



Australian Government

Australian Radiation Protection and Nuclear Safety Agency

SAFETY GUIDE

Radiation Protection in Nuclear Medicine

Radiation Protection Series Publication No. ??

Public Comment draft: 24 August 2007

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All submissions will be held in a register of submissions, and unless marked confidential, may be made public.

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 prescriptive 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 prescriptive 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-prescriptive 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, prescriptive 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
dd mmmm yyyy, and endorsed for publication by the
Radiation Health & Safety Advisory Council on dd mmmm yyyy

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ISBN ? ??? ????? ?

ISSN 1445-9760

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 [month yyyy]

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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* (2007).

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* (2007) (hereafter called 'the Code'). It provides advice and guidance on measures that should be employed to assist in meeting the requirements of the Code.

1.3 PURPOSE

The guidance offered in the Safety Guide is in itself not mandatory, however, it is recommended that the measures included in the Safety Guide should be implemented in the interests of reducing radiation **exposure** and risks. It provides information to help obtain satisfactory clinical outcomes with minimum exposure to radiation of the patient, the clinician and other persons involved with the procedure. It includes information on:

- allocation of responsibilities;
- clinical assessment of the indications 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 may voluntarily assist patients undergoing nuclear medicine procedures; and
- the exposure of individuals as part of occupational health surveillance.

This Safety Guide applies to individuals, **practices** or institutions where nuclear medicine examinations or nuclear medicine therapeutic procedures are undertaken. It does not apply to the practice of dentistry, radiology, veterinary nuclear medicine

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

35 procedures, radiotherapy using external radiation beams or sealed radioactive
36 sources, or the individuals involved with them, as they are covered by separate Codes
37 and Safety Guides (ARPANSA 2005a, ARPANSA 2005b, ARPANSA 200x, ARPANSA
38 200y, ARPANSA 200z).

39 **1.5 STRUCTURE**

40 This Safety Guide sets out information that should assist in achieving the levels of
41 protection defined in the Code. It does not form part of the material that must be
42 adopted into regulatory frameworks by State, Territory or Australian Government
43 Regulatory Authorities.

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

46 Material in the Annexes provides clarification and guidance on issues discussed in
47 the Safety Guide with Annex H, in particular, outlining the health effects arising from
48 exposure to **ionizing radiation**. The Annexes provide examples of certain
49 procedures and of a template for a Radiation Management Plan, which are provided
50 to assist in the implementation of this Safety Guide.

51 **1.6 RADIATION MANAGEMENT PLAN**

52 The Code requires a Radiation Management Plan be developed that is specific for the
53 institution and includes detailed written working rules and protocols. The plan
54 should be signed and dated by the **Responsible Person** and the Radiation Safety
55 Officer (RSO), where appointed (see Section 3.6 of this Safety Guide). It should be
56 viewed as a “living document” so that as changes occur to equipment, operators or
57 work practices, it is updated to reflect the changing nature of the use of radiation at
58 the practice. Subsequent versions should again be signed and dated by the
59 Responsible Person and the RSO.

60 The nuclear medicine Radiation Management Plan will usually be a subset of the
61 institution’s Radiation Management Plan if the institution includes other radiation
62 modalities, such as diagnostic radiology and/or radiotherapy. In these
63 circumstances, the Radiation Management Plan could establish a Radiation Safety
64 Committee whose members will include the RSO and representatives from the
65 various radiation modalities. The Radiation Safety Committee would, on behalf of
66 the Responsible Person, oversee the development and implementation of the
67 Radiation Management Plan.

68 Annex A provides information to assist in the preparation of the plan.

69 2. Justification

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

73 1. The practice involving exposure to radiation needs to be justified in principle.
74 In this context, the continuing involvement of medical professional societies
75 should be ensured, as matters of effective medical practice will be central to
76 this judgement (IAEA 2002).

77 2. Each procedure should be subject to a further case-by-case justification by the
78 medical practitioner (radiation) responsible for the overall conduct of the
79 procedure involving the exposure of the patient to ionizing radiation (ICRP
80 2004). In nuclear medicine, this person will usually be a **nuclear medicine**
81 **specialist**.

82 The decision to perform a nuclear medicine procedure rests upon a professional
83 judgement of the benefits that accrue to the total health of the patient, as opposed to
84 any effects that might be caused by the ionizing radiation. The benefit will be the
85 potential diagnostic information or therapeutic effect of a radionuclide therapy
86 procedure resulting from the **medical exposure**, including the direct health
87 benefits to an individual as well as the benefits to society. The **detriment** will be the
88 potential deleterious effects of ionizing radiation. For the radiation doses generally
89 arising in diagnostic nuclear medicine the only possible detriment is the low
90 probability of inducing a cancer or a genetic mutation which may be passed on to
91 future offspring. These effects are thought to be stochastic in nature, meaning that
92 the probability of occurrence increases with increasing dose and there is no safe
93 threshold below which they cannot occur. The age of the patient and the anatomical
94 region being examined are also relevant in the risk assessment.

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

99 There are special cases that warrant further justification including the medical
100 exposure of the pregnant or potentially pregnant patient as there is evidence to
101 suggest that the embryo or fetus is more radiosensitive than the mature adult
102 (DeLongchamp et al 1997, Doll and Wakeford 1997). Likewise, nuclear medicine
103 examinations of children under the age of 18 years require a higher level of
104 justification since children are more susceptible to the induction of radiation induced
105 cancers (ICRP 1991a, ICRP 1991b, DeLongchamp et al 1997) and they have a longer
106 life expectancy during which the manifestation of possible harmful effects of
107 radiation may occur.

108 Repeat nuclear medicine examinations for medico-legal purposes should not be
109 undertaken if clinical indications no longer exist, unless the **referrer** considers such
110 a procedure is essential for the adequate assessment of long-term disability.

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

119 Mass screening (non-referral) of targeted population groups is rarely justified.
120 Breast cancer screening in radiology provides an example of one screening program
121 that may be justified on the basis of studies that have demonstrated net benefit to
122 society. In all instances a full disclosure of the potential detriment, including but not
123 limited to the radiation risks, need to be made to the individual.

124 **3. Duties and Responsibilities**

125 **3.1 RESPONSIBLE PERSON**

126 The major responsibility for adherence to the Code lies with the Responsible Person.
127 Although some tasks may be delegated to others such as the RSO, the ultimate
128 responsibility lies with the Responsible Person. First and foremost, the Responsible
129 Person needs to ensure that a Radiation Management Plan is in place for the control
130 of radiation exposure. The Radiation Management Plan would normally be
131 developed by the RSO or other qualified expert, working closely with relevant staff
132 and practitioners, and would be expected to specifically reference or include written
133 procedures or protocols to address the following issues:

- 134 • the protection of employees, patients and members of the public;
- 135 • the protection of health professionals other than those with nuclear
136 medicine training who may have close contact with patients undergoing
137 nuclear medicine procedures, e.g. nurses, porters and ultrasonographers;
- 138 • the protection of individuals (carers), who voluntarily help in the care,
139 support or comfort of patients undergoing nuclear medicine procedures.
140 The Responsible Person needs to be able to demonstrate that the **effective**
141 **dose** received by the carer is unlikely to exceed 5 mSv per year. Carers are
142 individuals who are not normally occupationally exposed (e.g. relatives and
143 friends over the age of eighteen years who are not pregnant). For nuclear
144 medicine therapy procedures, nurses and support staff should assist as a
145 carer only if a carer is not available;
- 146 • the correct identification of the patient prior to the procedure being
147 performed;
- 148 • irradiation of pregnant or potentially pregnant women with specific advice
149 about how to minimise the possibility of unintentionally irradiating the
150 embryo or fetus (see also Section 5);
- 151 • the unintended irradiation of an infant by ingestion of radioactivity in
152 breast milk from a nursing mother or from external exposure arising from
153 an adult undergoing a nuclear medicine procedure (see also Section 6);
- 154 • the breast-feeding status of a female patient if there is the potential for a
155 significant radiation dose to the breast glandular tissue of that patient;
- 156 • concerns about the risks from ionizing radiation and how to explain them to
157 patients, guardians and carers;
- 158 • documented working protocols should be implemented for each
159 radionuclide therapy procedure (e.g. treatment of hyperthyroidism with
160 iodine-131, treatment of thyroid carcinoma with iodine-131, radiation
161 synovectomy, treatment of liver metastases with radioactive microspheres,
162 palliative treatment of bone metastases with strontium-89 or
163 samarium-153 etc);
- 164 • the irradiation of volunteers as part of research programs;
- 165 • accidental, abnormal or unplanned exposures to radiation; and

166 • regulatory requirements that need to be satisfied.

167 Guidelines for the preparation of a Radiation Management Plan are given in Annex
168 A.

169 The Responsible Person should ensure that examinations using mobile nuclear
170 medicine equipment are only performed when it is impractical, or not medically
171 acceptable, to transfer the patient to a nuclear medicine facility.

172 The Code requires that the Responsible Person provides a personal radiation
173 monitor to all employees who are likely to receive an annual effective dose of more
174 than 1 mSv. When a single personal radiation monitoring device is utilised it should
175 be worn on the trunk, between the waist and the chest, and under any protective
176 garments. It may be appropriate in some circumstances for an individual to be
177 issued with two personal monitoring devices. For example, an electronic dosimeter
178 may be used to measure any exposure during a particular task in addition to the
179 integrating dosimeter which would be routinely worn. For staff performing
180 radiopharmaceutical preparation or dispensing, or radiopharmaceutical
181 administration to the patient, it may be appropriate to issue extremity monitors to
182 confirm that doses to the fingers are well below the dose limits. Monitors
183 manufactured in the form of a ring are most suitable for this purpose.

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

191 With regard to patient doses and in the spirit of ALARA, when a patient is
192 transferred to a different institution or practice, the Responsible Person should
193 ensure that all relevant images, or duplicates of the images, are provided to the new
194 practice.

195 The Responsible Person needs to ensure that a qualified expert, usually a **nuclear**
196 **medicine physicist**, is involved, as appropriate, for consultation on optimisation
197 (including patient dosimetry, quality assurance) and to give advice on matters
198 relating to radiation protection, as required.

199 The Responsible Person should ensure that the installed structural shielding,
200 security of radioactive sources, and radioactive waste disposal and other radiation
201 safety measures are adequate to meet the requirements of the Code.

202 **3.2 NUCLEAR MEDICINE SPECIALIST (MEDICAL PRACTITIONER** 203 **(RADIATION))**

204 The Nuclear Medicine Specialist, being the person who fulfils the role of the medical
205 practitioner (radiation) specified in the Code and who approves the diagnostic or
206 therapeutic nuclear medicine procedure, needs to be satisfied that the procedure is
207 justified.

208 The Code (see also IAEA 2002) requires that the ultimate decision to perform or
209 reject each individual nuclear medicine procedure resides with the specialist
210 responsible for overseeing the nuclear medicine exposure. This decision should be
211 based on the specialist's knowledge of the hazard associated with the nuclear
212 medicine exposure and the clinical information supplied by the referrer.
213 Accordingly, the specialist may need to liaise closely with the referrer about the merit
214 of performing a particular procedure. Any decision to proceed, or not to proceed,
215 with a diagnostic procedure should be made after consideration of the timely
216 availability of alternative tests, which involve less or no exposure to ionizing
217 radiation. This is particularly pertinent in cases when a nuclear medicine procedure
218 for a pregnant woman, or where pregnancy status is uncertain, is being
219 contemplated. The implications of delaying a diagnostic test on patient management
220 in order to confidently exclude pregnancy should be weighed against the potential
221 detriment associated with the increased radiation burden to the patient that would
222 arise from a test involving ionizing radiation.

223 The nuclear medicine specialist should:

- 224 • consider current practices in relation to the appropriate use of imaging
225 investigations and therapeutic procedures including their advantages and
226 disadvantages, and the approximate dose of radiation each modality will
227 deliver;
- 228 • ensure, when approving a diagnostic or therapeutic nuclear medicine
229 procedure, that the procedure is clinically needed;
- 230 • prior to commencing a therapeutic procedure, provide counselling for the
231 patient (or guardian) on the potential radiation-related risks associated
232 with the procedure (ICRP 2000a, p12).

233 **3.3 REFERRER**

234 Although not mandated in the Code, the referrer of the patient for a diagnostic or
235 therapeutic procedure also needs to be satisfied that the procedure is justified. The
236 Code does, however, require that a written referral that states the
237 procedure/treatment requested and provides sufficient relevant clinical information
238 be provided to the nuclear medicine specialist before the procedure is performed.
239 The referral will contain suitable patient identifying information (name, date of
240 birth, and address) and adequate referrer contact details for consultative purposes.
241 The referral should state a provisional diagnosis for investigation or a medical
242 condition for treatment.

243 The referrer should also be satisfied that:

- 244 • the necessary clinical information is not available either from previous
245 nuclear medicine examinations or from other tests and investigations;
246 and
- 247 • the nuclear medicine procedure may provide the required information to
248 address the clinical question.

249 In this regard, the merit of a particular procedure may need to be discussed with the
250 nuclear medicine specialist who approves the procedure.

251 When practicable, the request should also alert the nuclear medical specialist to the
252 possibility that a female patient may be pregnant or breast-feeding.

253 **3.4 ADMINISTERING PERSON**

254 Before any procedure is undertaken, the **administering person** needs to comply
255 with the Responsible Person's written operating procedures on how to identify the
256 patient correctly and ensure that the correct procedure will be performed.
257 Identification should be established by the name, date of birth, address and any
258 unique patient number if possible. If there is a concern about the relevance of the
259 procedure indicated on the request form, then this issue should be taken up with the
260 nuclear medicine specialist.

261 Other administering person responsibilities are outlined in Section 4 of this Safety
262 Guide, which deals with optimisation of protection of the patient.

263 The administering person needs to:

- 264 • have undertaken suitable intravenous injection and cannulation training
265 before commencing any administration procedures;
- 266 • use protective equipment designed to reduce radiation exposure (e.g.
267 syringe shields, lead pots) and wear an approved personal radiation
268 monitoring device when handling radioactive materials;
- 269 • report any instance of accidental, abnormal or unplanned exposure to the
270 Responsible Person in accordance with the requirements of the
271 Responsible Person's Radiation Management Plan; and
- 272 • ensure that only essential staff are present when performing
273 administrations.

274 **3.5 NUCLEAR MEDICINE TECHNOLOGIST**

275 Following the administration of a radiopharmaceutical, the **nuclear medicine**
276 **technologist** should comply with imaging protocols to ensure adequate
277 imaging/data collection and analysis are performed for reporting purposes.

278 **3.6 RADIATION SAFETY OFFICER (RSO)**

279 The Responsible Person may decide to delegate certain duties to a person such as a
280 RSO. Delegating duties to an RSO does not, however, absolve the Responsible
281 Person from their legal responsibility for ensuring that those duties are carried out.
282 In some Australian jurisdictions, the appointment of an RSO is, in fact, mandatory
283 following the issue of an authorisation by the relevant **regulatory authority**.
284 Typically, an RSO will:

- 285 • have sufficient professional and/or technical training to perform the RSO
286 duties as detailed below; and
- 287 • undertake the measurements, investigations and assessments, make the
288 reports, keep the records and perform any or all of the specified duties;

- 289 • have the necessary authorisation, equipment, procedures and employee
290 cooperation to undertake the measurements, investigations and assessments,
291 make the reports and keep the required records; and
- 292 • ensure that the Responsible Person is kept informed of the radiation safety
293 status of the practice.

294 The RSO can be an employee of the organisation and the duties can, for example, be
295 added as an extra level of duties for a medical physicist or other qualified expert. An
296 external provider of such services or a radiation protection consultant could also be
297 used to perform the RSO functions. Where the appointment of an RSO is mandated
298 by a given jurisdiction, such an appointment will be subject to the requirements of
299 the relevant regulatory authority.

300 The ultimate responsibility for developing a Radiation Management Plan lies with
301 the Responsible Person. Nevertheless, in practice, the RSO may be directed by the
302 Responsible Person to develop an institutional radiation safety manual or Radiation
303 Management Plan to cover the use of radioactive sources. The RSO may, in turn,
304 seek advice from other individuals who are deemed to have the requisite level of
305 expertise to develop such a plan. The Radiation Management Plan should
306 encompass all requirements of the Code and satisfy any additional requirement of
307 the relevant regulatory authority. The RSO may also be directed by the Responsible
308 Person to perform the duties required under the Radiation Management Plan.

309 The RSO should liaise closely with the relevant nuclear medicine physicist to provide
310 suitable administrative support and guidance for the approval of radiation safety
311 procedures by the Responsible Person. The RSO should also ensure that satisfactory
312 quality assurance (QA) programs and quality control (QC) testing for radiation safe
313 practices are performed.

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

- 316 • to maintain and review the Radiation Management Plan;
- 317 • to ensure that the facility meets the requirements of the Radiation
318 Management Plan;
- 319 • to maintain the occupational exposure records on behalf of the Responsible
320 Person;
- 321 • to ensure that records of receipt and patient administration of radionuclides
322 are maintained;
- 323 • to provide appropriate personal radiation monitors to staff;
- 324 • to maintain the radiation safety records;
- 325 • to ensure the appropriate storage and maintenance and the regular calibration
326 and testing of radiation monitoring instruments;
- 327 • to have responsibility for the safety, security and documentation of radioactive
328 sources;
- 329 • to ensure the correct use of personal protective equipment by all staff;

- 330 • to provide radiation safety training for staff;
- 331 • to develop and implement safe work practices when using radiation sources;
- 332 • to provide advice on the radiation safety of individual patients undergoing
- 333 diagnostic or therapeutic nuclear medicine procedures;
- 334 • to provide advice to ensure that any exposure of the patient's relatives, friends
- 335 and carers is minimised;
- 336 • to provide advice on the discharge of patients who have been treated with
- 337 radionuclides and advice on the disposal of corpses containing radionuclides;
- 338 • to arrange for the safe storage of radioactive materials and ensuring the safe
- 339 disposal of any radioactive waste;
- 340 • to ensure that that all necessary shielding, radiation safety equipment and
- 341 radiation monitoring and surveying devices are provided by the Responsible
- 342 Person;
- 343 • to carry out any measurements, investigations or assessments which are
- 344 deemed necessary to verify radiation safety or in the event of a **radiation**
- 345 **incident**;
- 346 • to undertake appropriate risk assessments, appropriate emergency procedures
- 347 and contingency plans, in co-operation with departmental management;
- 348 • to review, audit and report on radiation practices to ensure their continued
- 349 effectiveness;
- 350 • to provide reports on radiation incidents to the Responsible Person and to
- 351 regulatory authorities which include what happened, estimates of radiation
- 352 exposure to individuals, action taken and recommendations on how to prevent
- 353 a recurrence;
- 354 • to provide local approval, regular review and advice to the Responsible
- 355 Person;
- 356 • to ensure that measures are in place for the physical security of sealed and
- 357 unsealed sources ; and
- 358 • to perform any other tasks that may be required to maintain a high standard
- 359 of radiation safety.

