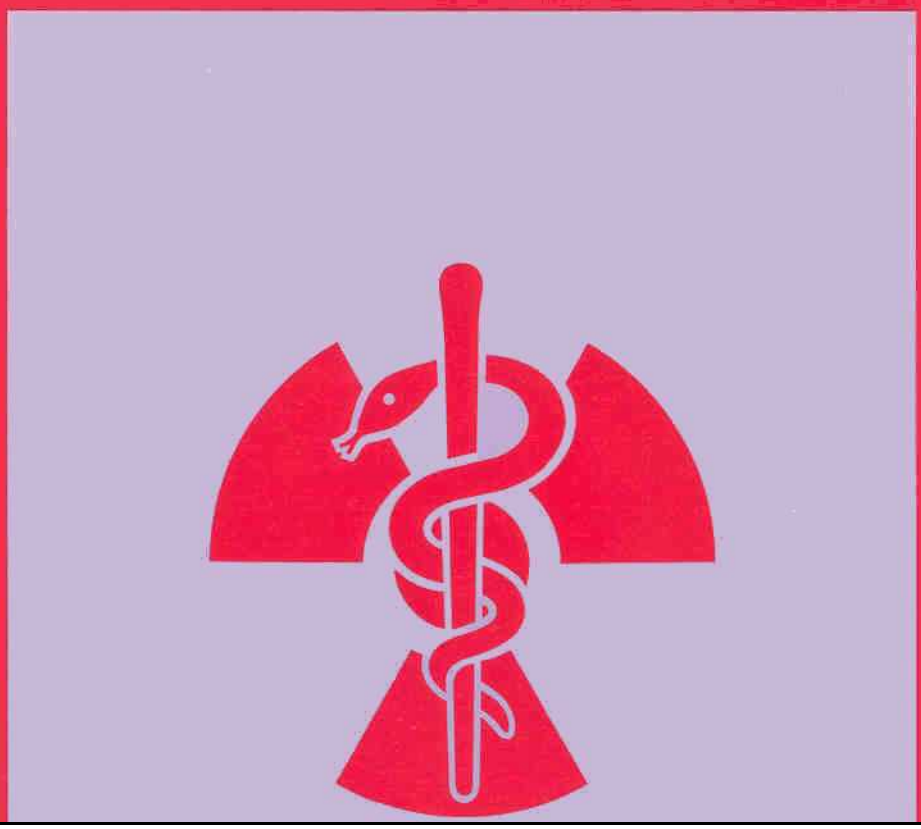
Code of practice for the design and safe operation of non-medical irradiation facilities (1988)



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NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

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Code of practice for the design and safe operation of non-medical irradiation facilities (1988)

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The objective of the National Health and Medical Research Council is to advise the Australian community on the achievement and maintenance of the highest practicable standards of individual and public health and to foster research in the interests of improving those standards.

Contents

1. Introduction

This code establishes requirements for the design and operation of irradiation facilities which use X-rays, electrons or gamma radiation for non-medical purposes such as the sterilisation of therapeutic goods.[1]

Non-medical irradiators may incorporate sealed sources of cobalt-60 or caesium-137, or incorporate machines such as linear accelerators designed to produce electron or X-ray beams.

2. General

2.1 Scope

The code is restricted to consideration of:

(a) irradiators incorporating the radioactive substances cobalt-60 or caesium137, as sealed sources, referred to as *sealed source irradiators*. This type of irradiator is further restricted to a controlled human access irradiator in which the sealed source is contained in a storage pool (usually containing water), and the sealed source is exposed within a radiation room that is maintained inaccessible during use by interlocked controls; and

(b) irradiators incorporating machine sources which produce electrically generated radiation, such as linear accelerators, referred to as *machine source irradiators*. This type of irradiator is further restricted to a controlled human access irradiator in which the radiation beam from the machine source is contained within a radiation room that is maintained inaccessible during use by interlocked controls. The radiation produced in a machine source irradiator is restricted to X-rays or electrons generated by machine sources operated at or below an energy level of 10 MeV.

In the future, should it be proposed that an existing or planned facility be used for the purpose of irradiating food for human consumption, this code of practice will need to be assessed to ensure it provides adequate guidance for that purpose.[2]

2.2 Purpose of code

The purpose of the code is to define all necessary criteria such that:

(a) exposure of workers and members of the public to ionizing radiation is controlled through the design of engineering safety features (barriers, interlocks, shields, etc.), compliance with approved administrative controls and appropriate radiation monitoring;

(b) exposure of workers and members of the public to non-ionizing radiation and noxious gases is controlled through the design of engineering safety features (shields, ventilation, etc.), compliance with approved administrative controls and appropriate monitoring; and

(c) environmental and facility contamination with radioactive substances is controlled through the design of engineering safety features (transport containers, etc.), compliance with approved administrative controls and appropriate radiation monitoring.

2.3 Health considerations

An absorbed dose to the whole body or critical organs of only a few gray may produce acute radiation syndrome with severe illness and possible death. The nature, severity and duration of these effects depend on, among other factors, the dose and type of ionizing radiation, rate of exposure, part of the body exposed, and individual sensitivity. It is essential that access to the radiation room of an irradiator is controlled so that under no circumstances are personnel accidentally exposed to primary radiation from the source.

Under normal operating conditions the exposure of personnel to secondary or scattered radiation from the source is controlled by the design of engineering safety features, administrative controls and radiation monitoring. These measures are required to ensure compliance with the requirements of the National Health and Medical Research Council.[3]

In irradiators, ozone and other noxious gases are produced by radiolysis. As these gases may be harmful to health, their nature and concentration need to be determined and effective measures taken to ensure that personnel are not exposed to concentrations exceeding the limits set by the relevant statutory authority.

Some components of machine source irradiators are capable of generating radiofrequency radiation. As this radiation may be harmful to health, effective measures need to be taken to ensure compliance with the requirements of the Australian Standard AS2772.[4]

The service and maintenance of machine source irradiators present additional circumstances for personnel to be exposed to potential radiation hazards. Effective measures are required to protect personnel from these hazards.

2.4 Radioactive contamination considerations

The use of large quantities of radioactive substances in sealed source irradiators requires the provision of adequate safeguards to protect the environment and facilities from contamination.

The potential exists for machine source irradiators to become contaminated from induced radioactivity. Effective measures need to be taken to ensure that beam energies cannot exceed any pre-determined maximum as a consequence of incorrect operator procedures, modifications to equipment or failure of components. The possibility of induced radioactivity caused by machine sources should be taken into consideration when planning repairs or service to equipment.

