



Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**

SAFETY GUIDE

Radiation Protection in Nuclear Medicine

RADIATION PROTECTION SERIES No. 14.2

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
16 July 2008, and endorsed for publication by the
Radiation Health & Safety Advisory Council on 8 August 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 Chief Executive Officer of ARPANSA in August 2008

Foreword

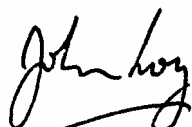
The *Safety Guide for Radiation Protection in Nuclear Medicine* is one of three guides that support the application of the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (the Code)*.

The use of unsealed radionuclides in medicine is increasing throughout Australia as therapeutic and diagnostic radiopharmaceuticals as well as positron emission tomography (PET) imaging are becoming more common in the clinical environment. As *the Code* makes clear, the fundamentals of justification and optimisation must apply when undertaking nuclear medicine 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 diagnostic objective. This *Safety Guide* encourages the use of Diagnostic Reference Levels (DRLs) as a tool to support optimisation of protection to the patient. The protection of occupationally exposed staff and the general public are also 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.

The Code establishes the regulatory requirements for the use of ionizing radiation in medicine. This *Safety Guide* is written to give practitioners in nuclear medicine a best practice approach to 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 and was subsequently revised by the working group. 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 *Safety Guide for Radiation Protection in Nuclear Medicine* was again revised by the working group to take into account the comments made in the submissions. The Radiation Health Committee approved the final Safety Guide at its meeting of 16-17 July 2008 and the Radiation Health and Safety Advisory Council advised me to adopt the Safety Guide at its meeting on 8 August 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.



John Loy PSM
CEO of ARPANSA

27 August 2008

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1. Introduction

1.1 CITATION

This Safety Guide may be cited as the *Safety Guide for Radiation Protection in Nuclear Medicine* (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) (ARPANSA 2008b) (hereafter called 'the Code'). It provides advice and guidance on good radiation **practice** and on meeting the requirements of the Code.

1.3 PURPOSE

This Safety Guide applies to individuals and to centres where nuclear medicine procedures are undertaken for diagnostic and therapeutic purposes. The advice and guidance provided are not mandatory, however, it is recommended that good radiation practice should be implemented in the interests of reducing radiation **exposure** and risks. This Safety Guide provides information to help obtain satisfactory clinical outcomes that optimise exposure to the patient with minimum exposure to persons involved with the procedure and to the general public. It includes information on:

- allocation of responsibilities;
- principles of **justification** and **optimisation** for nuclear medicine procedures;
- provision of appropriate facilities and equipment; and
- adoption of procedures to minimise exposure to radiation.

1.4 SCOPE

This Safety Guide applies to the following radiation exposures in nuclear medicine:

- the exposure of patients as part of their medical diagnosis or treatment;
- the exposure of individuals as part of health screening programs;
- the exposure of individuals participating in research programs¹;
- the exposure of individuals as part of medico-legal procedures;
- the **occupational exposure** of individuals arising from the practice of nuclear medicine;
- the exposure of **carers**, being those individuals who voluntarily assist patients undergoing nuclear medicine procedures;
- the exposure of individuals as part of occupational health surveillance; and

¹ See also the *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes* (2005), ARPANSA (ARPANSA 2005a)

- the exposure of members of the public.

This Safety Guide does not apply to the practice of veterinary nuclear medicine, dentistry, radiology, radiotherapy using external radiation beams or sealed radioactive sources, or the individuals involved with them, as they are covered by separate Codes and Safety Guides (ARPANSA 2005a ARPANSA 2005b, ARPANSA 2008c, ARPANSA 200y, ARPANSA 200z).

1.5 STRUCTURE

This Safety Guide sets out information that should assist in achieving the levels of protection specified in the Code. Whilst 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 nuclear medicine and therefore the use of this Safety Guide is recommended for establishing appropriate radiation protection procedures. This Safety Guide does not restrict users from developing their own institutional 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 are 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.

2. Justification

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

1. The practice involving exposure to radiation needs to be justified in principle. In this context, the continuing involvement of medical professional societies is important, as matters of effective medical practice will be central to this judgement (IAEA 2002).
2. Each procedure should be subjected to a further case-by-case justification by the radiation medical practitioner responsible for the overall conduct of the procedure involving the exposure of the patient to ionizing radiation (ICRP 1996). In nuclear medicine, this person will usually be a **nuclear medicine specialist**.

The decision to perform a nuclear medicine procedure rests upon a professional judgement of the benefits that accrue to the total health of the patient, as opposed to any detrimental biological effects that might be caused by the ionizing radiation. The benefit will be the potential diagnostic information or therapeutic effect of a radionuclide therapy procedure resulting from the **medical exposure**, 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. For the radiation doses generally arising in diagnostic nuclear medicine a possible detriment is the low probability of inducing a cancer or a genetic mutation which may be passed on to future offspring. These effects are thought to be stochastic in nature, meaning that the probability of occurrence increases with increasing dose and there is no safe threshold below which they cannot occur. The age of the patient is also relevant in the risk assessment.

The justification process should also take into account the efficacy, benefits and risks of using other imaging modalities involving no, or less, ionizing radiation e.g. ultrasound and magnetic resonance imaging (IAEA 2002). Also influencing this choice will be the availability of the other imaging modalities.

Nuclear medicine examinations should only be undertaken where there is a valid clinical indication.

There are special cases that warrant further justification including the medical exposure of the 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, nuclear medicine examinations of children require a higher level of justification since children are more susceptible to the induction of radiation induced cancers (ICRP 1991a, ICRP 1991b, Delongchamp *et al* 1997, Preston *et al* 2008) and they have a longer life expectancy during which the manifestation of possible harmful effects of radiation may occur. The life-time cancer risk following *in utero* exposure is regarded as being similar to that following irradiation in

early childhood, i.e., at most about three times that of the population as a whole (ICRP 2007b).

Research that exposes humans to ionizing radiation should conform to the requirements published by ARPANSA (ARPANSA 2005a). Volunteers should, where practicable, be over 40 years of age, and preferably be over 50. Persons under the age of 18 years should normally not be permitted to be exposed to radiation for research purposes. Researchers have the responsibility to provide dose and risk information to volunteers and to enquire about previous exposures of the volunteers. In all cases, exposures should be permitted only when the volunteers understand the risks involved and participate willingly.

Mass screening (non-referral) of targeted population groups using ionizing radiation should be justified by clinical evidence. Breast cancer screening in radiology provides an example of one screening program that may be justified on the basis of studies that have demonstrated a net benefit to society. In all instances a full disclosure of the potential detriment, including but not limited to the radiation risks, needs to be made to the individual.

3. Roles, Duties and Responsibilities

A nuclear medicine centre may vary in size and scope from a small stand-alone facility to a large department within a large academic hospital. It is recognised that the types of procedures may vary between centres.

The following sections outline the roles, duties and responsibilities of the professional groups who perform those tasks within a centre. Some duties can only be performed by a specific professional group; for example medical matters requiring a specialist doctor can only be undertaken by the nuclear medicine specialist. Other roles such as that of Radiation Safety Officer (RSO) or radiopharmaceutical preparation may be performed by a range of professionals, depending upon the circumstances within the centre.

3.1 RESPONSIBLE PERSON

The **Responsible Person** is the legal entity which has overall management responsibility for radiation matters in the jurisdiction under which the centre operates (Clause 3.1 of the Code), and may be an individual person, a body corporate or a partnership. Whilst some tasks may be delegated to the nuclear medicine specialist or to the RSO, the ultimate responsibility lies with the Responsible Person.

3.1.1 Radiation Management Plan

The Responsible Person needs to ensure that a Radiation Management Plan is in place to ensure radiation safety. The nuclear medicine component of the Radiation Management Plan will normally be developed by the RSO working with the nuclear medicine specialist and other relevant staff.

The plan should be signed and dated by the Responsible Person and the RSO, where appointed (see Section 3.8 of this Safety Guide). It should be viewed as a 'living document' so that as changes occur to equipment, operators or work practices, it is updated to reflect the changing nature of the use of radiation at the centre. The Radiation Management Plan should be reviewed within a designated timeframe of no longer than every 5 years. Revisions should be signed and dated by the Responsible Person and the RSO.

The relevant sections of the Radiation Management Plan should form part of an orientation program for new staff.

Where the institution includes other radiation modalities, such as diagnostic radiology and/or radiotherapy, the nuclear medicine Radiation Management Plan will usually be a subset of the institution's Radiation Management Plan. In these circumstances, the Radiation Management Plan may establish a Radiation Safety Committee whose members will include the RSO and representatives from the various radiation modalities. The Radiation Safety Committee will normally, on behalf of the Responsible Person, oversee the development and implementation of the Radiation Management Plan.

Schedule A of the Code lists the requirements for the Radiation Management Plan and Annex A of this Guide provides guidelines for the preparation of the Plan specific for nuclear medicine. It includes the following issues:

- storage, handling and disposal of **radioactive materials**;
- the protection of employees, patients and members of the public;
- the protection of health professionals, other than those with nuclear medicine training, who may have close contact with patients undergoing nuclear medicine procedures;
- the protection of individuals (carers), who voluntarily help in the care, support or comfort of patients undergoing nuclear medicine procedures;
- the accidental, abnormal or unplanned exposures to radiation; and
- the relevant regulatory requirements that need to be satisfied.

3.1.2 Personal radiation monitoring and dose limits

Clause 3.1.9 of the Code requires that the Responsible Person provides a personal radiation monitor to all employees who are likely to receive an annual **effective dose** of more than 1 mSv, which is the case for the majority of professional staff in nuclear medicine centres.

Whilst the Code requires that the Responsible Person, when planning and designing the workplace or work practices, keeps 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 Responsible Person should endeavour to keep individual doses as low as reasonably achievable (**ALARA principle**), economic and social factors being taken into account.

3.1.3 Qualified expert

The Responsible Person needs to ensure that a **qualified expert** is available, either as an employee or retained as a consultant, for consultation on optimisation and to give advice on matters relating to radiation protection, as required. The qualified expert is a medical physicist with suitable training and experience, usually in nuclear medicine physics.

3.2 NUCLEAR MEDICINE SPECIALIST (RADIATION MEDICAL PRACTITIONER)

The nuclear medicine specialist, being the person who fulfils the role of the radiation medical practitioner specified in Clause 3.2 of the Code is responsible for the clinical management of the patient undergoing a diagnostic or therapeutic nuclear medicine procedure.

The ultimate decision to perform or reject each individual nuclear medicine procedure lies with the specialist responsible for overseeing the nuclear medicine exposure (IAEA 2002, IAEA 2005). This decision should be based on the specialist's knowledge of the potential risks and benefits of the procedure, taking into account the clinical information, and the sensitivity and specificity of the procedure. The specialist may need to consult with the

patient and liaise with the **referrer**. The decision to proceed, or not to proceed, with a diagnostic procedure should be made after consideration of the timely availability of alternative tests, which involve less or no exposure to ionizing radiation. This is particularly pertinent in cases involving a pregnant woman or young child.

The nuclear medicine specialist should:

- consider current practices in relation to the appropriate use of imaging investigations and therapeutic procedures including their advantages and disadvantages, and the approximate dose of radiation each modality will deliver;
- ensure, when approving a diagnostic or therapeutic nuclear medicine procedure, that the procedure is clinically needed;
- prior to commencing a therapeutic procedure, undertake a consultation with the patient, including counselling for the patient (or guardian), on the potential radiation-related risks associated with the procedure (ICRP 2000a); and
- make available a copy of relevant images and reports, when requested by another medical practitioner, consistent with the centre's policy on requests for information.

3.3 REFERRER

The referrer of the patient for a diagnostic or therapeutic procedure needs to be satisfied that the procedure is justified. A written referral² is required that specifies the procedure/treatment requested and provides sufficient relevant clinical information to the nuclear medicine specialist. The referral should contain suitable patient identifying information (name, date of birth and gender) and adequate referrer contact details for consultative purposes. The referral should state a provisional diagnosis for investigation or a medical condition for treatment.

The referrer should also be satisfied that:

- the necessary clinical information is not available either from previous nuclear medicine examinations or from other tests and investigations; and
- the nuclear medicine procedure is appropriate to provide the required information to address the clinical question.

The referral should also alert the nuclear medicine specialist when the referrer is aware that a female patient is pregnant or is breast-feeding.

3.4 ADMINISTERING PERSON

The **administering person** is the person who fulfils the role of the operator specified in Clause 3.3 of the Code.

Before any procedure is undertaken, the administering person needs to comply with the centre's operating procedures on how to identify the patient

² This referral may be in hard copy or electronic form.

correctly. Identification should be established by the name, gender and at least one of: date of birth, address and any unique patient number. The administering person needs to ensure that the correct procedure will be performed. If there is a concern about the relevance of the procedure, then this issue should be taken up with the nuclear medicine specialist.

The administering person needs to:

- have undertaken suitable intravenous injection and cannulation training before commencing any administration procedures;
- use protective equipment designed to reduce radiation exposure (e.g. syringe shields, lead pots) and wear an **approved** personal radiation monitoring device when handling radioactive materials;
- ensure that only persons necessary to the procedure are present when performing administrations; and
- report any instance of accidental, abnormal or unplanned exposure to the RSO, and where required also to the Responsible Person, in accordance with the requirements of the Radiation Management Plan.

Additional responsibilities are outlined in Section 4 of this Safety Guide, which deals with optimisation of protection of the patient.

3.5 NUCLEAR MEDICINE TECHNOLOGIST

The **nuclear medicine technologist** is responsible for performing nuclear medicine procedures as prescribed by the nuclear medicine specialist in accordance with the centre's written standard protocols.

This will include one or more of the following duties:

- perform imaging and *in vitro* protocols to ensure optimal data acquisition and analysis;
- prepare, dispense and administer radiopharmaceuticals;
- perform quality assurance procedures for radiopharmaceuticals, instrumentation and image quality.

The nuclear medicine technologist's role may include the responsibilities of the administering person (Section 3.4) and, depending on the size and scope of the centre where he/she is employed, the departmental radiation safety officer (Section 3.8), and some of the duties of the person preparing radiopharmaceuticals (Section 3.6) and of the **nuclear medicine physicist** (Section 3.7).

3.6 PERSON PREPARING RADIOPHARMACEUTICALS

Nuclear medicine centres have various ways of obtaining and preparing radiopharmaceuticals, ranging from the supply of unit doses by an outside provider, to preparing radiopharmaceuticals using commercial kits, to a full on-site service with manufacturing and blood cell labelling.

Within a nuclear medicine centre the person responsible for radiopharmaceuticals needs to develop systems for the:

- procurement of radionuclides/radiopharmaceuticals;
- storage and waste management of radionuclides/radiopharmaceuticals;
- development of safe procedures and practices for the preparation and manipulation of radiopharmaceuticals, in consultation with relevant staff; and
- implementation of a quality assurance program for radiopharmaceuticals.

In many institutions the procurement, storage, reconstitution of 'cold kits', dispensing of patient radiopharmaceutical doses, and cell labelling may be performed by a nuclear medicine technologist, or a medical physicist. More complex radiopharmaceutical preparation requires the expertise of a **radiopharmacist/radiochemist**.

The radiopharmacist/radiochemist, whether employed in a nuclear medicine department or a centralised **radiopharmacy**, plays, in addition to the above duties, a central role in the:

- in-house manufacture of radiopharmaceuticals;
- production of cyclotron radionuclides and derived radiopharmaceuticals;
- implementation of a comprehensive quality assurance program for radiopharmaceuticals; and
- provision of advice on the safe and efficacious use of radiopharmaceuticals.

In centralised radiopharmacies, the radiopharmacist/radiochemist may also be appointed as the RSO.

3.7 QUALIFIED EXPERT (NUCLEAR MEDICINE PHYSICIST)

Clause 3.1.24 of the Code requires that a Qualified Expert is available for consultation on optimisation of medical exposures, including clinical dosimetry and quality assurance, and to give advice on matters relating to radiation protection. A medical physicist with specialist experience in nuclear medicine – a nuclear medicine physicist – would satisfy these requirements. This person may be an employee or an external consultant.

The nuclear medicine physicist works closely with the nuclear medicine specialist and technologists in the optimisation of clinical studies - through image acquisition, analysis and display optimisation and ongoing oversight of the quality control of equipment. In many centres, some of these duties may also be undertaken by an experienced nuclear medicine technologist. The nuclear medicine physicist may also be appointed as the RSO.

In addition, a medical physicist is required to provide Human Research Ethics Committees with a radiation dose estimation and risk assessment for any research studies that involve the research participants receiving an exposure from ionizing radiation, in accordance with the requirements of RPS8 (ARPANSA 2005a).

3.8 RADIATION SAFETY OFFICER (RSO)

The Responsible Person may delegate radiation protection duties to an RSO. 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 centre. The RSO should ensure that the Responsible Person is kept informed of the radiation safety status of the centre.

The RSO may be an employee or an external consultant. 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.

The RSO may be directed by the Responsible Person to develop an institutional radiation safety manual or Radiation Management Plan to cover the use of radioactive sources. In developing and implementing the plan, the RSO should liaise with the relevant nuclear medicine staff. The Radiation Management Plan would normally assign the duties listed in Annex B to the RSO.

In a tertiary-level hospital, the RSO's duties will cover all uses of radiation within the institution including radiotherapy and diagnostic radiology as well as nuclear medicine. A departmental RSO may be designated who will be responsible for radiation safety within that department.

In nuclear medicine the departmental RSO may be a nuclear medicine physicist, an experienced nuclear medicine technologist or a radiopharmacist/radiochemist.

4. Optimisation of Protection for Medical Exposures

4.1 DIAGNOSTIC PROCEDURES

When considering the justification for a medical exposure, the benefit is weighed against the detriment, including radiation effects. For diagnostic procedures the potential detriment is the risk of inducing cancer. This risk is greater in children and decreases with age. For effective doses greater than 100 mSv the overall lifetime risk of fatal cancer is estimated to be 5% per Sv. (ICRP 2007b). Whilst there is no epidemiological evidence of an increased risk below about 100 mSv, using the LNT hypothesis it is possible to extrapolate the risk to lower doses although there is uncertainty in such estimates. An approximate guide is given by age-specific mortality risk factors in a general population. For an effective dose of 20 mSv, the nominal risk is about 1 in 1200 for adults aged 30 to 60 years at the time of exposure. For adults aged 70 or more the risk falls to less than 1 in 3000. However, for children up to 10 years old the risk is about 1 in 450 (NRPB 1993).

Most diagnostic procedures expose the patient to considerably less than 20 mSv (Table 1). However, patients may undergo multiple investigations, so minimising dose is a prudent approach.

