



RECOMMENDATIONS

Discharge of Patients Undergoing Treatment with Radioactive Substances

RADIATION PROTECTION SERIES No. 4

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**.

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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.

RECOMMENDATIONS

Discharge of Patients Undergoing Treatment with Radioactive Substances

Radiation Protection Series Publication No. 4

This publication was approved by the Radiation Health Committee on 31 July 2002, and the Radiation Health & Safety Advisory Council, at its meeting on 9 August 2002, advised the CEO to adopt the recommendations.

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

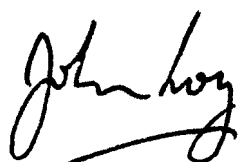
Published by the Chief Executive Officer of ARPANSA, September 2002.

Foreword

These *Recommendations for the Discharge of Patients Undergoing Treatment with Radioactive Substances* (2002) (hereafter referred to as the *Recommendations*) replace the NHMRC document published in 1983. The *Recommendations* are designed to provide guidance on the conditions that should be met for the discharge from a hospital or clinic of patients who are undergoing treatment with radioactive substances. The guiding principle is that the radiation dose to persons with whom the patient may make contact outside the hospital or clinic (i.e. members of the public, family members or carers) should be kept as low as reasonably achievable, taking into account the particular social and economic factors, and does not exceed the relevant dose limit prescribed by regulation. The *Recommendations* have been updated to include the radionuclides currently administered in nuclear medicine practice, and radionuclides that may come into common use. A rationale for the values chosen for the maximum activities of radionuclides at which patients may be discharged has been included as an Annex.

The *Recommendations* have been developed by a working group of the Radiation Health Committee, and were released for a public comment period from 19 April 2002 to 24 May 2002. The comments received were reviewed by the working group, and the final *Recommendations* were adopted by the Radiation Health Committee on 31 July 2002. The Radiation Health and Safety Advisory Council advised the CEO to adopt the *Recommendations* at their meeting of 9 August 2002.

The *Recommendations* will be reviewed from time to time to ensure that they continue to provide the highest standards of protection.

A handwritten signature in black ink, appearing to read 'John Loy', with a stylized flourish at the end.

John Loy
CEO of ARPANSA

25 September 2002

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1. Introduction

1.1 BACKGROUND

These *Recommendations* replace the publication *Recommendations Relating to the Discharge of Patients Undergoing Treatment with Radioactive Substances* (1983) in the NHMRC Radiation Health Series of publications. ARPANSA assumed responsibility for the administration of the Radiation Health Series in 1999. ARPANSA is progressively revising the Radiation Health Series publications and re-issuing them as part of the ARPANSA Radiation Protection Series. Current publications in both series are listed in Annex 6. Further information on the health effects of ionizing radiation is provided in Annex 4. Advice on the interpretation and implementation of these *Recommendations* can be obtained from the relevant Radiation Protection Authority listed in Annex 5.

1.2 PURPOSE

The purpose of these *Recommendations* is to provide guidance on the conditions which should be met for the discharge from a hospital or clinic of a patient who is undergoing treatment with a radioactive substance, and the conditions for the treatment of an outpatient.

In the context of these *Recommendations*, discharge of the patient means the return of the patient into the community, and applies equally to the patient who has been admitted to a hospital for the treatment and to the patient who has been administered the treatment as an outpatient.

These *Recommendations* are based on the premise that the radiation dose to persons with whom the patient may make contact outside the hospital or clinic should be kept as low as reasonably achievable, taking into account the particular social and economic factors, and does not exceed the relevant dose limit prescribed by regulation.

1.3 SCOPE

These *Recommendations* relate to the treatment of patients with sealed or unsealed forms of a radioactive substance. They take into account the dose rate external to the patient, the potential for loss of a sealed source from the patient, and the potential for the spread of contamination of an unsealed radioactive substance which is excreted by the patient.

The requirements for the discharge of individual patients should be assessed by a medical specialist who holds an appropriate radiation licence, preferably in consultation with an experienced medical physicist, having regard to the prevailing circumstances.

