

Appendix XV

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

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1. Introduction

1.1 This code replaces the earlier one entitled *Code of practice for the control and safe handling of sealed radioactive sources used in radiation therapy (other than teletherapy)*, published by the National Health and Medical Research Council in October 1962. It covers sealed sources used either superficially, interstitially or in body cavities to give a prescribed radiation dose to tissue in a predetermined time as well as unsealed sources which are administered orally or parenterally for therapeutic purposes. It does not cover sealed sources contained in teletherapy equipments and unsealed sources used for tracer studies in nuclear medicine.

1.2 For the purposes of this code, a *sealed (radioactive) source* is defined as 'radioactive material sealed in a container or having a bonded cover, with the container or cover being strong enough to prevent contact with and dispersion of the radioactive material under the conditions of use and wear for which it was designed' (ARL/TR055-1983). Any other source is referred to as an *unsealed (radioactive) source*. However, when 'source' is used in the general sense, it includes sealed and unsealed sources.

1.3 This code is intended as a guide to safe practices in the use of sealed and unsealed radioactive sources and in the management of patients being treated with them. It is recommended that hospitals and medical practitioners draw up their own detailed working procedures based on the appropriate legislation, this code and the *Recommended radiation protection standards for individuals exposed to ionizing radiation* (NHMRC, 1980), and that they issue such procedures as instructions to staff. The preparation of detailed working procedures should be undertaken with the advice and assistance of the radiation safety officer at the hospital or clinic.

1.4 This code has been prepared to supplement the radiation safety legislation which is administered in each State and Territory by its health department or commission. Matters such as permissible levels of exposure, working conditions, personal monitoring and use and transport of radioactive materials are covered by such legislation. The requirements of the legislation in any State or Territory should be ascertained from the appropriate officers listed in annexe 1.

1.5 In this code, the term 'shall' indicates that the particular requirement is considered necessary to ensure protection against ionizing radiation. The term 'should' indicates a procedure or precaution which is to be applied, wherever practical, in the interest of minimising hazards.

1.6 The use in medical practice of both sealed and unsealed radioactive sources is well established. Such sources may emit beta (β) and/or gamma (γ) rays, and these produce biological changes in the irradiated tissues. These changes are of direct benefit to the health of the patient, but there is a risk of deleterious effects arising in persons other than the patient if they are exposed to radiation (see annexe 2 on the biological effects of ionizing radiation).

1.7 It is essential that the exposure of persons other than the patient be reduced to a minimum. But it is also necessary to maintain a balance between the risks of deleterious effects from radiation exposure and the practical advantages of using such sources for the benefit of patients. The choice of sources, treatment techniques and facilities available should take these considerations into account.

1.8 In the use of unsealed sources, not only is there a risk from external radiation exposure but there may also be a significant risk from contamination of facilities, personnel or the public by radioactive material occasioned by accidental spill or loss. This is particularly the case with the use of iodine-131 because of the very high activities that may be involved and of its excretion in body fluids. In the case of sealed sources, it should be noted that, because of the inherent hazard of radium-226 sources and the need to reduce the exposure of persons to a minimum, the Council recommended at its eighty-second session in October 1976 that the use of radium-226 for medical purposes should be discontinued as early as practicable and that it be replaced by those artificially produced radionuclides that provide a satisfactory substitute.

1.9 The use and movement of radioactive sources should be subject to control at all times. This includes control of the movements of patients undergoing treatment, and restriction on the movements of patients who have been discharged beyond the immediate control of the hospital or clinic. It is essential that all persons working with radioactive sources, or associated with the care of patients undergoing treatment with such sources, receive appropriate instruction. This instruction should cover the potential dangers of exposure to radiation and contamination, as well as methods of minimising or preventing these. The advice of the radiation safety officer in the hospital or clinic should be sought in all matters relating to radiation safety and protection. The role of the radiation safety officer is outlined in annexe 3. There will always be occasions when the radiation safety officer is unable to be present to ensure that radiation safety measures are carried out. At these times a person who is well

trained in the particular requirements should be nominated to take responsibility for these activities.

1.10 When applying safe practices to prevent radioactive contamination or to reduce radiation dose, an awareness of concomitant hazards such as infection risks from body fluids must be borne in mind. The relative risks of the various hazards should be kept in perspective; the radiation hazard should not necessarily be assumed to be the overriding one.

2. Handling and preparation of radioactive sources

2.1 General requirements relating to sealed and unsealed radioactive sources

2.1.1 Properly equipped areas shall be provided for preparing, sterilising and cleaning sealed radioactive sources and for the preparation and sterilisation, where necessary, of unsealed radioactive sources. These areas should be well ventilated and well illuminated. Prominent signs indicating the presence of radioactive sources shall be displayed in these areas, but should not be displayed when the sources are no longer present. The number of persons present in the areas shall be restricted. Drinking, eating, smoking and application of cosmetics shall be prohibited in the areas. Disposable tissues shall be used instead of handkerchiefs when unsealed sources are involved.

2.1.2 Care shall be taken to ensure that the operator does not do without protection simply because working without it seems to be the 'easy' way. With training a high degree of dexterity can be attained while still taking advantage of established methods of protection. The operator shall not alter the approved method of working without consulting with the radiation safety officer.

2.1.3 All manipulations with radioactive sources shall be carried out as quickly as possible, compatible with safe working practice.

2.1.4 The use of lead-rubber gloves for manipulating radioactive sources is generally not advised as they provide insignificant protection against γ -rays and handicap the operator.

2.1.5 The skill of the operator is an important factor in reducing the amount of radiation received when radioactive sources are handled. A novice shall therefore be trained with dummy sources or inactive material until a high degree of competence has been attained. Dummy sources shall be clearly identified as such.

2.1.6 Protective shields which protect as much of the body as practicable and are sufficient to reduce the transmitted radiation to acceptable levels, should be provided. Shield design should provide protection for the body and head, including the eyes. Where possible shielding of the fingers and hands from beta rays should also be provided.

2.1.7 Care shall be taken that equipment is well designed and operates efficiently in order to minimise radiation exposure in its use.

2.1.8 In certain procedures it may be desirable to use a roster system of duties in order to reduce individual doses, but this should not be a substitute for good radiation protection practices.

