



Australian Government

Australian Radiation Protection and Nuclear Safety Agency

CODE OF PRACTICE

Radiation Protection in the Medical Applications of Ionizing Radiation

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

Note: Technical terms which are described in the Glossary appear in **bold type** on their first occurrence in the text.

1. Introduction

1.1 CITATION

This Code may be cited as the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2007)*.

1.2 PURPOSE

This Code establishes the regulatory requirements for the use of **ionizing radiation** in medicine that will, in the context of good practice, ensure that the risks associated with **radiation** exposure to the patient are optimised and those to staff and other persons are as low as reasonably achievable.

This Code establishes:

- (a) the radiation protection principles;
- (b) a requirement for the preparation of a comprehensive Radiation Management Plan addressing the radiation protection principles;
- (c) the specific roles and responsibilities of the following:
 - the **Responsible Person**, being the person who has the overall management responsibility of the radioactive source, radiation-producing equipment or medical practice;
 - the **medical practitioner (radiation)**, being the person responsible for the justification and optimisation of the procedure involving the exposure of the patient to ionizing radiation, either for each individual patient or by way of protocols specific for the procedure; and
 - the **operator** who exposes the patient to ionizing radiation, and
- (d) the management and reporting of **radiation incidents**.

1.3 SCOPE

This Code of Practice applies to the following ionizing radiation exposures in medicine¹:

- (a) the exposure of patients as part of their medical diagnosis or treatment;
- (b) the exposure of individuals as part of health screening programs;
- (c) the exposure of individuals participating in research programs²;
- (d) the exposure of individuals as part of medico-legal procedures;
- (e) the **occupational exposure** of individuals;
- (f) the exposure of health professionals other than those with training in the medical applications of ionizing radiation;
- (g) the exposure of **carers**; and

¹ A separate Code of Practice for radiation protection in dentistry applies to the use of ionizing radiation in dentistry.

² Specific requirements for research participants are given in the *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005)*, ARPANSA.

35 (h) the exposure of members of the public arising from the medical radiation-
36 producing equipment and radioactive sources.

37 This Code does not apply to the chiropractic use of radiation.

38 This Code is supplemented by three Safety Guides that address good practice in
39 radiation protection in:

40 (a) **diagnostic radiology** and **interventional radiology**;

41 (b) **nuclear medicine**; and

42 (c) **radiotherapy**.

43 **1.4 STRUCTURE**

44 This Code of Practice sets out regulatory requirements to be met to achieve a
45 satisfactory level of radiation protection in medicine. It sets out material that will be
46 adopted by State, Territory and Commonwealth Regulatory Authorities as part of
47 their regulatory controls, and in conditions of **authorisation** associated with the
48 use of ionizing radiation in medicine within their jurisdiction.

49 Schedules set out additional information that form part of this Code of Practice.

50 **1.5 INTERPRETATION**

51 The presence of the word 'must' in a section indicates that the requirement to which
52 it refers is mandatory.

53 There are a number of terms that have technical or legal significance, and are central
54 to the national radiation protection framework. The meanings of terms used in this
55 Code of Practice are those defined in the Glossary.

56

57 **2. Radiation Protection Principles**

58 In this Code, the radiation protection principles of justification, optimisation and
59 **dose** limitation are applied to radiation protection in medicine.

60 **2.1 JUSTIFICATION**

61 The justification principle is common to all **practices** involving exposure to ionizing
62 radiation. This principle can be stated as follows:

63 *No practice involving exposure of individuals to radiation should be*
64 *adopted unless it produces sufficient benefit to that individual or to society*
65 *to offset the detriment caused by the radiation.*

66 2.1.1 Before a procedure involving exposure to ionizing radiation is approved or
67 commenced, the procedure must be justified for that individual³.

68 **2.2 OPTIMISATION**

69 2.2.1 Radiation doses that arise from medical radiation exposures and that are
70 received by the public and occupationally exposed persons must be kept as
71 low as reasonably achievable, economic and social factors being taken into
72 account (**ALARA**).

73 2.2.2 Equipment and methods must be selected to ensure that radiation
74 administered to a patient for:

- 75 (a) diagnostic purposes, including interventional radiology, is:
- 76 (i) sufficient to enable the procedure to provide the required
77 information; and
- 78 (ii) not greater than is necessary to provide that information,
- 79 (b) therapeutic purposes:
- 80 (i) is consistent with the intended radiotherapeutic purpose of the
81 exposure; and
- 82 (ii) will achieve the required dose(s) to the target tissue(s), with
83 doses to non-target tissues as low as reasonably practical.

84 2.2.3 The radiation administered to a pregnant patient must be such that the
85 radiation dose to the embryo or fetus is minimised within the parameters of
86 the procedure.

87 **2.3 DOSE LIMITS**

88 2.3.1 All medical applications of ionizing radiation must be managed in such a way
89 that radiation doses to occupationally exposed persons and members of the
90 public do not exceed the dose limits specified in RPS1.

³ Justification may take into account a generic justification applicable to a well established procedure as defined through the relevant professional bodies.

91 2.3.2 Dose limits do not apply to the exposure of patients as part of their diagnosis
92 or treatment.

93 **3. Responsibilities**

94 **3.1 THE RESPONSIBLE PERSON**

95 **Radiation Management Plan**

96 3.1.1 The Responsible Person must ensure that:

97 (a) a Radiation Management Plan that incorporates the components listed
98 in section A1 of Schedule A of this Code is developed, documented,
99 resourced, implemented and regularly reviewed;

100 (b) the Radiation Management Plan prepared under 3.1.1(a) describes the
101 management and reporting arrangements that enable the medical
102 practitioner (radiation) and operator to discharge their obligations
103 under this Code; and

104 (c) all persons covered by the Radiation Management Plan follow and
105 comply with the Radiation Management Plan.