2. Radiation Protection Criteria for Patient Discharge

2.1 DOSE LIMITS AND DOSE CONSTRAINTS

The effective dose to any member of the general public should not exceed 1 millisievert (mSv) in a year, excluding exposure from natural background radiation and medical procedures. This dose limit applies to adults and children, including the unborn child. In the context of these *Recommendations*, the dose limit applies to persons who may make contact with the patient, for example, through work, travel, social or domestic activities.

Adult family members or persons who care for the patient are not necessarily subject to the 1 mSv dose limit for members of the public. The effective dose to an appropriately informed carer who knowingly and willingly provides comfort and support to the patient should not exceed a dose constraint of 5 mSv per treatment episode. This criterion need not be applied rigidly in all cases, as for example when a parent is assisting with the care of a sick child.

2.2 THE DISCHARGE OF PATIENTS FOLLOWING TREATMENT

Patients may be discharged from hospital or may leave a clinic following treatment with a radioactive substance when an estimate of the effective dose to family members and to members of the general public has been shown to comply with the dose limits and dose constraints given in Section 2.1. Such an estimate should be based on measurements of the external ambient dose equivalent rate from the patient, the physical half-life of the radionuclide, the biological clearance of the radioactive substance from the body, the patient's clinical condition and the proximity to other family members, especially children, and to other persons. The dose estimates, and the measurements on which they are based, should be recorded in the patient's clinical record.

2.3 MAXIMUM EXTERNAL DOSE RATE FROM AN INPATIENT AT THE TIME OF DISCHARGE FROM HOSPITAL

When patient-specific dose estimates to family members and to members of the general public are not available, it is recommended that, in order to comply with the criteria given in Section 2.1, the ambient dose equivalent rate at a distance of 1 metre from a patient who is undergoing treatment with a radioactive substance should not exceed 25 $\mu\text{Sv}/\text{hour}$ at the time of the patient's discharge from hospital. Measurements at distances of 2 metres or 3 metres may be more appropriate in the clinical setting, thus limiting the radiation exposure to the staff and minimising any effects

arising from the non-uniform activity distribution in the patient. The patient does not represent a point-source of activity, so that the inverse-square law often does not apply until at least 3 metres from the patient. The external ambient dose equivalent rate from iodine-131 distributed within a patient may be approximated by an 'inverse 1.5 power' relationship from 1 to 3 metres. Thus, 25 $\mu\text{Sv}/\text{hour}$ at 1 metre may be taken as equating to 9 $\mu\text{Sv}/\text{hour}$ at 2 metres and to 5 $\mu\text{Sv}/\text{hour}$ at 3 metres.

The total external radiation dose to members of the public and to family members will depend not only on the dose rate at the time of discharge but also on the physical decay rate of the radionuclide, the biological clearance rate of the radioactive substance from the patient, and the time spent by the patient in proximity to these persons. The above recommended level of 25 $\mu\text{Sv}/\text{hour}$ at 1 metre has primarily been derived from considerations of iodine-131 in the treatment of thyroid disorders. It should be equally applicable to other therapeutic uses of iodine-131, and to other therapeutic radionuclides, even though the rates of physical decay and biological clearance may differ. However, the rates of physical decay and biological clearance will determine the period during which radiation safety restrictions will apply, particularly in relation to the exposure of family members, and the time at which the patient may resume normal employment and social activities (see Section 3, Instructions for Patients).

Where the patient's circumstances are such that the dose limits or dose constraints given in Section 2.1 could be exceeded even though the ambient dose equivalent rate at 1 metre from the patient is below 25 $\mu\text{Sv}/\text{hour}$, the responsible medical specialist should postpone the discharge of the patient until such time that the limits or constraints can be met.

2.4 TREATMENT OF PATIENTS WITH SEALED SOURCES

The medical specialist with the appropriate radiation licence who is responsible for the treatment of patients with sealed sources of caesium-137 or iridium-192 must ensure the safe keeping of these sources at all times. Consequently, a patient who is undergoing treatment with a sealed source, or sources, of caesium-137 or iridium-192 is not to be discharged from a hospital or clinic until these sources have been removed from the patient's body.

Where one or more sealed sources of other radionuclides remain in a patient who is to be discharged from a hospital or clinic, consideration should be given to the possibility that these sources may be dislodged from the patient, and to the need for appropriate action to be taken by the patient or carer in this contingency.