2.2 Additional requirements relating to sealed radioactive sources

2.2.1 Sealed sources shall not be picked up with the fingers. Since distance is an important factor in radiation protection, all such sources shall be manipulated with long forceps, special remote handling devices or other suitable instruments.

2.2.2 All equipment used for manipulating sealed sources and loaded appliances shall be designed to ensure safe and smooth operation and make it unnecessary for the hands to come close to the radioactive source at any time.

2.2.3 Appliances shall be so designed that sealed sources can be loaded easily and can be readily removed even when stuck by coagulable body fluids. Screw threads shall be carefully cut and be of optimum size and pitch to allow fast, jam-proof operation.

2.2.4 All steps possible in the preparation and assembly of an appliance shall be carried out before the insertion of any sealed source.

2.2.5 When sealed sources of similar appearance but of different activities are used, the permanent markings on them shall allow unambiguous identification.

2.2.6 Care shall be taken at all times to ensure that sealed radioactive sources are not damaged or defaced. The treatment face of a beta ray applicator is susceptible to damage; care shall be taken to avoid scratching it, by only using the handle or knob to pick up an applicator. Forceps and such like shall not come into contact with the treatment face of an applicator.

2.2.7 A sealed source shall not be heated in any way without an evaluation of the possibilities of rupture of the source or of leakage of its contents. Consideration shall be given to these possibilities before using any method of heat sterilisation. Radium-226, caesium-137 and strontium-90 sources shall not be heat sterilised but radon-222 sources may be (but see paragraph 1.8). Heat sterilisation shall only be performed with purpose designed, temperature controlled equipment. Sealed sources shall not be heat sterilised by flaming.

2.2.8 Chemical sterilisation may be used, but attention shall be paid to possible deleterious effects of some chemicals on sealed radioactive sources and on any attached threads.

2.2.9 Sealed radioactive sources shall be adequately shielded during sterilisation and until immediately before their insertion in the patient.

2.3 Additional requirements relating to unsealed radioactive sources

2.3.1 Remote handling devices shall be used, such as long forceps, for handling containers with radioactive solutions. Pipetting by mouth shall be prohibited, and bulb or syringe operated units substituted.

2.3.2 The operator shall wear disposable gloves and gowns to reduce the risk of contamination.

2.3.3 Prior to any utilisation the unsealed source shall be checked regarding its nature, activity and expiry date to ensure that the correct material is administered to the patient.

2.3.4 Care shall be taken at all times to ensure that the vial holding an unsealed source is not accidentally damaged. For this purpose packages and internal containers should be inspected for damage and monitored for contamination as a package is opened.

2.3.5 Preparations for oral administration shall be fit for consumption and those for parenteral use—by injection either intravenously or into a body cavity—shall be sterile and prepared to the appropriate Pharmacopoeia specifications using the *Code of good manufacturing practice for therapeutic goods*. Steps shall be taken to maintain that status of adequacy and to avoid any contamination of the contents in its container. The clinical practice adopted for administration of unsealed sources to a patient shall take into account the radiation protection of personnel and the potential for contamination of the environment at the place of administration. If it is necessary to breach the sterile status of a source, as in the redispensing of part of a consigned unit, the dispensed source shall be sterilised prior to injection into the patient. For this unusual circumstance the radiation safety officer shall be informed prior to any attempt at

sterilisation so that proper and appropriate measures are taken to avoid possible contamination and subsequent isolation of expensive sterilising equipment.

3. Application of sealed sources and administration of unsealed sources

3.1 Records of radioactive sources used on patients

3.1.1 A written record shall be kept giving details of the radioactive sources used on each patient. This record shall include the activity, batch number and expiry date of the source, the date and time of application or administration of the source, the anticipated time when either the hazard from the patient becomes acceptably low for sealed sources and permanently implanted sealed sources or when non-permanently implanted sealed sources are to be removed and, finally, information on the region of the body being treated.

3.1.2 Standard methods of patient identification shall be employed immediately prior to administration of radioactive sources to ensure that the correct dose is given to the correct patient.

3.2 Use of sealed radioactive sources

3.2.1 The principles of working speed, shielding and remote handling shall be incorporated in both equipment and techniques used in the administration of sealed sources to a patient.

3.2.2 Where practicable 'after-loading' techniques shall be used.

3.2.3 When a new technical procedure is to be undertaken for the first time a trial run with dummy sources should be undertaken whenever practicable.

3.2.4 Immediately prior to the use of sealed sources on a patient the type, activity and nature of the sources shall be confirmed.

3.2.5 At times it may be impracticable to provide shielding protection and in such circumstances it becomes essential to make best possible use of distance and speed of working.

3.2.6 With the exception of procedures such as the application of beta ray applicators the radiation safety officer, or the nominated responsible officer, shall be present at the time of administration to assist with the monitoring, accounting of sources, checking the surrounding area when the procedure has been completed and ensuring that radiation safety procedures are appropriate.

3.2.7 Any prepared sources which are not used for treatment shall be returned promptly to the safe and recorded by the custodian (see also paragraphs 9.2 and 11.1).

3.3 Use of unsealed radioactive resources

3.3.1 The principles of working speed, shielding and remote handling, together with protection from contamination (see paragraphs 2.1, 2.3.1 and 2.3.2) shall be incorporated in both equipment and techniques utilised in the administration of an unsealed source to a patient.

3.3.2 When a new technical procedure is to be undertaken for the first time a trial run with inactive material should be undertaken; for example, it may be appropriate for a patient to practice with water before oral administration of a radionuclide.

3.3.3 In addition to normal patient care, basic protection against contamination of the patient or the environment consists essentially of an impervious layer such as a sheet of plastic, covered by a layer of absorbent material such as paper. This can be used as a bib for oral administration or be placed under the arm at the time of injection. Similar protection should be provided on the floor in both circumstances. The radioactive source that is brought in its container to the patient for administration

should similarly be on a stainless steel tray, covered by plastic and absorbent paper, onto which may be placed a sterile dressing pack, if necessary. Note that the layers of plastic and absorbent material may be achieved by laboratory plastic with absorbent bench paper or by incontinence pads placed absorbent side up.

