



Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**

SAFETY GUIDE

Radiation Protection in Radiotherapy

RADIATION PROTECTION SERIES No. 14.3

Radiation Protection Series

The ***Radiation Protection Series*** is published by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) to promote practices which protect human health and the environment from the possible harmful effects of radiation. ARPANSA is assisted in this task by its Radiation Health and Safety Advisory Council, which reviews the publication program for the ***Series*** and endorses documents for publication, and by its Radiation Health Committee, which oversees the preparation of draft documents and recommends publication.

There are four categories of publication in the ***Series***:

Radiation Protection Standards set fundamental requirements for safety. They are regulatory in style and may be referenced by regulatory instruments in State, Territory or Commonwealth jurisdictions. They may contain key procedural requirements regarded as essential for best international practice in radiation protection, and fundamental quantitative requirements, such as exposure limits.

Codes of Practice are also regulatory in style and may be referenced by regulations or conditions of licence. They contain practice-specific requirements that must be satisfied to ensure an acceptable level of safety in dealings involving exposure to radiation. Requirements are expressed in 'must' statements.

Recommendations provide guidance on fundamental principles for radiation protection. They are written in an explanatory and non-regulatory style and describe the basic concepts and objectives of best international practice. Where there are related **Radiation Protection Standards** and **Codes of Practice**, they are based on the fundamental principles in the **Recommendations**.

Safety Guides provide practice-specific guidance on achieving the requirements set out in **Radiation Protection Standards** and **Codes of Practice**. They are non-regulatory in style, but may recommend good practices. Guidance is expressed in 'should' statements, indicating that the measures recommended, or equivalent alternatives, are normally necessary in order to comply with the requirements of the **Radiation Protection Standards** and **Codes of Practice**.

In many cases, for practical convenience, regulatory and guidance documents which are related to each other may be published together. A **Code of Practice** and a corresponding **Safety Guide** may be published within a single set of covers.

All publications in the *Radiation Protection Series* are informed by public comment during drafting, and Radiation Protection Standards and Codes of Practice, which may serve a regulatory function, are subject to a process of regulatory review. Further information on these consultation processes may be obtained by contacting ARPANSA.



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This publication was approved by the Radiation Health Committee on
15 December 2008, and endorsed for publication by the
Acting Chief Executive Officer of ARPANSA on 19 December 2008

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The mission of ARPANSA is to provide the scientific expertise and infrastructure necessary to support the objective of the ARPANS Act – to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation.

Published by the Acting Chief Executive Officer of ARPANSA in December 2008

Foreword

The *Safety Guide for Radiation Protection in Radiotherapy* is one of three guides that support the application of the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (the Code)*.

The therapeutic use of ionizing radiation in medicine, either alone or in combination with other modalities, is recognised as one of the main forms of treatment for patients with malignancies and related diseases. For various reasons, in the past it has been under-utilised in Australia when compared to equivalent other countries, and hence its use is now increasing throughout Australia. In addition, developments in technology and clinical knowledge are resulting in increasingly complex, multi-field treatments becoming more common in the clinical environment, for example intensity modulated radiotherapy (IMRT), intra-operative radiotherapy (IORT) and high dose rate (HDR) brachytherapy. As *the Code* makes clear, the fundamentals of justification and optimisation must apply when undertaking radiotherapy procedures. Exposure to radiation during a medical procedure needs to be justified by weighing up the benefits against the detriments that may be caused. This includes considering the benefits and risks of alternative methods that do not involve any exposure to radiation. In the case of optimisation, practitioners need to ensure that the minimum amount of radiation is used to achieve the intended objective. The use of radiotherapy has overall societal benefit, but the high radiation doses involved with therapeutic exposures have the potential to cause harm to those who benefit from the treatment and to health care staff and members of the public if inadvertent radiation exposure occurs. The protection of occupationally exposed staff and the general public is an important aspect of the optimal use of ionizing radiation in medicine. Special concern in relation to radiation protection is afforded to children, and pregnant or potentially pregnant females.

As radiotherapy techniques become more complex it is difficult to rely on a manual checking process to detect and minimise errors. A rigorous ongoing quality assurance process is essential.

The Code establishes the regulatory requirements for the use of ionizing radiation in medicine. This *Safety Guide* is written to give practitioners in radiotherapy a best practice approach to radiation protection in their day-to-day clinical work. It should also assist in providing practical means to meet the mandatory requirements of *the Code*. One such area is the preparation, implementation and review of a Radiation Management Plan.

A draft of the *Safety Guide* was released for industry consultation between 18 May 2007 – 2 July 2007. A public consultation period from 24 August 2007 to 26 October 2007 followed. A one-day *National Conference on Radiation Protection in Medicine* was held on 3 October 2007, during the public consultation period, to provide the stakeholders a forum to discuss the Code and Safety Guides. The draft *Safety Guide for Radiation Protection in Radiotherapy* was revised by the working group to take into account the comments made in the submissions. The Radiation Health Committee approved the final Safety Guide on 15 December 2008 and I approved the publication of the Safety Guide on 19 December 2008.

I expect that the Radiation Health Committee will review the *Safety Guide* in two years, and update it if necessary, to ensure that it provides the highest standards of protection for the medical use of ionizing radiation.

A handwritten signature in black ink that reads "PA Burns". The signature is written in a cursive, flowing style.

PA Burns
Acting CEO of ARPANSA

19 December 2008

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1. Introduction

1.1 CITATION

This Safety Guide may be cited as the *Safety Guide for Radiation Protection in Radiotherapy (2008)*.

1.2 BACKGROUND

This Safety Guide has been prepared as a supplement to the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)* (hereafter called 'the Code') (ARPANSA 2008b). The Safety Guide provides advice and guidance on good radiation **practice** and on meeting the requirements of the Code. In relation to radioactive sources, the relevant parts of the Code and this Safety Guide supersede the NHMRC *Code of Practice for the control and safe handling of radioactive sources used for therapeutic purposes (1988)*.

Radiotherapy is the branch of clinical medicine that uses **ionizing radiation**, either alone or in combination with other modalities, for the treatment of patients with malignancies or other diseases. It includes responsibility for the diagnosis, treatment, follow-up and supportive care of the cancer patient as an integral part of the multidisciplinary management of patients.

The use of radiotherapy has overall societal benefit, but the high radiation **doses** involved with therapeutic **exposures** have the potential to cause harm to those who benefit from the treatment and to health care staff and members of the public if inadvertent radiation exposure occurs.

1.3 PURPOSE

This Safety Guide provides information to assist the relevant persons to meet the requirements of the Code in the delivery of radiotherapy. Although the guidance offered in this Safety Guide is in itself not mandatory, it is recommended that the measures included in it should be implemented in the interests of controlling radiation exposure and reducing risks. It includes information on:

- the roles of the members of the multidisciplinary team and delegation of responsibilities;
- procedures for optimising protection through treatment planning and delivery;
- recommendations regarding quality assurance activities; and
- recommendations regarding documentation and departmental protocols.

1.4 SCOPE

This Safety Guide applies to the following:

- the exposure of patients as part of their treatment;

- the exposure of individuals participating in research programs¹;
- the **occupational exposure** of individuals arising from radiotherapy practice; and
- the exposure of members of the public arising from the use of medical radiation equipment and radioactive sources including:
 - the exposure of health professionals, other than those occupationally exposed; and
 - the exposure of **carers**.

This Safety Guide applies to **sealed source brachytherapy** and **teletherapy** (external beam radiotherapy using photons, electrons and charged or uncharged particles).

This Safety Guide does not apply to the therapeutic use of unsealed radioactive sources, where the *Safety Guide for Radiation Protection in Nuclear Medicine* (ARPANSA 2008c) applies.

1.5 STRUCTURE

This Safety Guide sets out information to assist in achieving the levels of protection specified in the Code. While it does not form part of the material directly adopted into the regulatory frameworks of the State, Territory or Commonwealth Authorities, it does set out best practice in radiotherapy and therefore the use of this Safety Guide is recommended for establishing appropriate radiation protection procedures. The Safety Guide does not restrict users from developing their own procedures to meet the requirements of the Code that provide an equivalent level of safety.

The meaning of terms defined in the Glossary to this Safety Guide is the same as the meaning defined in the Glossary to the Code.

Material in the Annexes provides clarification and guidance on issues discussed in the Safety Guide with Annex L, in particular, outlining the health effects arising from exposure to ionizing radiation.

¹ Specific requirements for research participants are given in the Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005), ARPANSA.

2. Justification

All therapeutic exposures to ionizing radiation are subject to the principles of **justification** and **optimisation**. For doses received by a patient undergoing medical diagnosis or treatment, there are two levels of justification:

1. The practice involving exposure to radiation should be justified in principle. This applies to both new and existing procedures. In this context, the continuing involvement of medical professional societies should be ensured, as matters of effective medical practice will be central to this judgement (IAEA 2002).
2. Each procedure should be subject to a further, case-by-case justification by the prescribing **Radiation Medical Practitioner** (ICRP 1991a).

The decision to perform a radiotherapeutic procedure rests upon a professional judgement of the benefits that accrue to the total health of the patient, while accounting for any detrimental biological effects that might be caused by the ionizing radiation. The benefit will be the potential therapeutic effect resulting from the **medical exposure** of that procedure, including the direct health benefits to an individual as well as the benefits to society. The **detriment** will be the potential deleterious effects of ionizing radiation. The objective of radiotherapy is to deliver a radiation dose to a selected target volume of an organ or tissue for the purpose of killing cells. Such therapy results in **absorbed doses** that are orders of magnitude greater than those encountered in diagnostic studies. The potential for complications with normal tissue is significant. Some deleterious effects will often be an unavoidable part of a properly justified procedure. Therefore, the justification for each procedure should be carefully considered (IAEA 2002).

The justification process should also take into account the efficacy, benefits and risks of using alternative procedures, for example surgery or chemotherapy, either alone or in combination with radiotherapy (IAEA 2002). Influencing this choice will be patient preference, practitioner expertise, suitable resources and availability of alternative procedures.

There are special cases that warrant further justification, including the medical exposure of the pregnant or potentially pregnant patient, as there is evidence to suggest that the embryo or fetus is more radiosensitive than the mature adult (DeLongchamp et al. 1997, Doll and Wakeford 1997). Likewise, radiotherapy involving children under the age of 18 years requires a higher level of justification since children may be more susceptible to radiation related developmental damage and the induction of radiation induced cancers (ICRP 1991a, ICRP 1991b, DeLongchamp et al. 1997) and they have a longer life expectancy during which manifestation of possible harmful effects of radiation may occur. Paediatric radiotherapy is best performed in facilities with an experienced paediatric radiation oncology treatment team, linked to paediatric oncology groups that use internationally endorsed treatment protocols.

Research that exposes humans to ionizing radiation should conform to the requirements published by ARPANSA in Radiation Protection Series (RPS) No. 8 (ARPANSA 2005), which requires that proposals for research involving

ionizing radiation be submitted for approval to a properly constituted Human Research Ethics Committee, including details of the level of exposure and the reasons justifying its use. Radiotherapy clinical trials involve high radiation doses at levels which cause tissue effects, specifically destruction of the cancer with an acceptably minimised level of radiation induced complications. The risk and benefit associated with the radiation exposure need to be explained to the research participant/patient.

3. Roles, Duties and Responsibilities

The delivery of radiotherapy requires a multi-disciplinary approach, with input from a number of professional groups, interacting with manufacturers and **suppliers** of equipment and sources, maintenance engineers, and the **relevant regulatory authorities** (see Annex M). All members of the multi-disciplinary team have an individual and joint responsibility to ensure their contribution to safe practices in the delivery of radiotherapy. Consideration needs to be given to occupational exposure, medical exposure to the patient and exposure of the general public.

The following sections outline the roles, duties and responsibilities, and the professional groups who perform those tasks within a radiotherapy **facility**. Some duties can only be performed by a specific professional group; for example, medical matters requiring a specialist doctor can only be dealt with by the authorised Radiation Medical Practitioner. Other roles can be performed by a range of professionals, depending upon the circumstances within the facility.

3.1 THE RESPONSIBLE PERSON

The **Responsible Person** may be a natural person or a corporation, and in the context of the practice of radiotherapy may be the Chief Executive Officer, or a Director of Medical Services, of the hospital or clinic. The Responsible Person has overall management and control of the radiotherapy facility. The individual who embodies the Responsible Person should be clearly identified. Although tasks may be delegated, the legal responsibility for adherence to the Code (Section 3.1) lies with the Responsible Person.

The Responsible Person's radiation safety policy documentation should clearly demonstrate the commitment of senior management to restrict unnecessary or unintended radiation exposure during the use of **radiotherapy equipment**. It should include consideration of radiation protection for public, occupational and medical exposures, and should clearly identify those designated with responsibility and the scope of their responsibility.

3.1.1 Radiation Management Plan

Under Clause 3.1.1 of the Code, the Responsible Person is required to ensure that a Radiation Management Plan is in place for the control of radiation exposure. The Responsible Person may delegate the development of the institution's Radiation Management Plan to the Radiation Safety Officer (see Section 3.6 of this Safety Guide). All the professional groups involved in radiotherapy should contribute to the formulation of the Radiation Management Plan. The coordination and documentation of the radiotherapy component of the Radiation Management Plan is usually delegated to a **Qualified Expert**, with specific expertise in radiation protection.

It is a requirement in Clause 3.1.1 of the Code that the Radiation Management Plan and its implementation be reviewed and updated at regular intervals and after any significant changes in practice. The Radiation Management

Plan should be viewed as a 'living document' so that as changes occur to equipment, operators or work practices, it is reviewed or updated to reflect the changing nature of the use of radiation at the practice.

The relevant sections of the Radiation Management Plan should form part of an orientation program for new staff involved with a radiotherapy facility.

Schedule A of the Code lists the requirements for the Radiation Management Plan and Annex A of this Safety Guide provides guidelines for the preparation of the Plan specific for Radiotherapy. The Plan is expected to specifically include **written** procedures or protocols to address the following issues:

- protection of **employees**, patients and members of the public;
- personal monitoring requirements;
- shielding and design of installations and an inventory of radiotherapy equipment (see Annex C);
- the correct identification of the patient prior to performing the radiation exposure of the radiotherapy treatment or planning procedure;
- irradiation of pregnant or potentially pregnant patients with specific advice about how to minimise irradiation of the embryo or unborn child;
- concerns about the risks from ionizing radiation and how to explain them to patients, guardians and carers;
- the protection of individuals (carers), who voluntarily help in the care, support and comfort of patients undergoing brachytherapy. Nurses and support staff, for example, should only assist in close caring during treatment if a carer is not available. The Plan should enable the Responsible Person to demonstrate that the **effective dose** received by the carer is unlikely to exceed 5 mSv per year (IAEA 1996);
- accidental, abnormal or unplanned exposures to radiation; and
- regulatory requirements that need to be satisfied.

3.1.2 Radiotherapy Equipment

In the provision of radiotherapy equipment, the Responsible Person is obliged to meet:

- the relevant clauses of the Code, such as Clauses 3.1.19 to 3.1.31; and
- the registration/licensing criteria of the relevant regulatory authority.

The Responsible Person should also ensure regular review of the equipment for safety and performance.

In relation to brachytherapy equipment, the Responsible Person should ensure that all radioactive sources are:

- stored and handled in accordance with the guidance given in Section 12.2 and Annexes G and H of this Safety Guide;
- stored with appropriate security, in accordance with the *Code of Practice for the Security of Radioactive Sources* (ARPANSA 2007);

3.1.3 Quality Assurance

As part of the Quality Assurance Program required by Clause 3.1.21 of the Code, the Responsible Person should ensure that a comprehensive clinical protocol and treatment policy document for the treatment facility is readily available, followed and regularly updated (IAEA 2008). Section 6 of this Safety Guide provides further detail.

3.1.4 Personal Radiation Monitoring and Dose Limits

Clause 3.1.9 of the Code requires that the Responsible Person provide a personal radiation monitor to all employees who are likely to receive an annual effective dose of more than 1 mSv, either as a result of chronic exposure or as a result of incidents that are reasonably foreseeable. Wearing periods for personal radiation monitors will vary depending on the likelihood of the individual receiving an accidental or high dose but in any event should be for no longer than three months (being a reasonable maximum period for reliability of the monitors and memory recall of any incidents).

Whilst the Code requires that the Responsible Person, when planning and designing the workplace or work practices, keep all exposures below the individual dose limits specified in RPS1 (ARPANSA 2002), it should be recognised that these dose limits represent the boundary between unacceptable doses and doses that are tolerable. Thus, the aim is to keep individual doses as low as reasonably achievable (ALARA), economic and social factors being taken into account.

3.1.5 Qualified Personnel

The Responsible Person should ensure that all tasks directly related to the servicing and maintenance of radiotherapy equipment, and the planning and delivery of radiotherapy, should be performed by appropriately qualified and trained personnel. Clause 3.1.24 of the Code requires that a Qualified Expert is available for consultation on optimisation and to give advice on matters relating to radiation protection, calibration, dosimetry and quality assurance in radiotherapy.

3.2 RADIATION MEDICAL PRACTITIONER

Clause 3.2.1 of the Code states that radiotherapy may be administered only on the prescription of an authorised Radiation Medical Practitioner. This person has the primary task and obligation of ensuring protection and safety of the patient in the prescription of, and during the delivery of, the treatment (BSS No. 115 Appendix II, IAEA 1996) and is required by Clause 3.2.1(c) of the Code to ensure that radiation doses are justified and optimised.

Authorised in this context means holding qualifications acceptable to the relevant professional specialty and authorised by the relevant regulatory authority and is normally restricted to the following:

- external beam therapy: **Radiation Oncologists**, Dermatologists (superficial radiotherapy only);

- intra-operative photon or electron radiotherapy: Radiation Oncologists; and
- sealed source brachytherapy: Radiation Oncologists, Ophthalmologists (eye plaque treatment only), Dermatologists (superficial radiotherapy only).

However during treatment application, members of other medical specialties may work with the prescribing doctor (e.g. urologists and gastroenterologists for relevant brachytherapy procedures; cardiologists for intravascular brachytherapy).

3.2.1 Justification

Section 3.2 of the Code requires that the ultimate decision to perform a radiotherapy treatment resides with the Radiation Medical Practitioner responsible for the patient's care. The decision is a professional judgement based on the specialist's knowledge of the patient's medical diagnosis, a clinical examination of the patient's clinical state and extent of disease, together with knowledge of any relevant investigational procedures, including the patient's pathology results. A knowledge of the efficacy of other available forms of treatment (used alone or in combination with radiotherapy) and their toxicities is required, as well as an understanding of the expected and potential toxicity of the particular radiation therapy proposed.

The Radiation Medical Practitioner should:

- consider current practice in relation to the appropriate use of imaging and therapeutic procedures, including their advantages and disadvantages and the radiation dose and effects associated with each;
- ensure that the procedure is clinically needed;
- provide counselling for the patient (or guardian) and where relevant the carer, on the potential radiation-related risks associated with the treatment; and
- obtain informed consent from the patient (or guardian).

3.2.2 Treatment Prescription

Clause 3.2.4(a) of the Code requires a written prescription for the procedure from the Radiation Medical Practitioner, as well as approval of the treatment plan. The written treatment prescription should state:

- the site (and side) to be treated;
- the intent of the treatment;
- the total dose and number of fractions (stating the fraction size), and the time-frame for completion of the treatment;
- the treatment modality (radiation type and quality) and technique;
- **dose constraints** for critical normal tissues (organs at risk (OAR));
- the radionuclide to be used for brachytherapy; and
- whether concurrent chemotherapy is to be given.

3.2.3 Treatment Plan Approval

The Radiation Medical Practitioner should sign and date the treatment plan, before treatment commences, to indicate approval of the plan when satisfied that the planning and dosimetry processes will adequately achieve the aim of the treatment, in terms of coverage of the target volume, appropriate dose to the target and appropriate dose constraints to protect normal tissue.

3.2.4 Supervision of Treatment

The responsibility for treatment planning and overseeing the delivery of radiotherapy rests with the Radiation Medical Practitioner. Overseeing of treatment will include:

- definition of the target volume and critical normal structures;
- setting of constraints for normal tissue tolerance;
- approval of the treatment plan; and
- evaluation of the effects of the therapeutic radiation exposure.

Whilst unable to monitor every part of the process, the Radiation Medical Practitioner should have adequate interaction throughout the process to fulfil this responsibility. The Radiation Medical Practitioner should ensure that records of the treatment are retained in line with the recommendations of the Royal Australian and New Zealand College of Radiologists (RANZCR 2005).

3.2.5 Brachytherapy

Clause 3.2.11 of the Code requires the Radiation Medical Practitioner to be immediately available to the patient in person for all high dose rate (HDR) brachytherapy procedures where immediate medical issues may arise during the application of the treatment. Thus, for interstitial, intraluminal or intracavitary HDR brachytherapy, the Radiation Medical Practitioner should be in the close vicinity of the treatment room for the duration of the treatment. This is to ensure that medical assistance is immediately available to remove the source applicator from the patient in the event of an emergency where the source cannot be rewound from an in situ applicator. A medical practitioner trained in the relevant emergency procedures may carry out this role but the Radiation Medical Practitioner remains responsible for this task.

Other than for non-surgical plaque applications, the Radiation Medical Practitioner should administer the treatment or be present for the initiation of low dose rate (LDR) or manual brachytherapy, including intravascular brachytherapy.

3.2.6 Intra-Operative Radiotherapy (IORT)

The Radiation Medical Practitioner should be present at the initiation of the treatment and remain in close vicinity of the patient during the application of intra-operative radiotherapy.

3.2.7 Other Responsibilities

The Radiation Medical Practitioner should be responsible for the development and adoption of protocols defining treatment schedules, prescribed doses and doses to relevant organs and other tissues.

The Radiation Medical Practitioner should maintain currency by meeting the requirements in training, certification and continued professional development as approved by the relevant professional body. Professional registration to practice the relevant medical specialty and **authorisation** by the relevant regulatory authority for the prescription of the therapeutic radiation modalities must be maintained.