106 3.1.2 Where radioactive waste is generated by the practice, the Responsible Person
107 must ensure that the Radiation Management Plan includes a section on
108 Radioactive Waste Management that incorporates the components listed in
109 section A2 of Schedule A of this Code.

110 **Justification of a medical radiation procedure**

111 3.1.3 The Responsible Person must have protocols in place to ensure that no
112 radiation procedure is carried out unless:

113 (a) it has been justified, either:

114 (i) generically or on an individual basis by the medical practitioner
115 (radiation), in accordance with clause 3.2.2 depending on the
116 nature of the procedure and the patient; or

117 (ii) generically by an accredited body;

118 (b) it has been approved for each individual by:

119 (i) the medical practitioner (radiation); or

120 (ii) the operator in accordance with written guidelines established by:

121 a. the medical practitioner (radiation); or

122 b. an accredited body;

123 (c) in the case of a female patient of childbearing age, the pregnancy status
124 of that patient has been addressed; and

125 (d) where a radiopharmaceutical is to be administered, the breast-feeding
126 status of that patient has been established if there is the potential for a
127 radiation dose of more than 1 mSv to a breast-fed child.

128 **Optimisation of protection, limitation of radiation doses and recording**
129 **of radiation doses**

130 3.1.4 The Responsible Person must ensure that radiation doses to occupationally
131 exposed persons and members of the public:

- 132 (a) do not exceed the dose limits specified in RPS1; and
133 (b) are kept ALARA.
- 134 3.1.5 The Responsible Person must ensure that the medical facility is designed,
135 constructed, shielded, used, and maintained so that the:
- 136 (a) dose constraints acceptable to the relevant regulatory authority are
137 applied; and
- 138 (b) dose limits to occupationally exposed persons and members of the
139 public are not exceeded.
- 140 3.1.6 The Responsible Person must ensure that systems are in place to ensure that
141 a patient is correctly identified for the intended medical radiation procedure.
- 142 3.1.7 The Responsible Person must establish a program to ensure that radiation
143 doses administered to a patient for diagnostic purposes are:
- 144 (a) recorded in accordance with clause 3.1.8;
- 145 (b) periodically compared with **diagnostic reference levels (DRLs)** for
146 diagnostic procedures for which DRLs have been established in
147 Australia; and
- 148 (c) if DRLs are consistently exceeded, reviewed to determine whether
149 radiation protection has been optimised.
- 150 3.1.8 The Responsible Person must ensure that a record is kept of:
- 151 (a) for a diagnostic radiology procedure,
152 (i) the radiation dose administered to the patient; or
153 (ii) sufficient information on the procedure or administration
154 parameters that would allow the radiation dose to the patient to
155 be estimated;
- 156 (b) for a nuclear medicine procedure, the radionuclide,
157 radiopharmaceutical form and confirmed⁴ activity administered to the
158 patient;
- 159 (c) for a radioactive source implant or applicator:
160 (i) the radionuclide;
161 (ii) form;
162 (iii) confirmed activity or dose administered to the patient; and
163 (iv) the duration of the implant; or
- 164 (d) for external beam radiotherapy, intra-operative radiotherapy or remote
165 afterloading brachytherapy, the radiation dose administered to the
166 patient and technique parameters used.

⁴ “confirmed” means that the radionuclide, form and activity for a diagnostic procedure are verified by at least one trained and qualified staff member and for a therapeutic procedure, a second such person witnesses and verifies the measurement of the dispensed activity.

167 **Occupational radiation exposures**

168 3.1.9 The Responsible Person must ensure that:

- 169 (a) a **personal radiation monitoring device** supplied by a Personal
170 Radiation Monitoring Service, approved in accordance with the criteria
171 specified in the *National Directory for Radiation Protection*, is
172 provided to each occupationally exposed person who is likely to be
173 exposed to ionizing radiation in excess of 1 mSv in any one year;
- 174 (b) for each occupationally exposed person who is likely to be exposed to
175 internal radioactive material resulting in an **effective dose** in excess of
176 1 mSv in any one year, internal radiation dose assessments and
177 biological monitoring are carried out as detailed in the *National*
178 *Directory for Radiation Protection*;
- 179 (c) a record is kept of the radiation doses received by each occupationally
180 exposed person in accordance with the requirements of RPS1; and
- 181 (d) work practices are investigated and reviewed if an occupationally
182 exposed person receives effective doses in excess of the dose constraints
183 acceptable to the relevant regulatory authority.

184 3.1.10 When an occupationally exposed female declares that she is pregnant, the
185 Responsible Person must, if necessary, adapt the working conditions of the
186 pregnant female so as to ensure that the embryo or fetus is afforded the same
187 level of protection as that of a member of the public as specified in RPS1.

188 **Radiation incident**

189 3.1.11 In the event of a radiation incident, the Responsible Person must:

- 190 (a) ensure that the radiation incident is investigated;
- 191 (b) submit a written report of a **reportable radiation incident**,
192 including the preventative action to avoid a recurrence, to the **relevant**
193 **regulatory authority** within 7 days; and
- 194 (c) in the case of a radiation-producing equipment or radioactive source
195 that is, or may be, lost or stolen, immediately report the event to the
196 relevant regulatory authority.

197 3.1.12 The Responsible Person must ensure that:

- 198 (a) an internal report on each radiation incident is written and kept in the
199 institution's radiation incident report register; and
- 200 (b) measures are implemented so that the possibility of the recurrence of
201 the radiation incident investigated in 3.1.11(a) is minimised.