360 **3.7 RADIOPHARMACIST/RADIOCHEMIST**

361 The **radiopharmacist/radiochemist** whether employed in either a nuclear
 362 medicine department or a centralized radiopharmacy plays a central role in:

- 363 • the management, development and scientific direction of the radiopharmacy
- 364 service;
- 365 • the procurement and storage of radiopharmaceuticals;
- 366 • implementation of a comprehensive quality assurance program for both
- 367 diagnostic and therapeutic radiopharmaceuticals;
- 368 • the leadership of research and development into new and current diagnostic
- 369 and therapeutic radiopharmaceuticals;

- 370 • the development, in consultation with the nuclear medicine physicist or RSO,
371 of safe procedures for the production and manipulation of
372 radiopharmaceuticals;
- 373 • provision of clinical and professional advice on the safe and efficacious use of
374 radiopharmaceuticals;
- 375 • teaching and training of nuclear medicine staff (including technologists,
376 doctors and research scientists);
- 377 • the monitoring of adverse events such as adverse drug reactions, altered
378 biodistribution or the effects of concomitant drug therapy, including any
379 reporting to the appropriate authority; and
- 380 • the procurement, preparation and storage of clinical radiopharmaceutical
381 supplies required for clinical trials.

382 In fulfilling these roles, the radiopharmacist/radiochemist needs to ensure the safe
383 and efficacious use of radiopharmaceuticals for both diagnosis and therapy. In the
384 course of these duties the radiopharmacist/radiochemist also plays a key role in
385 ensuring that the radiation safety of both the radiopharmacy staff and patients is of
386 primary importance and all steps are taken to minimize radiation exposure. In
387 centralised radiopharmacies, the radiopharmacist/radiochemist may also be
388 appointed as the RSO and will fulfil both roles.

389 **3.8 NUCLEAR MEDICINE PHYSICIST (QUALIFIED EXPERT)**

390 The Code requires that the Responsible Person utilise a Qualified Expert for
391 consultation on optimisation, to advise on matters relating to radiation protection
392 and, for therapeutic uses, calibration, dosimetry and quality assurance. In a nuclear
393 medicine department, this person will normally be a nuclear medicine physicist who
394 will have the following duties:

- 395 • assess the accuracy of nuclear medicine diagnosis to ensure the accurate
396 delivery of prescribed treatment through dose calculation procedures and
397 ongoing quality control of equipment;
- 398 • provide Human Research Ethics Committees with a radiation dose estimation
399 and risk assessment for any research study that involves the research
400 participants receiving a radiation exposure from radioactive substances; and
- 401 • manage the clinical computer systems and undertake software design and
402 development.

403 The nuclear medicine physicist will also normally play a key role in:

- 404 • the management, development and scientific direction of the nuclear medicine
405 service;
- 406 • participation in the planning and delivery of patient procedures for diagnosis
407 and treatment;
- 408 • the design and implementation of new and innovative diagnostic procedures
409 and treatments;

- 410 • the leadership of research and development, especially in the technological
411 basis of nuclear medicine;
- 412 • providing technical advice on appropriate diagnostic and treatment
413 techniques;
- 414 • the management and procurement of nuclear medicine equipment, including
415 acceptance testing of the equipment; and
- 416 • teaching and training of staff (including medical physicists, technologists,
417 doctors and nurses).

418 In fulfilling these roles, the nuclear medical physicist should be actively involved in
419 the radiation safety of the patient, staff and the public. He or she should be available
420 to consult on all steps that need to be taken to minimise radiation exposure
421 commensurate with obtaining the necessary diagnostic information or providing the
422 appropriate radiation therapy. The nuclear medical physicist should also undertake
423 periodic surveys of administered activities and the corresponding effective doses as
424 part of the quality assurance program, and as required by the relevant regulatory
425 authority. The patient activities and/or doses should be compared with published
426 diagnostic reference levels (DRLs), where relevant, and action taken if they are
427 deemed to be unacceptable (ICRP 1996). In many institutions, the nuclear medicine
428 physicist may also be appointed as the RSO and will fulfil both roles.

429 **3.9 NUCLEAR MEDICINE EQUIPMENT SUPPLIERS**

430 The suppliers of nuclear medicine equipment need to be cognisant of their
431 responsibilities and the nuclear medicine equipment specifications noted in this
432 Safety Guide.

433 In particular, suppliers of PET/CT or SPECT/CT hybrid scanners should, when
434 appropriate, implement anatomy dependent, Automatic Exposure Control (AEC) for
435 the CT scan using an objective predefined setting of image quality, defined in terms
436 of image noise and image sharpness (ICRP 2000b).

437

4. Optimisation of Protection for Medical Exposures

4.1 GENERAL CONSIDERATIONS

Diagnostic

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 strict limits on the doses received from fully justified examinations. However, patient activity surveys indicate wide variations in the activity administered to achieve satisfactory image quality indicating that there is significant scope for the implementation and optimisation of patient protection (Smart and Towson 2000). To this end, the Code requires the implementation of quantitative guidance in the form of DRLs as a practical tool to aid in dose optimisation.

The optimisation process necessarily requires a balance between administered activity (and thus patient radiation dose) and image quality. It is important that dose reductions are not achieved with a loss of diagnostic image quality that may accompany the dose reduction. Images of unacceptable quality may ultimately lead to repeat examinations and higher patient doses. The requirement for image quality should be tailored to the clinical problem and lower levels may be acceptable in some circumstances. The size and age of the patient, and the time for which the patient can comfortably remain still, will influence the activity required. Accordingly, the operator of nuclear medicine equipment should minimise the activity administered to the patient under the constraint that the image quality is acceptable for the diagnostic information being sought.

It is important to plan the examination to fit the clinical problem. This ensures that the investigation has the best opportunity to address the diagnostic question at hand and minimise the need for any repeat tests. If a nuclear medicine procedure needs to be repeated this of necessity will result in increased exposure to both the patient and staff. 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, should highlight any systematic errors or problems and ultimately lead to a lower repeat rate. In any event, repeat procedures should not be undertaken simply because the images may not be of the highest quality. If the images contain the required information then a repeat procedure should not be performed.

Therapy with Unsealed Radioactive Substances

Therapeutic nuclear medicine requires special consideration because of the high dose of radiation involved. In diagnostic nuclear medicine the radiation doses are very low with a very low possibility of any harmful effects. However, in therapeutic nuclear medicine the doses of radiation are very high, at a level where they produce a

482 biological effect. The level of radiation constitutes a much greater hazard to the
483 patient, staff, the patient's carer and the general public.

484 In therapeutic nuclear medicine, the radionuclides used often differ from those in
485 diagnostic nuclear medicine; they are usually beta emitters with longer physical and
486 biological half-lives. Therapy radionuclides may require different facilities to
487 radionuclides used for diagnostic procedures, to ensure the safe preparation and
488 administration of the radiopharmaceutical.

489 **4.2 PROCEDURES FOR THE PREPARATION OF** 490 **RADIOPHARMACEUTICALS**

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

498 The customary principles for the layout of radioisotope laboratories, designed to
499 protect the staff and the external environment in the event of radioactive
500 contamination in the laboratory, should be followed (AS/NZS 2982.1:1997). The
501 radiation hazard needs to be controlled in accordance with radiation protection
502 regulations.

503 **4.3 HOT LABORATORY PROCEDURES**

504 **Consignment arrival**

505 On arrival, packages containing radioactive materials should be inspected for signs of
506 damage. A wipe test should be performed to determine radioactive contamination
507 on the surface of any shipment container and any leakage should be reported to the
508 supplier. Serious spills may require evacuation of the area before any cleanup is
509 undertaken and should be first reported to the RSO.

510 **Daily schedule**

511 A radiopharmacist/radiochemist or senior member of staff should be designated to
512 review the schedule of diagnostic and therapeutic procedures to be performed in the
513 nuclear medicine department and ensure that appropriate radiopharmaceuticals are
514 available.

515 **Preliminary activities**

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

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

522 A radiopharmaceutical record sheet should be maintained that includes the batch
523 numbers, manufacturer, date received, expiration time/date, preparation procedure,
524 quality assurance, and calibration results.

525 **Reconstitution of 'cold-kits'**

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

532 Where possible, visual inspection of the preparation through a lead glass shield
533 should be performed to confirm that the appearance complies with the
534 manufacturers specification. The total activity of the vial should be measured and
535 the activity, calibration and expiry times calculated and recorded.

536 **Dispensing**

537 The following rules should be observed in the radiopharmacy when working with
538 radioactive materials:

- 539 • Laboratory coats and disposable gloves should be worn at all times. Safety
540 glasses should be used if the work is of a hazardous nature to the eyes. Gloves
541 should be changed at regular intervals in order to minimise the spread of
542 contamination.
- 543 • Personal dosimeters are to be worn at all times when handling radioactive
544 materials or working in areas where they are handled or stored.
- 545 • All working surfaces should be covered with absorbent paper that has an
546 impermeable plastic coating – facing the bench-top.
- 547 • Radioactive materials should be kept in closed, sealed vials within shielding
548 containers at all times.
- 549 • All shielding containers and vials should bear a label identifying the
550 radiopharmaceutical, the total radioactivity, the volume and the time and date
551 of calibration.
- 552 • Small spills that present no radiological hazard to persons should be cleaned
553 up as soon as possible. More serious spills may require evacuation of the area
554 before cleanup is undertaken and need to be reported immediately to the RSO.
555 General reference should be made to Australian Standard AS 2243.4 – 1998 –
556 Safety in laboratories Part 4: Ionizing radiations (AS2243.4-1998). The
557 procedures should follow written instructions.
- 558 • Eating, drinking, smoking, the administration of medication or the application
559 of cosmetics are prohibited in areas where radioactive materials are handled
560 or stored.
- 561 • In order to demonstrate confinement of radioactivity, a suitable electronic
562 radiation detector should always be available when radioactive materials are
563 manipulated.

- 564 • Appropriate radioactive waste management (storage and disposal) should be
565 in place in accordance with individual State/Territory radiation control
566 legislation.
- 567 • Hands, shoes and clothing should be monitored for contamination in a low-
568 background area, allowing sufficient time for instrument response, before
569 leaving the hot laboratory.

570 **Labelling with radioiodine**

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

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

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

589 Additional protective clothing should be used when handling megabecquerel
590 activities of radioiodine. Personnel should be double gloved and use shoulder-length
591 sleeve guards. The gloves and glove seals on gloveboxes should be checked
592 periodically and replaced when needed.

593 **4.4 PREVENTION OF ERRONEOUS ADMINISTRATION OF** 594 **RADIOPHARMACEUTICALS TO PATIENTS**

595 Only appropriately qualified persons may administer radioactivity to individuals.
596 **Maladministrations** of radiopharmaceuticals have been shown to occur when:

- 597 • the request for the procedure is misread or misinterpreted;
- 598 • the wrong dose is selected from a number of pre-prepared single doses or
599 multi-dose vials; or
- 600 • the contents of vials or syringes are wrongly labelled.

601 The risk of maladministration is increased when:

- 602 • two patients have the same or similar names; or
- 603 • the patient has poor comprehension of spoken English.

604 The Code provides detailed responsibilities and procedures which, if fully adopted,
605 will decrease the possibility of a maladministration of a radiopharmaceutical. The
606 most common cause of maladministration is the inattention to detail at key times
607 during the dispensing or administration of the radiopharmaceutical (Yenson et al
608 2005). This can lead to:

- 609 • incorrect radiopharmaceutical dispensing
- 610 • incorrect reading of the label attached to the syringe
- 611 • incorrect patient identification.

612 A maladministration may result from circumstances such as the confusion of
613 radioactivity units (e.g. mCi confused with GBq). All references to quantity of
614 radioactivity should be in becquerel.

615 **4.5 RADIONUCLIDE THERAPY PROCEDURES**

616 **Pregnancy and Avoidance of Conception**

617 **Confirmation of absence of pregnancy**

618 All female patients of childbearing age who are to be administered therapeutic
619 radionuclides need to have pregnancy excluded by a definitive biochemical test e.g.
620 serum β -HCG, within 24 hours before the commencement of the treatment. It is
621 preferable to also determine the β -HCG result on a separate occasion in the week
622 prior to the treatment. However, a careful clinical history is necessary at all times to
623 facilitate accurate interpretation of these laboratory investigations (ANZSNM 1999).

624 **Avoidance of conception**

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

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

Nuclide 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

Nuclide and form	For treatment of	All activities up to (MBq)	Avoid pregnancy (months)
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

635 (ARSAC 2000, and ICRP Publication 94, 2004)

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

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

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

648 **The discharge of patients undergoing treatment with unsealed** 649 **radioactive substances**

650 The ARPANSA publication *Recommendations for the Discharge of Patients Undergoing*
651 *Treatment with Radioactive Substances*, RPS No. 4 (ARPANSA 2002a) provides
652 guidance on the conditions which should be met for the discharge from a hospital or
653 clinic of a patient who is undergoing treatment with a radioactive substance, and the
654 conditions for the treatment of an outpatient. The recommendations take into
655 account the dose rate external to the patient, the potential for loss of a sealed source
656 from the patient, and the potential for the spread of contamination from an unsealed
657 radioactive substance excreted by the patient.

658 A patient who has received a therapeutic radiopharmaceutical, and who is involved
659 with close care of a child, should be provided with advice relative to external
660 radiation dose on:

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

664 **Design of treatment areas and wards**

665 Where there is a significant risk of exposure from external radiation arising from the
666 patient, or from any associated radioactive contamination, it may be necessary to

667 admit the patient to a dedicated treatment facility. Advice should be sought from the
668 RSO, and/or the relevant regulatory authority, on:

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

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

684 **Procedures for therapeutic radionuclides**

685 Written protocols for each of the therapeutic radionuclide procedure should include:

- 686 • indications for therapy;
- 687 • type of radionuclide;
- 688 • the range of activity of the radionuclide generally used;
- 689 • the method of administration;
- 690 • the radiation hazard;
- 691 • the radiation safety procedures; and
- 692 • whether treatment is as an inpatient or outpatient.

693 When the risks and requirements for a particular patient are being assessed, factors
694 specific for the circumstances of the particular patient need to be considered in
695 addition to the above issues. Such factors include the patient's general medical
696 condition, as well as family or home circumstances such as the presence of infants at
697 home, or in the case of the elderly, whether a carer is available at home. Based upon
698 all the factors a decision is made as to whether treatment as an in-patient is required.

699 **Preparation of therapeutic radiopharmaceuticals**

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

707 Laboratories used for preparation of therapeutic radiopharmaceuticals should meet
708 the requirements set out for 'hot' laboratories in AS 2243.4-1998: Safety in
709 laboratories - Ionizing radiations [AS 1998] and conform to the design standards in
710 AS/NZS 2982.1:1997 Laboratory design and construction – General requirements
711 [AS/NZS 1997].

712 Additional requirements to that for diagnostic radiopharmaceutical preparations.
713 need to be considered for therapy. These include:

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

727 **Patient information**

728 **Prior to radiopharmaceutical administration**

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

- 733 • the manner and place of administration;
- 734 • whether an in-patient stay will be required;
- 735 • the precautions that the patient should follow to limit the amount of exposure
736 to family and friends while in hospital and subsequently at home. These
737 precautions will vary depending on the patient's domestic circumstances, such
738 as whether the patient is the sole carer of any young children. (These
739 precautions should be given verbally and confirmed in writing);
- 740 • whether the patient (he or she) is involved with close care of a child;
- 741 • the arrangements for transport home or to another institution, such as a
742 nursing home;
- 743 • any restrictions that may apply if the patient is returning to work. The
744 restrictions will vary depending on the type of work and whether the patient is
745 in close proximity to other workers; and
- 746 • how long any restrictions or precautions should last.

747 **After radiopharmaceutical administration**

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

- 749 • the type and radioactivity of the radiopharmaceutical administered;
- 750 • the date of administration;
- 751 • any specific radiation safety precautions;
- 752 • any restrictions on activity including travel home; and
- 753 • how long the restrictions or precautions should last.

754 The period of time during which patients (and their family and friends) should
 755 observe the restrictions will depend on the initial external dose rate from the patient
 756 and the rate of clearance of the radionuclide from the body. Tables 2 to 5 provide
 757 information on recommended restriction periods in the case of radioiodine
 758 (iodine-131) therapy. The recommended values are based on data from Woodings
 759 (2004) and the European Commission (EC, 1998) using a **dose constraint** of 1
 760 mSv, and 5 mSv for partner/carer (RPS4, ARPANSA 2002a).

761 Advice should be sought from the nuclear medicine physicist or RSO for other
 762 therapies.

763 Annex B gives an example of written instructions for radioiodine (iodine-131)
 764 therapy, based on recommendations from the European Commission (EC, 1998).
 765 These can be adapted for therapy with other radiopharmaceuticals.

766 **Table 2. Periods of restriction for patients receiving radioiodine (iodine-131)**
 767 **therapy for thyrotoxicosis**

Dose Equivalent Rate at a distance of 1 metre from the patient	Corresponding to an administered activity of	Recommended periods for following instructions		
		Close contact with children under age of 5 years [#]	Close contact with children over age of 5 years	Sleeping with non-pregnant partner
<30 µSv/h	<600 MBq	20 days	14 days	9 days
<20 µSv/h	<400 MBq	16 days	11 days	6 day
<10 µSv/h	<200 MBq	10 days	4 days	1 day
<5 µSv/h	<100 MBq	4 days	1 day	1 day
<3 µSv/h	<60 MBq	2 days	1 day	None

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

771 **Table 3. Thyrotoxicosis patients: Periods of restriction for return to work**

Administered	Office worker	Close worker	Child care/nursery
--------------	---------------	--------------	--------------------

radioactivity	(2 hours at 1 metre)	(8 hours at 1 metre)	worker (2 hours at 0.1 metre and 6 hours at 1 metre)
600 MBq	1 day	4 days	21 days
400 MBq	1 day	1 day	17 days
200 MBq	1 day	1 day	11 days
100 MBq	None	None	8 days
60 MBq	None	None	6 days

772

773 **Table 4. Periods of restriction, after discharge, for patients receiving**
774 **radioiodine (iodine-131) therapy for thyroid cancer**

Dose Equivalent Rate at a distance of 1 metre from the patient	Corresponding to a residual activity of	Recommended periods for following instructions		
		Close contact with children under age of 5 years[#]	Close contact with children over age of 5 years	Sleeping with non-pregnant partner
<30 µSv/h	<600 MBq	5 days	3 days	2 days
<20 µSv/h	<400 MBq	4 days	2 days	1 day
<10 µSv/h	<200 MBq	2 days	1 day	1 day
<5 µSv/h	<100 MBq	1 day	1 day	1 day
<3 µSv/h	<60 MBq	1 day	None	None

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

778 **Table 5. Thyroid cancer patients: Periods of restriction for return to work**

Discharge radioactivity	Dose Equivalent Rate at 1 metre from patient	Office worker (2 hours at 1 metre)	Close worker (8 hours at 1 metre)	Child care/nursery worker (2 hours at 0.1 metre and 6 hours at 1 metre)
600 MBq	30 µSv/h	1 day	1 day	6 days
400 MBq	20 µSv/h	1 day	1 day	4 days
300 MBq	18 µSv/h	1 day	1 day	3 days

200 MBq	12 μ Sv/h	1 day	1 day	2 days
100 MBq	6 μ Sv/h	None	None	1 day

779

780 Travel in a private car does not give a significant dose to other people, so long as the
781 patient does not sit alongside the driver or passenger(s). However, public transport
782 (airline, bus, coach or boat) can involve people sitting close to each other and
783 restrictions may be required on travel of long duration (>4 hours). In these cases
784 advice should be sought from a nuclear medicine physicist or RSO. Travel
785 immediately after administration is not recommended due to the potential for travel
786 sickness and the possibility for contamination.

