

GUIDANCE NOTES

Safe Practice for the Use of Sealed Radioactive Materials for Brachytherapy

National Radiation Laboratory
Ministry of Health
PO Box 25-099
Christchurch
NEW ZEALAND

October 2003

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Ministry of Health

<http://www.nrl.moh.govt.nz>

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INTRODUCTION

These *Guidance Notes* have been written to provide information for establishments providing brachytherapy services. They give practical guidance, to managers, licensees and anyone else involved, on compliance with the requirements of radiation protection legislation and the *Code of safe practice for the use of sealed radioactive materials for brachytherapy, NRL C14*. The purpose of radiation safety is to protect:

- patients, by setting standards to optimise treatments and minimise errors
- staff, by setting safe working conditions and procedures
- the public, by minimising radiation exposure from patients with radioactive implants and ensuring the security and safety of radioactive materials.

The *Notes* cover any use of sealed radioactive materials for medical therapy by means of direct contact with or proximity to the tissue treated, other than Sr-90 ophthalmic applicators. This includes the use of radioactive liquid within a catheter or balloon that is withdrawn from the patient after treatment. In particular the following modalities are covered:

- manual afterloading
- low dose-rate remote afterloading
- high dose-rate remote afterloading
- interstitial brachytherapy
- intravascular brachytherapy.

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

The *Code of safe practice for the use of sealed radioactive materials for brachytherapy, NRL C14* is written in as general terms as possible. However, the range of modalities covered is large, and there may be some particular equipment or use for which some sections of the *Code* are inappropriate. Instead of the *Code* attempting to list all possible exceptions, there is a provision for a facility to apply for an exemption from any specific requirements of the *Code* that may be inappropriate. This must be formally documented.

LEGAL REQUIREMENTS AND RESPONSIBILITIES

The ownership and use of radioactive materials in New Zealand is controlled by the *Radiation Protection Act 1965*¹ and the *Radiation Protection Regulations 1982*². The purchase and importation of radioactive materials is controlled through a consent process, and users must be licensed under the *Act*. The *Regulations* contain more detailed general requirements for both owners and licensed users of radioactive materials.

Both ownership and use of radioactive materials are controlled by law

The additional requirements specific to the safe use of radioactive material for brachytherapy are contained in the *Code of safe practice for the use of sealed radioactive materials for brachytherapy, NRL C14*. Anyone licensed to treat patients using brachytherapy must comply with this *Code*.

NRL C14 must also be complied with

Importing, exporting, buying and selling radioactive material

Section 12 of the *Act* states that no-one can sell, import or export any radioactive material without having a consent under the *Act* to do so. An application must be made to NRL for a consent prior to any such transaction. If the radioactive sources are being imported by a NZ agent, then the agent must apply for a consent. If you are importing directly, then you must apply for a consent. There is a sample copy of the application form in Appendix 2 in these *Notes*. The form can be obtained from NRL or downloaded from the NRL web site www.nrl.moh.govt.nz.

A consent to import, export, buy or sell must be obtained from NRL

The owner of any radioactive material (above an exempt activity) must ensure there is someone suitably licensed under the *Act* to take responsibility for its continuing safety (*regulation 9*). There are also requirements placed on the owner concerning provision of suitable facilities and safety equipment to allow the radioactive material to be used safely (see below). A consent for a particular importation or purchase will be granted only after consideration is given to whether these requirements are satisfied.

The owner has specific responsibilities

Licences to use radioactive sources for brachytherapy

Anyone using radioactive materials for any purpose must either hold a licence for that purpose under the *Act* or be acting under the supervision or instructions of a licensee (see section 13 of the *Act*).

Who needs a licence?

<i>What is supervision?</i>	“Supervision” means the maintenance of a sufficient degree of surveillance to be able to intervene, correct, or give guidance if required for the sake of radiation safety. It applies in the context of the supervised person not having sufficient training and/or experience to carry out the task unsupervised.
<i>Who may act under instructions?</i>	“Instructions” mean specific directions or general authorisation to carry out a task that a person has sufficient training and experience to do safely. It applies to a person who has the professional skill for a task but not the authority to initiate it.
<i>Does the concept of oversight apply?</i>	The concept of “oversight” as used in the <i>Medical Practitioners Act</i> is not directly applicable to the <i>Radiation Protection Act</i> .
<i>In a brachytherapy facility there are specific people who must have licences</i>	<ul style="list-style-type: none"> • Any vocationally registered medical practitioner who treats patients with radiation must have a licence for medical therapy (these licensees are required to comply with the <i>Code C14</i>). • The senior medical physicist must have a licence for medical physics. • Any other medical physicist who has sufficient training and experience to act and advise without supervision must have a licence for medical physics.
<i>There are those who are considered to be acting under instructions</i>	<ul style="list-style-type: none"> • A registered medical radiation technologist as instructed by a licensed physician. • A junior medical physicist or physics technician acting under the instructions of a licensed medical physicist. • A trained nurse attending to a brachytherapy patient under the instructions of a licensed physician.
<i>Oncology registrars</i>	Under normal circumstances an oncology registrar may be considered to be using radiation under supervision up until they have passed the Part II examination and have been working in the specialty for five years from entry to the radiation oncology registrar training scheme. After this time the registrar would be considered to be working independently and must hold a licence.
<i>Non-licensed registrars</i>	When a non-licensed registrar uses radiation to treat a patient, this must be under the supervision of the consultant responsible for that patient. In particular, any registrar prescription must be countersigned by a consultant.
<i>The principal licensee still has some responsibilities</i>	General supervision responsibility for oncology registrars (eg, radiation safety training) rests with the principal licensee (see below).
<i>There must be written procedures for registrars</i>	Every oncology department that employs registrars must have current auditable documentation on the registrars under supervision, the protocol for effecting the supervision, and a record of radiation safety training of each registrar.

Applying for a licence

A licence information pack, containing an application form for a licence for medical therapy or medical physics, and copies of the *Code of safe practice*, *NRL C14*, these *Guidance notes*, the *Act*, and *Regulations* can be obtained from NRL.

Obtaining a licence information pack

In the case of any applicant who is not a vocationally registered radiation oncologist, the application will generally be referred to the Medical Licensing Advisory Committee (MLAC), which will make a recommendation on the basis of the training and experience documented in the application.

The application may be referred to MLAC

To be eligible for a licence for medical physics the applicant needs to have a tertiary degree in physics or a related discipline, have at least four years' experience working as a clinical physicist, and provide satisfactory references.

