpose

The purpose of this *Code of safe practice* is to provide mandatory requirements for the protection of staff, patients, and members of the public by ensuring that:

- any exposure to radiation is justified
- the risk from any actual or potential exposure to radiation other than that intended for treatment is as low as reasonably achievable
- the relevant dose limits are not exceeded (Sections 3.1.1 and 4.1.1)
- the risk of medical misadministration is minimised
- there is sufficient documentation to enable verification of compliance.

1.2 Scope

1.2.1 This *Code* covers any use of sealed radioactive materials for medical therapy by means of direct contact with, or proximity to, the tissue treated. It includes the use of radioactive liquid within a catheter or balloon that is withdrawn from the patient after treatment. Any such treatment method is referred to as “brachytherapy”. The coverage includes, but is not limited to:

- manual afterloading
- low dose-rate remote afterloading
- high dose-rate remote afterloading
- interstitial brachytherapy (permanent and temporary)
- intravascular brachytherapy.

The use of strontium-90 applicators for ophthalmological treatments is separately covered in the *Code of safe practice for the use of strontium-90 ophthalmic applicators, NRL C13*.

1.2.2 This *Code* deals with radiation safety only. Other legislation covering hazardous substances, transport, occupational safety, protection of the environment, local body planning and other issues may overlap with the radiation protection legislation. Compliance with this *Code* in no way implies that all or any of these other requirements have been satisfied.

1.3 Application of this Code

1.3.1 The ownership and use of radioactive materials is controlled by the *Radiation Protection Act 1965* and *Radiation Protection Regulations 1982*. As well as mandatory compliance with the *Act* and *regulations*, anyone licensed under the *Act* to use radioactive material for a modality of brachytherapy covered in this *Code* will be required by a condition on the licence to comply with the *Code*. Whenever the term “licensed” is used in this *Code* it means licensed under the *Radiation Protection Act*.

1.3.2 This *Code* stipulates the specific way in which some parts of the *Act* and *regulations* must be satisfied with respect to brachytherapy. As well, there are further requirements that are recognised as good practice necessary for safety. All of these requirements are indicated by the word “**must**”. They are binding on **all** licensees subject to the *Code*. Whenever the requirements pertain to the facility as a whole rather than individual users, to avoid ambiguity, one person must take the role of ensuring the responsibility is carried out. This licensee is referred to in this *Code* as the **principal licensee** (Section 2.1.1).

1.3.3 General advice on compliance with the radiation protection legislation and this *Code* is given in *Guidance notes: safe practice for the use of sealed radioactive materials for brachytherapy*.

1.3.4 Where the term “*source strength*” is used in conjunction with brachytherapy sources, this refers to whatever quantity is used on the manufacturer’s calibration certificate (reference air kerma rate, activity, etc).

- 1.3.5 Where the terms “*effective dose*” and “*equivalent dose*” are used for protection purposes they have the meanings defined in ICRP Publication 60 (1990 *Recommendations of the International Commission on Radiological Protection*, Annals of the ICRP 21(1-3), Pergamon Press, Oxford), and they can be practically represented by the ICRU operational quantities (see *Quantities and units in radiation protection dosimetry*, ICRU Report 51, International Commission on Radiation Units and Measurements, Bethesda, Maryland).
- 1.3.6 Where a facility is required by this *Code* to have equipment, it is acceptable for the equipment to be owned and provided by a third party as long as there is a written guarantee that the equipment will be available when required.

1.4 Exemptions from requirements of this Code

- 1.4.1 If for purely technical reasons relating to a particular piece of equipment or procedure it is either not possible or deemed unnecessary to comply with any requirement or requirements in this *Code* then an exemption from the requirement or requirements for that specific piece of equipment or procedure may be granted on application to the National Radiation Laboratory (NRL).
- 1.4.2 An application for exemption will need to demonstrate that the proposed alternative to the requirement does not compromise the intent of the relevant section of the *Code*.
- 1.4.3 Written evidence of this exemption must be retained for audit purposes (Section 2.2.1).