Table 1: Approximate radiation dose to adults from diagnostic nuclear medicine procedures

Effective Dose Range ^a (mSv)	Procedures
< 1 mSv	GIT motility, lymphoscintigraphy, cystogram, GFR
1-5 mSv	Biliary system, liver/spleen, lung V/Q, renal, thyroid, parotid imaging with ^{99m} Tc
5 – 10 mSv	Bone, parathyroid, GHPS, infection, blood pool, brain or tumour imaging with ^{99m} Tc; tumour imaging with ¹²³ I-MIBG
10 – 20 mSv	Myocardial perfusion imaging with all ^{99m} Tc stress/rest protocols; PET/CT ^b , SPECT/CT ^b
> 20 mSv	Infection or tumour imaging with ⁶⁷ Ga; tumour imaging or myocardial perfusion with ²⁰¹ Tl

^a Corresponding to the diagnostic reference levels, where available, of radiopharmaceutical activity administered to adult patients (www.anzsnm.org.au).

^b Includes a low-dose CT scan for anatomic localisation and attenuation correction.

Once clinically justified, each diagnostic examination should be conducted so that the dose to the patient is the lowest necessary to achieve the clinical aim. The quality of the images and the complexity of the examination should be sufficient for the intended purpose of the procedure. Since patients may accrue direct benefits from medical exposures, it is not appropriate to impose limits on the doses received from justified examinations.

The optimisation process necessarily requires a balance between administered activity (and thus patient radiation dose) and image quality. The activity administered should be sufficient to produce acceptable image quality for the diagnostic information being sought. It is important to plan the examination, including the requirement for image quality, to fit the clinical problem. This ensures that the investigation has the best opportunity to address the diagnostic question at hand. The size and age of the patient, and the time for which the patient can comfortably remain still for the study, will influence the activity required to be administered.

Patient activity surveys indicate wide variations in the activity administered to patients of standard body size (Smart and Towson 2000). This suggests that there may be scope for optimisation of patient protection and lower levels may be acceptable in some circumstances. However, it is important that dose reductions are not to such a degree that an unacceptable loss of diagnostic image quality or diagnostic information results. Clause 3.1.8 of the Code requires that **diagnostic reference levels** be implemented as a practical tool to aid in dose optimisation. (See also Section 7.7 of this Guide).

Repeat examinations should be minimised. If a nuclear medicine procedure needs to be repeated, this will result in increased exposure to both the patient and staff. Images of unacceptable quality may ultimately lead to repeat examinations. Repeat procedures may be necessary due to the poor quality of the radiopharmaceutical, incorrect administration of the radiopharmaceutical, technical problems with the imaging equipment or if the image does not provide the clinical information required. A comprehensive quality assurance program (see Section 7), which includes radiopharmacy and equipment quality control, is important to obtain optimal diagnostic information from the procedures. It should highlight any systematic errors or problems and ultimately lead to a lower repeat rate. Repeat procedures should not be undertaken unless the images are of a non-diagnostic quality.

4.2 RADIOPHARMACEUTICALS

4.2.1 Receipt and use of unit patient doses

For all unit patient doses (syringes, capsules or vials) the patient's name and the radionuclide and radiopharmaceutical form should be verified on arrival and the activity should be confirmed in a dose calibrator prior to administration to the patient.

4.2.2 Reconstitution of 'cold-kits'

The amount of radioactivity required for the reconstitution of kits is based on the number of patient doses for the day. The appropriate volume of generator eluate, or radionuclide solution, should be withdrawn and diluted if necessary. The withdrawal of the required activity and subsequent reconstitution of the kit should be performed behind a lead glass screen, preferably using a shielded syringe. Calculations should be checked, and the activity, volume and time recorded.

Where possible, visual inspection of the preparation through a lead glass shield should be performed to confirm that the appearance complies with the

manufacturer's specification. The total activity of the vial should be measured and the activity, calibration and expiry time calculated and recorded.

4.3 PATIENT IDENTIFICATION AND PROCEDURE CONFIRMATION

It is important that there is correct patient identification prior to administration of the radiopharmaceutical. The procedures for patient identification may depend upon institutional or practice guidelines. The following steps are suggested:

- Immediately prior to administration of the radiopharmaceutical, the patient identity should be rechecked by confirming patient name and one other form of identification such as date of birth or address. Questions should be asked in an open ended way, such as 'I need to check your details again, could you please tell me your name and date of birth.'
- The type of procedure should also be checked by asking the patient a question such as 'could you also tell me what type of scan you are to have'. If relevant, the administering person should also ask about pregnancy status and confirm the absence of breast-feeding.
- If the patient has poor comprehension of oral English, or is confused, a carer or an interpreter may be necessary to confirm the above details. Identity wrist bands on inpatients should always be checked.
- Immediately prior to the administration of the radiopharmaceutical the administering person should confirm that the patient identification matches that on the request form; and that the radiopharmaceutical (form and activity) and route of administration are appropriate for the study requested. At least one suitably trained and qualified person should verify the form and activity of the dispensed radiopharmaceutical. For a therapy procedure a second such person is required to verify the measurement of the dispensed activity (Clause 3.1.7 (b) of the Code).

4.4 RADIONUCLIDE THERAPY PROCEDURES

4.4.1 General

Therapeutic nuclear medicine requires special consideration because the high doses of radiation involved are at a level where a biological effect is produced. The levels of radiation constitute a much greater hazard to the patient, staff, the patient's carer and to the general public. In therapeutic nuclear medicine, the radionuclides used are often different from those used in diagnostic nuclear medicine; they are usually beta emitters with longer physical and biological half-lives. Therapy radionuclides may require different facilities to radionuclides used for diagnostic procedures, to ensure the safe preparation and administration of the radiopharmaceutical.

4.4.2 Medical supervision

It is important that the nuclear medicine specialist consults with the patient so that clinical issues and possible side-effects of the radiopharmaceutical are

discussed. The specialist should supervise the checking of the activity and the administration of the dose.

When radioiodinated compounds are to be administered for conditions other than thyroid disease, the use of a thyroid blocking agent should be considered for the patient in order to reduce the radiation dose to the thyroid.

4.4.3 Pregnancy and avoidance of conception

CONFIRMATION OF ABSENCE OF PREGNANCY

All female patients of childbearing age who are to be administered therapeutic radionuclides need to have pregnancy excluded by a definitive biochemical test, e.g. serum or urinary β -HCG, within 24 hours before the commencement of the treatment. However, a clinical history is necessary in all cases in order to facilitate accurate interpretation of these laboratory investigations (ANZSNM 1999).

AVOIDANCE OF CONCEPTION

Advice is to be given to females and males concerning the avoidance of conception after therapeutic administrations, if appropriate for the particular radionuclide therapy. The period of time for which pregnancy should be avoided is determined by the rate of clearance of the radionuclide from the body and by the time necessary to ensure that the underlying disease is controlled. The ICRP has recommended that a woman not become pregnant until the potential fetal dose would not exceed 1 mGy (ICRP 2000a). The female patient should be advised to avoid pregnancy according to Table 2:

Table 2: Periods for avoiding pregnancy to ensure that the dose to the fetus will not exceed 1 mGy after radionuclide therapy

Radionuclide and form	For treatment of	All activities up to (MBq)	Avoid pregnancy (months)
¹⁹⁸ Au-colloid	Malignancy	10 000	2
¹³¹ I-iodide	Thyrotoxicosis	800	4*
¹³¹ I-iodide	Thyroid carcinoma	6 000	4*
¹³¹ I-MIBG	Phaeochromocytoma	7 500	3
³² P-phosphate	Polycythemia	200	3
⁸⁹ Sr-chloride	Bone metastases	150	24
⁹⁰ Y-colloid or microspheres	Malignancy	4 000	1
⁹⁰ Y-colloid	Arthritic joints	400	0

(ARSAC 2000 and ICRP Publication 94, 2004)

* Most female patients are advised (ICRP 2004) not to become pregnant for at least six months after therapy with radioiodine. This is not primarily based upon potential heritable radiation effects or radiation protection considerations *per se*, but is based upon the need to be sure that: (1) the hyperthyroidism or cancer is controlled; and (2) another treatment with radioiodine will not be needed when the patient is pregnant.

Although there is no evidence that preconceptual irradiation of males can cause any abnormality in their offspring, it may be prudent to advise males receiving radionuclide therapy to avoid fathering children for a period of 4 months, which is greater than the life of a sperm cell (ARSAC 2000).

4.4.4 Design of treatment areas and wards

Where there is a risk of significant exposure from external radiation arising from the patient, or from any associated radioactive contamination, it may be necessary to admit the patient to a dedicated treatment facility. Advice should be sought from a medical physicist and/or the relevant regulatory authority on:

- the design of these facilities, including the need for extra shielding in the walls, ceiling or floors;
- the precautions for the protection of staff and visitors, including comforters and carers;
- a suitable waste management system; and
- any necessary radiation monitoring requirements.

Often these patients need to be accommodated in a single room with their own toilet, washing facilities and, perhaps, food preparation area. Ensuite toilet facilities are essential when significant amounts of radioactivity will be excreted in the urine or faeces (e.g. the use of ^{131}I -iodide for the treatment of thyroid cancer). Radioactive excreta should not be stored in containers, as this is likely to result in unnecessary exposure of staff and would also create a biological hazard. In most cases, excreta may be disposed of directly via the sewer system (ICRP 2004), although the relevant regulatory authority may require the use of delay tanks in certain circumstances.

4.4.5 Procedures for therapeutic radionuclides

Written protocols for each therapeutic radionuclide procedure should include:

- indications for therapy;
- type of radionuclide;
- the range of activity of the radionuclide generally used;
- the method of administration;
- the radiation hazard;
- the radiation safety procedures; and
- whether treatment is as an inpatient or outpatient.

In addition to the above issues, factors specific for the particular patient need to be considered. Such factors include the patient's general medical condition, as well as family or home circumstances such as the presence of infants at home, or in the case of the elderly, whether a carer is available at home. Based upon all the factors a decision is made as to whether treatment as an inpatient is required.

4.4.6 Preparation of therapeutic radiopharmaceuticals

Because of the physical nature of the radionuclides used and the activities required for therapy, the processes of preparing and dispensing therapeutic radiopharmaceuticals have a greater potential to expose operators to radiation than do procedures for diagnosis. These operations should therefore be performed in a **controlled area** with entry restricted to essential staff only. Careful consideration should be given to the amount of shielding required and to the measures to be taken to avoid radiation exposure from internal contamination.

Laboratories used for the preparation of therapeutic radiopharmaceuticals should meet the requirements set out in AS 2243.4-1998: *Safety in laboratories - Ionizing radiations* (AS 1998) and conform to the design standards in AS/NZS 2982.1:1997 *Laboratory design and construction – General requirements* (AS/NZS 1997). Laboratories for the preparation of therapeutic radiopharmaceuticals are generally graded as medium level, with some additional requirements to those for laboratories used only for the preparation of diagnostic radiopharmaceuticals.

It should be noted that:

- the introduction of shielding may interfere with laminar flow in a cabinet. Only items of equipment which are needed for the preparation should be present in the cabinet. Validation of the cabinet efficiency should therefore be performed with shielding in place;
- totally enclosed systems should be considered where there is a risk of airborne contamination of the operator;
- for routine preparations, remote handling equipment should be considered;
- the interaction of high energy beta particles with high atomic number materials (e.g. lead) will lead to the production of high energy X-rays (bremsstrahlung). Materials of low atomic number (e.g. plastic or aluminium) should be used for shielding pure beta emitters; and
- there may be high dose rates near the surface of open solutions of beta emitters. Where possible, tongs should be used for handling.

4.4.7 The discharge of patients undergoing treatment with unsealed radioactive substances

The ARPANSA publication *Recommendations for the Discharge of Patients Undergoing Treatment with Radioactive Substances*, RPS4 (ARPANSA 2002a) provides guidance on the conditions which should be met for the discharge from a hospital or clinic of a patient who is undergoing treatment with a radioactive substance, and the conditions for treatment as an outpatient. The recommendations take into account the dose rate external to the patient, and the potential for the spread of contamination from an unsealed radioactive substance excreted by the patient.

The Responsible Person needs to be able to demonstrate that the effective dose received by the carer is unlikely to exceed 5 mSv per treatment episode and the dose to children and members of the public is unlikely to exceed

1 mSv per annum. Carers are individuals who are not normally occupationally exposed and who are appropriately informed of the radiation risks. Carers may be relatives and friends over the age of 18 years who are not pregnant.

4.4.8 Patient information

PRIOR TO RADIOPHARMACEUTICAL ADMINISTRATION

The arrangements for the treatment should be fully discussed with the patient prior to the administration of the radiopharmaceutical. In addition to the clinical issues and possible side effects of the radiopharmaceutical administration, the following should be discussed:

- the method of administration;
- whether an inpatient stay will be required;
- the precautions that the patient should follow to limit the amount of exposure to family and friends while in hospital and subsequently at home. These precautions will vary depending on the patient's domestic circumstances, such as whether the patient is the sole carer of any young children. (These precautions should be given verbally and confirmed in writing);
- whether the patient is involved with the close care of a child;
- the arrangements for transport home or to another institution, such as a nursing home;
- any restrictions that may apply if the patient is returning to work. The restrictions will vary depending on the type of work and whether the patient is in close proximity to other workers; and
- how long any restrictions or precautions should last.

AFTER RADIOPHARMACEUTICAL ADMINISTRATION

The patient and/or their carer should receive written information on:

- the type and radioactivity of the radiopharmaceutical administered;
- the date of administration;
- any specific radiation safety precautions;
- any restrictions on activities including travel home; and
- how long the restrictions or precautions should last.

The period of time during which patients (and their family and friends) should observe the restrictions will depend on the initial external dose rate from the patient and the rate of clearance of the radionuclide from the body. Tables 3 to 6 provide information on recommended restriction periods in the case of radioiodine (^{131}I) therapy. The recommended values are based on data from Woodings (2004) and Woodings *et al* (2005) using a **dose constraint** of 1 mSv (0.3 mSv for travel) for children and members of the public, and 5 mSv for the carer/partner (ARPANSA 2002a).

In the following tables 'minimise close contact' means that the patient should avoid spending more than 15 minutes a day within 1 metre of another person

and should attempt to maintain distances greater than 2 metres whenever possible (including while sleeping).

In cases of multiple treatments with radioiodine (and also for other therapies), advice on restriction periods should be sought from the nuclear medicine physicist or RSO.

Annex C gives an example of written instructions for radioiodine (¹³¹I) therapy. These can be adapted for therapy with other radiopharmaceuticals.

Table 3: Periods of restriction for patients receiving radioiodine (¹³¹I) therapy for thyrotoxicosis

Administered activity (MBq)	Recommended restriction periods (days)*		
	Minimise close contact with		
	Child 0 - 5 yrs or pregnant woman#	Person over 5 yrs	Carer or partner
600	20	14	5
500	18	13	3
400	16	11	1
300	14	8	1
200	10	4	1
100	4	1	1

* Patients should sleep alone during the restriction period.

It is recommended that a family member other than the patient (for example, the partner, or a grandparent) look after children under 3 years of age for at least the first 5 days of the restriction period – preferably in separate accommodation.

Table 4: Periods of restriction (days) for thyrotoxicosis patients to return to work

Administered activity (MBq ¹³¹ I)	Close worker (2 hours at 1 metre)	Close worker (8 hours at 1 metre)	Child care/nursery worker (1 hour at 0.3 metre and 4 hours at 1 metre)
600	1	4	5
500	1	3	4
400	1	1	2
300	1	1	1
200	1	1	1
100	1	1	1

Table 5: Periods of restriction, after discharge, for patients receiving radioiodine (¹³¹I) therapy for thyroid cancer after thyroidectomy

Residual activity (MBq ¹³¹ I)	Corresponding dose equivalent rate (µSv/h) at 1 metre from patient	Recommended restriction periods (days)*		
		Minimise close contact with		
		Child 0- 5 yrs or pregnant woman#	Person over 5 yrs	Carer or partner
600	36	5	3	1
500	30	5	3	1
400	24	4	2	1
300	18	3	1	1
200	12	2	1	1
100	6	1	1	1

* Patients should sleep alone during the restriction period.

It is recommended that a family member other than the patient (for example, the partner, or a grandparent) look after children under 3 years of age for at least the first day of the restriction period – preferably in separate accommodation.

Thyroid cancer patients may return to work the day after being discharged from hospital.

Travel in a private car does not give a significant dose to other people, so long as the patient does not sit alongside the driver or passenger(s). However, public transport (airline, bus, or boat) can involve people sitting close to each other and restrictions may be required on travel of long duration (Table 6). For long trips patients should be encouraged to find a place where they can sit alone. Long distance travel immediately after administration is not recommended due to the potential for travel sickness and the possibility for contamination.

Table 6: Number of hours of public transport allowed sitting next to the same person[#]

Residual activity (MBq ¹³¹I)	Corresponding dose equivalent rate (µSv/h) at 1 metre from patient	Travel time (h)
600	36	1.5
500	30	2.0
400	24	2.5
300	18	3.5
200	12	5.5
100	6	12.5

For more detailed advice consult the nuclear medicine specialist, a nuclear medicine physicist or RSO. Similar restrictions (in terms of limiting the amount of time) would apply to social activities that require a person to be close to other people.

Additional considerations are necessary if the patient is incontinent of urine. Annex 2 of RPS4 (ARPANSA 2002a) provides radionuclide-specific guidance in these circumstances.

4.4.9 Administration of therapeutic radioactive substances

The administered activity should not vary from the prescribed activity by more than 10%. However, it is recognised that for logistic reasons, there may be considerable variation between the activity of the radiopharmaceutical originally intended or ordered, and the activity available at the time of administration. For instance, iodine-131 may only be available in capsule form in certain discrete activities, or there may be some delay in time between calibration of the radioactivity at the time of manufacture and administration. If the delivered activity varies by more than 10% from the intended activity, a decision needs to be made by the nuclear medicine specialist on whether to administer the total available activity or if the delivered activity is greater than 10% from the intended activity, to defer the time of administration.

Treatments should be administered in a designated treatment area within the nuclear medicine centre or in the patient's own room on the ward, whichever creates the lesser radiation hazard. If the administered activity is such that the patient needs to be isolated after receiving the dose, the administration should be performed in the patient's own room. An additional wrist band which displays the radiation warning sign, the radionuclide, the administered activity, the date of administration and a contact number may be helpful.

If the patient has a condition likely to induce nausea or vomiting, this should be considered prior to oral therapy and at the time of discharge.

Prolonged intravenous infusion of gamma emitting radionuclides is an uncommon method of treatment but its use is increasing. Examples include

^{131}I -MIBG and ^{131}I -labelled antibodies. The prolonged infusion time and requirements for patient monitoring create a significant radiation hazard for staff. Some patients receiving infusion of ^{131}I -labelled antibodies require intensive monitoring both during and for a period immediately after administration. Local shielding will often be required to limit irradiation of the staff. Automatic methods of administration (e.g. a syringe pump) and remote patient monitoring devices should be used to minimise the time that the staff need to spend in close proximity to the patient.