2.5 Nature of code

The possession and use of irradiating apparatus in Australia is subject to control under the relevant State and Territory radiation control legislation. The possession, use, transport and disposal of radioactive substances is subject to control under the same legislation. In a number of States the same legislation makes provision for the control of sources of potentially hazardous non-ionizing radiation (e.g. radiofrequency radiation).

Information on the requirements of the relevant radiation control legislation may be obtained from the appropriate statutory authority (annexe 2).

This code supplements the radiation control legislation referred to above.

2.6 Specialised meanings for 'shall' and 'should'

The words 'shall' and 'should', where used in this code, have specialised meanings. 'Shall' indicates that the particular requirement is necessary to ensure protection from radiation. 'Should' indicates a procedure or precaution which is to be applied, wherever practicable, in the interest' of reducing radiation risks.

2.7 Definitions - personnel

- *Authorised personnel* are those individuals authorised by the relevant statutory authority to perform a specific function such as periodic contamination testing, or installation, maintenance and service of the irradiator.
- An *operator* is a radiation worker given the responsibility by the user to operate and control access to an irradiator.
- A *radiation safety officer* is a person having appropriate, qualification and experience in radiation safety who is appointed to carry out the responsibilities of radiation safety officer as specified in this code.
- A *radiation worker* is a person who, in the course of his or her employment, may be exposed to ionizing radiation arising from his or her direct involvement with sources of such radiation.
- A *supplier* is the person or corporation, including any repacker, relabeller or importer who manufactures, assembles, processes or imports an irradiator, and who is responsible for the supply of the irradiator.
- A *user* is the person having administrative responsibility for use of a particular irradiation facility. This person shall be the owner or hirer of the facility or their agent or, if the facility is owned or hired by an institution or organisation, the agent of that body.

2.8 Dose limits

Dose limits are applied in operations involving ionizing radiation to ensure that the upper limits of the risks to health of exposed persons are appropriately small. Radiation protection standards have been published by the National Health and Medical Research Council in its *Recommended radiation protection standards for indiviiduals exposed to ionising radiation.*[3] The Council has recommended that these standards be used throughout Australia.

Background information on the biological effects of ionizing radiation and a summary of the dose limits given in these standards are given in annexe 1. Further advice on interpretation and application of the standards and dose limits is available from the relevant statutory authority.

3. Radiation sources

3.1 Sealed sources

3.1.1 General

For general sealed source requirements, refer to International Standard ISO 2919[5], 'Sealed radioactive sources – Classification'. In addition to the general requirements, the supplier and user shall consider the possible effects of fire, explosion, corrosion, and continuous use of the sealed source. Factors which should be considered are:

(a) consequences of failure of source integrity influenced by:
  • quantity of radioactive material contained in the sealed source;
  • radiotoxicity, leachability, and solubility; and
  • chemical and physical form of radioactive material;
(b) environment in which the source is stored, moved, and used; and
(c) protection afforded the sealed source by the irradiator.

3.1.2 Performance requirements and classification

3.1.2.1 Using the International Standard ISO 2919 sealed source classification system, sources used in irradiators shall have a minimum classification of either C53424 or E53424, and meet the bend test requirements specified in clause 3.1.2.2.

To improve sealed source corrosion resistance, all outer encapsulation components (including any weld filler material which may be utilised) shall meet the same material specification. Consideration shall be given to the selection of materials to reduce thermal fatigue of the source during irradiator operation.

All outer source capsule materials shall be compatible with the permanent pool components to reduce the possibility of corrosion (see clause 10.1.2).

3.1.2.2 Bend test classification requirement

Sealed sources used in irradiators shall have a minimum bend test classification of 5 based on the bend test procedures shown in clause 3.1.3, 'Sealed source bend test.'

Compliance with the test is determined by the ability of the sealed source to maintain its integrity after the test is performed, as defined in 5.1.4 of International Standard ISO 2919.

A source shall have complied with the bend test if the source, due to its flexibility, passes through the test rig while under test (the centre of the force cylinder passes through the centreline of the two support cylinders) and maintains its integrity.

3.1.3 Sealed source bend test

Bend tests shall apply for all sources having an L/D of 15 or more, where L = active length and D = minimum outer capsule diameter of the active length or the smallest cross-sectional dimension of non-circular sources.

Bend test classifications are based on applied static force, using the following test parameters:

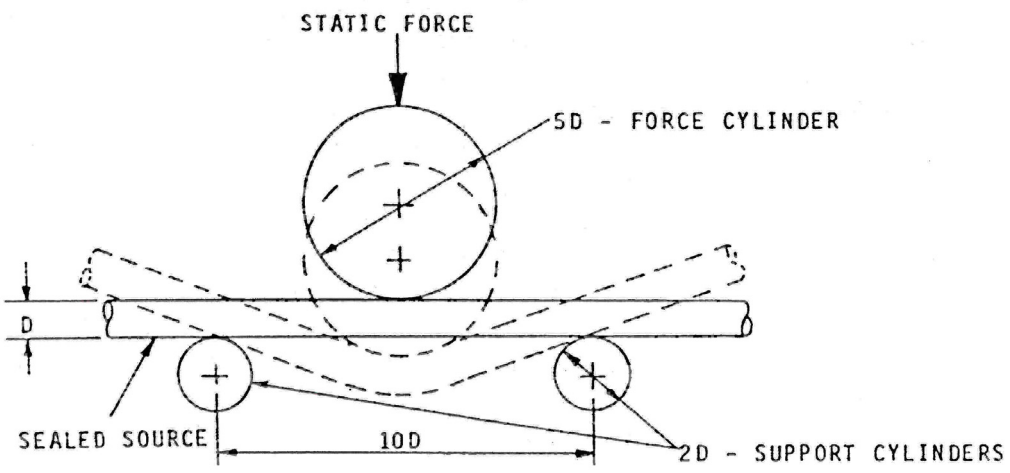
(a) all three cylinders shall not rotate and shall have longitudinal axes that are parallel to each other;

(b) the cylinders shall have smooth surfaces and shall be of sufficient length to accommodate the full contact surface of the capsule during the test procedure; and

(c) all cylinders are to be of a solid nature. Cylinder hardness should be ROCKWELL 'C' 50-55.

In applying the static force, care should be taken not to apply this force suddenly as this will increase the effective force. The applicable static force shall be applied at the most vulnerable part of the sealed source.