2.5 TREATMENT OF PATIENTS WITH UNSEALED SOURCES

When a patient is to be discharged from a hospital or a clinic following treatment with an unsealed source of a radionuclide, consideration should be given to the possibility of contamination arising from the escape of body fluids, for example as a result of urinary incontinence or vomiting. After oral administration of an unsealed radionuclide (*e.g.* iodine-131 for thyroid therapy), the patient should remain at the hospital or clinic until such time as the patient is unlikely to vomit the administered dose.

2.6 MAXIMUM RADIONUCLIDE ACTIVITY TO BE ADMINISTERED TO AN OUTPATIENT

In general, the patient may be treated as an outpatient if the activity of the radionuclide to be administered does not exceed the activity given in Annex 1 for sealed sources or Annex 2 for unsealed sources. Where the patient's circumstances are such that the dose limits and dose constraints given in Section 2.1 could be exceeded even though the activity to be administered complies with that listed in Annex 1 or Annex 2, then the responsible medical specialist should postpone the discharge of the patient until these conditions can be met.

The maximum radionuclide activities given in Annex 1 and Annex 2 are recommendations for radionuclide therapies used clinically at the time of the writing of these *Recommendations*. It is acknowledged that new treatment procedures may be developed in the future which could render these limits unnecessarily restrictive. If it can be shown for a particular treatment that the dose limits and dose constraints given in Section 2.1 will not be exceeded, then the regulatory authority may grant permission to discharge patients receiving this treatment at activities greater than those given in these *Recommendations*, upon application from the responsible medical specialist.

Where the patient is undergoing a novel treatment with a radioactive substance not listed in these Annexes, guidance should be sought from the regulatory authority. Further information on the rationale for the maximum activities at which patients may be discharged from hospital, or treated as an outpatient, is provided in Annex 3.

2.7 POSTPONEMENT OF THE DISCHARGE OF A PATIENT FROM A HOSPITAL OR CLINIC

A patient should not be discharged from a hospital or clinic if it seems likely that:

- (a) a sealed source may be lost;

- (b) a spread of contamination may occur as a result of the excretion of an unsealed source; or
- (c) the patient may vomit shortly after oral administration of an unsealed source.

2.8 DISCHARGE OF A PATIENT TO PREMISES OTHER THAN A PRIVATE DWELLING

If a patient is to be transferred to an institution or place of care other than a private dwelling, for example to a nursing home, appropriate notification of the patient's radioactive status should be sent to that place at the time of the transfer. The notification should include details of the form and activity of the radionuclide, the time and date of administration of the radionuclide to the patient, the relevant radiation characteristics of the radionuclide, and the precautions that should be observed for a specified time by the persons who will care for the patient. The name of the hospital or clinic from which the patient was discharged should also be provided, together with the name and telephone number of the person who may be contacted in order to obtain further information on radiation protection matters or advice in the event of a medical emergency.

2.9 USE OF PUBLIC TRANSPORT BY THE PATIENT

The time of travel by public transport for the patient returning home should not exceed two hours when the patient is discharged at a maximum ambient dose equivalent rate of 25 $\mu\text{Sv}/\text{hour}$ at 1 metre or, for a radionuclide that emits penetrating radiation, at the maximum activity given in Annex 1 or Annex 2. If it is known that the journey would be of longer duration and that the patient intends to use public transport, then the patient should remain either in hospital or in local premises after discharge so that the journey may be deferred until the external ambient dose equivalent rate has fallen to an acceptable level. Alternatively, after taking into consideration the possible dose to a carer or any other person accompanying the patient, the patient may be advised to travel by means other than public transport. This is of particular importance where the public transport involves confined adjacent seating at distances of considerably less than 1 metre.

3. Instructions for Patients

Individualised instructions relevant to the patient's medical and social circumstances should be provided to each patient by the licensed medical specialist responsible for the treatment, in consultation with an experienced medical physicist. The instructions should state the radionuclide, the form of the radionuclide and the activity administered, should be designed to suit the patient's own particular travel and domestic arrangements and should be based on the need to minimise the radiation dose to other persons, taking into account the social and economic costs. The instructions should be given to the patient orally and in writing.