787 Additional considerations are necessary if the patient is incontinent of urine. Annex
788 2 of RPS4 (ARPANSA 2002a) provides radionuclide-specific guidance in these
789 circumstances.

790 **Administered activity**

791 The administered activity should not vary from the prescribed activity by more than
792 10%. However, it is recognized that for logistic reasons, there may be considerable
793 variation between the activity of the radiopharmaceutical originally intended or
794 ordered, and the activity available at the time of administration. For instance,
795 iodine-131 may only be available in capsule form in certain discrete activities, or
796 there may be some delay in time between calibration of the radioactivity at the time
797 of manufacture and administration. If the delivered activity varies by more than 10%
798 from the intended activity, a decision needs to be made on whether to administer the
799 total available activity or, if the delivered activity is greater, to only administer a part.
800 Where practicable, and provided it is clinically appropriate, it is recommended that,
801 in order to minimize radiation exposure of staff, the amount of the
802 radiopharmaceutical administered be that which is provided from the manufacturer.
803 For instance, and provided it is clinically appropriate, it is recommended that iodine-
804 131 capsules are not broken prior to administration. The prescription may need to be
805 amended from that originally ordered and if so, such amendments are to be
806 performed before administration.

807 **Administration of therapeutic radioactive substances**

808 Treatments should be administered in a designated treatment area within the
809 nuclear medicine practice or in the patient's own room on the ward, whichever
810 creates the lesser radiation hazard. If the administered activity is such that the
811 patient needs to be isolated after receiving the dose, the administration should be
812 performed in the patient's own room, and an additional wrist band should be
813 attached to the patient's wrist. This wrist band should display the radiation warning
814 sign and have space for the radionuclide, the administered activity and the date of
815 administration to be clearly written.

816 Prolonged intravenous infusion of gamma emitting radionuclides is an uncommon
817 method of treatment but its use is increasing. Examples include ¹³¹I-iodine-MIBG and
818 ¹³¹I-iodine-labelled antibodies. The prolonged infusion time and requirements for

819 patient monitoring create a significant radiation hazard for staff. Some patients
820 receiving infusion of ¹³¹Iodine-labelled antibodies require intensive monitoring both
821 during and for a period immediately after administration. Local shielding will often
822 be required to limit external irradiation of the staff. Automatic methods of
823 administration (e.g. a syringe pump) and remote patient monitoring devices should
824 be used to minimise the time that the staff need to spend in close proximity to the
825 patient.

826 **Procedures in wards used by patients receiving radionuclide** 827 **therapy**

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

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

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

846 Patients receiving radionuclide therapy should not leave the treatment facility
847 without approval of the attending physician or the RSO. Documented procedures
848 should be in place to respond to a patient who wishes to leave hospital prior to their
849 normal discharge.

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

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

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

866 In the event of the death of the patient, special precautions may need to be taken.
867 RHS 18 (NHMRC 1986) provides regulations for the safe handling of radioactive
868 corpses, including the precautions necessary during autopsies and disposal of the
869 corpses by cremation or burial.

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

873 **4.6 MEDICAL EMERGENCIES INVOLVING PATIENTS UNDERGOING** 874 **RADIONUCLIDE THERAPY**

875 The condition of a patient undergoing radionuclide therapy may deteriorate such
876 that urgent surgery or intensive monitoring in an Intensive Care Unit is required.
877 Whenever possible the RSO should be consulted on any necessary precautions
878 against external radiation and against possible contamination from body fluids. If
879 surgery is not urgent, it should be postponed until the radioactivity in the patient has
880 fallen to a suitable level.

881 **In life-threatening situations, the patient's medical management will**
882 **always take precedence over radiation safety considerations.** In the case of
883 cardiac or respiratory arrest only those staff essential for the patient's resuscitation
884 should be involved. All other staff should remain at least 2 metres from the patient.
885 If the patient requires ventilation as part of resuscitation, ventilation should be by a
886 mask-bag system, or the patient may be intubated. Mouth to mouth resuscitation
887 should not be used.

888 If the patient requires surgery, the wearing of two pairs of surgical gloves will give
889 some protection to the hands against beta radiation. If the surgeon's gloves are
890 breached during the procedure, personal decontamination procedures should be
891 followed. The surgical team should plan the procedure in order to minimise any staff
892 radiation exposure. This can be achieved by ensuring that only essential staff are
893 present in the operating theatre, that, where possible, staff stand away from any
894 organs containing high concentrations of radioactivity and that close contact with the
895 patient is minimised.

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

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

902 **4.7 PET/CT AND SPECT/CT EXAMINATIONS**

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

914 **5. Protection of the Embryo/Fetus**

915 Illustrated signs are required by the Code to be posted in prominent places within the
916 Nuclear Medicine Department advising patients to notify staff if they may be
917 pregnant. An example might read as follows:

918 IF IT IS POSSIBLE THAT YOU MIGHT BE PREGNANT, NOTIFY
919 THE PHYSICIAN OR TECHNOLOGIST BEFORE YOU HAVE YOUR
920 INJECTION FOR YOUR NUCLEAR MEDICINE EXAMINATION.

921 However, the posting of signs in no way absolves the nuclear medicine technologist
922 and the nuclear medicine specialist of their responsibility to enquire about the
923 possibility of pregnancy in all female patients of childbearing age. When asking the
924 patient about the possibility of pregnancy it is also important to indicate to the
925 patient why there is a need to know, to avoid them taking offence and refusing to
926 answer or answering less than truthfully. When language barriers exist it may be
927 useful to seek the service of an appropriate interpreter.

928 Amenorrhea occurring in a patient who usually has regular periods should be
929 considered due to pregnancy unless proven otherwise. In any event, when doubt
930 exists about the pregnancy status of an individual woman, serum β -HCG testing
931 before medical exposure may be considered. The Code requires that the pregnancy
932 status of all women of childbearing age is confirmed by a definitive biochemical test,
933 e.g. with a β -HCG test, before the administration of therapy radiopharmaceuticals. It
934 is also preferable to determine the β -HCG result on a separate occasion in the week
935 prior to the treatment. However, a careful clinical history is necessary at all times to
936 facilitate accurate interpretation of these laboratory investigations (ANZSNM 1999).

937 If a study is justified on a pregnant patient, and will be proceeded with, then in order
938 to advise the pregnant patient, the nuclear medicine specialist responsible for the
939 procedure should communicate the risks to the patient in a meaningful manner.

940 Fetal radiation dose estimates may be required in some circumstances and this
941 would normally require the services of a nuclear medicine physicist. If this expert
942 service is not available, advice on fetal doses may be obtained from the NRPB
943 publication, *Diagnostic Medical Exposures – Advice on Exposure to Ionising
944 Radiation during Pregnancy* (NRPB 1998).

6. Protection of an Infant

Illustrated signs are required by the Code to be posted in prominent places within the Nuclear Medicine practice requesting the patient to inform the staff if they are breast-feeding. An example might read as follows:

IF YOU ARE BREAST-FEEDING YOUR BABY 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 queried by the administering person whether she is breast-feeding a child.

If the patient is breast-feeding, advice about the possible need to restrict breast-feeding needs to be given to the patient. The advice will depend on the radiopharmaceutical and its activity so as to ensure that the infant will receive an effective dose of no greater than 1 mSv. In practice, it is preferable to use a dose **constraint** of 0.3 mSv rather than the dose limit of 1 mSv as this will ensure that the sum of both internal and external irradiation will be below the dose limit.

A patient who is breast-feeding a child should be advised of the risks, to the both the child and the patient, of continued breast-feeding before:

- (a) commencing radiopharmaceutical therapy; or
- (b) the intravenous administration of a diagnostic gallium-67 radiopharmaceutical.

The published data on the excretion of radiopharmaceuticals in breast milk has been reviewed by Stabin and Breitz (2000) and Table 6 provides a summary of their recommendations concerning the requirements for interruption of breast-feeding, together with additional data collated by Cormack *et al* (2004). 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 appropriate 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 6 provides concentrations in kBq/mL below which the effective dose to the infant will be below 0.3 mSv.

It is important that breast-feeding be stopped before commencing therapy with an unsealed radionuclide. The only possible exception would be when the radionuclide is administered directly into a body cavity and negligible activity can enter the blood stream. Radiation synovectomy using ⁹⁰yttrium-colloid is an example of such an exception.

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 6, the mother should regularly express and discard her milk. It should be explained that if this advice is followed the radiation dose to the infant

986 will be less than a quarter of the annual natural background dose and within the
987 range of geographical variations in natural background in Australia.

988 The parent or carer should be provided with advice on the length of time for which he
989 or she can hold their child and the time at which no restrictions will be necessary in
990 order to minimise the external irradiation of the child. This advice will ensure that
991 the child receives an effective dose of not more than 1 mSv and preferably less than
992 0.3 mSv. (If the child is also being breast-fed consideration will need to be given to
993 the combined effective dose from the internal and external exposure so that the total
994 dose does not exceed 1 mSv.)

995 The exposure of the child by being in close contact with the carer can be estimated
996 from the external dose rate of the carer and the pattern of close contact between the
997 carer and child (which will vary with the age of the child). The close contact doses
998 can be calculated using the method of Cormack and Shearer (1998). This method
999 allows the pattern and duration of the close contact to be specified and the total dose
1000 to the infant can be calculated using external dose rate measurements from
1001 published data and knowledge of the body biological clearance rates. Table 6
1002 includes the close contact restrictions necessary to ensure that the dose to the child
1003 does not exceed 0.3 mSv using a close contact pattern of 30 minutes each hour
1004 during the day (7 am to 7 pm) together with two 30 minute periods during the night,
1005 which probably represents the “extreme case” of a fretful, sick or demanding infant.
1006 For other infants and for older children the close contact restriction periods are likely
1007 to be less. The biological clearance rates used to derive Table 6 were taken from
1008 ICRP Publications 53 and 80 (ICRP 1987, ICRP 1998).

1009 For most diagnostic studies the radiopharmaceuticals that are typically administered
1010 will rarely give rise to a dose to the child of greater than 1 mSv even with the most
1011 pessimistic close contact pattern, but may exceed 0.3 mSv. A notable exception is
1012 ⁶⁷Ga-citrate. The initial external dose rate from patients containing gallium-67 will
1013 exceed that from many technetium-99m radiopharmaceuticals even though the
1014 administered activity will often be less. Combined with the longer physical half-life
1015 and slow biological clearance, this can give rise to significant external exposure of the
1016 child. A cooperative child, who is held by the carer for only 5 minutes in each hour,
1017 would receive approximately 0.6 mSv if no other restrictions were applied. To
1018 reduce this dose to 0.3 mSv close contact would need to be restricted for 3 days.

1019 **Table 6. Advice to patients concerning the need to restrict close contact**
1020 **with an infant and/or the need to interrupt breast-feeding in order to**
1021 **ensure that the infant receives no more than 0.3 mSv from either**
1022 **external or internal irradiation. The close contact pattern is that typical**
1023 **of a fretful, sick or demanding infant. The contact time restrictions may**
1024 **be relaxed for a less demanding child.**

Radiopharmaceutical	Administered activity (DRL) to mother (MBq)	Advice to patient concerning the need to restrict close contact with child	Advice to patient concerning the need to interrupt breast-feeding	Milk activity concentration at which breast-feeding can resume (kBq/mL)
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Radiopharmaceutical	Administered activity (DRL) to mother (MBq)	Advice to patient concerning the need to restrict close contact with child	Advice to patient concerning the need to interrupt breast-feeding	Milk activity concentration at which breast-feeding can resume (kBq/mL)
¹⁸ F-FDG	400	Restrict contact for 1 h	7 h interruption	4
⁵¹ Cr-EDTA	8	Not required	Not required	Not required
⁶⁷ Ga-citrate	400	Restrict contact for 10 days	Cessation	0.06
^{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	12 h interruption	6
^{99m} Tc-MAG ₃	350	Not required	Not required	Not required
^{99m} Tc-MDP or HDP	900	Restrict contact for 0.5 h	Not required	Not required
^{99m} Tc-MIBI	400 rest + 1100 stress	Restrict contact for 6 h	Not required	Not required
^{99m} Tc-pertechnetate (thyroid)	200	Not required	24 h interruption	5
^{99m} Tc-pertechnetate (Meckels)	400	Not required	24 h interruption	5
^{99m} Tc-PYP	800	Not required	Not required	Not required
^{99m} Tc-red cells (in vitro labelled)	1000	Restrict contact for 5 h	Not required	Not required
^{99m} Tc-red cells (in vivo labelled)	1000	Restrict contact for 5 h	12 h interruption	8
^{99m} Tc-Tetrofosmin	400 rest + 1100 stress	Restrict contact for 6 h	31 h interruption	7
^{99m} Tc-white cells	750	Restrict contact for 4 h	24 h interruption	4

Radiopharmaceutical	Administered activity (DRL) to mother (MBq)	Advice to patient concerning the need to restrict close contact with child	Advice to patient concerning the need to interrupt breast-feeding	Milk activity concentration at which breast-feeding can resume (kBq/mL)
¹¹¹ In-octreotide	200	Restrict contact for 4 h	Not required	Not required
¹¹¹ In-white cells	20	Restrict contact for 4 days	Not required	Not required
¹²³ I-MIBG	370	Restrict contact for 8 h	28 h interruption	0.3
¹²³ I-sodium iodide	20	Not required	9 h interruption	0.5
¹²⁵ I-HSA	0.2	Not required	6 day interruption	0.0009
¹³¹ I-sodium iodide (post-ablation)	200	Restrict contact for 10 h	Cessation	0.0003
²⁰¹ Tl-chloride	120	Restrict contact for 2 days	32 h interruption	0.04

1025

1026 **7. Quality Assurance**

1027 **7.1 GENERAL**

1028 The Code requires that all nuclear medicine practices establish a Quality Assurance
1029 (QA) program. The QA should place particular emphasis on image quality
1030 optimisation and patient dose reduction. The extent of the QA program will depend
1031 on the complexity and resources of the nuclear medicine practice but at the very least
1032 it will need to address the issues outlined in Annex C and have a well-defined
1033 responsibility and reporting structure. The QA program also needs to include a
1034 system of checks and procedures to ensure that the aims of the QA program are met.

1035 The Responsible Person should endeavour to seek the advice of a nuclear medicine
1036 physicist on matters relating to image quality optimisation, patient dosimetry,
1037 quality assurance (IAEA 2002), and other matters relating to radiation protection, as
1038 required.

1039 **7.2 ACCEPTANCE TESTING OF NUCLEAR MEDICINE EQUIPMENT**

1040 At initial installation, the nuclear medicine equipment and its associated equipment
1041 (e.g. film imagers) needs to undergo a series of acceptance tests to ensure that the
1042 performance of the equipment complies with the manufacturer's specifications and is
1043 in accordance with any requirements of the relevant regulatory authority. These
1044 tests should preferably be performed by a nuclear medicine physicist and the results
1045 of the acceptance tests should be thoroughly documented. Some of these results
1046 should be used to define the acceptable range of parameters that will be monitored in
1047 any subsequent **constancy** testing.

1048 Following acceptance, constancy tests designed to assess the subsequent
1049 performance of the equipment, should be performed. These are usually simple tests
1050 that may be performed by technologists and are designed to assess image quality and
1051 reproducibility of results.

1052 The results of constancy testing need to be reviewed as a matter of routine and any
1053 anomalous results reported immediately to the person responsible for the QA
1054 program management.

1055 In extreme instances, when the results of constancy tests indicate that the equipment
1056 is outside tolerance, the results may be used to justify replacement of equipment.

1057 **7.3 TESTING FREQUENCY**

1058 The frequency with which any particular parameter is assessed will need to be
1059 carried out at intervals at least as often as those specified by the relevant regulatory
1060 authority and should take into account:

- 1061 • the likelihood of an equipment failure or a measured parameter falling outside
1062 an acceptable tolerance range; and

- 1063 • the consequences that follow when such an event occurs. For example, dose
1064 calibrator performance should be monitored frequently as any changes may
1065 have a substantial impact on both image quality and patient dose.

1066 **7.4 DOSE CALIBRATORS**

1067 Contamination in the chamber or drift in the electronics can result in a nonzero
1068 background reading (positive or negative reading). If this is not checked and
1069 corrected, then measurements taken will be systematically either too high or too low.
1070 Contamination in the chamber or sample holder should be eliminated as much as
1071 possible and zero offsets and general background should be set to zero with the
1072 controls provided on most dose calibrators. The detectable background activity
1073 should be checked on each work day before any patient dosages are prepared and
1074 again whenever any contamination of the dose calibrator is suspected. It is
1075 recommended that a second chamber liner be available which can be used if the first
1076 chamber liner becomes contaminated.

1077 Procedures that may be used to meet the following test requirements are provided in
1078 Annex D.

1079 **(a) Constancy**

1080 Assay at least one relatively long-lived source such as caesium-137, cobalt-60,
1081 cobalt-57, or radium-226 using a reproducible geometry each day before using the
1082 calibrator. Consider the use of two or more sources with different photon energies
1083 and activities.

1084 **(b) Linearity**

1085 This test is done using a vial or syringe of technetium-99m, the activity of which is at
1086 least as high as the maximum radiopharmaceutical activity normally assayed in a
1087 prepared radiopharmaceutical kit, in a unit dosage syringe, or in a
1088 radiopharmaceutical therapy, whichever is highest. The activity should be assayed
1089 repeatedly over several days and the recorded activity compared to that predicted by
1090 the radioactive decay of the radionuclide to detect any departures from **linearity**.

1091 **(c) Accuracy**

1092 The calibration of the dose calibrator should be traceable to a national primary
1093 standard or a secondary or tertiary standard that is traceable to the national
1094 standard. The term “traceable to the national standard” may be interpreted as
1095 traceable to the Australian National Standard or a recognised foreign reference
1096 standard. Certified calibration sources are available from ANSTO (the holder of the
1097 Australian primary and secondary measurement standards for radioactivity) and
1098 from many radioisotope suppliers. However, only ANSTO will be able to provide
1099 certified sources of the short-lived radionuclides used clinically in Nuclear Medicine

1100 **(d) Geometry independence**

1101 The test for **geometry independence** should be performed using a syringe that is
1102 normally used for injections. Nuclear medicine practices where generators and
1103 radiopharmaceutical kits are used should also perform the test using a vial similar in

1104 size, shape, and construction to the radiopharmaceutical kit vials normally used. The
1105 test detailed in Annex D assumes injections are prepared in 3-mL plastic syringes
1106 and that radiopharmaceutical kits are reconstituted in 30-mL glass vials. If these are
1107 not used, the procedure should be changed so that the syringes and vials are tested
1108 throughout the range of volumes commonly used.

1109 **7.5 FILM PROCESSING**

1110 For nuclear medicine departments that print film, one aspect of the constancy testing
1111 relates to the film processor. Substantial image quality degradation may occur
1112 through subtle changes in the processor chemistry, replenishment rate, temperature
1113 and development time. As such, sensitometry and densitometry measurements
1114 should be performed regularly on the processor. Once established tolerance levels
1115 have been exceeded, investigative action may be necessary to determine the cause of
1116 the problem. Any artefacts appearing on the test films should be investigated.