3.3 PERSONS ADMINISTERING RADIATION (OPERATOR)

The person administering radiation to a patient for radiotherapy treatment is the person who fulfils the role of operator specified in Section 3.3 of the Code. This will usually be a qualified **Radiation Therapist**, although in some circumstances, such as brachytherapy or IORT, a Radiation Medical Practitioner or a Qualified Expert may also carry out this function. Radioactive plaque application for ophthalmology and dermatology (not involving surgery) may be administered by a Radiation Therapist or a Radiation Medical Practitioner.

Before any procedure is undertaken, the person administering the radiation needs to comply with the Responsible Person's written operating procedure on how to identify the patient correctly and ensure that the correct procedure will be performed. Identification should be established by asking the patient to state their name, gender, date of birth, and address where ever possible, as well as using any unique patient number as supporting evidence. Photographic identification will assist this process. Additionally, it is appropriate to establish the pregnancy status of any female patient at this time.

Clause 3.3.1 of the Code mandates that each person administering radiation must have the appropriate authorisation from the relevant regulatory authority.

In addition, no person may use or operate any radiotherapy equipment unless they:

- have received the training detailed in the Responsible Person's Radiation Management Plan (Clause 3.3.2 of the Code); and
- are familiar with the Responsible Person's **defence in depth** procedures for all major treatment parameters and monitor units or treatment times.

Clause 3.3.4(e) of the Code requires the person who administers the radiation to be aware that:

- a person approved by the Responsible Person to check treatment plans should check the plan, confirming this by their signature and date;
- all treatment plans are required to be approved by an authorised Radiation Medical Practitioner, who should sign and date the treatment plan;

- the radiation dose is delivered in accordance with the treatment plan;
- there is continuous observation of the patient and operating parameters of the equipment during external beam radiotherapy and HDR brachytherapy; and
- radiation exposure is terminated immediately if there is any concern that the correct dose will not be delivered to the patient.

In addition, the person who administers radiation to a patient for radiotherapy treatment should:

1. For external beam radiotherapy and intra-operative photon and electron radiotherapy:
 - create a document for the delivery of the **prescribed radiotherapy treatment** to the patient;
 - ensure that a double-check of the prescription has been performed and recorded; and
 - ensure that the record includes the following details:
 - date of treatment;
 - treatment site and field size(s);
 - total radiation dose at the reference point;
 - number of fractions;
 - radiation type and quality; and
 - doses received by critical normal tissues (OARs).
2. For radiotherapy treatment with brachytherapy:
 - make a written record of the details of the sealed sources used on the patient;
 - ensure that the written record includes the following details:
 - the radionuclide and activity;
 - the batch number and expiry date of the source;
 - the date and time of application or administration of the source;
 - for permanently implanted sealed sources, the anticipated time when the radiation hazard from the sources becomes acceptably low and radiation precautions may cease;
 - for non-permanently implanted sealed sources, the anticipated time when the sources are to be removed;
 - the site being treated; and
 - the dose administered to the treatment site; and
 - follow the relevant written protocols and the appropriate procedures for the delivery of brachytherapy.

There are situations where matters of calibration, dosimetry, quality assurance or potential emergency might arise during a radiation

administration. A Qualified Expert should be present in addition to the person administering the radiation, in particular for:

- intra-operative photon or electron radiotherapy that may occur in the operating theatre, or in the treatment room following surgical exposure of the area for treatment;
- sealed source HDR brachytherapy throughout the surgical and treatment procedures (the Qualified Expert has an integral role during treatment in relation to safety and emergency precautions);
- the insertion of sealed sources for LDR brachytherapy (such as iodine-125 seed prostate implants);
- the application or insertion of sealed radioactive sources for manual brachytherapy (other than non-surgical plaque application). Specific examples are the surgical placement of plaques for orbital retinoblastoma, mould implants to superficial tumours or interstitial implants using radioactive iridium-192; and
- external beam therapies where a new protocol or technique is being implemented which requires detailed assessment of the accuracy of dosimetry and/or of the reliability of radiation equipment operation, or where the dosimetry needs to be calibrated prior to treatment or measured during treatment.

3.4 RADIATION THERAPIST

Section 3.3 of this Safety Guide broadly outlines the duties of a Radiation Therapist. Safe and accurate administration of radiation is a fundamental role of the Radiation Therapist who can undertake each aspect of the planning and treatment process. In addition, a Radiation Therapist works in the multidisciplinary team underpinning the safe and effective delivery of radiotherapy. A Radiation Therapist will be trained in all aspects of the delivery of radiotherapy, which includes megavoltage, orthovoltage, superficial and brachytherapy treatments. The Radiation Therapist may operate a broad range of radiotherapy equipment including linear accelerators, kilovoltage **X-ray** units, CT scanners (for planning) and brachytherapy afterloading units.

Close interaction with the Radiation Medical Practitioner and the Qualified Expert should ensure that the most appropriate technique for planning and delivering the dose prescription, particularly in determining the appropriate treatment technique for more complex cases.

The Radiation Therapist will typically:

- calculate and document the relevant clinical dosimetry parameters for the planning and treatment of the patient;
- participate in the development, approval, implementation and regular review of the facility's comprehensive quality assurance program, conforming to the standards endorsed by the appropriate professional bodies;
- manage quality control for patient related treatment/planning activities;

- adhere to the manufacturer's operating manual and any additional safe practice procedures for operating the radiotherapy equipment that may be prepared by the Qualified Expert;
- record any equipment error or malfunction and report it to the Qualified Expert and, where necessary, to the Responsible Person and the Radiation Medical Practitioner (as required by the Code); and
- undertake continuing professional development to ensure that knowledge and skill base is current and satisfy any certification/registration requirements of their relevant professional association.

3.5 QUALIFIED EXPERT (RADIATION ONCOLOGY MEDICAL PHYSICIST)

Clause 3.1.24 of the Code requires that a Qualified Expert is available to:

- consult on optimisation of medical exposures;
- perform or supervise radiotherapy calibration, dosimetry and quality assurance; and
- give advice on matters relating to radiation protection.

The Qualified Expert will have suitable qualifications and experience in radiotherapy physics. A medical physicist with specialist experience in radiotherapy – a **Radiation Oncology Medical Physicist** – would satisfy these requirements.

The duties of the Qualified Expert will typically include the following components:

- specify building design and shielding requirements of a radiotherapy facility to ensure appropriate level of radiation protection for the staff and general public;
- advise the Responsible Person on the purchase of suitable radiotherapy equipment;
- perform commissioning, acceptance tests and calibration of the output of the radiotherapy equipment, ensuring that the equipment complies with the manufacturer's performance specifications and other national and/or international standards;
- ensure that all physics data being used at the site are accurate and adequate;
- carry out full safety assessments of equipment where there is no appropriate national or international standard for the equipment design and operation;
- following maintenance or repair work on radiotherapy equipment, ensure the equipment is returned to clinical use only after receiving a satisfactory work report from the service personnel and carrying out any necessary checks and tests to ensure safe operation of the equipment in relation to radiation safety;

- ensure that all planning dosimetry data are correct, that new dose calculation methods are verified by measurement or by simulation, and that sufficient planning dosimetry data are available;
- be present to provide expert advice in the application of physics and dosimetry principles or physics measurements for techniques that require:
 - detailed assessment of the accuracy of dosimetry; or
 - evaluation of the operational reliability of the radiation equipment; or
 - validation of a high dose/doserate treatment; or
 - dose calibration prior to or during treatment;
- oversee and assist in the implementation of the quality assurance program;
- oversee and assist in the development, implementation and regular reviews of radiation safety procedures;
- carry out the investigation of incidents as delegated by the Responsible Person, and ensure the development of corrective measures to prevent a recurrence of similar incidents. A suitable report should be submitted (where necessary) to the facility's RSO, to the facility's radiation safety committee and to relevant authorities; and
- be available to provide general supervision for brachytherapy during the administration of the treatment (placement of the sources) and, where relevant, during an in-patient course of treatment (such as gynaecological insertions, prostate implants and special applicators using caesium-137, iodine-125 and iridium-192). This supervision should include confirming that sources intended for removal at the end of the treatment have been removed and returned to the radioactive source store at the scheduled time.

Qualified Experts should be involved in activities such as the development, implementation, maintenance and quality control of the infrastructure (facilities, equipment and computer systems) and the implementation processes necessary for the provision of new radiation treatments when a thorough understanding of the physical principles in the production, attenuation and shaping of photon and electron beams is required.

The Qualified Expert should work in close collaboration with the facility's Radiation Safety Officer.

3.6 RADIATION SAFETY OFFICER (RSO)

The Responsible Person may delegate radiation protection duties to an RSO. Delegating duties to an RSO does not, however, absolve the Responsible Person from their legal responsibility for ensuring that those duties are carried out. In some Australian jurisdictions, the appointment of an RSO is required for the issue of an authorisation by the relevant regulatory authority.

An RSO will have sufficient professional and/or technical training to oversee and provide advice on radiation safety within the practice. The RSO ensures

that the Responsible Person is kept informed of the radiation safety status of the practice.

The RSO may be an employee of the organisation and the duties can, for example, be added as an extra level of duties for a Qualified Expert. An external provider of such services or a radiation protection consultant may also perform the RSO function. Where the appointment of an RSO is mandated by a given jurisdiction, such an appointment will be subject to the requirements of the relevant regulatory authority.

In some organisations, the RSO may not be a Qualified Expert in Radiotherapy nor have direct involvement with the radiotherapy facility. For example, the RSO of a hospital might be a Qualified Expert in the hospital's medical physics group but not directly involved with radiotherapy. In such cases, the organisation's RSO would still be expected to have an appreciation of radiotherapy and its infrastructure. The RSO would closely liaise with the radiotherapy facility's Qualified Expert and other relevant radiotherapy staff to ensure the most appropriate management of radiation protection and radiation safety practices.

In a tertiary-level hospital, the RSO may not personally be able to carry out the radiation safety duties needed for all the uses of radiation within the organisation, including radiotherapy, diagnostic radiology and nuclear medicine. The RSO may deputise a Qualified Expert to be responsible for the radiotherapy facility's day-to-day radiation safety.

The Responsible Person may direct the RSO to develop a radiation safety manual or Radiation Management Plan to cover the use of radiotherapy equipment and radioactive sources. In developing and implementing the Plan, the RSO should liaise with the Qualified Expert and other relevant radiotherapy staff. The Radiation Management Plan would normally assign the duties listed in Annex B to the RSO.

3.7 THE SUPPLIER

The supplier of radiotherapy equipment should routinely incorporate current national standards in the design of their equipment and, when national standards are not defined, should ensure adherence to appropriate international standards. Accompanying documentation should make reference to which standards have been adopted and record the stringency of adherence to those standards. Implicit in this is the assurance that the required levels of radiation protection are met, all safety controls are in full working order and that there is redundancy within the system in case of failure of one component.

When negotiating contracts with radiotherapy facilities, the suppliers should demonstrate how their products fulfil the safety requirements of the purchaser and that the appropriate standards are reached, and should work with the purchaser to ensure that the standards are achieved when the equipment is operational. Any deviation from the required standards should be resolved through mutual collaboration of both parties.

The supplier should provide at least two sets of comprehensive manuals for each piece of equipment installed. Especially critical for safety in radiotherapy is the understanding of equipment displays and the accompanying operational and maintenance documents. If they are in a foreign language, their written translation into the English language and terminology should be prepared and should be accessible at any time to the operational staff.

Suppliers of radioactive sources have particular obligations, including the assurance of safe transportation until accepted by the purchaser. The supplier should be fully conversant with the regulatory requirements in each jurisdiction, and be confident that any agent employed during source transportation is also fully conversant with the regulations.

The supplier also has ongoing obligations to the source purchasers. When the activity and **half-life** of a radioactive source makes it impractical to store it for the required decay time at the hospital or clinic the suppliers should make arrangements to repossess the source for safe storage and disposal. This requirement should be included in the contract agreement between the supplier and the hospital or clinic. The return of the source to the supplier typically applies for larger activities of nuclides with half-lives of months or years and should apply when:

- iridium-192 sources are used for HDR brachytherapy (the supplier normally repossesses the original source when the new source is loaded);
- caesium-137 LDR remote afterloading sources, caesium-137 sources used with manual applicators, eye or skin strontium-90, cobalt-60, or ruthenium-106 plaques and strontium-90 intravascular brachytherapy sources have reached the end of their useful life due to low activity or poor source integrity. (Phosphorus-32 intravascular brachytherapy sources, have a relatively short half-life of 14 days, but should normally be repossessed by the supplier.)

Other sources with shorter half-lives (such as gold-198 and palladium-103 seeds) and sources of small activity but with half-lives of months (such as iodine-125 seeds and iridium-192 wire) may be stored at the facility until the sources are sufficiently decayed to be legally non-radioactive and then disposed in a suitable manner as non-radioactive material. All references indicating radioactivity on the sources or container should be removed.

3.8 THE EQUIPMENT SERVICING AGENCY

Equipment service personnel may be employed by the supplier of the equipment or by the organisation housing the equipment. The responsibility to conform to the protection requirements and procedures of the organisation remain the same in either instance. The **equipment servicing agency** has a responsibility to employ appropriately trained and licensed personnel to service the equipment. Its personnel should:

- meet the requirements in training and certification as endorsed by the relevant professional body and any authorisation required by the relevant regulatory authority;

- be responsible for installing and/or maintaining equipment according to the relevant specifications laid down in the contract between the supplier and radiotherapy facility or between the service firm and facility; and
- undertake continuing professional development to ensure that knowledge and skill base remain current.

In addition to any formal qualification and training required by the relevant professional body, service personnel should attend training courses offered by the manufacturers for installation of new or upgraded equipment. Manufacturers should notify all service personnel when there are equipment updates or equipment function warnings. This applies equally if a contractor is involved in equipment maintenance.

Equipment servicing agencies should action the retrofitting of safety modifications in a timely manner.

4. Optimisation of Protection for Medical Exposures

4.1 GENERAL CONSIDERATIONS

Once clinically justified, each radiotherapeutic procedure should be performed so that the dose to the patient is the lowest necessary to achieve the desired therapeutic effect. Since patients may accrue direct benefits from medical exposures, it is not appropriate to impose limits on the doses received from fully justified procedures.

In radiotherapy, it is necessary to differentiate between the dose to the target tissue and the dose to other parts of the body (ICRP 1996). If the dose to the target tissue is insufficient, the radiotherapy will be ineffective. The exposures will not have been justified appropriately and the optimisation of protection will not be achieved. The distribution of dose, and consequently protection of tissues outside the target volume, is an integral part of dose planning which can be regarded as having the same aims as the optimisation of protection.

4.2 DESIGN AND OPERATIONAL CONSIDERATIONS

The magnitude of effects on tissue surrounding the target volume is a matter for the Radiation Medical Practitioner to evaluate (IAEA 2002). However, if the side effects from radiotherapy consistently differ from the expectations of the clinician, this will be a matter of concern to the relevant regulatory authority as it may indicate a systematic error or equipment malfunction. Furthermore, in the case of accidental patient overdoses there may be no opportunity to correct the mistake during the remainder of the treatment course. Any unplanned or unexpected outcome resulting from doses that are either higher or lower than intended should be reported to the relevant regulatory authority (see Section 7 of this Safety Guide).

The Code highlights the need for individuals performing or directing exposures of ionizing radiation to take particular care when irradiating pregnant or potentially pregnant patients. Guidance on protection of patients who may be pregnant is provided in Section 5.

Multiple safeguards (the *defence in depth* principle) in the design and usage of all critical components of radiotherapy equipment should aim to prevent maladministration of the radiation dose, particularly in cases that may lead to serious consequences (IAEA 2000a, IAEA 2002, ICRP 2000b).

4.3 CALIBRATION OF RADIOTHERAPY EQUIPMENT

Guidance on the calibration of radiotherapy equipment is given in Annexes D and G of this Safety Guide. To ensure accurate and safe clinical usage of radiotherapy equipment, calibration and performance testing according to the tendered specifications, should be undertaken at the initial commissioning stage, after a source change, and after major repairs or modifications that may affect the accuracy of patient dose delivery. The

intervals for repeat calibrations may differ, depending on the type of source and unit. In particular, errors in the calibration of radiotherapy equipment can result in an inappropriate treatment to a large number of patients before the error is detected with serious consequences for these patients. Consequently, for the calibration of radiotherapy equipment, the *defence in depth* principle should include a strategy of redundancy and diversity in the procedures to ensure optimum safe practice and radiation protection for the patient.

4.4 CLINICAL DOSIMETRY

The prescribed dose and methods of planning and delivering the patient's treatment should be based on clinically acceptable, consistent protocols that provide an optimum outcome. Procedures used for planning and treatment delivery should minimise the risk of errors occurring to as low as reasonably achievable. Methods of prescribing, planning, dose delivery and documentation should conform to national and/or international guidelines.

To optimise the clinical dosimetry and to check the dose actually delivered to the patient, direct measurements in a phantom simulated set-up or an in-vivo patient measurement should be obtained prior or on the commencement of the course of treatment when:

- a new protocol is implemented;
- there is a change of supplier of **radioactive material**;
- a non-standard technique is planned or;
- there may be uncertainty that the treatment planning system dose calculations are sufficiently accurate.

4.5 QUALITY ASSURANCE

Guidance on Quality Assurance is given in Section 6 of this Safety Guide. In order to maintain optimum radiation protection for the radiotherapy patient, the Code requires the establishment of a Radiation Management Plan which should include a comprehensive Quality Assurance program. The Quality Assurance program should be regularly reviewed and updated. The Quality Assurance program should be linked to the facility's Radiation Management Plan in order to strengthen all aspects of radiation safety while at the same time improving quality and efficiency of patient care and radiotherapy services.

5. Pregnancy and the Protection of the Embryo/Fetus

5.1 RADIATION EFFECTS ON THE EMBRYO/FETUS

The risk from radiation is related to the fetal dose and to the gestational age at which the exposure occurs (ICRP 2000a). Data on radiation damage comes directly from studies of Atomic Bomb or unintentional exposure and indirectly from animal studies. Doses greater than 100 mGy to the embryo/fetus can cause failure to implant (conceptus up to week 2 or 3 of gestation), but this is considered an 'all-or-nothing' effect, with normal progression if the conceptus survives. Developmental abnormalities occur during organogenesis (days 10-40) with neurological effects (eg microcephaly, mental retardation) identified as well as growth retardation and fetal death (ICRP 2000a, NRPB 1998, Psyrrri & Burtnessl 2005). After 20 weeks, major malformations become uncommon but functional disorders, such as bone marrow abnormalities and sterility, have been noted (Psyrrri & Burtnessl 2005). There is evidence of a slightly increased risk of induction of childhood cancer or leukaemia for doses more than 10mGy. This latter risk is considered to be uniform throughout the pregnancy after the first 3 to 4 weeks of gestation. Radiotherapy procedures may result in a significant fetal dose and may well exceed the threshold doses for direct harm to an embryo/fetus, including death of the embryo/fetus.

5.2 DEPARTMENTAL PROTOCOLS

Schedule A of the Code states that assessment of risk and individual justification is required in considering the irradiation of a pregnant patient. Clause 3.2.7 of the Code requires that reasonable steps be taken immediately before the commencement of the procedure to establish whether the patient is pregnant. It is also recommended that there are protocols for the three different possible scenarios:

- irradiation of the known non-pregnant woman;
- accidental irradiation of the pregnant woman; and
- deliberate irradiation of the pregnant woman.

In every case it is ideal to be aware of the pregnancy status of a woman within the child-bearing age range.

Illustrated signs, preferably in several languages relevant to the community, are required to be posted in prominent places within the radiotherapy facility advising patients to notify staff if they may be pregnant. An example might read as follows:

IF IT IS POSSIBLE THAT YOU MIGHT BE PREGNANT, NOTIFY THE DOCTOR OR ANY STAFF MEMBER BEFORE YOUR PLANNING OR TREATMENT COMMENCES.

In addition to the signage, staff have a responsibility to enquire about the possibility of pregnancy in all female patients of childbearing age. When asking the patient about the possibility of pregnancy it is also important to

indicate to the patient why there is a need to know, to avoid her taking offence and refusing to answer or providing an incorrect response. The discussion about excluding pregnancy and whether to offer pregnancy testing requires tact and discretion. It may be a sensitive issue to teenage women. History alone may not be reliable because a woman may not be aware that she is pregnant. When language barriers exist, it may be useful to seek the service of an appropriate interpreter.

5.3 CONFIRMING ABSENCE OF PREGNANCY

In women of childbearing age, pregnancy is very unlikely or physically impossible when the woman has:

- had a hysterectomy;
- had a normal menstrual period within the past 10 days and she has regular menstrual periods;
- had tubal ligation more than three months previously and had other means of contraception for that period;
- not had a sexual relationship for more than 9 months;
- taken contraceptive measures, such as the contraceptive pill provided it has been taken regularly on consecutive days.

In all other cases pregnancy should be regarded as possible. Amenorrhoea occurring in a patient who usually has regular periods should be considered due to pregnancy unless proved otherwise.

When doubt exists about the pregnancy status of an individual woman and moderate or high doses to the lower abdomen are involved, a decision needs to be taken about whether to defer the treatment until after the next menstrual period, or to perform a pregnancy test (urinary or serum β -HCG) to confirm absence of pregnancy, or to proceed with treatment. Since the woman is most probably being treated for a cancer it is likely that other diagnostic procedures involving radiation will have been performed, and possibly therapeutic procedures such as chemotherapy, so it is unlikely that the woman will be unknowingly pregnant. Therefore, it is more a matter of taking reasonable measures to confirm the patient is not pregnant rather than absolutely excluding pregnancy.

If a β -HCG test result is positive or equivocal the Radiation Medical Practitioner should be consulted. If the test is equivocal it may be advisable to defer the start of planning for a few days and repeat the test.

If a woman, whose pregnancy status is uncertain, declines β -HCG testing before the procedure, the procedure should be postponed until the referring doctor has been contacted by the Radiation Medical Practitioner and appropriate counselling has been obtained.

5.4 INADVERTENT EXPOSURE OF THE FETUS

Clause 3.1.14 of the Code requires that a protocol is in place to deal with an inadvertent exposure of an embryo or fetus to a dose of 1 mSv or more. This

should be considered as likely if any therapeutic radiation has been delivered to a pregnant woman.