2 RADIATION SAFETY MANAGEMENT

2.1 Organisational structure and responsibilities

- 2.1.1 A licensed physician at a brachytherapy facility **must** be designated by the management of the organisation that operates the facility as the principal licensee in terms of this *Code* (Section 1.3.2).
- 2.1.2 For an individual patient, the licensed physician who prescribes the treatment **must** be responsible for the patient's care, including details of the treatment and the patient's follow-up evaluation.
- 2.1.3 There **must** be available a licensed medical physicist to consult on calibration, dosimetry, quality control and maintenance of equipment, treatment planning, and radiation safety. A licensed medical physicist **must** be present at any high dose-rate brachytherapy treatment, and available on call for any low dose-rate remote afterloaded treatment.
- 2.1.4 Nurses engaged to care for brachytherapy patients **must** be appropriately instructed in radiation safety and emergency procedures.

2.2 Radiation safety plan

- 2.2.1 The principal licensee **must** ensure that there is documentation, referred to collectively in this *Code* as the *Radiation Safety Plan*, covering the following:
- a) details of radiation safety policy, responsibilities and authorisations;
 - b) induction and training procedures for staff;
 - c) personal monitoring policy and procedures (Section 3.2);
 - d) a register and records of radioactive sources;
 - e) procedures for keeping medical records of treatments (Section 5.4);
 - f) radiation safety quality assurance (Section 2.3);
 - g) safety procedures and local rules (Sections 3.1.2, 4.2.1, 5.3);

- h) incident, accident and emergency procedures (Section 6);
- i) any exemptions granted under Section 1.4.

2.3 Quality assurance of radiation safety procedures

2.3.1 The principal licensee **must**, in consultation with a licensed medical physicist, develop a programme for supervising and reviewing policies and procedures that give assurance of the safety of radioactive sources, patients, personnel, and members of the public.

2.3.2 The radiation safety quality assurance programme **must** be documented in the *Radiation Safety Plan* (Section 2.2) and cover all of the following:

- a) a programme for the routine maintenance, calibration and checking the correct functioning of all safety and treatment equipment against established tolerances;
- b) procedures for managing reported faults, incidents or complaints;
- c) routine internal audits to verify procedures, documentation and inventories;
- d) an annual review cycle of the quality system.

2.4 New facilities

2.4.1 Notification of any proposed brachytherapy facility, installation of new remote afterloading equipment, or substantial changes to an existing facility **must** be forwarded to the NRL prior to commissioning. The notification **must** include the following details:

- a) the type of brachytherapy modality and radioactive source to be used;
- b) location of storage, preparation room, treatment rooms, and patient wards;
- c) details of controlled areas.

2.4.2 Any new or substantially changed facility or remote after-loading device **must** not be put into clinical service until:

- a) any new equipment has been fully commissioned and found to be in compliance with the manufacturer's specifications;
- b) a radiation safety survey verifying the relevant requirements of this *Code* has been completed by a licensed medical physicist, and a report of the survey sent to the NRL (in particular see Section 3.2.1).

2.5 Controlled areas

2.5.1 The following **must** be controlled areas in terms of *regulation 21*:

- a) a room where manually loaded sources are stored and prepared;
- b) a room used for brachytherapy in-patients where access must be restricted in order to limit radiation exposure to staff and/or visitors;
- c) a high dose-rate brachytherapy treatment room.

2.6 Shielding

2.6.1 The equipment used for handling sources **must** provide sufficient shielding or distance so that staff are exposed to an effective dose-rate that is as low as reasonably achievable and not more than 7.5 μSv in any hour.

2.6.2 The shielding of any facility in which radioactive sources are used or stored **must** be such that any individual not involved in the use is very unlikely to receive an effective dose of more than 300 μSv in a year.

2.7 Safety devices and other equipment

2.7.1 Every facility **must** have:

- a) a well-type ionisation chamber plus electrometer, or equivalent instrument, to verify independently the source strength provided by the manufacturer. The instrument **must**

be calibrated in terms of the source strength of each radioisotope used, by an NRL-approved service or method every two years and after repairs;

- b) a long half-life source suitable for constancy checks on the ionisation chamber;
- c) a radiation survey instrument capable of measuring the external radiation emitted by the brachytherapy sources. The instrument **must** be capable of measuring from a minimum rate of less than 1 $\mu\text{Sv/h}$ and a satisfactory indication of over-range. The instrument **must** be calibrated by an NRL-approved service or method every two years and after any repair.