1117 **7.6 RADIOPHARMACEUTICAL QUALITY TESTING**

1118 The *in vivo* behaviour of a radiopharmaceutical is dependent upon its quality, which
1119 includes high standards of radionuclidic, radiochemical and chemical purity. The
1120 specifications and quality control testing for most of the currently used
1121 radiopharmaceuticals are given in the British Pharmacopoeia (BP) or other suitable
1122 Pharmacopoeia (e.g. USP). There should be a written procedure detailing all aspects
1123 of quality control testing that should be considered before the radiopharmaceutical is
1124 administered to the patient.

1125 **technetium-99m Generator**

1126 A molybdenum-99 breakthrough measurement needs to be performed on all elutions
1127 from each technetium-99m generator and the following records kept of all generator
1128 elutions:

- 1129 • dose calibrator setting where the isotope is manually dialled;
- 1130 • reading of long-lived reference source;
- 1131 • time of elution;
- 1132 • volume of eluate;
- 1133 • technetium- 99m activity;
- 1134 • molybdenum-99 activity; and
- 1135 • radionuclidic purity.

1136 BP specification for molybdenum-99 impurity in sodium pertechnetate eluate is 0.1%
1137 or a limit of 1 MBq of molybdenum-99 per GBq of technetium-99m at the time of
1138 administration. If this level is exceeded, then the technetium-99m solution has
1139 failed quality control and is not to be used in the preparation of
1140 radiopharmaceuticals for patient use.

1141 Aluminium ion breakthrough should also be checked on any eluate used to prepare
1142 products that are adversely affected by the presence of aluminium.

1143 **Technetium-99m cold kits**

1144 All technetium-99m cold kits should be reconstituted in accordance with the
1145 manufacturer's instructions. There should be written procedures detailing all quality
1146 control testing that should be carried out on each particular product.

1147 This should include appropriate radiochemical purity testing on every reconstituted
1148 cold kit before patient administration.

1149 **7.7 RECORD KEEPING**

1150 A key element of any QA program is proper record keeping so that any long term
1151 trends associated with a particular item of equipment or batch of
1152 radiopharmaceuticals can be identified and acted on before image quality and/or
1153 patient dose are compromised. Control charts, which plot the behaviour of a
1154 measured parameter as a function of time, represent a convenient way to keep
1155 records of constancy tests. For equipment, such record keeping should extend to
1156 noting:

- 1157 • the results of acceptance testing;
- 1158 • the results of any constancy tests; and
- 1159 • equipment unscheduled downtime and the reason for the failure.

1160 **7.8 PATIENT ACTIVITY SURVEYS AND DIAGNOSTIC REFERENCE**
1161 **LEVELS (DRLs)**

1162 As part of the nuclear medicine practice QA program, patient activity surveys should
1163 be undertaken periodically to establish that the activities are acceptable when
1164 compared with currently published DRLs. To encourage institutions to perform
1165 activity surveys it is recommended that accrediting bodies, such as the ANZAPNM
1166 and the Australian Council on Health Care Standards (ACHS), consider including
1167 compliance with DRLs for a core set of examinations as one element in achieving
1168 accreditation (NRPB 1999). In any event, action needs to be taken if patient
1169 activities are deemed to be unacceptable (ICRP 1996). DRLs being repeatedly and
1170 substantially exceeded may indicate an underlying fundamental problem that
1171 warrants investigation. However, DRLs should be applied with flexibility to allow
1172 higher activities if these are indicated by sound clinical judgement (ICRP 1996).
1173 Furthermore, as emphasized earlier in Section 4, patient activity surveys should
1174 always be undertaken in parallel with image quality assessments.

1175 Technical matters relating to DRLs that should be borne in mind are:

- 1176 • DRLs have been established for both adults and paediatric patients for most
1177 common examinations by the relevant professional societies in consultation
1178 with Regulatory Authorities;
- 1179 • the DRLs for adults are usually defined for a person of average size, which is
1180 taken to be about 70 to 80 kg. When performing dose surveys patients within
1181 this weight range should be selected;
- 1182 • recommended values for DRLs are frequently chosen as a percentile point
1183 (typically the 75% level) in a substantive survey of the observed distribution of
1184 activities to patients. They do not represent best practice, so that the ultimate

1185 target for any institution should be to lower their doses to a level regarded as
1186 achievable. For any procedure, an achievable activity is one which maximises
1187 the difference between the benefit and risk without compromising the clinical
1188 purpose of the examination (NRPB 1999); and

- 1189 • DRL values are reviewed and adjusted by the relevant professional societies in
1190 consultation with the relevant regulatory authority at intervals that represent
1191 a compromise between the necessity for stability and long term changes in the
1192 activity distributions arising from technological improvements. Usually the
1193 adjustment results in a lowering of the DRLs as a result of technological
1194 improvements. It may be envisaged that the difference between DRLs and
1195 achievable doses will narrow with the passage of time.

1196 Records of radiopharmaceutical administration may be kept by either using the label
1197 prepared for each patient or a printout from the dose calibrator, if available.

1198

1199 **8. Radiation Incidents**

1200 **8.1 INVESTIGATIVE AND REPORTING REQUIREMENTS**

1201 The investigation of accidental, abnormal or unplanned exposures arising from
1202 diagnostic or therapeutic nuclear medicine procedures should be aimed at:

- 1203 • establishing what happened;
- 1204 • identifying the failure;
- 1205 • deciding on remedial action to minimise the chance of a similar failure; and
- 1206 • estimating the likely radiation doses received by the patient and staff.

1207 As a matter of good practice, any patient accidentally or unintentionally irradiated
1208 should be informed of the event and counselled as to the likely implications of the
1209 unintended exposure. It would be very unusual for there to be a good reason for not
1210 informing the patient or their guardian. When the patient is unable to comprehend
1211 the information given, it may be more appropriate to inform the patient's
1212 representative or parent/guardian.

1213 **9. Occupational Exposure**

1214 **9.1 GENERAL CONSIDERATIONS**

1215 A radiation hazard may arise from unsealed radioactive substances, either through
1216 external irradiation of the body or through the entry of radioactive substances into
1217 the body. The main precautions required in dealing with external irradiation will
1218 depend on the physical characteristics of the radiation emitted, the total activity and
1219 the physical half-life of the radionuclide. In nuclear medicine studies the main
1220 source of external irradiation to other persons comes from the radioactive patient.
1221 Unsealed radioactive substances may produce a further external hazard as a result of
1222 contamination.

1223 When an unsealed radioactive substance enters the body, the internal radiation dose
1224 will depend on factors such as the physical and chemical form of the material, the
1225 activity, the mode of entry and the pharmacokinetics of the radiopharmaceutical.

1226 **9.2 PREGNANT OR BREAST-FEEDING STAFF**

1227 If an occupationally exposed member of the nuclear medicine staff is pregnant then
1228 the fetus should be afforded the same level of protection as a member of the public.
1229 This may be achieved by controlling the exposure of the employee such that the dose
1230 received by the fetus is less than the public effective dose limit of 1 mSv for the
1231 remainder of the pregnancy. For external irradiation from technetium-99m or
1232 iodine-131, a dose of 1.3 mSv to the surface of the maternal abdomen has been shown
1233 to give rise to a dose of 1 mSv to the fetus (Mountford and Steele, 1995). For higher
1234 energy photons, such as those from positron emitters, the dose to the fetus may be
1235 similar to the dose at the surface of the abdomen.

1236 Employers are to assess the likely dose to the fetus of a pregnant employee from each
1237 work activity. This will usually require an examination of the employee's personal
1238 monitoring records and an assessment of the likelihood of incidents leading to either
1239 external or internal exposure of the fetus. If the fetus could receive more than 1 mSv
1240 over the declared term of the pregnancy a change in work practice should be
1241 discussed and agreed to with the employee. It would be prudent to provide an
1242 occupationally exposed pregnant staff member with a personal dose monitor if they
1243 do not already have one.

1244 Pregnant women, or those intending a pregnancy or breast-feeding, should not work
1245 with large amounts of radioiodine.

1246 If a member of staff is breast-feeding she should not take part in procedures or work
1247 in areas where there is a significant risk of bodily contamination, e.g. cleaning up a
1248 large spill of radioactivity. An assessment should be undertaken of the potential
1249 radiation dose to the infant resulting from a chance inhalation by the mother of
1250 radioactive gases or aerosols arising from her work and appropriate procedures put
1251 in place to restrict this dose if necessary.

1252 **9.3 EXPOSURE FROM RADIOACTIVE PATIENTS**

1253 In clinical practice a patient may be required to undertake a number diagnostic
1254 imaging or other procedures in addition to the nuclear medicine test. Those
1255 procedures may include X-ray or ultrasound investigations. As a general rule,
1256 whenever practicable, other procedures should be performed before the
1257 administration of the radiopharmaceutical mainly to avoid any radiation exposure of
1258 staff outside of the nuclear medicine facility.

1259 There may be occasions when a patient who has already been administered a
1260 radiopharmaceutical and is then required to undergo another procedure. A
1261 radioactive patient presents a source of radiation exposure to other staff, but the risk
1262 to others may be small. It is important to note that the prior administration of a
1263 radiopharmaceutical to a patient is not of itself a contraindication to performing x-
1264 ray, ultrasound or other procedures. The decision to proceed with the other test
1265 should be made based on clinical need. A decision about what precautions should be
1266 adopted depends upon an assessment of the amount of radiation exposure to others
1267 from the patient as a result of the nuclear medicine procedure. Application of the
1268 ALARA principle requires that steps should be taken to reduce radiation exposure to
1269 staff to the minimum reasonably achievable level.

1270 As stated, in general, medical imaging (particularly ultrasound) and other
1271 procedures which require staff to be in the close proximity of the patient should be
1272 performed before the administration of a radiopharmaceutical to a patient. The
1273 institutional protocol should alert the nuclear medicine department of other
1274 procedures that the patient will need and if it is considered necessary, to liaise with
1275 staff from other departments about scheduling and of any special arrangements
1276 required.

1277 The following procedures should be adopted to inform and minimise radiation to
1278 staff in other areas of the hospital:

- 1279 • A prominent radiation sticker should be attached to the patient's file or notes.
1280 The sticker should state that the radionuclide, the activity, the time that the
1281 radiopharmaceutical was administered and the route of administration. The
1282 sticker should also state that the patient is radioactive and the time after the
1283 administration that the patient will remain a source of radiation exposure.
- 1284 • In order to reduce patient radioactivity, the patient should be asked to empty
1285 their bladder prior to any other medical procedure provided that is not
1286 required for the other test.
- 1287 • Staff should avoid any unnecessary proximity to the patient.
- 1288 • Staff performing other procedures on the radioactive patient should be made
1289 aware of the contamination hazard that may arise from the excretion of body
1290 fluids, in particular from incontinent patients. Any such spill or excretion
1291 should be immediately referred to the RSO for measurement and
1292 decontamination.
- 1293 • The nuclear medicine department should have a person to whom queries can
1294 be directed; who is able to answer questions from staff outside the nuclear
1295 medicine department about the radiation they may exposed to from the

1296 nuclear medicine procedure and risks, and about any precautions that may be
1297 needed.

1298 Some other imaging procedures may interfere with the nuclear medicine procedures.
1299 Barium can attenuate the photon emission from the administered gamma-emitting
1300 radiopharmaceutical, and so if the patient requires barium contrast studies, the
1301 nuclear medicine study should be performed before the barium contrast study.
1302 Administration of iodinated contrast media may interfere with some iodine nuclear
1303 medicine procedures, by blocking uptake of radioactive iodine in the thyroid.

1304 **9.4 DESIGNATION OF AREAS**

1305 The risk to any person working with unsealed radioactive materials should be
1306 assessed before the work commences and should be kept under review. This will
1307 require an assessment as to whether particular areas need to be designated as
1308 “controlled” or “supervised”. A controlled area is an area into which access is subject
1309 to control and in which employees are required to follow specific procedures aimed
1310 at controlling any radiation exposure. Radiopharmacies, imaging rooms, medium-
1311 level laboratories where unsealed radioactive materials are used (as defined in AS
1312 2234.4) and treatment rooms for patients undergoing radionuclide therapy are to be
1313 designated as controlled areas. A **supervised area** is one in which the working
1314 conditions are kept under review but in which special procedures to control radiation
1315 exposure are not normally necessary. Patient waiting areas within a nuclear
1316 medicine practice will normally be designated as supervised areas.

1317 The risks associated with each controlled area need to be assessed and control
1318 measures to restrict exposure documented. The documentation may be in the form
1319 of local rules or protocols and often will form part of the institution’s Radiation
1320 Management Plan. The documentation should also contain a clear indication of the
1321 roles and responsibilities of each different category of staff.

1322 The specific circumstances of the area that need to be taken into account are:

- 1323 • the external radiation hazard, both in terms of instantaneous dose rates and
1324 doses averaged over a working day;
- 1325 • the risk and possible level of radioactive contamination;
- 1326 • the control of access to the area;
- 1327 • whether staff untrained in radiation protection need to enter;
- 1328 • the length of time for which persons need to remain in the area;
- 1329 • whether the only radioactive substances present are within the body of a
1330 person; and
- 1331 • the special procedures that need to be followed to restrict significant exposure.

1332 Periodic review of the use of radioactive materials in each area, together with
1333 environmental monitoring, will be necessary to confirm the appropriate designation.

1334 **9.5 EQUIPMENT AND CLOTHING**

1335 Radiopharmacies, laboratories and other work areas where unsealed radioactive
1336 substances are handled should be provided with radiation protection equipment kept
1337 specifically for this purpose. This equipment may include:

- 1338 • lead barriers with lead glass windows for work with photon emitters;
- 1339 • perspex barriers for work with beta emitters;
- 1340 • syringe shields;
- 1341 • shielded containers;
- 1342 • drip trays to contain any spillage;
- 1343 • tongs or forceps to maximise the distance of the worker from the source;
- 1344 • radiation and contamination monitoring equipment;
- 1345 • dose calibrators;
- 1346 • shielded transport containers; and
- 1347 • equipment and materials to deal with spills.

1348 Protective clothing is to be used in work areas where there is a likelihood of
1349 contamination, both to protect the body or clothing of the worker and to help prevent
1350 contamination to other areas. The clothing should be monitored and removed before
1351 leaving designated areas, e.g. when visiting the staff room. The clothing may include:

- 1352 • laboratory coats or protective gowns; and
- 1353 • waterproof gloves.

1354 Overshoes are not routinely required but may be needed in radiopharmacies
1355 handling greater than 200 GBq of technetium-99m and should be included in the
1356 decontamination kit, to be worn when cleaning up a major spill.

1357 In certain circumstances staff may need to wear a protective lead apron. This may be
1358 necessary if staff need to be in close contact with patients containing greater than
1359 800 MBq of technetium-99m, such as during myocardial perfusion studies or gated
1360 cardiac blood pool studies. Protective aprons should preferably have a thickness of
1361 0.5 mm lead equivalence. Preferred designs are those comprising a separate vest and
1362 skirt that wrap around fully, as open back designs are not recommended. All
1363 protective clothing should be examined under fluoroscopy at least annually to
1364 confirm the integrity of the protection.

1365 Lead aprons provide little or no protection for higher energy photons and should not
1366 be used for radionuclides such as gallium-67 or iodine-131 or for positron emitters.

1367 Staff leaving designated areas should remove protective clothing, wash their hands
1368 and monitor their hands, clothing and body as appropriate.

1369 Mobile shielding barriers may be required for therapeutic nuclear medicine
1370 procedures using gamma-emitting radionuclides.

1371 **9.6 PERSONAL MONITORING**

1372 All staff who are occupationally exposed to ionising radiation should be issued with,
1373 and wear, a personal radiation monitoring device from an approved Personal
1374 Radiation Monitoring Service. This will normally include all nuclear medicine staff
1375 who need to handle radioactivity or radioactive patients and may include other staff
1376 such as receptionists. A direct-reading device, such as an electronic dosimeter, may
1377 also be worn if an immediate indication of the dose received is necessary.

1378 The length of time for which a dosimeter will be allocated will depend on the doses
1379 likely to be received during the wearing period. Technologists and radiochemists
1380 who routinely handle radiopharmaceuticals may require monthly monitors, whilst a
1381 3-monthly cycle may be appropriate for staff who may be exposed less frequently,
1382 such as nuclear medicine physicists.

1383 Pregnant staff may also wear a direct-reading dosimeter which will enable them to
1384 monitor their body dose on a daily basis so that they can ensure that the dose to the
1385 fetus is unlikely to exceed 1 mSv for the duration of the pregnancy.

1386 Routine monitoring of extremity doses is advisable if doses to the hands or other
1387 extremities are likely to exceed 1/10 of the appropriate dose limit. Therefore persons
1388 who reconstitute, dispense or administer radiopharmaceuticals should wear a
1389 thermoluminescent dosimeter (TLD) on a finger as a ring. Although the maximum
1390 dose will usually be received by the fingertip, it is customary to wear the monitor at
1391 the base of the finger, as wearing the monitor at the fingertip may adversely affect
1392 tactile functions.

1393 **9.7 DOSIMETRY INVESTIGATION**

1394 The Responsible Person should establish an investigational level such that any
1395 exposures received during a monitoring period which exceed this level require a
1396 formal investigation and require appropriate measures to be identified to minimise
1397 future exposures. The investigational level may be specified by the relevant
1398 regulatory authority in which case a report of the investigation may also be required
1399 by the relevant regulatory authority. Alternately, the Responsible Person may
1400 establish an investigational level for the institution. For example, the level could be
1401 set at 1/20 of the annual dose limit in a month.

1402 **9.8 GENERAL PROCEDURES TO REDUCE OCCUPATIONAL EXPOSURE**

1403 The advice of the RSO and/or nuclear medicine physicist should be sought before
1404 new procedures are introduced or major changes are made to existing procedures.
1405 New or changed procedures should be rehearsed, where possible, without using
1406 radioactive substances.

1407 Working procedures should be designed to prevent the occurrence of spillage, and in
1408 the event of a spillage, to minimise the spread of contamination. This will usually
1409 require the use of a drip-tray to contain any spilled liquid.

1410 No food or drink (except that used for medicinal purposes) or cosmetics should be
1411 brought into an area where unsealed radioactive substances are used, nor should
1412 food or drink be stored in a refrigerator used for storing radioactive materials.

1413 Any cut or break in the skin should be covered with a waterproof dressing before a
1414 person enters an area where unsealed radioactive substances are handled.

1415 Staff leaving a controlled area should, after removing protective clothing, wash their
1416 hands and then monitor their hands, clothing and body, as appropriate. If
1417 contamination is detected, staff should follow the decontamination procedures
1418 detailed in the Radiation Management Plan.

1419 Equipment provided specifically for the safe handling of unsealed radioactive
1420 substances should always be used and should not be removed from the work area.
1421 Pipettes should never be operated by mouth. Syringe needles should not be recapped
1422 prior to disposal unless assessment of residual activity in the syringe is required.

1423 The work area should be kept tidy and free of articles not required for the work. It
1424 should be cleaned often to ensure minimal contamination. Cleaning methods should
1425 be chosen in order to avoid raising dust or spreading contamination.