Figure 1. Bend test parameters



BEND TEST	CLASS						
	1	2	3	4	5	6	X
STATIC FORCE	NO TEST	100 N (10.2 kg.)	500 N (51 kg.)	1,000 N (102 kg.)	2,000 N (204 kg.)	4,000 N (408 kg.)	SPECIAL TEST

3.1.4 Certification and documentation

The source manufacturer or supplier shall maintain records relating to the sealed source(s) and provide this information to meet requirements such as those of licensing and transportation. The records shall include the following:

(a) model number and identification number of the source(s), the contained radionuclide, source activity, and date of measurement;.
(b) classification certificate;
(c) bend test certificate;
(d) leak test certificate;
(e) contamination test certificate;
(f) special form test certificate if required by the transport authorities; and
(g) any other documentation required by the relevant statutory authority.

3.1.5 Periodic contamination tests

Periodic contamination tests shall be conducted as described in section 17.

3.1.6 Removal of sources

For removal, transfer and disposal of sources and contaminated material see section 19.

3.2 Machine sources

3.2.1 Limitation of beam energy

The supplier shall provide information on the maximum beam energy which can result from malfunction or removal of components.

3.2.2 Control and display of operating parameters

Provision shall be made for the adjustment and display, at the control console, of operating parameters which determine the energy of the useful beam, the dose rate, exposure duration and any other parameters which influence the dose received by the product being irradiated.

Provision shall be made for making permanent records of relevant operating parameters, as designated by the appropriate statutory authority.

3.2.3 Control of ionizing radiation levels in vicinity of electrical components

Certain electrical components, such as klystrons, can emit ionizing radiation. Special attention must be paid to requirements for protective shielding of these components.

Provision shall be made to ensure that the ionizing radiation levels measured at 30 cm from accessible surfaces of panels near components such as klystrons do not exceed those specified in clause 7.3.

Where the components emitting the radiation are located in the radiation room and are subject to the, same interlock protection and other safety provisions as the machine source the shielding requirements may be relaxed (see clause 7.3.3).

3.2.4 Coupling of safety interlock circuits and radiation producing circuits

Radiation producing circuits shall include all circuits that, when sequentially or simultaneously activated, can create a radiation hazard; an example is the modulator activation circuits in linear accelerators.

The control system of a machine source irradiator shall couple in series the facility interlock circuits with the radiation producing circuits so that radiation cannot be produced until the interlock system has been completely dosed.

3.2.5 Limitation of radiofrequency fields

Provision shall be made to ensure that the radiofrequency exposure levels in accessible areas comply with the requirements of the Australian Standard AS2772.

3.2.6 Safety interlocks on panels and shields

All inspection panels and all removable shields shall be interlocked in compliance with the provisions of clause 8.7.

3.2.7 Safety interlocks for protection against electrical hazards

Interlocks shall be provided to protect personnel from electrical hazards such as high voltage power supplies and linear accelerator modulators.

3.2.8 Warning signs on Panels and shields and safety interlocks

All inspection panels, removable shields, and interlocks shall be posted with appropriate warning signs advising of their intended function, where this is pertinent, and of the hazards which might occur if they are removed.

Signs are to be durable and kept in a clean and readable condition. Signs that fade should be replaced.

4. Irradiator building

4.1 Design

The design of the building, or those parts of it which are essential for the establishment and maintenance of a safe radiation environment, shall:

(a) be such as to ensure the safe operation of the irradiator under normal circumstances for the design life of the structures. The design life shall be twice the projected operational life;

(b) for a sealed source irradiator, ensure that the safety integrity of the source and its shielding are not altered significantly as a consequence of a maximum credible accident;

(c) for a sealed source irradiator, be such that the risk of environmental contamination under all foreseeable circumstances is negligible;

(d) for a sealed source irradiator, ensure that fire resistant materials are used, wherever possible;

(e) for a machine source irradiator, ensure that the shielding design is based on the maximum radiation emission rate of the machine source as specified by the supplier.

4.2 Construction

The supplier shall ensure that the construction is in accord with the design intent.

4.3 Approval by relevant statutory authority

4.3.1 The shielding design and all radiation safety features shall have the written approval of the relevant statutory authority before construction commences.

4.3.2 The user shall arrange for the relevant statutory authority to be given prior notice of the projected completion date of a sealed source irradiator building in order that an inspection can be made prior to installation of the source(s).

5. Ionizing radiation measurements

5.1 General

Normally there are four types of radiation protection measurements required during installation and use of an irradiator:

(a) personal radiation monitoring (sections 13 and 14);

(b) surveys of the radiation shields (section 7);

(c) radiation checks during room entry (clause 8.1);

(d) contamination tests (sections 17 and 18).

Annexe 3 describes currently acceptable radiation measurement methods and instrument considerations.

5.2 Radiation surveys

Ionizing radiation surveys shall be carried out by an authorised person who has the knowledge and training necessary to select and use suitable survey instruments (see annexe 3).

5.3 Instrument calibration

The survey instrument(s) shall be calibrated at intervals not exceeding twelve months and before use following repair.

5.4 Survey report of radiation levels outside the radiation shields

The survey data shall be recorded in writing. The report shall indicate whether or not the irradiator is in compliance with this code. A copy of the survey report shall be retained by the user of the irradiator for inspection by the relevant statutory authority.

The survey report shall include the following information:

(a) identity of the irradiator by manufacturer, model, and serial number; (b) location of irradiator;

(c) type of radionuclide and calculated activity on survey date; or type of radiation and nominal energy if a machine source;

(d) date of survey;

(e) measured radiation levels outside the radiation shield under the source-in-use condition (section 7);

(f) measured radiation levels inside the radiation room under the fully shielded or de-energized condition (section 7);

(g) survey instrument identification by manufacturer, model and serial number;

(h) date of most recent instrument calibration;

(i) the correction factors, if used, to compensate for survey instrument variables and environmental conditions;

(j) the identity of the individual responsible for the survey report.

5.5 Contamination test report

The contamination test results shall be recorded in writing. The report shall indicate whether or not the irradiator is in compliance with this code. Contamination test reports shall be maintained by the user of the irradiator for inspection by the relevant statutory authority.

Copies of contamination test reports on tests which confirm the presence of contamination (section 17) shall be forwarded to the relevant statutory authority without delay.