The protocol following an unintended exposure of a woman who is pregnant may include the following:

- determine whether the patient has had any other diagnostic imaging such as nuclear medicine or radiological procedures during the pregnancy;
- determine what other exposures, such as to drugs or surgery, may have occurred during the pregnancy, and determine if any of them may have the risk of causing potential harm to the embryo/fetus;
- obtain an estimate of the radiation dose to the embryo/fetus for all procedures from a Qualified Expert;
- determine at which points during the course of the pregnancy these events occurred, and extrapolate the potential severity of risk to the embryo/fetus; and
- inform the patient and referrer and provide counselling in accordance with the estimated dose, in conjunction with the referring doctor or the patients' obstetrician.

Termination should not be recommended for fetal absorbed doses less than 100 mGy on purely dosimetric considerations. Many other issues are of great significance, including:

- patient factors such as their individual beliefs and wishes;
- disease factors such as the type of malignancy, its site and stage; and
- treatment factors such as site of radiotherapy, planned dose, and associated chemotherapy.

5.5 DELIBERATE IRRADIATION OF THE PREGNANT PATIENT

Sometimes there may be good reasons to use ionizing radiation for therapeutic purposes in a pregnant patient to provide optimal care for the mother and indirect potential benefit for the fetus.

Some situations necessitate the use of radiotherapy, others exist where it can be considered as one of a series of options of treatment strategy (for instance in combination with breast conserving surgery, versus the alternative of mastectomy). Where choice exists, preference should be given to minimising or avoiding entirely any radiation dose to the fetus. The Canadian Association of Radiation Oncologists recommends not irradiating women in this situation (CARO 1998).

If the decision to proceed is made on clinical grounds then, prior to starting, an individual fetal radiation dose estimate must be made. This will require the services of a Qualified Expert. Doses not only to the fundus but also to the cervix of the uterus must be estimated, allowing for expansion of the fundus as the pregnancy progresses through the course of treatment. This evaluation of dose allows identification of risks and strategies to minimise them.

The Radiation Medical Practitioner should assess the potential fetal dose and communicate the risks to the mother in a meaningful manner. The potential dose and damage to the fetus, and consequently the child, should be discussed with the patient and her partner. The option of termination of pregnancy should be discussed and also the physical and psychological issues of dealing with a pregnancy as well as the morbidity of malignancy and the potential for recurrence and death. Written documentation of the discussion, and the signature of both parents, should be obtained if possible confirming their awareness and acceptance of possible consequences.

Techniques to reduce risk include the use of lead aprons (doubled 0.5 mm aprons draped over the abdomen and flanks, or other suitable means for megavoltage radiation, will allow some reduction of external radiation scatter) but this has no impact on internal scatter arising from treatment. External lead shielding can be considered to reduce the contribution of scatter from head leakage, beam modifiers and collimator scatter. The radiation beams can be angled away from the fetus/embryo with the aim of lowering internal scatter. The total dose prescribed can also be reviewed and lowered where possible. The fetal dose should be monitored with the use of thermoluminescent or other forms of in-vivo dosimetry, with pre-agreed simulated plans for projected fetal dose measurements (ICRP 2000a).

6. Quality Assurance

6.1 GENERAL

The Code requires that each radiotherapy facility establish a Quality Assurance (QA) program, which places emphasis on equipment performance, patient safety and patient dose minimisation.

The aim of the QA program is to ensure that all procedures are appropriately defined, documented, understood, implemented and regularly reviewed in order to ensure consistent and accurate delivery of treatment, realising the Radiation Medical Practitioner's clinical intent and ensuring maximal radiation protection to the patient and any other person exposed during the delivery of the treatment.

An effective QA program involves all activities in the delivery of radiotherapy, including the physical, mechanical and technical aspects of equipment used for the treatment delivery, the decision process of the clinical practice and the procedures for administration of radiation. The QA program should clearly define responsibilities and line of reporting for all radiotherapy employees and external contractors. A reporting structure for the review of faults and errors should be established together with documentation so that the details are easily accessible for the information of all staff.

The QA program should also allow non-standard approaches to be reviewed prior to introduction or implementation into practice.

The extent of the QA program will depend on the complexity and resources of the radiotherapy practice, but at the very least it will need to address the issues outlined in Annex E.

Because of variations which may occur between sites and equipment options, each QA protocol will be designed from first principles for the particular situation. Basic aspects that should be considered include:

- safety of the patient, the public and the facility;
- positional accuracy;
- temporal accuracy; and
- dose delivery accuracy.

The development and monitoring of the program may be facilitated by the establishment of a Quality Assurance Committee (QAC) comprising representatives from all the relevant professional groups. In the multidisciplinary radiotherapy environment, no one professional group has expertise in all areas. The QAC should oversee the quality assurance program, focussing on radiotherapy equipment maintenance, servicing, dosimetry, radiation safety and software release and testing. Regular **constancy testing**, dosimetry and preventative maintenance services of radiotherapy equipment should be carried out and this process monitored appropriately.

The QAC should meet on a regular basis to review the program and to oversee QA activities.

The responsibility for setting up and conducting the QA program will usually be delegated to the Quality Assurance Committee (QAC). In other situations, for example in a smaller facility, the responsibility may be delegated to either the Qualified Expert, the RSO, the Chief Radiation Therapist, or the Radiation Medical Practitioner.

Clinical QA is usually supervised by the Radiation Medical Practitioner, where as responsibility for all aspects of equipment QA is usually undertaken by the Radiation Oncology Medical Physicist.

6.2 QUALITY ASSURANCE – CLINICAL

6.2.1 Clinical Protocols and Treatment Policies

Clause 3.1.3 of the Code states that the Responsible Person is responsible for having protocols in place to ensure no radiation procedure is carried out unless it has been first both justified and approved for each individual. In practice it will be the Radiation Medical Practitioner, in collaboration with other staff members including the Qualified Expert and the Radiation Therapists, who will undertake these functions.

A comprehensive program of clinical protocols or treatment policies for patient care should be developed and implemented in each facility, and this should include the above requirement of the Code. Such protocols should be widely and easily available and regularly updated.

The protocols and policies should include details for the radiotherapy prescription, and also the required procedures for planning, verification, dose delivery and quality assurance activities. It may also be useful to include background information discussing the evidence that supports the protocol or procedure.

6.3 QUALITY ASSURANCE – TECHNICAL

Reference should be made to the ACPSEM QA recommendations (ACPSEM 1997) in arranging an appropriate QA program for satisfactory accuracy of treatment.

6.3.1 Acceptance Testing of Radiotherapy Equipment

At initial installation, the radiotherapy and associated equipment needs to undergo a series of acceptance tests to ensure that the performance of the equipment agrees with the manufacturer's specifications, complies with Australian standards and/or international standards (where applicable) and is in accordance with any requirements of the relevant regulatory authority. Clause 3.1.24 (b) of the Code mandates that calibration and dosimetry must be performed by, or under, the supervision of a Qualified Expert. The results of the acceptance tests should be thoroughly documented and are used in part to define the acceptable range of parameters that will be monitored in any subsequent constancy testing.

6.3.2 Constancy Testing and Preventative Maintenance

Constancy Testing

Following acceptance, constancy tests designed to assess the subsequent performance of the equipment should be performed on a regular basis (see Section 6.3.3). The results of constancy testing should be routinely reviewed by a Qualified Expert and any anomalous results reported immediately to the person responsible for the QA program. If the constancy testing indicates that the equipment is exceeding acceptable tolerance, the cause of this needs to be identified and appropriate remedial action taken, which may include equipment replacement.

Preventative Maintenance

Preventative maintenance is necessary to monitor proper functioning of the equipment, minimise machine breakdowns, and ensure that the equipment operates within the manufacturer's specifications. This includes routine servicing and replacement of parts during regularly programmed inspections. The preventative maintenance program should be carried out by the facility's and/or supplier's X-ray engineers, who are specifically trained in servicing the equipment. Qualified Experts and Radiation Therapists should also be closely associated with the planned preventative maintenance program. The Qualified Expert should be advised of details of the work carried out prior to the equipment returning to clinical use.

6.3.3 Testing Frequency

The frequency with which any particular parameter is tested will need to be at least as often as specified by the relevant regulatory authority. The frequency of the various tests should take into account:

- the likelihood of equipment failure or the likelihood of a measured parameter falling outside an acceptable tolerance range; and
- the consequences that follow when such an event occurs.

For example, dose calibration should be monitored frequently as any change in dose may have a substantial impact on the patient's tumour control and normal tissue toxicity.

6.3.4 Record Keeping

A key element of any QA program is proper record keeping so that any long term trends associated with the equipment's accuracy of dose delivery or safe operation can be detected. Action levels should be set to ensure optimum patient and staff safety. Control charts, which show the behaviour or trend of a measured parameter as a function of time, provide a convenient means of keeping the records of constancy testing. Equipment records should include:

- results of acceptance testing;
- results of any constancy tests;

- unscheduled downtime and the reason for the failure; and
- **radiation incidents** (see Section 7).

The length of time for which QA records should be maintained is uncertain. To protect against possible future litigation, records of acceptance and constancy testing should be kept for at least the lifetime of the equipment. Individual radiation facilities will need to make their own assessment of whether these records need to be kept for a longer time.

7. Radiation Incidents

7.1 MANAGEMENT OF A RADIATION INCIDENT

Unplanned exposure can occur in the following situations:

- Radiation incidents arising when a radioactive source is not under control, for example, when a remote-controlled brachytherapy source fails to return to the safe, or the failure of a fail-safe mechanism designed to terminate an external beam treatment; or
- Medical incidents, when a patient suffers a medical event during treatment.

Radiotherapy facilities will need to develop generic plans that can cover all possibilities and ensure that all staff members are thoroughly educated in the types of potential incidents and the procedures to follow. The aim in education on types of potential incidents and rehearsal of appropriate responses is to ensure that all parties are able to act promptly to minimise the radiation risks arising from the emergency. Staff education also helps develop a safety culture aimed at reducing the occurrence of incidents.

Procedures to consider when dealing with an incident should include:

- immediate action to reduce exposure;
- action to prevent non-essential access; and
- action to prevent dispersion of radioactive substances.

Radiation incidents other than emergencies may arise because of errors in the delivery of radiotherapy. Annex F discusses the different levels of errors or incidents that may occur in delivery of the prescribed radiotherapy dose to the patient, and the obligations of staff in such events. Errors in the planning or intended delivery of treatment, which are detected before a treatment occurs, should also be considered as radiation incidents.

By convention (ICRU 1993, ICRU 1999), the acceptable dose variation permitted across a target volume is limited to +7% to –5% of the prescribed dose. When errors in treatment planning or delivery occur that have an effect on dose that is less than 5%, these should be recorded but are not considered clinically significant.

Unintended variations in total dose of greater than 10% require formal reporting to the relevant regulatory authorities (ARPANSA 2004).

Errors of total dose between 5% and 10% in any individual treatment are unlikely to have serious clinical consequences but a systematic error of this magnitude, however, may have greater consequences. These errors should therefore still be appropriately investigated to identify the cause and the means by which to minimise the risk of repetition, and they may need to be reported to the relevant regulatory authority.

7.2 INCIDENT PREVENTION

Operators of radiotherapy facilities need to take all reasonably practicable steps to prevent incidents, such as (although not limited to) those described above (IAEA 2000a, ICRP 2000b).

The following factors are recognised as important components of any program devised to address this requirement (IAEA 2008):

- structural organisation;
- awareness of position of responsibility and acceptance of the responsibility;
- education and training;
- acceptance testing and commissioning of new equipment; quality assurance programs; multiple levels of independent checks (redundancy);
- repair and maintenance programs;
- follow-up of equipment faults;
- communication and transfer of essential information;
- awareness and attention to procedures and protocols;
- patient and anatomical site identification;
- external beam radiotherapy – beam calibration, treatment planning systems, treatment simulation, set-up and delivery;
- brachytherapy – source ordering, delivery, calibration and acceptance, source preparation, source removal; attention to unsecured long-term storage or abandonment of radiotherapy sources; and
- **public exposure and environmental contamination.**

7.3 INCIDENT INVESTIGATION AND REPORTING REQUIREMENTS

All radiation incidents should be investigated, including ‘near misses’, to minimise the likelihood of such incidents occurring again.

The investigation of accidental, abnormal or unplanned exposures arising from radiotherapy procedures should be aimed at:

- establishing what happened;
- identifying the failure;
- deciding on remedial action to minimise the chance of a similar failure; and
- estimating the likely radiation doses received by the patient and staff.

As a matter of good practice, any patient accidentally or unintentionally irradiated should be informed of the event and counselled as to the likely implications of the unintended exposure. It would be very unusual for there to be a good reason for not informing the patient or their guardian. When the

patient is unable to comprehend the information given, it may be more appropriate to inform the patient's representative or parent/guardian.

The investigation will normally be undertaken by the facility's RSO together with the supervisor of the area in which the incident occurred. A written report should be prepared that describes the occurrence, its cause(s) and effects, the radiation doses received, and which recommends all necessary corrective and preventive actions. The Radiation Management Plan should detail the necessary lines of reporting within the organisation and, where required by legislation, reporting to the relevant regulatory authority. Mechanisms need to be in place to audit compliance with the report's recommendations.

A review of incident reports, including near misses, in local training sessions is a key educative element in preventing errors.

Annex F provides more information, as well as outlining the reporting of radiation incidents by the radiation protection regulatory authorities of the Commonwealth, States and Territories to ARPANSA's Australian Radiation Incident Register (ARIR).

General provisions for the reporting of other incidents to the relevant regulatory authority are detailed in the National Directory for Radiation Protection (ARPANSA 2004).

8. Planning and Delivery of a Radiotherapy Treatment

8.1 PLANNING OF A RADIOTHERAPY TREATMENT

8.1.1 Treatment Prescription

The treatment prescription is provided by the Radiation Medical Practitioner (see 3.2.2 of this Safety Guide) and should clearly state:

- the site (and side) to be treated;
- the intent of the treatment;
- the total dose and number of fractions (stating the fraction size), and the time frame for completion of the treatment;
- the treatment modality and technique. This should specify the radiation type and beam quality;
- dose constraints for critical normal tissues;
- the radionuclide to be used for brachytherapy. The symbol of the radionuclide with its atomic number should be clearly defined as part of the radiation treatment prescription; and
- whether concurrent chemotherapy is to be given.

8.1.2 Treatment Planning – External Beam

There should be a well-defined and documented pathway for each patient treatment process, with each stage showing:

- action required;
- expected time for stage;
- staff responsible;
- independent check process and method; and
- action to be taken if any changes required.

Each stage of treatment planning should be clearly documented and initialled by the staff member undertaking each treatment planning procedure, independently checked and countersigned by a second person.

The patient's treatment record should contain the following information:

- the patient's personal details for identification purposes;
- the informed consent of the patient to receive the radiation treatment;
- the treatment prescription as outlined in Section 8.1.1, and treatment plan, including treatment position and set-up details;
- a record of the dose delivered; and
- any other information considered relevant for a particular technique.

Patient Immobilisation

The type of immobilisation method to be used during external beam radiotherapy should be predetermined before any planning process begins to ensure the patient is in the same position for treatment planning and delivery.

The staff who manufacture immobilisation devices, such as facemasks or customised polyurethane moulds, should be appropriately trained for this work. This is to ensure that these devices provide the required comfort, stability and restriction of movement needed for the planning and treatment procedures.

Target Localisation and Simulation

The X-ray simulation or CT scanning procedure should be carried out with the patient positioned as for the treatment. This provides optimum localisation of the volume to be treated. In certain circumstances, it may be preferable to define the target volume using surface markings.

The use of CT scans for treatment planning should be standard for all radical and high-dose palliative treatments. Additional information obtained from diagnostic CT, MRI, PET/CT and SPECT/CT techniques should be used (if available) in cases when the definition of the target volume may be enhanced by this additional information. Such images should also be acquired with the patient lying in the intended treatment position and with fiducial markers or other such devices to facilitate co-registration of images for planning.

The target volume should be delineated by the Radiation Oncologist, according to the criteria outlined in ICRU Report 62 (ICRU 1999). In some facilities, this task is assigned to a Radiation Therapist who has advanced training specific to this area but the target volume should still be approved by the Radiation Oncologist. The treatment target, relative position of organs at risk and potential organ movement should be taken into account when determining the additional margins added to the target volume for planning and the siting and direction of radiation beams for the treatment plan.

Computerised Planning

Where an electronic approval system is in use, the Responsible Person should ensure that all users have, and continue to have, individual and secure passwords.

Before a computer treatment planning system (TPS) is clinically introduced, the software must be tested and the data verified by a Qualified Expert (Clause 3.1.27 of the Code). This is to ensure that the:

- computed dose distributions for external radiotherapy beams are within acceptable tolerance to measured data;
- computed dose distributions for brachytherapy sources are within acceptable tolerance of published or measured data; and

- coordinate dimensions for the treatment plan produced by the TPS input or output devices are correctly calibrated.

A standard set of beam profiles and depth dose measurements should be generated by the TPS during the clinical acceptance stage and checked against the treatment machine's physical beam data measured during commissioning. Any changes in the operating characteristics of the treatment machine or replacement of this treatment machine may require a repeat of this TPS acceptance procedure.

Where the TPS software is changed or upgraded, the TPS generated plans for a comprehensive range of treatment techniques should be compared with:

- original baseline plans; or
- manually calculated plans; or
- directly simulated phantom dosimetry measurements.

Any discrepancy between these dosimetry plans will need to be resolved before the TPS may be used clinically.

The planning Radiation Therapists should be trained in the use and basic fundamentals of the TPS. Radiation Therapists who are newly rostered in computer planning should initially work under the supervision of an experienced Radiation Therapist until satisfactory competence is obtained in the TPS. The more complex and non-standard treatment techniques should involve input into planning and treatment by the Radiation Oncologist, Radiation Therapist and Radiation Oncology Medical Physicist who have each obtained specialised experience in the clinical and dosimetric aspects of these techniques. Some examples of when this is needed are total body irradiation, total body electron therapy and dynamic techniques such as intensity modulated radiotherapy, image-guided and 4-D gated radiotherapy.

A conformal beam approach should be employed when selecting the treatment technique whenever possible, in order to minimise adverse side effects to adjacent normal tissues and organs at risk. Dose corrections should be made where there are well-defined tissue inhomogeneities.

Further information on the commissioning and quality assurance of computerised planning systems can be found in IAEA Technical Report No. 430 (IAEA 2004).

Dose, Time and Monitor Unit Calculation

Monitor units (MUs) calculated by the TPS are normally checked by the use of an independent inverse dose calculation computer program. In routine practice, this is the preferred method over manual calculation. Knowledge of manual calculation methods should be maintained as a *defence in depth* strategy.

As with any types of radiotherapy equipment, the computer programs should undergo commissioning and testing before their introduction into clinical use. The computer or the manual calculation requires a separate,

independent, check to ensure that there are no errors. Any changes to the original treatment plan (e.g. due to change in patient thickness because of weight loss) should be subjected to the same checking requirements as the initial calculation.

For orthovoltage or superficial X-ray therapy, where computer methods are not available, manual calculation of treatment times or MUs are required. A separate, independent, check is required to ensure that there are no errors.

8.1.3 Treatment Planning - Brachytherapy

Where an electronic approval system is in use, the Responsible Person should ensure that all users have, and continue to have, individual and secure passwords.

The planning process incorporates source placement and source strength to calculate accurately the time required for the source to remain in position in and around the target volume. This can be achieved by manual or computerised planning methods.

Different vendors supply computerised planning programs based on different dose calculation techniques; the Qualified Expert, the Radiation Medical Practitioner and person(s) administering radiation should be included in the decision to obtain and use such software.

After planning the brachytherapy procedure and determining the source strength and source arrangement, the radionuclide and its administered activity should be clearly shown on the treatment prescription, and countersigned by a Qualified Expert responsible for the radionuclide dosimetry.

In addition to pre-planning, dose evaluation should be carried out after the permanent implantation of a radioactive source. This is the assessment of the quality of the procedure to ensure that the required dose was delivered to the target area. This can be done by estimation for single line source insertions, but most commonly requires replanning with repeat capture of anatomical data (as, for example, with perineal implantation of prostates with permanent seed sources).

The data for each brachytherapy computer treatment planning program will need to be verified for:

- correct exposure rate constant;
- parameters for tissue attenuation and scatter;
- anisotropy;
- source activity; and
- the half-life of the radionuclide.

Isodose plans of point sources and line sources should be generated for comparison with published or measured data. The prescription and recording of brachytherapy doses should be in accordance with the

international protocols of clinical dosimetry, notably ICRU Report 58 (ICRU 1997).

Computerised planning of brachytherapy implants should be used as the ideal form of planning process. Manual planning should be avoided whenever possible for clinical use. It is a useful way of checking the accuracy of computerised planning, but is being used less and less frequently. Methods for manual planning include:

- Manchester system;
- Paris system;
- Quimby system; and
- Memorial monographs.

See Annex G and H for further information regarding brachytherapy sources.

8.2 DELIVERY OF RADIOTHERAPY

8.2.1 Treatment Delivery – External Beam

The safe delivery of radiotherapy requires adequate equipment design, departmental protocols and a radiotherapy record and verification system (R&V). The R&V system should be able to compare the predetermined treatment setting recorded for an individual patient treatment with the actual treatment settings of each treatment.

The planning Radiation Therapist should enter the treatment parameters into the R&V system, preferably by electronic transfer, directly from the simulator or planning computer. Manual transfer of the treatment parameters should be avoided where possible as errors are more likely. All parameters should then be checked independently by a second Radiation Therapist before treatment commences. The predetermined treatment parameters should be assigned appropriate tolerances to allow for daily set up inconsistencies.

Only a designated Radiation Therapist should be authorised under departmental protocol to override the predetermined treatment verification settings when they exceed the R&V tolerance values. The Radiation Therapist and overridden parameters should be identified and recorded in the patient treatment record for audit purposes.

The Radiation Medical Practitioner, Radiation Therapist, Qualified Expert and oncology nurse should collaboratively develop protocols for the review of patients during their radiotherapy treatment course, which describe the assessment and management of acute side effects as well as assessment of the patient's progress through the treatment. Collaboration with other staff involved in the patient's care should be encouraged.

Simulator films, or digitally reconstructed radiographs, produced for a patient's treatment plan should be available as a baseline reference that may be compared with the patient's subsequent portal images recorded during the course of treatment.