Minimum requirements for a medical physics licence

Principal licensee

Many of the requirements in the *Code* concern the brachytherapy facility as a whole, rather than individual users. They relate to safety standards for equipment, maintenance of a quality system, etc. The legislation does not have provision for licensing or registering a facility and giving overall responsibility to the owner. Instead, each user licensee must ensure that all the requirements of the *Code* are satisfied. There is obviously a problem determining who is responsible for a particular compliance issue when there are several licensees. To avoid any ambiguity a clinical licensee must be designated the *principal licensee*. The principal licensee takes on all of the corporate responsibilities for compliance (see *NRL C14* sections 1.3.2, 2.1.1, 2.2.1, 2.3.1, 6.1.2, 6.2.2, 6.2.3). More information on principal licensee responsibilities can be found in *NRL matters no 10* available from the web site or by contacting NRL.

What does the term "principal licensee" mean?

Use by an unlicensed person

When a person other than a licensee uses radioactive sources then, as discussed above, the person must be acting under the supervision or instructions of a licensee. The licensee carries the ultimate responsibility for the safety of any aspect of the use. While the legislation places this responsibility on the individual licensee who may have given the instructions, the principal licensee has overall responsibility for staff training and review of safe work procedures.

Use under supervision or instructions

Compliance with the Medical Auxiliaries Act

A person who is not licensed under *the Radiation Protection Act* and who is directly involved in treating patients must comply with the *Medical Auxiliaries Act 1966*. This means they must be registered, or exempted from registration, as a Medical Radiation Technologist. It is generally accepted that *removal* of brachytherapy sources does not constitute *treatment*, and so this may be done by any suitably trained person. This is an important consideration for emergency planning.

Responsibilities of owners

Who is regarded as the owner?

The owner of a brachytherapy facility is not formally registered under the radiation protection legislation. In reality the actual owner of the radioactive sources may be a trust fund or charitable organisation (and for permanent implants the final owner will be the patient). However, for the purpose of identifying legal obligations, the owner is taken to be the corporate owner of the facility, as represented by its chief executive officer.

The owner has specific responsibilities

The owner must provide safe facilities (*regulation 9(1)*). They must ensure that as far as possible there is someone holding a suitable licence to take responsibility for the physical safety of the sources (*regulation 9(1)*). If for any reason there is no licensee available the owner must take appropriate steps to secure or dispose of the sources (*regulation 9(4)*).

Consultation between owners and licensees is important

There is considerable overlap in the responsibilities of the owner and of user licensees to ensure safe working conditions (eg, compare *regulations 9(1)* and *11(1)(e)*). In practice there should be extensive consultation between the owner and both clinical and medical physics licensees at the planning stage of a new facility.

Transport

Transport is controlled by Regulations

The *Regulations* require that all transport of radioactive material be done in compliance with the IAEA Transport Regulations³. These deal mainly with packaging, labels, documentation, and placarding of vehicles.

Packaging may be re-used

When a shipment of sources arrives at a facility, it will have been the shipper's responsibility to meet the requirements of the Regulations. If sources are intended to be transported again in the near future then the packaging should be kept, because it will continue to be in compliance, provided the sources are packed the same way.

Labelling may also be re-used

The labelling on the package is also likely to be correct, although if the activity has changed significantly, both this and the transport index will need to be altered if the same label is re-used.

A dangerous goods declaration must accompany the package. This can either document one specific shipment or can be made “multiple use” if sources are going to be transported regularly between the same two sites.

There must be a dangerous goods declaration

If the sources are carried in a motor vehicle it must carry appropriate placards.

Vehicles must be placarded

For more details on the specific requirements either refer to the IAEA Transport Regulations³ or contact NRL.

Where to obtain more information

RADIATION SAFETY MANAGEMENT

What is radiation safety management?

Radiation safety management refers to the process of identifying the risks from radiation and taking a quality management approach to minimising them in the most efficient way possible.

Management structure and staffing

Documentation required will depend on whether the facility is a stand-alone unit or integrated within another department

In most situations the “brachytherapy facility” will not be a stand-alone unit but will be an integral part of an oncology, or other, department. There may be only one or two individuals specifically involved with brachytherapy treatments, in which case this can be considered a separate facility with its own principal licensee. Alternatively brachytherapy may be integrated into a radiotherapy department as one of the treatment modalities. In the latter case there is no need to duplicate any documentation specifically for the *NRL Code C14* if it is already required by another *NRL Code*.

There must be clear lines of responsibility

The *Code* places some requirements on the management structure of a brachytherapy facility to ensure that there is a clear line of responsibility and that all critical work is done by personnel with appropriate expertise and training. Because most of the *Code* is concerned with the facility as a whole, rather than individual users, most of the requirements must be addressed by the principal licensee (in conjunction with the owner). However, each licensed physician must take full responsibility for the safe treatment of patients under their care.

The role of the medical physicist

Because of the importance of the physical safety of the radioactive sources, of correct operation of equipment and of accurate dosimetry, there is a requirement for the involvement of a licensed medical physicist. The medical physicist should be consulted at all stages of the planning of a new facility and should play a major role in the development and review of safety aspects of the quality system and in the review of any incidents or accidents. The degree of availability required of the medical physicist during treatments depends on the severity of the consequences of anything going wrong. Generally any high dose-rate treatments using mechanised applicators of any type require the presence of the physicist.

Safety and training of other personnel

Other personnel performing tasks, such as caring for patients, removal and handling of sources, and who may receive exposure to radiation are deemed to be working under the supervision or instructions of a licensee (see above). Such people must receive documented training to ensure they can carry out the instructions safely.

There have been several international reviews of the incidence and causes of accidents in radiotherapy (IAEA⁴, ICRP⁵). Strong recommendations concerning management structure emerge from an analysis of what went wrong in each case. They include a need for:

Preventive recommendations

- strong top-management commitment to quality assurance and continuous improvement
- staffing at all levels of sufficient expertise and in sufficient numbers
- clarity of roles and responsibilities of each staff member with particular care in the induction of new staff members
- clear and free communication both of procedures and concerns.

Liability under the Radiation Protection Act within the management structure

A licence under the *Radiation Protection Act* is primarily an authorisation to allow a person to carry out a particular activity. It also confers liability on the licensee for the consequences of their actions. In an establishment with a number of clinical and physics licensees, and others working “under” one or other of the licensees, the question arises: if something goes wrong who is liable under the *Act*?

A licence confers liabilities

This question would ultimately be decided in a law court. If charges were pressed following an incident, the decision would be based on the usual principles of duty of care, due diligence and level of responsibility.

The courts would ultimately determine liability

But if the issue is an item of non-compliance with a regulatory requirement that causes an unsafe practice, it may not be so clear. Whose responsibility is it to remedy the non-compliance?

If the problem is in dosimetry, is the physicist legally responsible? Can the physicist be held liable if he/she does not have the authority within the establishment to fix the problem?

If the principal licensee sets up a standard procedure required in the *Code* but another licensee claims that the licence gives autonomy and refuses to follow it, who is in breach?