3.3.4 If material is to be injected into the patient and air has entered the syringe, the air shall be expelled into a sterile swab to avoid the risk of droplet contamination of the air in the room. The swab shall subsequently be disposed of as contaminated waste.

3.3.5 The radiation safety officer or the nominated responsible officer shall be present at the time of the administration to assist with monitoring, check avoidance of contamination, identify contamination if present, and arrange appropriate measures if the contaminated material cannot readily be stored pending ultimate disposal.

3.3.6 Any unused radioactive material shall be suitably labelled and returned promptly to the radioactive store and recorded by the custodian.

4. Precautions to be taken for patients undergoing treatment

4.1 General precautions

4.1.1 When a patient with sealed sources in situ or unsealed source in vivo is admitted to a ward, the radiation safety officer shall provide relevant information and instructions to the registered nurse-in-charge in the ward, especially in terms of the nature and duration of the hazard, in accordance with the requirements given in annexe E of the *Code of nursing practice for staff exposed to ionizing radiation (1984)*, (see annexe 4 to this code). Other requirements in the 'code of nursing practice' in regard to nursing procedures shall also be followed.

4.1.2 An assessment of external dose rate from a patient undergoing treatment with radioactive sources to nearby occupied areas shall be made by the radiation safety officer in order to select a room and bed for the patient that will minimise exposure of other patients and staff. Consideration should be given to the relative merits of using a single room with solid walls between the patient and occupied areas, and distancing from these areas. Consideration shall also be given to the possible exposure of patients located in adjoining rooms and on the floors above and below.

4.1.3 Mobile shields of adequate lead equivalence and size near the bed can often be of value in reducing radiation exposure and should be used whenever practicable, but the advice of the radiation safety officer should be sought in this regard.

4.1.4 In attending patients, staff shall work at the maximum practical distance from sources of radiation. Remotely operated after-loading sources shall be withdrawn from the patient during these periods and reinserted afterwards.

4.1.5 The bed of a patient undergoing treatment shall be marked with a warning sign indicating the presence of a radioactive source in the patient. Where remotely operated after-loading sources are in use a warning sign shall be placed on the door to the treatment area.

4.1.6 A patient undergoing treatment with radioactive sources shall carry an identification on his or her person, giving the name and activity of the radioisotope and the date of application. If the patient is to be discharged whilst still undergoing treatment with sources, the name and telephone number of the physician to be called in an emergency shall be included (see also paragraph 6.6).

4.1.7 While a patient is undergoing treatment as an outpatient to the hospital or clinic he or she shall be isolated for the duration of the treatment, kept under observation and any movement of the patient shall be restricted within the premises pending discharge.

4.2 *Movement of a patient within the hospital or clinic*

4.2.1 If a patient is to leave the ward during treatment, the following procedures shall be adopted:

- the radiation safety officer shall be informed and his or her instructions followed;
- the person in charge of the department to receive the patient shall be informed of the hazard and of the movement;
- the patient shall be escorted by a staff member competent to ensure that any radiation risk or risk of contamination presented by the patient's activities outside the ward is minimised;
- where a risk of loss or dislodgment of a sealed source occurs, checks shall be made when a patient leaves and re-enters a ward to ensure that the sealed source complement or array is intact.

4.2.2 When a patient with gamma emitting sources in situ is moved within the hospital or clinic on a trolley or a wheelchair, the trolley or wheelchair shall be moved so that the sources are as far from the attendant as practicable. A suitable sign, indicating the presence of radioactive sources, shall be displayed on the trolley or wheelchair whilst occupied by the patient.

4.2.3 When the movement of a patient undergoing treatment with sources necessitates the use of a lift an exclusive lift shall be used.

4.3 *Visitors to patients*

4.3.1 Attention should be given to restricting the time visitors spend in the vicinity of patients undergoing treatment. Visitors shall be instructed to maintain the maximum practicable distance from the patient.

4.3.2 In general, women of reproductive capacity and children should not be permitted to visit patients undergoing treatment but, where their visiting is permitted, adherence to time and distance constraints shall be mandatory.

4.4 *Additional precautions for patients with sealed sources in situ*

4.4.1 In general, a single room with solid walls between the patient and other occupied areas should be used to minimise exposure of other patients and staff (see also 4.1.2). In addition, the door to the room shall be marked with a radiation warning sign to indicate that a radiation hazard exists. If possible the sign should direct visitors to seek advice from the ward staff before entering, provide basic information on the type of hazard, list any special restrictions or conditions and indicate names and contact telephone numbers for radiation personnel.

4.4.2 If it is impossible to use a single room the bed occupied by a patient being treated with radioactive sources should be located in a less frequented part of the ward, with solid walls between the patient and occupied areas; a mobile barrier should be used to shield the rest of the ward. When two or more patients are being treated beds should be grouped together rather than be distributed throughout a ward.

4.4.3 A patient with sealed sources in situ shall have his or her bathing and toilet arrangements clearly defined.

4.4.4 While any sealed source is in or on the patient a suitable radiation shielded container for the source and a pair of forceps shall be readily available at all times, close to the bed. A lock and key should be available to secure the container.

4.4.5 All dressings, bed linen and bed pans from a patient with sealed sources in situ shall be checked before disposal in order to guard against loss of sources. This check shall be made by a suitably trained person using a radiation monitor.

4.4.6 Specific instructions written by the radiation safety officer covering action to be taken in the event of suspected loss of a sealed source shall be kept in the ward where the patient is located. These instructions should cover the following:

- immediate action to prevent movement of any related material such as bed linen, bed pans, clothing and so on;
- notification of the loss or suspected loss to the radiation safety officer for the purpose of supervising the search procedures; and
- follow-up reporting of the incident and its outcome.

4.5 Additional precautions for patients with unsealed sources in vivo

4.5.1 In general a single room with solid walls where an external radiation hazard exists should be used to minimise exposure to other patients and staff. Where relevant, the room should be equipped with its own shower and toilet facilities. Because of possible contamination this room shall be easy to clean, with its walls and floor having smooth impermeable surfaces. In addition, the door to the room shall be marked with a radiation warning sign to indicate that a radiation hazard exists. If possible the sign should direct visitors to seek advice from the ward staff before entering, provide basic information on the type of hazard, list any special restrictions or conditions and indicate names and contact telephone numbers for radiation personnel.