202 **Accountability for radiation-producing equipment and radioactive**
203 **sources**

204 3.1.13 The Responsible Person must, at all times, be able to account for all
205 radiation-producing equipment or radioactive sources within his or her
206 control.

207 **Inadvertent irradiation of an embryo or fetus**

208 3.1.14 The Responsible Person must ensure that protocols are in place to address
209 situations where an embryo or fetus inadvertently receives a radiation dose of
210 more than 1 mSv, the Responsible Person must ensure that the requirements
211 of Schedule B are met.

212 **Deterministic effects from interventional radiology**

213 3.1.15 The Responsible Person must ensure that, following an interventional
214 radiological procedure where there is a possibility of radiation induced
215 **deterministic effects**, there are protocols in place for the medical
216 practitioner (radiation) to liaise with the referrer to ensure follow up of the
217 patient.

218 **Training**

219 3.1.16 The Responsible Person must ensure that all individuals who may be
220 occupationally exposed to ionizing radiation have training⁵ or instruction that
221 relates to:

- 222 (a) the type of work being undertaken;
- 223 (b) the radiation-producing equipment or radioactive source, and related
224 ancillary equipment, that the individual may be required to use;
- 225 (c) any potential radiation hazards associated with the practice; and
- 226 (d) the means of protection and minimisation of unwanted radiation
227 exposure.

228 **Radiation shielding**

229 3.1.17 The Responsible Person must ensure that radiation shielding:

- 230 (a) meets the requirements of the Radiation Management Plan; and
- 231 (b) is documented:
- 232 (i) as part of the commissioning procedure of the radiation-
233 producing equipment or radioactive source; and
- 234 (ii) where shielding modifications are made subsequent to
235 commissioning.

236 **Warning notices**

237 3.1.18 The Responsible Person must ensure that:

- 238 (a) illustrated notices requesting that the patient inform staff before the
239 radiation procedure if she may be pregnant are prominently displayed
240 within the facility;
- 241 (b) illustrated notices requesting that the patient inform staff before the
242 administration of a radiopharmaceutical if she is breast-feeding are
243 prominently displayed in the waiting rooms and administration rooms;

⁵ Specific competency requirements are established in the *National Directory for Radiation Protection*.

- 244 (c) each access point into a radiation area has a visible warning sign or
245 device to indicate that the room contains an ionizing radiation hazard;
- 246 (d) an illuminated radiation warning sign displaying the illuminated words
247 'IONIZING RADIATION – DO NOT ENTER' (or equivalent) is
248 positioned directly adjacent to any entry door of any room housing:
- 249 (i) fixed radiation-producing equipment used for external beam
250 radiotherapy, fluoroscopy and computed tomography; or
- 251 (ii) remote afterloading brachytherapy equipment; and
- 252 (e) the illuminated sign required in (d) is illuminated immediately:
- 253 (i) as the radiation-producing equipment is placed in the
254 preparation mode prior to exposure and continues to illuminate
255 during the exposure; or
- 256 (ii) as the radioactive source is driven out of its shielded housing
257 and continues to illuminate until the source has been returned to
258 the shielded position.

259 **Radiation-producing equipment and radioactive sources**

260 3.1.19 The Responsible Person must ensure that specialist procedures, such as
261 mammography, interventional radiology, and therapeutic procedures, are
262 performed using equipment designed for that purpose.

263 3.1.20 The Responsible Person must:

- 264 (a) ensure that a Radiation Source Register is maintained and updated with
265 information relating to:
- 266 (i) the acquisition, movement, replacement or disposal of each
267 radiation-producing equipment or sealed radioactive source; and
- 268 (ii) the maximum activity of each unsealed radionuclide that the
269 medical facility has been authorised to possess.
- 270 (b) advise the relevant regulatory authority of the receipt or disposal of any:
- 271 (i) radiation-producing equipment; or
- 272 (ii) sealed radioactive source (unless given a generic approval in
273 accordance with an authorisation issued by the relevant
274 regulatory authority).

275 **Quality Assurance Program**

276 3.1.21 The Responsible Person must ensure that a comprehensive equipment
277 Quality Assurance program is established, performed, maintained and
278 regularly reviewed at any site where radiation-producing equipment or
279 radioactive sources are used.

280 3.1.22 The Responsible Person must ensure that a Quality Assurance program for
281 all dosimetry and associated measuring instruments is implemented and
282 regularly reviewed to:

- 283 (a) ensure their continued accuracy; and

284 (b) provide a means by which trends in the performance of each such
285 instrument can be monitored.

286 3.1.23 The Responsible Person must ensure that the results of the Quality
287 Assurance program and its outcomes are clearly documented.

288 **Calibration of a survey meter**

289 3.1.24 The Responsible Person must ensure that the calibration of a radiation
290 survey meter for X-ray and gamma rays is maintained and traceable to:

- 291 (a) the Australian National Standard of air kerma; or
- 292 (b) a foreign reference Standard of air kerma recognised by the Chief
293 Metrologist⁶; or
- 294 (c) a National Standard of a country with which Australia has a mutual
295 recognition arrangement for that Standard.

296 **Expert advice**

297 3.1.25 The Responsible Person must ensure that:

- 298 (a) **a qualified expert** is involved:
 - 299 (i) for consultation on optimisation, including patient dosimetry
300 and quality assurance; and
 - 301 (ii) to give advice on matters relating to radiation protection in
302 **medical exposure**, and
- 303 (b) for therapeutic uses of radiation, the calibration, dosimetry and quality
304 assurance requirements of this Code are conducted by, or under the
305 supervision of, a qualified expert.