In order to avoid ambiguity and to harmonise with what we understand would be the interpretation in court, NRL enforcement of compliance is as follows:

NRL enforcement is based on the following:

- *Owner's responsibilities* The owner of the facility is responsible for:
- appointing a principal licensee
 - providing the safety equipment, shielding, etc, as advised by the principal licensee. (Note that this includes the carrying out of any maintenance and quality assurance of all equipment that may cause a radiation hazard.)
- *Principal licensee's responsibilities* The principal licensee is responsible for:
- advising the owner of requirements for radiation safety
 - producing (or facilitating production of) safety procedures and local rules to be followed by anyone working in the facility
- *Responsibilities of each licensee* All licensees are responsible for:
- the safety of their own work
 - following the safety procedures and local rules for the facility
 - the training and safety of anyone working without a licence under their supervision or instructions.
- Where to obtain more information* For more information see *NRL matters no. 10*, available on the web site or by contacting NRL.

Radiation safety plan (RSP) (NRL C14 Section 2.2)

- What is an RSP and why is it important?* The Radiation Safety Plan (RSP) is central to safety management at a facility. This is a document or collection of documents that sets up the formal responsibility structure, approved standard procedures and record keeping. It also acts as an induction and training document to be used to ensure all staff are familiar with standard safety procedures. Any audit of the facility for compliance with regulatory requirements will normally start with the RSP for an indication of how all the requirements have been addressed, and for documentation that the written procedures are being followed.
- The RSP will overlap with other documentation* There will be considerable overlap between the RSP, the safety manual required by the *Health and Safety in Employment Act* and the procedure manuals required for an accredited quality system. Duplication should be avoided where possible. The RSP can be simplified largely to a directory of pointers to where documentation can be found, but there must be an RSP to ensure that each item required does exist and can be easily located.
- What should it contain?* Section 2.2.1 of the *Code* prescribes the content of the RSP. In many cases the individual items are further prescribed in other sections of the *Code*. An example RSP is included (see Appendix 8). Brief comments on the intent of each section follow.

- a) There must be a policy statement that demonstrates a commitment to ensuring the safety of anyone who may be exposed to radiation as a result of the facility carrying out the practice of brachytherapy. It must name who has overall responsibility as principal licensee, and list all other staff who are authorised by way of licensing or training to carry out particular tasks and responsibilities.
- b) All staff, including licensees, must be familiar with the contents of the RSP. This section must set up a procedure for every new staff member to acknowledge having read and understood the RSP. It must also detail the training or qualifications necessary before any unlicensed person is authorised to work and document how these have been fulfilled in each case.
- c) This must state who should be monitored, the reasoning behind the policy, procedures for notifying staff of the results and the keeping of personal dose records. One person should take responsibility for reviewing staff personal doses and investigating any readings above the action level (see *NRL C14* Section 3.2.2). There must be a document control procedure to ensure that the results of the investigation are available for each such case.
- d) This section contains the documentation associated with the radioactive sources in compliance with *regulation 16*. Its purpose is to provide assurance of the identity, location and source strength of every source at all times. The documentation can be kept in any convenient place but the RSP must state where it is kept, how it is maintained and who is responsible for it. It must contain the following:
- current inventory
 - calibration certificates
 - records of purchase documentation
 - records of disposal documentation
 - a system for logging out and back in, for sources that are manually re-used.
- e) *Regulation 22* requires that a record be kept of any treatment that is sufficient to allow an appraisal of the dose received by the patient in each case. This must be kept for at least 10 years. It may be kept as part of the patient record, but if this is not held by the facility then a separate record must be filed. The RSP should provide a template and procedure and indicate who is responsible for maintaining the record. Section 5.4 of the *Code* details information about treatments that must be put on the patient records including a warning if the patient is going to be released from care with radioactive material implanted. The procedure and templates for this must be documented in the RSP.
- *Details of radiation safety policy, responsibilities and authorisations*
- *Radiation protection Induction and training for staff*
- *Personal monitoring policy and procedures*
- *A register and records of radioactive sources*
- *Procedures for keeping medical records of treatments*

- *Radiation safety quality assurance*
 - f) Quality assurance documentation must be kept in the RSP. Requirements are elaborated in Section 2.3 of the *Code*. There may be an overlapping need for a written quality system for hospital or facility accreditation. When procedures such as routine equipment checks are covered elsewhere, the RSP should simply refer to where the procedures and results are documented. However, it must be possible from the RSP to establish that all of the necessary elements of quality assurance as it applies to radiation safety are covered.
- *Safety procedures and local rules*
 - g) Because the RSP is a policy and staff induction manual the master copy of each of the written procedures, local rules or written instructions required by the *Code* should be included, whether or not they are displayed and used elsewhere. There should also be a statement concerning who can make changes and how they are promulgated.
- *Incident, accident and emergency procedures*
 - h) This is an extension of the previous section but is separated from it for easy reference. Section 6 of the *Code* lists the procedures that must be covered and gives specific requirements. The RSP must give details of who has responsibility for the necessary reports and investigations. The use of template forms is strongly recommended for reports. In the case of earthquake, fire, etc, procedures and forms may already be contained in a health and safety manual. The RSP should give a pointer to this manual but, if possible, a copy should also be included in the RSP.
- *Exemptions granted under Section 1.4 of the Code*
 - i) If the facility has been granted an exemption from any of the requirements of the *Code* this must be filed in the RSP. Note that an exemption is specific to a particular piece of equipment or a procedure. It will apply only at the facility for which the application was made.

Quality assurance of radiation safety (NRL C14 Section 2.3)

Reasons for QA

In the context of radiation safety, quality assurance (QA) provides a second layer of safety. The standard operating procedures and equipment are designed to be as foolproof and fail-safe as possible – this is the first layer. The second layer is the set of checks to make sure the first layer is working as intended.

Responsibilities for QA

The principal licensee has overall responsibility for QA. In practice it is usually convenient to designate another staff member such as the medical physicist as the “quality manager” to draw up and organise the routine checks and audits. The “Level 1” documentation that summarises the QA programme must be filed in the Radiation Safety Plan, with pointers to any other manuals or records.

The coverage of the programme as required by the *Code* follows and examples are given in Appendix 8.

What should it contain?

- | | |
|---|---|
| a) Requirements for the maintenance and calibration programme will depend on the facility. Some calibration requirements are mandatory (see <i>NRL C14</i> section 2.7.1). It must include at least the dose calibrator, radiation survey meter, and any mechanical applicators, afterloaders, or interlocks. The RSP needs to contain the inventory of items included, overall programme, and directory of other information. See the example in Appendix 8. (Guidance on calibration can be obtained from the following references: AAPM ⁶ , Thomadsen ⁷ and IAEA ⁸). | ➤ <i>A programme for the routine maintenance, calibration and checking the correct functioning of all safety and treatment equipment against established tolerances</i> |
| b) The simplest procedure for the reporting of faults, incidents or complaints, is to have a standard form in the RSP (see Appendix 3 for an example form). | ➤ <i>Procedures for managing reported faults, incidents or complaints</i> |
| c) Internal audits can also be taken care of with a standard checklist. It is important to have a definite schedule for audits and a designated person responsible, to ensure it is not put off or forgotten. A sample check sheet is given in Appendix 4. | ➤ <i>Routine internal audits to verify procedures, documentation and inventories</i> |
| d) Once a year there should be a formal review of QA that includes input from: <ul style="list-style-type: none">• relevant staff on the appropriateness of standard procedures• equipment QA reports• any reported faults, incidents or complaints• morbidity and mortality data• patient outcomes information. | ➤ <i>An annual review cycle of the quality system</i> |

Any recommendations for changes to procedures, equipment or other aspects arising from the review should be implemented or programmed for implementation.