The instructions should include, where appropriate, the need to restrict close proximity to other members of the household, especially children, young persons and pregnant women, the importance of good personal hygiene in order to prevent the spread of contamination, and the date when normal social and employment activities may be resumed. The resumption of normal employment should take into account the duration and distance of interaction with other persons in the workplace. Similarly, social activities which involve close proximity to other persons for extended periods, such as going to the cinema or long journeys by public transport, should be distinguished from activities such as shopping, where there are only brief encounters with other persons.

Instructions should also be given, where appropriate, on the precautions to follow in situations such as medical emergencies requiring hospitalisation.

On the day of treatment, a written record of the treatment should be provided to the referring doctor and, where appropriate, to the patient and/or carers. This record should include the following information:

- the radionuclide administered, the activity administered and date of administration;
- name(s) and contact number(s) of the prescribing doctor and/or radiation safety officer or medical physicist, for emergencies or other hospitalisation; and
- the duration of any pertinent radiation safety restrictions.

The patient should also be provided with a card containing the above information. The card should be carried by the patient at all times until the date specified.

The Bibliography lists publications that contain guidance on precautions for several specific radionuclide therapies.

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Annex 1

Maximum Activities of Radionuclides in Sealed Forms at which a Patient may be Discharged*

RADIONUCLIDE	PHYSICAL HALF-LIFE	ACTIVITY IN MBq	Note
Caesium-137	30.1 years	none	1
Gold-198	2.69 days	400	-
Iodine-125	59.4 days	2,000	2, 3
Iridium-192	73.8 days	none	1
Palladium-103	17.0 days	10,000	2, 3

* This Annex should be used in conjunction with Sections 2.2 and 2.6.

Notes:

1. Sources are to be removed before the patient is discharged from hospital.
2. Because of the relatively long physical half-life of this radionuclide the patient should be instructed to limit periods spent in close proximity to other persons, particularly children or someone who is pregnant, until the administered radionuclide has decayed to at least one-eighth of the amount listed in this Annex. There would normally be no restrictions on the time spent with a person who is at a distance of 1 metre or more from the patient.
3. No activity limit is necessary for shielded iodine-125 or palladium-103 plaques/applicators.

Annex 2

Maximum Activities of Radionuclides in Unsealed Forms which may be Administered to Outpatients*

RADIONUCLIDE	PHYSICAL HALF-LIFE	ACTIVITY IN MBq	Note
Indium-111	2.81 days	400	1
Iodine-131	8.02 days	600	2
Phosphorus-32	14.3 days	1,200	3
Rhenium-188	17.0 hours	4,000	1, 4
Samarium-153	1.93 days	4,000	1, 4
Strontium-89	50.5 days	300	2, 4
Yttrium-90	2.67 days	4,000	2, 4

* This Annex should be used in conjunction with Sections 2.2 and 2.6.

Notes:

These notes do not apply to radionuclides in radiopharmaceutical forms that are insoluble or are totally retained in the body, e.g. labelled microspheres or colloids.

1. An incontinent patient should not be discharged to a private dwelling or other non-controlled premises in the first two days after administration of this radionuclide unless monitoring of the patient or of the excreted activity indicates that an earlier discharge date is appropriate.
2. An incontinent patient should not be discharged to a private dwelling or other non-controlled premises in the first week after administration of this radionuclide unless monitoring of the patient or of the excreted activity indicates that an earlier discharge date is appropriate.
3. An incontinent patient should not be discharged to a private dwelling or other non-controlled premises in the first two weeks after administration of this radionuclide unless monitoring of the patient or of the excreted activity indicates that an earlier discharge date is appropriate.
4. In the case of pharmaceutical forms of the radionuclide where there is rapid renal excretion of activity, the patient should remain in hospital or at the clinic until one, or preferably two, urinary voids have occurred. Monitoring of the patient or of the excreted activity may indicate that an earlier or later discharge time is appropriate. The patient should receive appropriate instructions to minimise the spread of contamination from excreta for at least the next 24 hours after discharge from the hospital or clinic.