Results shall be recorded using the unit becquerel and the report shall include the following information:

(a) identity of the irradiator by manufacturer, model, serial number, and type(s) of radioactive substance;
(b) location of irradiator;
(c) date of test;
(d) test sample collection method;
(e) measuring instrument identification by manufacturer, model and serial number;
(f) date of the most recent measuring instrument calibration;
(g) the correction factors, if used, to compensate for measuring instrument variables and environmental conditions;
(h) the conversion factor(s) used to convert from $\mu Gy\ h^{-1}$ or count rate to becquerels for the type(s) of radioactive material under test;
(i) measuring instrument reading of test sample;
(j) measuring instrument background reading;
(k) calculation of activity detected: (i-j) x h x g becquerel;
(l) evaluation of test results;
(m) action taken;
(n) the identity of the individual responsible for the test.

6. Supplier responsibilities

6.1 General

Responsibility for safe design of the irradiator interlock and control system lies with the manufacturer and devolves to the manufacturer's agent or supplier. Responsibility for installation in accord with the design lies with the contractor. The supplier should supervise the installation in order to determine that the design intent is realised during construction.

6.2 Particular requirements

The supplier shall ensure that:

(a) irradiators are supplied only to users who have been authorised in writing by the relevant statutory authority to possess such devices;
(b) irradiators supplied comply with the requirements of this code;
(c) operating instructions which include a general description of the irradiator and detailed operating procedures are supplied to the user;
(d) instructions for the periodic inspection and maintenance of the irradiator, including, in the case of sealed source irradiators, test procedures for contamination detection are supplied to the user;
(e) instructions specifying procedures to be followed in an emergency situation, which has caused or may cause a radiation hazard to any individual, are supplied to the user;
(f) copies of all drawings, operating and service manuals, radiation surveys, and other records held by the supplier relating to the irradiator and its source of radiation, are assembled and maintained in accordance with the requirements of the relevant statutory authority until such time that the irradiator has been decommissioned;
(g) services are available to maintain and repair the irradiator;
(h) prompt corrective action is taken in the case of emergencies relating to the irradiator and its source of radiation;
(i) on learning of a situation which could result in any breach of this code, the relevant statutory authority and all users of the particular type of irradiator are advised forthwith of the situation and the corrective action required;
(j) unwanted sealed sources, if a sealed source irradiator has been installed, may be returned to the supplier.

7. Maximum permissible radiation levels*

7.1 General

7.1.1 Instrumentation

For instrument requirements to measure radiation levels, refer to section 5 and annexe 3.

7.1.2 Measurement configuration

The air-kerma rates measured at 30 cm from the accessible surface of the radiation shield, or machine source, to the effective centre of the monitoring instrument shall be averaged over an area of not more than 100 square centimetres having no linear dimension greater than 20 cm.

* The shielding requirements in clauses 7.2 and 7.3 are stated in a manner commonly used in building specifications and recognise minor variations inherent in construction. Compliance with these clauses will result in radiation doses well within the limits referred to in clause 2.8 and be consistent with maintaining closes as low as reasonably achievable.

7.2 Radiation levels outside radiation shields

7.2.1 Unrestricted areas

All irradiators shall have sufficient shielding such that the air-kerma rate from leakage radiation measured at 30 cm from any accessible surface of the radiation shield shall not exceed an average of 0.5 microgray per hour (μGy h^{-1}). Air-kerma rates of up to 4 μGy h^{-1} averaged over any 100 square centimetre area are allowed, providing these contributions do not raise the average air-kerma rate at 30 cm to more than 0.5 μGy h^{-1} over a one metre square area parallel to the accessible surface of the radiation shield.

7.2.2 Restricted areas

All irradiators shall have sufficient shielding such that the air-kerma rate from leakage radiation measured at 30 cm from any accessible surface of the radiation shield shall not exceed an average of 25 μGy h^{-1}. Air-kerma rates of up to 200 μGy h^{-1} averaged over any 100 square centimetre area are allowed, providing these contributions do not raise the average air-kerma rate at 30 cm to more than 25 μGy h^{-1} over a one metre square area parallel to the accessible surface of the radiation shield.

Special cases may arise where, in normally restricted areas, the air-kerma rates specified above may be exceeded, for example a roof area occupied only for occasional maintenance or a manipulator port well above head height. Prior written approval must be obtained from the relevant statutory authority for shielding which will result in air kerma rates exceeding the specified values.

7.2.3 Irradiator control console

The radiation levels in the vicinity of the irradiator control console shall not exceed the radiation levels specified in clause 7.2.1 of this code.

7.3 Radiation levels outside accessible surfaces of machine sources

Part of the machine source will be located within the radiation room. The remainder of the machine source may be located in restricted or unrestricted areas.

7.3.1 Unrestricted areas

All machine sources shall have sufficient shielding such that, at every rating specified by the manufacturer, the air-kerma rate from leakage radiation measured at 30 cm from the accessible surface of the machine source shall not exceed an average of 0.5 μGy h^{-1}. Air-kerma rates of up to 4 μGy h^{-1} averaged over any 100 square centimetre area are allowed, providing these contributions do not raise the average air-kerma rate at 30 cm to more than 0.5 μGy h^{-1} over a one square metre area parallel to the accessible surface of the machine source.

7.3.2 Restricted areas

All machine sources shall have sufficient shielding such that, at every rating specified by the manufacturer, the air-kerma rate from leakage radiation measured at 30 cm from the accessible surface of the machine source shall not exceed an average of 25 μGy h^{-1}. Exposure rates up to 200 μGy h^{-1} averaged over any 100 square centimetre area are allowed, providing these contributions do

not raise the average air-kerma rate to more than 25 μGy h^{-1} over a one square metre area parallel to the accessible surface of the shield.

7.3.3 Within radiation room

Where the surfaces are located in the radiation room and are subject to the same interlock protection and other safety provisions as the machine source, and will never be accessible for servicing with the machine source energized, the shielding requirements of clause 7.3.2 may be relaxed.

8. Operational safety features

This section covers radiation safety features which are not specifically covered in other parts of this code.

It shall not be possible to resume irradiator operations after any return of the source to the fully shielded or de-energized condition without complying with the requirements of section 8.1.