Radical treatment patients should have a clearly defined protocol for the frequency of portal films or electronic portal images. Additional portal images may need to be obtained if the consistency of patient positioning is in doubt. The protocol should define action levels for positional errors. The dose given by portal imaging should, if possible, be included as part of the dose received. The monitor units should be kept to a minimum to achieve the best quality portal images. In so doing, additional dose to the patient is minimised.

Special care should be taken when there are complex or unusual treatment plans or when there is a change in procedures (IAEA 2000a), such as:

- a non-typical dose;
- an unusual target area;
- a treatment with the patient in an unusual position; or
- a complex treatment.

The expected dose calculated should be double checked by some form of in-vivo direct measurement. The IAEA strongly recommends that a dose measurement from a simulated treatment, or a direct measurement on the patient, is arranged as a *defence in depth* safeguard against an unintended treatment error (IAEA 2008).

8.2.2 Treatment Delivery - Brachytherapy

All staff involved in caring for brachytherapy patients need to be familiar with the appropriate safety precautions for both staff and visitors, including protocols that deal with unexpected interruptions or emergencies.

A suitably calibrated portable radiation survey meter, designed for the purpose (see Annex K), should be available for staff to use and check for a possible displaced source when it has:

- inadvertently remained inside a patient after completion of a treatment; or
- not been returned to its shielded container after use.

It is desirable to keep brachytherapy treatment times reasonably short to ensure that the potential for movement of the sources within the patient during treatment is minimised. The replacement of brachytherapy sealed sources should be undertaken before the source activity becomes too low to provide acceptable treatment times.

9. Radiation Protection in the Care of a Patient with Brachytherapy Sources In Situ

The rate of dose delivery in brachytherapy determines the quality of radiation protection and shielding required (AAPM 1993, ICRU 1985). Dose rates in brachytherapy are defined using reference air kerma rate in $\text{Gy}\cdot\text{m}^2\cdot\text{h}^{-1}$. Dose rates are divided clinically into:

- High Dose Rate (HDR): greater than $12 \text{ Gy}\cdot\text{h}^{-1}$, where the individual treatment fraction is delivered in minutes.
- Medium Dose Rate (MDR): greater than $2 \text{ Gy}\cdot\text{h}^{-1}$ and less than $12 \text{ Gy}\cdot\text{h}^{-1}$.
- Low Dose Rate (LDR) ($0.4\text{-}2.0 \text{ Gy}\cdot\text{h}^{-1}$), which usually utilises a permanent implant.
- Pulsed Dose Rate (PDR), where a high activity source is used with cyclic administration during the treatment fraction, so that the dose rate is similar to HDR during the active part of the cycle but mimics the LDR delivery rate over the total treatment fraction. The instantaneous dose rates are 1.0 to $3.0 \text{ Gy}\cdot\text{h}^{-1}$.

Informed patient consent to receiving treatment should normally be obtained before undertaking brachytherapy. If an operative procedure is required, permission should be given in writing before it is commenced.

Critical parameters such as radioactive source activity, time of treatment and the applicator source positions (where applicable) should be independently checked by a second trained staff member and countersigned and dated on the treatment documentation before treatment commences.

With the exception of procedures such as the application of beta-ray applicators, a Qualified Expert, RSO, or an authorised responsible officer, should be present for the duration of high dose rate brachytherapy and for the administration of the low dose rate brachytherapy sources. This is to ensure that all sources are accounted for before, during and after the procedure and that radiation safety procedures are appropriate.

For additional detailed information refer to Annexes G and H.

9.1 HIGH DOSE RATE (HDR) BRACHYTHERAPY

Before the treatment may commence, the prescription is written and verified, the source containers positioned and the sources checked. Two trained staff should identify that the correct patient is being treated, then connect the appropriate equipment with cross-checking of all connections, load the programming information into the computer, and ensure that the source-out alarms are set before closing the doors to the suite.

9.1.1 HDR Brachytherapy Emergency Protocols

The primary consideration in any brachytherapy emergency is to ensure the safety of the patient.

All radiotherapy facilities offering HDR brachytherapy should have a site-specific emergency procedure protocol (including any necessary surgical procedures). This document should be located at the brachytherapy control unit outside the treatment room for quick reference.

The emergency protocol should be simple and clear. The location of a suitably shielded container and remote handling tool(s) kept in the treatment room should be detailed. Any malfunction of the radiation equipment should be managed as a radiation emergency (see Section 7).

All HDR brachytherapy staff should undertake regular emergency procedure rehearsals at regular intervals.

9.1.2 After a HDR Brachytherapy Treatment

At the end of the patient's prescribed treatment, all radioactive sources should have been retracted. The patient should be monitored with a suitable radiation monitor to ensure all the sources have been removed from the patient and are stored in the safe.

9.2 LOW DOSE RATE (LDR) BRACHYTHERAPY

LDR brachytherapy may be delivered using either a manual technique or a remote afterloading unit. It may be in the form of temporary plaques or inserted applicators, or permanently implanted sources. The use of remote afterloading apparatus is strongly recommended rather than manual application because it provides greater radiation protection for the staff and the general public.

9.2.1 LDR Brachytherapy Emergency Protocols

The main considerations in any brachytherapy emergency are to ensure the safety of the patient and control of the radioactive sources.

All radiotherapy facilities offering LDR brachytherapy should have a site-specific emergency procedure protocol (including any necessary surgical procedures). This document should be readily accessible for staff attending to the patient and near to where the patient is being treated.

The emergency protocol should be simple and clear. The location of a suitably shielded container and remote handling tool(s) kept in the treatment room should be detailed. Any malfunction of the radiation apparatus should be managed as a radiation incident.

The emergency instructions should cover the following:

- immediate action to prevent movement of any related material such as bed linen, bed pans, clothing;

- notification of the loss or suspected loss of radioactive sources to the facility's RSO for the purpose of supervising the search procedures; and
- follow-up reporting of the incident and its outcome according to regulatory requirements and the facility's procedures (see Section 7).

In the event of a medical emergency to the patient or physical emergency on the ward, the patient's medical management and safety take priority. However, attention to the radiation safety of staff should be incorporated as far as practicable and ward staff should be adequately trained to manage such events.

9.2.2 After LDR Brachytherapy Placement

Any prepared radioactive sources that are not used for treatment should be promptly returned to the safe in the radioactive source store and its return recorded by the custodian.

For LDR sources which are to be removed from the patient, the Radiation Medical Practitioner should arrange for the sources to be returned as soon as practicable to a secure store. In the case of remote afterloading, the treatment unit automatically returns each source to a shielded safe which should be sited securely. When a radioactive appliance is removed from a patient, it should be immediately checked (with protected inspection if relevant) that no part has become detached. A Qualified Expert should routinely check the immediate environment using a suitable radiation monitor to check that no sources have been inadvertently left in the patient or room. A Qualified Expert should also document the time of removal and number of sources or applicators in the patient's notes. The sources are then returned to the safe where each source is recorded by the custodian.

Any sealed source that is dislodged or removed prematurely from a patient will also require immediate return to safe housing, and the incident recorded. The matter should be reported as soon as possible to the Radiation Medical Practitioner in charge of the treatment or appointed deputy and a designated Qualified Expert.

9.2.3 Ward Care for a Patient undergoing LDR Brachytherapy

The ward radiation safety issues are managed by the Qualified Expert involved with the administration of the brachytherapy or by the facility's RSO.

Staff should follow the general principles of radiation protection by:

- minimising the period of time with the patient; and
- maximising the distance from the patient.

The dose-rates to nearby occupied areas should be assessed by a Qualified Expert or RSO and any necessary steps taken to minimise exposure of other patients, staff and the general public.

The maximum allowable contact time for each patient/radionuclide configuration should be determined by a Qualified Expert. This information should be given to the nursing staff and displayed as appropriate.

The radiation shielding requirements for ward rooms used for brachytherapy patients depend upon the type of radiation emitted from the radioactive sources, the activity of the sources and the general distance to surrounding areas that may be occupied by staff or the public. The shield requirements should be specified by a Qualified Expert experienced in brachytherapy techniques. The estimates of dose levels in adjacent areas for the various types of treatments should be confirmed by a dose rate survey carried out by the facility's Qualified Expert or RSO.

A warning sign should be posted at the brachytherapy patient's room entrance. The radiation warning sign on the door² should have an additional instruction such as 'Visitors must contact the Ward Sister-in-Charge before entering'. Any special conditions should be listed and contact telephone numbers of the facility's RSO, Qualified Expert or deputy should be displayed in case of a radiation emergency. The bed of a patient undergoing treatment should also be marked with a warning sign indicating the presence of a radioactive source in the patient.

A suitably shielded container should be located in the patient's room in case a radioactive source becomes dislodged during the course of the treatment and for use when the radioactive sources are removed at the end of the patient's treatment. The shielded source container should be able to be securely fastened, preferably lockable. If a dislodged source is stored in the container, details of the source and time of removal should be attached to the container. The Ward Sister-in-Charge, the Qualified Expert or the RSO, and the Radiation Medical Practitioner should be informed as soon as possible.

All dressings, bed linen and bedpans from the patient should be checked using a radiation monitor before disposal to guard against the loss of radioactive sources. The person carrying out these checks should be suitably trained.

9.2.4 Ward Staff

A Qualified Expert and/or RSO should provide radiation safety tuition for all staff involved with caring for brachytherapy patients. Nursing staff should be familiar with the precautions to be undertaken for brachytherapy patients, including safety requirements for domestic staff and visitors, and the nature and duration of the hazard. The Qualified Expert or RSO should provide individual protocols for the different types of brachytherapy and actions to take when unexpected interruptions occur. Documentation on radiation safe practices and treatment procedures should be readily available for staff.

Nursing staff should be instructed to wear a personal dose meter. Nursing staff who are, or think they might be, pregnant should not be involved in the care of patients with sealed radionuclides. In certain circumstances (such as when frequent nursing care is required) it may be desirable to use a roster

system of duties in order to reduce individual doses, but this should not be a substitute for good radiation protection practices.

9.2.5 Visitors to LDR Brachytherapy Patients

A Qualified Expert or the RSO should specify the maximum time and minimum distance away from the patient that visitors may spend in the brachytherapy patient's ward room. When low energy radioactive sources such as iodine-125 or similar radionuclides are used, minimal restrictions may be needed.

In general, women of reproductive capacity and children under 16 years of age should not be permitted to visit patients undergoing brachytherapy treatment, but, where their visiting is permitted, adherence to time and distance constraints should be strictly observed.

9.2.6 Movement of the Patient within the Facility

In the unlikely event that an LDR brachytherapy patient needs to be transferred from the ward to elsewhere, ideally the source should first be removed from the patient. If this cannot be done, the Qualified Expert or the facility's RSO or their delegate should be consulted for advice on precautions and procedures.

9.2.7 Discharge of a Patient Undergoing LDR Brachytherapy

The recommendations and principles contained in ARPANSA Radiation Protection Series (RPS) No. 4 (ARPANSA 2002b) should be noted and followed.

In general, patients with temporary sealed implants or moulds should not be discharged without removal of the source(s) (penetrating radiation from sources such as caesium-137 or iridium-192 presents a greater radiation hazard to the general community). In certain instances, such as the use of iodine-125 seed eye plaques, it may be permissible for a patient to be treated at home. In such settings the principles of protection as described in the Section 9.2.3 should be followed. Effective doses to members of the public and to adult persons who care for the patient are unlikely to exceed the dose limits and constraints given in ARPANSA/NOHSC Recommendations and National Standard, RPS 1 (ARPANSA 2002a/NOHSC 2002).

With a permanent sealed source implant, the Radiation Medical Practitioner in conjunction with the Qualified Expert will provide the patient with written details of the implant source(s) and activity, and written and verbal instructions regarding radiation protection, with particular reference to contact with children and pregnant women. Patients should be advised of the period in which radiation safety precautions continue to apply.

The patient should be provided with the means of retrieval and storage of dislodged sources, to be returned to the Qualified Expert or the RSO for disposal.

Information should also be supplied to the patient's general practitioner including details of procedures to be followed in the event of unexpected death.

The medical responsibility for a decision to allow a LDR brachytherapy patient to leave the facility lies with the Radiation Medical Practitioner. The radiation protection responsibility for such a decision lies with the Qualified Expert and ultimately the RSO, in accordance with the requirements of the relevant regulatory authority.

9.2.8 Procedures to Avoid Secondary Radiation Exposure of a Child Under Close Care

Before a radioactive implant is administered, the Radiation Medical Practitioner should query the patient as to whether they are involved with close care of a child.

All patients discharged with radioactive sources should be provided with advice relating to the external radiation dose on:

- the length of time for which he or she can hold, or be in close proximity to, a child; and
- the date or time after which no restrictions will be necessary.

10. Radiation Protection in the Event of the Death of a Patient Undergoing Treatment with Brachytherapy Sources In Situ

If a patient dies during treatment with a radioactive applicator/implant in situ, certain measures may be required in order to keep occupational and public exposure within the relevant limits and as low as reasonably achievable.

10.1 NOTIFICATION OF DEATH OF A PATIENT TO THE RADIATION SAFETY OFFICER

Brachytherapy radioactive implantation may be administered:

- as inpatient treatment, where the sources are removed before the patient is discharged from the hospital or clinic (e.g. caesium-137 tube applicator, iridium-192 wire implant); or
- to patients who are discharged but return subsequently for removal of the sources (e.g. iodine-125 seed eye attachment); or
- to patients who are subsequently discharged with the sources permanently in situ (e.g. iodine-125 seed prostate implant).

In all cases, written information should be provided by the Qualified Expert or RSO in the patient's medical notes, and, as relevant, to the ward staff, the family or carer, and the patient's general practitioner (see Section 9). This information should include the appropriate actions and contact person (treating Radiation Medical Practitioner, Radiation Safety Officer and/or Qualified Expert) in the event of death of the patient, and should state the relevant date until which the radiation safety precautions apply. In the event that the patient dies within this time with radioactive sources in situ, the information facilitates the notification to the Radiation Safety Officer at the hospital or clinic which administered the treatment. The notification to the Radiation Safety Officer will normally be given by the ward staff in the case of an inpatient; it would normally be given by the patient's family or carer, patient's doctor, or funeral personnel in the case of a patient dying outside hospital.

10.2 TEMPORARY APPLICATOR/IMPLANT

A temporary applicator/implant, i.e. one which was designed to be removed after a preset time (such as caesium-137 tubes, iridium 192 wire, or iodine-125 seed eye attachment), should be removed (surgically if required) from the body by an authorised person as soon as possible after death to avoid unnecessary exposure of further persons.

Provision should have been made for a shielded container for the planned or premature removal of the applicator/implant to be available.

10.3 PERMANENT APPLICATOR/IMPLANT

10.3.1 Radiation Safety Considerations for Post-mortem and Funeral Personnel

The extent of exposure to attending persons will depend on the type of radiation (penetrating or non-penetrating), the amount of remaining activity, the site of the implant and the management of the body (post-mortem, embalming, cremation, burial or entombment).

If a permanent implant is known to be still sufficiently active to be a radiation hazard, radiation safety instructions should be provided to post mortem and funeral personnel by the radiation safety officer of the hospital or clinic which administered the implant so that appropriate care can be taken when dealing with the body. Sufficiently active could be considered as giving an ambient dose equivalent rate greater than 25 $\mu\text{Sv}/\text{hour}$ at one metre from the body, which is consistent with descriptors from ARPANSA Radiation Protection Series (RPS) No. 4 (ARPANSA 2002b).

In the case of iodine-125 seed implants, studies have shown that, for the commonly administered activity range, the ambient dose equivalent rate at a distance of one metre from the implant at time of administration would generally be less than 25 $\mu\text{Sv}/\text{hour}$ (Smathers et al. 1999). In consequence, it is unlikely that morticians or embalmers would be exposed to significant doses during these processes when the implant is seeded iodine-125.

10.3.2 Radiation Safety Considerations for Cremation

Encapsulated radioactive sources can survive the cremation process and could therefore be present in the cremated remains and/or the working area of the crematorium personnel. It is thus desirable that they do not enter the cremation process if these individual sources (or a post cremation aggregation of them) are above the relevant radioactive substances exemption levels of the National Directory for Radiation Protection (NDRP) – refer to Table 1.

If the NDRP exemption levels are likely to be exceeded, cremation should only be permitted if the implant tissue (or most of it) is first excised from the body. This would normally be done by a pathologist under the direct supervision of a Qualified Expert to ensure radiation safety precautions for the pathologist. The excised tissue should be treated as radioactive waste.

In particular, iodine-125 seeds (titanium encapsulated) have been shown to survive the cremation process, and it is recommended that cremation is not carried out within one year following insertion of an iodine-125 seed prostate implant of typical individual source and implant activities unless the implant tissue is first excised.³

³ Aerts, MG, *Cremation following iodine-125 seed implant treatment for prostate cancer*, Paper posted at the Australasian Radiation Protection Society (ARPS) Conference, ARPS28, 2003.

10.3.3 Radiation Safety and Burial or Entombment

Permanently implanted sources are not normally an impediment to burial or entombment since, once the body is buried or entombed, the sources are well shielded.

TABLE 1: Cremation: Permanent sealed source implants which will persist with the cremated bone and cremains

Radionuclide, physical half-life & physical form	Treatment & administered activity	Exemption levels Exempt Activity; Exempt Activity Concentration as per the NDRP (IAEA 1996 sup by NRPB R306 1999)	Time from implant administration until activity decreases to the Exempt Activity	NFA after the following time from implant administration
iodine-125 59.9 d titanium encapsulated seeds mp ~1700°C	Prostate implant 0.9 – 1.5 GBq typically ~1.2 GBq (implant) 10 – 12 MBq (individual seed)	1 MBq; 1 MBq/kg	20 months (implant) 7 months (individual seed)	1 year* within this time, excision of the implant should be carried out before the body of the deceased is released for cremation
gold-198 2.7 d platinum encapsulated seeds mp ~1770°C	Interstitial implant Up to 6 GBq (implant) Up to 185 MBq (individual seed)	1 MBq; 0.1 MBq/kg	34 days (implant) 20 days (individual seed)	1 month**

* After 1 year from date of implant:

- individual seeds will typically be about 0.17 MBq, well below the Exempt Activity for iodine-125 of 1 MBq; and
- any small collection of seeds in at least 2 kg cremains should meet the Exempt Activity Concentration for iodine-125 of 1 MBq/kg, assuming that only some of the seeds will end up in the collected cremains and the remainder will drop out into cremation furnace and cremulator (processing machine).

** Gold seed implants not currently done in most jurisdictions; included here to illustrate the principle and for future reference if applicable.

11. Occupational Exposure

11.1 GENERAL CONSIDERATIONS

Schedule A1.1 of the Code requires that employees are provided with personal safety and protective devices when involved in radiotherapy planning and treatment.

To reduce occupational radiation exposure to as low as reasonably achievable (ALARA), building design, shielding, equipment and procedures should be adequately designed and tested (see Section 12).

The provision of adequate shielding should always be considered for all radiation sources. A prior assessment of potential occupational doses should identify the type, form and thickness of shielding required. The design and specifications can then be determined to meet the safety requirements.

The advice of a Qualified Expert and/or Radiation Safety Officer should be sought before new procedures are introduced or significant modifications are made to the radiotherapy facilities, equipment or procedures, since levels of radiation protection or safe practice may be affected. In the case of a radioactive source, any new or changed radiation procedures should be rehearsed, preferably without using the source.

11.2 PERSONAL MONITORING

All persons operating or otherwise dealing with radiotherapy equipment or radioactive sources for radiotherapy purposes should be monitored with personal radiation monitors (such as film or OSL dosimeters, or TLDs) unless it can be shown that the exposure is controlled by integral shielding with an effective dose below 1 mSv per year. The monitors should be provided and assessed by a personal radiation monitoring service recognised by the relevant regulatory authority. The monitors should normally be worn on the trunk, between the waist and the shoulder, and under any protective garments. In some circumstances, a personal direct-reading electronic dosimeter may be deemed appropriate in addition to, or instead of, the personal radiation monitors (for example, for use by ward nurses instead of the monitor, or immediately available for emergency use in facilities such as HDR brachytherapy in addition to the monitors).

The length of time for which a monitor will be allocated will depend on the expected doses to be received during the wearing period. Personal radiation monitors should be changed at regular intervals, and the appropriate monitoring period should be determined by the type of radiation and the type of procedures being carried out. Where the exposure is from behind fixed structural shielding (such as for linear accelerators or remotely-controlled brachytherapy), a monitoring period such as 3 months is generally satisfactory. Where the exposure involves operator skill to keep doses as low as possible (e.g. with manual brachytherapy or source handling), a shorter monitoring period such as one month is recommended.

Where an unusual exposure situation with potential for a reportable dose occurs (see Section 11.3), the monitor should be processed immediately and a replacement provided.

For some brachytherapy and source handling procedures, monitoring of extremity doses is advisable if doses to the hands are likely to exceed 1/10 of the appropriate dose limit. Although the maximum dose will usually be received by the fingertip, it is customary to wear the monitor at the base or middle of the finger, as wearing it at the fingertip may adversely affect tactile functions.

11.3 INVESTIGATION OF PERSONAL RADIATION MONITORING RESULTS

The Responsible Person (through the Radiation Safety Officer) should establish an investigational level such that any exposures received during a monitoring period which exceed this level require formal investigation by the Radiation Safety Officer. Appropriate action should then follow to identify the cause and to minimise any future excessive exposures. As an example, the level could be set at one third the pro-rata dose limit for the monitoring period.

An investigation level, together with a report, may be specified by the relevant regulatory authority, and therefore a copy of the report may also be required by that authority.

If the investigation shows that it is possible that the staff member has received this dose, the Responsible Person should be informed. The relevant regulatory authority may also need to be informed depending upon the legislative requirements.

In cases where the radiation monitor may have received a radiation dose when not being worn by the staff member, or as a result of the staff member undergoing a medical radiation procedure while still wearing the monitor, the exposure should be documented as a non-occupational exposure in their personal radiation history. The incident should be reported to the staff member's immediate supervisor as soon as the incident is discovered, even though the dose received may not be known. The original monitor should be evaluated and a new monitor issued.