4.5.2 If a single room is not available a patient treated with an unsealed source should have the area of movement restricted and bathing and toilet arrangements clearly defined. Additional spatial and/or shielding arrangements will be necessary for some therapy doses. The recommendations of the radiation safety officer shall be followed in such cases.

4.5.3 Under certain circumstances, when there is negligible external hazard and very small contamination hazard, the patient may be housed as an ordinary patient after consultation with the radiation safety officer.

4.5.4 When a patient is not incapacitated, and where it is relevant, use of a special toilet connected to delay tanks, or of a normal toilet which has been reserved solely for that patient's use during treatment, shall be made in accordance with the recommendations of the radiation safety officer. The toilet shall be monitored and decontaminated as necessary at the end of treatment.

4.5.5 Collecting contaminated urine or faeces is not recommended as this involves potential contamination problems and unnecessary staff exposures during handling. Where collection is necessary the transfer of all contaminated material to containers for disposal shall be carried out on metal or plastic trays large enough to contain the full volume of fluid and lined with absorbent material to prevent splashing. Containers for disposal shall remain in the vicinity of the patient and their subsequent transport and disposal should be under the supervision of the radiation safety officer.

4.5.6 Specific instructions written by the radiation safety officer covering action to be taken in the event of a spill of radioactive fluid shall be kept in the ward where the patient is located. These instructions should cover the following:

- immediate action to prevent spread of contamination, that is restriction of numbers of persons and their movements in the vicinity of the spill;
- notification of the spill to the radiation safety officer, for the purpose of supervising decontamination procedures;
- immediate action to commence personnel decontamination;
- decontamination of the area in the event of a minor spill;
- follow-up reporting of all spills to the radiation safety officer.

4.5.7 Staff attending the patient should be protected from the risk of contamination by wearing suitable disposable gloves and gowns. Suitable overshoes should also be available.

4.5.8 All attire, bed linen and utensils used by an inpatient treated with radioactive material in vivo shall be checked for contamination before removal from the room, in order to guard against exposure of personnel. This check shall be made by a suitably trained person using a radiation monitor.

5. Removing sealed sources from the patient

5.1 Sealed sources and loaded appliances removed from a patient shall be placed immediately in the radiation shielded container referred to in paragraph 4.4.4 and the precautions of paragraphs 2.1.2, and 2.1.8 to 2.2.2 inclusive, and 2.2.6 shall apply.

5.2 Sealed sources dislodged or removed prematurely from a patient shall be placed immediately in the radiation shielded container referred to in paragraph 4.4.4. Such sources shall be checked against the record made at the time of application of the sources to the patient and the matter reported as soon as possible to the medical practitioner in charge of the treatment or appointed deputy and the radiation safety officer.

5.3 When a loaded appliance is removed from a patient it shall be inspected immediately in case a part has become detached. The patient shall then be monitored with a suitable radiation monitor to ensure all sources have been removed.

5.4 When transferring sealed sources and loaded appliances to the preparation area after removal from a patient, the precautions of paragraphs 2.1.1 to 2.2.2 inclusive, and 12.1 shall apply.

5.5 Precautions shall be taken during cleaning and sterilising of sealed sources to prevent damage or loss. During these procedures the sources shall be adequately shielded (see also paragraphs 2.2.6 to 2.2.9 inclusive). After the sources have been sterilised and accounted for, they shall be stored in accordance with section 11.

6. Discharge of a patient with sources in situ

6.1 A patient shall not be discharged from the hospital or clinic while being treated with long-lived sealed sources such as radium-226, cobalt-60, tantalum-182, caesium-137 or iridium-192.

6.2 The decision to allow a patient with radioactive sources in situ to leave the hospital or clinic shall be the medical responsibility of the medical practitioner in charge of the treatment or an appointed deputy. The radiation protection responsibility for such a decision shall lie with the radiation safety officer.

6.3 Maximum activities of radionuclides at which patients may be discharged from hospital are stated in *Recommendations relating to the discharge of patients undergoing treatment with radioactive substances (1983)* (see annexe 5 to this code).

6.4 If the patient is to return home where a pregnant woman or young children dwell special consideration shall be given to the possible radiation risks to them.

6.5 If the patient is to be transferred to another hospital or nursing home the radiation safety officer shall appraise the situation and advise whether the transfer is appropriate so that the patient is only transferred if safety from radiation exposure is assured.

6.6 When a patient is to be discharged whilst still undergoing treatment with sources, the following action shall be taken:

- the patient's family physician shall be informed of the proposed discharge;
- the patient shall be instructed only to use public transport during treatment in accordance with the requirements given in annexe 5;
- the patient and/or guardian shall be given written and verbal instructions on precautions to be observed to reduce the doses received by other members of the family and by the general public. The patient shall be instructed to avoid close

proximity to children and pregnant women during radiation treatment. The patient and family should, however, be reassured against unwarranted fears of consequences from occasional brief contact with the patient. The instructions shall be in accordance with the ability of the patient and/or guardian to understand them; and

- the patient and/or guardian shall also be given written instructions on the precautions to be observed if a sealed radioactive source is lost or displaced.

6.7 The patient shall carry on his or her person a clear identification, giving the name and activity of the radioisotope and the date of administration. If the patient is being allowed home whilst being treated with sources the name and telephone number of the physician to be called in an emergency shall be included (see annexe 5). The radiation safety officer is to be advised of the situation by the physician.

6.8 When the patient lives in a remote area and sealed sources are to be removed by him or her, detailed written instructions for the removal, storage and return of the sources shall be given to the patient and/or a guardian. For the storage and return of the sources, the following procedures shall be adopted:

- Upon removal of the sources at specified time the sources or loaded appliances shall be placed in a strong container which is suitably identified. The container should be provided by the hospital or clinic.
- Any identification worn by the patient shall be removed at the same time as the sources and placed in the container.
- The container shall be securely locked and then stored away from occupied space in some inaccessible position so that children cannot obtain it. It shall be left in that position for a specified period, which should be not less than one month. Care should be taken that the container is not placed near undeveloped photographic materials.
- After the specified period the container and its contents should be returned, as instructed, to the hospital or clinic.

6.9 Any identification worn by the patient and not covered by paragraph 6.8 should be removed by the medical practitioner responsible for the treatment at the time when the precautions can be relaxed.