306 **Equipment calibration – Radiotherapy**

307 3.1.26 The Responsible Person must ensure that:

- 308 (a) all radiation-producing therapy equipment and remote afterloading
309 brachytherapy equipment is calibrated for the proposed clinical
310 techniques by a qualified expert at the time of acceptance following
311 installation;
- 312 (b) before release for clinical use, all newly commissioned radiation-
313 producing therapy equipment and remote afterloading brachytherapy
314 equipment is subjected to an independent⁷ series of calibration tests for
315 the proposed clinical techniques that confirm that the conditions under
316 which it was calibrated produce acceptable clinical accuracy of dose
317 output;
- 318 (c) clinical use of radiation-producing therapy equipment and remote
319 afterloading brachytherapy equipment is restricted to those techniques
320 that have been calibrated and independently checked as described in (a)
321 and (b);

⁶ The Chief Metrologist is defined under section 18A of the *National Measurement Act 1960*.

⁷ “Independent” means by a qualified expert using equipment where neither the expert nor the equipment was associated with the initial calibration.

- 322 (d) before any additional techniques of radiation-producing therapy
323 equipment and remote afterloading brachytherapy equipment are used
324 clinically, those techniques are calibrated and independently checked as
325 described in (a) and (b);
- 326 (e) each of the clinically-used treatment beams for radiation-producing
327 therapy equipment and all clinical parameters for equipment containing
328 radioactive sources (in relation to both planning and treatment
329 delivery) are checked and recalibrated by a qualified expert at intervals
330 specified in international and national protocols; and
- 331 (f) all calibrations of reference and radiation-measuring equipment are
332 traceable to relevant national standards.

333 **Radiotherapy treatment planning**

334 3.1.27 The Responsible Person must ensure that all dosimetry data used for
335 treatment planning are clearly documented and have a reference trace to the
336 original data source.

337 3.1.28 The Responsible Person must ensure that:

- 338 (a) the brachytherapy treatment planning procedures are followed;
- 339 (b) a treatment planning equipment is tested;
- 340 (c) the basic data for each available computer treatment planning program
341 must be verified by a qualified expert on initial acceptance or after any
342 change or upgrade; and
- 343 (d) patient-specific independent calculations of monitor unit or treatment
344 time are performed for radiotherapy.

345 **Equipment repair and maintenance**

346 3.1.29 The Responsible Person must ensure that, following any repairs or
347 maintenance on radiation-producing equipment or equipment containing
348 radioactive source(s) that could alter the integrity of the radiation shielding:

- 349 (a) the operation of the equipment is re-assessed so that the radiation
350 safety of patients, staff and the public is maintained; and
- 351 (b) a radiation survey is carried out by a qualified expert.

352 3.1.30 The Responsible Person must ensure that, following any repairs or
353 maintenance on radiation-producing therapy equipment, including source
354 changes, that could alter the dose output, the equipment is calibrated by a
355 qualified expert before it is returned to clinical use.

356 3.1.31 Where the Responsible Person is informed that corrective maintenance has
357 been identified in radiation-producing equipment or equipment containing
358 radioactive source(s) and the fault could be one which might be present in
359 other similar equipment, the Responsible Person must:

- 360 (a) report the details of the fault to the relevant regulatory authority; and
- 361 (b) keep a record of such faults and the necessary corrective maintenance
362 performed.

363 3.1.32 The Responsible Person must ensure that a written record is kept detailing
364 the work performed on radiation-producing equipment or equipment
365 containing radioactive source(s) following any maintenance or repairs on
366 that equipment.

367 **Death of a patient**

368 3.1.33 The Responsible Person must have systems in place to ensure that in the
369 event of the death of a patient with radioactive material *in situ*:

- 370 (a) exposure to radiation of any person handling the body is minimised;
- 371 (b) each temporarily implanted sealed source or radioactive applicator is
372 removed;
- 373 (c) consideration is given as to whether a permanent radioactive implant or
374 tissue containing unsealed radioactive material is to be excised;
- 375 (d) the level of activity of a permanent implant or unsealed radioactive
376 material remaining in the body is calculated and documented; and
- 377 (e) where a permanent implant or unsealed radioactive material remains in
378 the body, written instructions regarding handling and safety are
379 provided to each person who handles the body.

380 **3.2 MEDICAL PRACTITIONER (RADIATION)**

381 **Authorisation for a medical radiation procedure**

382 3.2.1 A medical practitioner (radiation) who approves a procedure involving the
383 exposure of a patient to ionizing radiation must:

- 384 (a) be appropriately authorised by the relevant regulatory authority;
- 385 (b) comply with the relevant provisions of the Radiation Management Plan;
386 and
- 387 (c) ensure that the radiation exposures are justified in accordance with
388 3.2.2 and optimised in accordance with 3.2.5.

389 **Justification of a medical radiation procedure**

390 3.2.2 In determining the net benefit from a medical radiation procedure, the
391 medical practitioner (radiation) must take into account:

- 392 (a) the specific objectives of the procedure;
- 393 (b) the characteristics of the individual patient involved;
- 394 (c) the total potential clinical benefits, including the direct health benefits
395 to the patient and, where relevant, the benefits to society in general;
- 396 (d) the individual detriment to the patient that may result from the
397 procedure;
- 398 (e) the pregnancy status of a female patient of child bearing age;
- 399 (f) the breast-feeding status of the female patient to be administered a
400 radiopharmaceutical if there is the potential for a radiation dose of
401 more than 1 mSv to a breast-fed child;

- 402 (g) the efficacy, benefits and risk of available alternate techniques having
403 the same objectives, either with less exposure to ionizing radiation or in
404 combination with the medical radiation procedure; and
- 405 (h) any medical data and patient records relevant to the medical exposure.