FACILITIES AND EQUIPMENT

New or modified facilities (*NRL C14 Section 2.4*)

NRL must be notified of any new or modified facility

NRL must have full details about any facility where radiation is used so that appropriate compliance monitoring can be arranged. This is the reason for the notification required by the *Code*. A notification must be sent in the case of either a new facility or a substantial change in location or the type of equipment used. A sample notification form is provided in Appendix 1.

A copy of the initial safety survey must be sent to NRL

Before a new or substantially modified facility is put into continuous use there must be an initial safety survey carried out, and a copy of the report sent to NRL. The purpose of this is to provide NRL with assurance that the facility is safe until a compliance monitoring visit is scheduled. The receipt of this report will be acknowledged. It must be stressed that receipt by NRL of either the notification or the audit report should not be interpreted as a guarantee of regulatory compliance. This can only be given following an on-site compliance monitoring visit by NRL.

Requirements for the contents of the safety survey

The safety survey needs to include verification that all the requirements in the *Code* regarding equipment and facilities are satisfied, that all interlocks, warning lights, etc function as intended, and include dose measurements taken at key locations relevant to occupational and public exposure using a simulated source/phantom set-up. Note that the requirement for personal monitoring of staff is determined by the results of this survey. If the survey is considered unsatisfactory NRL may consider that personal monitoring should be mandatory under *regulation 20(1)*.

Facility requirements

Controlled areas

Designating an area as a “controlled area” in terms of the *Regulations* means that it must be indicated with signs prescribed in the Second Schedule, and that only authorised people who are suitably trained are permitted to enter. Any area can be designated as controlled by the principal licensee if desired, but the *Code* lists some areas that must be controlled (see *NRL C14 Section 2.5*).

Controlling the ward

Controlling the storage, preparation and treatment rooms is straightforward, but controlling the ward during treatment has implications for visitors. There will need to be a suitably trained nurse or other person on duty all the time visiting is allowed to make sure that any visitors understand and comply with safety rules. (See below.)

There are two requirements in Section 2.6 of the *Code* that determine shielding. The first is a requirement on handling equipment. There must be sufficient protection in the source containers, workstation and implements to ensure the worker will not receive an effective dose of more than 7.5 μSv in any hour. A conservative estimate of this is the instantaneous dose rate measured at the position of the body of the worker. However, for tasks that always take significantly less than an hour the integral dose can be measured.

Shielding requirements

The second is a restriction on permitted dose rates in areas accessible to the public. In this context other patients who are not receiving radiation therapy are members of the public. The constraint is 300 μSv in a year to any individual. Realistic occupancy and use factors should be taken into account, but be aware of future changes that could affect these.

Restrictions in places of public access

If one brachytherapy patient is exposed to radiation from the treatment of another, then the limits for workers or members of the public do not apply.

Patient exposures

The radioactive sources must be stored so that they are secure and shielded. There must be a warning sign at the point of access. The warning sign is prescribed in clause 4 of the Second Schedule of the *Regulations*. (A trefoil for this sign can be downloaded from the NRL web site.) It is recommended that where practical the sources are stored in a lockable cabinet within the preparation room, thus limiting the need to move them around the department. The sign can be placed on the door of the cabinet.

Storage and warning signs for radioactive sources

Section 2.7 of the *Code* lists minimum requirements for the inventory and specifications for both hardware and software. Generally the manufacturer of a particular brachytherapy system will be marketing it internationally and will present a package of ancillary equipment, facility requirements, and safety specifications that meet international standards. Compliance with the *Code* should therefore not be a problem; however, it is still necessary to systematically verify each item, particularly if the equipment is not obtained from a major supplier.

Safety devices and other equipment

Whenever sources are due for replacement or a facility is being upgraded, high priority should be given to the purchase of remote afterloading equipment if this is not already used. This equipment significantly reduces the radiation exposure of personnel involved, and should be seen as the industry standard for protection.

Remote afterloading equipment affords greater protection

A dose calibrator and survey meter are required

Ancillary equipment required includes a dose calibrator with a long-life check source, and a survey meter. Both instruments need to be calibrated every two years using NRL-approved methods that can demonstrate traceability to acceptable primary standards. The dose calibrator can be calibrated using a source of the type to be measured that has been individually certificated for the purpose. Note that such certificates are usually issued subject to expiry dates, to account for possible radionuclide impurities.

Leak testing of sources (NRL C14 Section 2.9)

A carefully considered policy must be in place to minimise exposure...

The leak testing of sources is an exercise in optimisation. The process exposes the tester to radiation, so should only be done if it is justified. However, a leaking source can be a major hazard both occupationally and medically. Therefore, if the physical form of the source and encapsulation make it virtually impossible for any of the radioactive material to disperse, regular testing is probably not justified. The testing policy should be carefully worked through and written up in the RSP. The testing or counting may be provided by an outside NRL-approved service. If testing is done by a third party, evidence of NRL approval should be requested, and a certificate of results supplied for each test.

and to provide an accurate result

The physics of testing needs to be worked through as well. The process must involve a traceable calibration and assessments of the uncertainty of the measurement and the minimum detectable activity. In most cases a null result is expected, but this can only be declared within certain confidence limits. (A good reference is Thomadsen⁷).

There must be clear instructions in the event that a source is leaking

The standard procedure for leak tests must include clear instructions on procedures in the unlikely event of a source actually leaking. The source must be packaged for disposal so that contamination cannot be spread. If the leak is significant, the possibility of contamination during the leak test process and during previous use must be investigated.

Obsolescence of sources (NRL C14 Section 2.10)

How long can a source be used for?

Once re-usable sources reach the end of the working life recommended by the manufacturer, consideration should be given to how much confidence can be placed in their continued use. The encapsulation may have degraded and, if there are any radionuclide impurities within the source, it may be decaying in strength at a rate different from the theoretical half-life. As long as routine quality assurance checks verify that neither of these is the case, the decision may be made to continue to use a source until other factors such as treatment time determine when it must be withdrawn.

Conversely, if sources in a remote afterloading system or other device can only be checked when they are loaded, then they must be replaced when the working life recommended by the manufacturer is reached.