7. Emergency surgery

7.1 If after the administration of a radioactive source to a patient some complication or disease process arises necessitating surgery the consultant responsible for the administration of the source and the radiation safety officer shall discuss with the surgeon the probable exposure in theatre and methods of minimising it. Consideration shall be given to the removal of sealed sources from the patient before the procedure.

8. Death of a patient with sources in situ

8.1 Should a patient die with radioactive sources in situ the medical practitioner in charge of the treatment, or an appointed deputy, shall be notified at once in order that appropriate action may be taken for protection of personnel and for the recovery and safe handling of any recoverable sealed sources.

8.2 The radiation safety officer shall be notified also of the death in order to ensure compliance with the *Code of practice for the safe handling of corpses containing radioactive materials (1986)*.

8.3 Proper safeguards should be taken to ensure that the amount of radiation received by any person handling the body is minimal.

8.4 A post-mortem examination shall not be performed until all sealed sources in the body have been removed or accounted for, and appropriate radiation safety arrangements made for the person performing the post-mortem examination.

8.5 The body shall not be released for burial or cremation until all sealed radioactive sources have been accounted for.

9. Accountability of sources

9.1 In every hospital or clinic holding radioactive sources there shall be a custodian responsible for these sources. The custodian or deputy shall keep a permanent record of these sources. This record should include:

- the particular radionuclide in the source;
- the serial number or other identification of each source;
- the physical or chemical form of the radioactive substance;
- the date of receipt and the activity on that date;
- the location of each source in the safe or store;
- the date and manner of ultimate disposal from the establishment (see references 2, 6 and 9); and
- details relating to the use and/or administration of each source (see paragraphs 3.1.1 and 9.2).

9.2 In addition, the custodian or deputy shall keep a record of:

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

9.3 Sealed sources issued by the custodian shall be capable of being accounted for at all times.

9.4 The custodian of sealed sources shall take periodic inventories of all such sources at least every six months.

10. Suspected or actual loss of a sealed source or spill of unsealed material

10.1 If a source is suspected or known to be lost or stolen, all movement of associated material, particularly waste, shall cease and the appropriate authority shall be notified at once so that a search with radiation monitors may be made as soon as practicable.

10.2 If a spill of body fluid or excreta suspected of containing radioactive material occurs action as required in paragraph 4.5.6 shall be initiated.

10.3 If a source is lost or there has been a significant spill the statutory authority shall be notified.

10.4 If a lost sealed source is not recovered the loss shall be recorded.

11. Storage of sources

11.1 When not in use radioactive sources shall be kept in a fixed safe or store assigned for this purpose only. This safe or store shall be secure against tampering and so shielded that the radiation outside it is reduced to an acceptable level. The movement of sources to and from the safe or store shall be controlled by the radiation safety officer.

11.2 Notification of the safe or store, and instructions in the event of a fire, should be provided to the local fire service.

11.3 There shall be a prominent sign outside the safe to indicate the presence of sources, and there should be another on the outside of any store housing the safe or any sources or items containing radioactivity. Each sign shall have the radiation trefoil and words such as 'Caution. Store for radioactive substances' in black lettering on a yellow background.

11.4 Any safe or store used for sources should be sited as far from occupied areas as practicable, but close to or in a room designed for preparation of sources prior to use. The safe or store shall be readily accessible for transport of sources.

11.5 When a gas or vapour is likely to be emitted from a stored source the safe or store should be ventilated to the outside air in accordance with the requirements of the statutory authority.

11.6 Special requirements for the storage of sealed radioactive sources

11.6.1 The safe should be provided with a number of separate drawers or compartments, each of which incorporates protective material to reduce the radiation outside the drawer to an acceptable level. Each drawer or compartment shall be clearly labelled to indicate the contents, and its shielding capacity defined; for example, x MBq of Cs-137, or equivalent. Attention is drawn to the fact that wood and plastics deteriorate with prolonged exposure to ionizing radiation.

11.6.2 The protective shielding of the safe shall be labelled to indicate its material and thickness. Any lead used in shielding shall be encased in material of high melting point, such as steel.

11.7 Special requirements for the storage of unsealed radioactive sources

11.7.1 Adequate shielding shall be provided for the storage of gamma emitting sources. Sources emitting beta radiation only shall be stored in containers which are appropriately shielded, with due allowance for bremsstrahlung.

11.7.2 To minimise risks of contamination unsealed sources shall be stored in tightly closed vessels and under such circumstances that, should an accidental spill occur, it would be contained in the immediate vicinity. The store shall be constructed with walls and floor which are smooth and without joins or breaks so as to be relatively easy to decontaminate if necessary.

11.7.3 A store shall be provided for the temporary storage of contaminated linen and equipment and body fluids or excreta containing high levels of radioactivity. Such material shall be stored in the same manner as referred to in 11.7.2 for unsealed sources.

12. Transport of sources within a hospital or clinic

12.1 When radioactive sources are transported within an establishment they shall be placed in special containers which are carried securely on trolleys or are provided with long handles or straps. These special containers shall incorporate protective material such that the external radiation is reduced to acceptable levels. When used for transport of unsealed sources they shall be further protected by sufficient absorbent material inside an impervious container, so as to completely absorb all liquids in case of leakage or accidental damage. The container shall be labelled and have a secure lid.

12.2 All movement of radioactive sources shall be carried out expeditiously.

12.3 All movement of patients undergoing treatment with radioactive sources shall be in accordance with the requirements of paragraphs 4.2.

13. Routine testing of sealed sources

13.1 Sealed sources which are used on several patients shall be tested periodically for uniformity of distribution of radioactive material and tested at least once each year for leakage of radioactive material and for radioactive contamination of the external surfaces. Any unsatisfactory sources shall be removed from service, hermetically sealed in a suitable container which is appropriately labelled, and stored in accordance with section 11. For remotely controlled after-loading systems, the testing of applicators and transfer tubes for contamination will suffice.