11.4 PREGNANT STAFF

If an occupationally exposed female employee declares a pregnancy, the fetus needs to be afforded the same level of protection as a member of the public (Clause 3.1.10 of the Code). This may be achieved by controlling the exposure of the employee so that the dose received by the fetus is less than the public effective dose limit of 1 mSv per year for the remainder of the pregnancy.

The Responsible Person should assess the likely dose to the fetus of a pregnant employee from each work activity. This will usually require an examination of the employee's personal monitoring records and an assessment of the likelihood of incidents leading to internal or external

exposure of the fetus. If the fetus could receive more than 1 mSv over the declared term of the pregnancy, a change in work practice or job description should be discussed and agreed to with the employee. The most appropriate action is to reallocate the duties of the pregnant employee to duties with a low risk of radiation exposure.

In cases where the radiation exposure might not be predictably controlled, it would be prudent to provide an occupationally exposed pregnant employee with an electronic personal dose monitor to allow monitoring of the employee's dose on a daily basis.

12. Site Requirements

The Responsible Person should ensure that the location of radiotherapy facilities and the provision of adequate structural shielding are given careful consideration, particularly when the equipment is operated in close proximity to occupied areas.

The following considerations should be reviewed for the design of teletherapy and brachytherapy facilities to ensure appropriate protection of patients, personnel and visitors:

- room design features;
- design criteria for shielding;
- shielding assessment;
- radiation warning signs;
- radiation treatment controls;
- commissioning;
- calibration; and
- maintenance.

12.1 SHIELDING DESIGN AND SPECIFICATIONS

In designing a radiotherapy treatment facility, the Responsible Person should be aware of, and fulfil, their obligations to limit the dose to employees and members of the general public and to meet the dose constraints required by the relevant regulatory authority (Clauses 3.1.4 and 3.1.5 of the Code).

Specification of shielding material and shielding design should be chosen so that dose constraints can be met with due consideration to the occupancy of the areas adjacent to the treatment room. Due consideration should be given to the provision of floor and/or ceiling shielding when rooms immediately below or above the radiotherapy treatment area, are occupied.

If there is any change to radiotherapy equipment and/or any other modifications which impact on the shielding or change in the use of the adjacent areas (including above or below), the adequacy of the shielding should be reassessed (NCRP 2005).

The Responsible Person should employ a Qualified Expert (suitably experienced in radiotherapy shielding requirements and approved by the relevant regulatory authority) at the architect's or builder's early planning stage for buildings which will house radiotherapy equipment. The Qualified Expert provides advice on optimum shielding design, and determines and documents the radiation shielding specifications. All protective barriers in the rooms housing radiotherapy equipment, including the mobile shielding requirements for IORT or LDR brachytherapy, should be specified. Full details of the parameters on which the shielding calculations are based should also be documented in the report provided by the Qualified Expert. The site Qualified Expert should continue to be involved throughout the

planning and construction stages to ensure that the building design and facilities satisfy radiation safety standards and practice.

12.2 ROOM DESIGN

Treatment rooms should have emergency switches controlling the mains power to the radiotherapy equipment to allow for emergency termination of a radiation exposure. They should be both visible and easily accessible to staff from any point in the treatment room, and should be of 'mushroom' or similar simple 'hit-it' type. They should be installed such that each and every switch will terminate all power (including the radiation exposure and the gantry movement) so that it stays out ('latch out'). These devices might be used, for example, to terminate a patient treatment:

- in the event of uncontrolled movement of the patient;
- in the event of a staff member being accidentally left in the treatment room after commencement of the treatment; or
- to allow urgent access to the patient.

All staff members should be familiarised (by the appropriate manager) with the positions of all 'emergency off' buttons before being allowed to operate the unit.

The operator (usually the Radiation Therapist) needs to be able to observe the patient/couch area throughout the entire radiation exposure. Closed circuit TV monitoring of the patient from beside the control panel is the usual method of achieving this. There should be an intercom system to allow 2-way audible communication between the operator and the patient. The operating consoles should be placed outside the treatment room. Where a treatment room has operating controls within it (for example, some cases of superficial X-ray equipment), scattered radiation may scatter off ceilings and walls exposing the operator behind the protective screen. Redesign of such rooms to move the controls outside the treatment room is strongly recommended.

Engineering and physics personnel may wish to by-pass dosimetry interlocks when tuning the linear accelerator beam steering while attempting to diagnose operating faults of the treatment machine. Normal interlocks on linear accelerators, such as 'under dose rate', 'flatness' and 'symmetry', may trip when the beam parameters are outside the normal limits. Interlock by-pass should not involve a patient's treatment or allow anyone to remain in the room during the exposure. Service and physics personnel should follow the manufacturer's procedures when any interlock is by-passed to maintain safe standards of operation and to avoid damaging the equipment. These personnel should be thoroughly trained in the safe operation, design and technical aspects necessary for on-going repair and physics quality assurance and calibration.

The manufacturer's software should be used to set up particular user groups with different levels of access to the machine controls. Where an electronic approval system is in use, the Responsible Person should ensure that all users have, and continue to have, individual and secure passwords.

Brachytherapy

For clinical or laboratory areas where remote afterloading brachytherapy radioactive sources are prepared, sterilised and cleaned, the facilities and design should conform to the relevant requirements for radiation laboratories using sealed sources detailed in the Australian Standards AS/NZS 2982.1:1997 (Standards Australia 1997) and AS 2243.4 1998 (Standards Australia 1998) or provide an equivalent level of safety as these.

The Qualified Expert or RSO should be consulted if the brachytherapy treatment room is used for any purpose other than brachytherapy treatment, whilst the brachytherapy source(s) contained in the treatment unit remain stored in that room.

Occasionally it may be required to move a brachytherapy device from one area to another. The Qualified Expert should be consulted if this is proposed, to ensure that the dose limits for individuals and the shielding and design aspects comply with the requirements of the relevant regulatory authority.

12.3 RADIATION SURVEY FOR NEW RADIOTHERAPY EQUIPMENT

Prior to initial use of radiotherapy equipment and sources, the Responsible Person should ensure that a radiation survey is undertaken to confirm the shielding meets the relevant requirements.

12.4 WARNING SIGNS

Clause 3.1.18 of the Code requires that the Responsible Person provides visible warning signs or other devices at any general access point to a room to indicate that the room contains an ionizing radiation hazard. Warning signs need to be positioned and illuminated according to the requirements of the Code. Where possible, warning signs should be at eye level. Annex J provides examples of appropriate signage.

12.5 EQUIPMENT INVENTORY

Clause 3.1.13 of the Code requires the Responsible Person to be able to account for all radiation-producing equipment and radioactive sources under their control at all times. Advice on equipment and source inventories is contained in Annex C.

13. Training

13.1 RADIATION HEALTH PROFESSIONALS

Clause 3.1.16 of the Code requires that operators and other practitioners have appropriate training to:

- perform; or
- oversee

exposures using ionizing radiation.

Although radiation health professionals, such as Radiation Oncologists, Radiation Oncology Medical Physicists, and Radiation Therapists have knowledge of radiation safety by virtue of undertaking a course leading to their professional qualification, the Responsible Person should ensure that a program of continuing professional development is available for all relevant staff and provide additional training specific to the equipment used at the facility, particularly with the introduction of new technologies or techniques. The Responsible Person should also provide refresher training on other radiation safety related matters, for example an annual update from the facility's Radiation Safety Officer.

Where the person operating or otherwise dealing with radiotherapy equipment or radioactive sources is acting under the supervision of an authorised person, this may be general supervision⁴, personal supervision⁵ or immediate personal supervision⁶ depending on the level of experience and qualification of the person under supervision.

13.2 OTHER HEALTH PROFESSIONALS

Nurses, other health professionals and support staff working in radiotherapy facilities and who care for patients undergoing radiotherapy procedures should also have appropriate training. This training should be delivered by suitably qualified personnel and should be specific for each group to include:

- the responsibility of the individual in maintaining a safe workplace;
- occupational dose limits and the ALARA principle;
- methods of minimising radiation doses to staff and carers during the delivery of radiotherapy, including time, distance and shielding;
- minimising the occupational hazards arising from the use of radiotherapy equipment;
- knowledge of the magnitude of typical radiation doses from different radiotherapy treatment procedures;

⁴ General supervision is the exercise of control over radiation safety without the person exercising such control necessarily being present on the premises of operation.

⁵ Personal supervision is the exercise of control over radiation safety with the person exercising such control being present on the premises of operation.

⁶ Immediate personal supervision is the exercise of control over radiation safety with the person exercising such control being present and directly observing the use of the **ionizing radiation apparatus** or sealed source apparatus.

- risk factors such as age and the sensitivity of different types of tissue; and
- methods of measurement of radiation dose, if appropriate.

Professional bodies and relevant regulatory authorities should ensure that such a core of knowledge is included in courses that they accredit and the individuals who receive such training should be issued with a certificate signed by a representative of the sponsoring organisation.

13.3 OTHER STAFF INVOLVED IN THE DELIVERY OF BRACHYTHERAPY

Additional and continuing training should be provided for staff involved in the delivery of brachytherapy to patients. This training should be delivered by suitably qualified personnel and should include the topics listed above plus:

- an awareness of the potential for occurrence of incidents and accidents and the nature of the harm;
- the limitations of shielding;
- procedures to minimise the likelihood of radioactive contamination;
- procedures to handle radioactive waste;
- restrictions, if any, for the patient's visitors;
- appropriate signage during treatment;
- requirements, if any, for the patient's discharge from hospital; and
- appropriate documentation of the patient's treatment and discharge.

14. Security, Storage and Transport

14.1 SECURITY

Security for radioactive sources includes physical security and also security against unauthorised access to or acquisition of the sources by persons with malicious intent. This latter aspect will need to comply with the *Code of Practice for the Security of Radioactive Sources* (ARPANSA 2007) .

The Responsible Person should provide the local fire service with details of the location of any sealed source safe or store, and instructions in the event of a fire.

Radiation warning signs that include the contact details of the RSO or other representative of the Responsible Person (for the benefit of emergency personnel), should be in place at all access points to the store or relevant room, and other relevant sites within and outside the building⁷.

14.2 STORAGE AND HANDLING

Clause 3.1.20 of the Code requires that the Responsible Person, in whose name the brachytherapy sources are held, keeps a register of the sealed sources. The Sealed Source Register should track all movement of the sources so that they can be accounted for at all times.

Details of the sealed source(s) (i.e. radionuclide, activity, date of activity measurement and, where relevant, the source identification numbers such as serial numbers) should be clearly attached to the outer case of brachytherapy apparatus or sealed source container. Each container should be labelled with a radiation trefoil.

Each radioactive source used for radiotherapy needs to be safely and securely stored when it is not in use and should be subject to the following requirements:

- when in storage, each source should be placed securely into the shielded position;
- each source should be placed in a store for radioactive materials or designated area and not be stored with explosives, or combustible, corrosive or oxidising chemicals; and
- a permanent record of the fact that the radioactive source is stored, or has been issued, should be kept by the Responsible Person.

The store for radioactive sources should be constructed of durable materials capable of physically securing the radioactive sources. It should be designed and constructed so that the radiation levels outside the store:

- do not result in an ambient dose equivalent rate or directional dose equivalent rate, as appropriate, that exceeds $10 \mu\text{Sv h}^{-1}$;
- are as low as reasonably achievable in occupied areas; and

54 ⁷ Examples of a suitable signs are given in Annex J of this Safety Guide.

- are such that no member of the public can receive a dose exceeding 1 mSv per year.

When radioactive sources are in the store, the store should be labelled with a conspicuous sign⁸, the letters and symbol of which should be black on yellow background, bearing the radiation hazard warning symbol and the warning 'Store for Radioactive Materials' or similar. The store should be kept locked with a designated staff member having responsibility for the key (usually the Radiation Oncology Medical Physicist).

14.3 TRANSPORT

The transport of a radioactive source is governed by the *Code of Practice for the Safe Transport of Radioactive Material* (ARPANSA 2008a) and any existing national and State legislation.

Although the supplier is normally responsible for the packaging and transport of a radioactive source (by mutual agreement with the purchaser), the Responsible Person should immediately report to the relevant regulatory authority any breach of the transport regulations.

When acquiring a radioactive source the Responsible Person of the radiotherapy facility should ensure that the Supplier is aware of its responsibilities in transporting a radioactive source. Once ownership of a source is taken by the radiotherapy facility, the Responsible Person is responsible for the safe transport of the radioactive source between practice sites and other places where the source is to be used. The Responsible Person may delegate the task to the RSO, or to a transporter authorised by the relevant regulatory authority. In either case, the Responsible Person will need to ensure that, before dispatch, the source is packaged for transport according to the requirements of the Transport Code and to any further requirements of the relevant regulatory authority.

Before dispatch of the source, there should be close liaison between the Responsible Person, the supplier and any transporter to ensure that the transport route, means of transport and responsibility for each stage of the journey is clearly defined. This will ensure that all appropriate documentation is completed and received, that the timing of shipment is known and acceptable, that the transport method and route are confirmed, and that individual responsibilities are understood. Relevant points for consideration include:

- the need for special handling equipment for a sealed source, during transfer from one mode of transport to another, or between vehicles;
- checking of radiation dose rates from the package or container;
- confirmation of the integrity of the packaging;
- confirmation of the absence of contamination on the packaging;
- checking the correct transport labels are attached to the package or container, and replacing any that are damaged or illegible;

⁸ An example of a suitable sign is given in Annex J of this Safety Guide.

- completion of a Consignor's Declaration for Dangerous Goods form;
- ensuring that the package or container is securely attached to the vehicle;
- ensuring the vehicle is correctly labelled; and
- security of the consignment during transport, particularly during delays or overnight stops.

Radiation placards, as required by the Transport Code, need to be displayed on a vehicle transporting a radioactive source even when there are other compatible dangerous goods present. 'Mixed class' placards cannot be used in place of the standard radiation placard.

In the event of an incident during transport, the person in charge of the vehicle, or a person who is otherwise charged with the care of the radioactive source during transport, should immediately notify the Responsible Person for the source and the relevant regulatory authority.

Some radioactive sources may be returned to the supplier at the end of their working life. The Responsible Person may take responsibility through the RSO for return of these sources or pass this responsibility back to the supplier at the time of source change. The Responsible Person or supplier, as relevant, may engage the services of a carrier authorised by the relevant regulatory authority for the transport.

When returning an empty package to the Supplier, the Responsible Person should follow similar procedures in liaising with the supplier to confirm responsibility, route, modality and date of transport. The package should be examined to ensure it is in good condition, tested for residual contamination, has all warning labels removed and replaced by a label stating 'UN 2908 RADIOACTIVE MATERIAL EXCEPTED PACKAGE — EMPTY PACKAGING', and relevant transport documentation should be completed. The Responsible Person will normally be responsible from dispatch until the consignment reaches the consignee's premises. Other arrangements are satisfactory provided they are agreed in advance by both parties and are also acceptable to the regulatory authorities.

14.3.1 Transport within the Radiotherapy Facility

When a radioactive source is transported within premises, it should be placed in a suitably shielded container and carried in a way that minimises exposure to radiation and is secured to prevent tampering or theft. All movements of a source within the premises should be supervised, including to and from the radioactive source safe or store.

Annex A

Guidelines for the Radiation Management Plan

The Radiation Management Plan should contain all the necessary background and operational information for working with radiation. The Plan should be the first point of reference for staff, and should provide supervisors with all necessary policies and procedures. The Plan will usually be published in the form of a radiation safety manual. For radiotherapy facilities, the Radioactive Waste Management Plan will usually form part of the Radiation Management Plan. In addition to general incident or emergency procedures, the Plan should consider some specific scenarios, such as fire, flood, loss of control of source(s), or unintended radiation exposure to persons.

The content of the Radiation Management Plan should include:

1. General Information
 - 1.1 Authority of the manual (e.g. executive policy statement)
 - 1.2 Persons who should read the document
 - 1.3 How the centre uses radiation
 - 1.4 Regulatory requirements (list the required regulations, codes of practice or standards - copies (or hyperlinks to the document location) should be available with the plan)
 - 1.5 Licensing/registration requirements and any special conditions of each relevant regulatory authority in whose jurisdiction the radiotherapy equipment or sealed sources will be used
 - 1.6 Responsibilities of **employer** and employees
 - 1.7 Penalties for legislative contravention
 - 1.8 Contact details (facility's RSO, approved provider of personal radiation monitoring, equipment servicing agency, relevant regulatory authority, as well as their after hours emergency numbers, etc.)
2. General information on radiation risk etc.
 - 2.1 Nature of radiation and units
 - 2.2 Sources of radiation exposure (including background)
 - 2.3 Objectives of radiation protection
 - 2.4 Dose limits and dose constraints
3. Local rules/procedures for minimising staff exposure
 - 3.1 Description of the area/procedure
 - 3.2 Nature of the hazard
 - 3.3 Procedure/equipment/facilities required
 - 3.4 Emergency procedures (should include a brief description of the type of emergencies that could occur)
 - 3.5 Responsible staff and contact procedures
 - 3.6 Personal monitoring details (name of approved supplier, type of personal monitor to be worn, wearing position, requirements for storage when not in use, storage location of the control monitor, etc.)
4. Local rules/procedures for optimising medical exposure
 - 4.1 Procedures for dose calculation quality control
 - 4.2 Procedures for the delivery of radiotherapy
 - 4.3 Prevention of erroneous administration
 - 4.4 Procedures to avoid unintentional irradiation of embryo/fetus

- 4.5 Procedures to avoid unnecessary irradiation of others, particularly children (from prolonged close proximity to a patient with sealed radioactive sources in situ)
- 4.6 Special procedures for the delivery of radiotherapy
- 4.7 Reviews of radiotherapeutic doses delivered
5. Quality Assurance (QA) procedures
 - 5.1 Calibration, acceptance and tests of radiotherapy equipment
 - 5.2 Repair and maintenance of the radiotherapy equipment
 - 5.3 Radiotherapy QA program
 - 5.4 Use, maintenance and calibration of radiation measuring instruments
6. Storage and disposal of radiotherapy equipment
 - 6.1 Storage procedures (identification, location, record keeping, etc.)
 - 6.2 Disposal procedures (when, how, who authorises the disposal, etc.)
 - 6.3 Disposal/sale of X-ray apparatus (e.g. linear accelerator)
7. Storage and disposal of radioactive materials
 - 7.1 Storage procedures (identification, location, record keeping, etc.)
 - 7.2 Sources and categorisation of radioactive waste
 - 7.3 Mixed waste hazards
 - 7.4 Conditioning/packaging
 - 7.5 Disposal procedures (when, how, who authorises the disposal, etc.)
8. Record-keeping
 - 8.1 Inventory of radiotherapy equipment (see Annex C)
 - 8.2 Records in relation to radioactive sources (see Annex C)
 - 8.3 Records required by the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation* (ARPANSA 2008b)
 - 8.4 Testing where required (e.g. QA results, wipe tests on radioactive sources)
 - 8.5 Storage of records, including records of staff occupational exposure
 - 8.6 Who is responsible?
9. Environmental issues
 - 9.1 Radiation shielding to ensure compliance with the appropriate dose constraints
 - 9.2 Ventilation and maintenance of sterility
 - 9.3 Structural facilities within the centre to facilitate decontamination when necessary
 - 9.4 Appropriate storage of radioactive material
10. Handling of radiation incidents
 - 10.1 Possible types of incidents
 - 10.2 Procedures for handling each type
 - 10.3 Decontamination procedures
 - 10.4 General emergency procedures
 - 10.5 Contact names and numbers
 - 10.6 Reporting requirements
11. Training (details of training initial and ongoing training requirements, training providers etc.)
12. Transport (work rules for transport both within and between facilities)
13. Examples of any forms to be used in implementing the plan
14. Mechanisms for the periodic review of the Radiation Management Plan

EMERGENCY PROCEDURES

Written emergency procedures for inclusion in the Radiation Management Plan should include the following items:

- instructions on the immediate actions that need to be taken to protect human life, limit injury and provide first aid where required;
- instructions on the immediate procedures needed to bring the incident under control, including details on the action necessary to:
 - prevent the further spread of contamination (if this possibility arises);
 - prevent unauthorised and unnecessary access to the secured area;
 - provide or augment shielding against external radiation; and
 - allay panic;
- instructions for the operator involved to report the incident to the facility's RSO or the Responsible Person;
- instructions for the facility's RSO to:
 - assess the nature and scope of any radiation hazard;
 - implement any further action required to bring the incident under control;
 - immediately report the incident to the Responsible Person, and to the relevant regulatory authority;
 - investigate the circumstances of the incident and undertake assessments, measurements and calculations, in order to determine the optimum corrective action plan and to estimate the doses of the operators and members of the public involved in the incident;
 - assemble the necessary resources and implement the required corrective action, taking into account any instructions from the Responsible Person and the relevant regulatory authority;
 - prepare a detailed report of the incident as soon as possible after the incident and submit this report, within seven days of the incident, to the relevant regulatory authority, through the Responsible Person; and
 - advise the Responsible Person and the relevant regulatory authority on changes required to prevent the recurrence of a similar incident;
- names, addresses and telephone numbers required in the event of an emergency (these should be checked and updated at least once every 12 months and whenever changes in arrangements are made);
- any other instructions to cover possible emergencies, such as:
 - observed or suspected damage to radiotherapy equipment or a radioactive source, e.g. displacement from a moving vehicle, crushing by a vehicle etc.;
 - observed or suspected malfunction of the radiotherapy equipment;
 - suspected or actual loss of radiotherapy equipment or source(s);
 - failure of safety procedures or a breach of the working rules; and
 - fire, flood, explosion or other disaster or incident in relation to the radiotherapy equipment or sources.