Some sources must automatically be replaced

OCCUPATIONAL SAFETY

Safety procedures (NRL C14 Section 3.1)

Sound procedures will be created through consultation

Section 3.1.2 of the Code has a list of tasks that must be covered by standard written procedures and local rules. These serve the purpose of establishing safe practice and as induction documents. They specify safety equipment that must be used and may incorporate standard checklists and templates. The production of these written procedures must have the participation of all involved and not be “cut and pasted” or imposed by management or there is a danger they will be ignored. They should contain only what is necessary, pitched at the level of someone who has been trained, but may not be totally familiar with how things are done at a particular facility.

Written procedures must match actual practices

There is always a danger that practice will drift away from procedure, either through creative initiative or slothfulness. Both the written procedures and actual practice must be in the review loop, otherwise the written procedures will be ineffective, and merely a paper exercise.

Personal monitoring (NRL C14 Section 3.2)

When should a monitor be worn?

The purpose of personal monitoring is twofold. It acts as a check on good practice, and also it provides dose information in case of an accident involving an uncontrolled exposure. The factors in determining whether a monitor should be worn are the likelihood of receiving, during normal practice, a measurable dose that can potentially be reduced and the likelihood of a situation where there is a risk of an uncontrolled exposure.

There are dose limits above which a monitor is required

Every facility must carefully analyse who can potentially be exposed to radiation and at what level. This is required as part of the initial safety survey of a new or modified facility. The survey must include measurements under routine working conditions and estimates of credible accidents, such as stuck or detached sources, dropped sources, etc. If any individual can receive more than 2 mSv effective dose in a year, or 50 mSv equivalent dose to the hands then personal or finger monitoring (respectively) is required.

PUBLIC SAFETY

Controls on visitors and caregivers (NRL C14 Section 4.2)

It is generally accepted that the dose constraints on relatives or caregivers of a sick person being treated with radiation are not as strict as for members of the general public. A member of the public neither sees any benefit nor is informed about the dose, so is justified in receiving protection of the highest standard.

Dose constraints will vary

On the other hand a visitor must be made aware of the radiation, and is likely to be more accepting of it for sake of the person they are visiting. Part of the purpose of written rules for visitors therefore, is to make them aware that they will be exposed to radiation to give them the option of cutting short their stay if they are concerned. The other purpose is to give simple guidelines on how to minimise the dose. The details of this will depend on the type of treatment, the layout of the room, etc, and will need to be worked out by the medical physicist.

Visitors must be made aware of the risks

A system of control must be set up to ensure that nobody can visit when the room is not supervised by an attendant with the training to ensure the rules are followed, even if the visitor is not able to read the written instructions.

Controls must be effective

Release of patients from hospital with implanted sources (NRL C14 Section 4.3)

This is a problem and every solution will be a balance between exposure of hospital staff and exposure of the public, and between the patient's rights to freedom and the public's rights to protection. The basic principles of the required safety standards are given in the *Code*, but it is largely left to each facility to decide what constitutes "all reasonable steps" (see *NRL C14* Section 4.3.4).

It is important to balance protection with rights

The patient must be given written instructions, if the external dose rate at 1 metre initially exceeds 5 $\mu\text{Sv/h}$. The safety precautions need to be discussed thoroughly with the patient and, depending on the circumstances, with the family or next of kin.

There must be clear instructions

Account must be taken of travel arrangements on leaving hospital, of the family situation where the patient lives and of the possibility of the patient needing other hospital care or of dying.

All relevant factors must be taken into account

MEDICAL EXPOSURES

Calibration of sources (NRL C14 Section 5.1)

There must be a certificate of calibration

Any radioactive source used for therapy must have a calibration traceable to an accredited primary standard. The internationally preferred quantity to be used for calibration is reference air kerma rate. (See ICRU Report 38⁹, or 58¹⁰.) Every source must have an accompanying certificate of calibration on delivery from the manufacturer. This must be kept on file for all the time the source is in use.

There must also be independent calibration checks

As well as the manufacturer's calibration, an independent check must be done with an ionisation well chamber. For long half-life sources that are re-used on patients, this check must be repeated after a year and then every two years to demonstrate that the sources are decaying at the expected rate, as any significant radionuclide impurity could cause otherwise.

Any disparities found during calibration checks must be resolved

When there is a significant disagreement (Section 5.1.2 of the *Code* specifies tolerances) between the manufacturer's certificate and the check measurement, this must be resolved conclusively before the source is used. Once the disparate check measurement has been confirmed (and the stability of the well chamber) the source should be returned to the manufacturer if at all possible.

Clinical safety (NRL C14 Section 5.3)

Written procedures will minimise errors...

The intent behind the requirements in the *Code* is to optimise the quality of the treatment then, as far as reasonably possible, deliver the treatment exactly as planned. As emphasised before, whenever there is ambiguity or the possibility of confusion, or anything that could be forgotten because of the complexity of the procedure, there must be written procedures, and where necessary a check sheet that is ticked, signed, countersigned and filed with the treatment record.

providing they have been arrived at with care

Having stressed the need for documentation of procedures, it must also be said that over-documentation is self-defeating. The things that must be documented are the procedural steps that are worth pausing over and checking for safety. *In the end it is up to the licensee responsible for the procedure to decide what goes into a written procedure.* If the person preparing it feels "This is going to be really helpful – I'm glad the Code has required me to do it" then they are probably on the right track. But if the feeling is "This is a complete waste of time – I am only doing it because the regulators require me to" then it will be a waste of time. The procedure may be as short as "This procedure must be done by Dr X in the presence of a licensed physicist". Or it may be a complete set of step-by-step instructions.

The important thing is that the principal licensee has gone through the process of arriving at what is needed, has written it down, and can justify the content.

Records of treatments (NRL C14 Section 5.4)

Regulation 22 places quite specific requirements on licensees for keeping records of treatments. As long as records of sufficient detail are kept in recoverable form, then each facility can choose how this is done. However, the *regulation* requires the records to be kept for at least 10 years. This means that if sole reliance is placed on the patient record and there is any possibility that this will be passed to the patient or another establishment, a separate record must be kept.

There are specific requirements for record keeping

INCIDENTS, ACCIDENTS AND EMERGENCIES

Medical misadministrations (NRL C14 Section 6.1)

The Code defines what is termed a misadministration

Medical misadministrations are defined in the *Code*. It is important to note that the term “misadministration” applies only to *mistakes, equipment failures or other misadventures*. It does not include a case when, after all due care, a satisfactory dose delivery was not achieved. There will always be a grey area between unintended variations and misadministrations, but the cases that it is important to report (an HDR source sticking in a patient, treating the wrong patient, etc) should always be clear.