14. Bibliography

1. Commonwealth Department of Health (1983) *Code of good manufacturing practice for therapeutic goods*, National Biological Standards Laboratory, Canberra (together with subsequent amendments and appendixes).
2. International Commission on Radiological Protection (1977) 'The handling, storage, use and disposal of unsealed radionuclides in hospital and medical research establishments', *Annals of the ICRP* 1, 2 (ICRP publication 25), Pergamon Press, Oxford.
3. International Commission on Radiological Protection (1982) 'Protection against ionizing radiation from external sources used in medicine', *Annals of the ICRP* 9, 1 (ICRP publication 33), Pergamon Press, Oxford.
4. National Council on Radiation Protection and Measurements (1970) *Precautions in the management of patients who have received therapeutic amounts of radionuclides*, NCRP report 37.
5. National Health and Medical Research Council (1981) *Recommended radiation protection standards for individuals exposed to ionising radiation*, AGPS, Canberra.
6. National Health and Medical Research Council (1980) *Code of practice for the design of laboratories using radioactive substances for medical purposes*, AGPS, Canberra.
7. National Health and Medical Research Council (1984) *Recommendations relating to the discharge of patients undergoing treatment with radioactive substances (1983)*, AGPS, Canberra.
8. National Health and Medical Research Council (1985) *Code of nursing practice for staff exposed to ionizing radiation (1984)*, AGPS, Canberra.
9. National Health and Medical Research Council (1986) *Code of practice for disposal of radioactive waste by the user (1985)*, AGPS, Canberra.
10. National Health and Medical Research Council (1987) *Code of practice for the safe handling of corpses containing radioactive materials (1986)*, AGPS, Canberra.
11. Standards Association of Australia (1986) *Safety in laboratories. Part 4: Ionizing radiations*, Australian Standard 2243.4—1986, Standards Association of Australia.
12. Swindon, T., Kennedy, K. N. and Elliott, G. (1983) *Glossary of terms recommended for use in radiation control legislation and associated codes of practice*, Australian Radiation Laboratory technical report ARL/TR055.

Annexe I

Statutory authorities

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

- 1. Australian Capital Territory**
Consultant, Radiation Safety
ACT Community and Health Services
GPO Box 825
CANBERRA ACT 2601
Telephone (062) 47 2899
Fax (062) 47 2851
- 2. New South Wales**
Officer-in-Charge
Radiation Health Services
Department of Health
PO Box 163
LIDCOMBE NSW 2141
Telephone (02) 646 0222
Fax (02) 646 0333
- 3. Northern Territory**
Director
Occupational and Environmental
Health Branch
Department of Health and
Community Services
GPO Box 1701
DARWIN NT 5794
Telephone (089) 80 2911
Fax (089) 41 0560
- 4. Queensland**
Director
Division of Health and
Medical Physics
Department of Health
535 Wickham Terrace
BRISBANE QLD 4000
Telephone (07) 224 5611
Fax (07) 839 5847
- 5. South Australia**
Senior Health Physicist
Occupational Health and
Radiation Control Branch
South Australian Health
Commission
GPO Box 1313
ADELAIDE SA 5001
Telephone (08) 226 6521
Fax (08) 232 0334
- 6. Tasmania**
Health Physicist
Division of Public Health
Department of Health Services
PO Box 191B
HOBART TAS 7001
Telephone (002) 30 6421
- 7. Victoria**
Chief Radiation Officer
Radiation Safety Section
Health Department Victoria
555 Collins Street
MELBOURNE VIC 3000
Telephone (03) 616 7777
Fax (03) 616 7147
- 8. Western Australia**
The Director
Radiation Health Branch
Health Department of Western
Australia
Verdun Street
NEDLANDS WA 6009
Telephone (09) 389 2713
Fax (09) 381 1423

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

Annexe 2

Biological effects of ionizing radiation and limits on exposure to such radiations

Note: This statement provides background information. Not all of it is relevant to this code.

Considerable knowledge has been gained, particularly during the past three decades, on the biological effects of ionizing radiation on humans. When such effects are manifested in the exposed individual they are referred to as somatic effects; when they arise in the descendants of the exposed individual, they are referred to as hereditary effects. It is important to recognise, however, that many biological effects may occur spontaneously or can be caused by ionizing radiation or by exposure to other agents and it is not always possible to determine the cause of an effect.

Humans have always been exposed to radiation from terrestrial sources, from cosmic radiation and from radionuclides deposited in the body. This natural background radiation varies from place to place, but generally results in individuals receiving about 2 millisievert (mSv)* per year on average, although there are a few places where the terrestrial levels are much higher. The levels of exposure are such that it is not possible to ascribe any of the ill effects in human specifically to natural background radiation. On the other hand, radiation induced effects have been observed in individuals who have been exposed to very large doses. It is from such doses that our knowledge of biological effects is derived.

Injury to tissue became evident in the past from a number of different sources. For example, many workers developed bone sarcoma as a result of using radium luminous compounds for painting dials on watches and instruments; some miners working in uranium mines developed lung cancer; some radiologists developed skin erythema and leukaemia because they did not use adequate protection; and there was a small excess of leukaemia and other malignant diseases above the normal incidence rates among survivors of the atomic bombs in Hiroshima and Nagasaki in Japan. In all these examples, and there are many more demonstrated radiation induced effects, the doses received by individuals were very large—many times greater than the doses arising from natural background radiation.

The effects arising from large radiation doses are well known. However, it has not been possible to obtain any correlation between radiation induced effects and small doses because of the low numbers of human cases available to provide adequate statistics. Accordingly, studies have been carried out to determine if there is any correlation between effects and dose delivered and dose rate in plants and animals. It has been shown that the incidence of many biological effects produced is related to the total dose delivered, whilst for other effects there appear to be threshold doses below which those effects may not occur. Whilst it is not possible to extrapolate the results of these studies to humans, they serve a very useful purpose in identifying possible dose—effect relationships.

The effects arising from exposure to ionizing radiation fall into two categories: stochastic and non-stochastic effects. Stochastic effects are those for which the probability of an effect, but not its severity, is regarded as a function of the dose to which the individual is exposed. It is considered that there is no threshold dose below which the probability of such an effect occurring is zero. On the other hand, non-stochastic effects are those for which the severity of the effect varies with the dose to which the individual is exposed. A threshold may exist, below which such an effect does not occur.

* The sievert is the unit used in radiation protection for dose equivalent and is equal to 100 rem. 1 mSv = 10^{-3} Sv; 10 mSv = 1 rem.