406 **Approval of a medical radiation procedure**

407 3.2.3 Other than for patients involved in approved health screening programs or
408 individuals involved in approved research projects, the medical practitioner
409 (radiation) must not undertake or approve a procedure involving exposure to
410 ionizing radiation unless a written referral⁸ is provided that:

- 411 (a) contains adequate patient identifying information;
- 412 (b) states the:
- 413 (i) specific clinical question that the diagnostic procedure should try
414 to answer; or
- 415 (ii) clinical condition that the therapeutic treatment is seeking to
416 treat, and
- 417 (c) provides the referrer's contact details for consultative purposes.

418 3.2.4 In approving a procedure involving exposure to ionizing radiation, the
419 medical practitioner (radiation) must for:

- 420 (a) a therapeutic procedure, before the first treatment delivery:
- 421 (i) provide a written prescription for the procedure; and
- 422 (ii) approve the treatment plan;
- 423 (b) a diagnostic procedure:
- 424 (i) specify the radiological procedure to be performed;
- 425 (ii) provide a written prescription for a nuclear medicine procedure;
426 or
- 427 (iii) have provided generic written guidelines for the procedure.

428 **Optimisation of protection**

429 3.2.5 The medical practitioner (radiation) must ensure that the radiation dose
430 arising from a diagnostic procedure is optimised.

431 **Provision of advice to patients and carers**

432 3.2.6 In the case of a patient discharged while undergoing treatment with an
433 implanted radioactive implant/attachment or with a therapeutic
434 radiopharmaceutical, the medical practitioner (radiation) must ensure that
435 the patient, carer or the patient's legal guardian is provided with written
436 information and instructions that address:

- 437 (a) the risks associated with ionising radiation exposure to carers and other
438 persons;

⁸ This referral may be in written or electronic form.

- 439 (b) how to restrict exposures to carers and other persons that could result
440 from proximity to the patient, if relevant;
- 441 (c) storage or disposal of any dislodged radioactive sources, if relevant; and
- 442 (d) prevention of contamination, if relevant,
- 443 before the patient leaves the place where the radiation procedure took place.

444 **Potentially pregnant or pregnant patients**

445 3.2.7 Immediately before the commencement of a radiation procedure that is likely
446 to result in a radiation dose of more than 1 mSv to the embryo or fetus, the
447 medical practitioner (radiation) must ensure that reasonable steps are taken
448 to establish whether a female patient is pregnant.

449 3.2.8 Before administering a therapeutic nuclear medicine treatment to a female
450 patient of childbearing age that is likely to result in a radiation dose of more
451 than 1 mSv to the embryo or fetus, the medical practitioner (radiation) must
452 establish the pregnancy status of that patient with a definitive biochemical
453 test within 24 hours before the commencement of the treatment.

454 3.2.9 The medical practitioner (radiation) must comply with the requirements of
455 Schedule B for females for whom pregnancy has been established.

456 3.2.10 The medical practitioner (radiation) must take reasonable steps to advise a
457 pregnant patient of the potential risks to the embryo or fetus before the
458 radiation exposure is delivered or a radioactive source is administered.

459 **Patient who is breast-feeding a child**

460 3.2.11 The medical practitioner (radiation) must, when a radiopharmaceutical is
461 administered to a patient who is breast-feeding a child, take reasonable
462 measures to ensure that any exposure of the breast-fed child is eliminated or
463 minimised.

464 3.2.12 The medical practitioner (radiation) must, when a therapeutic
465 radiopharmaceutical is administered to a patient who is providing close care
466 of a child, take reasonable steps to ensure that any exposure of the child is
467 eliminated or minimised.

468 **Patient with an implanted electronic device**

469 3.2.13 Before approving a radiotherapy treatment plan for a patient who has an
470 implanted electronic device that might be affected by the radiation⁹, the
471 medical practitioner (radiation) must obtain an:

- 472 (a) estimate from a qualified expert of the dose and the dose rate to the
473 device; and
- 474 (b) assessment from a qualified expert of the need for additional shielding
475 of the device.

⁹ Such a device could be a cardiac pacemaker, cochlear implant or other device with a microchip controller.

476 **Interstitial or intraluminal high dose rate brachytherapy**

477 3.2.14 For interstitial or intraluminal high dose rate brachytherapy procedures, the
478 medical practitioner (radiation) must be immediately available in person
479 while a radioactive source is within the patient in the event that medical
480 assistance is required for the emergency removal of the applicator.

481 **3.3 OPERATOR**

482 **Authorisation for a medical procedure**

483 3.3.1 Only a person who is appropriately authorised by the relevant regulatory
484 authority to administer ionizing radiation to an individual for diagnostic or
485 interventional **radiology**, nuclear medicine or radiotherapy may administer
486 ionizing radiation to an individual.

487 **General requirements for an operator**

488 3.3.2 The operator must comply with the relevant provisions of the Radiation
489 Management Plan.

490 3.3.3 The operator must wear:

- 491 (a) all personal protective equipment provided by the Responsible Person
492 where applicable to the procedure; and
493 (b) a personal radiation monitoring device where provided by the
494 Responsible Person.