NRL must be notified

The mandatory notification to NRL serves to provide feedback on whether the regulatory process is effectively addressing the risks and allows for the alerting of other users to potential hazards. Most cases of misadministration are minor, and are the result of a simple equipment failure or human error. If a more serious case occurs that could result in charges of negligence or incompetence being brought, there could be an initial reluctance to self-report the incident. This is understandable, but not judicious because in the case of any legal actions the defence would be that due diligence was taken. Failing to comply with a requirement in the *Code* does not demonstrate due diligence. Conversely, if something does go wrong and an investigation ensues, the best defence against a charge of incompetence or negligence is the active promotion of a safety culture. Fully reporting and investigating any misadministration is an essential part of this. For convenience a sample standard report form is given in Appendix 7.

Other incidents and accidents (NRL C14 Section 6.2)

There must be an investigation of any accidental exposure

Anything other than patient treatment that goes wrong, either equipment failure or human error that could or does lead to accidental radiation exposure, must also be taken seriously. This is an essential part of a policy of continuous improvement. Management should encourage a free and open communication of any reasons for safety concern. A formal investigation and report of any incident or accident is required by Section 6.2.2 of the *Code*.

Emergency procedures (NRL C14 Section 6.3)

Careful thought must be given to planning what the response should be to any emergency. A list of possible emergencies that must be considered is given in Section 6.3.1 of the *Code*. Documentation for each of these must be kept up to date (personnel named, etc) and be an important part of induction or training. The main concern will be to ensure there is always someone available with sufficient training who knows what to do with the radioactive sources, particularly if a patient with sources implanted needs emergency medical treatment or has to be evacuated from a building.

The Code has specific requirements

The master copy of the written procedures should be kept in the RSP and, where relevant, the emergency instructions should also be posted on walls in treatment rooms, supervising nurses' offices and anywhere else they may be needed for immediate reference.

Written procedures should be easily accessible

COMPLIANCE MONITORING

NRL carries out audits of facilities

The National Radiation Laboratory, as New Zealand's Regulatory Authority, is empowered to carry out compliance monitoring audits of facilities where ionising radiation is used. These compliance monitoring audits occur at frequencies determined by the National Radiation Laboratory. Advance notification of an impending audit is normally given to the principal licensee of a facility where radiation is used.

Compliance with legislation and the Code is required

During the audit the representative from the National Radiation Laboratory will be looking for evidence that the use of radiation at the facility is in compliance with the *Radiation Protection Act 1965*, the *Radiation Protection Regulations 1982* and the *Code NRL C14*.

The audit process

In the case of a brachytherapy facility, the audit would commence with an entrance interview between the NRL representative and the principal licensee, the medical physicist, and any other person the principal licensee wishes to have present.

Documentation including the RSP must be made available

At the entrance interview the principal licensee would make available the facility's radiation protection documentation including the Radiation Safety Plan. This would be reviewed by the National Radiation Laboratory representative, checking for compliance with the above documents.

Checks will be carried out

An inspection of the facilities would follow, including checks of safety equipment and measurement of radiation dose rates, where relevant.

Items of non-compliance

The compliance monitoring audit would conclude with an exit interview at which the results of the audit would be presented and discussed. Any items of concern would be explained and for those items of actual non-compliance, corrective actions would be agreed upon, including a time-frame for compliance.

Corrective actions must be implemented

The compliance monitoring audit cycle for a given facility would remain open in those cases where there was non-compliance until such time that the principal licensee has notified the National Radiation Laboratory in writing that the agreed corrective actions have been implemented. At this stage, or if in the first instance there were no non-compliance items, the compliance monitoring audit cycle would be closed, and a notice of compliance issued.

Further information on compliance monitoring can be found in NRL Matters no 10, available from the web site or by contacting NRL.

REFERENCES

- 1 *Radiation Protection Act 1965*. Govt. Print, Wellington.
- 2 *Radiation Protection Regulations 1982*. Govt. Print, Wellington.
- 3 IAEA. *Regulations for the safe transport of radioactive material*. 1996 rev ed. International Atomic Energy Agency, Vienna, 2000. *Safety standards series TS-R-1*.
- 4 IAEA. *Lessons learned from accidental exposures in radiotherapy*. International Atomic Energy Agency, Vienna, 2000. *Safety series no. 17*.
- 5 ICRP. *Prevention of accidental exposures to patients undergoing radiation therapy*, Pergamon Press, Oxford, 2000. *ICRP publication 86. Annals of the ICRP 30(3)*.
- 6 AAPM Radiation Therapy Committee Task Group No. 56. *Code of practice for brachytherapy physics: report of the AAPM Radiation Therapy Committee Task Group No. 56. Medical physics 24(10): October 1997*.
- 7 Thomadsen B. *Achieving quality in brachytherapy*. Institute of Physics Publishing, Bristol, 2000.
- 8 IAEA. *Design and implementation of a radiotherapy programme: clinical, medical physics, radiation protection, and safety aspects*. International Atomic Energy Agency, Vienna, 1998. *IAEA-TECDOC-1067*.
- 9 ICRU. *Dose and volume specification for reporting intracavitary therapy in gynaecology*. International Commission on Radiation Units and Measurements, Bethesda Md, 1985. *ICRU Report no 38*.
- 10 ICRU. *Dose and volume specification for reporting interstitial therapy*. International Commission on Radiation Units and Measurements, Bethesda Md, 1997. *ICRU report no 58*.

Radiation protection - sealed radioactive sources - general requirements and classification. Geneva: International Standards Organization. *ISO 2919:1999*.

Radiation protection - sealed radioactive sources - leakage test methods. Geneva: International Standards Organisation. *ISO 9978:1992*.

ICRP (1991). *1990 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 60. *Annals of the ICRP 21(1-3)* Pergamon Press, Oxford.

APPENDIX 1

Notification of a new or changed brachytherapy facility sample form

NOTIFICATION OF A NEW OR CHANGED BRACHYTHERAPY FACILITY

DETAILS

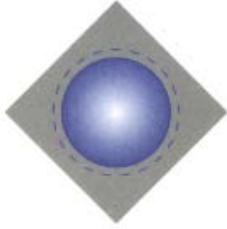
This facility is:			
New <input type="checkbox"/>		Moved <input type="checkbox"/>	
Changed <input type="checkbox"/>			
Name and physical address of the facility			
Name of Principal Licensee			
Description of brachytherapy modality			
Details of radioactive sources	Radionuclide	Number of sources	Nominal activity
Details of location (provide an area plan if possible)	Storage:		
	Preparation room:		
	Treatment room:		
	Patient ward:		
These areas have been designated Controlled Areas			
More information can be found attached <input type="checkbox"/>			
Name of person submitting the notification			
Signature		Date	

APPENDIX 2

Application form for a Consent to import sealed radioactive sources

Sample form over page

(Note: this is available on www.nrl.moh.govt.nz)



APPLICATION TO IMPORT A SEALED RADIOACTIVE SOURCE

I hereby apply for consent to import a sealed radioactive source, pursuant to Section 12 of the Radiation Protection Act 1965.