4.4.10 Procedures in wards used by patients receiving radionuclide therapy

In the case of patients containing high activities of gamma-emitting radionuclides, the nursing staff should be instructed that only essential nursing procedures should be carried out and that these should be done as rapidly as is consistent with good nursing practice. Nurses should wear gloves for any procedure which requires them to be in contact with the patient.

When patients are treated in a dedicated treatment facility, a notice to this effect, including a radiation warning sign, needs to be displayed on the door of the treatment room. The nursing staff should be made familiar with the implications of this notice.

Following a risk assessment, measures to control the radiation exposure of visitors and staff should be established and documented in the institution's Radiation Safety Manual or Plan. These will include the identification of areas which can be accessed by staff and visitors, and the periods of time for which visitors are permitted. This information should be readily available to visitors and should preferably be available in multiple languages. The plan should also clarify the limits of attendance, restrictions and risks for any other hospital personnel such as ward staff, cleaners and catering staff, and what their duties are when therapeutic radionuclides are used.

Patients receiving radionuclide therapy should not leave the treatment facility without approval of the nuclear medicine specialist or the RSO. Documented procedures should be in place to respond to a patient who wishes to leave hospital prior to their normally expected time of discharge.

If the patient's excreta are likely to be radioactive, simple precautions such as laying plastic-backed absorbent paper securely to the floor around the toilet bowl and instructing the patient to flush twice after each use will help to minimise the external radiation and contamination hazards. Where a patient needs to use a bedpan or urine bottle it should be kept for the exclusive use by the patient, preferably in the toilet, and should not be used by another patient until it has been checked and decontaminated, as appropriate.

Crockery and cutlery may become contaminated and it may be more convenient to use disposable items, which should then be treated as radioactive waste. Similarly, the patient's bed linen and/or towels may become contaminated. These need to be monitored and any contaminated items stored to allow for radioactive decay, before the items are laundered.

If the patient is transferred to a different ward, to another hospital or to another institution, such as a nursing home, the receiving institution should be provided with any necessary information concerning the radiation safety requirements of the patient's ongoing care.

Following the discharge of a patient receiving radionuclide treatment, the area of the ward used by the patient should be monitored and, if necessary, decontaminated before further use.

Procedures and precautions in the event of the death of a patient being treated with radioactive materials are provided in Annex D (refer also NHMRC 1986).

4.5 MEDICAL EMERGENCIES INVOLVING PATIENTS UNDERGOING RADIONUCLIDE THERAPY

In life-threatening situations, the patient's medical management will always take precedence over radiation safety considerations.

In the case of cardiac or respiratory arrest only those staff essential for the patient's resuscitation should be involved. All other staff should remain at least 2 metres from the patient. If the patient requires ventilation as part of resuscitation, ventilation should be by a mask-bag system. Mouth to mouth resuscitation should not be used.

Whenever the medical condition of the patient deteriorates a nuclear medicine specialist should be consulted. If surgery is not urgent, it should be postponed until the radioactivity in the patient has fallen to a suitable level. If urgent surgery or monitoring in an Intensive Care Unit is required, precautions against external radiation and possible contamination from body fluids need to be considered.

If the patient requires surgery, the wearing of two pairs of surgical gloves will give some protection to the hands against beta radiation. The surgical team should plan the procedure in order to minimise any staff radiation exposure. This can be achieved by ensuring that only essential staff are present in the operating theatre, and where possible, staff stand away from any organs containing high concentrations of radioactivity and that close contact with the patient is minimised.

After the operation has been completed, the operating theatre, surgical instruments, equipment and surgical drapes, and anaesthetic equipment should be checked for contamination and, if necessary, decontaminated or stored until the radioactivity has decayed to negligible levels.

All staff involved in the management of the emergency should be checked for any radioactive contamination and, if necessary, decontaminated before leaving the area.

In all cases of an emergency involving a patient who has received a therapeutic dose, the RSO should be consulted as soon as possible.

4.6 PET/CT AND SPECT/CT EXAMINATIONS

There is an increasing use of combined PET/CT or SPECT/CT scanners where the CT component is used to provide accurate data for attenuation correction purposes and for dual-modality images (often called fusion images). The effective dose to the patient from the CT component may be larger than that from the administered radiopharmaceutical. The CT exposure factors (kVp, mA, time per rotation and pitch) need to be optimised so that the **absorbed dose** from the CT component is minimised whilst still obtaining the required information. This is particularly important for examinations on paediatric patients, who may also be at greater risk from **stochastic effects** than the general population. Accordingly, protocols should be developed for all common procedures involving CT using Automatic Exposure Control wherever possible. (ICRP 2000b, ICRP 2007a).

If the CT component of the apparatus is capable of producing diagnostic quality images, the guidance provided in the *Safety Guide for Radiation Protection in Diagnostic and Interventional Radiology (ARPANSA 2008c)* should be followed.

5. Protection of the Embryo/Fetus

5.1 RADIATION EFFECTS ON THE FETUS

The risk from radiation is related to the fetal dose and to the stage of pregnancy at which the exposure occurs (ICRP 2000a). Doses above thresholds of 100 mGy or more can cause failure to implant (conceptus up to week 2 or 3 of gestation), developmental abnormalities (embryo weeks 3 to 8) or neurological effects (fetus weeks 8 to 25). There is evidence of a slightly increased risk of induction of childhood cancer or leukemia for doses of more than 10 mGy. This latter risk is considered to be uniform throughout the pregnancy after the first 3 to 4 weeks of gestation. The life-time cancer risk following intra-uterine exposure is assumed to be similar to that following irradiation in early childhood. In addition to carcinogenesis, radioiodinated compounds can also cause subsequent hypothyroidism in the infant (ICRP 2007b).

5.2 RISK FROM RADIATION DOSES USED IN NUCLEAR MEDICINE

Absorbed dose coefficients for the uterus and embryo/fetus from radiopharmaceuticals administered to a woman in early pregnancy are listed in Table 7. Sometimes CT is used in combination with radionuclide scanning i.e. with SPECT or PET. The radiation doses from the CT component depend upon the settings used and upon the region of the body scanned. The doses associated with diagnostic nuclear medicine procedures are much lower than the levels where developmental and neurological effects are known to occur. The main physical risk, although very low, may be a slight increased risk of childhood cancer or leukemia. Most diagnostic nuclear medicine procedures pose little risk to the mother or fetus compared to other risks during pregnancy. However, anxiety or even distress can occur if a woman has had radiation to the pelvis and subsequently finds that she was pregnant.

Radionuclide therapy procedures can exceed the threshold doses for direct harm to an embryo/fetus.³

5.3 CONFIRMING ABSENCE OF PREGNANCY

Illustrated signs are required by the Code (Clause 3.1.18) to be posted in prominent places within the nuclear medicine department, 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, PLEASE
INFORM THE STAFF **BEFORE** YOU HAVE YOUR INJECTION
FOR YOUR NUCLEAR MEDICINE EXAMINATION.

In addition to the signage, staff have a responsibility to enquire about the possibility of pregnancy in all female patients of childbearing age. Clause 3.2.7 of the Code requires that reasonable steps be taken immediately

³ Advice on the risk of fetal exposure may be obtained from referenced documents ICRP 2000a, NRPB 1998 and RANZCR 2005.

before the commencement of the procedure to establish whether the patient is pregnant. 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 the patient taking offence and not answering fully. The discussion about excluding pregnancy and whether to offer pregnancy testing requires tact and discretion. It may be a sensitive issue in a teenage woman.

When language barriers exist it may be useful to seek the service of an interpreter. History alone may not be reliable because a woman may not be aware 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 (in a person with 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 several months; or
- been taking contraception measures, such as the contraceptive pill provided it has been taken regularly.

In all other cases pregnancy should be regarded as uncertain.

When doubt exists about pregnancy status, the nuclear medicine specialist should be consulted to make a decision about whether to defer the nuclear medicine study 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 the study. As the doses from most nuclear medicine diagnostic procedures are very low, often below the level where harmful effects are known to occur, it is more a matter of what are reasonable steps to be taken with an informed patient, rather than absolutely excluding pregnancy. The decision about what are reasonable steps may be influenced by the level of radiation dose. For potential doses to the embryo/fetus of less than 1 mSv a simple question about pregnancy may suffice. Where a procedure is likely to result in a radiation dose of more than 1 mSv to an embryo/fetus, more information might be appropriate.

If a β -HCG test is performed and the test is positive, or an equivocal result, the nuclear medicine specialist should be consulted. If the β -HCG test is equivocal it may be advisable to defer the nuclear medicine procedure for a few days and repeat the test. If a woman whose pregnancy status is uncertain declines β -HCG testing before the nuclear medicine procedure, the offer and refusal should be documented.

If the procedure is for a therapeutic radionuclide dose, the pregnancy status of all women of childbearing age must be confirmed by a definitive biochemical test, e.g. with a serum or urinary β -HCG test, prior to administration of therapy radiopharmaceuticals (a requirement of Clause 3.2.7 of the Code).

5.4 PREGNANT PATIENT

Sometimes there may be good reasons to use ionizing radiation for diagnostic purposes in a pregnant patient in order to provide optimal care for the mother and, indirectly, potential benefit for the fetus. If a diagnostic radiation study is medically indicated the risk to the mother and fetus from not performing the study is usually greater than the risk from the radiation associated with the procedure. If a nuclear medicine study is justified and will be proceeded with, the administered activity should be as low as possible, provided it is sufficient to supply the required diagnostic information. Prior to the procedure the nuclear medicine specialist should assess the potential dose and communicate the risks to the mother in a meaningful manner. Individual fetal radiation dose estimates may require the services of a nuclear medicine physicist.

5.5 INADVERTENT EXPOSURE OF A FETUS

Clause 3.1.14 of the Code requires that a protocol is in place to deal with an inadvertent exposure of 1 mSv or more to an embryo or fetus. The dose is likely to exceed 1 mSv for most radiopharmaceuticals.

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

- implement dose-reduction strategies appropriate to the radiopharmaceutical, e.g. hydration and frequent voiding, use of stable iodine prophylaxis;
- determine whether the patient has had any other nuclear medicine or radiological procedures during the pregnancy;
- obtain an estimate of the radiation dose to the embryo/fetus for all procedures from a medical physicist; and
- inform the patient and referrer and provide counselling in accordance with the estimated dose, in conjunction with the referring doctor or the patient's obstetrician. Termination should not, on purely dosimetric considerations, be recommended for doses less than 100 mGy.

The radiation dose to an embryo/fetus from radiopharmaceuticals administered early in a pregnancy is shown in Table 7. Estimates are based mainly on the fetal dose coefficients from Russell *et al* (1997) which are similar to, or moderately higher than, the uterus dose coefficients from ICRP Publications 53 and 80 (ICRP 1987, ICRP 1998). Fetal doses from CT scans performed in association with SPECT or PET imaging require individual evaluation and would generally exceed 1 mSv for scans of the pelvic region.

Table 7: Radiation dose to the uterus and embryo/fetus from a radiopharmaceutical administered to the mother in early pregnancy.

Radio-pharmaceutical^a	Uterus dose^b (mSv/MBq administered)	Embryo/fetus dose^c (mSv/MBq administered)	Activity administered (MBq)^d	Corresponding dose to Embryo/fetus (mSv)
¹⁸ F-FDG	0.021	0.022	400	8.8
⁶⁷ Ga-citrate	0.076	0.093	200 infection 400 tumour	19 37
^{99m} Tc- aerosol ^{99m} Tc -Technegas ^e	0.0059 DTPA 0.0003 Tc-gas	n/a – use uterus coefficients	40	0.23 0.012
^{99m} Tc-colloid	0.0019	0.0018	200 liver/spleen	0.36
^{99m} Tc-colloid – small ^e	0.0018	0.0018	400 bone marrow	0.72
^{99m} Tc-Disofenin	0.013	0.017	200	3.4
^{99m} Tc-DMSA	0.0045	0.0051	185	0.94
^{99m} Tc-DTPA	0.0079	0.012	500 renal scan 400 transplant 110 GFR	6.0 4.8 1.3
^{99m} Tc-HDP ^{99m} Tc-MDP	0.0063 0.0063	0.0052 0.0061	900	4.7 5.5
^{99m} Tc-HMPAO	0.0066	0.0087	800	7.0
^{99m} Tc-MAA	0.0022	0.0028	200	0.56
^{99m} Tc-MAG ₃	0.012	0.018	350	6.3
^{99m} Tc-MIBI	0.0078 (rest) 0.0072 (stress)	0.015 (rest) 0.012 (stress)	400 rest 1100 stress	6.0 13
^{99m} Tc-pertechnetate	0.0081	0.011	200 thyroid 400 Meckel's 800 venogram	2.2 4.4 8.8
^{99m} Tc-PYP	n/a	0.006	800	4.8
^{99m} Tc-red cells	0.0039	0.0068 (<i>in vitro</i>) 0.0064 (<i>in vivo</i>)	1000	6.8 6.4
^{99m} Tc- damaged red cells	0.0014	0.0017	400	0.68
^{99m} Tc-white cells	0.0034	0.0038	740	2.8
¹¹¹ In-octreotide	0.039	0.082	200	16
¹²³ I-MIBG	0.010	0.018	370	6.7
¹³¹ I-sodium iodide ^f	0.052 (25% thyroid uptake)	0.072	200	14

Radio-pharmaceutical ^a	Uterus dose ^b (mSv/MBq administered)	Embryo/fetus dose ^c (mSv/MBq administered)	Activity administered (MBq) ^d	Corresponding dose to Embryo/fetus (mSv)
²⁰¹ Tl-chloride	0.051	0.097	160 (tumour) 120 (rest) 100 (stress) 40 (re-injection)	16 12 10 3.9

Notes to Table 7:

- ^a Shaded entries represent radiopharmaceuticals which may cross the placenta resulting in maternal and fetal self-dose contributions beyond the initial stage of pregnancy.
- ^b Uterus dose coefficients from ICRP Publication 80, 1998.
- ^c Embryo/fetus dose coefficients from Russell *et al*/1997, Stabin 2004.
- ^d The activities quoted are the DRLs from the Australian and New Zealand Society of Nuclear Medicine website (www.anzsnm.org.au).
- ^e DRL activity not specified
- ^f Fetal dose is greatly increased if there is radioiodine in the maternal circulation once fetal thyroid function begins at about 10 to 12 weeks gestation. To avoid serious damage to the fetal thyroid, any procedure resulting in free ¹³¹I⁻ ions at that time, even in small activities, is contraindicated (ICRP 2001).

6. Protection of an Infant

Illustrated signs are required by the Code (Clause 3.1.18) to be posted in prominent places within the nuclear medicine centre requesting the patient to inform the staff if they are breast-feeding, or caring for, an infant. An example might read as follows:

IF YOU ARE BREAST-FEEDING OR CARING FOR A YOUNG CHILD, PLEASE INFORM THE STAFF **BEFORE** YOU HAVE YOUR INJECTION FOR YOUR NUCLEAR MEDICINE EXAMINATION.

Before commencing a nuclear medicine procedure, every female patient of childbearing age should be asked by the administering person whether she is breast-feeding or caring for a young child. Steps can then be taken (if necessary) to minimise the external radiation dose to the child during periods of close contact with the patient, and the internal radiation dose from ingested breast milk.

6.1 EXTERNAL RADIATION DOSE FROM CLOSE CONTACT

The patient should be provided with advice on the length of time for which she or he can hold their child and the time at which no further restrictions will be necessary in order to minimise the external irradiation of the child. This advice will ensure that the child receives an effective dose of no more than 1 mSv.

The exposure of the child by being in close contact with the patient can be estimated from the external dose rate from the patient and the pattern of close contact between the patient and child (which will vary with the age of the child). The close contact doses can be calculated using the method of Cormack and Shearer (1998). This method allows the pattern and duration of the close contact to be specified and the total dose to the infant can be calculated using external dose rate measurements from published data and knowledge of the radiopharmaceutical's biological clearance rates. Estimates of the close contact restrictions necessary to ensure that the dose to the child does not exceed 1 mSv are given in Table 8 for a selection of commonly used radiopharmaceuticals. This assumes a close contact pattern of 30 minutes each hour during the day (7 am to 7 pm) together with two 30 minute periods during the night, which probably represents the 'extreme case' of a fretful, sick or demanding infant. For other infants and for older children the close contact restriction periods are likely to be less. Further information, and details of the methodology used, can be obtained from the ANZSNM website (www.anzsnm.org.au).

For most diagnostic studies, the activities of the radiopharmaceuticals that are typically administered will rarely give rise to an external dose to the child of greater than 1 mSv even with the conservative close contact pattern used above. Notable exceptions are ^{67}Ga -citrate and ^{111}In -octreotide where the cumulative external dose from patients containing gallium-67 or indium-111 will exceed that from many $^{99\text{m}}\text{Tc}$ -radiopharmaceuticals. Even though the administered activity will often be much less with those agents, the longer

physical half-life and slow biological clearance can give rise to a significant external dose to a child.

6.2 RADIATION DOSE FROM BREAST-FEEDING

A patient who is breast-feeding a child should be advised of the risks of continued breast-feeding before any therapeutic or diagnostic nuclear medicine procedure. This includes an increased radiation dose to the breasts of the patient as well as the radiation dose to the child (Stabin and Breitz 2000).

If the patient is breast-feeding, the child will receive an internal dose from ingested breast milk in addition to an external dose from close contact with the patient. Advice about the possible need to restrict breast-feeding needs to be given to the patient; this advice will depend on the radiopharmaceutical and its activity, and should ensure that the infant will receive a total effective dose of no more than 1 mSv.

It is important that breast-feeding be stopped before commencing therapy with any unsealed radionuclide.

Table 8 provides a summary of recommendations concerning the requirements for interruption of breast-feeding for some commonly used diagnostic radiopharmaceuticals. This is based on data collated by Cormack *et al* (2004), and takes into account both external and internal radiation exposure. As the concentration in the breast milk is highly variable and often differs by at least a factor of 2 between patients the advice in the table is based on a conservative approach. Where sample counting facilities are available it may be preferable to directly measure the concentration of the radionuclide in the breast milk to determine the time at which breast-feeding can resume. Table 8 provides concentrations in kBq/mL corresponding to the interruption period, below which resumption of breast-feeding will result in a total dose of less than 1 mSv. The close contact pattern is that typical of a fretful, sick or demanding infant. The contact time restrictions may be relaxed for a less demanding child. Further information, including details of the computational model and data used, can be obtained from the ANZSNM website (www.anzsnm.org.au).

Where interruption of breast-feeding is necessary it may be possible to express some milk prior to the study and to store at least one feed in a refrigerator or freezer. The baby should be fed naturally just before the study. During the period of interruption recommended in Table 8, the mother should regularly express and discard her milk. It should be explained that, if this advice is followed, the radiation dose will be no more than the infant would receive in six months from natural background radiation in Australia and that the radiation risk will be extremely small.