1426 Shielding should always be considered for any radioactive source. The prior risk
1427 assessment should identify what shielding that is required and what type and form it
1428 should take. Appropriate shielding may be obtained using a variety of materials such
1429 as perspex, lead, lead glass, tungsten or aluminium depending on the characteristics
1430 of the radionuclide to be shielded.

1431 The radiation dose to the operator can be minimised by prudent positioning relative
1432 to the patient and/or by structural shielding. If there is no structural shield and the
1433 operator has to remain in the room, the operator should stand at least two metres
1434 away from the patient whilst the images are acquired.

1435 Where the work involves the possibility of air-borne radioactivity, the work should be
1436 undertaken in an enclosure such as a fume cupboard, glove box or biological safety
1437 cabinet. When radioactive gases or aerosols are administered to patients it may be
1438 necessary to provide an additional room exhaust system to minimise any internal
1439 contamination of the operator.

1440 Systems should be in place to detect when maintenance work is to be performed on
1441 equipment that might be contaminated, particularly for enclosures for controlling
1442 airborne activity, ventilation ducting, sinks and waste pipes. In hospitals, this should
1443 include signs on appropriate access points instructing any maintenance staff to
1444 contact the RSO before commencing work on particular equipment. Direct
1445 supervision of the work may be required if, for example, the dose rate or activity is
1446 likely to be high.

1447 If radionuclides are to be administered outside the nuclear medicine department,
1448 such as in wards or clinics, the local rules for the department need to be extended to
1449 cover these areas. It may be necessary to cover surfaces with a plastic-backed
1450 adsorbent material to prevent contamination.

1451 In the case of nuclear medicine procedures performed in operating theatres,
1452 standard procedures should protect the staff from any contamination. Normal
1453 cleaning and sterilisation procedures should be adequate to remove any
1454 contamination from equipment. If any potentially contaminated waste is generated,
1455 it should be collected in a clearly labelled plastic bag and removed by trained staff for

1456 monitoring and disposal. Any waste is also likely to be biologically contaminated and
1457 would need to be handled accordingly.

1458 **9.9 MONITORING OF WORK AREAS**

1459 Laboratories and other areas in which unsealed radioactive substances are used
1460 should be monitored, both for external radiation and for surface contamination,
1461 using a survey meter on a systematic basis. For each controlled area there should be
1462 a regular monitoring schedule appropriate for the areas. Survey meters should be
1463 suitable for the task and be regularly tested.

1464 Contamination should be kept as low as reasonably achievable. Wipe tests of
1465 surfaces in the work areas should be undertaken.

1466 General requirements for a survey meter are given in Annex E. Details of ambient
1467 dose rate surveys and surface contamination monitoring are given in Annex F.

1468

1469 **10. Environmental Issues**

1470 **10.1 RADIATION SHIELDING AND SIGNS**

1471 Careful consideration should be given to both the siting of nuclear medicine practices
1472 and to the provision of structural shielding particularly if PET studies are to be
1473 performed. Advice on structural shielding may be obtained from the relevant
1474 regulatory authority.

1475 As a general requirement all barriers should be designed to a height of at least two
1476 metres and the effectiveness of shielding at penetrations and joints should be
1477 ensured. It follows that any viewing windows in walls or doors will need at least the
1478 same lead equivalence as the minimum shielding specifications for the barrier in
1479 which they are located. Due consideration should be given to the provision of floor
1480 and/or ceiling shielding when rooms immediately below and above the nuclear
1481 medicine installation, respectively are occupied.

1482 In the particular instance of estimating shielding for PET/CT or SPECT/CT
1483 installations the calculation may be expedited by insisting that the equipment
1484 suppliers provide radiation scatter contour maps around the scanner as part of the
1485 required documentation.

1486 Visible warning signs are to be provided at any general access point to a room where
1487 unsealed radioactive material is stored or used. Warning signs using the trefoil
1488 symbol should conform to the specifications noted in the Australian Standard (AS
1489 1319 1994). An example warning sign is shown in the accompanying figure.



1490

1491 In the case of CT equipment, the provision of a warning light that is illuminated
1492 whenever the X-rays are being produced is recommended and may be required by
1493 the relevant regulatory authority.

1494 **10.2 DECONTAMINATION PROCEDURES**

1495 **Decontamination of persons**

1496 Persons suspected of being significantly contaminated by radioactive material (e.g.
1497 therapy sodium iodide [¹³¹I]) should be removed from the area of contamination and
1498 the situation reported immediately to the Responsible Person and the RSO. While
1499 waiting for assistance any obvious injuries should be treated immediately, taking
1500 care to avoid the spread of contamination.

1501 In nuclear medicine, personal contamination will, in most cases, be due to spills,
1502 breakages of vials or contact with radioactive liquid, including patient excreta.
1503 Contaminated clothing should be removed and personal decontamination should be
1504 undertaken according to the area(s) of the body contaminated, as follows:

- 1505 • Eyes should be irrigated with saline solution (a 0.9 percent sodium chloride
1506 solution), or with distilled or mains water.
- 1507 • Hands should be washed with soap and warm water, scrubbing lightly with a
1508 soft nail brush. If this fails, repeat using a detergent. For contamination that
1509 is difficult to remove, tight fitting rubber gloves may be worn for several hours
1510 to promote perspiration of the hands, which often assists in the removal of
1511 contamination.
- 1512 • Skin, other than that of the hands, should be rubbed gently with a cotton wool
1513 pad soaked in a complexing agent. Do not vigorously scrub the skin so as to
1514 produce abrasions.
- 1515 • Contaminated wounds should be washed under a fast running tap and
1516 bleeding encouraged. If the wound is on the face, care should be taken not to
1517 contaminate the eyes, mouth or nostrils. Finally, the wound should be washed
1518 with water, and a gentle antiseptic and first aid dressing applied.

1519 If the contamination is due to iodine radioisotopes, the affected area should not be
1520 treated with any material that contains oxidising agents or acids as these can result
1521 in the production and inhalation of volatile molecular radioiodine

1522 Personal decontamination should be continued until monitoring shows that the
1523 contamination has been reduced to an acceptable level, unless there is the risk of the
1524 contamination entering the bloodstream through the roughening or breaking of the
1525 skin.

1526 **Decontamination of surfaces or contaminated equipment**

1527 Many of the radioisotopes used in nuclear medicine have relatively short half-lives.
1528 In many cases it will be preferable to store or isolate the item until the level of
1529 contamination is reduced to an acceptable level rather than to attempt
1530 decontamination. If the decision is made to decontaminate the item, advice should
1531 be sought from the RSO on appropriate methods. Corrosive methods should not be
1532 used on items contaminated with iodine radioisotopes because of the risk of
1533 oxidation to volatile molecular radioiodine.

1534 The use of acid on metal surfaces may cause unnecessary corrosion and result in
1535 greater difficulty in future decontamination procedures. It is desirable to first

1536 attempt decontamination with detergents. The use of a customized detergent (e.g.
1537 Decon 90) and specialised cleaning methods such as the use of ultrasonic cleaning
1538 baths may be appropriate. The use of chelating agents such as a 10 percent solution
1539 of sodium citrate may prove effective.

1540 The contaminated item should be monitored before and after decontamination has
1541 been performed. Decontamination seldom exceeds 99.9% effectiveness and is
1542 usually much less effective. If the measurement of residual contamination indicates
1543 that the level of radioactive contamination remains greater than permissible, the
1544 item should be allowed to either decay in storage or action should be taken in order
1545 to prevent the accidental return of the item into stock or other use.

1546 Benches should be covered with disposable plastic backed adsorbent paper in order
1547 to absorb any spills. When a spill occurs on a bench or the floor care should be taken
1548 to avoid the spread of contamination. If the surface is wet, the liquid may be mopped
1549 up by the use of an absorbent material such as a paper towel. Commercially available
1550 spill kits may be useful for this purpose. The mopped up material should be stored
1551 as radioactive waste. If a wet mop will not remove the residual contamination, a
1552 decontamination method suitable for the particular surface material should be used.
1553 For linoleum, kerosene or ammonium citrate may prove effective. Localised
1554 contamination on a floor may be shielded by covering the area with lead sheeting
1555 until the radioactivity has decayed to an acceptable level.

1556

1557 **11. Training**

1558 **11.1 RADIATION HEALTH PROFESSIONALS**

1559 Staff who perform or direct exposures of patients to ionizing radiation, are required
1560 to have appropriate training. It would be anticipated that radiation health
1561 professionals (nuclear medicine specialists and technologists) should be deemed to
1562 have such knowledge by virtue of undertaking a course leading to their professional
1563 qualification. However, the Responsible Person should provide additional training
1564 specific to the equipment used at a particular institution and should ensure that a
1565 programme of continuing professional development is available for all the staff.

1566 **11.2 OTHER HEALTH PROFESSIONAL GROUPS**

1567 Nurses working in nuclear medicine departments and who care for patients
1568 undergoing nuclear medicine procedures, particularly therapeutic procedures,
1569 should also have appropriate training. This training should be delivered by suitably
1570 qualified personnel and should be specific for each group to include:

- 1571 • the responsibility of the individual in maintaining a safe workplace;
- 1572 • occupational dose limits and the ALARA principle;
- 1573 • methods of reducing occupational radiation doses during nuclear medicine
1574 examinations;
- 1575 • knowledge of the magnitude of typical doses from different examinations;
- 1576 • risk factors such as age and the tissue type being irradiated; and
- 1577 • measurement of radiation dose, if appropriate.

1578 Professional bodies should ensure that such a core of knowledge is included in
1579 courses that they accredit and the individuals who undertake such training should be
1580 issued with a certificate signed by a representative of the sponsoring organisation.

1581 Other health professional and ancillary staff should be provided with information on
1582 the basic principles of radiation protection such as time, distance and shielding.

1583 **11.3 STAFF INVOLVED IN RADIONUCLIDE THERAPY**

1584 Additional training should be provided for staff involved in the administration of
1585 radioactivity to patients for therapeutic purposes, or who care for patients receiving
1586 radionuclide therapy. This training should be delivered by suitably qualified
1587 personnel and should include the topics listed above plus:

- 1588 • the limitations of shielding for gamma radiation of high energy ;
- 1589 • procedures to minimise the likelihood of radioactive contamination;
- 1590 • procedures to handle potentially radioactive waste;
- 1591 • potential problems with incontinent patients;
- 1592 • contamination monitoring of the patient's room;

- 1593 • restrictions, if any, for the patient's visitors;
- 1594 • appropriate signage during treatment;
- 1595 • requirements for the patient's discharge from hospital; and
- 1596 • appropriate documentation of the patient's treatment and discharge.

1597

12. Transport

1598 The person responsible for the transport of radioactive material (the consignor) is
1599 required to comply with the current Code of Practice for the Safe Transport of
1600 Radioactive Material (ARPANSA 2001) and any existing national and State
1601 legislation. As the Transport Code is very comprehensive, the guidelines given in
1602 Annex G (to be used in regard to transport of radioactive material between
1603 institutions) have been extracted and compiled solely for the purpose of this Safety
1604 Guide.

1605 **Annex A**

1606

1607 **Guidelines for the Radiation Management Plan**

1608 The plan should contain all the necessary background and operational information for
1609 working with radiation, and be kept up-to-date. It should be the first point of reference for
1610 staff, and should provide supervisors with all necessary policies and procedures. The plan
1611 will usually be published in the form of a radiation safety manual. For nuclear medicine
1612 practices, the Radioactive Waste Management Plan will usually form part of the Radiation
1613 Management Plan.

1614 The content should include (although this is not a fully inclusive list):

1615 1. General Information

- 1616 1.1 Authority of the manual (e.g. executive policy statement)
- 1617 1.2 Persons who should read the document
- 1618 1.3 How the practice uses radiation
- 1619 1.4 Regulatory requirements (list the required regulations, codes of practice or
1620 standards - copies (or hyperlinks to the document location) should be available
1621 with the plan
- 1622 1.5 Licensing/registration requirements (list details of all sealed sources, ionizing
1623 apparatus etc.)
- 1624 1.6 Responsibilities of employer and employees
- 1625 1.7 Penalties for legislative contravention
- 1626 1.8 Contact details (RSO, approved provider of personal radiation monitoring etc.)

1627

1628 2. General information on radiation risk etc.

- 1629 2.1 Nature of radiation and units
- 1630 2.2 Effect and risks associated with radiation (including radiation and pregnancy)
- 1631 2.3 Sources of radiation exposure (including background)
- 1632 2.4 Objectives of radiation protection
- 1633 2.5 Dose limits and dose constraints

1634

1635 3. Local rules/procedures for minimizing staff exposure

- 1636 3.1 Description of the area/procedure
- 1637 3.2 Nature of the hazard
- 1638 3.3 Procedure/equipment/facilities required
- 1639 3.4 Emergency procedures (should include a brief description of the type of
1640 emergencies that could occur)
- 1641 3.5 Responsible staff and contact procedures
- 1642 3.6 Personal monitoring details (name of approved supplier etc.)

1643

1644 4. Local rules/procedures for optimising medical exposure

- 1645 4.1 Procedures for the preparation and dispensing of radiopharmaceuticals
- 1646 4.2 Prevention of erroneous administration
- 1647 4.3 Procedures to avoid unintentional irradiation of embryo/fetus, or child (from
1648 breast-feeding)
- 1649 4.4 Special procedures for therapy administration
- 1650 4.5 Reviews of administered activities

1651

- 1652 5. Quality Assurance (QA) procedures
- 1653 5.1 Acceptance and constancy equipment tests
- 1654 5.2 Radiopharmaceutical QA
- 1655 5.3 Use, maintenance and calibration of radiation measuring instruments
- 1656
- 1657 6. Handling of radiation incidents
- 1658 6.1 Possible types of incidents
- 1659 6.2 Procedures for handling each type
- 1660 6.3 Decontamination procedures
- 1661 6.4 General emergency procedures
- 1662 6.5 Contact names and numbers
- 1663 6.6 Reporting requirements
- 1664
- 1665 7. Disposal of radioactive waste/x-ray apparatus
- 1666 7.1 Sources and categorisation of radioactive waste
- 1667 7.2 Mixed waste hazards
- 1668 7.3 Conditioning/packaging
- 1669 7.4 Storage procedures (identification, location, record keeping, etc.)
- 1670 7.5 Disposal procedures (when, how, who authorises the disposal, etc.)
- 1671 7.6 Disposal/sale of x-ray apparatus (e.g. SPECT/CT machines)
- 1672
- 1673 8. Record-keeping, general requirements
- 1674 8.1 Inventory of radioactive sources and x-ray units
- 1675 8.2 Testing where required (e.g., QA results, wipe tests on radioactive sources)
- 1676 8.3 Storage of records
- 1677 8.4 Who is responsible?
- 1678
- 1679 9. Environmental issues
- 1680 9.1 Radiation shielding to ensure compliance with the appropriate dose constraints
- 1681 9.2 Ventilation and maintenance of sterility
- 1682 9.3 Structural facilities within the practice to facilitate decontamination when
- 1683 necessary
- 1684 9.4 Appropriate storage of radioactive material
- 1685
- 1686 10. Training (details of training requirements, training providers etc.)
- 1687 11. Transport (work rules for transport both within and between facilities)
- 1688 12. Examples of possible radiation doses associated with nuclear medicine and other
- 1689 diagnostic medical procedures
- 1690 13. Examples of any forms to be used in implementing the plan
- 1691 14. Mechanisms for the periodic review of the Radiation Management Plan

1692 **Annex B**

1693

1694 **Radiation safety information for patients undergoing**
1695 **radioiodine therapy**

1696

1697 **Example of written instructions to patients or their legal guardians before**
1698 **leaving the hospital or practice after treatment with iodine-131**

1699 You have been treated with radioactive iodine to cure a thyroid problem. Most of the iodine
1700 will leave your body through the urine. For several weeks, however, some of the iodine will
1701 stay inside your body, which means that you in turn can irradiate other people physically
1702 close to you.

1703 It is your responsibility to protect relatives, friends, colleagues and others. The following
1704 questions and answers are designed to inform you about simple precautions to be taken.

1705 Your doctor will inform (or has already informed) you how long you should follow these
1706 instructions:

1707 **1. What is the most important precaution?**

1708 Do not sit or stay close to any person either at home or at work. Try to maintain a
1709 distance of at least 1 metre. For long periods (more than one hour), stay at least 2
1710 metres away.

1711 Passing someone briefly, for example in the street, or while shopping, is permissible -
1712 as is a quick hug. The restrictions above only apply if you are to be in close proximity
1713 to another person for more than a few minutes.

1714 **2. What about contacts with pregnant women?**

1715 Contact with pregnant women should be minimised. Try to stay at least 2 metres
1716 away from a pregnant woman.

1717 **3. Is it safe to become pregnant / father children?**

1718 Some of the iodine will remain in your body for four months. During this time period
1719 you should not become pregnant or father children.

1720 **4. Can I still see my children and care for them?**

1721 If your children are under ten years old, please minimize hugging or holding and
1722 avoid prolonged contact for the restriction period.

1723 The risk is higher for young children than for adults, therefore it is prudent to avoid
1724 additional unnecessary contact for an additional week on top of the recommended
1725 period.

1726 **5. What about infants?**

1727 Children under two years old should be looked after by someone else. If possible,
1728 arrange for them to stay with relatives or friends.

- 1729 **6. Can I go on with breast-feeding?**
- 1730 Radioactive iodine is passed on in breast milk for quite a long time. Therefore, it is
1731 important that breast-feeding be stopped completely!
- 1732 **7. Can I be in close contact with my partner or other people at home?**
- 1733 Any close contact such as hugging or sex should be limited to half an hour a day. You
1734 should sleep in a separate bed. Beds should be at least 2 metres apart, even if there is
1735 a wall separating them. This is because the walls of a house do not provide good
1736 protection against the type of radiation emitted by iodine-131.
- 1737 **8. What if my partner is pregnant?**
- 1738 If your partner is pregnant, it is important to avoid close contact with her.
- 1739 **9. Do the precautions apply to those over 60?**
- 1740 For those over 60 years, the risk is much lower than for other people. Special
1741 precautions are for that reason less important.
- 1742 **10. Can I receive visitors?**
- 1743 Short visits, less than two hours, create no problem. Keep at a distance of about 2
1744 metres and preferably avoid close contact. You should discourage visits by young
1745 children and pregnant women.
- 1746 **11. Can I go to work?**
- 1747 Most people can go to work. If, by the nature of your work, you are within 2 metres
1748 of the same individual(s) for more than two hours per day, you should seek advice
1749 from your doctor.
- 1750 You should in any case inform your manager.
- 1751 **12. What if I am a nursery school teacher?**
- 1752 Nursery school teachers, or others who are in close contact with young children
1753 during working hours, should stay off work. Your doctor will indicate the required
1754 period of time for this restriction.
- 1755 **13. Can I go to the movies or other entertainment?**
- 1756 Avoid visiting cinemas and other social events where you are close to other people for
1757 more than one hour.
- 1758 **14. May I use public transport?**
- 1759 For the first week you should restrict public transport to journeys lasting no more
1760 than two hours. Longer trips should only be undertaken if unavoidable. In that case,
1761 try to find a place where you can sit alone. Ask your doctor for advice if the trip is
1762 longer.
- 1763 **15. What about using a taxi?**
- 1764 Sit in the back on the opposite side from the driver. Do not spend more than two

1765 hours with any one taxi driver.