2.7.2 Visual and audio contact with the patient in a treatment room **must** be possible throughout the course of treatment.

2.7.3 If a facility offers treatment modalities such that the planning of individual treatments requires the estimation of the three-dimensional dose field to the planning target volume, then the facility **must** have a suitable computerised planning system for this purpose.

2.8 Remote afterloading equipment

2.8.1 Any remote afterloading device **must** have a position accuracy (relative to the applicator) of better than ± 2 mm.

2.8.2 Any remote afterloading device **must** have a timing accuracy of better than $\pm 2\%$ of the set time.

2.8.3 Any remote after-loading device **must** be failsafe, and there **must** be a clear indication both at the control panel and in the treatment room, using a method independent from the source control system, as to whether the sources are exposed or retracted.

2.8.4 New and refurbished remote afterloading units **must** be provided with an automatic timer and a back-up timer to terminate the treatment after a preset time has elapsed.

2.9 Leak-testing of sources

- 2.9.1 All radioactive sources for multiple use **must** be leak-tested on delivery and annually thereafter using an NRL-approved wipe or immersion method, unless the source has a physical form or containment that makes it impossible for any leaked radioactive material to reach either the user or the patient.
- 2.9.2 All radioactive sources ordered for an individual patient **must** be accompanied on delivery by a certificate stating they were leak-tested and all passed by the manufacturer. The shipping container of the sources **must** be checked at the time of delivery for any evidence of leakage or other contamination.
- 2.9.3 If the leak test of any source evidences a removable activity of greater than 185 Bq then the source **must** be removed from use and disposed of by a means approved by the NRL.

2.10 Obsolescence of sources

- 2.10.1 If an exemption from carrying out any of the quality assurance requirements in this *Code* associated with radiation sources has been granted (Section 1.4), then the sources **must** be withdrawn from use once they reach the end of their working life as stated by the manufacturer.

3 OCCUPATIONAL SAFETY

3.1 Safety procedures

3.1.1 All handling of radioactive material **must** follow procedures designed to keep the radiation doses to all personnel as low as reasonably achievable, social and economic considerations being taken into account, and such that the doses to radiation personnel do not exceed the following dose limits:

- a) an *effective dose* of 20 mSv per year averaged over any five year period and 50 mSv in any one year;
- b) an *equivalent dose* of 500 mSv to the skin (at the nominal depth of 7 mg/cm²) averaged over 1 cm², regardless of the total area exposed, in any one year;
- c) an *equivalent dose* of 150 mSv to the lens of either eye in any one year;
- d) an *equivalent dose* of 500 mSv to the hands and feet in any one year;
- e) for women who declare themselves pregnant, a dose of 2 mSv at the surface of the abdomen over the remainder of the pregnancy.

3.1.2 There **must** be written local rules covering the following:

- a) purchasing, receiving and commissioning new radioactive sources;
- b) decommissioning and disposal of old radioactive sources;
- c) calibration of sources;
- d) leak-testing sources;
- e) handling of sources during clinical use;
- f) nursing care of brachytherapy patients.

3.2 Personal monitoring

3.2.1 If the radiation safety survey carried out in accordance with Section 2.4.2(b) indicates that any staff member may be exposed to radiation, either from routine controlled exposures or as a result of a credible accident, that may result in a dose that exceeds ten

percent of the dose limits given in Section 3.1.1 then that staff member **must** be monitored using a method approved by the NRL to provide a continuous measure of effective dose or equivalent dose as appropriate.

- 3.2.2 If any person required to be monitored under Section 3.2.1 receives in any one month an indicated effective dose of more than 0.5 mSv or an equivalent dose of more than 10 mSv to the hands, the reason for this **must** be investigated. If the dose was received under normal working conditions, procedures **must** be reviewed with the aim of reducing the occupational dose. Full records of the result of the investigation and any resulting changes to standard practice **must** be kept.
- 3.2.3 Records of personal monitoring **must** be provided to all monitored staff, and copies held for at least 7 years.