Annex 3

Rationale for the Recommended Maximum Activities Administered to Outpatients and the Maximum Dose Rate for Discharge of Inpatients from Hospital

The purpose of the *Recommendations for the Discharge of Patients Undergoing Treatment with Radioactive Substances* (2002) is to provide guidance on the conditions which should be met for the discharge of a patient who is undergoing treatment with a radioactive substance. The principal criterion is that the effective dose to any member of the general public, including children and the unborn child, should not exceed 1 millisievert (mSv) in a year, excluding exposure from natural background radiation and from medical procedures to the recipient. The 1 mSv dose limit is chosen to be consistent with the ARPANSA *Recommendations for limiting exposure to ionizing radiation* (ARPANSA 2002), which set a public exposure limit of 1 mSv in a year (public exposure covers all exposures arising from practices; that is, all exposures that are neither occupational nor medical). This limit does not necessarily apply to adult family members or carers who are appropriately informed and knowingly and willingly provide comfort and support to the patient. An effective dose constraint of 5 mSv is recommended for adult family members and carers, but this criterion need not be rigidly applied in all cases, as for example when a parent is assisting with the care of a sick child.

The approach taken in these *Recommendations*, in order to achieve the above criteria under normal circumstances, is that the ambient dose equivalent rate at a distance of 1 metre from the patient undergoing treatment with a radioactive substance should not exceed 25 $\mu\text{Sv}/\text{hour}$ at the time of discharge from a hospital or clinic. It is recognised that the patient does not represent a point-source of activity, and that as a consequence the inverse-square law does not normally apply until distances of at least 3 metres from the patient. It has been shown that, in the case of iodine-131 distributed within a patient, the ambient dose equivalent rate at distances from 1 to 3 metres from the patient follows an approximate 'inverse 1.5 power' relationship (HURSOG 1997). Thus, 25 $\mu\text{Sv}/\text{hour}$ at 1 metre may be taken as equating to 9 $\mu\text{Sv}/\text{hour}$ at 2 metres and to 5 $\mu\text{Sv}/\text{hour}$ at 3 metres.

The recommended maximum ambient dose equivalent rate of 25 $\mu\text{Sv}/\text{hour}$ at 1 metre from the patient at the time of discharge has been derived primarily from considerations of iodine-131 in the treatment of thyroid disorders. Experience has shown that the dose limits and constraints for exposure to members of the public, family and carers are unlikely to be exceeded if a patient is treated with up to 600 MBq of iodine-131 as an outpatient or if a patient is discharged from a hospital or clinic when the external ambient dose equivalent rate is less than 25 $\mu\text{Sv}/\text{hour}$ at 1 metre, provided that the patient observes some simple precautions such as restrictions on close proximity to other persons (Eschner et al. 1999).

In general, the radiation dose to persons other than the patient will depend upon:

- (a) the activity and distribution of the radionuclide retained in the patient at the time of discharge;
- (b) the specific exposure rate constant of the radionuclide;

- (c) the shielding provided by the patient's body;
- (d) the physical decay rate and the biological clearance rate of the radioactive substance in the patient's body; and
- (e) the time spent by such persons at relevant distances from the patient.

These *Recommendations* do not specify a different external ambient dose equivalent rate for each radiopharmaceutical even though the radiation dose received by family members during the course of treatment will depend on the physical decay rate and the biological clearance rate of the radioactive substance in the patient. Rather, the *Recommendations* require that the period during which radiation safety restrictions should be applied should be varied to reflect the different half-lives.

The doses received by persons who may be close to the patient for only short periods of time (for example, during travel by public transport or shopping) will depend on the external dose rate and the time period of the proximity. Thus, it is recommended that the time of travel by public transport of the discharged patient returning home should not exceed two hours when the patient is discharged at a maximum ambient dose equivalent rate of 25 $\mu\text{Sv}/\text{hour}$ at 1 metre or, for a radionuclide that emits penetrating radiation, at the maximum activity given in Annex 1 or Annex 2. This is of particular importance where the public transport involves confined adjacent seating at distances of considerably less than 1 metre.

Radionuclides in Sealed Forms

Caesium-137 and Iridium-192

Caesium-137 and iridium-192 emit penetrating gamma radiation and have significantly long physical half-lives (30.1 years and 73.8 days, respectively). Sealed sources of these radionuclides present a major radiation hazard if dislodged from the patient or otherwise lost. These sources are to be removed from the patient before discharge from hospital.