Table 8: Advice to patients concerning the need to restrict close contact with an infant and/or the need to interrupt breast-feeding in order to ensure that the infant receives a total effective dose (from both external and internal irradiation) of no more than 1 mSv.^a

Radiopharmaceutical	Administered activity to mother (MBq)	Advice to patient concerning the need to restrict close contact with a child^b	Advice to patient concerning the need to interrupt breast-feeding^c	Milk activity concentration below which breast-feeding can resume^c (kBq/mL)
¹⁸ F-FDG	400	Not required	1 h interruption	8
⁵¹ Cr-EDTA	8	Not required	Not required	Not required
⁶⁷ Ga-citrate	400	Restrict contact for 3 days	Cessation	0.3
^{99m} Tc- aerosol or Technegas	40	Not required	Not required	Not required
^{99m} Tc-colloid	200	Not required	Not required	Not required
^{99m} Tc-DISIDA or HIDA	200	Not required	Not required	Not required
^{99m} Tc-DMSA	185	Not required	Not required	Not required
^{99m} Tc-DTPA	500	Not required	Not required	Not required
^{99m} Tc-MAA	200	Not required	13 h interruption	12
^{99m} Tc-MAG ₃	350	Not required	Not required	Not required
^{99m} Tc-MDP or HDP	900	Restrict contact for 1 h	1 h interruption	1
^{99m} Tc-MIBI	400 rest + 1100 stress	Restrict contact for 4 h	4 h interruption	1
^{99m} Tc-pertechnetate (thyroid)	200	Not required	26 h interruption	14
^{99m} Tc-pertechnetate (Meckels)	400	Not required	34 h interruption	14
^{99m} Tc-PYP	800	Not required	2 h interruption	8
^{99m} Tc-red cells (<i>in vitro</i> or <i>in vivo</i> labelled)	1000	Restrict contact for 2 h	12 h interruption	15
^{99m} Tc-Tetrofosmin ^d	400 rest + 1100 stress	Restrict contact for 4 h	4 h interruption	1
^{99m} Tc-white cells ^e	750	Not required	24 h interruption	14

Radiopharmaceutical	Administered activity to mother (MBq)	Advice to patient concerning the need to restrict close contact with a child ^b	Advice to patient concerning the need to interrupt breast-feeding ^c	Milk activity concentration below which breast-feeding can resume ^c (kBq/mL)
¹¹¹ In-octreotide	200	Restrict contact for 42 h	45 h interruption	Not required
¹¹¹ In-white cells	20	Not required	Not required	Not required
¹²³ I-MIBG ^f	370	Not required	22 h interruption	0.5
¹²³ I-sodium iodide	20	Not required	6 h interruption	1
¹²⁵ I-HSA	0.2	Not required	6 day interruption	0.003
¹³¹ I-sodium iodide (post-ablation)	200	Restrict contact for 6 h	Cessation	0.0005
²⁰¹ Tl-chloride	120	Not required	15 h interruption	0.22

Notes to Table 8:

- a This table gives estimates of the minimum close contact restriction or interruption period required to limit the dose to less than 1 mSv. Where the restriction or interruption period calculated is very short (e.g. for ¹⁸F-FDG), or is indicated as not required, it may be prudent to apply a restriction or interruption period of at least 4 hours for ALARA purposes.
- b Takes into account external exposure from the patient only. The contact restriction times specified are post-administration (i.e. the time lapse from the time the radiopharmaceutical is administered to the patient to the resumption of normal contact).
- c Takes into account both external exposure from the mother and internal dose from ingested milk. The interruption periods specified are post-administration.
- d There is a lack of scientific data relating to the uptake and clearance of ^{99m}Tc-Tetrofosmin from breast milk. For the purposes of these calculations, it has been assumed that its behaviour *in vivo* is similar to that of ^{99m}Tc-MIBI.
- e Assumes a labelling efficiency of greater than 75%.
- f Assumes the chemical species appearing in the breast milk is ¹²³I-sodium iodide.

7. Quality Assurance

7.1 GENERAL CONSIDERATIONS

Clause 3.1.21 of the Code requires that all nuclear medicine centres establish a Quality Assurance (QA) program, which may be a component of a quality management program. The QA program should place particular emphasis on image quality, radiopharmaceutical quality and patient dose.

The benefits of the QA program include:

- continued production of images with optimal diagnostic quality;
- ability to identify problems before they impact on clinical procedures; and
- ability to evaluate the performance of the equipment.

The extent of the QA program will depend on the complexity and resources of the nuclear medicine centre but at the very least it will need to address the issues outlined in Annex E and have a well-defined responsibility and reporting structure.

Advice should be sought from a nuclear medicine physicist on quality assurance matters relating to image quality optimisation and patient dosimetry (IAEA 2002).

7.2 TESTING FREQUENCY

The frequency with which any particular parameter is assessed should be at least as often as that specified by the relevant regulatory authority, and the manufacturer, and should take into account:

- the likelihood of an equipment failure or a measured parameter falling outside an acceptable tolerance range; and
- the consequences that may follow if a measured parameter fell outside an acceptable tolerance range. For example, dose calibrator performance should be monitored frequently as any changes may have a substantial impact on both image quality and patient dose.

7.3 RECORD KEEPING

A key element of any QA program is proper record keeping so that any long term trends associated with a particular item of equipment or batch of radiopharmaceuticals can be identified and acted on before image quality and/or patient dose are compromised. Control charts, which plot the behaviour of a measured parameter as a function of time, represent a convenient way to keep records of **constancy** tests. For equipment, such record keeping should extend to noting:

- the results of acceptance testing;
- the results of any constancy tests; and
- equipment unscheduled downtime and the reason for the failure.

7.4 TESTING OF NUCLEAR MEDICINE EQUIPMENT

At installation, the nuclear medicine equipment needs to undergo a series of acceptance tests to ensure that the performance of the equipment complies with the manufacturer's specifications and is in accordance with any requirements of the relevant regulatory authority. These tests should preferably be performed by a nuclear medicine physicist and the results of the acceptance tests should be fully documented. Some of these results should be used to define the acceptable range of parameters that will be monitored in any subsequent constancy testing.

Following acceptance, constancy tests designed to assess the subsequent performance of the equipment should be performed. These are usually tests that may be performed by technologists and are designed to assess image quality and reproducibility of results. The results of constancy testing need to be reviewed as a matter of routine and any anomalous results reported immediately to the person responsible for the management of the QA program. If equipment is outside tolerance it should not be used until either the equipment is repaired and re-calibrated so that it is within tolerance, or the equipment is replaced.

Recommended testing procedures for gamma cameras and PET scanners are provided by the manufacturer and also by the ANZSNM (www.anzsnm.org.au).

7.5 TESTING OF DOSE CALIBRATORS

Contamination in the chamber or drift in the electronics can result in a non-zero background reading (positive or negative reading). If this is not checked and corrected, then measurements taken will be systematically either too high or too low. Contamination in the chamber or sample holder should be removed as much as possible; and zero offsets and general background should be set to zero with the controls provided on most dose calibrators. It is recommended that a spare chamber liner and sample holder be available, which can be used if contamination has occurred.

The background activity should be checked on each work day before any patient dosages are prepared and again whenever any contamination of the dose calibrator is suspected.

Procedures that may be used to meet the following test requirements are provided in Annex F.

(a) Constancy

Assay at least one relatively long-lived source such as caesium-137, cobalt-60, cobalt-57, or radium-226 using a reproducible geometry before using the calibrator on that day. Consider the use of two or more sources with different photon energies and activities.

(b) Linearity

This test is usually performed with a vial or syringe of technetium-99m or other suitable radionuclide, the activity of which is at least as high as the maximum activity used at the centre. The activity should be assayed repeatedly over several days and the recorded activity compared to that predicted by the calculated decay of the radionuclide in order to detect any departure in **linearity**.

(c) Accuracy

The calibration of the dose calibrator should be traceable to a national primary standard or a secondary or tertiary standard that is traceable to the national standard. The term ‘traceable to the national standard’ may be interpreted as traceable to the Australian National Standard or a recognised foreign reference standard. Certified calibration sources are available from ANSTO (the holder of the Australian primary and secondary measurement standards for radioactivity) and from many radioisotope suppliers. However, only ANSTO will be able to provide certified sources of the short-lived radionuclides used clinically in nuclear medicine.

Radionuclides with significant low energy gamma emissions, particularly ¹²³I or ¹⁵³Sm, will have some absorption of the low energy photons by the container wall and the radionuclide solution, which will affect the readings of the dose calibrator. For such radionuclides it is important to standardise the method of calibration, particularly the nature and shape of the container. For ¹²³I calibration, and for pure beta emitters, it may be necessary to rely mainly on the calibration information provided by the supplier.

(d) Geometry independence

The test for **geometry independence** should be performed using a syringe that is normally used for injections. Nuclear medicine centres where generators and radiopharmaceutical kits are used should also perform the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. If these are not used, the procedure should be changed so that the syringes and vials are tested throughout the range of volumes commonly used.

The recommended frequency of testing is provided in Table 9.

Table 9: Recommended testing frequencies for dose calibrator quality control procedures

Quality Control Procedure	Testing Frequency
Constancy	Daily
Linearity	Annually
Accuracy	Annually
Geometry independence	At calibrator acceptance and then for any change in sample geometry

7.6 TESTING OF RADIOPHARMACEUTICAL QUALITY

The *in vivo* behaviour of a radiopharmaceutical is dependent upon its quality, which includes high standards of radionuclidic, radiochemical and chemical purity. The specifications and quality control testing for most of the currently used radiopharmaceuticals are given in the British Pharmacopoeia (BP) or other suitable Pharmacopoeia (e.g. USP). There should be a written procedure detailing all aspects of quality control testing that should be considered before the radiopharmaceutical is administered to the patient.

Technetium-99m Generator

A molybdenum-99 breakthrough measurement needs to be performed on all elutions from each technetium-99m generator and the following records kept of all generator elutions:

- dose calibrator setting where the isotope is manually dialled;
- reading of long-lived reference source;
- time of elution;
- volume of eluate;
- technetium- 99m activity;
- molybdenum-99 activity; and
- radionuclidic purity.

BP specification for molybdenum-99 impurity in sodium pertechnetate eluate is 0.1% or a limit of 1 MBq of molybdenum-99 per GBq of technetium-99m at the time of administration. If this level is exceeded, then the technetium-99m solution has failed quality control and is not to be used in the preparation of radiopharmaceuticals for patient use.

Aluminium ion breakthrough should also be checked on any eluate used to prepare products that are adversely affected by the presence of aluminium.

Technetium-99m cold kits

All technetium-99m cold kits should be reconstituted in accordance with the manufacturer's instructions. There should be written procedures detailing all quality control testing that should be carried out on each particular product. The procedure should include appropriate radiochemical purity testing on every reconstituted cold kit before patient administration.

7.7 ADMINISTERED ACTIVITY AND DIAGNOSTIC REFERENCE LEVELS (DRLs)

As part of the Quality Assurance program, the activity administered to patients needs to be recorded and periodically compared to diagnostic reference levels (DRLs). Records of radiopharmaceutical administration may be kept, for example, by using the label prepared for each patient or a printout from the dose calibrator, if available.

DRLs are advisory, allowing for flexible application to individual patients on the basis of sound clinical judgment by the nuclear medicine specialist. However, if a DRL is consistently and substantially exceeded, the usual administered activity should be re-examined to ensure that the activity administered has been optimised. Although Clause 3.1.8 of the Code requires the implementation of DRLs, the actual values should be determined by the relevant professional bodies, for example by using a percentile point on the distribution of values observed in a national or regional survey of practitioners from time to time.

Technical matters relating to DRLs that should be borne in mind are:

- the DRLs for adults are usually defined for a person of average size, which is taken to be about 70 to 80 kg. When performing dose surveys patients within this weight range should be selected;
- recommended values for DRLs are chosen from a substantive survey of the distribution of the activities administered to patients. They do not represent best practice, so that the ultimate target for any institution should be to lower their doses to a level regarded as achievable. For any procedure, an achievable activity is one which maximises the difference between the benefit and risk without compromising the clinical purpose of the examination (NRPB 1999); and
- DRL values should be reviewed and adjusted by the relevant professional societies at intervals that represent a compromise between the necessity for stability and long term changes in the activity distributions arising from technological improvements.

DRLs for common nuclear medicine procedures have been obtained from a survey of practices in Australia. Reference activities for adult and paediatric patients, together with the corresponding effective doses, are available on the ANZSNM website (www.anzsnm.org.au).

8. Radiation Incidents

8.1 TYPES OF RADIATION INCIDENTS

A variety of incidents may occur in nuclear medicine practice which can result in the inadvertent radiation exposure of a patient, a member of the public or a staff member. These include:

- procedure performed on the wrong patient;
- wrong procedure performed on the correct patient;
- incorrect activity administered to a patient for the correct procedure;
- inadvertent or unjustified exposure of pregnant or lactating female patients;
- incorrect or failed acquisition or processing of images, which requires a repeat study;
- incorrect use of shielding or personal protective equipment;
- loss of a sealed radioactive source; and
- radioactive contamination of the environment.

8.2 MISADMINISTRATION OF RADIOPHARMACEUTICALS

Errors in the administration of radiopharmaceuticals have been called misadministration, or sometimes maladministration. These are more likely to occur when there are communication problems, a busy environment or distraction, lack of awareness of local rules, ill-defined individual responsibilities and substandard QA processes (IAEA 2006, IAEA 2007). Inattention to detail at key times during the dispensing or administration of the radiopharmaceutical is a common cause of error (Yenson *et al* 2005).

Some errors which may subsequently lead to misadministration include:

- referral contains wrong patient identification or wrong study for the clinical problem;
- the request for the procedure is misread or misinterpreted, which may be influenced by the legibility of writing on the request, or poor quality fax copy;
- the wrong single-dose syringe or multi-dose vial is selected;
- the contents of a vial or syringe are wrongly labelled;
- confusion about the units of measured activity, such as MBq or mCi; and
- mistaken patient identity.

The risk of mistaken patient identity is increased when two patients have the same or similar names, or poor comprehension of English.

An error that is detected before the administration of a radiopharmaceutical and then corrected is a 'near miss'.

The low radiation dose from misadministration of radiopharmaceuticals for diagnostic procedures is unlikely to cause injury or complication, with the

possible exception of extravasated injections of high activity, small volume and a long retention time which can cause a very high localised dose. Radiation injury may occur from the misadministration of therapy radiopharmaceuticals.

Errors involving CT X-ray exposure may also occur in nuclear medicine facilities. Staff should be alert to the consequence for radiation dose to the patient if scans have to be repeated because of equipment or software problems, especially if scanning children or the pelvic region in women of child-bearing age.

8.3 INVESTIGATION AND REPORTING REQUIREMENTS

All 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 diagnostic or therapeutic nuclear medicine 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 RSO together with the supervisor of the area in which the incident occurred. A written report should be prepared which 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 regulatory authority. Mechanisms need to be in place to audit compliance with the report's recommendations.

The Responsible Person should be informed as soon as possible where the incident has resulted in a patient or member of the public receiving a radiation dose of more than 1 mSv or a staff member received more than 2 mSv. The regulatory authority may also need to be informed, depending on the requirements of the relevant legislation.

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

9. Occupational Exposure

9.1 GENERAL CONSIDERATIONS

A radiation hazard may arise from unsealed radioactive materials, either through external irradiation of the body or through the entry of radioactive substances into the body. The main precautions required in dealing with external irradiation will depend on the physical characteristics of the radiation emitted, the total activity and the physical half-life of the radionuclide. In nuclear medicine studies the main source of external irradiation to other persons comes from the radioactive patient. Contamination from unsealed radioactive substances may produce a further external radiation hazard.

When an unsealed radioactive substance enters the body, the internal radiation dose will depend on factors such as the physical and chemical form of the material, the activity, the mode of entry and the pharmacokinetics of the radiopharmaceutical.

Particular attention should be given to the handling of iodine-131 therapy doses, where there is the potential for high radiation doses to the operator, and in radioiodination (iodine-131, iodine-125 and iodine-123) procedures where there is the additional potential hazard for inhalation of volatile molecular iodine produced by the radioiodination reaction (Section 9.11.4).

9.2 PREGNANT OR BREAST-FEEDING STAFF

If an occupationally exposed member of the nuclear medicine staff is pregnant then the fetus should be afforded the same level of protection as a member of the public. This may be achieved by controlling the exposure of the employee such that the dose received by the fetus is less than the public effective dose limit of 1 mSv for the remainder of the pregnancy. For external irradiation from technetium-99m or iodine-131, a dose of 1.3 mSv to the surface of the maternal abdomen has been shown to give rise to a dose of 1 mSv to the fetus (Mountford and Steele, 1995). For higher energy photons, such as those from positron emitters, the dose to the fetus may be similar to the dose at the surface of the abdomen.

Employers are to 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 either external or internal 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 should be discussed and agreed to with the employee. It would be prudent to provide an occupationally exposed pregnant staff member with an electronic personal dose monitor.

Pregnant women, or those intending a pregnancy or breast-feeding, should not work with large amounts of radioiodine.

If a member of staff is breast-feeding she should not take part in procedures or work in areas where there is a significant risk of bodily contamination, e.g. cleaning up a large spill of radioactivity. An assessment should be undertaken of the potential radiation dose to the infant resulting from a chance inhalation by the mother of radioactive gases or aerosols arising from her work and appropriate procedures put in place to restrict this dose if necessary.

9.3 EXPOSURE FROM RADIOACTIVE PATIENTS

In clinical practice a patient may be required to undergo a number diagnostic imaging or other procedures in addition to the nuclear medicine test. These procedures may include X-ray or ultrasound investigations or radiotherapy planning. As a general rule, whenever practicable, other procedures should be performed before the administration of the radiopharmaceutical, mainly to minimise radiation exposure of staff outside the nuclear medicine facility (refer to Table 8 for advice concerning the need to restrict close contact with a child).

There may be occasions when a patient who has already been administered a radiopharmaceutical is then required to undergo another medical procedure. A radioactive patient presents a source of radiation exposure to other staff, but the risk to others may be small. It is important to note that the prior administration of a radiopharmaceutical to a patient is not of itself a contraindication to performing X-ray, ultrasound or other procedures. The decision to proceed with the other test should be made based on clinical need. A decision about what precautions should be adopted depends upon an assessment of the amount of radiation exposure to others from the patient as a result of the nuclear medicine procedure. Application of the ALARA principle requires that steps should be taken to reduce radiation exposure to staff to the minimum reasonably achievable level.