Name and postal address of importing agent: _____

Contact person: _____

Phone No: _____ **Fax No:** _____

Name and postal address of company for whom importation is being made: _____

Contact person: _____

Phone No: _____ **Fax No:** _____

This importation will be: above* below the activity limit for exemption from licensing.

Name of licensee: _____ **Licence number:** _____

**The buyer must name a suitably licensed person to be responsible for the safe care of the radioactive source, unless it is below the exempt limit (regulation 4).*

Details of proposed importation:

Radionuclide: _____
(eg, Caesium-137, Americium-241 etc)

Activity per item: _____ **No. of items:** _____ if more than 1)
(Either becquerel (kBq, MBq, GBq) or curie (μ Ci, mCi, Ci) units of activity may be used)

Year of manufacture: _____ **Source serial no:** _____
(if known) (if known)

Instrument type: _____
(If the source is part of an instrument or other equipment)

Model: _____ **Serial no:** _____
(if known)

Country of origin: _____ **Expected arrival date:** _____
(if known)

Consent and invoice (\$20 + GST) to be sent to: Agent Licensee Company for whom importation is being made

Signature: _____ (Importing agent/Buyer/licensee) **Date:** _____
(Circle as appropriate)

Please send to: National Radiation Laboratory Fax: 03 353 5667
PO Box 25099, Christchurch Phone: 03 366 5059

APPENDIX 3

Investigation of a fault, incident or complaint sample form

INVESTIGATION OF A FAULT, INCIDENT OR COMPLAINT

DETAILS

This is a			Fault <input type="checkbox"/>	Incident <input type="checkbox"/>	Complaint <input type="checkbox"/>
Name of person reporting		Date of report:			
Brief description of problem					
More information can be found attached <input type="checkbox"/>					

INVESTIGATION PROCESS

Name of person investigating
People questioned
Tests/measurements taken
Other information gathered

ASSESSMENT

<input type="checkbox"/> Immediate remedial action is necessary Details
<input type="checkbox"/> Procedures/equipment/facilities should be reviewed at the first opportunity Details
<input type="checkbox"/> This report needs to be considered at the annual Quality Review meeting
Signature of person completing form: _____

APPENDIX 4

Annual internal audit checksheet sample form

Annual internal audit checksheet

Item	Pass	Fail	Notes
All authorisations valid			
All consultants, medical physicist/s currently licensed			
All brachytherapy nurses trained			
All staff wearing film badges			
All film badge readings over 0.5 mSv reviewed and documented			
Current radioactive source inventory correct			
Radioactive material records complete			
Patient treatments recorded as per templates			
Treatment log up to date			
All posted written rules match master copies in RSP			
Equipment maintenance, calibration, and QA as per schedule, with results and certificates filed			
Action on all faults/complaints forms completed and documented			
Name of auditor	Signature		Date

APPENDIX 5

Investigation of personal dose above action level sample form

INVESTIGATION OF PERSONAL DOSE ABOVE ACTION LEVEL

DETAILS

Name of person reported with dose:	
The dosimeter was worn from date	to date
Total wearing period was:	
Part of the body monitored:	Dose recorded

INVESTIGATION RESULTS

Wearer's explanation	
Other details	
Was this dose actually received by the wearer?	Yes <input type="checkbox"/> No <input type="checkbox"/>

ASSESSMENT

If this was an occupational dose what can be done to reduce the exposure?		
If this was not an occupational dose what can be done to prevent invalid dose reports?		
Is a review of quality assurance procedures taking place?	yes <input type="checkbox"/>	no <input type="checkbox"/> undecided <input type="checkbox"/>
Name and signature of person completing form: _____ Date		

APPENDIX 7:
Medical misadministration report sample form

MEDICAL MISADMINISTRATION REPORT

ESTABLISHMENT AND LICENSEE DETAILS

Establishment:		
Address:		
Phone:	Fax:	E-mail:
Principal Licensee's name:	Licence no:	

DETAILS OF MISADMINISTRATION

Date & time of misadministration:	Date NRL notified:	
Date form sent to NRL:	Total number of pages:	
The procedure was:	Diagnostic <input type="checkbox"/>	Therapeutic <input type="checkbox"/>
Name of the patient:		
Name(s) and designation(s) of persons involved:		
Description:		
Expected consequences for patient:		
Actions taken immediately:		

ASSESSMENT

Reasons for the misadministration:			
Main cause was:	Equipment failure <input type="checkbox"/>	Inadequate procedures <input type="checkbox"/>	Individual error <input type="checkbox"/> other <input type="checkbox"/>
What steps have been taken to prevent a recurrence?			
Is a review of quality assurance procedures taking place?	yes <input type="checkbox"/>	no <input type="checkbox"/>	undecided <input type="checkbox"/>
Name and signature of person completing form: _____			

PLEASE SEND TO: National Radiation Laboratory
PO Box 25 099
Christchurch
New Zealand

Fax no. (64) (03) 366 1156
Phone no. (64) (03) 366 5059

APPENDIX 8:

Sample Radiation Safety Plan

<< *Note: details given are just suggestions. Any comments that are part of the Guidance Notes and not intended to be part of the Radiation Safety Plan are bracketed like this.* >>

Acme Brachytherapy Centre (ABC)

Radiation Safety Plan (RSP)

Radiation safety policy

ABC will ensure, as far as reasonably possible, the health and safety of its employees, contractors working on the premises, and members of the public who may be exposed to the hazards arising from the use of radioactive material.

ABC will ensure that every treatment of a patient is justified in terms of an expected beneficial outcome that outweighs the risk from the exposure to radiation.

ABC will ensure that all brachytherapy treatments given to patients are optimised in terms of the desired clinical outcome, while keeping the radiation dose to the patient as low as reasonably achievable.

No member of ABC staff is permitted to treat or care for brachytherapy patients, or handle radioactive sources unless they are so authorised in this Radiation Safety Plan and have signed the relevant entry to indicate familiarity with and acceptance of the requirements and procedures in this RSP.

Responsibilities and authorisations

Principal licensee

Overall responsibility for ensuring this Radiation Safety Plan is implemented and reviewed lies with the principal licensee for ABC.

Name	Licence number	Position title	Signature
Dr L1	11011	Clinical director	

Licensed physicians

The following licensed clinicians are authorised to use radioactive materials for medical therapy at ABC and are responsible for complying with the procedures in this Radiation Safety Plan.

Name	Licence number	Position title	Signature
Dr L2	11012	Consultant oncologist	
Dr L3	11013	Consultant oncologist	

Registrars

The following registrars are authorised to use radioactive materials for medical therapy at ABC under the supervision of the named licensed physicians, and are responsible for complying with the procedures in this Radiation Safety Plan.

Name	Name of supervising licensee	Licence number	Signature
Dr R1	Dr L1	11012	
Dr R2	Dr L2	11013	

Licensed medical physicist

The following licensed medical physicist is authorised at ABC to carry out calibration, dosimetry, quality control and maintenance of equipment, treatment planning and advise on quality assurance and radiation safety.