From the studies undertaken it is believed that the induction of malignancies, including leukaemia, is a stochastic effect of radiation. Such malignancies may not become manifest until many years after the radiation exposure. Mutagenic effects are also stochastic effects and may be propagated through the population for many generations. Defects arising from such mutations are more likely to become apparent in the first or second generation. A defect causing slight physical or functional impairment, and which may not even be detectable, will tend to continue in the descendants, whereas a severe defect will be rapidly eliminated by the early death of the zygote or of the individual carrying the defective gene. The risk of mutagenic effects arising will decrease with increasing age of the irradiated individuals due to their decreasing child expectancies with age.

Non-stochastic effects are specific to particular tissues; for example, non-malignant damage to the skin, cataract of the eye, gonadal cell damage leading to impaired fertility etc. For many of these, a minimum or threshold dose may be required for the effect to be manifest. If an individual receives a dose greatly in excess of the threshold, manifestation of the effect will occur in a relatively short period. However, if the dose is not greatly in excess of the threshold, many effects will be temporary and reversion to normal conditions usually occurs.

From our knowledge of biological effects arising from exposure to radiation it is possible to identify the risks of stochastic effects for the various organs and tissues of the body. These risks are derived from exposure of persons to very high doses and from studies on animals etc. As there is very little information on the effects of exposure to low doses it is cautiously assumed that risk is directly proportional to dose, right down to zero dose, and that there is no threshold below which these effects do not occur. These assumptions may lead to overestimates of the risks associated with exposure to low doses of radiation. Although the risks derived from such assumptions may be very small it is important that they are kept as low as reasonably achievable (referred to as the ALARA principle) and that there be a demonstrated net benefit for each exposure.

Radiation protection is concerned with the protection of individuals involved in practices which involve radiation exposure, as well as with the protection of members of the public. It recognises that many practices involving radiation exposure are necessary for the well-being of individuals and for the good of mankind, but the doses resulting from those practices must be minimised in accordance with the ALARA principle. Good radiation protection practice requires the setting of standards for occupational exposure. These are such that the risk of fatalities from radiation induced malignancies resulting from the average doses received in such practices is no greater than the risk of fatalities in other occupations that have high standards of safety. Radiation protection standards were prepared for the National Health and Medical Research Council (NHMRC) in 1980 for use in Australia and are based on the recommendations of the International Commission on Radiological Protection. The standards assume, for stochastic effects, a linear relationship between risk and dose and that there is no threshold below which effects do not occur. For non-stochastic effects the standards set a limit on the dose received, below which such effects would not be manifest in an organ. The limit to be used for an organ is the lower dose limit of that for stochastic effects and that derived for non-stochastic effects when that organ is the only one irradiated.

For purposes of radiation protection the limits given in the standards are specified in terms of annual dose equivalent limits. For whole body exposure the annual limit for radiation workers is 50 mSv (or 50 000 μ Sv). In certain circumstances it is possible that only partial exposure of the body occurs or that single organ exposure occurs. In these circumstances limits are prescribed so that the risks are the same as those for

uniform whole body exposure. Accordingly, higher dose limits are prescribed when only part of the body is exposed.

When exposure is from external sources only, the doses received can be determined by the use of personal monitors. As they record only the dose received at the point of wearing the dose to the whole body or to specific organs cannot be easily determined. However, if the monitor is worn on the body in the position most likely to receive the highest dose, and if the total of monitor doses for an individual in a year does not exceed 50 mSv, then the dose equivalent limits for the whole body and for the various organs will not be exceeded.

Although the standards prescribe dose limits on an annual basis it is desirable that doses do not exceed 1000 μ Sv per week (or 4000 μ Sv per four-weekly period). It will then become obvious during a year if there is any likelihood of the annual limits either being approached or exceeded.

Doses from natural background radiation and from undergoing radiological procedures (i.e. medical and dental X-ray examination, radiotherapy and nuclear medicine) are not to be included in determining occupational doses. Limits are not set for emergency or accidental exposures, but attempts must be made to assess the dose equivalents received as carefully and as quickly as possible so that remedial action can be taken.

The radiation protection standards do not make any special provisions for females of reproductive capacity. However, they state that when a pregnancy is confirmed (normally within two months) arrangements should be made to ensure that the woman works only under such conditions that it is most unlikely that doses received during the remainder of the pregnancy would exceed three-tenths of the pro-rata annual dose equivalent limits for occupationally exposed persons.

For members of the public the principal annual limit of effective dose equivalent is 1mSv, not including natural background radiation or radiation received as a patient undergoing radiological procedures. A subsidiary limit of 5 mSv in a year is permissible for some years provided that the average annual effective dose equivalent over a lifetime does not exceed 1mSv. The non-stochastic dose equivalent limit for the skin and the lens of the eye is 50mSv in a year.

References

International Commission on Radiological Protection (1977) 'Recommendations of the International Commission on Radiological Protection', *Annals of the ICRP* 1, 7 (ICRP publication 26), Pergamon Press, Oxford.

National Health and Medical Research Council (1981) *Recommended radiation protection standards for individuals exposed to ionising radiation* AGPS, Canberra.

Annexe 3

Role of a radiation safety officer

1. Every institution where radioactive materials are employed should appoint a radiation safety officer (RSO) who shall have training, qualifications and experience acceptable to the relevant statutory authority.
2. The role of the RSO is to oversee radiation safety where sources are used for treatment. This complements the role of the medical practitioner who is responsible for the treatment of the patient.
3. The RSO should specifically:
 - (a) document and issue, in the form of written notices and manuals, working procedures governing radiation hazards and safe working practices associated with the storage, handling and disposal of radioactive materials;
 - (b) educate and train relevant staff about general and specific radiation hazards. This should include practical tuition in procedures to avoid excessive exposure and contamination, the routine use of monitoring equipment, and practical methods of dealing with contamination;
 - (c) control the preparation and dispensing of radioactive materials and be responsible for ensuring that the activity and form of radioactive sources conform to prescription;
 - (d) carry out regular surveys so that he or she is properly aware of actual and potential radiation hazards arising from the use of radioactive sources. These should include surveys of areas, staff and handling procedures;
 - (e) carry out regular checks of radiation monitoring and dosimetry apparatus to ensure proper functioning and calibration;
 - (f) regularly review all aspects of radiation safety to ensure that radiation hazards are always reduced to an acceptable level;
 - (g) ensure that the patient is monitored after administration of the radioactive materials and that radioactive waste from the patient is monitored and controlled;
 - (h) document and issue in the form of notices, procedures to be followed in the event of a radiation emergency such as a spill or loss of radioactive material. In the event of such a spill or loss, he or she should take control of decontamination and monitoring procedures.