Gold-198

The recommended maximum discharge activity of 400 MBq for gold-198 corresponds to an ambient dose equivalent rate of approximately 25 $\mu\text{Sv}/\text{hour}$ at 1 metre (calculated from the unshielded gamma dose rate with allowance made for limited shielding by the patient's body).

Iodine-125 and Palladium-103

The 'no limit' maximum discharge activity for iodine-125 (sealed) contained in the 1983 *Recommendations* is not generally useful. The major factor determining the external dose rate from implanted iodine-125 and palladium-103 is the depth of implantation from the skin surface, which is primarily determined by the patient's weight. Studies have shown that, for the commonly administered activity range of these radionuclides, the ambient dose equivalent rate at a distance of 1 metre is less than 0.3 $\mu\text{Sv}/\text{hour}$ (Smathers et al. 1999).

The recommended maximum discharge activities of 2,000 MBq for iodine-125 and 10,000 MBq for palladium-103 are expected to cover activities administered in current practice.

The need for the discharged patient to limit periods spent in close proximity to other persons, including pregnant women, until the administered radionuclide has decayed to at least one-eighth of the recommended maximum discharge activity is emphasised in the Notes listed in Annex 1. This is due to the high dose rate at the skin surface of the patient in the proximity of the implant.

No activity limit is necessary for shielded iodine-125 or palladium-103 plaques or applicators.

Radionuclides in Unsealed Forms

Indium-111

The ambient dose equivalent rate at 1 metre from a patient containing 400 MBq of indium-111 is approximately 25 $\mu\text{Sv}/\text{hour}$ (Greaves and Tindale 1999).

Iodine-131

The maximum activity of iodine-131 in unsealed forms at which a patient may be treated as an outpatient is 600 MBq in these *Recommendations*. The main determining factor in this recommendation was the external dose rate, but potential contamination from excreted activity was also considered. A residual patient activity of 600 MBq of iodine-131 results in an ambient dose equivalent rate in the range 25 - 40 $\mu\text{Sv}/\text{hour}$ at 1 metre, taking into account the shielding provided by the patient's body. The more restrictive criterion of 25 $\mu\text{Sv}/\text{hour}$ at 1 metre is included in these *Recommendations*. The maximum discharge activity for iodine-131 of 600 MBq is unchanged from the previous 1983 *Recommendations*.

The European Commission, Radiation Protection 97, *Radiation Protection following Iodine-131 therapy (exposures due to out-patients or discharged in-patients)*, notes that within the European Union maximum levels for patient discharge range from 95 MBq to 800 MBq of iodine-131, but that in most Member States the discharge level is set at between 400 MBq and 600 MBq. The US Regulatory Guide 8.39, *Release of Patients Administered Radioactive Materials*, allows a default patient release at 1,200 MBq of iodine-131, but under the constraint that the effective dose to any other individual from the discharged patient is not likely to exceed 5 mSv, which is considerably less stringent than the public exposure limit of 1 mSv adopted in these *Recommendations*.

Rhenium-188

The ambient dose equivalent rate at 1 metre from a patient containing 4,000 MBq of rhenium-188 is approximately 25 $\mu\text{Sv}/\text{hour}$ (Fox 2002). In addition, because of the high energy beta emission, the potential contamination from excreted activity needs to be considered. Where excretable forms are administered, the time for discharge of incontinent patients to non-controlled premises should take into account the 17 hour physical half-life of this radionuclide.

Samarium-153

The reported ambient dose equivalent rate at 1 metre from patients 1-2 hours after the administration of 3,700 MBq of samarium-153-EDTMP is 20-30 $\mu\text{Sv}/\text{hour}$ (Eary et al. 1993). This, taken together with the further recommendation that the patient should not be discharged until one, or preferably two, urinary voids have occurred is consistent with a recommended maximum discharge activity of 4,000 MBq.

Beta Emitters (Phosphorus-32, Yttrium-90 and Strontium-89)

External dose rate limits are not applicable to these radionuclides when they remain within the patient's body. There is minimal external dose rate from the activities normally administered because the beta radiation is absorbed within the patient's body tissue. The small external dose rate that does exist in some cases is chiefly from bremsstrahlung radiation.