The following procedures should be adopted to inform and minimise radiation to staff in other areas of the hospital:

- a prominent radiation sticker should be attached to the patient's file or notes. The sticker should state the radionuclide, the activity, the time that the radiopharmaceutical was administered and the route of administration. The sticker should also state that the patient is radioactive and the time after the administration that the patient will remain a source of radiation exposure;
- in order to reduce patient radioactivity, the patient should be asked to empty his/her bladder prior to other medical procedures;
- staff should avoid any unnecessary proximity to the patient;
- staff performing other procedures on the radioactive patient should be made aware of the contamination hazard that may arise from the excretion of body fluids, in particular from incontinent patients. Any such spill or excretion should be immediately referred to the RSO for measurement and decontamination; and
- the nuclear medicine department should have a designated person to whom queries can be directed; who is able to answer questions from staff

outside the nuclear medicine department about the radiation that they may be exposed to from the nuclear medicine procedure and the risks, and about any precautions that may be needed.

Some other imaging procedures may interfere with nuclear medicine procedures. Barium X-ray contrast media can attenuate the photons emitted from the administered gamma-emitting radiopharmaceutical, and hence, if the patient requires barium contrast studies the nuclear medicine study should be performed before the barium contrast studies. Administration of iodinated contrast media may interfere with some iodine nuclear medicine procedures, by blocking uptake of radioactive iodine in the thyroid.

9.4 FACILITIES FOR THE PREPARATION OF RADIOPHARMACEUTICALS

The radiopharmacy facility and equipment should be located, designed, constructed and maintained to suit the operations to be carried out. The layout and design should be such as to minimise the risk of errors and to permit effective cleaning and maintenance, the avoidance of cross-contamination, the build-up of dust or dirt and any other influences that may adversely affect the quality of radiopharmaceuticals. The facility needs to be designed to give proper radiation and contamination protection to personnel and the environment and to maintain the quality of the product.

The customary principles for the layout of radioisotope laboratories, designed to protect the staff and the external environment in the event of radioactive contamination in the laboratory, should be followed (AS/NZS 2982.1:1997).

9.5 DESIGNATION OF AREAS

The risk to any person working with unsealed radioactive materials should be assessed before the work commences and should be kept under review. This will require an assessment as to whether a particular area needs to be designated as a '**controlled area**' or as a '**supervised area**'. Radiopharmacies, imaging rooms, medium-level laboratories where unsealed radioactive materials are used (as defined in AS 2243.4) and treatment rooms for patients undergoing radionuclide therapy should be designated as controlled areas. Patient waiting areas within a nuclear medicine centre will normally be designated as supervised areas.

The risks associated with each controlled area need to be assessed and control measures to restrict exposure documented. The documentation may be in the form of local rules or protocols and will normally form part of the institution's Radiation Management Plan. The documentation should also contain a clear indication of the roles and responsibilities of each different category of staff.

The specific circumstances of the area that need to be taken into account are:

- the external radiation hazard, both in terms of instantaneous dose rates and doses averaged over a working day;
- the risk and possible level of radioactive contamination;

- the control of access to the area;
- whether staff untrained in radiation protection need to enter;
- the length of time that persons need to remain in the area;
- whether the only radioactive substances present are within the body of a person; and
- the special procedures that need to be followed to restrict significant exposure.

Periodic review of the use of radioactive materials in each area, together with environmental monitoring, will be necessary to confirm the appropriate designation.

9.6 EQUIPMENT AND CLOTHING

Radiopharmacies, laboratories and other work areas where unsealed radioactive substances are handled should be provided with radiation protection equipment kept specifically for this purpose. This equipment may include:

- lead barriers (fixed or mobile) with lead glass windows for work with photon emitters;
- perspex barriers for work with beta emitters;
- syringe shields;
- shielded containers;
- drip trays to contain any spillage;
- tongs or forceps to maximise the distance of the worker from the source;
- radiation and contamination monitoring equipment;
- dose calibrators;
- fume cupboards;
- biohazard cabinets;
- shielded transport containers; and
- equipment and materials to deal with spills.

Protective clothing is to be used in work areas where there is a likelihood of contamination, both to protect the body or clothing of the worker and to help prevent contamination to other areas. The clothing should be monitored and removed before leaving designated areas, e.g. when visiting the staff room. The clothing may include:

- laboratory coats or protective gowns;
- waterproof gloves; and
- face masks where there is a risk of airborne droplets.

Overshoes are not routinely required but may be needed in radiopharmacies handling greater than 200 GBq of technetium-99m and should be included in the decontamination kit, to be worn when cleaning up a major spill.

In certain circumstances staff may need to wear a protective lead apron. This may be necessary if staff need to be in close contact with patients containing greater than 800 MBq of technetium-99m, such as during myocardial perfusion studies or gated cardiac blood pool studies. Protective aprons should preferably have a thickness of 0.5 mm lead equivalence. Preferred designs are those comprising a separate vest and skirt that wrap around fully, as open back designs are not recommended. All protective clothing should be examined under fluoroscopy at least annually to confirm the integrity of the protection.

Lead aprons provide little or no protection for higher energy photons and should not be used for radionuclides such as gallium-67 or iodine-131 or for positron emitters.

Staff leaving designated areas should remove protective clothing, wash their hands and monitor their hands, clothing and body as appropriate.

Mobile shielding barriers may be required for therapeutic nuclear medicine procedures using gamma-emitting radionuclides.

9.7 PERSONAL MONITORING

All staff who are occupationally exposed to ionizing radiation should be issued with, and wear, a personal radiation monitoring device from an approved personal radiation monitoring service. This will normally include all nuclear medicine staff who need to handle radioactivity or radioactive patients and may include other staff such as receptionists. A direct-reading device, such as an electronic dosimeter, may also be worn for an immediate indication of the dose received. Local jurisdictions may require monitoring of personnel in defined occupations such as nuclear medicine, irrespective of the likely annual dose.

When a single personal radiation monitoring device is utilised it should be worn on the anterior trunk, between the waist and the chest, and under any protective garments. It may be appropriate in some circumstances for an individual to be issued with two personal monitoring devices. For example, an electronic dosimeter may be used to measure any exposure during a particular task in addition to the integrating dosimeter which would be routinely worn.

The length of time for which a dosimeter will be allocated will depend on the doses likely to be received during the wearing period. Technologists and radiochemists who routinely handle radiopharmaceuticals may require monthly monitors, whilst a 3-monthly cycle may be appropriate for staff who may be exposed less frequently, such as nuclear medicine physicists.

Pregnant staff should be monitored on a one monthly cycle. They may also wear a direct-reading dosimeter which will enable them to monitor their body dose on a daily basis so that they can ensure that the dose to the fetus is unlikely to exceed 1 mSv for the duration of the pregnancy.

Routine monitoring of extremity doses is advisable if doses to the hands or other extremities are likely to exceed 1/10 of the appropriate dose limit.

Therefore, persons who reconstitute, dispense or administer radiopharmaceuticals should wear a thermoluminescent dosimeter (TLD) on a finger as a ring. Although the maximum dose will usually be received by the fingertip, it is customary to wear the monitor at the base of the finger, as wearing the monitor at the fingertip may adversely affect tactile functions.

9.8 DOSIMETRY INVESTIGATION

The Radiation Safety Officer (RSO) should establish an investigational level such that any exposures received during a monitoring period which exceed this level require a formal investigation and require appropriate measures to be identified to minimise future exposures. The investigational level may be specified by the relevant regulatory authority in which case a report of the investigation may also be required by the relevant regulatory authority. Alternatively, the Responsible Person may establish an investigational level for the institution. For example, the level could be set at 1/40 of the annual dose limit in a month.

In some instances 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 radiology or nuclear medicine procedure while still wearing the monitor. This needs to be documented in the person's radiation history as a non-occupational exposure.

Where the investigation shows that the staff member is likely to have actually received a dose equal to or above the investigational level, the Responsible Person should be informed. The regulatory authority may also need to be informed depending on the requirements of the relevant legislation.

9.9 GENERAL PROCEDURES TO REDUCE OCCUPATIONAL EXPOSURE

The advice of the RSO and/or nuclear medicine physicist should be sought before new procedures are introduced or major changes are made to existing procedures. New or changed procedures should be rehearsed, where possible, without using radioactive materials.

Radioactive materials should be received, handled, and stored at the specifically designated controlled location. Vessels containing radioactive materials should be labelled with the radionuclide name, chemical form, activity, and date and time of calibration, and should be properly shielded while in use and in storage.

Working procedures should be designed to prevent spills, and in the event of a spillage, to minimise the spread of contamination. This will usually require the use of a drip-tray to contain any spilled liquid.

No food or drink or cosmetics should be brought into an area where unsealed radioactive materials are used, nor should food or drink be stored in a refrigerator used for storing radioactive materials.

Any cut or break in the skin should be covered with a waterproof dressing before a person enters an area where unsealed radioactive materials are handled.

If staff have been performing procedures that require handling of radiopharmaceuticals, or where there is potential for radionuclide contamination, they should wash their hands and monitor their hands, clothing and body, as appropriate, when they complete the procedure. If contamination is detected, staff should follow the decontamination procedures detailed in the Radiation Management Plan.

Equipment provided specifically for the safe handling of unsealed radioactive materials should always be used and should not be removed from the work area. Pipettes should never be operated by mouth. Recapping of syringe needles should be performed using a suitable recapping device.

The work area should be kept tidy and free of articles not required for the work. It should be cleaned often to ensure minimal contamination. Cleaning methods should be chosen in order to avoid raising dust or spreading contamination.

Shielding should always be considered for any radioactive source. The prior risk assessment should identify the shielding that is required and what type and form it should take. Appropriate shielding may be obtained using a variety of materials such as tungsten, lead, lead glass, aluminium or Perspex, depending on the characteristics of the radionuclide to be shielded.

Radiopharmaceutical preparation should be performed behind protective lead barriers. A lead glass viewing panel should be used when appropriate. Lead syringe holders should be used to transport syringes containing radioactive materials. Syringe shields should be provided for ready use during radiopharmaceutical preparation and administration whenever practicable. It should be noted that any additional time spent in manipulating the syringe when adjusting the activity to be administered to a patient can result in additional dose to the hands of the administering person.

The radiation dose to the administering person can be minimised by prudent positioning relative to the patient and/or by structural shielding. If there is no structural shield and the operator has to remain in the room, the administering person should, whenever possible, be at least two metres from the patient.

Where the work involves the possibility of air-borne radioactivity, the work should be undertaken in an enclosure such as a fume cupboard or biological safety cabinet. When radioactive gases or aerosols (including Technegas) are administered to patients it may be necessary to provide an additional room exhaust system to minimise any contamination of the operator, environment and equipment.

Systems should be in place to detect when maintenance work is to be performed on equipment that might be contaminated, particularly for enclosures for controlling airborne activity, ventilation ducting, sinks and waste pipes. In hospitals, this should include signs on appropriate access

points instructing any maintenance staff to contact the RSO before commencing work on particular equipment. Direct supervision of the work may be required if, for example, the dose rate or activity is likely to be high.

If radionuclides are to be administered outside the nuclear medicine department, such as in wards or clinics, the local rules for the department need to be extended to cover these areas. It may be necessary to cover surfaces with a plastic-backed absorbent material to prevent contamination.

In the case of nuclear medicine procedures performed in operating theatres, standard procedures should protect the staff from any contamination. Normal cleaning and sterilisation procedures should be adequate to remove any contamination from equipment. If any potentially contaminated waste is generated, it should be collected in a clearly labelled plastic bag and removed by trained staff for monitoring and disposal. Waste that is likely to be biologically contaminated should be handled accordingly.

9.10 MONITORING OF WORK AREAS

Laboratories and other areas in which unsealed radioactive materials are used should be monitored, both for external radiation and for surface contamination, using a survey meter on a systematic basis. For each controlled area there should be a regular monitoring schedule appropriate for the area. Survey meters should be suitable for the task and be regularly tested.

Contamination should be kept as low as reasonably achievable. Wipe tests of surfaces in the work areas should be regularly undertaken.

General requirements for a survey meter are given in Annex G. Details of ambient dose rate surveys and surface contamination monitoring are given in Annex H.

9.11 RADIOPHARMACY PROCEDURES

9.11.1 Consignment arrival

On arrival, packages containing radioactive materials should be inspected for signs of damage. If damage is suspected, a wipe test should be performed to determine radioactive contamination on the surface of the shipment container and any leakage should be reported to the supplier. Major spills may require evacuation of the area before any cleanup is undertaken and should be first reported to the RSO.

9.11.2 Unit patient doses

For all individual unit patient doses (syringes, capsules or vials) received from a centralised radiopharmacy, the patient's name and the radionuclide and radiopharmaceutical form should be verified on arrival and the activity should be confirmed in a dose calibrator prior to patient administration.

9.11.3 Radiation safety procedures for radiopharmacy

The work area should be prepared and set up by covering surfaces with plastic-backed absorbent material and laying out needles, syringes, shields, forceps, diluents, gloves and other necessary items.

Identifying labels with a dated batch number should be affixed to radiopharmaceutical vials and shielding containers prior to the preparation of patient doses.

A radiopharmaceutical record sheet should be maintained that includes the batch numbers, manufacturer, date received, expiration time/date, the name of the person preparing the radiopharmaceutical, and any quality assurance tests performed.

The following rules should be observed when preparing or dispensing radiopharmaceuticals:

- eating, drinking, smoking, or the application of cosmetics are prohibited
- disposable gloves should be worn at all times and preferably laboratory coats or gowns. Safety glasses should be used if the work is of a hazardous nature to the eyes. Gloves should be changed at regular intervals in order to minimise the spread of contamination;
- personal dosimeters are to be worn at all times when handling radioactive materials or working in areas where they are handled or stored;
- all working surfaces should be covered with absorbent paper that has an impermeable plastic coating – facing the bench-top;
- radioactive materials should be kept in closed, sealed vials within shielding containers;
- all shielding containers and vials should bear a label identifying the radiopharmaceutical, the total radioactivity, the volume and the time and date of calibration;
- small spills that present no radiological hazard to persons should be cleaned up as soon as possible. Major spills may require evacuation of the area before cleanup is undertaken and need to be reported immediately to the RSO. General reference should be made to Australian Standard AS 2243.4 – 1998 – *Safety in laboratories Part 4: Ionizing radiations* (AS2243.4-1998);
- interruptions to the preparation or dispensing of radiopharmaceuticals should be avoided;
- in order to demonstrate confinement of radioactivity, a suitable electronic radiation detector should always be available when radioactive materials are handled; and
- hands, shoes and clothing should be monitored for contamination in a low-background area, allowing sufficient time for instrument response, before leaving the radiopharmaceutical laboratory ('hot lab').

9.11.4 Labelling with radioiodine

Radioiodination (iodine-123, iodine-125 and iodine-131) reactions should be performed in a dedicated laboratory using approved procedures. Iodine labelling is usually performed with a reductant-free solution of radioactive sodium iodide supplied in a small volume of 0.1 M sodium hydroxide. A small fraction of the radioactivity may be present in a volatile form and the gaseous iodine can escape when the vial is opened. For this reason, all labelling operations should be performed either in a **hot cell**, or in a well-ventilated fume cupboard.

Because of the long physical and biological half lives of iodine-125 and iodine-131, operators should take precautions to minimise exposure, skin contamination and inhalation. Gloves, gowns etc. should be checked for contamination. Thyroid gland activity should also be regularly monitored. Standard operating procedures should exist for the handling of spills and contamination.

Laboratories, radiopharmacies and other work areas where unsealed radioactive materials are handled should be provided with equipment designed to minimise external exposure of the operator and to minimise the likelihood of radioactive contamination occurring. Activities greater than 10 GBq of iodine-131 in liquid form are to be handled in a hot cell. All radioiodination reactions where less than 10 GBq of iodine-131 in liquid form is used should be performed in an adequately shielded fume cupboard or fully enclosed pharmaceutical isolator. The fume cupboard performance should meet AS/NZS 2243.8:2006.

Radiation shielding should be designed to minimise the radiation exposure of the operator and to preserve the integrity of the labelling operation. Preparation of iodine-131 labelled therapy doses has the potential to result in high radiation doses to the operator and procedures should be initially validated using either non-radioactive or low activity preparations. Low activity preparations should be used to assess the potential radiation hazards of the procedure.

Additional protective clothing should be used when handling megabecquerel activities of radioiodine. Personnel should be double-gloved and use shoulder-length sleeve guards.

All persons handling greater than 100 GBq of iodine-131 in liquid form in any 12 month period are to undergo thyroid monitoring. The frequency of monitoring should be set so that intakes corresponding to more than 5 per cent of the annual dose limit are not missed (IAEA 1999). As a minimum, measurements should be conducted annually (NRC 1993).

9.11.5 Blood cell labelling procedures

Blood products should preferably be handled in a biohazard cabinet (for example a laminar flow cabinet). Dedicated radiation safety apparatus and procedures should apply to radiolabelling of body fluids and to the dispensing of patient doses.

10. Environmental Issues

10.1 RADIOACTIVE WASTE

10.1.1 General considerations

It is necessary to manage radioactive wastes in such a way that the exposure to radiation of staff and the general public is as low as reasonably achievable and below prescribed limits. Radioactive waste may present a range of external radiation hazards depending on the activity and emissions and may, if ingested or inhaled, present a variety of internal radiation hazards to the human body dependent upon the radionuclide and its chemical and physical form.

The type of waste generated can take the following forms:

- airborne wastes such as radioactive gases, vapours, or particulate material;
- liquid radioactive wastes: These include patient excreta and aqueous solutions of radionuclides or suspensions of radioactive material in water or water-miscible liquid(s). Another category of liquid wastes is that of organic solvents which, because they are flammable or toxic, usually require special methods of disposal such as incineration in an approved incinerator;
- solid wastes include liquid in solid containers, sealed sources and rubbish. Sealed sources are generally in the form in which they were originally purchased; whilst rubbish includes contaminated packing materials, laboratory glassware, pipette tips, plastic vials and trays, paper tissues, used syringes, etc; and
- radioactive animal carcasses (from research activities) need special consideration. Carcasses of small animals such as mice and rats, and excised organs of larger animals, may be macerated and treated as liquid waste, and disposed of in a tip as solid waste or incinerated. The nature and quantity of radioactivity involved should be taken into account in selecting the appropriate option. Larger animals are not normally sacrificed as part of studies in which radioactive material is administered. However, should a large animal die whilst contaminated with radioactive material, the animal should be incinerated or buried as solid waste.

10.1.2 Authorisation

Before radioactive waste can be disposed of, the appropriate authorisation needs to be obtained from the relevant regulatory authority(ies). The waste management plan should consider all forms of waste - sealed sources, and unsealed sources in solid, liquid or airborne form. The plan should also take account of mixed waste hazards, e.g. if the waste is also flammable, toxic, infectious or putrescible.

10.1.3 Minimisation, segregation and disposal

The effective management of low and intermediate level waste depends on knowledge of the waste characteristics and the contained radioactivity. The

volume of radioactive waste should be kept to a minimum and should be categorised according to its method of disposal at as early a stage as possible.