Annex B

Radiation Safety Officer (RSO) Duties in the Radiation Management Plan

The Radiation Management Plan will normally assign the following duties to the RSO:

- to maintain and regularly review the Radiation Management Plan;
- to ensure that the facility meets the requirements of the Radiation Management Plan;
- to maintain the occupational exposure records on behalf of the Responsible Person;
- to ensure that records of receipt and patient administration of radionuclides are maintained;
- to provide appropriate personal radiation monitors to staff;
- to maintain the radiation safety records;
- to ensure the appropriate storage and maintenance and the regular calibration and testing of radiation monitoring instruments;
- to arrange for the safe calibration, repair and maintenance of the radiotherapy equipment and radioactive sources;
- to have responsibility for the safety, security and documentation of radioactive sources;
- to ensure the correct use of personal protective equipment by all staff;
- to provide radiation safety training for staff;
- to develop and implement safe work practices when using radiation sources;
- to provide advice, as required, to the Radiation Medical Practitioner on the radiation safety of individual patients undergoing radiotherapeutic procedures, including discharge planning and advice to ensure any exposure to patient's relatives friends and carers is minimised;
- to provide advice on the handling and disposal of corpses containing radioactive sources;
- to arrange for the safe storage of radioactive materials and ensure the safe disposal of any radioactive waste;
- to ensure that all necessary shielding, radiation safety equipment and radiation monitoring and surveying devices are provided by the Responsible Person;
- to ensure that instructions concerning the posting of radiation warning signs (see Annex J) when the radiotherapy equipment or sources are in use;
- to carry out any measurements, investigations or assessments which are deemed necessary to verify radiation safety or in the event of a radiation incident;
- to undertake appropriate risk assessments, appropriate emergency procedures and contingency plans, in co-operation with departmental management;
- to review, audit and report on radiation practices to ensure their continued effectiveness;
- to provide reports on radiation incidents to the Responsible Person and to regulatory authorities that include what happened, estimates of radiation

exposure to individuals, action taken and recommendations on how to prevent a recurrence;

- to ensure that measures are in place for the physical security of sealed radioactive sources; and
- to perform any other tasks that may be required to maintain a high standard of radiation safety.

The RSO should also ensure that satisfactory quality assurance (QA) programs and quality control (QC) testing for radiation safe practices are performed.

Annex C

Radiotherapy Equipment Records

All radiotherapy equipment: An equipment inventory list should contain details of:

- the type of equipment;
- the name of manufacturer;
- the model number;
- the serial number or other identifier;
- the year of manufacture;
- the date of commissioning; and
- the supplier of the equipment.

*For **ionizing radiation apparatus** used for radiotherapy,* the inventory list should detail the type and energy of radiation capable of being produced by the apparatus.

*For **sealed source apparatus** used for radiotherapy,* the inventory list should include the following information:

- the original source certificate;
- details about the radioactive source including the name of the radionuclide, and its physical and chemical form;
- the source activity and its date of calibration;
- the name of the source manufacturer;
- the source model or design details;
- the serial number or other identifier;
- the date of source installation or the date of receipt of the source; and
- details of the manufacturer, model and serial number of the sealed source apparatus.

For radiotherapy equipment controlled by computer software or firmware, the inventory list should include the following information:

- the names of the software modules;
- the versions in use; and
- date of the installation of the software.

For dosimetry equipment, including radiation survey meters, the inventory list should specify at least the following information:

- the type of equipment;
- the name of the equipment manufacturer;
- the equipment model number;
- the equipment serial number or other identifier;

- the year of manufacture of the equipment; and
- the equipment's calibration details.

EQUIPMENT INVENTORY

The Responsible Person should keep and maintain information records relating to the radiotherapy equipment or radioactive sources and update the inventory list following:

- a major upgrade;
- a radioactive source change;
- equipment replacement, decommissioning or removal; or
- the installation of new or updated software.

The following records should be kept for the operational life of radiotherapy equipment:

- equipment specifications;
- records of equipment acceptance tests;
- commissioning records;
- calibration records;
- quality assurance records;
- records of routine maintenance⁹;
- records of repairs or maintenance work; and
- records of the equipment's downtime.

The Custodian of the Register should review the inventory on a six monthly basis to ensure that the records are current and complete, and all equipment is accounted for.

BRACHYTHERAPY SOURCE REGISTER

The Brachytherapy Source Register should be stored where the brachytherapy sources are usually stored. The Brachytherapy Source Register should contain, at least, the following information:

- the name of each person authorised to store or use a source;
- the geographic location of the radioactive substances stored at the site;
- the location of each source within each radioactive substances store;
- the date of receipt of each source and the activity on that date;
- the physical and chemical form of the radioactive substance in each source;
- details of change(s) in the activity of the sources within brachytherapy device(s);
- details of all source changes or loadings;
- details of the movements of all sources from their usual place of storage; and
- detail the date and manner of ultimate disposal of each source from the site.

⁹ Work intended by the manufacturer of the radiation source to be performed by the Responsible Person.

Records for each radioactive source should detail:

- the date the radioactive source was received;
- the whereabouts and identification details of each radioactive source;
- the type of radioactive source;
- the activity and date of measurement of the activity of the radioactive source;
- if the radioactive source is incorporated in a sealed source apparatus, the identification details of the apparatus; and
- if the radioactive source was disposed of, the date of disposal.

When sources are removed to treat a patient the following details should be recorded in the Register:

- written authority for issuing the sources required;
- name of the medical practitioner requiring the sources;
- name and location of the patient for whom the sources are required;
- identification and activity of each source issued and the total number and activity of the sources issued;
- name and signature of the person receiving the sources and the date and time of issue;
- date(s) of expected return of sealed sources; and
- date(s) and time(s) of actual return of sealed sources and the signature of the custodian on receipt of the sources.

An annual audit of all radiation sources should be carried out to confirm that there is no variation in the expected inventory and that the safety and security arrangements for the radioactive sources are still appropriate for the type of source.

Each entry in the Brachytherapy Source Register should be accompanied by a signature, legibly printed name, and the date and time of the entry.

Copies of the approved shielding specifications should be kept on site and include details of:

- the shielding design including details of the radiation source (including source configuration) for which the design was undertaken;
- the radiation shielding specifications;
- the radiation survey and assessment of the shielding effectiveness on completion of building works; and
- the maximum workload rating for the shielded premises.

Annex D

Equipment Commissioning, Calibration and Servicing

CALIBRATION OF RADIOTHERAPY EQUIPMENT

Protocols for the dosimetric calibration of radiotherapy equipment should be in accordance with those adopted (and reviewed from time to time) by the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM). Relevant national and international calibration protocols include the IAEA Technical Report Series No. 398 (IAEA 2000b) and the IPEMB Code of Practice (IPEMB 1996).

All aspects of dosimetric calibration, including ensuring that all absolute dosimetry measurements are recorded, should be performed by or under supervision of a Qualified Expert and, once the measurements have been completed, the records given to the person within the radiotherapy facility designated as having overall responsibility for physics data (usually the person in charge of Medical Physics).

A Qualified Expert should compare the equipment or source test data to the technical specifications certified by the manufacturer or supplier. More detailed physics data are generally required to be measured and documented during the subsequent commissioning stage following acceptance. The Qualified Expert should:

- carry out full acceptance testing of new or modified radiotherapy treatment planning or dosimetry equipment. Where non-standard equipment is used, the tests need to take due regard of protocols provided by the supplier and include a risk assessment;
- ensure that records of all acceptance tests and commissioning data are kept and are readily available for later referral (refer Section 6.3.4 of this Safety Guide);
- ensure that the equipment is clinically used only for modes of treatment for which it has been tested and accepted for use, and that all operators are duly informed of the limited conditions of use; and
- confirm the basic physics data stored in the planning computer system and that doses calculated by the computer treatment planning system are correct to within the accepted limits of accuracy.

In most circumstances there are national or international standards to satisfy when commissioning or calibrating radiotherapy equipment. With the emergence of new technology, some component parts of radiotherapy equipment do not yet have national or international guidelines. Manufacturers should supply to the Responsible Person, a list of other sites with the same equipment installed, so that the Qualified Expert may consult with other physicists experienced with that equipment configuration. No radiotherapy treatment or planning equipment should be released for clinical use until a Qualified Expert is satisfied that the equipment is satisfactorily operating, calibrated and safe to use.

Radiotherapy equipment should be re-calibrated after initial commissioning and calibration, at least at the frequencies prescribed in the ACPSEM quality assurance recommendations (ACPSEM 1997) and under the conditions prescribed in the current ACPSEM protocol. This procedure will ensure that the equipment will undergo sufficient recommission tests to confirm that the previous standards of operation are still satisfactory in accordance with the calibration recommendations for that equipment (ACPSEM 1997). The maximum interval between radiation output calibration (measured under reference conditions and in accordance with the

ACPSEM recommendations (ACPSEM 1997)) for all beam energies and types should not be greater than one year. The test frequencies and tolerances for radiotherapy equipment and treatment planning systems are based on Kutcher et al. (1994) and on Van Dyk et al. (1993).

DOSE CALIBRATION AND EQUIPMENT PERFORMANCE

Clause 3.1.24 of the Code requires the Responsible Person to ensure that a Qualified Expert is available to provide advice on optimisation, dosimetry, calibration and quality assurance.

Further guidance can be obtained from the International Atomic Energy Agency (IAEA) publication 'Setting Up a Radiotherapy Programme' (IAEA 2008).

In practice a Qualified Expert should perform or oversee:

- after the installation or modification of any radiotherapy equipment, the initial dosimetry and acceptance tests to verify that the equipment conforms to the technical specifications specified in the manufacturer's or supplier's purchase agreement;
- that all dosimetry calibrations, clinical dosimetry data and methods of calculation for radiotherapy equipment are re-confirmed at intervals of not more than three years;
- that the measurements and checks carried out for the dosimetry re-confirmation are sufficiently comprehensive to detect any significant variations from the data in use;
- that the physical data and the accuracy of imaging modalities used for anatomical information and for quantitative purposes in treatment planning computer systems are determined; and
- the in-vivo dosimetry (e.g. thermoluminescent dosimeters or diodes) is used for direct clinical measurements as requested by the Radiation Medical Practitioner.

In relation to Clauses 3.1.24, 3.1.25 and 3.1.28-31 of the Code, it is recommended that:

- following initial acceptance or a major modification of the radiotherapy equipment, a second verification of the dose calibration be carried out by an independent Qualified Expert using an independently calibrated dosimetry instrument. This is to minimise the risk of errors occurring during acceptance and to confirm the dose calibration before patients may be treated;
- following maintenance, repair or modification work on radiotherapy equipment, the equipment is not returned to clinical use until the Qualified Expert has:
 - received and accepted as satisfactory, a work report from the equipment servicing agency who performed it;
 - assessed whether any specific tests or measurements need to be made;
 - carried out any necessary checks and tests to ensure safe operation of the equipment;
 - verified the dosimetric accuracy; and
 - provided a recommendation that the equipment can be returned to clinical use.

RECOMMISSIONING

In addition to the initial acceptance and commissioning, the same test and measurement procedures should be followed whenever a major upgrade or overhaul of the equipment is undertaken. 'Major' would mean that the calibration or performance specification of the equipment might have changed sufficiently to warrant re-evaluation of the clinical suitability of the equipment or that the associated planning/treatment data needs to be updated. Some examples of situations considered as major are as follows:

- External beam radiotherapy:

Critical situations to consider for X-ray tube equipment are the replacement of the X-ray tube itself, repairs or modifications to the high voltage and current controls and timer. Damage to filters or applicators may require detailed measurement as well as inspection after repair. Similarly, maintenance of the gun, target, waveguide, microwave source, dosimetry control circuits, ion chamber, flattening filter/scatterer replacement, machine tuning, its light optics and mechanical bearing system, all require a reassessment of the equipment's calibration and accuracy of radiation delivery. A mini-commissioning procedure is necessary when the X-ray tube or linear accelerator waveguide is replaced affecting the dosimetry, or when major bearings are replaced affecting the mechanical alignment of beam delivery.

- Intra-operative radiotherapy:

A linear accelerator for intra-operative radiotherapy in the treatment room, or a small mobile electron accelerator or low energy X-ray device in the operating theatre, should follow the same guidelines as described above.

- Remote afterloading brachytherapy:

Remote afterloading brachytherapy devices require a modified commissioning procedure after each new replacement radioactive source is loaded. For example, the accuracy of source activity, positional accuracy and source integrity should be determined prior to use. Any maintenance of the mechanical or electrical controls would necessitate a similar range of essential tests.

- Manual brachytherapy:

Apart from regular quality assurance tests and safe practice housekeeping, individual radioactive sources should be tested if there is any indication of physical damage or wear, particularly if there is a possibility of radioactive source leakage from its inert, sealed container.

All physical data procured during the acceptance testing and commissioning should be appropriately documented and should be used as a reference baseline from which to monitor the performance of the radiotherapy equipment during subsequent quality control performance or operational tests.

For brachytherapy, where such data exists, source strength may be measured by one of three methods as in the report on the Code of Practice for Brachytherapy Physics (Nath et al. 1997):

- direct traceability, when the source or transfer instrument (e.g. well chamber) is calibrated against a national standard;
- secondary traceability, when the source is calibrated by comparison with the same radionuclide and design that has a directly traceable calibration or by a transfer instrument that bears a directly traceable calibration;

- secondary traceability by statistical inference which is established when a source is one of a group of sources of which a suitable random sample has direct or secondary traceability; or
- for sources that do not yet have a national standard, users should develop a constancy check calibrated against the vendor's standard and use this consistency check to verify the source strength. Other options also exist (for example the interpolative free-air standard method), but a clear protocol should be clearly established before such sources are used clinically.

The measurement technique designed to check the source manufacturer details supplied with the source should take account of:

- any inaccuracy of measurements arising from the very high dose rate emitted from sealed radioactive sources; and
- keeping to a minimum the positional errors that may occur between the sealed radioactive source(s) and the radiation instrument used for the calibration.

SERVICING

Local procedures should ensure clear lines of communication between service engineers, the Qualified Expert and the Radiation Therapist. Defined procedures for taking a machine out of, and returning it to, clinical use should be developed and clearly understood by the relevant staff.

In situations where the Qualified Expert cannot be contacted at the completion of the service work, then the site should ensure a local protocol is documented and made available such that out-of-hours service reports or records are transferred to the in-house medical physics and engineering services and entered as part of the equipment service history. The Qualified Expert would then authorise that the radiotherapy equipment may be returned to clinical use.

There should be a clear sign or record book to show which staff group or individual is responsible for the equipment at any time.

The responsibility for radiation safety extends to all staff, with the reporting of incidents or malfunctions and the returning of the equipment to safe working order at the end of the maintenance/repair session.

Annex E

Equipment Quality Assurance

LINEAR ACCELERATORS

The Quality Assurance program for linear accelerators should be designed to ensure that:

- the equipment complies with the accepted tolerances listed in the ACPSEM QA recommendations (ACPSEM 1997);
- the equipment is tested and calibrated at regular intervals in accordance with accepted recommendations for linear accelerators at frequencies listed in the ACPSEM QA recommendations (ACPSEM 1997) and in accordance with the ACPSEM dosimetry protocols;
- the following specific tests are carried out at intervals of not greater than fourteen days:
 - photon and electron output constancy checks are carried out with a field or local standard dosimeter (ACPSEM 1997), using temperature and pressure corrections;
 - backup monitor constancy;
 - light/radiation field coincidence;
 - field size indicator (collimator setting);
 - cross-hair centring; and
 - gantry and collimator angle indicator;
- radiation leakage is within required limits:
 - the leakage radiation (excluding neutrons) measured at a distance of 1 metre from the axis of the accelerating waveguide, does not exceed 0.5% of the ambient dose equivalent rate measured on the central axis of the beam at the normal treatment distance;
 - adjustable collimation for photons attenuates the radiation in the area shielded by the collimation, to limit the ambient dose equivalent rate at the normal treatment distance so that it does not exceed 4% of the absorbed dose on the beam axis at the same distance; and
 - adjustable or interchangeable beam-limiting devices for electrons attenuate the radiation in the area shielded by the devices to the extent that the absorbed dose at the normal treatment distance does not exceed:
 - 2% of the central axis absorbed dose, averaged over the area bounded by the line 40 mm outside the 50% dose contour and the maximum field size; and
 - 10% of the central axis absorbed dose, at any point in the area bounded by the line 20 mm outside the 50% dose contour and the maximum field size;

KILOVOLTAGE X-RAY THERAPY UNITS

The Quality Assurance program for kilovoltage units (up to 400 kVp or maximum 4.5 mm Cu HVL) should be designed to ensure that:

- the apparatus:
 - complies with accepted tolerances for kilovoltage X ray apparatus listed in the ACPSEM QA recommendations (ACPSEM 1997) for kilovoltage X-ray equipment; and
 - is tested and calibrated at regular intervals in accordance with the accepted protocol for kilovoltage X ray equipment frequencies listed in the ACPSEM QA recommendations (ACPSEM 1997) and in accordance with the ACPSEM dosimetry protocol for kilovoltage X-ray equipment;
- specific maximum QA frequencies for:
 - field or local standard dosimeter checks of X-ray output constancy are not greater than one month;
 - the output calibrations, measured under reference conditions, are not greater than one year; and
 - the half value layer (HVL) checks are not greater than one year;
- radiation leakage produces an ambient dose equivalent rate as indicated for each energy (ACPSEM 1997). These measurements should be made under the following conditions:
 - for apparatus operating in the range of 1 – 8mm Al HVL:
 - 1 metre from the focal spot;
 - averaged over any area of 100 cm²;
 - no principal linear dimension exceeds 20 cm;
 - the nominal X-ray tube voltage;
 - an X-ray output loading for the maximum specified energy input in one hour; and
 - an ambient dose equivalent rate not exceeding 1.0 mSv in one hour;
 - for apparatus operating in the range of 0.4 – 4mm Cu HVL:
 - 1 metre from the focal spot;
 - averaged over any area of 100 cm²;
 - no principal linear dimension exceeds 20 cm;
 - the nominal X-ray tube voltage;
 - an X-ray output loading for the maximum specified energy input in one hour; and
 - an ambient dose equivalent rate not exceeding 10 mSv in one hour;
- X-ray transmission through the diaphragms and the sides of the applicators does not exceed 2% of the useful beam.

BRACHYTHERAPY SOURCES

In arranging an appropriate QA program for brachytherapy, the Qualified Expert should take into account the design and operation of the brachytherapy device (refer to ACPSEM QA recommendations (ACPSEM 1997)) to ensure satisfactory accuracy of treatment. The computer program should be checked for accuracy in dose calculation after every modification or upgrade. The calibration of any new source should be checked, the correct source strength determined, and then the new source strength should be incorporated into the brachytherapy treatment planning calculations (manual or computerised) for dose calculations.

Annex F

Quantification of Error and Monitoring of Incidents in the Delivery of the Radiotherapy Treatment Process

BACKGROUND

By convention (ICRU 1993, ICRU 1999), the acceptable dose variation permitted across a target volume is limited to +7% to –5% of the prescribed dose. Errors considered to be of potential significance are those where the delivered dose is outside this accepted range of dose variation. Currently, evaluation of error in the delivery of radiotherapy is generally categorised by the size of the variation from the planned treatment: below 5%, 5-10% and above 10% variation. It is recognised by the radiation community that the accuracy of measurement of the delivery of a dose of external beam radiation treatment is a sum of all the errors (both random and systematic) in the machine, the planning dosimetry, the planning set-up and the delivery of radiotherapy. A total variation within 5% of the planned dose is considered as acceptable and appropriate clinical practice, although all effort should be made to reduce it to the lowest value possible. Variations less than 5% are unlikely to detectably influence outcome. It should be noted that a treatment error occurs not only when an inaccurate dose is delivered, but also when the wrong site is treated, or there is a geographic miss.

Deviation of 10% or more from the prescribed dose is internationally accepted as being clinically detectable (ICRP 2000b). In view of this, it is considered by the Australian radiotherapy community to be a serious and reportable error. As such, the operator of the machine in question is required to inform the relevant authorities about the incident. The background to the incident should be investigated, and the cause(s) identified. Relevant changes to the procedural policies of the reporting facility should be considered, and if necessary promulgated through the rest of the radiotherapy community.

COLLECTION OF TREATMENT INCIDENT INFORMATION

An isolated treatment incident where the total delivered dose is assessed as being over 5% but less than 10% from the prescribed dose¹⁰:

- is considered potentially clinically relevant;
- is not considered severe enough to merit a formal report to the relevant regulatory authority;
- needs to involve the preparation of a detailed written report for the Responsible Person; and
- will be used as information for the internal quality assurance of the facility but in such a way that the employee and the facility are protected from penalty.

COLLECTION OF THREE LEVELS OF ERROR IN EXTERNAL BEAM RADIOTHERAPY

Detailed information on the incidence and type of error that occur in the delivery of external beam treatment should be collected in a formal and quantified fashion. It is recommended that a three-tiered system be utilised, whereby facilities collect information on the errors that can occur on a daily basis, allocating them into three levels. Detailed information on the efficacy of safety procedures, and the degree of

¹⁰ Awareness of incidents at this level may highlight inadequacies in the procedural processes of the department, and may thus prevent errors of the next level.

adherence to policies will be collated through this approach, and intervention¹¹ can be instituted by internal audit at a point before a major incident occurs.

These levels are:

Level 1 error: An error noted and assessed as being less than 5% of the total prescribed dose.

This falls within the prescription delivery limitations, and thus is of no clinical significance. Occurrence and incidence of level 1 errors should be collected by the radiotherapy facility for internal audit, as awareness of these errors will allow modification of treatment policies and will thus reduce the risk of the next level of error. No stigma should be attached to these errors, and the data should be collected in a fashion that renders it anonymous to both internal and external audit.

Level 2 error: An error noted and assessed as being over 5% but less than 10% of the total prescribed dose.

This error is considered as potentially clinically relevant, but not severe enough to merit formal report to the relevant regulatory authority. It is unlikely that such an error would produce a detectable result. It will need to be collected as part of the internal QA of the radiotherapy facility. Again, awareness of incidents at this level may highlight inadequacies in the procedural processes of the facility, and may thus prevent errors of the next level. This information should be collected in a fashion that protects the employee and the facility from penalty.

Level 3 error: An error noted and assessed as being greater than 10% of the total prescribed dose.

This level of error needs to be considered as significant and formally reported to the relevant authority as a radiation incident. This error may result in either over-dosage or under-dosage, both of which may have clinical significance. An internal audit will need to occur and policies revised if a flaw is identified. External review may also be instigated.

MONITORING OF INCIDENTS

Current monitoring of incidents occurs at a national level through the ARPANSA Australian Radiation Incident Register (ARIR), which collates information on radiation incidents of types specified in the National Directory for Radiation Protection (ARPANSA 2004). Reports of incidents to the ARIR are usually provided by the radiation protection regulatory authorities of the Commonwealth, States and Territories.