Annexe 4

Information and instruction to nurses in wards where patients are undergoing treatment with radioactive sources

Extracted from 'Code of nursing practice for staff exposed to ionizing radiation (1984)'.*

(The numbers refer to the notes which follow the pro forma.)

Patients receiving treatment with radioactive sources

<p>Patient's Name:⁽¹⁾ Hospital number: Radioactive source:⁽²⁾ Nature of hazard:⁽³⁾</p> <p>Instructions relating to patient</p> <p>Identification:⁽⁴⁾ Movement:⁽⁵⁾ Nursing:⁽⁶⁾ Hygiene:⁽⁷⁾ Visitors:⁽⁸⁾</p> <p>Instructions relating to control of radioactive source</p> <p>Body fluid:⁽⁹⁾ Linen, etc:⁽¹⁰⁾ Emergency:⁽¹¹⁾</p> <p>Relaxation of precautions⁽¹²⁾</p>
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Notes

1. *Patient's name*
Record name and other relevant details, in accordance with normal hospital practice.
2. *Radioactive source*
Record the name and activity of the radionuclide with date, time and method of administration of the radioactive source (e.g. Caesium 137, 7500 MBq, 22 March, 1983, 11.30 a.m., implantation or, Iodine-131, 4000 MBq, 22 March 1982, 11.30 a.m., oral administration).
3. *Nature of hazard*
For example:
 - from beta or gamma rays;
 - from inhalation of radioactive material e.g. iodine vapour;
 - from ingestion of radioactive material;
 - from surface contamination.

Display the above information on the warning sign attached to the bed.

* Amendments to this code may be issued from time to time and these should be consulted.

4. Identification

State the method of identifying the patient as containing a radioactive source and the person responsible for removing the identification when the radiation or any contamination hazard ceases.

5. Movement

Define restriction on patient movement as follows:

- restricted to bed;
- restricted to bed space;
- restricted to ward; or
- NO restriction.

6. Nursing

State any specific nursing procedures to be followed.

7. Hygiene

List the items (if any) to be reserved for the use of the particular patient, e.g. pans, urinals, sputum mugs, toilet bowls, cutlery, crockery, etc. Give a clear statement that the patient:

- is/is not permitted to use toilet;
- is/is not permitted to use shower;
- is/is not permitted to use bath.

8. Visitors

Give precise instructions concerning the permissible conditions under which visitors may be allowed (e.g. number of visitors, pregnant women, children, length of each visit and distance from patient).

9. Body fluid

List the body fluids (if any) which may be expected to be contaminated (e.g. saliva, blood, urine, faeces, exudate from wound, vomitus, sweat) and the method of collection and disposal of these fluids.

10. Linen etc.

List the items of linen, etc., which may be contaminated (e.g. personal linen and clothing, bed linen, gloves, gowns, aprons, dressings, paper tissues, etc.). Define the methods of collection and the arrangements for checking and disposal of such items.

11. Emergency

Give instructions for the procedures to be followed in the event of a spill of radioactive material and in the loss or suspected loss of a sealed source. These should include the name and telephone numbers (both day and after-hours) of the radiation safety officer and any other person to be notified.

12. Relaxation of precautions

Earliest date at which precautions may be relaxed, in whole or in part, should be stated. The earliest date for release of patient as far as possible radiation hazard is concerned should be defined.

Annexe 5

Recommendations relating to the discharge of patients undergoing treatment with radioactive substances (1983)

These recommendations relate to the conditions under which in-patients who are undergoing treatment with radioactive substances may be discharged from a hospital in order to return home. The conditions are presented for general guidance only: the requirements for individual patients should be assessed by the attending physician in collaboration with an experienced health physicist and having regard to the prevailing circumstances. The recommendations are based mainly on considerations of the external radiation from the patient and the need to reduce the exposure of other persons with whom contact may be made.

Patients being treated with the radionuclides shown in the table below may be discharged from hospital under the conditions subsequently stated.

Maximum activities of radionuclides at which patients may be discharged from hospital*

<i>Radionuclide</i>	<i>Activity in MBq</i>
^{198}Au	2000
^{131}I	600
^{125}I (sealed)	No limit
^{32}P	1200
^{222}Rn	800
^{90}Y	1200

* Amendments to these recommendations may be issued from time to time and should be consulted.

Note 1: A patient shall not be discharged from hospital if it seems likely that a sealed source may be lost or that spread of radioactive contamination may occur as a result of leakage from an unsealed source.

Note 2: In deriving the maximum activities shown in the table it is assumed that the time of travel by public transport will not exceed one hour. If it is known that a journey of longer duration is involved either the activity on leaving the hospital should be reduced in proportion or the patient should travel by means other than public transport.

Note 3: Patients should be given written and oral instructions to avoid close contact with other members of the household, especially children, young people and pregnant women. Where appropriate the importance of good personal hygiene in order to prevent the spread of contamination should also be stressed in these instructions.

Note 4: Patients should be instructed to remain at home and follow the instructions in note 3 until the specified date on which it is estimated that their retained activity will be one quarter of that given in the table.

Patients being treated with sealed sources of ^{226}Ra , ^{60}Co , ^{137}Cs or ^{192}Ir shall not be discharged from hospital until the sources have been removed from the patient. Where sealed sources remain in a patient on discharge from hospital (e.g. ^{198}Au , ^{222}Rn and ^{125}I), the possibility of these being dislodged from the patient should be discussed and appropriate action outlined.

References

1. *Precautions in the management of patients who have received therapeutic amounts of radionuclides*. NCRP report no. 37, Washington, DC, 1970.
2. *Code of practice for the protection of persons against ionising radiations arising from medical and dental use*. Her Majesty's Stationery Office, London, 1972.
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