The major concern is from the excreted activity. The activity restrictions for discharge in respect of urinary excretion and for incontinent patients have been listed in the Notes in Annex 2. These Notes do not apply to radiopharmaceutical forms that are insoluble or are totally retained in the body. The recommended maximum discharge activity for phosphorus-32 has been retained at 1,200 MBq, but the maximum discharge activity for yttrium-90 has been increased from 1,200 MBq to 4,000 MBq in these *Recommendations*. It has been shown that the ambient dose equivalent rate at 1 metre from a patient containing 4,400 MBq of yttrium-90, when mostly concentrated in the abdominal organs, is approximately 5 $\mu\text{Sv}/\text{hour}$ (Smart 2002).

The recommended maximum discharge activity of 300 MBq for strontium-89 is consistent with the relatively long physical and biological half-life of this radionuclide, and should impose no practical restrictions since the administered doses are generally less than this.

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Annex 4

Health Effects of Ionizing Radiation and Standards for Control of Exposure

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

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

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

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

There is evidence that a dose accumulated over a long period carries less risk than the same dose received over a short period. Except for accidents and medical exposures, doses are not normally received over short periods, so that it is appropriate in determining standards for the control of exposure to use a risk factor that takes this into account. While not well quantified, a reduction of

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

the high-dose risk factor by a factor of two has been adopted internationally, so that for radiation protection purposes the risk of radiation-induced fatal cancer (the risk factor) is taken to be about 1 in 20,000 per millisievert of dose for the population as a whole.

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

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

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

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

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

Limit on effective dose*

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

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

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

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

Annual limit on equivalent dose*

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

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

In the case of occupational exposure during pregnancy, the general principle is that the embryo or fetus should be afforded the same level of protection as is required for a member of the public. For medical workers, the ICRP recommends that there should be a reasonable assurance that fetal dose can be kept below 1 mGy[‡] during the course of the pregnancy. This guidance may be generalised to cover all occupationally exposed pregnant workers by keeping the fetal dose below 1 mSv. A full explanation of radiation protection principles and of the recommended standards for Australia is given in ARPANSA/NOHSC Radiation Protection Series 1: *Recommendations for limiting exposure to ionizing radiation (1995)* and *National standard for limiting occupational exposure to ionizing radiation* (both republished in 2002).

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

Annex 5

Radiation Protection Authorities

Where advice or assistance is required from the relevant radiation protection authority, it may be obtained from the following officers (refer www.arpansa.gov.au for updates):

COMMONWEALTH, STATE / TERRITORY	CONTACT
Commonwealth	Director, Regulatory Branch ARPANSA PO Box 655 Tel: (02) 9545 8333 Miranda NSW 1490 Fax: (02) 9545 8348 Email: arpansa@health.gov.au
New South Wales	Director, Radiation Control Section Environment Protection Authority P.O. Box A290 Tel: (02) 9995 5000 Sydney South NSW 1232 Fax: (02) 9995 6603 Email: radiation@epa.nsw.gov.au
Queensland	Director, Radiation Health Department of Health 450 Gregory Terrace Tel: (07) 3406 8000 Fortitude Valley QLD 4006 Fax: (07) 3406 8030 Email: radiation_health@health.qld.gov.au
South Australia	Manager, Radiation Protection Branch Environment Protection Authority PO Box 721 Tel: (08) 8130 0700 Kent Town SA 5071 Fax: (08) 8130 0777 Email: radiationprotection.branch@state.sa.gov.au
Tasmania	Senior Health Physicist Department of Health & Human Services GPO Box 125B Tel: (03) 6222 7256 Hobart TAS 7001 Fax: (03) 6222 7257 Email: health.physics@dhhs.tas.gov.au
Victoria	Manager, Radiation Safety Unit Department of Human Services GPO Box 4057 Tel: (03) 9637 4167 Melbourne VIC 3001 Fax: (03) 9637 4508 Email: radiation.safety@dhs.vic.gov.au
Western Australia	Secretary Radiological Council Locked Bag 2006 Tel: (08) 9346 2260 Nedlands WA 6009 Fax: (08) 9381 1423 Email: radiation.health@health.wa.gov.au
Australian Capital Territory	Director, Radiation Safety Section Department of Health, Housing and Community Care GPO Box 825 Tel: (02) 6207 6946 Canberra ACT 2601 Fax: (02) 6207 6966 Email: radiation.safety@act.gov.au
Northern Territory	Manager, Radiation Health Radiation Health Section Department of Health & Community Services GPO Box 40596 Tel: (08) 8999 2939 Casuarina NT 0811 Fax: (08) 8999 2530 Email: envirohealth@nt.gov.au