1766 **16. Can I use the same toilet as other people?**

1767 Yes, but spilling of urine needs to be avoided. Therefore, (also for men) pass urine
1768 while seated. Always dry your genitals with toilet paper and flush the toilet. It is also
1769 important to wash your hands immediately afterwards, even when only urinating.

1770 **17. What about cutlery, crockery, bed linen, towel etc?**

1771 Radioactive iodine also leaves the body in the saliva and the sweat of patients.
1772 Therefore, cutlery, crockery, towels, bed linen etc. should not be shared with others.
1773 After washing they are completely safe. There is no need to wash them separately.

1774 **18. What happens if I have to go to hospital?**

1775 If you have to go to hospital unexpectedly, please inform the doctor that you have
1776 been treated with radioactive iodine recently. This applies even when it is the same
1777 hospital where you were treated.

1778 **If in doubt, you should always ask the advice of the doctor treating you.**

1779 **Annex C**

1780

1781 **Quality Assurance**

1782 **GENERAL**

1783 Each nuclear medicine practice will need to have a comprehensive Quality Assurance (QA)
1784 program that places particular emphasis on image quality optimisation and patient dose
1785 optimisation as its primary and secondary goals.

1786 The basic elements of the QA program should include:

- 1787
- equipment acceptance testing;
 - 1788 • equipment constancy testing;
 - 1789 • radiopharmaceutical quality testing;
 - 1790 • record keeping;
 - 1791 • patient activity surveys; and
 - 1792 • keeping records of equipment unscheduled downtime and the reason for the
1793 failure.

1794 The QA program should:

- 1795
- include a system of checks and procedures to ensure that the aims of the QA
1796 program are met; and
 - 1797 • have a well defined responsibility and reporting structure.

1798 The results of all QA tests will need to be documented and retained for possible inspection by
1799 external auditors.

1800 All personnel working in diagnostic and therapeutic nuclear medicine will need to follow the
1801 working procedures defined in the QA program.

1802 **ACCEPTANCE TESTING OF NUCLEAR MEDICINE EQUIPMENT**

1803 At initial installation, the nuclear medicine equipment (e.g. radionuclide dose calibrators,
1804 gamma cameras, PET cameras, autogamma counters, laser film imagers) need to undergo
1805 acceptance testing to ensure that the equipment performance complies with the
1806 manufacturer's specifications.

1807 Any radionuclide sources used in performing **accuracy** checks of radionuclide dose
1808 calibrators will need to have a calibration traceable to a national or international standard.

1809 The results of the acceptance testing will need to be documented and available for inspection
1810 by the relevant regulatory authority.

1811 **TESTING OF NUCLEAR MEDICINE EQUIPMENT**

1812 Tests designed to assess the performance of the equipment need to be conducted and will
1813 take into account:

- 1814
- the likelihood of an equipment failure or a measured parameter falling
1815 outside an acceptable tolerance range; and

1816 • the consequences that follow when such an event occurs.

1817 The QA program should clearly define the:

- 1818 • types of constancy tests;
- 1819 • frequency of tests;
- 1820 • tolerance of each parameter being monitored; and
- 1821 • procedure for staff to follow when tolerance is exceeded.

1822 The results of constancy testing need to be reviewed as a matter of routine and any
1823 anomalous results reported immediately to the Responsible Person.

1824 The following tests should be conducted for dose calibrators at the indicated frequency after
1825 repair or movement of the calibrator, and to the indicated tolerance:

- 1826 • background – at least once each work day prior to the first assay of patient
1827 dosages or whenever contamination of the dose calibrator is suspected;
- 1828 • constancy – at least once each work day prior to the first assay of patient
1829 dosages (± 10 per cent);
- 1830 • linearity – at installation and at least annually thereafter (± 10 per cent);
- 1831 • accuracy – at installation and at least annually thereafter, and after repair or
1832 movement (± 10 per cent); and
- 1833 • geometry dependence – at installation and after repair or movement (± 10 per
1834 cent).

1835 Repair, replacement, or arithmetic correction will need to be conducted if the dose calibrator
1836 falls outside the indicated tolerances.

1837 **RADIOPHARMACEUTICAL QUALITY ASSURANCE**

1838 The in vivo behaviour of a radiopharmaceutical is dependent upon its quality, which includes
1839 high standards of radionuclidic, radiochemical and chemical purity. Radiopharmaceuticals
1840 will need to comply with both radiation and pharmaceutical standards in order to ensure
1841 their safe and efficacious use.

1842 **Technetium-99m Generator**

1843 Technetium-99m generators should be sited in a clean area away from general traffic and
1844 additional lead shielding might need to be used to reduce the external dose rate to acceptable
1845 levels.

1846 The following records need to be kept of all generator elutions:

- 1847 • dose calibrator setting where the isotope is manually dialled;
- 1848 • reading of long-lived reference source;
- 1849 • time of elution;
- 1850 • volume of eluate;
- 1851 • technetium-99m activity;
- 1852 • molybdenum-99 activity; and
- 1853 • radionuclidic purity.

1854 A molybdenum-99 breakthrough measurement should be performed on all elutions from
1855 each technetium-99m generator and where there is a breakthrough level of greater than
1856 1 MBq of molybdenum-99 per GBq of technetium-99m at the time of administration, the
1857 technetium-99m solution should not be used in the preparation of radiopharmaceuticals for
1858 patient use.

1859 **RECORD KEEPING**

1860 **Testing Records**

1861 Record keeping is a key component of a successful QA program and should at the very least
1862 include details of:

- 1863 • acceptance testing;
- 1864 • all constancy tests; and
- 1865 • radiopharmaceutical testing.

1866 Failures identified at acceptance or constancy testing and radiopharmaceutical testing, and
1867 the actions taken to remedy those failures should be documented and those records kept for
1868 the lifetime of the equipment.

1869 **Records of Receipt**

1870 Complete records of the radionuclide, activity, chemical form, supplier, supplier's batch
1871 number and purchase date need to be kept.

1872 On arrival, if a package containing radioactive material is suspected of being damaged, the
1873 package should be:

- 1874 • monitored for leakage with a wipe test; and
- 1875 • checked with a survey meter for unexpectedly high external radiation levels.

1876 If a package is damaged or suspected of being damaged, the supplier should be contacted
1877 immediately.

1878 All records need to be kept for two years.

1879 **Records of Dispensing**

1880 The preparation of radiopharmaceuticals needs to be performed in accordance with the
1881 requirements specified in the Radiation Management Plan. The preparation should be safe,
1882 straightforward and reliable.

1883 Records of each preparation should include the:

- 1884 • name of the radiopharmaceutical;
- 1885 • cold kit batch number;
- 1886 • date of manufacture;
- 1887 • batch number of final product;
- 1888 • radiochemical purity results; and
- 1889 • expiry date.

1890 A record detailing:

- 1891 • each patient dose dispensed and measured on a dose calibrator;
1892 • the name of the patient;
1893 • name of radiopharmaceutical;
1894 • measured radioactivity; and
1895 • time and date of measurement,

1896 also needs to be kept and an appropriate label attached to the dose holder for each
1897 preparation. The activity should not be made available for patient administration until all
1898 these steps described in above have been completed.

1899 All dispensing records should be kept for at least two years.

1900 **Records of Administration**

1901 The person administering a dose will need to keep records of the radiopharmaceutical
1902 activity administered to each patient and should be kept for a minimum of 3 years from the
1903 last radiopharmaceutical administration.

1904 **Annex D**

1905

1906 **Test Procedures for Dose Calibrators**

1907 **CONSTANCY**

1908 The following procedure may be used to meet the constancy requirement:

- 1909 1. Assay each reference source using the appropriate dose calibrator setting (i.e., use
1910 the caesium-137 setting to assay caesium-137).
- 1911 2. Measure background at the same setting, and subtract or confirm the proper
1912 operation of the automatic background subtract circuit if it is used.
- 1913 3. For each source used, either plot on graph paper or log in a book the background
1914 level for each setting checked and the net activity of each constancy source.
1915 Computer plotting programs may be used and are encouraged.
- 1916 4. Using one of the sources, repeat the above procedure for all commonly used
1917 radioisotope settings. Plot or log the results.
- 1918 5. Establish an action level or tolerance for each recorded measurement at which the
1919 individual performing the test will notify the chief technologist or nuclear
1920 medicine physicist of the suspected malfunction of the calibrator. These action
1921 levels should be written in the log book or posted on the calibrator. Repair or
1922 replacement is required if the error exceeds 10 percent.

1923 Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner
1924 is in place and that the instrument is zeroed according to the manufacturer's instructions.

1925 **LINEARITY**

1926 **Decay Method**

- 1927 1. Assay the technetium-99m syringe or vial in the dose calibrator, and subtract
1928 background to obtain the net activity in megabecquerels. Record the date, time to
1929 the nearest minute, and net activity on a linearity test form. This first assay
1930 should be performed in the morning at a fixed time, for example, 8 am.
- 1931 2. Repeat the assay at about noon, and again at about 4 pm. Continue on
1932 subsequent days until the assayed activity is less than 400 kilobecquerels. For
1933 dose calibrators on which the range is selected with a switch, select the range that
1934 would normally be used for the measurement.
- 1935 3. Convert the time and date information you recorded to hours elapsed since the
1936 first assay.
- 1937 4. On a sheet of semilog graph paper, label the logarithmic vertical axis in
1938 megabecquerels and label the linear horizontal axis in hours elapsed. At the top
1939 of the graph, note the date and the manufacturer, model number, and serial
1940 number of the dose calibrator. Then plot the data. Computer plotting programs
1941 may be used and are encouraged
- 1942 5. Draw a "best fit" straight line through the data points. For the point farthest from
1943 the line, calculate its deviation from the value on the line. $(A_{\text{observed}} - A_{\text{line}}) / A_{\text{line}} = \text{deviation}$.
1944
- 1945 6. If the worst deviation is more than +0.10, the dose calibrator should be repaired
1946 or adjusted. If this cannot be achieved, it will be necessary to make a correction
1947 table or graph that will allow the activity indicated by the dose calibrator to be
1948 converted to the "true activity."

1949 7. Attach a sticker on the dose calibrator that states when the next linearity test is
1950 due.

1951 **Shield Method**

1952 1. Begin the linearity test as described in the decay method described above. After
1953 making the first assay, the sleeves can be calibrated as follows. Steps 2 to 4 below
1954 need to be completed within 6 minutes.

1955 2. Perform sleeve method per manufacturer's instructions

1956 3. Complete the decay method linearity test steps 2 through 7 above.

1957 4. From the graph made in step 4 of the decay method, find the decay time
1958 associated with the activity indicated with sleeve 1 in place. This is the
1959 "equivalent decay time" for sleeve 1. Record that time with the data recorded in
1960 step 2.

1961 5. Find the decay time associated with the activity indicated with sleeve 2 in place.
1962 This is the "equivalent decay time" for sleeve 2. Record that time with the data
1963 recorded in step 2

1964 6. Continue for all sleeves.

1965 7. The table of sleeve numbers and equivalent decay times constitutes the
1966 calibration of the sleeve set.

1967 The sleeves may now be used to test dose calibrators for linearity.

1968 1. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background
1969 to obtain the net activity in megabecquerels. Record the net activity.

1970 2. Steps 3 through 5 below need to be completed within 6 minutes.

1971 3. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve
1972 number and indicated activity.

1973 4. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated
1974 activity.

1975 5. Continue for all sleeves.

1976 6. On a sheet of semilog graph paper, label the logarithmic vertical axis in
1977 megabecquerels, and label the linear horizontal axis in hours elapsed. At the top
1978 of the graph, note the date and the model number and serial number of the dose
1979 calibrator. Computer plotting programs may be used and are encouraged.

1980 7. Plot the data using the equivalent decay time associated with each sleeve.

1981 8. Draw a "best fit" straight line through the data points. For the point farthest from
1982 the line, calculate its deviation from the value on the line. $(A_{\text{observed}} - A_{\text{line}}) / A_{\text{line}} = \text{deviation}$.
1983

1984 9. If the worst deviation is more than +0.10, the dose calibrator should be repaired
1985 or adjusted. If this cannot be done, it will be necessary to make a correction table
1986 or graph that will allow you to convert from activity indicated by the dose
1987 calibrator to "true activity."

1988 10. Attach a sticker on the dose calibrator that states when the next linearity test is
1989 due.

1990 **ACCURACY**

1991 It is recommended that where technetium-99m, iodine-131, gallium-67 and thallium-201 are
1992 used within the practice that calibrated sources of these radionuclides be obtained from the

1993 Australian Nuclear Science and Technology Organisation (ANSTO), or by a supplier who has
1994 compared that source to a source that was calibrated by ANSTO.

1995 1. Assay a calibrated reference source at the appropriate setting (i.e., use the
1996 technetium-99m setting to assay technetium-99m), and then remove the source
1997 and measure background. Subtract background from the indicated activity to
1998 obtain the net activity. Record this measurement on a dose calibrator geometry
1999 and accuracy form. Repeat for a total of three determinations.

2000 2. Average the three determinations. The average value should be within 10 percent
2001 of the certified activity of the reference source, mathematically corrected for
2002 decay.

2003 3. Repeat the procedure for other calibrated reference sources.

2004 4. If the average value does not agree, within 10 percent, with the certified value of
2005 the reference source, the dose calibrator may need to be repaired or adjusted.
2006 The dose calibrator should be either repaired or replaced if the error exceeds 10
2007 percent, and not used until it meets this requirement. For those dose calibrators
2008 for which the calibration factor can be adjusted by the operator, this factor should
2009 be adjusted and steps 1 and 2 repeated to bring the dose calibrator back into
2010 calibration.

2011 5. At the same time that the accuracy test is performed, assay the source that will be
2012 used for the daily constancy test (it need not be a certified reference source) on all
2013 commonly used radioisotope settings. Record the settings and indicated activity
2014 (MBq) values with the accuracy data.

2015 6. Attach a sticker on the dose calibrator that states when the next accuracy test is
2016 due.

2017 **GEOMETRY INDEPENDENCE**

2018 1. In a small beaker or vial, mix 2 mL of a solution of technetium-99m with an
2019 activity concentration between 40 and 400 MBq/mL. Set out a second small
2020 beaker or vial with nonradioactive saline. You may also use tap water.

2021 2. Draw 0.5 mL of the technetium-99m solution into the syringe and assay it.
2022 Record the volume and megabecquerels indicated on the Dose Calibrator
2023 Geometry and Accuracy Form.

2024 3. Remove the syringe from the calibrator, draw an additional 0.5 mL of
2025 nonradioactive saline or tap water, and assay again. Record the volume and
2026 megabecquerels indicated.

2027 4. Repeat the process until you have assayed a 2.0-mL volume.

2028 5. Select as a standard the volume closest to that normally used for injections. For
2029 all the other volumes, divide the standard megabecquerels by the megabecquerels
2030 indicated for each volume. The quotient is a volume correction factor.
2031 Alternatively, you may graph the data and draw horizontal 10 percent error lines
2032 above and below the chosen "standard volume." Computer plotting programs
2033 may be used and are encouraged.

2034 6. If any correction factors are greater than 1.10 or less than 0.90, or if any data
2035 points lie outside the 10 percent error lines, it will be necessary to make a
2036 correction table or graph that will allow the conversion from "indicated activity"
2037 to "true activity." If this is necessary, label the table or graph "syringe geometry
2038 dependence," and note the date of the test and the model number and serial
2039 number of the calibrator.

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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 reassay 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.

2065 **Annex E**

2066

2067 **Survey Meters**

2068 **GENERAL REQUIREMENTS OF THE SURVEY METER**

2069 The radiation survey meter should:

- 2070 (a) have sufficient measurement range to measure ambient dose equivalent rates
2071 at least throughout the ranges of $0.5 \mu\text{Sv h}^{-1}$, or its equivalent, to 1 mSv h^{-1} , or
2072 its equivalent, for the radiations emitted from the radioactive sources used in
2073 nuclear medicine;
- 2074 (b) continue to indicate, either visibly or audibly, when radiation levels exceed the
2075 maximum reading in any measurement range; and
- 2076 (c) indicate the measured quantity with a measurement uncertainty not greater
2077 than ± 25 per cent inclusive of uncertainty due to response variation with
2078 energy over the range of energies of the radiation to be measured.

2079 **CALIBRATION OF THE SURVEY METER**

2080 Radiation survey meters should have an operational and calibration check:

- 2081 (a) prior to initial use;
- 2082 (b) at intervals not exceeding 12 months; and
- 2083 (c) following damage or repairs.

2084 **Annex F**

2085

2086 **Monitoring of ambient radiation and surface contamination**

2087 **AMBIENT DOSE RATE SURVEYS**

2088 **At the end of each working day:** all radiopharmaceutical elution, preparation, assay and
2089 administration areas (except patient treatment rooms which should be surveyed at
2090 the end of the therapy instead of on the day of administration).

2091 **Weekly:** all radionuclide use, storage and waste storage areas.

2092 **Monthly:** all laboratory areas where only small quantities (≤ 10 MBq) of gamma-emitting
2093 radioactive materials are used.

2094 **Ambient dose rate trigger levels:** if the levels listed below are exceeded the source of the
2095 increased dose rate should be identified and removed. If the dose rate can not be
2096 reduced the RSO or the Responsible Person, should be notified immediately.

2097 Unrestricted area: 0.5 $\mu\text{Sv/h}$

2098 Restricted area: 10 $\mu\text{Sv/h}$

2099 **CONTAMINATION SURVEYS**

2100 **At the end of each working day:** users and immediate work area where radioactive
2101 substances are used.

2102 **Weekly:** radiopharmaceutical elution, preparation, assay and administration areas,
2103 radionuclide storage areas and radionuclide waste storage areas.

2104 **Monthly:** all laboratory areas where only small quantities (≤ 10 MBq) of gamma-emitting
2105 radioactive material are used.

2106 There should be a written record of each survey. This record should:

- 2107
- 2108 • identify the work area;
 - 2109 • specify the date on which the survey was undertaken;
 - 2110 • indicate if radioactive contamination was detected;
 - 2111 • indicate if a high ambient dose rate was detected due to unattended sources;
 - 2112 • indicate what action(s) were taken to remove any contamination or unattended sources;
 - 2113 • indicate that the contamination or sources had been successfully removed;
 - 2114 and
 - 2115 • include the signature of the person undertaking the survey.

2116 When wipe tests indicate the presence of removable radioactive contamination, personnel or
2117 surfaces should be decontaminated until the activity is as low as reasonably achievable and
2118 below the limits recommended by the NHMRC (NHMRC 1995).

2119 **Annex G**

2120

2121 **Transport**

2122 **PACKAGE TYPE**

2123 The Transport Code specifies a classification of Excepted Packages. Packages in this
2124 classification are exempt from many of the stringent requirements which otherwise are
2125 required to be followed. If a package does not meet the Excepted Packages classification,
2126 then it is usually transported as Type A. For the Type A category, the package has to satisfy
2127 various performance tests such as drop and penetration tests to demonstrate an ability to
2128 withstand the normal conditions of transport. The advice of the institution's RSO, or the
2129 relevant regulatory authority, should be obtained if a Type A (or rarely, a higher category
2130 Type B package) has to be transported.