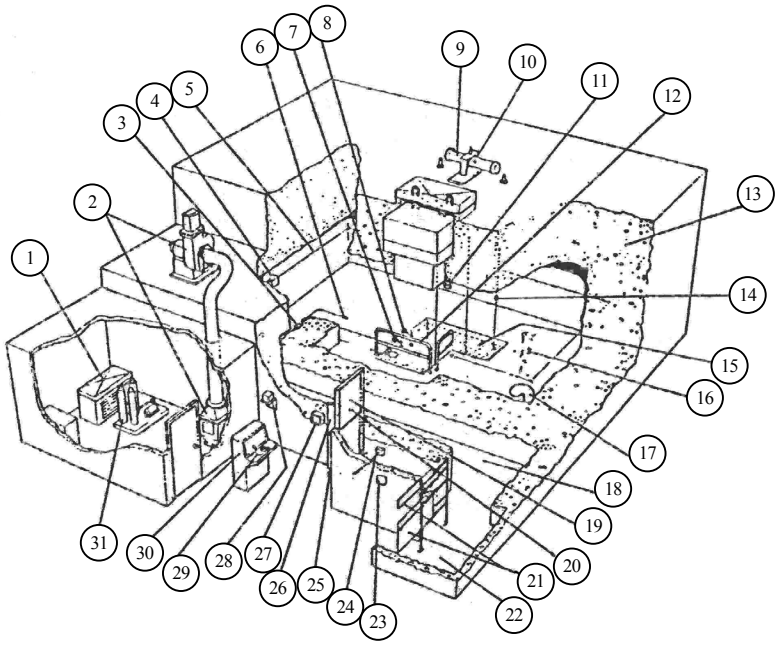
Safety features for a typical sealed source irradiator are shown in Figure 2.

Safety features shown in figure 2, except those numbered 1, 7, 8, 9, 10, 11, 12, 14, 15, 20, 23, 24, 31 are also required for a typical machine source irradiator.

Figure 2. Typical Safety features for sealed source irradiators

Key for figure 2 with reference to the pertinent part of this code

1. Water cooler 10.4
2. Radiation room ventilation system 8.23.2
3. Radiation room monitor probe 8.4
4. Safety delay timer alarms 8.9
5. Emergency stop device 8.11
6. Heat and smoke sensors 8.22.2
7. Water level control – normal 9.3.3
8. Water level control – abnormal (low) 9.3.3
9. Source hoist 8.15
10. 'Source down' switch 8.15
11. Roof plug interlock switch(es) 8.17
12. Pool guard 8.21
13. Radiation room shield – concrete 9.1
14. 'Source up' switch 8.16.1
15. Source storage pool 9.3
16. Safety delay timer keyswitch 8.9
17. Exhaust air intake 8.23.2
18. Personnel and product entry/exit maze 8.8 & 8.13
19. Radiation warning light 8.16.1
20. 'Source moving' light 8.16.1
21. Product entry/exit barrier doors 8.13
22. Product entry/exit maze 8.13
23. Product exit monitor 8.14
24. Source hoist power disconnect 8.24
25. Check source location 8.3
26. Personnel access door with interlocks 8.8
27. Radiation room monitor with alarms 8.4
28. Seismic detector 8.28.3
29. Master key attached to portable survey meter 8.2 & 8.3
30. Control console 11
31. Water conditioner 10.3



Notes:

1. All required safety features are described in detail in part 8 of this code.
2. For ease in presentation, certain irradiation components and safety features have been omitted from this illustration e.g. product pass mechanism and radiation source.

8.1 Operating procedures and sequentially interlocked controls

Sequentially interlocked controls shall be provided for personnel access, radiation room lockup sequence, and source energizing or exposing operations. The controls shall be designed such that any attempt to pre-empt or apply the controls out of sequence will automatically abort the intended operation.

Examples of these sequential control operations are:

(a) personnel access:
- ensure that the radiation room access controls are energized at the control console with the single multipurpose key;
- test the portable radiation room monitor (detector and electronics) for proper function;
- verify that the radiation level in the room is acceptable (clause 8.4);
- open the access door with the multipurpose key (clause 8.2);
- continuously monitor the radiation levels with the portable radiation survey meter on entry (clause 8.3).

(b) radiation room lockup sequence:
- ensure that no other persons are in the radiation room;
- actuate the safety delay timer in the radiation room with the multipurpose key (clause 8.9);
- close and lock the radiation room access door.

(c) source exposure operation:
- actuate the source exposure mechanism at the control console with the single multipurpose key before the pre-set safety delay time period has elapsed.

8.2 Single multipurpose key

The irradiator controls shall be designed such that a single multipurpose key is necessary to operate the irradiator during normal use. This key is used to operate the control console, to gain access to the radiation room, and to actuate the safety delay timer. The key shall be attached to the portable radiation survey meter or audible warning device by chain or cable long enough to allow easy operation of all key-switches. Only one operating key shall be available for use by operators. With the irradiator in full operation, it shall not be possible to remove the single multipurpose key without aborting irradiator operation.

Duplicate keys shall not be made except for emergency purposes. Such keys shall be kept under strict security.

8.3 Portable radiation survey meter and check source (annexe 3)

A portable radiation survey meter or a portable audible warning device, with the single multipurpose key attached, shall be carried by the operator when entering the radiation room. A check source shall be used to verify that the meter or audible warning device is operating before each room entry is made.

8.4 Radiation room monitor with alarms

8.4.1 A fixed monitor shall be provided to detect the radiation level in the radiation room when the source is indicated to be in the fully shielded condition for a sealed source irradiator or in the 'Off' condition for a machine source irradiator.

8.4.2 The monitor shall continue to indicate correctly in the presence of high radiation fields (see also annexe 3, clause 3.1.7).

8.4.3 The monitor shall be integrated with the personnel access door interlocks to prevent room access when the monitor:

(a) detects a radiation level in excess of that specified in section 7.2.2;

(b) malfunctions; or

(c) is turned off.

8.4.4 The monitor shall generate visible and audible alarm signals if the radiation level exceeds that specified in clause 7.2.2 when the source is indicated to be in the fully shielded or de-energized condition.

8.4.5 The monitor, both detector and electronics, shall be tested to assure proper functioning before access to the radiation room can be attained (clauses 8.1a, 16.2).

Records shall be kept of these tests showing date, results and name of operator.

8.4.6 The monitor and associated interlocks shall be tested monthly (clause 18.2.1.3).

8.5 Irradiation device warning sign

There shall be a clearly visible sign bearing the radiation symbol at the personnel access door to the radiation room.

For a sealed source irradiator, the sign shall also bear the words:

DANGER RADIOACTIVE MATERIAL

For a machine source irradiator, the words on the sign shall be:

DANGER MACHINE PRODUCES IONIZING
RADIATION WHEN ENERGIZED

8.6 Safety and warning systems

8.6.1. Critical safety systems

Each critical safety system, such as that intended to prevent access to the radiation room or to protect personnel servicing machine sources, shall be duplicated with another system which is independent in every respect.