4 PUBLIC SAFETY

4.1 Dose limits

- 4.1.1 The exposure of any member of the public to radiation from sources used for brachytherapy **must** be controlled so as to keep the radiation doses as low as reasonably achievable, social and economic considerations being taken into account, and such that the doses received do not exceed the following dose limits:
- a) an *effective dose* of 1 mSv per year averaged over any five year period and 5 mSv in any one year;
 - b) an *equivalent dose* of 50 mSv to the skin (at the nominal depth of 7 mg/cm²) averaged over 1 cm², regardless of the total area exposed, in any one year;
 - c) an *equivalent dose* of 15 mSv to the lens of either eye in any one year.

4.2 Controls on visitors and caregivers

- 4.2.1 There **must** be clear local rules displayed at the entrance to a room where a patient is being treated that state the precautions necessary to ensure that the radiation dose received by any visitor is as low as reasonably achievable, and that there is minimal chance that any visitor can receive a total effective dose of 5 mSv or more over the entire time of treatment. For children and pregnant women this limit is reduced to 1 mSv. The rules **must** stress the need to minimise time and maximise distance.
- 4.2.2 Anyone other than the patient **must not** be in the treatment room during a high dose-rate treatment.

4.3 Release from hospital of patients with implanted sources

- 4.3.1 A patient **must not** be released from hospital with an implanted Co-60, Cs-137 or Ir-192 source.

- 4.3.2 A patient **must not** be released from hospital until there is reasonable certainty that the effective dose to any adult family member or other person voluntarily accompanying the patient will be less than 5 mSv, and to any child or member of the public will be less than 1 mSv.
- 4.3.3 The patient **must** be given written instructions of any measures necessary to minimise the dose to others if the dose-rate at 1 metre from the patient initially exceeds 5 μ Sv/h.
- 4.3.4 The licensed physician responsible for treating a patient **must** take all reasonable steps to ensure that, should the patient die when the remaining activity of implanted radionuclide is greater than the activity in Part 2 of the First Schedule to the *regulations*, any necessary advice on limiting the radiation dose is given to any person who may come in contact with the body or remains.
- 4.3.5 If there is a possibility of an implanted source becoming dislodged after the release of the patient, the patient **must** be given clear written instructions on the actions to be taken.

5 MEDICAL EXPOSURES

5.1 Calibration of sources

- 5.1.1 All radioactive sources used for brachytherapy **must** have documented source strength calibration traceable to a national primary standard of activity, air kerma, or absorbed dose.
- 5.1.2 The source strength of each source **must** be independently measured (subject to Section 5.1.3), to verify the certificated source strength before the source is used. A difference of more than 5% from the certificated strength (incorporating calculated decay) **must** be resolved with the manufacturer. All correspondence **must** be recorded.
- 5.1.3 The source strength of sources that are re-used **must** be re-measured after one year and subsequently every two years in order to verify radionuclide purity.
- 5.1.4 When non-reusable sources are used in batches of more than 10, the source strength of a sufficient sample of the sources **must** be measured to give assurance that the dose delivered to the patient in the particular treatment for which they will be used will not differ from the intended dose to an extent that will be clinically significant. All correspondence relating to anomalous measurements **must** be recorded.
- 5.1.5 The calibration factor for the ion chamber used for source calibration **must** be checked for constancy with a long-life source before each use.

5.2 Clinical planning and dosimetry

- 5.2.1 Every brachytherapy treatment **must** be planned in order to take account of individual patient anatomy and to optimise the radiation dose distribution.
- 5.2.2 Whenever a brachytherapy modality allows optimisation of the planning target volume in three dimensions, a dose distribution showing coverage of the clinical target volume **must** be generated by a suitable computer planning system as required in Section 2.7.3.

5.2.3 The treatment plan **must** be independently checked and signed by a suitably competent person before implementation, and after implementation if significant modification is indicated by dosimetry.

5.3 Clinical safety

5.3.1 There **must** be a written procedure for establishing positive patient identity and, where relevant, pregnancy status.