495 **Delivery of a medical radiation procedure**

496 3.3.4 The operator must:

- 497 (a) not expose a person to ionizing radiation unless the procedure has been
498 approved or prescribed:
499 (i) by a medical practitioner (radiation); or
500 (ii) in accordance with written protocols established by:
501 a. the medical practitioner (radiation); or
502 b. an accredited body,
503 (b) follow the established protocol for the procedure;
504 (c) ensure that the protection of the patient is optimised within the scope of
505 the parameters under the control of the operator;
506 (d) ensure that the radiation exposure of persons other than the patient is
507 minimised; and
508 (e) in the case of radiotherapy, ensure that:
509 (i) the radiation treatment plan has been approved by the medical
510 practitioner (radiation);
511 (ii) the radiation dose to the patient is delivered in accordance with
512 the radiation treatment plan;

- 513 (iii) there is a continuous oversight of the operating parameters of
514 radiation-producing equipment during the radiation dose
515 delivery; and
- 516 (iv) the exposure from radiation-producing equipment is immediately
517 terminated if there is any concern that the equipment will not
518 deliver the correct patient radiation dose.

519 **Identification of a patient**

520 3.3.5 Immediately before conducting a radiation procedure on a patient, the
521 operator must:

- 522 (a) take reasonable steps to ensure that the patient is correctly identified;
523 and
- 524 (b) ensure that the prescribed procedure is to be performed on the patient.

525 **Potentially pregnant or pregnant patients**

526 3.3.6 Before conducting a procedure on a female patient of child-bearing age that
527 is likely to result in a radiation dose to an embryo or fetus of more than
528 1 mSv, the operator must:

- 529 (a) seek confirmation from the medical practitioner (radiation) that the
530 pregnancy status of the patient has been established; or
- 531 (b) in circumstances where an approved procedure is conducted in
532 accordance with clause 3.3.4(a)(ii), take reasonable steps to establish
533 the pregnancy status of the patient.

534 3.3.7 The operator must take into account the requirements of Schedule B for
535 females in whom pregnancy cannot be excluded and who are undergoing a
536 radiation exposure, particularly if abdominal and pelvic regions are involved.

537 **Control of exposure to persons other than the patient**

538 3.3.8 During all procedures involving administration of ionizing radiation to a
539 patient, the operator must:

- 540 (a) ensure that any person who is not required to be in attendance during
541 the radiation exposure or the administration of a radioactive source to
542 the patient leaves the imaging, administration or treatment area before
543 the procedure commences; and
- 544 (b) ensure that visual surveillance of the imaging room is maintained
545 throughout an imaging procedure.

546 3.3.9 The operator of equipment that delivers external beam radiotherapy,
547 intra-operative radiotherapy or High Dose Rate brachytherapy must:

- 548 (a) ensure that no-one other than the patient receiving the treatment is in
549 the room during the time that the equipment is emitting radiation or
550 the radioactive source is exposed unless:
- 551 (i) the circumstances are specified in the Radiation Management
552 Plan; and
- 553 (ii) such persons remain behind protective screens;

- 554 (b) ensure that visual surveillance of the treatment room is maintained for
555 the time that:
- 556 (i) the radiation-producing equipment is delivering the exposure; or
557 (ii) the radioactive source is exposed; and
- 558 (c) immediately terminate the exposure if any person other than the
559 patient might be accidentally exposed.

560 **Equipment**

561 3.3.10 The operator of radiation-producing equipment and equipment containing
562 radioactive sources must ensure that safety interlock devices are not
563 bypassed at any time during routine clinical use of the equipment.

564 **Equipment malfunction or error**

565 3.3.11 The operator of medical radiation-producing equipment, equipment
566 containing radioactive sources or other associated apparatus, who
567 experiences any malfunction or error of equipment or system, or unusual
568 operating behaviour must:

- 569 (a) immediately cease using the equipment or apparatus until the
570 malfunction, error or unusual operating behaviour is rectified;
- 571 (b) record the details of the malfunction, error or unusual operating
572 behaviour; and
- 573 (c) where the malfunction could compromise patient safety, diagnosis or
574 treatment, report it to:
- 575 (i) the Responsible Person; and
576 (ii) the medical practitioner (radiation).

577 **Radiation incidents**

578 3.3.12 The operator must report any radiation incident within 24 hours to:

- 579 (a) the medical practitioner (radiation); and
580 (b) the Responsible Person.

581
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583

Schedule A

Radiation Management Plan

A1 PREPARATION OF THE RADIATION MANAGEMENT PLAN

584 A1.1 The Radiation Management Plan¹⁰ must address the following:

- 586 (a) work practices and protocols for all procedures involving medical exposure to
587 ionizing radiation, including those:
- 588 (i) to ensure that the prescribed radiation procedure is performed on the
589 correct patient;
 - 590 (ii) for the proper planning and delivery of radiotherapy doses;
 - 591 (iii) for preparation and dispensing of radiopharmaceuticals; and
 - 592 (iv) for optimising the protection of the patient consistent with section 2 of
593 this Code,
- 594 (b) construction and shielding of the medical practice so that dose constraints
595 acceptable to the relevant regulatory authority are applied for occupationally
596 exposed persons or members of the public;
- 597 (c) the action to be taken if the radiation doses to occupationally exposed persons
598 or members of the public are found to exceed the dose constraints;
- 599 (d) optimisation of the shielding so that external radiation exposure rates are kept
600 ALARA;
- 601 (e) observation¹¹ of the patient by the operator throughout procedures where the
602 dosimetry or image quality could be affected by patient movement;
- 603 (f) arrangements for isolation of hospital in-patients undergoing treatment with
604 sealed or unsealed radioactive sources;
- 605 (g) the training, qualifications and supervision of the staff of the medical facility
606 and their roles and responsibilities;
- 607 (h) the licensing requirements of the radiation regulatory authority;
- 608 (i) personal radiation monitoring requirements for persons involved in the use of
609 radiation;
- 610 (j) personal protective equipment to be worn by persons involved in the use of
611 radiation;
- 612 (k) actions necessary to manage a radiation incident, including reporting (both
613 internal and to the radiation regulatory authority) and investigation of the
614 radiation incident;
- 615 (l) emergency procedures in response to radiation incidents;
- 616 (m) a quality assurance program that includes planned and systematic actions
617 necessary to provide adequate confidence that a structure, system, component
618 or procedure will:
- 619 (i) perform satisfactorily and safely;
 - 620 (ii) comply with agreed standards; and

¹⁰ The Radiation Management Plan may make reference to, and utilise, other documented safety procedures and work practices.