8.6.2 All safety and warning systems

All systems shall be designed to be failsafe, i.e. any failure of the system or of power to the system shall cause it to revert to the safe condition.

8.6.3 Protection front radiofrequency interference

In machine source irradiators particular care shall be taken to ensure that the integrity of safety and warning systems cannot be diminished as a consequence of radiofrequency radiation from components, of the machine source. The reliability of the systems shall be demonstrated under the most adverse credible conditions.

8.7 Interlocks

8.7.1 Design

All interlocks fitted in accordance with the requirements of this code shall:

(a) be designed so that it is very difficult to render them ineffective;

(b) be based on linkages that have been, or can be shown to be, reliable and efficient;

(c) if electrical contacts such as rnicroswitches are used, be positioned so that it is very difficult to operate them except by the appropriate interlocked component;

(d) incorporate dual microswitches wired in series for each interlock for which microswitches are used.

All mechanical and electrical components should be rugged, reliable and tamper proof in design.

Where appropriate, interlocks should be resistant to high radiation fields or, alternatively, should be shielded from high radiation fields (clause 8.27).

8.7.2 Resetting of interlocks

When an interlock is tripped, operation shall resume only after manually resetting the interlock at the location where the interlock was tripped.

The interlock shall be reset only by the radiation safety officer (clause 2.7), if, following an investigation to establish the cause of the trip, he is satisfied as to the continued safety of the interlock and the irradiator.

8.7.3 Interlock bypass provisions for machine source irradiators

Interlock system bypasses shall not be allowed during normal operation. Their use for servicing shall be kept to a minimum, and shall be permitted only under carefully controlled and monitored conditions.

The radiation safety officer shall be the only individual who can authorise bypassing of interlocks and he shall be responsible for the removal of all bypasses before normal operation is resumed (section 13).

8.8 Personnel access door interlocks

Means shall be provided such that the radiation room personnel access door shall be closed and secured before the source can be exposed or energized.

The door interlocks shall be integrated with the master control system such that violation of the interlock system or use of the door shall cause the source to return automatically to the fully shielded or de-energized condition. Opening of the door with the source not in its fully shielded or

de-energized condition, through malfunction or violation of any interlock, shall generate visible and audible alarm signals to make an individual attempting to enter the radiation room aware of the hazard.

8.9 Safety delay timer with alarms

The radiation room shall be equipped with a key operated safety timer that will automatically activate visible and audible warning signals to alert personnel in the area that the source exposure sequence has begun and provide sufficient time for any individual in the room to leave the area or operate a clearly identified emergency stop device which will abort the source exposure sequence.

The safety timer shall be integrated with the master control system such that the source cannot be exposed or energized unless the source exposure sequence is complete and the control console indicates that it is safe to expose or energize the source. The visible warning signal in the radiation room shall remain activated during irradiation.

8.10 Emergency egress

Means shall be provided to ensure that personnel may leave the radiation room at any time.

8.11 Emergency stop device(s) in radiation room

Means shall be provided within the radiation room to prevent, quickly interrupt, or abort irradiator operations and return the radiation source to the fully shielded or de-energized condition at any time. The device(s) shall be conspicuous, clearly labelled and readily accessible to personnel in the radiation room.

8.12 Emergency stop device for control console

Means shall be provided at the control console to prevent, quickly interrupt, or abort irradiator operations and return the radiation source to the fully shielded or de-energized condition at any time. This emergency stop device shall be conspicuous, clearly labelled and provided in addition to any other means normally provided at the control console to shut down the irradiator.

8.13 Product entry and exit port interlocks

8.13.1 Physical means shall be provided on product entry and exit ports to prevent inadvertent or accidental entry of personnel into high radiation areas.

8.13.2 If the entry or exit port control mechanism malfunctions the source shall return automatically to the fully shielded or de-energized condition.

8.13.3 An audible or visible alarm shall be provided to indicate that the entry or exit port control mechanism has malfunctioned.

8.13.4 Each product entry and exit port shall be posted with appropriate warning signs.

8.14 Product exit monitor for sealed source irradiators

Duplicate fixed radiation monitors with an audible alarm shall be located such that they shall detect radiation emitted through the product exit port. This monitoring system shall be interlocked with the irradiator controls such that if radiation at the exit port exceeds a predetermined level, the conveyor which carries product from the radiation room to the exit port shall stop and the source shall return automatically to the fully shielded position.

8.15 Source status and exposure system interlocks

8.15.1 Means shall be provided to ensure that, if a malfunction occurs in the source exposure mechanism, the radiation source will return automatically to the fully shielded or de-energized condition and the irradiator will shut down.

8.15.2 The source exposure system shall be equipped with a device which positively indicates at the control console when the source is in the fully shielded or de-energized condition.

8.16 Indicators

8.16.1 Source status indicators

A source status indicator shall be visible at each personnel or product entry and exit port in the radiation shield to indicate when the radiation source is not fully shielded or is not de-energized.

8.16.1.1 Sealed source irradiators

A warning signal, which is audible both inside the radiation room and at all access ports, shall be provided to indicate when the radiation source is not fully shielded nor in source-in-use status.

Source status indicators shall be provided at the control console to indicate:

(a) when the radiation source is fully shielded;

(b) when the radiation source is not fully shielded nor in the source-in-use status; and

(c) when the radiation source is in the source-in-use status.

8.16.1.2 Machine source irradiators Source status indicators shall be provided at the control console to indicate:

(a) when the radiation source is fully shut down; and

(b) when the radiation source is fully energized.

8.16.2 Audible signals

Each audible signal designed into the irradiator control system shall be distinct and loud enough to gain the immediate attention of persons in the area.

8.17 Removable radiation room shield plugs

Removable radiation room shield plugs shall be interlocked with the master control system to prevent or abort irradiator operations, causing the source to return automatically to the fully shielded or de-energized condition if a plug is removed.

8.18 Source holder for scaled source irradiators

Means shall be provided to position and retain the sealed source in the design position.

In the event of failure of the sealed source retainer it shall not be possible for the source to move into a position where any part of the sealed source may fall onto the product boxes or carriers, or into a position which during normal use of the irradiator may cause a radiation hazard to any individual.

8.19 Source guard

The radiation source shall be provided with adequate mechanical protection to prevent interference from items such as product boxes or carriers. For example, this may take the form of a protective shroud, guide bars, or floor guides on the product positioning system.

Product positioning systems shall not be able to apply force directly or indirectly to the radiation source.

8.20 Product positioning system

It is detrimental to the irradiator and product to continue operations when a malfunction of the product positioning system occurs.