Non-radioactive waste and very low level waste (that is, below the exemption levels set by the regulatory authority) should be kept separate from waste that needs to be disposed of as radioactive waste. This waste should be monitored to confirm its status before being removed from a controlled area.

It is useful to segregate radioactive waste on the basis of half-life in order to facilitate appropriate storage and disposal. For example, waste can be segregated into short-lived and long-lived radionuclide bins. The bins should be well shielded and the content disposed of when the activity drops to a sufficiently low level (for example after 10 half-lives).

As a general rule, the majority of liquid radioactive waste from nuclear medicine departments may be disposed of in the sewage system while most solid waste can be allowed to decay to levels when it may be disposed of as non-radioactive waste.

If possible, sealed sources should be returned to the supplier when no longer required.

10.2 RADIATION SHIELDING AND SIGNS

Careful consideration should be given to both the location of nuclear medicine centres within a building and to the provision of structural shielding, particularly if PET studies are to be performed. Advice on structural shielding may be obtained from the relevant regulatory authority.

As a general requirement, all barriers should be designed to a height of at least two metres. Viewing windows in walls or doors should have the same lead equivalence as the minimum shielding specifications for the barrier in which they are located. Due consideration should be given to the effectiveness of shielding at penetrations and joints and to the provision of floor and/or ceiling shielding when rooms immediately below and/or above the nuclear medicine installation are occupied.

In the particular instance of estimating shielding for PET/CT or SPECT/CT installations, the calculation may be expedited by requiring that the equipment suppliers provide radiation scatter contour maps around the scanner as part of the documentation. The effectiveness of shielding at penetrations and joints should be ensured. Viewing windows in walls or doors will need at least the same lead equivalence as the minimum shielding specifications for the CT requirements for the barrier in which they are located.

Visible warning signs are to be provided at all general access points to a room where unsealed radioactive material is stored or used. Warning signs using the trefoil symbol should conform to the specifications noted in the Australian Standard (AS 1319 1994). An example warning sign is shown in the figure below.



In the case of CT equipment, the provision of a warning light that is illuminated whenever X-rays are being produced is recommended and may be required by the relevant regulatory authority.

10.3 MANAGEMENT OF RADIOACTIVE CONTAMINATION

10.3.1 Decontamination of persons

In nuclear medicine, personal contamination will, in most cases, be due to contact with radioactive liquid (including patient excreta) as a result of spills, breakages of vials or insecure connections between syringes, 3-way taps and tubes used for radiopharmaceutical dispensing and injection.

Persons suspected of being significantly contaminated by radioactive material (e.g. therapy sodium iodide [^{131}I]) should be removed from the area of contamination and the situation reported immediately to the nuclear medicine specialist and the RSO. In the event of a major spill involving iodine radioisotopes, the use of thyroid blocking agents (for example potassium iodide) should be considered. Such thyroid blocking agents are most effective in blocking uptake of radioiodine by the thyroid if they are given immediately after exposure.

Any obvious injuries should be treated immediately, taking care to avoid the spread of contamination. Take particular care in the case of yttrium [^{90}Y] colloid or particulates to avoid spread to wounds, eyes, nostrils or mouth.

Contaminated clothing should be removed and a contamination survey of the person should be performed. Personal decontamination should be undertaken according to the area(s) of the body contaminated, as follows:

- eyes should be irrigated with saline solution (a 0.9 percent sodium chloride solution), or with distilled or mains water;
- hands should be washed with tepid water and mild soap or handwash solution (preferably neutral pH). If this is inadequate, repeat once or twice.

Contaminated fingernails may be scrubbed lightly with a soft nail brush. For contamination that is difficult to remove, disposable rubber gloves may be worn for several hours to promote perspiration of the hands, which may assist in removal of contamination while preventing its spread to other surfaces;

- skin, other than that of the hands, should be swabbed gently with a cotton wool pad soaked in a mild soap or handwash solution (preferably neutral pH) and rinsed well. Do not vigorously scrub the skin or use detergents as this may affect the natural skin barrier and increase the risk of internal contamination;
- contaminated wounds should be washed under a fast running tap. If the wound is on the face, care should be taken not to contaminate the eyes, mouth or nostrils. Finally, the wound should be washed with water, and a gentle antiseptic and a waterproof dressing applied; and
- attempts to remove all contamination from skin may not be feasible or desirable. Some radioactivity may be trapped in the outermost layers and will remain until normal sloughing occurs (12-15 days). Personal decontamination should be continued until monitoring shows that less than 10% of the residual contamination is removed at each cycle, unless there is the risk of the contamination entering the bloodstream through the roughening or breaking of the skin (US Department of Health and Human Services website).

10.3.2 Decontamination of surfaces or contaminated equipment

Many of the radioisotopes used in nuclear medicine have relatively short half-lives. In many cases it will be preferable to store or isolate the contaminated item until the level of radioactivity is reduced to an acceptable level rather than to attempt decontamination. If the decision is made to decontaminate the item, advice should be sought from the RSO on appropriate methods.

It is usually desirable to initially attempt decontamination with detergents, such as a customised commercially available detergent. Specialised cleaning methods such as the use of ultrasonic cleaning baths may also be appropriate. The use of chelating agents such as a 10 percent solution of sodium citrate may prove effective. If the contamination is due to iodine radioisotopes, the affected area should not be treated with any material that contains oxidising agents or acids as these can result in the production of volatile molecular radioiodine and the risk of inhalation. The use of acid on metal surfaces may also cause unnecessary corrosion and result in greater difficulty in future decontamination procedures.

The contaminated item should be monitored before and after decontamination has been performed. Decontamination seldom exceeds 99.9% effectiveness and is usually much less effective. If the measurement of residual contamination indicates that the level of radioactive contamination remains greater than permissible, the item should be stored to allow the radioactivity to decay; and also action should be taken to prevent the accidental return of the item into stock or other use.

If a spill occurs, care should be taken to avoid the spread of contamination. The liquid may be absorbed with disposable plastic backed absorbent paper or mopped-up by the use of a commercially available radioactive spill kit. All material used in the clean-up should be monitored and stored appropriately. If a wet mop will not remove the residual contamination, a decontamination method suitable for the particular surface material should be used. The contaminated area should be covered and isolated until the residual radioactivity has decayed to an acceptable level. In rare instances it may be necessary to cover the contaminated area with lead sheeting in order to provide adequate shielding, or to remove and replace the covering material on a bench surface or floor.

10.3.3 Contents of spill kit

A spill kit containing the necessary cleaning materials and protective clothing to deal with possible radioactive spills should be available in suitable locations and include items such as:

- plastic overshoes and gloves;
- disposable absorbent materials for liquids;
- plastic bags for radioactive waste;
- self-adhesive labels, marking pens and radiation warning signs;
- detergent such as Decon 90;
- remote handling tools such as forceps; and
- a container of **alkaline sodium iodide/sodium thiosulphate solution (0.1 mol/L NaI, 0.01 mol/L NaOH and 0.1 mol/L Na₂S₂O₃)** (if radioiodine is manipulated).

10.4 STORAGE AND SAFE HANDLING OF SEALED RADIOACTIVE SOURCES

Sealed radioactive sources have a number of uses within a nuclear medicine centre and need to be stored and handled in a safe and secure manner.

The sources should be:

- stored in appropriately shielded and labelled containers;
- licensed/registered with the relevant regulatory authority, where appropriate; and
- checked on a regular basis for any damage and to ensure the integrity of encapsulation.

In the case of physically small marker sources, care should be taken to ensure that loss does not occur and that all sources are accounted for at the end of the day. Any loss or damage of a source should be immediately reported to the RSO.

11. Training

11.1 RADIATION HEALTH PROFESSIONALS

Staff who perform or direct exposures of patients to ionizing radiation are required to have appropriate training. Although radiation health professionals such as nuclear medicine specialists and technologists have knowledge of radiation safety by virtue of undertaking a course leading to their professional qualification, the Responsible Person should provide additional training specific to the equipment used at a particular institution and should ensure that a program of continuing professional development is available for all the staff.

11.2 OTHER HEALTH PROFESSIONALS

Nurses working in nuclear medicine departments and who care for patients undergoing nuclear medicine procedures, particularly therapeutic 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 reducing occupational radiation doses during nuclear medicine examinations including time, distance and shielding;
- knowledge of the magnitude of typical doses from different examinations;
- risk factors such as age and the tissue type sensitivity; and
- measurement of radiation dose, if appropriate.

Professional bodies 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.

Other health professionals and ancillary staff should be provided with information on the basic principles of radiation protection such as time, distance and shielding.

11.3 STAFF INVOLVED IN RADIONUCLIDE THERAPY

Additional training should be provided for staff involved in the administration of radioactivity to patients for therapeutic purposes, or who care for patients receiving radionuclide therapy. This training should be delivered by suitably qualified personnel and should include the topics listed above plus:

- the limitations of shielding for gamma radiation of high energy;
- procedures to minimise the likelihood of radioactive contamination;
- procedures to handle potentially radioactive waste;

- potential problems with incontinent patients;
- contamination monitoring of the patient's room, and any necessary decontamination;
- restrictions, if any, for the patient's visitors;
- appropriate signage during treatment;
- requirements for the patient's discharge from hospital; and
- appropriate documentation of the patient's treatment and discharge.

12. Transport

The person responsible for the transport of radioactive material (the consignor) is required to comply with the current *Code of Practice for the Safe Transport of Radioactive Material* (ARPANSA 2008a) and any existing national and State legislation. As the Transport Code is very comprehensive, the guidelines given in Annex I (to be used in regard to transport of radioactive material between institutions) have been extracted and compiled solely for the purpose of this Safety Guide.

Annex A

Guidelines for the Radiation Management Plan

The plan should contain all the necessary background and operational information for working with radiation, and be kept up-to-date. It 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. Schedule A of the Code sets out the matters that must be addressed in the Radiation Management Plan. The Code requires that the Radiation Management Plan for a nuclear medicine centre which generates radioactive waste includes a section on radioactive waste management that incorporates the components listed in section A2 of Schedule A of the Code.

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 Responsibilities of employer and employees
 - 1.4 Procedures to ensure that employees understand and comply
 - 1.5 How will the plan be implemented
 - 1.6 Sources of radiation exposure
 - 1.7 Objectives of radiation protection
 - 1.8 Regulatory requirements, including dose limits and dose constraints
 - 1.9 Licensing/registration requirements (list details of unsealed and sealed sources, ionizing radiation equipment etc.)
 - 1.10 Penalties for legislative contravention
 - 1.11 Contact details (RSO, approved provider of personal radiation monitoring etc.)
2. The optimisation of nuclear medicine exposures
 - 2.1 Procedures to prevent erroneous administration of radiopharmaceuticals
 - 2.2 Procedures to avoid unintentional irradiation of embryo/fetus, or child (from breast-feeding)
 - 2.3 Procedures for the preparation and dispensing of radiopharmaceuticals
 - 2.4 Special procedures for therapy administration
 - 2.5 Reviews of administered activities
 - 2.6 Arrangements for obtaining expert advice in radiation protection
 - 2.7 Procedures for observation of the patient where required
3. Local rules/procedures for minimising exposure to staff and the general public
 - 3.1 Description of the area/procedure
 - 3.2 Nature of the hazard
 - 3.3 Procedure/equipment/facilities required
 - 3.4 Arrangements for the management of patients undergoing treatment with unsealed radionuclides
 - 3.5 Arrangements for obtaining expert advice in radiation protection
 - 3.6 Responsible staff and contact procedures
 - 3.7 Personal monitoring details (name of approved supplier etc.)
 - 3.8 Personal protective equipment

- 3.9 Actions to be taken if the radiation doses to staff or the general public are found to exceed the dose constraints
- 3.10 Emergency procedures (should include a brief description of the type of emergencies that could occur)
4. Record-keeping, general requirements
 - 4.1 Personal radiation monitoring doses
 - 4.2 Inventory of radioactive sources and X-ray units
 - 4.3 Testing where required (e.g., QA results, wipe tests on radioactive sources)
 - 4.4 Storage of records
5. Quality Assurance (QA) procedures
 - 5.1 Acceptance and constancy equipment tests
 - 5.2 Radiopharmaceutical QA
 - 5.3 Use, maintenance and calibration of radiation measuring instruments
6. Storage and disposal of radioactive materials
 - 6.1 Storage procedures (identification, location, record keeping, etc.)
 - 6.2 Sources and categorisation of radioactive waste
 - 6.3 Mixed waste hazards
 - 6.4 Conditioning/packaging
 - 6.5 Disposal procedures (when, how, who authorises the disposal, etc.)
7. Storage and disposal of X-ray apparatus
 - 7.1 Storage procedures (identification, location, record keeping, etc.)
 - 7.2 Disposal procedures (when, how, who authorises the disposal, etc.)
 - 7.3 Disposal/sale of X-ray apparatus (e.g. SPECT/CT radiation-producing equipment)
8. Environmental issues
 - 8.1 Radiation shielding to ensure compliance with the appropriate dose constraints
 - 8.2 Ventilation and maintenance of sterility
 - 8.3 Structural facilities within the centre to facilitate decontamination when necessary
 - 8.4 Appropriate storage of radioactive material
9. Handling of **radiation incidents**
 - 9.1 Possible types of incidents
 - 9.2 Procedures for handling each type
 - 9.3 Decontamination procedures
 - 9.4 General emergency procedures
 - 9.5 Contact names and numbers
 - 9.6 Reporting requirements
10. Training (details of initial training and ongoing training requirements, training providers etc.)
11. Transport (work rules for transport both within and between facilities)
12. Examples of any forms to be used in implementing the Radiation Management Plan
13. Mechanisms for the periodic review of the Radiation Management Plan.

Annex B

Radiation Safety Officer 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 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 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 nuclear medicine specialist on the radiation safety of individual patients undergoing diagnostic or therapeutic nuclear medicine 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 radionuclides;
- to arrange for the safe storage of radioactive materials and to ensure the safe disposal of any radioactive waste;
- to ensure that that all necessary shielding, radiation safety equipment and radiation monitoring and surveying devices are provided by the Responsible Person;
- 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 which 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 and unsealed 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 safety practices are performed.

Annex C

Radiation Safety Information for Patients Undergoing Radioiodine Therapy

The following is an example of written instructions⁴ to be given to patients or their legal guardians before they leave the hospital or centre after treatment with iodine-131.

You have been treated with radioactive iodine to cure a thyroid problem. Most of the iodine will leave your body through the urine. For several weeks, however, some of the iodine will stay inside your body, which means that you in turn can irradiate other people physically close to you.

It is your responsibility to protect relatives, friends, colleagues and others. The following questions and answers are designed to inform you about simple precautions to be taken.

Your doctor will inform (or has already informed) you how long you should follow these instructions (i.e. the 'restriction period'):

1. What are the most important precautions to minimise radiation to others?

The most important factors are distance and time. Try to maintain a distance of at least 1 metre from other people. Do not sit or stay close to any person either at home or at work. If you are with someone for longer periods (perhaps more than one hour), stay at least 2 metres away.

Passing someone briefly, for example in the street, or while shopping, is permissible - as is a quick hug.

2. What about contacts with pregnant women?

Contact with pregnant women should be minimised. Try to stay at least 2 metres away from a pregnant woman.

3. Can I still see my children and care for them?

If your children are under five years old, minimise hugging or holding and avoid prolonged contact for the specified restriction period.

4. What about infants?

Children under three years old should be looked after by someone else. If possible, arrange for them to stay with relatives or friends.

5. Can I go on with breast-feeding?

Radioactive iodine is passed on in breast milk for quite a long time. Therefore, it is important that breast-feeding be stopped completely.

⁴ Based on recommendations from the European Commission (EC 1998)

6. Can I be in close contact with my partner or other people at home?

You should sleep in a separate bed and restrict sexual contact for the specified restriction period. Beds should be at least 2 metres apart, even if there is a wall separating them. This is because the walls of a house do not provide good protection against the type of radiation emitted by iodine-131. Kissing should be avoided in order to prevent the transmission of radioactivity in the saliva.

7. What if my partner is pregnant?

If your partner is pregnant, it is important to avoid close contact with her.

8. Do these precautions apply for my contact with people over 60 years of age?

The radiation related risk is much lower for people over 60 years of age than it is for younger people. For that reason, special precautions are less important.

9. Can I receive visitors?

Short visits, less than two hours, create no problem. Keep at a distance of about 2 metres and preferably avoid close contact. You should discourage visits by young children and pregnant women.

10. Can I go to work?

Most people can go to work. If, by the nature of your work, you are within 1 metre of the same individual(s) for more than two hours per day, you should seek advice from your doctor.

You should in any case inform your manager.

11. What if I am a nursery school teacher?

Nursery school teachers, or others who are in close contact with young children during working hours, should stay off work. Your doctor will indicate the required period of time for this restriction.

12. Can I go to the movies or other entertainment?

Avoid visiting cinemas and other social events for the first 2 days where you are close to other people for more than one hour.

13. May I use public transport?

Public transport can involve you sitting close to another person and restrictions may be required on travel of long duration. For long trips you should try to find a place where you can sit alone. Long distance travel immediately after administration is not recommended due to the potential for travel sickness and the possibility for contamination.

Your doctor will advise you on appropriate travel times.

14. What about using a taxi?

Sit in the back on the opposite side from the driver. Do not spend more than two hours with any one taxi driver.

15. Can I use the same toilet as other people?

Yes, but spilling of urine needs to be avoided. Therefore, (also for men) pass urine while seated. Always dry your genitals with toilet paper and flush the toilet. It is also important to wash your hands immediately afterwards, even when only urinating.

16. What about cutlery, crockery, bed linen, towels etc?

Radioactive iodine also leaves the body in the saliva and the sweat of patients. Therefore, cutlery, crockery, towels, bed linen etc. should not be shared with others. After washing they are completely safe. There is no need to wash them separately.

17. What happens if I have to go to hospital?

If you have to go to hospital unexpectedly, please inform the doctor that you have been treated with radioactive iodine recently. This applies even when it is the same hospital where you were treated.

18. Is it safe to become pregnant/father children?

Some of the radioactive iodine will remain in your body for several months and it is recommended that females should avoid becoming pregnant for six months and males should not father children for four months following the treatment.

19. What happens if I have to go overseas?

Some airports, as part of their security, have extremely sensitive radiation detectors that are able to detect minute amounts of radioactivity. If you are travelling by air soon after your treatment you should take some documentation about your treatment.

If in doubt, you should always ask the advice of the doctor treating you.