¹¹ Observation may be by indirect means such as video surveillance.

- 621 (iii) include quality control, with particular emphasis on the optimisation of
622 radiation protection,
- 623 (n) arrangements for the storage of radioactive material;
- 624 (o) arrangements for the transport of radioactive material;
- 625 (p) arrangements for radioactive waste management, if relevant;
- 626 (q) mechanisms for implementation and review of the Radiation Management
627 Plan;
- 628 (r) arrangements for obtaining expert advice in radiation protection; and
- 629 (s) any other requirement that may have a bearing on radiation safety.

630 A1.2 Where other documented safety procedures and work practices that exist within the
631 organisation are referred to or used:

- 632 (a) the Responsible Person must have authority over the safety procedures and
633 work practices referred to; and
- 634 (b) the safety procedures and work practices referred to must not be modified
635 without consideration of the effect on the Radiation Management Plan.

636 **A2 REQUIREMENTS FOR RADIOACTIVE WASTE MANAGEMENT**

637 A2.1 A Radiation Management Plan that includes Radioactive Waste Management must
638 address the following:

- 639 (a) mixed waste hazards¹²;
- 640 (b) the necessary equipment and instructions for the safe handling and disposal of
641 all radioactive waste in accordance with any authorisation issued by the
642 relevant regulatory authority;
- 643 (c) procedures to ensure that all persons involved in the handling of radioactive
644 waste receive, understand and comply with the radioactive waste management
645 requirements;
- 646 (d) the storage of all radioactive waste in adequately shielded containers or in a
647 secure shielded room, as appropriate to the nature of the waste, so as to
648 ensure no member of the public receives an effective dose greater than the
649 relevant limit specified in RPS1;
- 650 (e) procedures to ensure that all radioactive waste leaving the facility, either as
651 gaseous or liquid effluent discharged to the environment or sewerage system,
652 does so within the relevant requirements specified in the *National Directory*
653 *of Radiation Protection*; and
- 654 (f) notification to the relevant regulatory authority of any radiation incident
655 which has, or may have, resulted, or may result in:
- 656 (i) a discharge of effluent in excess of the relevant discharge limit; or
- 657 (ii) spillage of radioactive waste during transport.
- 658

¹² The radioactive waste may also be flammable, toxic, infectious or putrescible material.

659 **Schedule B**

660

661 **Protection of an Embryo or Fetus**

662 **B1 PROTOCOL IF A PATIENT IS PREGNANT**

663 B1.1 A procedure on a pregnant patient that may result in a radiation dose of more than
664 1 mSv to an embryo or fetus must:

665 (a) be justified on an individual basis; and

666 (b) include an assessment of the risks to:

667 (i) the embryo or fetus from the radiation exposure; and

668 (ii) the patient if the procedure is not performed.

669 B1.2 Where it is decided that a medical radiation procedure that may result in a radiation
670 dose of more than 1 mSv to the embryo or fetus is necessary or advisable for a
671 woman who is pregnant, the risks must be fully explained to:

672 (a) the referrer; and

673 (b) the pregnant patient,

674 before the procedure is carried out.

675 B1.3 Before approving a radiation procedure for a pregnant patient that may result in a
676 radiation dose of more than 1 mSv to an embryo or fetus, an estimate of the expected
677 radiation dose to the embryo or fetus must be made and recorded.
678

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679
680

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703 **Glossary**

704 **Absorbed dose**

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

706 Absorbed dose, D , is defined by the expression:

$$707 \quad D = \frac{dE}{dm}$$

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

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

710 **ALARA**

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

717 **Authorisation**

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

720 **Carer**

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

723 **Deterministic effect**

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

727 **Detriment**

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

732 **Diagnostic radiology**

733 the use of X-rays to diagnose disease, injury or provide imaging information for medical
734 purposes.

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

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

743 **Dose**

744 a generic term that may mean **absorbed dose, equivalent dose** or effective dose
745 depending on context.

746 **Dose constraint**

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

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

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

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

755 **Effective dose**

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

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

760
$$E = \sum_T w_T H_T$$

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

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

764 **Equivalent dose**

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

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

770
$$H_T = \sum_R w_R D_{T,R}$$

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

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

776 **Interventional radiology**

777 procedures comprising guided therapeutic and diagnostic interventions, by percutaneous or
778 other access, usually performed under local anaesthesia or sedation, with fluoroscopic or
779 computed tomographic imaging used to localise, in conjunction with a surgical procedure,
780 the lesion/treatment site, monitor the surgical procedure, or control and document the
781 therapy or diagnosis.

782 **Ionizing radiation**

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

786 **Medical exposure**

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

790 **Medical practitioner (radiation)**

791 the practitioner authorised by the relevant regulatory authority and responsible for the
792 overall conduct of the procedure involving the exposure of the patient to ionizing radiation.
793 In nuclear medicine, this person will normally be a nuclear medicine specialist, in radiation
794 oncology, this person will normally be a radiation oncologist and in diagnostic or
795 interventional radiology, this person will usually be a radiologist, but might also be, for
796 example, a cardiologist or, for limited procedures, a general practitioner.