2131 **EXCEPTED PACKAGES**

2132 Excepted packages are required to meet the following criteria:

- 2133 • the activity does not exceed the limits listed for the radionuclides in Table 7 below;
- 2134 • the radiation level at any point on the external surface is not greater than 5 µSv/h;
- 2135 • the removable radioactive contamination on any external surface averaged over any
2136 area of 300 cm² of any part of the surface does not exceed 4 Bq/cm². If this value is
2137 exceeded, the package needs to be checked for damage and repackaged;
- 2138 • the package will retain its radioactive contents under routine conditions of transport;
- 2139 • the package bears the marking “**RADIOACTIVE**” on an internal surface in such a
2140 manner that a warning of the presence of radioactive material is visible on opening
2141 the package;
- 2142 • the transport document with each consignment gives the United Nations Number
2143 “**2910**”; and
- 2144 • All items are described as “**RADIOACTIVE MATERIAL, EXCEPTED**
2145 **PACKAGE**”, and include the proper shipping name of the substance or article being
2146 transported i.e.: “**LIMITED QUANTITY OF MATERIAL**”.

2147 If the package does not satisfy the activity and surface dose-rate limits, it will require a Type
2148 A (or B) classification.

2149 **TABLE 7. ACTIVITY LIMITS FOR EXCEPTED PACKAGES**

	Solids (MBq)	Liquids (MBq)		Solids (MBq)	Liquids (MBq)
Bromine-82	400	40	Phosphorus-33	1000	100
Carbon-14	3000	300	Samarium-153	600	60
Chromium-51	30000	3000	Selenium-75	3000	300
Cobalt-57	10000	1000	Sodium-22	500	50
Cobalt-58	1000	100	Sodium-24	200	20
Fluorine-18	600	60	Strontium-89	600	60
Gallium-67	3000	300	Strontium-90	300	30
Indium-111	3000	300	Sulphur-35	3000	300
Iodine-123	3000	300	technetium-99m	4000	400
Iodine-125	3000	300	Thallium-201	4000	400
Iodine-131	700	70	Tritium (H-3)	40000	4000
Iron-59	900	90	Xenon-133	10000	1000

Molybdenum-99	600	60	Yttrium-90	300	30
Phosphorus-32	500	50			

2150 Note: Contact the RSO for radionuclides not listed above, or for non-standard packages.

2151 **TYPE A PACKAGES**

2152 Type A packages fit the following criteria:

- 2153 • The activity does not exceed the limits listed for the radionuclides in Table 8 below.
- 2154 • The removable radioactive contamination on any external surface averaged over any
2155 area of 300 cm² of any part of the surface does not exceed 4 Bq/cm². If this value is
2156 exceeded, the package needs to be checked for damage and repackaged.

2157 **TABLE 8. ACTIVITY LIMITS FOR TYPE A PACKAGES**

	GBq		GBq
Bromine-82	400	Phosphorus-33	1000
Carbon-14	3000	Samarium-153	600
Chromium-51	30000	Selenium-75	3000
Cobalt-57	10000	Sodium-22	500
Cobalt-58	1000	Sodium-24	200
Fluorine-18	600	Strontium-89	600
Gallium-67	3000	Strontium-90	300
Indium-111	3000	Sulphur-35	3000
Iodine-123	3000	technetium-99m	4000
Iodine-125	3000	Thallium-201	4000
Iodine-131	700	Tritium (H-3)	40000
Iron-59	900	Xenon-133	10000
Molybdenum-99	600	Yttrium-90	300
Phosphorus-32	500		

2158 Note: Contact the RSO for radionuclides not listed above, for non-standard packages, and for activities greater
2159 than can be transported in Type A packages.

2160 **Category Labels**

2161 Type A packages have category labels attached to two opposite sides. The label to be used
2162 depends on the radiation dose rate at the surface and the transport index. The transport
2163 index is the maximum radiation dose rate at any point 1 metre from the surface of the
2164 package in µSv/h, divided by 10 and then rounded up to one decimal place. For example a
2165 package with a radiation reading of 4.3 µSv/h at one metre will have a transport index of 0.5
2166 (i.e. 4.3 ÷ 10 = 0.43 rounded up to 0.5). The criteria for labelling the packages are outlined
2167 in Table 9 below.

2168 **TABLE 9. LABEL CATEGORIES FOR PACKAGES**

Conditions		
<i>Transport index</i>	Maximum radiation level at any point on external surface	Category
0 ^a	Not more than 5 µSv/h	I-WHITE
More than 0 but not more than 1	More than 5 µSv/h but not more than 500 µSv/h	II-YELLOW
More than 1 but not more than 10	More than 500 µSv/h but not more than 2000 µSv/h	III-YELLOW

2182 ^a If the measured transport index is not greater than 0.05, the value quoted may be zero.
2183

2184
2185 **Note:** both the *transport index* and the surface *radiation level* conditions are taken into account in determining
2186 the appropriate category. Where the *transport index* satisfies the condition for one category but the surface
2187 *radiation level* satisfies the condition for a different category, the *package* will be assigned to the higher category.

2188 The category labels will need to indicate the radionuclide, its activity in becquerel units and,
2189 for category II and III, the Transport Index (consult ARPANSA Code of Practice – Safe
2190 Transport of Radioactive Material, RPS 2, (ARPANSA 2001) for further details).

2191 **Segregation from Other Dangerous Goods**

2192 The Transport Code and the Australian Dangerous Goods Code require segregation of
2193 radioactive material from some other dangerous goods. Under the Australian Dangerous
2194 Goods Code, radioactive materials are not to be carried on the same vehicle as any dangerous
2195 goods listed in Table 10.

2196 **TABLE 10: Items NOT PERMITTED to be Transported with Radioactive**
2197 **Materials**
2198

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	Oxidizing Agents
5.2	Organic Peroxide
8	Corrosive

2199 Foodstuffs should not be carried on the same vehicle as radioactive material.

2200 The following classes of dangerous goods may be carried on the same vehicle carrying
2201 radioactive materials:

- 2202 • Non-flammable non-toxic gases.
- 2203 • Poisonous gases.
- 2204 • Poisonous (toxic) substances.
- 2205 • Miscellaneous dangerous goods.

2206 **Documentation**

2207 The consignor needs to complete the following documents prior to commencement of the
2208 transport of the radioactive material:

- 2209 • Consignor's Certificate (Dangerous Goods Declaration Form). (An example form is
2210 given on the ARPANSA website at
2211 http://www.arpansa.gov.au/pubs/rps/cons_dec.pdf).

- 2212 • A minimum of two copies is required. One is for the driver and one, enclosed in a
2213 stout envelope, is to be firmly fixed to the outside of the package for inspection in
2214 transit. Where more than one driver is involved, it may be necessary for each driver
2215 to receive a copy of the Consignor's Certificate.

2216 **Information for drivers – a document which provides:**

- 2217 • any supplementary operational requirements for loading, transport, storage (away
2218 from persons, dangerous goods, etc.); and
2219 • emergency arrangements specific for the package.

2220 **Instructions to the Person Organising Transport**

2221 The person organizing the transport should comply with the following:

- 2222 • taxis, motorcycles, or public transport are not used to transport radioactive material;
2223 • the institution's transport vehicle may be used to transport the package provided the
2224 driver has been instructed in how to handle and secure the package in the vehicle and
2225 in the actions to be taken in case of an accident or an emergency. Written
2226 instructions also need to be provided (see the kit at the end of this Annex);
2227 • when the delivery is urgent, private cars may be used (insurance provisions may
2228 apply). A person who is conversant with the hazards involved and with handling
2229 emergency situations, and preferably authorised to use the radioactive material being
2230 transported, will either drive the vehicle transporting the material, or will accompany
2231 the driver; and
2232 • the package needs to be addressed and delivered to a specific authorised person. It
2233 should not be addressed generally to a “Department”, nor delivered to a specified
2234 “area” or to the “front desk”. It should be transferred to the custody of an authorised
2235 person or left at a secured location.

2236 **Packaging Procedure**

2237 A written procedure for the packaging of the radioactive material should be developed along
2238 the following lines:

- 2239 • Package appropriately:
- 2240 – contain liquids in a sealed vial with appropriate labelling including:
 - 2241 • the approved name of the radiopharmaceutical;
 - 2242 • the (quantitative) composition;
 - 2243 • (for liquid radiopharmaceuticals) the total radioactivity (in SI units) or the
2244 radioactive concentration per mL at a stated date and time and the
2245 volume; or (for capsules) the radioactivity of each capsule (in SI units) at a
2246 stated date and time and the number of capsules in the container;
 - 2247 • the route of administration;
 - 2248 • (for radiopharmaceuticals to be administered parentally) the name and
2249 concentration of any antimicrobial preservatives;
 - 2250 • the manufacturer's name;
 - 2251 • the batch number; and
 - 2252 • the expiry date and time.
 - 2253 – place the vial or other source in a shielded (lead etc) container with sufficient
2254 liquid absorber. Label the container “RADIOACTIVE” and give the name and

- 2255 activity of the compound, and the date. Close the container with a tight fitting
2256 lid, and tape;
- 2257 – place this sealed container inside an outer transport box with cushioning
2258 material to prevent movement within the box and seal the transport box.
- 2259 • Measure and record the surface dose rate. Check that there is no contamination on
2260 the outer surface.
- 2261 • Determine whether the package is classified as an Excepted Package, or Type A.
- 2262 • Fill out a “Dangerous Goods Declaration Form” and attach to the package.
- 2263 • Label the package with:
- 2264 – the name and address of addressee,
- 2265 – the sender's name and address,
- 2266 – appropriate category label if Type A.
- 2267 • Give the package and the transport kit (detailing transport instructions) to the driver.
2268

2269 **Radioactive Material Transport Kit**

2270 The following is an example of a kit to be provided to the driver of a vehicle transporting
2271 radioactive materials.

2272 **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 or
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)

2273
2274

2275 **Page 2**

2276 **INSTRUCTIONS FOR THE DRIVER**

2277 All drivers carrying labelled packages of radioactive materials should:

- 2278 • Check that a Radioactive Goods (consignment) form is attached to each package and
2279 that it has been completed with details of each radioactive material being delivered,
2280 destination and name of the addressee.
- 2281 • Ensure that there are three placard signs in this kit. Attach one placard on each side
2282 of the vehicle and one on the rear of the vehicle.
- 2283 • Secure transport packages either:
 - 2284 – in the boot of a car; or
 - 2285 – away from the driver of a van or station wagon, and
 - 2286 – segregated as per *Australian Dangerous Goods Code* from other incompatible
2287 Dangerous Goods.
- 2288 • Carry these instructions in the vehicle in the document holder.
- 2289 • Carry a mobile phone to be used in the event of an accident.
- 2290 • Deliver the appropriate package together with its consignment form, to the addressee
2291 or their agent.
- 2292 • At the last destination, remove the three yellow transport placards from the outside
2293 of the vehicle and replace them in this kit. It is illegal to display Dangerous Goods
2294 signs if Dangerous Goods are not in or on the vehicle.
- 2295 • Ensure that passengers are not travelling in the vehicle at the same time as packages
2296 containing radioactive material. However, an authorised person responsible for the
2297 radioactive material being carried may travel in the vehicle, or if two or more people
2298 are required for radionuclide procedures off site, they may all travel in the same
2299 vehicle.
- 2300 • The vehicle needs to be left in a secured state when packages containing radioactive
2301 substances remain in the vehicle.

2302 **Page 3**

2303 **TRANSPORT ACCIDENTS**

2304 In the event of an accident, **DON'T PANIC**. The packaging complies with international
2305 standard requirements and is designed to withstand accidents. If the package is not severely
2306 damaged, the radioactive material is unlikely to be damaged, and its container is unlikely to
2307 leak. It is therefore important to **attend first to the needs of any injured persons**.

2308 If a road vehicle transporting radioactive materials is involved in an accident that results in a
2309 dangerous situation (injury, road hazard, escape/leakage of materials, fire, vehicle
2310 immobilised, etc), the driver of the vehicle needs to:

- 2311 • notify Emergency Services “000”;
- 2312 • notify the institute’s RSO and/or the responsible head of department; and
- 2313 • provide assistance to Emergency Services, or the responsible authority officer in
2314 charge.

2315 In addition to the above:

- 2316 • If possible, get out of vehicle and assess the injury status of others involved in the
2317 accident.
 - 2318 • Provide assistance if it is safe to do so. If in doubt leave it to emergency services.
 - 2319 • Assess the integrity of the radioactive packages, with minimal contact (or exposure).
 - 2320 • With the results of the assessment in mind it may be necessary to complete the above
2321 actions of notification.
 - 2322 • If possible, gain the assistance of passers-by to keep onlookers and other traffic at a
2323 safe distance.
 - 2324 • Inform Emergency Services of any environmental or human hazards (fire, spill, etc).
 - 2325 • Wait for and assist Emergency Services.
- 2326 If the packages are undamaged and the damage sustained by the vehicle does not have to be
2327 reported to the police, and if the vehicle can still be safely driven, deliver the package(s) to
2328 the addressee(s), and inform them that the vehicle was involved in a minor accident on the
2329 way. Give a detailed report to the RSO(s).

2330 **Annex H**

2331

2332 **Health Effects of Ionizing Radiation and Standards for Control** 2333 **of Exposure**

2334 It is well known that high doses of ionizing radiation can cause harm, but there is continuing
2335 scientific uncertainty about effects at low doses. At levels of dose routinely encountered by
2336 members of the public and most present-day radiation workers, there is little or no
2337 epidemiological evidence of health effects. Radiation protection standards recognize that it
2338 is not possible to eliminate all radiation exposure, but they do provide for a system of control
2339 to avoid unnecessary exposure and to keep doses in the low dose range.

2340 Extreme doses of radiation to the whole body (around 10 sievert* and above), received in a
2341 short period, cause so much damage to internal organs and tissues of the body that vital
2342 systems cease to function and death may result within days or weeks. Very high doses
2343 (between about 1 sievert and 10 sievert), received in a short period, kill large numbers of
2344 cells, which can impair the function of vital organs and systems. Acute health effects, such as
2345 nausea, vomiting, skin and deep tissue burns, and impairment of the body's ability to fight
2346 infection may result within hours, days or weeks. The extent of the damage increases with
2347 dose. However, '**deterministic**' effects such as these are not observed at doses below
2348 certain thresholds. By limiting doses to levels below the thresholds, deterministic effects can
2349 be prevented entirely.

2350 Doses below the thresholds for deterministic effects may cause cellular damage, but this does
2351 not necessarily lead to harm to the individual: the effects are probabilistic or 'stochastic' in
2352 nature. It is known that doses above about 100 mSv, received in a short period, lead to an
2353 increased risk of developing cancer later in life. There is good epidemiological evidence –
2354 especially from studies of the survivors of the atomic bombings - that, for several types of
2355 cancer, the risk increases roughly linearly with dose, and that the risk factor averaged over all
2356 ages and cancer types is about 1 in 100 for every 100 mSv of dose (i.e. 1 in 10,000 per mSv).

2357 At doses below about 100 mSv, the evidence of harm is not clear-cut. While some studies
2358 indicate evidence of radiation-induced effects, epidemiological research has been unable to
2359 establish unequivocally that there are effects of statistical significance at doses below a few
2360 tens of millisieverts. Nevertheless, given that no threshold for stochastic effects has been
2361 demonstrated, and in order to be cautious in establishing health standards, the
2362 proportionality between risk and dose observed at higher doses is presumed to continue
2363 through all lower levels of dose to zero. This is called the linear, no-threshold (LNT)
2364 hypothesis and it is made for radiation protection purposes only.

2365 There is evidence that a dose accumulated over a long period carries less risk than the same
2366 dose received over a short period. Except for accidents and medical exposures, doses are not
2367 normally received over short periods, so that it is appropriate in determining standards for
2368 the control of exposure to use a risk factor that takes this into account. While not well
2369 quantified, a reduction of the high-dose risk factor by a factor of two has been adopted
2370 internationally, so that for radiation protection purposes the risk of radiation-induced fatal
2371 cancer (the risk factor) is taken to be about 1 in 20,000 per mSv of dose for the population as
2372 a whole.

2373 If the LNT hypothesis is correct, any dose carries some risk. Therefore, measures for control
2374 of exposure for stochastic effects seek to avoid all reasonably avoidable risk. This is called

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

2375 optimising protection. However, risk in this sense may often be assessed in terms of risk to a
 2376 population, and may not ensure sufficient protection of the individual. Consequently, the
 2377 optimisation approach is underpinned by applying dose limits that restrict the risk to
 2378 individuals to an acceptable level. The fundamental regulatory philosophy is expressed in
 2379 three principles, based on the recommendations of the International Commission on
 2380 Radiological Protection (ICRP), which may be summarized as follows:

2381 *Justification:* human activities that cause exposure to radiation may be permitted only if
 2382 they do more good than harm;

2383 *Optimisation of protection:* exposure to radiation from justified activities should be kept
 2384 as low as reasonably achievable, social and economic factors being taken into account;
 2385 and

2386 *Limitation of individual dose:* doses must not exceed the prescribed dose limits.

2387 Determining what is an acceptable risk for regulatory purposes is a complex value
 2388 judgement. The ICRP reviewed a number of factors in developing its recommendations,
 2389 which have in general been internationally endorsed, including by the World Health
 2390 Organization, the International Labour Organisation and the International Atomic Energy
 2391 Agency. Australia's Radiation Health Committee, now established under the ARPANS Act[†],
 2392 has recommended that the international standards be adopted in Australia. The
 2393 recommended dose limits are summarized as follows:

2394 **Limit on effective dose***

	For occupational exposure	For members of the public
2395 To limit individual risk	20 mSv per year, 2396 averaged over 5 years*	1 mSv in a year*

2399 *for details, see ARPANSA's *Recommendations for limiting exposure to ionizing radiation (2002)*

2400 In most situations, the requirements for limiting individual risk ensure that doses are below
 2401 deterministic thresholds, but for cases where this does not apply, the recommended limits
 2402 are as follows:

2403 **Annual limit on equivalent dose***

	For occupational exposure	For members of the public
2404 To prevent deterministic effects		
2405 in the lens of the eye	150 mSv	15 mSv
2406 in the skin	500 mSv	50 mSv
2407 in the hands and feet	500 mSv	—

2410 *for details, see ARPANSA's *Recommendations for limiting exposure to ionizing radiation (2002)*

2411 In the case of occupational exposure during pregnancy, the general principle is that the
 2412 embryo or fetus should be afforded the same level of protection as is required for a member
 2413 of the public. For medical workers, the ICRP recommends that there should be a reasonable
 2414 assurance that fetal dose can be kept below 1 mGy[‡] during the course of the pregnancy. This

[†] The Australian Radiation Protection and Nuclear Safety Act (1998)

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

2415 guidance may be generalised to cover all occupationally exposed pregnant workers by
2416 keeping the fetal dose below 1 mSv. A full explanation of radiation protection principles and
2417 of the recommended standards for Australia is given in ARPANSA/NOHSC Radiation
2418 Protection Series No. 1: *Recommendations for limiting exposure to ionizing radiation*
2419 *(1995)* and *National standard for limiting occupational exposure to ionizing radiation*
2420 *(both republished in 2002)*.