Annex D

Death of a Patient Being Treated with Radioactive Materials – Procedures and Precautions

If a patient dies during treatment with radioactive materials, the nuclear medicine specialist concerned should ensure, after consultation with the nuclear medicine physicist, that exposure to radiation of any persons handling the body is minimised. At the time of death, the body should be clearly labelled with the radionuclide, form and estimated residual activity. The body should be handled as little as possible, using strict procedures for prevention of contamination with body fluids, until the nuclear medicine physicist has been contacted. If a patient dies shortly after undergoing a diagnostic nuclear medicine procedure, no special precautions are required.

Table 10: Maximum activities proposed for autopsy, embalming, burial or cremation of the body of a patient who has died during treatment with unsealed radioactive substances (IAEA 2007)

	Half life (days)	Indicative maximum activity administered (MBq)	Autopsy/ Embalming (MBq)	Burial (MBq)	Cremation (MBq)
³² P	14.3	200	100	2 000	30
⁸⁹ Sr	50.7	200	50	2 000	20
⁹⁰ Y	2.7	2 000	200	2 000	70
¹³¹ I	8.0	10 000	10	400	400

Note: Samarium-153, an alternative to strontium-89 for the palliation of malignant bone disease, is not included in Table 10 as the short half life of 1.95 days allows significant reduction in residual activity after a few days delay.

All corpses released for autopsy, embalming, cremation or burial above these limits should have a label attached, identifying the radionuclide and its activity at the time of release, together with a release statement signed by the qualified expert or a nuclear medicine physicist.

Precautions for handling the corpse are given below. In addition the requirements of the Transport Code will need to be taken into account if a body is to be transported, such as repatriation to another country.⁵

AUTOPSIES

If an autopsy is required, consideration should be given as to whether a CT examination would be sufficient.

⁵ Guidance on radiation safety procedures following the death of a patient with a sealed form of radioactive material *in situ*, such as iridium-192 or iodine-125, is given in the *Safety Guide for Radiation Protection in Radiotherapy*. (ARPANSA 200z)

When a corpse contains less radioactive material than the activities shown in Table 10, procedures for personal protection normally observed during an autopsy will provide adequate protection against external radiation exposure or contamination with radioactive material.

If a corpse contains activity in excess of the levels shown in Table 10 and autopsy cannot be postponed for a suitable period for radioactive decay, the pathologist should be informed of the radiation levels likely to be encountered and of the hazards involved. The methods employed and the precautions adopted should be chosen accordingly in consultation with a nuclear medicine physicist.

If it is known that the radioactive material used for treatment will have been selectively absorbed in a particular organ, e.g. iodine-131 in the thyroid, the organ should be excised and removed from the work area before the autopsy examination proceeds. It may later be disposed of with the body.

If it is known that radioactive material will be distributed in particular body fluids, e.g. iodine-131 or strontium-89 in the bladder, these should be drained off, using suitable equipment, before the examination proceeds. In general, these fluids may be safely disposed of via the sewerage system. The equipment should later be decontaminated by thorough rinsing in a detergent solution followed by washing in running water.

Annex E

Quality Assurance

GENERAL

Each nuclear medicine centre will need to have a comprehensive Quality Assurance (QA) program that places particular emphasis on image quality optimisation, radiopharmaceutical quality and patient dose optimisation.

The basic elements of the QA program should include:

- equipment acceptance testing;
- equipment constancy testing;
- radiopharmaceutical quality testing;
- record keeping;
- patient activity surveys; and
- keeping records of equipment unscheduled downtime and the reason for the failure.

The QA program should:

- include a system of checks and procedures to ensure that the aims of the QA program are met; and
- have a well defined responsibility and reporting structure.

The results of all QA tests will need to be documented and retained for possible inspection by external auditors.

All personnel working in diagnostic and therapeutic nuclear medicine will need to follow the working procedures defined in the QA program.

ACCEPTANCE TESTING OF NUCLEAR MEDICINE EQUIPMENT

At initial installation, the nuclear medicine equipment (e.g. radionuclide dose calibrators, gamma cameras, PET cameras, autogamma counters, laser film imagers) need to undergo acceptance testing to ensure that the equipment performance complies with the manufacturer's specifications.

Any radionuclide sources used in performing **accuracy** checks of radionuclide dose calibrators will need to have a calibration traceable to a national or international standard.

The results of the acceptance testing will need to be documented and available for inspection by the relevant regulatory authority.

TESTING OF NUCLEAR MEDICINE EQUIPMENT

Tests designed to assess the performance of the equipment need to be conducted and will take into account:

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

The QA program should clearly define the:

- types of constancy tests;
- frequency of tests;
- tolerance of each parameter being monitored; and
- procedure for staff to follow when tolerance is exceeded.

The results of constancy testing need to be reviewed as a matter of routine and any anomalous results reported immediately to the Responsible Person.

The following tests should be conducted for dose calibrators at the indicated frequency, and to the indicated tolerance:

- background – at least once each work day prior to the first assay of patient dosages or whenever contamination of the dose calibrator is suspected;
- constancy – at least once each work day prior to the first assay of patient dosages (± 10 per cent);
- linearity – at installation and at least annually thereafter, and after repair or movement (± 10 per cent);
- accuracy – at installation and at least annually thereafter, and after repair or movement (± 10 per cent); and
- geometry independence – at installation and after repair or movement (± 10 per cent).

Repair, replacement, or arithmetic correction will need to be conducted if the dose calibrator falls outside the indicated tolerances.

RADIOPHARMACEUTICAL QUALITY ASSURANCE

The *in vivo* behaviour of a radiopharmaceutical is dependent upon its quality, which includes high standards of radionuclidic, radiochemical and chemical purity. Radiopharmaceuticals will need to comply with both radiation and pharmaceutical standards in order to ensure their safe and efficacious use.

Technetium-99m generator

Technetium-99m generators should be sited in a clean area away from general traffic and additional lead shielding may need to be used to reduce the external dose rate to acceptable levels.

The following records need to be kept of all generator elutions:

- dose calibrator setting where the isotope is manually dialled;
- reading of long-lived reference source;
- date and time of elution;
- volume of eluate;
- technetium-99m activity;
- molybdenum-99 activity; and
- radionuclidic purity.

A molybdenum-99 breakthrough measurement should be performed on all elutions from each technetium-99m generator and where there is a breakthrough level of

greater than 1 MBq of molybdenum-99 per GBq of technetium-99m at the time of administration, the technetium-99m solution should not be used in the preparation of radiopharmaceuticals for patient use.

RECORD KEEPING

Testing records

Record keeping is a key component of a successful QA program and should at the very least include details of:

- acceptance testing;
- all constancy tests; and
- radiopharmaceutical testing.

Failures identified at acceptance or constancy testing and radiopharmaceutical testing, and the actions taken to remedy those failures should be documented and these records kept for the lifetime of the equipment.

Records of receipt

Complete records of the radionuclide, activity, chemical form, supplier, supplier's batch number and purchase date need to be kept.

On arrival, if a package containing radioactive material is suspected of being damaged, the package should be:

- monitored for leakage with a wipe test; and
- checked with a survey meter for unexpectedly high external radiation levels.

If a package is damaged or suspected of being damaged, the supplier should be contacted immediately.

All records need to be kept for two years.

Records of dispensing

The preparation of radiopharmaceuticals needs to be performed in accordance with the requirements specified in the Radiation Management Plan. The preparation should be safe, straightforward and reliable.

Records of each preparation should include the:

- name of the radiopharmaceutical;
- cold kit batch number;
- date of manufacture;
- batch number of final product;
- radiochemical purity results; and
- expiry date.

A record detailing:

- each patient dose dispensed and measured on a dose calibrator;
- name of the patient;

- name of the radiopharmaceutical;
- measured radioactivity; and
- time and date of measurement,

also needs to be kept and an appropriate label attached to the dose holder for each preparation. The activity should not be made available for patient administration until all these steps described above have been completed.

All dispensing records should be kept for at least two years.

Records of administration

The radiopharmaceutical activity administered to each patient should be recorded and the records should be kept for a minimum of three years.

Annex F

Test Procedures for Dose Calibrators

The recommended frequency for each test is given in Table 9.

CONSTANCY

The following procedure may be used to meet the constancy requirement:

1. Assay each reference source using the appropriate dose calibrator setting (i.e., use the caesium-137 setting to assay caesium-137).
2. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.
3. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source. Computer plotting programs may be used and are encouraged.
4. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
5. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will notify the chief technologist or nuclear medicine physicist of the suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. Repair or replacement is required if the error exceeds 10 percent.

Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

LINEARITY

Decay method

1. Assay the technetium-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in megabecquerels. Record the date, time to the nearest minute, and net activity on a linearity test form. This first assay should be performed in the morning at a fixed time, for example, 8 am.
2. Repeat the assay at about noon, and again at about 4 pm. Continue on subsequent days until the assayed activity is less than 400 kilobecquerels. For dose calibrators on which the range is selected with a switch, select the range that would normally be used for the measurement.
3. Convert the time and date information you recorded to hours elapsed since the first assay.
4. On a sheet of semilog graph paper, label the logarithmic vertical axis in megabecquerels and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Then plot the data. Computer plotting programs may be used and are encouraged.
5. Draw a 'best fit' straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. $(\text{Activity-observed} - \text{Activity-line}) / (\text{Activity-line}) = \text{deviation}$.

6. If the worst deviation is more than ± 0.10 , the dose calibrator should be repaired or adjusted. If this cannot be achieved, it will be necessary to make a correction table or graph that will allow the activity indicated by the dose calibrator to be converted to the 'true activity'.
7. Attach a sticker on the dose calibrator that states when the next linearity test is due.

ACCURACY

It is recommended that where technetium-99m, iodine-131, gallium-67 and thallium-201 are used within the centre that calibrated sources of these radionuclides be obtained from the Australian Nuclear Science and Technology Organisation (ANSTO), or from a supplier who has compared that source to a source that was calibrated by ANSTO.

1. Assay a calibrated reference source at the appropriate setting (i.e., use the technetium-99m setting to assay technetium-99m), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement on a dose calibrator geometry and accuracy form. Repeat for a total of three determinations.
2. Average the three determinations. The average value should be within 10 percent of the certified activity of the reference source, mathematically corrected for decay.
3. Repeat the procedure for other calibrated reference sources.
4. If the average value does not agree, within 10 percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The dose calibrator should be either repaired or replaced if the error exceeds 10 percent, and not used until it meets this requirement. For those dose calibrators for which the calibration factor can be adjusted by the operator, this factor should be adjusted and steps 1 and 2 repeated to bring the dose calibrator back into calibration.
5. At the same time that the accuracy test is performed, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated activity (MBq) values with the accuracy data.
6. Attach a sticker on the dose calibrator that states when the next accuracy test is due.

GEOMETRY INDEPENDENCE

1. In a small beaker or vial, mix 2 mL of a solution of technetium-99m with an activity concentration between 40 and 400 MBq/mL. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.
2. Draw 0.5 mL of the technetium-99m solution into the syringe and assay it. Record the volume and megabecquerels indicated on a dose calibrator geometry and accuracy form.
3. Remove the syringe from the calibrator, draw an additional 0.5 mL of nonradioactive saline or tap water, and assay again. Record the volume and megabecquerels indicated.
4. Repeat the process until you have assayed a 2.0-mL volume.

5. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard megabecquerels by the megabecquerels indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 10 percent error lines above and below the chosen 'standard volume'. Computer plotting programs may be used and are encouraged.
6. If any correction factors are greater than 1.10 or less than 0.90, or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow the conversion from 'indicated activity' to 'true activity'. If this is necessary, label the table or graph 'syringe geometry dependence', and note the date of the test and the model number and serial number of the calibrator.
7. To test the geometry dependence for a 30-mL glass vial, draw 1.0 mL of the technetium-99m solution into a syringe and assay the syringe. Inject the solution into the vial and re-assay the syringe and record the activity added to the vial (the difference between the 2 syringe readings). Assay the vial and record the volume and activity (MBq) indicated. Divide the vial activity (MBq) by the injected activity. The quotient is the vial/syringe correction factor.
8. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 mL of non-radioactive saline or tap water, and assay again. Record the volume and activity (MBq) indicated.
9. Repeat the process until you have assayed a 19.0-mL volume. The entire process needs to be completed within 10 minutes.
10. Select as a standard the volume closest to that normally used for reconstituting radiopharmaceutical kits. For all the other volumes, divide the standard activity (MBq) by the activity indicated for each volume. The quotient is a volume correction factor. Alternately, graph the data and draw horizontal 10 percent error lines above and below the chosen 'standard volume'. Computer plotting programs may be used and are encouraged.
11. If any correction factors are greater than 1.10 or less than 0.90 or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow the conversion from 'indicated activity' to 'true activity'. If this is necessary, be sure to label the table or graph 'vial geometry dependence', and note the date of the test and the model number and serial number of the calibrator.

Annex G

Survey Meters

GENERAL REQUIREMENTS OF THE SURVEY METER

The radiation survey meter should:

- (a) have sufficient measurement range to measure ambient dose equivalent rates at least throughout the ranges of $0.5 \mu\text{Sv h}^{-1}$, or its equivalent, to 1 mSv h^{-1} , or its equivalent, for the radiations emitted from the radioactive sources used in nuclear medicine;
- (b) continue to indicate, either visibly or audibly, when radiation levels exceed the maximum reading in any measurement range; and
- (c) indicate the measured quantity with a measurement uncertainty not greater than ± 25 per cent 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:

- (a) prior to initial use;
- (b) at intervals not exceeding 12 months; and
- (c) following damage or repairs.

Annex H

Monitoring of Ambient Radiation and Surface Contamination

AMBIENT DOSE RATE SURVEYS

At the end of each working day: all radiopharmaceutical elution, preparation, assay and administration areas (except patient treatment rooms which should be surveyed at the end of the therapy instead of on the day of administration).

Weekly: all radionuclide use, storage and waste storage areas.

Monthly: all laboratory areas where only small quantities (≤ 10 MBq) of gamma-emitting radioactive materials are used.

Ambient dose rate trigger levels: if the levels listed below are exceeded the source of the increased dose rate should be identified and removed. If the dose rate cannot be reduced the RSO, or the Responsible Person, should be notified immediately.

Unrestricted area: $0.5 \mu\text{Sv/h}$

Restricted area: $10 \mu\text{Sv/h}$

CONTAMINATION SURVEYS

At the end of each working day: users and immediate work areas where radioactive materials are used.

Weekly: radiopharmaceutical elution, preparation, assay and administration areas, radionuclide storage areas and radionuclide waste storage areas.

Monthly: all laboratory areas where only small quantities (≤ 10 MBq) of gamma-emitting radioactive materials are used.

There should be a written record of each survey. This record should:

- identify the work area;
- specify the date on which the survey was undertaken;
- indicate if radioactive contamination was detected;
- indicate if a high ambient dose rate was detected due to unattended sources;
- indicate what action(s) was taken to remove any contamination or unattended sources;
- indicate that the contamination or sources had been successfully removed; and
- include the signature of the person undertaking the survey.

When wipe tests indicate the presence of removable radioactive contamination, personnel or surfaces should be decontaminated until the activity is as low as reasonably achievable and below the limits recommended by the NHMRC (NHMRC 1995).

Annex I

Transport

PACKAGE TYPE

The Transport Code (ARPANSA 2008a) specifies a classification of excepted packages. Packages in this classification are exempt from many of the stringent requirements which otherwise are required to be followed. If a package does not meet the excepted packages classification, then it is usually transported as Type A. For the Type A category, the package has to satisfy various performance tests such as drop and penetration tests to demonstrate an ability to withstand the normal conditions of transport. The advice of the institution's RSO, or the relevant regulatory authority, should be obtained if a Type A package (or rarely, a higher category Type B package) has to be transported.

EXCEPTED PACKAGES

Excepted packages are required to meet the following criteria:

- the activity does not exceed the limits listed for the radionuclides in Table 11 below;
- the radiation level at any point on the external surface is not greater than 5 $\mu\text{Sv/h}$;
- the removable radioactive contamination on any external surface averaged over any area of 300 cm^2 of any part of the surface does not exceed 4 Bq/cm^2 . If this value is exceeded, the package needs to be checked for damage and repackaged;
- the package will retain its radioactive contents under routine conditions of transport;
- the package bears the marking '**RADIOACTIVE**' on an internal surface in such a manner that a warning of the presence of radioactive material is visible on opening the package;
- the transport document with each consignment gives the United Nations Number '**2910**'; and
- all items are described as '**RADIOACTIVE MATERIAL, EXCEPTED PACKAGE**' and include the proper shipping name of the substance or article being transported i.e.: '**LIMITED QUANTITY OF MATERIAL**'.

If the package does not satisfy the activity and surface dose-rate limits, it will require a Type A (or B) classification.

Table 11: Activity Limits for Excepted Packages

	Solids (MBq)	Liquids (MBq)		Solids (MBq)	Liquids (MBq)
Bromine-82	400	40	Phosphorus-33	1 000	100
Carbon-14	3 000	300	Samarium-153	600	60
Chromium-51	30 000	3 000	Selenium-75	3 000	300
Cobalt-57	10 000	1 000	Sodium-22	500	50
Cobalt-58	1 000	100	Sodium-24	200	20
Fluorine-18	600	60	Strontium-89	600	60
Gallium-67	3 000	300	Strontium-90	300	30
Indium-111	3 000	300	Sulphur-35	3 000	300
Iodine-123	3 000	300	Technetium-99m	4 000	400
Iodine-125	3 000	300	Thallium-201	4 000	400
Iodine-131	700	70	Tritium (³ H)	40 000	4 000
Iron-59	900	90	Xenon-133	10 000	1 000
Molybdenum-99	600	60	Yttrium-90	300	30
Phosphorus-32	500	50			

Note: Contact the RSO for radionuclides not listed above, or for non-standard packages.

TYPE A PACKAGES

Type A packages fit the following criteria:

- The activity does not exceed the limits listed for the radionuclides in Table 12 below.
- The removable radioactive contamination on any external surface averaged over any area of 300 cm² of any part of the surface does not exceed 4 Bq/cm². If this value is exceeded, the package needs to be checked for damage and repackaged.

Table 12: Activity Limits for Type A Packages

	GBq		GBq
Bromine-82	400	Phosphorus-33	1 000
Carbon-14	3 000	Samarium-153	600
Chromium-51	30 000	Selenium-75	3 000
Cobalt-57	10 000	Sodium-22	500
Cobalt-58	1 000	Sodium-24	200
Fluorine-18	600	Strontium-89	600
Gallium-67	3 000	Strontium-90	300
Indium-111	3 000	Sulphur-35	3 000
Iodine-123	3 000	Technetium-99m	4 000
Iodine-125	3 000	Thallium-201	4 000
Iodine-131	700	Tritium (³ H)	40 000
Iron-59	900	Xenon-133	10 000
Molybdenum-99	600	Yttrium-90	300
Phosphorus-32	500		

Note: Contact the RSO for radionuclides not listed above, for non-standard packages, and for activities greater than can be transported in Type A packages.