The product positioning system shall be provided with controls that detect a malfunction of that system, and which shall cause the source to return automatically to the fully shielded or de-energized condition and the irradiator to shut down in the event of a malfunction.

8.21 Pool guard for sealed source irradiators

A physical barrier shall be placed around any open pool to prevent personnel from inadvertently falling into the source storage pool. This physical barrier may be removed during maintenance or service operations, but only after authorisation by the radiation safety officer.

8.22 Fire protection for sealed source irradiators

8.22.1 General

During extended periods of static irradiation of combustible materials, or when a malfunction prevents the source from becoming fully shielded, heat buildup to the point of combustion may occur. Provision shall be made to protect the integrity of the source if combustion occurs.

Inherent in this requirement is the prevention of damage to the irradiator which could inhibit efforts to shield the source fully.

8.22.2 Heat and smoke sensors

Heat and smoke sensing devices with visible and audible alarms shall be provided to detect combustion in the radiation room. The source shall return automatically to the fully shielded position and the product positioning and ventilation systems shall shut down if either device is actuated.

8.22.3 Fire extinguishing system

A fire extinguishing system shall be provided in the radiation room and adjoining spaces.

Provision should be made to control the overflow of water from rooms equipped with water sprinkling systems.

If other than water sprinkling systems are used, care shall be taken to avoid the use of chemicals and corrosive substances which could adversely affect the integrity of the sealed source.

8.23 Noxious gas control

8.23.1 General

Ozone and other noxious gases are produced by radiolysis (clause 2.2). Measures shall be taken to protect personnel against exposure to concentrations of such gases above the threshold limit values prescribed by the pertinent health authority.

8.23.2 Ozone

Ozone (O_3) is produced by the radiolysis of air in an irradiator. Care shall be taken to prevent the migration of ozone into areas which may be occupied and where the concentration could exceed the threshold limit value-time weighted average (TLV-TWA).[6] This can be achieved by using a ventilation system which creates a negative pressure in the radiation room.

Personnel shall be prevented from entering any area where it is possible for them to be exposed to more than the threshold limit value-time weighted average (TLV-TWA)[6] or threshold limit value-short term exposure limit (TLV-STEL).[6]

Ozone, being unstable, changes to the normal form of oxygen (O_2) and, when a large capacity, continuously operated ventilation system is used, the radiation room can normally be entered a few minutes after the radiation source exposure is terminated. Another advantage of using a continuously operated ventilation system is the significant reduction achieved in oxidation effects on radiation room components.

One method of controlling personnel access until the ozone level is at an acceptable level in the radiation room is to provide a time delay interlock mechanism which prevents personnel access doors from being opened before a preset time has elapsed after the radiation source exposure has terminated.

Where forced air systems are utilised, the flow of air shall be continuously monitored such that failure of the system will cause the source to return automatically to the fully shielded or de-energized condition and shut down the product positioning system.

8.23.3 Nitrogen oxides

Nitrogen oxides such as NO and NO_2 are also generated by the radiolysis of air, but measurements in radiation rooms associated with sealed source irradiators indicate that the levels are well below the TLV-TWA and TLV-STEL[6] limits.

8.23.4 Other noxious gases

Certain plastics, chemicals and other materials produce noxious gases as a result of radiolysis In these special instances, care shall be taken to ensure that personnel exposures do not exceed the appropriate TLV-TWA and TLV- STEL[6] limits.

8.24 Exposure prevention during servicing

8.24.1 Sealed source irradiators

A mechanism shall be provided to disconnect the motive power (e.g. electrical, pneumatic, hydraulic) used to expose the source, so that servicing can be carried out without the danger of the source being inadvertently exposed.

Means shall also be provided for positively securing this mechanism in the disconnected position.

8.24.2 Machine source irradiators

Positive and failsafe provision shall be made for service personnel to implement procedures designed to minimise hazards when servicing the machine source. Such procedures shall include provision to prevent the energizing of equipment or systems, which are capable of giving rise to hazards which energized. Even when beams are adjusted to negligible levels and limited by electronic devices, sufficient assurance cannot be provided that the mode of operation may not suddenly change, permitting dangerous beam levels.

8.25 Electrical power failure

8.25.1 Sealed source irradiators

Means shall be provided to ensure that, if an electrical power failure of more than ten seconds occurs, the source shall return automatically to the fully shielded position and the irradiator shall shut down.

In some localities, short-term power failures of not more than ten seconds occur frequently. In these cases, it may be detrimental to product throughput if automatic shutdown of irradiator operations were to be imposed as a result of these short-term power failures.

It is therefore acceptable for means to be provided to avoid unnecessary irradiator shutdowns under these short-term power failure conditions.

8.25.2 Machine source irradiators

Means shall be provided to ensure that, if an electrical power failure occurs, the source can only be re-energized by initiating the operating procedures specified in clause 8.1.

8.26 Non-electrical power failure in sealed source irradiators

Means shall be provided to ensure that failure of non-electrical power, such as pneumatic or hydraulic, which is used to control or operate any irradiator safety feature or device shall cause the source to return automatically to the fully shielded position and the irradiator to shut down.

8.27 Radiation induced damage

Some materials such as plastics suffer accelerated degradation in high radiation fields. Electrical wiring insulation may be particularly affected. Where appropriate, components should be resistant to high radiation fields or, alternatively, should be shielded from high radiation fields. All components in high radiation areas which may be subject to material degradation shall be inspected regularly and replaced at appropriate intervals.

8.28 Geologic and seismic site considerations

8.28.1 Geologic site considerations

Geologic features which could adversely affect the integrity of the radiation shields should be evaluated by an appropriately qualified engineer, taking into account the physical properties of materials underlying the irradiator site or its environs.

Areas of potential or actual surface or subsurface subsidence, uplift, or collapse should be taken into consideration when assessing the suitability of a site for an irradiator. Other factors which need not be due to natural features and could result in soil instability should also be considered.

8.28.2 Seismic area

For the purposes of this code, a 'seismic area' is any area located in a seismic zone with a rating in excess of one as determined using Australian Standard AS2121.[7]

8.28.3 Seismic detector

In seismic areas, all sealed source irradiators shall be equipped with a seismic detector which causes the radiation source to become fully shielded automatically should the detector be actuated. The seismic detector may be a horizontal omniaxial or vertical uniaxial type and shall be set to actuate at 0.05 g, this being 5 per cent of the acceleration due to gravity.