2421

2422 **Annex I**

2423 **Radiation Protection Authorities**

2425 Where advice or assistance is required from the relevant radiation protection authority, it
 2426 may be obtained from the following officers:

COMMONWEALTH, STATE / TERRITORY	CONTACT
Commonwealth	Director, Regulatory Branch ARPANSA PO Box 655 Miranda NSW 1490 Email: info@arpansa.gov.au Tel: (02) 95418333 Fax: (02) 9541 8348
Australian Capital Territory	Manager Radiation Safety Radiation Safety Section ACT Health Locked Bag 5 Weston Creek ACT 2611 Email: radiation.safety@act.gov.au Tel: (02) 6207 6946 Fax: (02) 6207 6966
New South Wales	Director Radiation Control Department of Environment and Conservation PO Box A290 Sydney South NSW 1232 Email: radiation@environment.nsw.gov.au Tel: (02) 9995 5000 Fax: (02) 9995 6603
Northern Territory	Manager Radiation Protection Radiation Protection Section Department of Health and Community Services (DHCS) GPO Box 40596 Casuarina NT 0811 Email: envirohealth@nt.gov.au Tel: (08) 8922 7152 Fax: (08) 8922 7334
Queensland	Director, Radiation Health Department of Health 450 Gregory Terrace Fortitude Valley QLD 4006 Email: radiation_health@health.qld.gov.au Tel: (07) 3406 8000 Fax: (07) 3406 8030
South Australia	Director Radiation Protection Division Environment Protection Authority PO Box 721 Kent Town SA 5071 Email: radiationprotection@state.sa.gov.au Tel: (08) 8130 0700 Fax: (08) 8130 0777
Tasmania	Senior Health Physicist Health Physics Branch Department of Health & Human Services GPO Box 125B Hobart TAS 7001 Email: health.physics@dhhs.tas.gov.au Tel: (03) 6222 7256 Fax: (03) 6222 7257
Victoria	Manager, Radiation Safety Program Department of Human Services GPO Box 4057 Melbourne VIC 3001 Email: radiation.safety@dhs.vic.gov.au Tel: (03) 9637 4167 Fax: (03) 9637 4508
Western Australia	Secretary Radiological Council Locked Bag 2006 Nedlands WA 6009 Email: radiation.health@health.wa.gov.au Tel: (08) 9346 2260 Fax: (08) 9381 1423

2427 **Please note:** This table was correct at the time of printing but is subject to change from time
 2428 to time. For the most up-to-date list, the reader is advised to consult the ARPANSA web site.

2429 For after hours emergencies only, the police will provide the appropriate emergency contact
 2430 number.

2431 **Annex J**

2432

2433 **ARPANSA Radiation Protection Series Publications**

2434 ARPANSA has taken over responsibility for the administration of the former NHMRC
2435 Radiation Health Series of publications and for the codes developed under the *Environment*
2436 *Protection (Nuclear Codes) Act 1978*. The publications are being progressively reviewed and
2437 republished as part of the *Radiation Protection Series*. Current publications in the
2438 *Radiation Protection Series* are:

2439 RPS 1. Recommendations for Limiting Exposure to Ionizing Radiation (1995) and
2440 National Standard for Limiting Occupational Exposure to Ionizing Radiation
2441 (republished 2002)

2442 RPS 2. Code of Practice for the Safe Transport of Radioactive Material (2001)

2443 RPS 3. Radiation Protection Standard for Maximum Exposure Levels to Radiofrequency
2444 Fields – 3 kHz to 300 GHz (2002)

2445 RPS 4. Recommendations for the Discharge of Patients Undergoing Treatment with
2446 Radioactive Substances (2002)

2447 RPS 5. Code of Practice and Safety Guide for Portable Density/Moisture Gauges
2448 Containing Radioactive Sources (2004)

2449 RPS 6. National Directory for Radiation Protection, Edition 1.0 (2004)

2450 RPS 7. Recommendations for Intervention in Emergency Situations Involving Radiation
2451 Exposure (2004)

2452 RPS 8. Code of Practice for the Exposure of Humans to Ionizing Radiation for Research
2453 Purposes (2005)

2454 RPS 10. Code of Practice and Safety Guide for Radiation Protection in Dentistry (2005)

2455 RPS 11. Code of Practice for the Security of Radioactive Sources (2007)

2456 RPS 12. Radiation Protection Standard for Occupational Exposure to Ultraviolet Radiation
2457 (2006)

2458 RPS 13. Code of Practice and Safety Guide for Safe Use of Fixed Radiation Gauges (2007)

2459

2460 Those publications from the NHMRC Radiation Health Series and the Environment
2461 Protection (Nuclear Codes) Act Series that are still current are:

2462

2463 **RADIATION HEALTH SERIES**

2464 RHS 2. Code of practice for the design of laboratories using radioactive substances for
2465 medical purposes (1980)

2466 RHS 3. Code of practice for the safe use of ionizing radiation in veterinary radiology: Parts
2467 1 and 2 (1982)

2468 RHS 8. Code of nursing practice for staff exposed to ionizing radiation (1984)

2469 RHS 9. Code of practice for protection against ionizing radiation emitted from X-ray
2470 analysis equipment (1984)

2471 RHS 10. Code of practice for safe use of ionizing radiation in veterinary radiology: part
2472 3-radiotherapy (1984)

- 2473 RHS 12. Administration of ionizing radiation to human subjects in medical research (1984)
- 2474 RHS 13. Code of practice for the disposal of radioactive wastes by the user (1985)
- 2475 RHS 14. Recommendations for minimising radiological hazards to patients (1985)
- 2476 RHS 15. Code of practice for the safe use of microwave diathermy units (1985)
- 2477 RHS 16. Code of practice for the safe use of short wave (radiofrequency) diathermy units
2478 (1985)
- 2479 RHS 18. Code of practice for the safe handling of corpses containing radioactive materials
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- 2481 RHS 19. Code of practice for the safe use of ionizing radiation in secondary schools (1986)
- 2482 RHS 21. Revised statement on cabinet X-ray equipment for examination of letters,
2483 packages, baggage, freight and other articles for security, quality control and other
2484 purposes (1987)
- 2485 RHS 22. Statement on enclosed X-ray equipment for special applications (1987)
- 2486 RHS 23. Code of practice for the control and safe handling of radioactive sources used for
2487 therapeutic purposes (1988)
- 2488 RHS 24. Code of practice for the design and safe operation of non-medical irradiation
2489 facilities (1988)
- 2490 RHS 25. Recommendations for ionization chamber smoke detectors for commercial and
2491 industrial fire protection systems (1988)
- 2492 RHS 28. Code of practice for the safe use of sealed radioactive sources in bore-hole logging
2493 (1989)
- 2494 RHS 30. Interim guidelines on limits of exposure to 50/60Hz electric and magnetic fields
2495 (1989)
- 2496 RHS 31. Code of practice for the safe use of industrial radiography equipment (1989)
- 2497 RHS 32. Intervention in emergency situations involving radiation exposure (1990)
- 2498 RHS 34. Safety guidelines for magnetic resonance diagnostic facilities (1991)
- 2499 RHS 35. Code of practice for the near-surface disposal of radioactive waste in Australia
2500 (1992)
- 2501 RHS 36. Code of practice for the safe use of lasers in schools (1995)
- 2502 RHS 37. Code of practice for the safe use of lasers in the entertainment industry (1995)
- 2503 RHS 38. Recommended limits on radioactive contamination on surfaces in laboratories
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2524 Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes
2525 (2005), Radiation Protection Series No. 8, ARPANSA, Yallambie.
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2528 Practice and Safety Guide for Radiation Protection in Dentistry, Radiation Protection
2529 Series No. 10.
- 2530 ARPANSA 200x, Australian Radiation Protection and Nuclear Safety Agency 200x, Code of
2531 Practice for the Safe Use of Radiation in Veterinary Science, Radiation Protection
2532 Series No. x.
- 2533 ARPANSA 200y, Australian Radiation Protection and Nuclear Safety Agency 200y, Safety
2534 Guide for Radiation Protection in Diagnostic and Interventional Radiology, Radiation
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2605 **Glossary**

2606 **Absorbed dose**

2607 the energy absorbed per unit mass by matter from ionizing radiation which impinges upon it.

2608 Absorbed dose, *D*, is defined by the expression:

$$2609 \quad D = \frac{dE}{dm}$$

2610 where *dE* is the mean energy imparted by ionizing radiation to matter of mass *dm*.

2611 The unit of absorbed dose is joule per kilogram (J kg⁻¹), with the special name gray (Gy).

2612 **Accuracy**

2613 for a given calibrated reference source, that the indicated activity (in bequerel) is equal to
2614 the activity value determined by the Australian Nuclear Science and Technology
2615 Organisation (ANSTO, possessor of the primary and secondary standard for Australia) or by
2616 a supplier who has compared that source to a source that was calibrated by ANSTO.

2617 **Administering person**

2618 a person who has been authorized to administer radiopharmaceuticals. This person will
2619 normally be a nuclear medicine technologist or a nuclear medicine specialist.

2620 **ALARA**

2621 A principle of radiation protection philosophy that requires that exposures to ionizing
2622 radiation should be kept as low as reasonably achievable, economic and social factors being
2623 taken into account. The ALARA principle is equivalent to the principle of optimisation
2624 defined by the ICRP, which states that protection from radiation exposure is optimum when
2625 the expenditure of further resources would be unwarranted by the reduction in exposure that
2626 would be achieved.

2627 **Approved**

2628 when applied to a plan or proposal, one which has received approval from the appropriate
2629 authority.

2630 **Carer**

2631 a person who voluntarily, willingly and knowingly assists or helps in the care, support or
2632 comfort of patients undergoing a diagnostic or therapeutic medical radiation procedure.

2633 **Constancy**

2634 reproducibility in measuring a constant source over a long period of time.

2635 **Constraint**

2636 either **dose constraint** in the case of exposures anticipated to be received, or **risk**
2637 **constraint** in the case of potential exposures (see **dose constraint** and **risk constraint**).

2638 **Deterministic effect**

2639 an effect, such as partial loss of function of an organ or tissue, caused by radiation and
2640 manifest only above some threshold of dose, the severity of the effect depending upon the
2641 dose received.

2642 **Detriment**

2643 a measure, or measures, of harm caused by exposure to radiation and usually taken to mean
2644 health detriment; it has no single definition, but can be taken to be an attribute or a
2645 collection of attributes which measure harm, such as attributable probability of death and
2646 reduction of life expectancy.

2647 **Diagnostic reference level (DRL) for medical exposure**

2648 dose levels for medical exposures in medical radiodiagnostic practices or levels of activity in
2649 the case of radiopharmaceuticals applied to groups of standard-sized patients or standard
2650 phantoms for common types of diagnostic examination and broadly defined types of
2651 equipment. These levels are expected not to be exceeded for standard procedures when good
2652 and normal practice regarding diagnostic and technical performance is applied. DRLs will
2653 be set by relevant professional bodies and published by ARPANSA or the relevant regulatory
2654 authority from time to time.

2655 **Dose**

2656 a generic term which may mean absorbed dose, equivalent dose or effective dose depending
2657 on context.

2658 **Dose constraint**

2659 a prospective restriction on anticipated dose, primarily intended to be used to discard
2660 undesirable options in an optimisation calculation.

2661 In occupational exposure, a dose constraint may be used to restrict the options considered in
2662 the design of the working environment for a particular category of employee.

2663 In medical exposure, a dose constraint for volunteers in medical research may be used to
2664 restrict the options considered in the design of an experimental protocol.

2665 In public exposure, a dose constraint may be used to restrict the exposure of the critical
2666 group from a particular source of radiation.

2667 **Effective dose**

2668 a measure of dose which takes into account both the type of radiation involved and the
2669 radiological sensitivities of the organs and tissues irradiated.

2670 Effective dose, E , is the sum of weighted equivalent doses in all organs and tissues of the
2671 body. It is given by the expression:

2672
$$E = \sum_T w_T H_T$$

2673 where H_T is the equivalent dose in organ or tissue T and
2674 w_T is the tissue weighting factor for that organ or tissue.

2675 The unit of effective dose is J kg^{-1} , with the special name sievert (Sv).

2676 **Equivalent dose**

2677 a measure of dose in organs and tissues which takes into account the type of radiation
2678 involved.

2679 Equivalent dose, H , is a weighted dose in an organ or tissue, with the radiation weighting
2680 factor(s) determined by the type and energy of the radiation to which the organ or tissue is
2681 exposed. The equivalent dose H_T in organ or tissue T is given by the expression:

2682
$$H_T = \sum_R w_R D_{T,R}$$

2683 where $D_{T,R}$ is the absorbed dose averaged over the organ or tissue T due to radiation
2684 R and
2685 w_R is the radiation weighting factor for that radiation.

2686 The unit of equivalent dose is the same as for absorbed dose, J kg^{-1} , with the special name

2687 **Exposure**

2688 either: the circumstance of being exposed to radiation,
2689 or: a defined dosimetric quantity now no longer used for radiation protection
2690 purposes.

2691 (The context in which the word is used should avoid ambiguity.)

2692 **Geometry independence**

2693 geometry independence means that the indicated activity does not change with volume or
2694 configuration.

2695 **Hot cell**

2696 a heavily shielded enclosure that may be used for handling or processing highly radioactive
2697 materials by remote means through lead-glass windows so that the radiation hazard to
2698 personnel is minimised.

2699 **Ionizing radiation**

2700 radiation which is capable of causing ionization, either directly (for example: for radiation in
2701 the form of gamma rays and charged particles) or, indirectly (for example: for radiation in
2702 the form of neutrons).

2703 **Justification**

2704 the notion that human activities which lead to exposure to radiation should be justified,
2705 before they are permitted to take place, by showing that they are likely to do more good than
2706 harm.

2707 **Linearity**

2708 the ability of the dose calibrator to measure the correct activity over the range of use of that
2709 calibrator.

2710 **Maladministration***

2711 mistaken administration of a radiopharmaceutical to a patient "... the radiopharmaceutical
2712 or its amount or route of administration was inappropriate....."

2713 e.g (i) incorrect radiopharmaceutical is administered

2714 (ii) radiopharmaceutical administered to the wrong patient

2715 (iii) misinterpretation of the request form

2716 (iv) dispensing/reconstituting incorrect radiopharmaceutical or dose.

2717 * refer to Williams ED and Harding LK, "Radiopharmaceutical maladministration: What
2718 action is required?", *Nuclear Medicine Communications* 1995, **16**:721-723.

2719 **Medical exposure**

2720 exposure of a person to radiation received as a patient undergoing medical diagnosis or
2721 therapy, or as a volunteer in medical research, or non-occupational exposure received as a
2722 consequence of assisting an exposed patient.

2723 **Nuclear medicine physicist**

2724 For the purpose of this Safety Guide, is a person who is qualified to perform the necessary
2725 dosimetric calculations, measurements and monitoring. A suitable person will:

2726 (a) be on the Register of Nuclear Medicine Physicists held by the Australasian
2727 College of Physical Scientists and Engineers in Medicine; or

2728 (b) have an equivalent level of training, skills, knowledge and expertise to a
2729 person listed on the Australasian College of Physical Scientists and Engineers
2730 in Medicine Register of Nuclear Medicine Physicists as determined by the
2731 relevant regulatory authority.

2732 **Nuclear medicine specialist**

2733 a specialist who has appropriate specialist recognition in Nuclear Medicine and

2734 (i) is eligible for approval by the Joint Specialist Advisory Committee in Nuclear
2735 Medicine RACP-RANZCR; and

2736 (ii) holds an authorization for the use of unsealed sources for diagnostic and
2737 therapeutic nuclear medicine in the relevant jurisdiction.

2738 **Nuclear medicine technologist**

2739 a person who has obtained a Bachelor of Applied Science in Medical Radiation Science
2740 (NMT) or its equivalent, in a course recognised by the Accreditation Board of the Australian
2741 and New Zealand Society of Nuclear Medicine and is eligible for accreditation by the Board
2742 and registration/licensing by the appropriate State Authority.

2743 **Occupational exposure**

2744 exposure of a person to radiation which occurs in the course of that person's work and which
2745 is not excluded exposure².

2746 **Optimisation**

2747 the process of maximising the net benefit arising from human activities which lead to
2748 exposure to radiation.

2749 **Practice**

2750 a type of human activity; in a radiological context, a human activity which may result in
2751 exposure to ionizing radiation and to which a system of radiation protection applies.

2752 **Public exposure**

2753 exposure of a person, or persons, to radiation which is neither occupational nor medical
2754 exposure.

2755 **Qualified expert**

2756 a person who:

2757 (a) is qualified in the application of the physics of therapeutic or diagnostic uses of
2758 ionizing radiation; and

2759 (b) has been recognised by the relevant regulatory authority as being able to perform
2760 the dosimetric calculations, radiation measurements and monitoring relevant to
2761 the person's area of expertise³.

2762 **Radiation incident**

2763 any unintended or ill-advised event when using ionizing radiation apparatus, specified types
2764 of non-ionizing radiation apparatus or radioactive substances, which results in, or has the
2765 potential to result in, an exposure to radiation to any person or the environment, outside the
2766 range of that normally expected for a particular practice, including events resulting from
2767 operator error, equipment failure, or the failure of management systems that warranted
2768 investigation.

2769 **Radioactive material**

2770 material which spontaneously emits ionizing radiation as a consequence of radioactive
2771 decay.

2772 **Radiochemist**

2773 a scientist with experience in the practice of radiopharmacy who provides a radiopharmacy
2774 service to Nuclear Medicine.

² Excluded exposure means the component of exposure that arises from natural background radiation.

³ Competency requirements for a qualified expert will be listed in future editions of the *National Directory for Radiation Protection*.

2775 **Radiopharmacist**

2776 a State pharmacy board registered pharmacist with experience in the practice of
2777 radiopharmacy who provides a radiopharmacy service to Nuclear Medicine.

2778 **Referrer**

2779 a registered medical practitioner, dentist or other health professional who is entitled to refer
2780 individuals to the medical practitioner (radiation) who will be responsible for the overall
2781 conduct of the procedure involving the exposure of the patient to ionizing radiation.

2782 **Relevant regulatory authority**

2783 the radiation protection authority or authorities designated, or otherwise recognized, for
2784 regulatory purposes in connection with protection and safety relating to medical applications
2785 of ionizing radiation.

2786 **Responsible Person**

2787 in relation to any radioactive source, radiation-producing equipment, prescribed radiation
2788 facility or premises on which radioactive sources are stored or used means the legal person⁴:

2789 (a) having overall management responsibility including responsibility for the security
2790 and maintenance of the source, radiation-producing equipment, facility or
2791 premises;

2792 (b) having overall control over who may use the source, radiation-producing
2793 equipment, facility or premises; and

2794 (c) in whose name the source, radiation-producing equipment, facility or premises
2795 would be registered if this is required.

2796 **Risk constraint**

2797 a restriction applied to potential exposure (see dose constraint).

2798 **Stochastic effect**

2799 an effect known to occur sometimes as a consequence of exposure to radiation, but which
2800 may or may not be expressed in a particular exposed person, the likelihood of the effect
2801 occurring being a function of the dose received.

2802 **Supervised area**

2803 an area in which working conditions are kept under review but in which special procedures
2804 to control exposure to radiation are not normally necessary.

⁴ 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.

2805 **Contributors to Drafting and Review**

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2827 Acknowledgement

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