797 **Nuclear medicine**

798 the use of **unsealed radioactive sources** for diagnostic imaging, physiological testing and
799 therapy.

800 **Occupational exposure**

801 exposure of a person to radiation which occurs in the course of that person's work and which
802 is not excluded exposure¹³.

803 **Operator**

804 any natural person who is authorised by the relevant regulatory authority to administer
805 radiation to a patient for radiology, nuclear medicine or radiotherapy.

806 **Personal radiation monitoring device**

807 a device designed to be worn by a person to monitor the radiation dose received by the
808 person.

809 **Practice**

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

812 **Public exposure**

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

815 **Qualified expert**

816 a person who:

- 817 (a) is qualified in the application of the physics of therapeutic or diagnostic uses of
818 ionizing radiation; and
- 819 (b) has been recognised by the relevant regulatory authority as being able to perform
820 the dosimetric calculations, radiation measurements and monitoring relevant to
821 the person's area of expertise¹⁴.

¹³ Excluded exposure means the component of exposure that arises from natural background radiation.

822 **Radiation**

823 electromagnetic waves or quanta, and atomic or sub-atomic particles, propagated through
824 space or through a material medium.

825 **Radiation incident**

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

832 **Radiation-producing equipment**

833 any equipment that produces ionizing radiation when energised.

834 **Radioactive material**

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

837 **Radioactive source**

838 any radioactive material that is either a sealed radioactive source or an unsealed radioactive
839 source.

840 **Radiotherapy**

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

843 **Referrer**

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

847 **Relevant regulatory authority**

848 the radiation protection authority or authorities designated, or otherwise recognized, for
849 regulatory purposes in connection with protection and safety relating to medical applications
850 of ionizing radiation. A list of relevant regulatory authorities in Australia is included in
851 Annex 1 of this Code.

852 **Reportable radiation incident**

853 a radiation incident as defined in Schedule 13 of the *National Directory for Radiation*
854 *Protection*.

855 **Responsible Person**

856 in relation to any radioactive source, radiation-producing equipment, prescribed radiation
857 facility or premises on which radioactive sources are stored or used means the legal person¹⁵:

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

¹⁴ Competency requirements for a qualified expert will be listed in future editions of the *National Directory for Radiation Protection*.

¹⁵ 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.

- 861 (b) having overall control over who may use the source, radiation-producing
862 equipment, facility or premises; and
- 863 (c) in whose name the source, radiation-producing equipment, facility or premises
864 would be registered if this is required.

865 **RPS1**

866 *the Recommendations for limiting exposure to ionizing radiation (1995) (NOHSC guidance*
867 *note) and the National standard for limiting occupational exposure to ionizing radiation.*
868 *Radiation Protection Series No. 1.*

869 **Sealed radioactive source**

870 a radioactive substance bonded within metals or sealed in a capsule or other container in
871 such a way as to-

- 872 (a) minimise the possibility of escape or dispersion of the radioactive substance;
873 and
- 874 (b) allow the emission of ionizing radiation for use as required.

875 **Transport Code, the**

876 *the Code of Practice for the Safe Transport of Radioactive Material 2001* published by the
877 Chief Executive Officer of ARPANSA in September 2001. *Radiation Protection Series No. 2.*

878 **Unsealed radioactive source**

879 a radioactive source that is not a sealed radioactive source.

880 **Annex 1**

881

882 **Regulatory Authorities**

883 Where advice or assistance is required from the relevant regulatory authority, it may be
884 obtained from the following officers:

COMMONWEALTH, STATE / TERRITORY	CONTACT
Commonwealth	Chief Executive Officer ARPANSA PO Box 655 Miranda NSW 1490 Email: info@arpansa.gov.au Tel: (02) 9541 8333 Fax: (02) 9541 8314
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	Manager Hazardous Materials and Radiation Section Department of Environment and Climate Change PO Box A290 Sydney South NSW 1232 Email: radiation@environment.nsw.gov.au Tel: (02) 9995 5000 Fax: (02) 9995 6603
Northern Territory	Manager Radiation Protection Radiation Protection Section Department of Health and Community Services 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@epa.sa.gov.au Tel: (08) 8130 0700 Fax: (08) 8130 0777
Tasmania	Senior Health Physicist Health Physics Branch Department of Health and Human Services GPO Box 125B Hobart TAS 7001 Email: health.physics@dhhs.tas.gov.au Tel: (03) 6222 7256 Fax: (03) 6222 7257
Victoria	Manager, Radiation Safety Section Department of Human Services GPO Box 4057 Melbourne VIC 3001 Email: radiation.safety@dhs.vic.gov.au Tel: 1300 767 469 Fax: 1300 769 274
Western Australia	Secretary, Radiological Council Locked Bag 2006 PO Nedlands WA 6009 Email: radiation.health@health.wa.gov.au Tel: (08) 9346 2260 Fax: (08) 9381 1423

885 **Please note:** This table was correct at the time of printing but is subject to change from
886 time to time. For the most up-to-date list, the reader is advised to consult the ARPANSA
887 web site (www.arpansa.gov.au). For after hours emergencies only, the police will provide the
888 appropriate emergency contact number.

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891 **WORKING GROUPS**

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893 **Convenors**

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896 **ORGANISATIONS/PERSONS CONTRIBUTING TO THE DEVELOPMENT OF THIS**
897 **PUBLICATION**

898 **Index**

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