The National Directory for Radiation Protection requires reporting to the ARIR of the following circumstances relating to medical exposure of radiotherapy patients:

- when during the administration of a radioactive substance for therapeutic purposes, the activity administered differs from that prescribed by 15% or more;
- when during administration of a therapeutic dose of radiation from a radiation apparatus or a sealed radioactive source, the dose delivered differs from the total prescribed treatment dose by more than 10%; and

¹¹ Intervention is an action intended to reduce or avert exposure or the likelihood of exposure to sources which are not part of a controlled practice or which are out of control as a consequence of an accident or other event.

- any therapeutic treatment delivered to either the wrong patient, the wrong site, or using the wrong beam type or beam quality, or wrong radionuclide.

In addition, the National Directory for Radiation Protection has general provisions for the reporting to regulatory authorities of other incidents, which could include near misses that may have led to incidents reportable under the above provisions. These span a wide continuum of delivery, communication and medical errors that are not satisfactorily captured by definitions of traditional dosimetric incidents.

It is recommended that data on all minor incidents and potential errors be collected within radiotherapy facilities. Any outcome (or near miss) which is unintended and has potential for harm to patient(s) or staff may be regarded as an incident by the relevant regulatory authority. Due to the repetitive and highly technical nature of radiotherapy administration, thousands of minor delivery errors occur across the country per year. The vast majority of these errors have no clinical consequence and are inevitable sequelae of clinical practice. However, pattern analysis of such data on a national scale may identify significant but otherwise unrecognised patterns of practice predicting for error or more major incidents, which might therefore be averted. Such an approach is supported by the three professional groups (ACPSEM, RANZCR and AIR) integral to the delivery of radiotherapy (APSF/FRO/ACPSEM/AIR 2002).

INCIDENT REPORTING FOR BRACHYTHERAPY

The delivery of dose in brachytherapy is subject to the same concerns regarding accuracy, but due to the nature of the technique, margins for dose variation are wider, in particular depending on the placement of the source(s). This is recognised and generally allowed for during target definition and dose prescription. If dose variation is identified beyond these limits, similar principles to incident recording and reporting should apply.

Errors may arise in a similar fashion to those of external beam radiotherapy, with the additional possibility that geographic placement of the sealed radioactive source(s) may not occur exactly as planned. This is dependent on factors beyond current clinical capabilities to control. As such, the limitations in planning and placement, and the necessary adjustments that may be required, should be explained as part of the counselling and informed consent which patients are given prior to their treatment.

Planning of brachytherapy should take into account both the potential to underdose the tumour target, and the potential to overdose surrounding normal structures. The tumour localisation and the dose prescription should acknowledge these possibilities and be designed to follow the optimal middle ground. Provided they are recognised and encompassed in the treatment intent, deviations from the treatment plan within these defined constraints are not considered errors or incidents. Deviation beyond these limits should be recorded as above.

As with external beam radiotherapy, other errors may occur, and all classes of error (including an unexpected shift in geographic position) should be recorded in a similar fashion so that the experience may be accumulated. As noted under Monitoring of Incidents, if the source activity deviates by 15% or more, or the delivered dose by 10% or more, from that prescribed, this should be recorded and reported.

Annex G

Brachytherapy Sources

GENERAL

Brachytherapy involves the use of radioactive sources placed within or immediately adjacent to the target volume. Brachytherapy sealed sources may be tubes, seeds, plaques, wire, applicators loaded with seeds, or equipment with encapsulated sealed source pellets. A sealed source is usually encased within an encapsulating jacket of a different substance, usually a metal or combination of metals. The encapsulating material acts to filter out unwanted effects such as low-energy radiation that contaminates the delivery of a therapeutic dose, and so permits accuracy in prescription. Size and shape of the source will depend upon its use, as will the surrounding filter that encases the source.

Source placement may be performed by:

- *Manual insertion or application*, in which the sources are directly implanted into or applied to the area of interest. This involves staff exposure and is the least desired form of delivery.
- *Manual afterloading*, where inert source guides are inserted within or adjacent to the target volume, and the radioactive sources are subsequently inserted manually into these source guides after surgery and imaging and planning procedures are completed.
- *Remote afterloading*, where inert source guides are inserted within or adjacent to the target volume during surgery or other procedures, and the radioactive sources are subsequently inserted by remotely-operated automated machinery into these source guides after completing the imaging and planning procedures.

Remote afterloading should be used where practicable as it minimises exposure to the personnel involved. All HDR and PDR brachytherapy equipment is designed to be operated by remote afterloading to eliminate the need for staff proximity to the high activity sources exposed during treatment administration to the patient.

The duration of placement of a sealed source will depend on the activity and dose rate being utilised. The source may be:

- briefly placed for a pre-set treatment time (seconds or minutes) in or adjacent to the target volume ;
- temporarily placed and left in place for a pre-set treatment time (usually days) in or adjacent to the target volume; or
- permanently implanted in or adjacent to the target volume.

The placement of a sealed source may be:

- *intracavitary*: inserted into a body cavity; or
- *intraluminal*: placed in a hollow organ or vessel (intravascular); or
- *interstitial*: placed into a tumour or tissue; or
- *superficial*: placed against an external body structure (mould).

Table 2 summarises the brachytherapy sealed sources currently or potentially in use in Australia:

TABLE 2: Sealed Source Brachytherapy

LOADING TYPE	EQUIPMENT TYPE	EXAMPLES			
		Nuclide	Placement		Use
<i>REMOTE AFTERLOADING</i>	High Dose Rate (HDR) apparatus	Ir-192; Cs-137	brief application	intracavitary; intraluminal; interstitial; superficial	
	Pulsed Dose Rate (PDR) apparatus	Ir-192; Cs-137	cyclic brief applications		
	Low Dose Rate (LDR) apparatus	Cs-137	temporary	intracavitary	gynaecology
<i>MANUAL AFTERLOADING</i>	tubes	Cs-137	temporary	intracavitary	gynaecology
	wire	Ir-192	temporary	interstitial	gut; liver; breast
	commercial applicator	Sr-90; P-32	brief application	intraluminal	intravascular
	custom-built applicator	Ir-192; Re-188 *	brief application	intraluminal	intravascular
	stent	eg. Tc-96 **	permanent	intraluminal	intravascular
<i>MANUAL INSERTION/ APPLICATION</i>	seeds	Au-198	permanent	interstitial	tongue; pharyngeal; neck;
	seeds	I-125	permanent	interstitial	prostate; breast
	seeds	Pd-103	permanent	interstitial	breast
	plaque	Sr-90	brief application	superficial	ophthalmology (pterygia); dermatology
	plaque	Ru-106	temporary	superficial (sutured)	ophthalmology (malignancies)
	applicator with seeds	I-125	temporary	superficial (sutured)	ophthalmology (malignancies)

* Liquid Re-188 contained in a balloon inserted into the artery is strictly an unsealed source, but is effectively a sealed source while inside the patient for the duration of the treatment.

** Permanent implants of radioactive stents are still under research development. This is included here as an example of the type of source that may be in use in this form in the future.

Note that radium-226 should not be used as a brachytherapy sealed source because of its inherent characteristic of build-up of radon gas and extreme hazards due to potential tube rupture and/or contamination leakage. Radon-222 seeds are no longer used in interstitial brachytherapy. Cobalt-60 is no longer used in eye applicators; less penetrating radionuclide alternatives (such as iodine-125) are now preferred. The use of strontium-90 plaques in ophthalmology and dermatology is decreasing due to superseding non-radioactive modalities.

SOURCE HANDLING

The relative risks of the hazards of handling brachytherapy sources should be kept in perspective. The radiation hazard should not necessarily be assumed to be the overriding factor; other considerations such as infection from bodily fluids may also be important. The radiotherapy facility's RSO or Qualified Expert should prepare and provide written instructions for radiation protection for any brachytherapy procedure involving manual handling of sources, or potential exposure to staff, visitors or public. These will contain details of specific restrictions for staff groups and the general public, with limitations on access by visitors based on the public dose limits.

The operator should not work without protection simply because working without it seems to be the 'easy' way. With proper training in the procedure and safe practice, a high degree of dexterity can be attained while still taking advantage of recommended methods of protection. If variation to methods of working is planned this should be discussed with the radiotherapy facility's RSO, and practised as a non-radioactive 'dry run' first.

All manipulations with sealed sources should be carried out as quickly as possible, compatible with safe working practice. The skill of the operator is an important factor in reducing the amount of radiation received when radioactive sources are handled. A novice should therefore be trained with dummy sources or inactive material until a high degree of competence has been attained. Dummy sources should be clearly identified as such.

All equipment used for manipulating sealed sources and loaded appliances should be designed and maintained to ensure safe and smooth operation and to minimise radiation exposure. Appliances should be so designed that sealed sources can be loaded easily and can be readily removed even when stuck by coagulable body fluids. Screw-threads should be carefully cut and be of optimum size and pitch to allow fast, jam-proof operation.

Personal monitoring devices¹² to measure exposure should routinely be worn when working with sealed sources.

All personnel (staff members or service technicians) operating brachytherapy devices (manual or automated afterloading equipment) should be trained and individually approved to use the sources and equipment. All staff working with brachytherapy devices, or associated with the care of patients undergoing treatment with such sources, should be fully trained and familiar in the proper operation of the device, including emergency procedures, prior to treating patients.

All sources prepared or used for treatment should be returned promptly to the radioactive source safe or store when no longer in clinical use.

Sealed sources with half-lives greater than 1 year should be tested at least once each year to confirm uniform distribution, and to identify any radioactive material leakage or surface contamination. Any sources found to be unsatisfactory will need to be immediately removed from service, sealed in an appropriately labelled suitable container, and stored.

SOURCE STERILISATION

Detailed consideration of the safety of methods of sterilisation is needed, to avoid damage to a sealed source that might result in leakage or rupture. For example, radium 226 (which should not be in clinical use), caesium 137 and strontium 90 sources may not be heat-sterilised. Heat-sterilisation requires purpose designed, temperature controlled equipment. Chemical sterilisation may be used, but attention should be paid to possible deleterious effects of some chemicals on sealed metal encapsulation of radioactive sources and on any attached threads. Staff responsible for cleaning and sterilising of sealed sources will be trained appropriately to prevent damage or loss, and follow the recommended shielding and sterilisation procedures.

Sealed radioactive sources require adequate shielding during sterilisation and until immediately before their insertion in the patient. Shield design should provide

¹² A device designed to be worn by a person to monitor any radiation dose received by the person.

protection for the body and head, including the eyes. Where possible, shielding of the fingers and hands from beta rays should also be provided. Sources should be manipulated with long forceps, special remote handling devices or other suitable instruments. At times it may be impracticable to provide shielding protection for manual or manual afterloading sources, and in such circumstances it becomes essential to make best possible use of distance and speed of working.

BRACHYTHERAPY: SOURCE CALIBRATION

The sealed source activity or kerma rate stated on the supplier's consignment details should be independently checked by an in-house radiation measurement. Clause 3.1.25 of the Code states that each source must be independently calibrated before any clinical use of the new source and the results of the check be documented in the Source Register. Where the results of the check measurement vary by more than 5% from the certified activity or kerma rate, the source should not be used until further independent verification of the source activity has been conducted.

A brachytherapy source calibrator should comply with the tolerances listed in the ACPSEM QA recommendations (ACPSEM 1997) for Brachytherapy Source Calibrators.

BRACHYTHERAPY CONTAMINATION CHECKS

Routine checks for integrity of the source, and for surface radioactive contamination of the source or associated equipment, should be performed with a minimum frequency of:

- high dose rate brachytherapy sources: each time before the source is replaced, or annually when in continuous use;
- plaques: annually;
- low dose rate brachytherapy sources: annually;
- manual afterloading tubes: annually; and
- eye/skin applicators: annually.

Contamination checks should be carried out by a Qualified Expert who is competent in operating the brachytherapy equipment or manipulating the source (as relevant) and in interpreting the contamination test results. Where the results of the contamination testing of afterloading brachytherapy equipment remote control equipment indicate the presence of significant contamination from the source, persons using the equipment will need to:

- cease using it immediately;
- arrange for appropriate shielding to be applied to render the area safe for personnel, as appropriate;
- arrange for the appropriately trained and authorised personnel to review the equipment and identify and correct the problem and/or replace the source, as appropriate;
- arrange thorough decontamination of the equipment before resumption of use; and
- report the incident to the relevant regulatory authority.

If the results of the contamination testing of manual afterloading tubes or of plaques indicate the presence of significant contamination, the affected tubes or plaques will need to be withdrawn from use.

If the results of the contamination testing of applicators into which radioactive seeds have been loaded indicate the presence of significant contamination, the applicators will need to be thoroughly decontaminated before resumption of use.

Brachytherapy source containers often have small internal diameters so that it may not be possible to wipe test inside the source container, although a wipe test should be performed wherever possible. Procedures for wipe testing are given in Annex I. When a wipe test is not possible, tests should be made to detect radiation emitted by any radioactive contamination inside or on the outer surface of the source transfer system or applicator.

Significant contamination of remote afterloading brachytherapy equipment is unlikely but is confirmed if the results of the contamination check indicate an activity of more than 200 Bq from the wipe test, or radiation greater than twice normal background from the check with a sensitive radiation detector.

Reporting to the relevant regulatory authority of significant contamination of remote afterloading brachytherapy equipment and sources is necessary so that relevant information can be disseminated to other sites using similar equipment.

Annex H

Specific Brachytherapy Uses

SUPERFICIAL BRACHYTHERAPY PROCEDURES

A superficial brachytherapy source will need to be stored and handled so that direct handling is avoided. The surface of the plaque or mould containing the radioactivity should always be pointed, and held at as great a distance as possible, away from treatment personnel. The following applies to the use of radioactive plaques in the treatment of ophthalmological or dermatological conditions:

- the plaque should be appropriately labelled;
- the front surface of the plaque should not be viewed directly during any manipulations or examinations of the plaque due to its high dose rate;
- the active surface should never be scratched or damaged in order to preserve the integrity of the activity across the surface of the plaque;
- the plaque should be stored in a shielded container whilst not in use in a manner that protects the active face from damage by abrasion and with orientation that allows extraction without exposure to the active face;
- on initial receipt, a plaque will need to be commissioned for clinical use by a Qualified Expert and include a check measurement of the dose rate from the surface of the plaque;
- the dose rates used for calculations of treatment dose times will need to be adjusted for radioactive decay at intervals appropriate to the decay of the nuclide;
- the patient's treatment should always correspond to the prescription of the prescribing medical practitioner;
- preparation of the applicator according to the medical prescription should always be undertaken by, or under the supervision of, a Radiation Oncology Medical Physicist;
- sterilisation of the plaque will need to be by chemical means and not by boiling or autoclaving due to the risk of mishap resulting in damage to the plaque or release of radioactive material; and
- application or suturing of the plaque to the patient should only be performed by a person who is trained in its use and who is authorised by the relevant regulatory authority for the purpose.

OPHTHALMOLOGY AND DERMATOLOGY

Strontium-90 Plaques for Operator Controlled Treatment

Strontium-90 plaques are used for treatment of eye conditions (such as pterygia) and skin lesions.

The plaque is typically a circular or elliptical curved disc of up to about 20 mm diameter. The strontium-90 (up to about 3 GBq) is contained in a 1 mm thick plate of silver, screened by 0.1 mm silver and protected against corrosion by a rolled gold coating. The plaque is mounted in an aluminium alloy case with a 1 mm deep guard ring. A stem handle is attached to the shielded back of the plaque mounting (in some cases the handle is screwed into the mounting and detachable). The dose rate from the concave front of the plaque is typically up to 0.15 Gy/sec.

Treatment time per treatment session is typically of the order of 1 to 3 minutes for a prescribed dose of 8 Gy, with the operator using the handle to apply the source. The ancillary equipment required for these treatments includes an accurate stopwatch for accurate timing of the short treatment time.

The manufacturer's calibrated dose rate from the active surface of the plaque is usually stated to within $\pm 20\text{-}30\%$, but it is desirable to establish a greater degree of accuracy by accurate measurement of the dose rate. The dose rate used for calculation of treatment time is generally adjusted annually for radioactive decay.

When unshielded, these plaques are capable of delivering biologically significant doses within minutes. The handling techniques during use should therefore include ensuring the active side of the plaque is always directed away from the operator and other people (including the patient except for the actual period of treatment).

The life of the strontium-90 plaque is considered by the manufacturers to be limited to 15 years, but may be longer subject to regulatory requirements and assuming it has been treated with care.

Sterilisation of the plaque should be by isolated chemical means, and not by autoclaving or boiling.

If the plaque is not handled with care, the active surface may become scratched or damaged in some way that will disrupt the integrity of the activity across the plate. This may result in shedding of the silver metal containing the strontium-90 and may compromise the even dose rate across the plate which is necessary for optimal patient treatment.

The annual testing of the plaque surface should involve both wipe and immersion tests to demonstrate that there is no labile activity removable from the active plate. A visual (indirect) inspection should also be made to ascertain that the active surface is free from damage.

It should be noted that the use of strontium-90 plaques in ophthalmology and dermatology is decreasing due to superseding modalities that do not use ionizing radiation.

Scleral Attachments

There are two types of radioactive scleral attachments in current use, namely plaque attachments and applicators loaded with radioactive seeds.

Treatment is often done on outpatients who then return to the hospital or clinic at the end of the treatment for removal of the scleral attachment.

The patient should wear an eye patch containing further shielding over the attachment (e.g. 1 mm lead for the iodine-125 seed eye applicator) for the duration of the treatment. The radiation dose rate in the vicinity of the patient when the applicator is in place should be able to be reduced to no more than 5 times natural background at 1 metre from the patient.

- Plaque applicators with radioactive material such as ruthenium-106: (Note that cobalt-60 is no longer recommended because less penetrating alternatives are available).

Ruthenium-106 applicators used for treatment of eye tumours are curved discs or kidney shapes, typically 11-25 mm diameter. The radioactive material (initially typically 10-20 MBq) is plated onto a silver substrate and screened by 0.1 mm silver. The dose rate at the centre of the applicator is of the order of 3-8 Gy/h.

The beta radiation of the daughter rhodium-106 enables treatment of the eye up to depths of 8 mm. Treatment time (which will vary with applicator age, given the 372.6 day half-life of ruthenium-106) is typically 2-7 days for a prescribed dose to the tumour of 100-120 Gy.

The manufacturer's calibrated dose rate from the active surface of the plaque, which is usually stated to within $\pm 20\text{-}30\%$, has often been used as the calibration figure. However accurate calibration methods of the dose rate from the plaque are available to the Qualified Expert and will ensure optimal treatment outcomes (which can otherwise be greatly reduced by as little as a 10% dose deviation). The dose rate used at each treatment should be adjusted for radioactive decay from the measured reference calibration.

The applicator should be appropriately sterilised with respect to the requirements of the plaque surface and mounting materials.

If the plaque is not handled with care, the active surface may become scratched or damaged in some way that will disrupt the integrity of the activity across the plate. This may result in shedding of the silver metal containing the radioactive material and may compromise the even dose rate across the plate which is necessary for optimal patient treatment.

The annual testing of the plaque surface should involve both wipe and immersion tests to demonstrate that there is no labile activity removable from the active plate. A visual (indirect) inspection should also be made to ascertain that the active surface is free from damage.

The life of a ruthenium-106 plaque is limited by the 372.6 day half-life.

- Applicators loaded with radioactive seeds such as iodine-125 seeds:

Iodine-125 seed applicators used for treatment of eye tumours are constructed of materials such as stainless steel and perspex, are typically 10 mm to 20 mm circular or elliptical diameter, and are loaded with typically 4-15 seeds up to a maximum of about 4 GBq. The dose rate at the front of the applicator is typically of the order of 0.5-0.6 Gy/h. The applicator geometry and seed activity are selected according to the treatment prescription. Prescribed doses and treatment times are typically: (melanoma) 80 Gy to apex of tumour in up to 6 days and (retinoblastoma) 40 Gy in 3-4 days.

The applicator should be loaded with the radioactive seeds in a clean environment using standard safety procedures for handling of radioactive sources, such as handling the seeds with tweezers and working behind a bench shield.

The loaded applicator should be appropriately sterilised with respect to the requirements of the seeds and of the applicator materials.

After use, the applicator should be thoroughly cleaned and the seeds stored in a labelled shielded container for re-use or until they have decayed sufficiently to be disposed of as non-radioactive material (normally less than the IAEA Exempt Activity).

INTRAVASCULAR BRACHYTHERAPY

Intravascular brachytherapy is used to prevent re-stenosis in arterial vessels such as coronary or femoral arteries.

Various radionuclides are used, either as sealed sources inserted briefly into the artery by automatic afterloading apparatus (e.g. phosphorus-32 and strontium-90 capsules, iridium-192 wire), or as contained unsealed liquid sources inserted briefly into the artery by manual afterloading techniques (e.g. liquid rhenium-188 contained in a balloon inserted into the artery, effectively making it a sealed source

for the duration of the treatment but an unsealed source at all other stages). Intravascular brachytherapy involving permanently implanted radioactive stents is also under research development.

Typical treatment doses for intravascular brachytherapy are 30 Gy, prescribed at a depth of 0.5 mm in the blood vessel wall, in a single fraction, with a source activity such that the dwell time within the artery is typically several minutes.

When the contained unsealed sources are used within the artery, the apparatus and procedure should be carefully designed to prevent all chances of the serious event of rupture of the containment during treatment.

A guide to intravascular brachytherapy has been published (RSU/RAC 2000).

Annex I

Procedure for Wipe Testing a Sealed Radioactive Source or Source Housing¹³

WIPE TEST REQUIREMENTS

An annual wipe test should be carried out for each sealed source or its housing to check for contamination and for the integrity of its sealing, i.e. by wipe or smear testing each source or its housing and a record of each wipe test kept in the source record.

Leak testing will need to be performed at 10-year intervals (see ISO 9978:1992) or whenever leakage is suspected with the particulars of the examinations be entered into the record.

WIPE TEST METHODS¹⁴

If a wipe test is used to determine leak tightness after mechanical or thermal prototype testing, the sealed sources to be tested should be cleaned or decontaminated before the tests.