Name	Licence number	Signature
MP	11014	

Registered Radiation Therapists

The following Radiation Therapists are authorised to treat patients with brachytherapy in accordance with prescriptions signed by one of the licensed physicians named above.

Name	Registration number	Signature
RT1		
RT2		

Nurses

The following nurses are authorised to care for patients who are being treated with brachytherapy.

Name	Date of last training course	Signature
N1		
N2		

Induction and training procedures for staff

All nurses caring for patients being treated with brachytherapy must have completed a 3-hour training session within the previous twelve months, run by MP that covers the following topics:

- Principles of radiation safety
- Safe handling of Cs-137 sources
- Safe caring of patients with implants
- Control of visitors
- Emergency source removal.

A copy of the course handout is filed with this Radiation Safety Plan.

Personal monitoring policy and procedures

All staff authorised above must wear personal dose meters supplied by NRL and worn on the trunk.

A copy of the Dose Report will be posted on the staff notice board in the tearoom each month. After removal from the notice board the Dose Report will be filed in the blue cabinet in the Preparation Room.

Monthly Dose Reports will be reviewed by MP. Any reading greater than 0.5 mSv will be investigated and reported back to Dr PL using *the Investigation of Personal Dose above Action Level* template filed with this Radiation Safety Plan << See Appendix 5 >>. A copy of this form will be filed with the Dose Report at the end of the month.

Register and records of radioactive sources

The following are filed in the blue cabinet in the Preparation Room:

- Current inventory of sources
- Calibration certificates
- Records of purchase documentation
- Records of disposal documentation
- A logbook for sources that are manually re-used, for logging out and in again.

Anyone removing a source from the Preparation Room for any reason must write the details in the log book and sign the entry.

Medical records of treatments

After treatment is completed the prescription form, planning form, and treatment forms are placed on the patient record file.

<< Templates for these forms should be appended >>

Because out-of-town patients are given their medical record when they are discharged, a separate record of the treatment, at the time the forms are added to the patient record file, must be entered into the treatment logbook kept in the blue cabinet in the Preparation Room << See Appendix 6 >>.

ABC Quality Assurance Programme

Programme for the routine maintenance, calibration and checking of equipment

Item	Action/test	Frequency	Location of test procedures	Location of results and certificates
Dose calibrator	Constancy	Monthly	In Quality Manual in Prep Room	Blue cabinet
	Linearity	Yearly		
	Calibration	2-yearly		
	Servicing	If faulty		
Radiation survey meter	Constancy	Monthly	In Quality Manual in Prep Room	Blue cabinet
	Calibration	2-yearly		
	Servicing	If faulty		

Procedures for managing reported faults, incidents or complaints

Any staff member who wishes to report a problem of any sort that may result (or have resulted) in an accidental exposure or patient misadministration should initiate an *Investigation of a Fault, Incident or Complaint* form and give it to MP to carry out an investigation if needed. A template for the form is filed at the end of this Radiation Safety Plan << See Appendix 3 >>.

Routine audits to verify procedures, documentation and inventories

In the first week of April each year, MP will carry out a full internal audit, using the template checksheet filed with this Radiation Safety Plan << See Appendix 4 >>.

If there are any failed items on the check sheet these must be discussed with Dr PL.

The completed checksheet together with any other notes must be filed with this Radiation Safety Plan in the section after the template.

An annual review cycle of the quality system

In the second week of April each year, there will be a meeting of all brachytherapy staff held to review:

- the results of the annual audit
- any reported misadministrations
- any reported faults, incidents or complaints
- equipment QA reports
- morbidity and mortality outcomes
- patient outcomes.

The minutes of this meeting and any changes in work procedures or documentation will be recorded and filed at the end of the Radiation Safety Plan.

Any changes to written procedures must be signed off by Dr PL and distributed to all places where they are filed or posted, as indicated in the table above.

Written instructions and local rules

The written procedures listed in the following table are controlled documents. Master copies are filed with this Radiation Safety Plan.

If any changes are required these must be made to the master copies here, signed by Dr PL, and copied to the other places they are posted or filed.

Ref	Safety procedures	Location/s of other copies	Date last modified
R1	Rules for visitors to brachytherapy patients	On the wall of Room B1	
R2	Purchasing, receiving and commissioning new radioactive sources	With the inventory	
R3	Decommissioning and disposal of old radioactive sources	With the inventory	
R4	Calibration of sources	With the dose calibrator manual	

R5	Leak testing sources	In the Prep Room Manual	
R6	Handling of sources during clinical use	In the Prep Room Manual	
R7	Nursing care of brachytherapy patients	In the Charge Nurse's Office	
R8	Procedure for establishing positive patient identity, and where relevant, pregnancy status	On the wall in the waiting room	
R9	Written clinical procedures	On the ceiling of the operating surgery	

Incident, accident and emergency procedures

The written procedures listed in the following table are controlled documents. Master copies are filed with this Radiation Safety Plan.

If there are any changes needed these must be made to the master copies here, signed by Dr PL, and copied to the other places they are posted or filed.

Ref	Incident, accident and emergency procedures	Location of other copies	Date last modified
R10	Medical misadministrations	In the Prep Room Manual	
R11	Other incidents and accidents	In the Prep Room Manual	
R12	Leaking source	In the Prep Room Manual	
R13	Loss of a source	In the Prep Room Manual	
R14	A stuck or detached source	In the Prep Room Manual	
R15	Medical emergency of a patient with a loaded source	In the Charge Nurse's Office	
R16	Evacuation of patients from the building	Health and Safety Manual	
R17	Security of radioactive sources in a civil emergency	Health and Safety Manual	

Associated documents filed with this Radiation Safety Plan

1. Copies of notification of the new facility to NRL and reply
2. Copies of current NRL licence verification certificates
3. Copies of RT Annual Practice Certificates
4. A copy of the handout for the safety course for nurses
5. Template form for investigation of personal dose above action level
6. Templates for prescription form, planning form and treatment forms
7. Template for treatment record log
8. Template for investigation of a fault, incident or complaint
9. Template for an internal audit
10. Copies of completed internal audits
11. Records of minutes and actions arising from annual quality review meetings
12. Master copies of all written procedures and local rules

CROSS-REFERENCE INDEX

These *Guidance notes* give practical advice for compliance with radiation protection legislation and the relevant *Code*, *NRL C14*. The references to the legislation in this index are not always directly cited in this document or the *Code*, but do provide the regulatory authority for the *Code's* requirements and the *Guidance notes'* recommendations.

The references are from these *Guidance notes: safe practice for the use of sealed radioactive materials for brachytherapy* to:

- *Code of safe practice for the use of sealed radioactive materials for brachytherapy, NRL C14 (NRL, August 2002)*
- *Radiation Protection Regulations 1982*
- *Radiation Protection Act 1965.*

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