Category labels

Type A packages have category labels attached to two opposite sides. The label to be used depends on the radiation dose rate at the surface and the transport index. The transport index is the maximum radiation dose rate at any point 1 metre from the surface of the package in $\mu\text{Sv/h}$, divided by 10 and then rounded up to one decimal place. For example, a package with a radiation reading of $4.3 \mu\text{Sv/h}$ at one metre will have a transport index of 0.5 (i.e. $4.3 \div 10 = 0.43$ rounded up to 0.5). The criteria for labelling the packages are outlined in Table 13 below.

Table 13: Label Categories for Packages

Conditions		
Transport index	Maximum radiation level at any point on external surface	Category
0 ^a	Not more than $5 \mu\text{Sv/h}$	I-WHITE
More than 0 but not more than 1	More than $5 \mu\text{Sv/h}$ but not more than $500 \mu\text{Sv/h}$	II-YELLOW
More than 1 but not more than 10	More than $500 \mu\text{Sv/h}$ but not more than $2000 \mu\text{Sv/h}$	III-YELLOW

^a If the measured transport index is not greater than 0.05, the value quoted may be zero.

Note: Both the transport index and the surface radiation level conditions are taken into account in determining the appropriate category. Where the transport index satisfies the condition for one category but the surface radiation level satisfies the condition for a different category, the package will be assigned to the higher category.

The category labels will need to indicate the radionuclide, its activity in becquerel units and, for category II and III, the transport index (consult ARPANSA *Code of Practice for the Safe Transport of Radioactive Material*, RPS2, (ARPANSA 2008a) for further details).

Segregation from other dangerous goods

The Transport Code and the Australian Dangerous Goods Code require segregation of radioactive material from some other dangerous goods. Under the Australian Dangerous Goods Code, radioactive materials are not to be carried on the same vehicle as any of the dangerous goods listed in Table 14.

Table 14: Items NOT PERMITTED to be Transported with Radioactive Materials

Dangerous Goods Hazard Class	Items
1	Explosive
2.1	Flammable Gas
3	Flammable Liquid
4.1	Flammable Solid
4.2	Spontaneously Combustible
4.3	Dangerous when Wet
5.1	Oxidising Agents
5.2	Organic Peroxide
8	Corrosive

Foodstuffs should not be carried on the same vehicle as radioactive material.

The following classes of dangerous goods may be carried on the same vehicle carrying radioactive materials:

- non-flammable non-toxic gases;
- poisonous gases;
- poisonous (toxic) substances; and
- miscellaneous dangerous goods.

Documentation

The consignor needs to complete the following documents prior to commencement of the transport of the radioactive material:

- a consignor's declaration (an example form is given on the ARPANSA website at www.arpansa.gov.au/pubs/rps/cons_dec.pdf). A minimum of two copies is required. One is for the driver and one, enclosed in a stout envelope, is to be firmly fixed to the outside of the package for inspection in transit. Where more than one driver is involved, it may be necessary for each driver to receive a copy of the consignor's declaration; and
- information for drivers – a document which provides:
 - any supplementary operational requirements for loading, transport, storage (away from persons, dangerous goods, etc.); and
 - emergency arrangements specific for the package.

Instructions to the person organising transport

The person organising the transport should comply with the following:

- taxis, motorcycles, or public transport are not to be used to transport radioactive material;
- the institution's transport vehicle may be used to transport the package provided the driver has been instructed in how to handle and secure the package in the

vehicle and in the actions to be taken in case of an accident or an emergency. Written instructions also need to be provided (see the kit at the end of this Annex);

- when the delivery is urgent, private cars may be used (insurance provisions may apply). A person who is conversant with the hazards involved and with handling emergency situations, and preferably authorised to use the radioactive material being transported, will either drive the vehicle transporting the material, or will accompany the driver; and
- the package needs to be addressed and delivered to a specific authorised person. It should not be addressed generally to a 'Department', nor delivered to a specified 'area' or to the 'front desk'. It should be transferred to the custody of an authorised person or left at a secured location.

Packaging procedure

A written procedure for the packaging of the radioactive material should be developed along the following lines:

- Package appropriately:
 - contain liquids in a sealed vial with appropriate labelling including:
 - the approved name of the radiopharmaceutical;
 - the (quantitative) composition;
 - (for liquid radiopharmaceuticals) the total radioactivity (in SI units) or the radioactive concentration per mL at a stated date and time and the volume; or (for capsules) the radioactivity of each capsule (in SI units) at a stated date and time and the number of capsules in the container;
 - the route of administration;
 - (for radiopharmaceuticals to be administered parentally) the name and concentration of any antimicrobial preservatives;
 - the manufacturer's name;
 - the batch number; and
 - the expiry date and time.
 - place the vial or other source in a shielded (lead etc.) container with sufficient liquid absorber. Label the container 'RADIOACTIVE' and give the name and activity of the compound, and the date. Close the container with a tight fitting lid, and tape;
 - place this sealed container inside an outer transport box with cushioning material to prevent movement within the box and seal the transport box.
- Measure and record the surface dose rate. Check that there is no contamination on the outer surface.
- Determine whether the package is classified as an excepted package, or Type A.
- Fill out a 'consignor's declaration' and attach to the package.
- Label the package with:
 - the name and address of addressee;
 - the sender's name and address; and
 - appropriate category label if Type A.
- Give the package and the transport kit (detailing transport instructions) to the driver.

Radioactive Material Transport Kit

The following is an example of a kit to be provided to the driver of a vehicle transporting radioactive materials.

Page 1 (Cover Page)

**RADIOACTIVE MATERIAL TRANSPORT KIT
AND
EMERGENCY PROCEDURES GUIDE**

**To be read and carried by all
drivers transporting radioactive materials**
*(To be kept in the document holder in the driver's door
or some conspicuous place in the driver's compartment)*

**Transport of radioactive materials by public
transport, taxis or motorcycles is
NOT PERMITTED**

Carry packages securely:

- in boot of car, or
- away from driver in vans and station wagons, and
- segregated from non-compatible Dangerous Goods

Do not leave packages unsecured at ANY time

In an Emergency, contact:
HAZMAT Team
Telephone: 000 (All hours)

Page 2

INSTRUCTIONS FOR THE DRIVER

All drivers carrying labelled packages of radioactive materials should:

- Check that a Radioactive Goods (consignment) form is attached to each package and that it has been completed with details of each radioactive material being delivered, destination and name of the addressee.
- Ensure that there are three placard signs in this kit. Attach one placard on each side of the vehicle and one on the rear of the vehicle.
- Secure transport packages either:
 - in the boot of a car; or
 - away from the driver of a van or station wagon; and
 - segregated as per Australian Dangerous Goods Code from other incompatible dangerous goods.
- Carry these instructions in the vehicle in the document holder.
- Carry a mobile phone to be used in the event of an accident.
- Deliver the appropriate package together with its consignment form, to the addressee or their agent.

- At the last destination, remove the three yellow transport placards from the outside of the vehicle and replace them in this kit. It is illegal to display dangerous goods signs if dangerous goods are not in or on the vehicle.
- Ensure that passengers are not travelling in the vehicle at the same time as packages containing radioactive material. However, an authorised person responsible for the radioactive material being carried may travel in the vehicle, or if two or more people are required for radionuclide procedures off site, they may all travel in the same vehicle.
- The vehicle needs to be left in a secured state when packages containing radioactive materials remain in the vehicle.

Page 3

TRANSPORT ACCIDENTS

In the event of an accident, **DON'T PANIC**. The packaging complies with international standard requirements and is designed to withstand accidents. If the package is not severely damaged, the radioactive material is unlikely to be damaged, and its container is unlikely to leak. It is therefore important to **attend first to the needs of any injured persons**.

If a road vehicle transporting radioactive materials is involved in an accident that results in a dangerous situation (injury, road hazard, escape/leakage of materials, fire, vehicle immobilised, etc.), the driver of the vehicle needs to:

- notify emergency services '000';
- notify the institute's RSO and/or the responsible head of department; and
- provide assistance to emergency services, or the responsible authority officer in charge.

In addition to the above:

- if possible, get out of vehicle and assess the injury status of others involved in the accident;
- provide assistance if it is safe to do so. If in doubt leave it to emergency services;
- assess the integrity of the radioactive package(s), with minimal contact (or exposure);
- with the results of the assessment in mind it may be necessary to complete the above actions of notification;
- if possible, gain the assistance of passers-by to keep onlookers and other traffic at a safe distance;
- inform emergency services of any environmental or human hazards (fire, spill, etc.); and
- wait for and assist emergency services.

If the packages are undamaged and the damage sustained by the vehicle does not have to be reported to the police, and if the vehicle can still be safely driven, deliver the package(s) to the addressee(s), and inform them that the vehicle was involved in a minor accident on the way. Give a detailed report to the RSO(s).

Health Effects of Ionizing Radiation and Standards for Control of Exposure

It is well known that high doses of ionizing radiation can cause harm, but there is continuing scientific uncertainty about effects at low doses. At levels of dose routinely encountered by members of the public and occupationally exposed persons, there is little or no epidemiological evidence of health effects. Radiation protection standards recognise that it is not possible to eliminate all radiation exposure, but they do provide for a system of control to avoid unnecessary exposure and to keep doses in the low dose range.

Extreme doses of radiation to the whole body (around 10 sievert⁶ and above), received in a short period, cause so much damage to internal organs and tissues of the body that vital systems cease to function and death may result within days or weeks. Very high doses (between about 1 sievert and 10 sievert), received in a short period, kill large numbers of cells, which can impair the function of vital organs and systems. Acute health effects, such as nausea, vomiting, skin and deep tissue burns, and impairment of the body's ability to fight infection may result within hours, days or weeks. The extent of the damage increases with dose. However, '**deterministic**' effects such as these are not observed at doses below certain thresholds. By limiting doses to levels below the thresholds, deterministic effects can be prevented entirely.

Doses below the thresholds for deterministic effects may cause cellular damage, but this does not necessarily lead to harm to the individual: the effects are probabilistic or 'stochastic' in nature. It is known that doses above about 100 mSv, received in a short period, lead to an increased risk of developing cancer later in life. There is good epidemiological evidence – especially from studies of the survivors of the atomic bombings – that, for several types of cancer, the risk increases roughly linearly with dose, and that the risk factor averaged over all ages and cancer types is about 1 in 100 for every 100 mSv of dose (i.e. 1 in 10 000 per mSv).

At doses below about 100 mSv, the evidence of harm is not clear-cut. While some studies indicate evidence of radiation-induced effects, epidemiological research has been unable to establish unequivocally that there are effects of statistical significance at doses below a few tens of millisieverts. Nevertheless, given that no threshold for stochastic effects has been demonstrated, and in order to be cautious in establishing health standards, the proportionality between risk and dose observed at higher doses is presumed to continue through all lower levels of dose to zero. This is called the linear, no-threshold (LNT) hypothesis and it is made for radiation protection purposes only.

There is evidence that a dose accumulated over a long period carries less risk than the same dose received over a short period. Except for accidents and medical exposures, doses are not normally received over short periods, so that it is appropriate in determining standards for the control of exposure to use a risk factor that takes this into account. While not well quantified, a reduction of the high-dose risk factor by a factor of two has been adopted internationally, so that for radiation protection purposes the risk of radiation-induced fatal cancer (the risk factor) is taken to be about 1 in 20 000 per mSv of dose for the population as a whole.

⁶ The sievert (Sv) is a unit of measurement of radiation dose (ARPANSA's *Recommendations for limiting exposure to ionizing radiation (2002)*).

If the LNT hypothesis is correct, any dose carries some risk. Therefore, measures for control of exposure for stochastic effects seek to avoid all reasonably avoidable risk. This is called optimising protection. However, risk in this sense may often be assessed in terms of risk to a population, and may not ensure sufficient protection of the individual. Consequently, the optimisation approach is underpinned by applying dose limits that restrict the risk to individuals to an acceptable level. The fundamental regulatory philosophy is expressed in three principles, based on the recommendations of the International Commission on Radiological Protection (ICRP), which may be summarised as follows:

Justification: human activities that cause exposure to radiation may be permitted only if they do more good than harm;

Optimisation of protection: exposure to radiation from justified activities should be kept as low as reasonably achievable, social and economic factors being taken into account; and

Limitation of individual dose: doses must not exceed the prescribed dose limits.

Determining what is an acceptable risk for regulatory purposes is a complex value judgement. The ICRP reviewed a number of factors in developing its recommendations, which have in general been internationally endorsed, including by the World Health Organization, the International Labour Organisation and the International Atomic Energy Agency. Australia's Radiation Health Committee, now established under the ARPANS Act⁷, has recommended that the international standards be adopted in Australia. The recommended dose limits are summarised as follows:

Limit on effective dose*

	For occupational exposure	For members of the public
To limit individual risk	20 mSv per year, averaged over 5 years*	1 mSv in a year*

*for details, see ARPANSA's *Recommendations for limiting exposure to ionizing radiation (2002)*

In most situations, the requirements for limiting individual risk ensure that doses are below deterministic thresholds, but for cases where this does not apply, the recommended limits are as follows:

Annual limit on equivalent dose*

	For occupational exposure	For members of the public
To prevent deterministic effects		
in the lens of the eye	150 mSv	15 mSv
in the skin	500 mSv	50 mSv
in the hands and feet	500 mSv	–

*for details, see ARPANSA's *Recommendations for limiting exposure to ionizing radiation (2002)*

In the case of occupational exposure during pregnancy, the general principle is that the embryo or fetus should be afforded the same level of protection as is required for a member of the public. For medical workers, the ICRP recommends that there

⁷ The *Australian Radiation Protection and Nuclear Safety Act (1998)*

should be a reasonable assurance that fetal dose can be kept below 1 mGy⁸ during the course of the pregnancy. This guidance may be generalised to cover all occupationally exposed pregnant workers by keeping the fetal dose below 1 mSv. A full explanation of radiation protection principles and of the recommended standards for Australia is given in ARPANSA/NOHSC Radiation Protection Series No. 1: *Recommendations for limiting exposure to ionizing radiation (1995)* and *National standard for limiting occupational exposure to ionizing radiation* (both republished in 2002).

⁸ The gray (Gy) is a unit of radiation dose. For X-rays and gamma radiation, it is essentially equivalent to the sievert.

Annex K

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

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 L

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 15 Safety Guide for Management of Naturally Occurring Radioactive Material (NORM)

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 23 Code of practice for the control and safe handling of radioactive sources used for therapeutic purposes (1988)

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 bore-hole 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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- ARPANSA 200y. Australian Radiation Protection and Nuclear Safety Agency 200y, *Code of Practice for the Safe Use of Radiation in Veterinary Science*, Radiation Protection Series No. x.
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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).

Accuracy

for a given calibrated reference source, that the indicated activity (in becquerel) is equal to the activity value determined by the Australian Nuclear Science and Technology Organisation (ANSTO, possessor of the primary and secondary standard for Australia) or by a supplier who has compared that source to a source that was calibrated by ANSTO.

Administering person

a person who has been authorised to administer radiopharmaceuticals. This person will normally be a nuclear medicine technologist or a nuclear medicine specialist.

ALARA principle

a principle of radiation protection philosophy that requires that exposures to ionizing radiation should be kept as low as reasonably achievable, economic and social factors being taken into account. The ALARA principle is equivalent to the principle of optimisation defined by the ICRP, which states that protection from radiation exposure is optimum when the expenditure of further resources would be unwarranted by the reduction in exposure that would be achieved.

Approved

when applied to a plan or proposal, one which has received approval from the appropriate authority.

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

reproducibility in measuring a constant source over a long period of time.

Constraint

either **dose constraint** in the case of exposures anticipated to be received, or **risk constraint** in the case of potential exposures (see **dose constraint** and **risk constraint**).

Controlled Area

an area to which access is subject to control and in which employees are required to follow specific procedures aimed at controlling exposure to radiation.

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.

Diagnostic reference level (DRL) for medical exposure

dose levels for medical exposures in medical radiodiagnostic centres or levels of activity in the case of radiopharmaceuticals applied to groups of standard-sized patients or standard phantoms for common types of diagnostic examination and broadly defined types of equipment. These levels are expected not to be consistently exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied. DRLs will be set by relevant professional bodies and published by ARPANSA or the relevant regulatory authority from time to time.

Dose

a generic term which may mean absorbed dose, **equivalent dose** or effective dose depending on 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 tissue weighting factor for that organ or tissue.

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

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.

Geometry independence

geometry independence means that the indicated activity does not change with volume or configuration.

Hot cell

a heavily shielded enclosure that may be used for handling or processing highly radioactive materials by remote means through lead-glass windows so that the radiation hazard to personnel is minimised.

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.

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.

Linearity

the ability of the dose calibrator to measure the correct activity over the range of use of that calibrator.

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.

Nuclear medicine 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 Nuclear Medicine Physicists held by the Australasian College of Physical Scientists and Engineers in Medicine; or
- (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 Nuclear Medicine Physicists as determined by the relevant regulatory authority.

Nuclear medicine specialist

a specialist who has appropriate specialist recognition in nuclear medicine and

- (a) is eligible for approval by the Joint Specialist Advisory Committee in Nuclear Medicine RACP-RANZCR; and
- (b) holds an authorisation for the use of unsealed sources for diagnostic and therapeutic nuclear medicine in the relevant jurisdiction.

Nuclear medicine technologist

a person who has obtained a Bachelor of Applied Science in Medical Radiation Science (NMT) or its equivalent, in a course recognised by the Accreditation Board of the Australian and New Zealand Society of Nuclear Medicine and is eligible for accreditation by the Board and registration/licensing by the appropriate State Authority.

Occupational exposure

exposure of a person to radiation which occurs in the course of that person's work and which is not excluded exposure⁹.

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.

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 expertise¹⁰.

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.

Radioactive material

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

Radiochemist

a scientist with experience in the practice of radiopharmacy who provides a radiopharmacy service to nuclear medicine.

⁹ Excluded exposure means the component of exposure that arises from natural background radiation.

¹⁰ Competency requirements for a qualified expert will be listed in future editions of the *National Directory for Radiation Protection, Edition 1.0* (ARPANSA 2004).

Radiopharmacist

a State pharmacy board registered pharmacist with experience in the practice of radiopharmacy who provides a radiopharmacy service to nuclear medicine.

Radiopharmacy

The preparation, reconstitution and dispensing of radiopharmaceuticals for patient administration.

Referrer

a registered medical practitioner, dentist or other health professional who is entitled to refer individuals to the radiation medical practitioner who will be responsible for the overall conduct of the procedure involving the exposure of the patient to ionizing radiation.

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 K 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 person¹¹:

- (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.

Risk constraint

a restriction applied to potential exposure (see also **dose constraint**).

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.

Supervised area

an area in which working conditions are kept under review but in which special procedures to control exposure to radiation are not normally necessary.

¹¹ 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.

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