Annex 6

ARPANSA Radiation Protection Series Publications

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

- RPS 1. Recommendations for Limiting Exposure to Ionizing Radiation (1995) and National Standard for Limiting Occupational Exposure to Ionizing Radiation (republished 2002)
- RPS 2. Code of Practice for the Safe Transport of Radioactive Material (2001)
- RPS 3. Radiation Protection Standard for Maximum Exposure Levels to Radiofrequency Fields – 3 kHz to 300 GHz (2002)
- RPS 4. Recommendations for the Discharge of Patients Undergoing Treatment with Radioactive Substances (2002)

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

RADIATION HEALTH SERIES

- RHS 2. Code of practice for the design of laboratories using radioactive substances for medical purposes (1980)
- RHS 3. Code of practice for the safe use of ionizing radiation in veterinary radiology: Parts 1 and 2 (1982)
- RHS 4. Code of practice for the safe use of radiation gauges (1982)
- RHS 8. Code of nursing practice for staff exposed to ionizing radiation (1984)
- RHS 9. Code of practice for protection against ionizing radiation emitted from X-ray analysis equipment (1984)
- RHS 10. Code of practice for safe use of ionizing radiation in veterinary radiology: part 3-radiotherapy (1984)
- RHS 11. Code of practice for the safe use of soil density and moisture gauges containing radioactive sources (1984)
- RHS 12. Administration of ionizing radiation to human subjects in medical research (1984)
- RHS 13. Code of practice for the disposal of radioactive wastes by the user (1985)
- RHS 14. Recommendations for minimising radiological hazards to patients (1985)
- RHS 15. Code of practice for the safe use of microwave diathermy units (1985)
- RHS 16. Code of practice for the safe use of short wave (radiofrequency) diathermy units (1985)
- RHS 17. Procedure for testing microwave leakage from microwave ovens (1985)

- RHS 18. Code of practice for the safe handling of corpses containing radioactive materials (1986)
- RHS 19. Code of practice for the safe use of ionizing radiation in secondary schools (1986)
- RHS 20. Code of practice for radiation protection in dentistry (1987)
- RHS 21. Revised statement on cabinet X-ray equipment for examination of letters, packages, baggage, freight and other articles for security, quality control and other purposes (1987)
- RHS 22. Statement on enclosed X-ray equipment for special applications (1987)
- RHS 23. Code of practice for the control and safe handling of radioactive sources used for therapeutic purposes (1988)
- RHS 24. Code of practice for the design and safe operation of non-medical irradiation facilities (1988)
- RHS 25. Recommendations for ionization chamber smoke detectors for commercial and industrial fire protection systems (1988)
- RHS 26. Policy on stable iodine prophylaxis following nuclear reactor accidents (1989)
- RHS 28. Code of practice for the safe use of sealed radioactive sources in bore-hole logging (1989)
- RHS 29. Occupational standard for exposure to ultraviolet radiation (1989)
- RHS 30. Interim guidelines on limits of exposure to 50/60Hz electric and magnetic fields (1989)
- RHS 31. Code of practice for the safe use of industrial radiography equipment (1989)
- RHS 32. Intervention in emergency situations involving radiation exposure (1990)
- RHS 34. Safety guidelines for magnetic resonance diagnostic facilities (1991)
- RHS 35. Code of practice for the near-surface disposal of radioactive waste in Australia (1992)
- RHS 36. Code of practice for the safe use of lasers in schools (1995)
- RHS 37. Code of practice for the safe use of lasers in the entertainment industry (1995)
- RHS 38. Recommended limits on radioactive contamination on surfaces in laboratories (1995)

ENVIRONMENT PROTECTION (NUCLEAR CODES) ACT SERIES

Code of Practice on the Management of Radioactive Wastes from the Mining and Milling of Radioactive Ores 1982

Code of Practice on Radiation Protection in the Mining and Milling of Radioactive Ores 1987

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