5.3.2 Each brachytherapy procedure **must** follow a standard written procedure established by the licensed physician.

5.3.3 The prescription and any substantial changes to a prescription **must** be signed by a licensed physician.

5.3.4 Before treatment is begun, a licensed physician or radiation therapist or medical physicist **must** independently check all relevant parameters.

5.3.5 Before the patient leaves the treatment room, both the room and the patient **must** be surveyed to check for misplaced sources.

5.4 Medical records

5.4.1 In conjunction with *regulation 22* a record **must** be kept by the facility of each treatment that shows:

- a) the name, age and sex of the patient;
- b) the date of treatment;
- c) a description of the treatment;
- d) the prescribed dose to the patient;
- e) the total irradiation time for temporary implants;
- f) a description of the sources used and total reference air kerma or activity;
- g) the identity of responsible persons.

5.4.2 The patient record of any person receiving a permanent implant of radioactive sources **must** have a clear warning to this effect that **must** remain in place until the activity of the implant has decayed to less than the activity in Part 2 of the First Schedule to the *regulations*.

6 INCIDENTS, ACCIDENTS AND EMERGENCIES

6.1 Medical misadministrations

6.1.1 A treatment **must** be classed as a medical misadministration if, as a result of a mistake in planning or dose delivery or because of equipment failure or any other misadventure:

- the dose actually delivered to the point, surface, or volume used as a reference for prescription purposes differs from the dose prescribed by more than 10%
- the treated volume differs sufficiently from the planning target volume to have clinical significance.

6.1.2 Every licensed physician **must** ensure that any person involved in the delivery of treatment immediately reports to them any suspected medical misadministration if that person has any reason to believe that such a misadministration has occurred. The principal licensee **must** then:

- a) fully investigate the misadministration in consultation with the medical physicist and other staff involved in the treatment to establish whether a misadministration has occurred, and if so, to find the cause and take whatever remedial steps are necessary for the patient;
- b) review, in consultation with the medical physicist, the standard treatment and quality assurance procedures to see if any deficiency was a factor in the occurrence;
- c) report the details to the NRL within 7 days.

6.2 Other incidents and accidents

6.2.1 An event **must** be classed as an incident or an accident if, because of a mistake, equipment failure or any other misadventure, there was an unintended potential or abnormal exposure of any staff member, patient visitor or any member of the public.

6.2.2 Every licensed physician or medical physicist **must** ensure that any person involved in an incident or accident reports the details of the event to them immediately. The principal licensee **must** then:

- a) fully investigate the event in consultation with the medical physicist and other staff involved;
- b) review, in consultation with the medical physicist, the standard working and quality assurance procedures to see if any deficiency was a factor in the occurrence;
- c) cause a record of the report and investigation to be kept for at least 10 years.

6.2.3 In the event of a suspected or actual exposure to radiation exceeding any of the dose limits given in Section 3.1.1 for a staff member or Section 4.1.1 for a member of the public, the principal licensee **must**:

- a) immediately advise the NRL of the circumstances;
- b) make available to the person exposed such medical examinations as may be appropriate to manage any injury.

6.3 Emergency procedures

6.3.1 There **must** be written procedures and documented evidence that all staff are currently familiar with the procedures for each of the following emergencies:

- a) leaking source;
- b) loss of a source;
- c) a stuck or detached source;
- d) medical emergency of a patient with a loaded source;
- e) evacuation of patients from the building;
- f) security of radioactive sources in a civil emergency.

CROSS-REFERENCE INDEX

The regulatory framework for this *Code* is provided by the radiation protection legislation.

This index provides references to specific parts of the legislation, some of which, while not directly cited in the *Code*, do provide the regulatory authority for its requirements. It also indicates where practical compliance information can be found in the *Guidance notes*.

The references are from this *Code of safe practice for the use of sealed radioactive materials for brachytherapy, NRL C14* to:

- *Radiation Protection Act 1965*;
- *Radiation Protection Regulations 1982*;
- *Guidance notes: safe practice for the use of sealed radioactive materials for brachytherapy* (NRL, October 2003).

| NRL C14 | Act | Regulation s | Guidance notes |
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