Wet Wipe Test: Wipe all external surfaces of the sealed source thoroughly with a swab of filter paper or another suitable highly absorbent material, moistened with a liquid which will not attack the material of which the external surfaces of the sealed source are made and which, under the conditions of this test, has been demonstrated to be effective in removing any radioactive material present. Measure the activity of the swab.

Dry Wipe Test: This test can be used in situations where it may not be appropriate to use a wet swab, for example for high activity cobalt-60 sources or in some recurrent inspections. To carry out the test, thoroughly rub all the external surfaces of the sealed source with a dry swab of filter paper and measure the activity.

Approval Criteria: If the activity detected does not exceed 200 Bq, the sealed source is considered to be leaktight.

¹³ The requirements in this Schedule have been adapted from AS 2243.4:1998, *Safety in laboratories – Ionizing radiations* (Standards Australia 1998), and ISO 9978:1992, *Radiation protection – Sealed radioactive sources – Leakage test methods* (ISO 1992).

¹⁴ Wipe tests should be performed as close as possible to the sealed source, taking account of radiation protection issues.

Annex J

Radiation Warning Signs and Notices

Radiation warning signs and notices, need to conform to Australian Standard AS 1319-1994, *Safety signs for the occupational environment* (Standards Australia 1994), and Australian Standard AS 2342-1992, *Development, testing and implementation of information and safety symbols and symbolic signs* (Standards Australia 1992). Examples of suitable warning notices are given below.

COLOURS FOR RADIATION WARNING SIGNS AND NOTICES

Background: yellow
Marking and trefoil: black

EXAMPLE OF SUITABLE RADIATION WARNING SIGNS TO BE DISPLAYED ON THE OUTSIDE OF THE ENTRY DOORS TO ANY ROOM HOUSING RADIOTHERAPY EQUIPMENT



EXAMPLE OF A SUITABLE WARNING SIGN AND NOTICE FOR A STORE OR STORAGE SAFE



For a storage safe, the word 'store' in the above sign should be replaced by the words 'storage safe'.

Annex K

Survey Meters

GENERAL REQUIREMENTS OF THE SURVEY METER

Where a radiation survey meter is required, it should:

- have sufficient measurement range to measure ambient dose equivalent rates or directional dose equivalent rates, as appropriate, at least throughout the ranges of $0.5 \mu\text{Sv}\cdot\text{h}^{-1}$, or its equivalent, to $2 \text{mSv}\cdot\text{h}^{-1}$, or its equivalent, for the radiations emitted from the radiation sources used in radiotherapy;
- continue to indicate, either visibly or audibly, when radiation levels exceed the maximum reading in any measurement range; and
- indicate the measured quantity with a measurement uncertainty not greater than ± 25 percent inclusive of uncertainty due to response variation with energy over the range of energies of the radiation to be measured.

CALIBRATION OF THE SURVEY METER

Radiation survey meters should have an operational and calibration check:

- prior to initial use;
- at intervals not exceeding twelve months;
- following damage or repairs; and
- when otherwise indicated by its performance.

Annex L

Health Effects of Ionizing Radiation and Standards for Control of Exposure

Annex L was removed January 2015.

For information on the health effects of ionising radiation, refer to

[RPS F-1 Fundamentals for Protection Against Ionising Radiation \(2014\)](#)

Annex L was removed January 2015.

**For information on the health effects of ionising radiation,
refer to**

[RPS F-1 Fundamentals for Protection Against Ionising Radiation \(2014\)](#)

Annex L was removed January 2015.

**For information on the health effects of ionising radiation,
refer to**

[RPS F-1 Fundamentals for Protection Against Ionising Radiation \(2014\)](#)

Annex M

Regulatory Authorities

Where advice or assistance is required from the relevant radiation protection authority, it may be obtained from the following officers:

COMMONWEALTH, STATE/TERRITORY	CONTACT
Commonwealth	Chief Executive Officer ARPANSA PO Box 655 Miranda NSW 1490 Email: info@arpansa.gov.au Tel: (02) 9541 8333 Fax: (02) 9541 8314
New South Wales	Manager Hazardous Materials and Radiation Section Department of Environment and Climate Change PO Box A290 Sydney South NSW 1232 Email: radiation@environment.nsw.gov.au Tel: (02) 9995 5000 Fax: (02) 9995 6603
Queensland	Director, Radiation Health Unit Department of Health 450 Gregory Terrace Fortitude Valley QLD 4006 Email: radiation_health@health.qld.gov.au Tel: (07) 3406 8000 Fax: (07) 3406 8030
South Australia	Director, Radiation Protection Division Environment Protection Authority PO Box 721 Kent Town SA 5071 Email: radiationprotection@epa.sa.gov.au Tel: (08) 8130 0700 Fax: (08) 8130 0777
Tasmania	Senior Health Physicist Health Physics Branch Department of Health and Human Services GPO Box 125B Hobart TAS 7001 Email: health.physics@dhhs.tas.gov.au Tel: (03) 6222 7256 Fax: (03) 6222 7257
Victoria	Team Leader, Radiation Safety Department of Human Services GPO Box 4057 Melbourne VIC 3001 Email: radiation.safety@dhs.vic.gov.au Tel: 1300 767 469 Fax: 1300 769 274
Western Australia	Secretary, Radiological Council Locked Bag 2006 PO Nedlands WA 6009 Email: radiation.health@health.wa.gov.au Tel: (08) 9346 2260 Fax: (08) 9381 1423
Australian Capital Territory	Manager Radiation Safety Radiation Safety Section ACT Health Locked Bag 5 Weston Creek ACT 2611 Email: radiation.safety@act.gov.au Tel: (02) 6207 6946 Fax: (02) 6207 6966
Northern Territory	Manager Radiation Protection Radiation Protection Section Department of Health and Families GPO Box 40596 Casuarina NT 0811 Email: envirohealth@nt.gov.au Tel: (08) 8922 7152 Fax: (08) 8922 7334

This table was correct at the time of printing but is subject to change from time to time. For the most up to date list, the reader is advised to consult the ARPANSA web site (www.arpansa.gov.au).

For after hours emergencies only, the police will provide the appropriate emergency contact number.

Annex N

ARPANSA Radiation Protection Series Publications

ARPANSA has taken over responsibility for the administration of the former NHMRC Radiation Health Series of publications and for the codes developed under the *Environment Protection (Nuclear Codes) Act 1978*. The publications are being progressively reviewed and republished as part of the *Radiation Protection Series*. All of the Nuclear Codes have now been republished in the *Radiation Protection Series*.

All publications listed below are available in electronic format, and can be downloaded free of charge by visiting ARPANSA's website at www.arpansa.gov.au/Publications/codes/index.cfm.

Radiation Protection Series publications are available for purchase directly from ARPANSA. Further information can be obtained by telephoning ARPANSA on 1800 022 333 (freecall within Australia) or (03) 9433 2211.

- RPS 1 Recommendations for Limiting Exposure to Ionizing Radiation (1995) and National Standard for Limiting Occupational Exposure to Ionizing Radiation (republished 2002)
- RPS 2 Code of Practice for the Safe Transport of Radioactive Material (2008)
- RPS 2.1 Safety Guide for the Safe Transport of Radioactive Material (2008)
- RPS 3 Radiation Protection Standard for Maximum Exposure Levels to Radiofrequency Fields – 3 kHz to 300 GHz (2002)
- RPS 4 Recommendations for the Discharge of Patients Undergoing Treatment with Radioactive Substances (2002)
- RPS 5 Code of Practice and Safety Guide for Portable Density/Moisture Gauges Containing Radioactive Sources (2004)
- RPS 6 National Directory for Radiation Protection – Edition 1.0 (2004)
- RPS 7 Recommendations for Intervention in Emergency Situations Involving Radiation Exposure (2004)
- RPS 8 Code of Practice for the Exposure of Humans to Ionizing Radiation for Medical Research Purposes (2005)
- RPS 9 Code of Practice and Safety Guide for Radiation Protection and Radioactive Waste Management in Mining and Mineral Processing (2005)
- RPS 10 Code of Practice and Safety Guide for Radiation Protection in Dentistry (2005)
- RPS 11 Code of Practice for the Security of Radioactive Sources (2007)
- RPS 12 Radiation Protection Standard for Occupational Exposure to Ultraviolet Radiation (2006)
- RPS 13 Code of Practice and Safety Guide for Safe Use of Fixed Radiation Gauges (2007)
- RPS 14 Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)
- RPS 14.1 Safety Guide for Radiation Protection in Diagnostic and Interventional Radiology (2008)
- RPS 14.2 Safety Guide for Radiation Protection in Nuclear Medicine (2008)

- RPS 14.3 Safety Guide for Radiation Protection in Radiotherapy (2008)
- RPS 15 Safety Guide for Management of Naturally Occurring Radioactive Material (NORM) (2008)
- RPS 16 Safety Guide for the Predisposal Management of Radioactive Waste (2008)

Those publications from the NHMRC *Radiation Health Series* that are still current are:

- RHS 3 Code of practice for the safe use of ionizing radiation in veterinary radiology: Parts 1 and 2 (1982)
- RHS 8 Code of nursing practice for staff exposed to ionizing radiation (1984)
- RHS 9 Code of practice for protection against ionizing radiation emitted from X-ray analysis equipment (1984)
- RHS 10 Code of practice for safe use of ionizing radiation in veterinary radiology: part 3-radiotherapy (1984)
- RHS 13 Code of practice for the disposal of radioactive wastes by the user (1985)
- RHS 14 Recommendations for minimising radiological hazards to patients (1985)
- RHS 15 Code of practice for the safe use of microwave diathermy units (1985)
- RHS 16 Code of practice for the safe use of short wave (radiofrequency) diathermy units (1985)
- RHS 18 Code of practice for the safe handling of corpses containing radioactive materials (1986)
- RHS 19 Code of practice for the safe use of ionizing radiation in secondary schools (1986)
- RHS 21 Revised statement on cabinet X-ray equipment for examination of letters, packages, baggage, freight and other articles for security, quality control and other purposes (1987)
- RHS 22 Statement on enclosed X-ray equipment for special applications (1987)
- RHS 24 Code of practice for the design and safe operation of non-medical irradiation facilities (1988)
- RHS 25 Recommendations for ionization chamber smoke detectors for commercial and industrial fire protection systems (1988)
- RHS 28 Code of practice for the safe use of sealed radioactive sources in borehole logging (1989)
- RHS 30 Interim guidelines on limits of exposure to 50/60Hz electric and magnetic fields (1989)
- RHS 31 Code of practice for the safe use of industrial radiography equipment (1989)
- RHS 34 Safety guidelines for magnetic resonance diagnostic facilities (1991)
- RHS 35 Code of practice for the near-surface disposal of radioactive waste in Australia (1992)
- RHS 36 Code of practice for the safe use of lasers in schools (1995)
- RHS 38 Recommended limits on radioactive contamination on surfaces in laboratories (1995)

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- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) 2002b, *Recommendations for the Discharge of Patients Undergoing Treatment with Radioactive Substances*, Radiation Protection Series No. 4, ARPANSA, Yallambie.
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- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) 2007, *Code of Practice for the Security of Radioactive Sources*, Radiation Protection Series No. 11, ARPANSA, Yallambie.
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) 2008a, *Code of Practice for the Safe Transport of Radioactive Material 2008 Edition*, Radiation Protection Series No. 2, ARPANSA, Yallambie.
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) 2008b, *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation*, Radiation Protection Series No. 14, ARPANSA, Yallambie.
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) 2008c, *Safety Guide for Radiation Protection in Nuclear Medicine*, Radiation Protection Series No. 14.2, ARPANSA, Yallambie.

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Some web sites of organisations where information on radiation protection in radiotherapy may be obtained are:

International Atomic Energy Agency (IAEA): <http://www.iaea.org/>

International Commission on Radiological Protection (ICRP): <http://www.icrp.org/>

International Commission on Radiation Units and Measurements (ICRU): <http://www.icru.org/>

Glossary

Absorbed dose

the energy absorbed per unit mass by matter from ionizing radiation which impinges upon it.

Absorbed dose, D , is defined by the expression:

$$D = \frac{dE}{dm}$$

where dE is the mean energy imparted by ionizing radiation to matter of mass dm .

The unit of absorbed dose is joule per kilogram (J kg^{-1}), with the special name gray (Gy).

Authorisation

a written permission granted by the relevant regulatory authority to perform specified practices. The form of an authorisation can include a licence, registration, or accreditation.

Brachytherapy

(brachy from the Greek for 'near', and therapy : treatment) involves the use of radioactive sources placed within or immediately adjacent to the target volume.

Carer

a person who voluntarily, willingly and knowingly assists or helps in the care, support or comfort of patients undergoing a diagnostic or therapeutic medical radiation procedure.

Constancy testing

a series of tests carried out; (a) to ensure that the functional performance of equipment meets established criteria; or (b) to enable the early recognition of changes in the properties of components of the equipment.

Contamination

the presence of radioactive substances in or on a material or the human body or other place where they are undesirable or could be harmful.

Defence in depth

the application of more than a single protective measure for a given safety objective such that the objective is achieved even if one or more of the protective measures fails.

Deterministic effect

an effect, such as partial loss of function of an organ or tissue, caused by radiation and manifest only above some threshold of dose, the severity of the effect depending upon the dose received.

Detriment

a measure, or measures, of harm caused by exposure to radiation and usually taken to mean health detriment; it has no single definition, but can be taken to be an attribute or a collection of attributes which measure harm, such as attributable probability of death and reduction of life expectancy.

Dose

a generic term which may mean absorbed dose, **equivalent dose** or effective dose depending on the context.

Dose constraint

a prospective restriction on anticipated dose, primarily intended to be used to discard undesirable options in an optimisation calculation.

In occupational exposure, a dose constraint may be used to restrict the options considered in the design of the working environment for a particular category of employee.

In **medical exposure**, a dose constraint for volunteers in medical research may be used to restrict the options considered in the design of an experimental protocol.

In **public exposure**, a dose constraint may be used to restrict the exposure of the critical group from a particular source of radiation.

Effective dose

a measure of dose which takes into account both the type of radiation involved and the radiological sensitivities of the organs and tissues irradiated.

Effective dose, E , is the sum of weighted equivalent doses in all organs and tissues of the body. It is given by the expression:

$$E = \sum_T w_T H_T$$

where H_T is the equivalent dose in organ or tissue T and
 w_T is the weighting factor for that organ or tissue T .

The unit of effective dose is the same as for equivalent dose, J kg^{-1} , with the special name sievert (Sv).

Employee

a person who works for an employer within an operation.

Employer

an operator who or which engages people to work within an operation; the term employer includes a self-employed person.

Equipment servicing agency

a person involved in the commissioning, maintenance or repair of radiotherapy equipment who is, or who employs, a service engineer or technician.

Equivalent dose

a measure of dose in organs and tissues which takes into account the type of radiation involved.

Equivalent dose, H , is a weighted dose in an organ or tissue, with the radiation weighting factor(s) determined by the type and energy of the radiation to which the organ or tissue is exposed. The equivalent dose H_T in organ or tissue T is given by the expression:

$$H_T = \sum_R w_R D_{T,R}$$

where $D_{T,R}$ is the absorbed dose averaged over the organ or tissue T due to radiation R and
 w_R is the radiation weighting factor for that radiation.

The unit of equivalent dose is the same as for absorbed dose, $J\ kg^{-1}$, with the special name sievert (Sv).

Exposure

the circumstance of being exposed to radiation.

Facility

for the purposes of this Safety Guide, a facility is any site where radiotherapy is conducted. This includes a hospital or hospital department, a clinic, or consulting rooms.

Half-life

in relation to radioactive decay, the time required for the quantity of a radionuclide to decrease to one half of its initial value.

Ionizing radiation

electromagnetic or particulate radiation capable of producing ions directly or indirectly, but does not include electromagnetic radiation of a wavelength greater than 100 nanometres.

Ionizing radiation apparatus

an apparatus that produces ionizing radiation when energised, or when assembled or repaired is capable of doing so when energised.

Justification

the notion that human activities which lead to exposure to radiation should be justified, before they are permitted to take place, by showing that they are likely to do more good than harm.

Medical exposure

exposure of a person to radiation received as a patient undergoing medical diagnosis or therapy, or as a volunteer in medical research, or non-occupational exposure received as a consequence of assisting an exposed patient.

Occupational exposure

exposure of a person to radiation which occurs in the course of that person's work and which is not excluded exposure¹⁵.

Optimisation

the process of maximising the net benefit arising from human activities which lead to exposure to radiation.

Practice

a type of human activity; in a radiological context, a human activity which may result in exposure to ionizing radiation and to which a system of radiation protection applies.

¹⁵ Excluded exposure is, in the context of occupational exposure, the component of exposure which arises from natural background radiation, provided that any relevant action level, or levels, for the workplace are not exceeded and that the appropriate authority does not prohibit its exclusion.

Prescribed radiotherapy treatment

means an order, in written or electronic form, for the intentional irradiation of a person for therapeutic purposes, stating:

- (a) particulars of the radiation source to be used; and
- (b) the amount, and method of delivery, of the radiation.

Public exposure

exposure of a person, or persons, to radiation which is neither occupational nor medical exposure.

Qualified Expert

a person who:

- (a) is qualified in the application of the physics of therapeutic or diagnostic uses of ionizing radiation; and
- (b) has been recognised by the relevant regulatory authority as being able to perform the dosimetric calculations, radiation measurements and monitoring relevant to the person's area of expertise¹⁶.

Radiation incident

any unintended or ill-advised event when using ionizing radiation apparatus, specified types of non-ionizing radiation apparatus or radioactive substances, which results in, or has the potential to result in, an exposure to radiation to any person or the environment, outside the range of that normally expected for a particular practice, including events resulting from operator error, equipment failure, or the failure of management systems that warranted investigation.

Radiation Medical Practitioner

the practitioner authorised by the relevant regulatory authority and responsible for the overall conduct of the procedure involving the exposure of the patient to ionizing radiation. In radiotherapy, this person will normally be a radiation oncologist, but in some circumstances might be, for example, a dermatologist or an ophthalmologist.

Radiation Oncologist

a person who:

- (a) is registered as a medical practitioner by the relevant Medical Board; and
- (b) (i) is a Fellow of the Royal Australian and New Zealand College of Radiologists (RANZCR) in the Faculty of Radiation Oncology; or
(ii) has obtained another postgraduate qualification in Radiation Oncology deemed to be equivalent to the Fellowship of the RANZCR by the relevant regulatory authority.

Radiation Oncology Medical Physicist

for the purpose of this Safety Guide, is a person who is qualified to perform the necessary dosimetric calculations, measurements and monitoring. A suitable person will:

- (a) be on the Register of Radiation Oncology Medical Physicists held by the Australasian College of Physical Scientists and Engineers in Medicine; or

¹⁶ Competency requirements for a qualified expert will be listed in future editions of the *National Directory for Radiation Protection*.

- (b) have an equivalent level of training, skills, knowledge and expertise to a person listed on the Australasian College of Physical Scientists and Engineers in Medicine Register of Radiation Oncology Medical Physicists as determined by the relevant regulatory authority.

Radiation Therapist

a person who:

- (a) has obtained a Bachelor of Applied Science in Medical Radiation Science (Radiation Therapy) or its equivalent, in a course recognised by the Professional Accreditation and Education Board of the Australian Institute of Radiography, and where applicable, has successfully completed a Professional Development Year (PDY); and
- (b) holds a current Statement of Accreditation, or equivalent, satisfying the requirement for ordinary membership of the Australian Institute of Radiography; and
- (c) is eligible for registration/licensing by the relevant regulatory authority.

Radioactive material

material which spontaneously emits ionizing radiation as a consequence of radioactive decay.

Radiotherapy

the therapeutic use of ionizing radiation from radiation-producing equipment and sealed radioactive sources to treat disease.

Radiotherapy equipment

means an ionizing radiation apparatus or a sealed source apparatus used in the delivery of radiotherapy.

Relevant regulatory authority

the radiation protection authority or authorities designated, or otherwise recognised, for regulatory purposes in connection with protection and safety relating to medical applications of ionizing radiation. A list of relevant regulatory authorities in Australia is included in Annex M of this Safety Guide.

Responsible person

in relation to any radioactive source, radiation-producing equipment, prescribed radiation facility or premises on which radioactive sources are stored or used means the legal person¹⁷:

- (a) having overall management responsibility including responsibility for the security and maintenance of the source, radiation-producing equipment, facility or premises;
- (b) having overall control over who may use the source, radiation-producing equipment, facility or premises; and
- (c) in whose name the source, radiation-producing equipment, facility or premises would be registered if this is required.

Sealed source

radioactive material that is permanently sealed in a capsule or closely bounded and in a solid form.

¹⁷ A legal person can be a natural person, a body corporate, a partnership or any other entity recognised as a 'legal person' by the legislation in the jurisdiction.

Sealed source apparatus

an apparatus that produces ionizing radiation by virtue of the fact that it contains radioactive material in the form of a sealed source.

Stochastic effect

an effect known to occur sometimes as a consequence of exposure to radiation, but which may or may not be expressed in a particular exposed person, the likelihood of the effect occurring being a function of the dose received.

Supplier

any person who designs, manufactures, produces, constructs, leases, or hires out radiotherapy equipment. (An importer of radiotherapy equipment is considered a supplier of the radiotherapy equipment).

Teletherapy

(tele from the Greek for 'at a distance') involves the use of irradiating equipment to deliver radiation doses to a target tissue volume at a distance from the source. Teletherapy equipment includes:

- X-ray tubes using beam of ionizing radiation generated electronically to produce kilovoltage X-ray beams, for direct field treatment;
- linear accelerators using electron beams to produce photons or electron beams of megavoltage energy, using either isocentric mounting or directional mounting;
- intra-operative radiotherapy (IORT) devices, using low energy X-rays or high energy electron beams; and
- sealed radioactive substances as the source of ionizing radiation, using isocentric mounting or direct field treatment.

Written

for the purposes of this Safety Guide, written can infer either handwritten, typewritten or electronic documentation.

X-ray

ionizing electromagnetic radiation emitted during the transition of an atomic electron to a lower energy state or during the rapid deceleration of a charged particle.

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