8.28.4 Design basis earthquake

In seismic areas, the radiation shields shall be designed to retain their integrity for the design basis earthquake (DBE).

The DBE is that earthquake which is based upon evaluation of the maximum earthquake potential considering the regional and local geology and seismology, and specific characteristics of local surface material.

8.29 Irradiator security

In addition to other security measures, all remotely located equipment, such as source hoists on radiation, room roofs, which could compromise personnel safety if misused, shall be located in locked restricted areas.

9. Integrity of radiation shields and barriers

9.1 Radiation room shield

Concrete is normally used to construct the radiation room shield but other materials such as earth fill and steel may be used in its construction.

All radiation shielding shall be to the satisfaction of the relevant statutory authority.

All tubes, pipes or conduits passing through the shielding wall shall take a curved or stepped path through the shielding material to minimise radiation leakage.

9.2 Personnel access door

The personnel access door shall meet the requirements for an Australian Standard fire resistance level of thirty minutes, while retaining its integrity as a personnel access barrier.[8]

9.3 Source storage pool for sealed source irradiators

9.3.1 Water is normally used as the radiation shielding medium in wet source storage irradiators when the source is in its fully shielded condition. All components below water level should be of material with a specific gravity equal to or greater than that of water. If hollow tubing is used, it shall be fully vented to allow the water to flood the tubing. This is to eliminate the risk of a high radiation beam up the tube.

9.3.2 Pool integrity

The pool shall be watertight and designed to support radiation source transport packages used during source transfer operations without compromising the integrity of the pool.

There shall be no penetration, say by pipes or plugged holes, through the bottom of the pool. There shall be no penetration through the walls of the pool more than 30 cm below normal water level.

9.3.3 Pool water controls

Means shall be provided to replenish water losses from the pool automatically. Normal water losses are principally due to evaporation. The system shall be capable of maintaining the pool water at a level sufficient to provide the radiation shielding necessary to satisfy the requirements of clause 7.2.2 of this code.

A metering device shall be installed in the replenishment water supply line to indicate major changes in replenishment water requirements which may be associated with pool leakage. Records shall be kept of the meter reading's at intervals not exceeding six months.

Means shall be provided to prevent the migration of pool water into municipal water supply systems.

Means shall be provided to activate audible and visible signals in the control area if the pool water falls abnormally to a level more than 30 cm below the normal water level.

It shall not be possible to enter the radiation room using normal entry procedures while the abnormal, low water level condition exists.

9.3.4 In-pool piping

Since pipes are used in source storage pools for the water level and water quality systems, suitable syphon breakers shall be provided to prevent the syphoning of pool water lower than 30 cm below the normal level.

All pool water circulation suction pipes shall have intakes no lower than 30 cm below the normal level.

10. Source storage pool and pool components for sealed source irradiators

10.1 General

Source storage facilities generally consist of a waterfilled pool located below floor level in the radiation room. Inserts, brackets, and other hardware are normally used within the pool to anchor or locate such items as the source holder guide rods or cables and various pipes for water circulation.

10.2 Pool component materials

All permanent pool components shall be made of material which will reduce the possibility of corrosion occurring and migrating to the sealed source. Where practical, stainless steel components such as brackets or pulleys should be passivated, particularly after fabrication.

10.3 Water conditioning

The pool shall be equipped with a system capable of maintaining the water in a clean condition and at a level of conductance not exceeding 1000 microsiemen/m (10 microsiemen/cm). This will reduce the possibility of corrosion of the sealed source.

Extreme care shall be exercised to avoid the introduction of contaminants into the water system such as deionizer regenerants, cleaning materials, corrosive fire extinguishing materials or spilled product.

All filter(s) and resin bed(s) in any water conditioning system shall be tested for radioactive contamination just prior to planned backwashing or regeneration of the system. Backwashing or regeneration shall not be started if the test reveals the presence of contamination (see also section 17).

10.4 Water cooling

Because heat is produced by gamma emitting sources, the resulting high humidity levels may damage the product and product positioning system. When such damage is likely to occur, an appropriate pool water cooling system should be provided.

Reducing evaporation loss from the pool will also facilitate maintaining the conductance of the water below 1000 microsiemen/m (10 microsiemen/cm) for a longer period of time before regeneration or replacement of deionizer resins is required.

10.5 Cleaning source storage pools

It may become necessary to clean the source storage pool to remove foreign matter which accumulates at the bottom.

Any vacuum system used for pool cleaning shall be fitted with an in-line filter. Typically, swimming pool filters are used for this purpose. The filter shall be continuously checked for the presence of radioactive material during the vacuuming operation. Should the exposure rate at the filter increase, the vacuuming operation shall be terminated. All underwater tools used for vacuuming shall satisfy the requirements of clause 15.5 of this code.

11. Control identification

11.1 Control console

The control panel or console shall be easily identifiable as being part of the irradiator.

11.2 Labelling

Each control shall be clearly and unambiguously labelled according to its function.

11.3 Status indicator colours

The following colours are recommended for use when illuminated or colour coded controls are used:

Condition	*Colour*
Emergency (stop buttons or lights)	Red
Warning-hazard	International trefoil or red
Critical information (source in use or malfunction)	Red
Caution (no emergency, but some function taking place to be aware of)	Yellow or orange
Normal (source not in use or function safe)	Green
Information	Blue

12. User responsibilities

The user responsible for the possession and use of the irradiator shall not commence operations until any licences, permits or authorisations necessary for these purposes have been obtained from the relevant statutory authorities.

12.1 Application for approval of an irradiation facility

12.1.1 An application for approval to possess and use an irradiator shall be accompanied by supporting information specified by the relevant statutory authority. As a guide the user should:

(a) describe the proposed use of the irradiator and the estimated hours of use;

(b) describe each sealed radioactive source to be used, if the application is for approval of a sealed source irradiator. The application should include a detailed description of the sources as well as information relating to tests which confirm the integrity of the sources under credible adverse conditions;

(e) describe the irradiating apparatus, if the application is for approval of a machine source irradiator; technical performance data and safety features should receive particular attention;

(d) describe the irradiator construction and operation paying particular attention to safety components;

(e) describe all safety interlock systems, indicators and warning systems;

(f) provide calculated radiation levels for all areas in the vicinity of the sources and radiation room with the source in both the exposed and stored positions, for a sealed source irradiator, and with the apparatus energized in the case of a machine source irradiator; the degree and type of occupancy should be included for each area. This information should also be provided for any areas accessible to members of the public;

(g) provide a copy of detailed written instructions for operating the irradiator;

(h) provide a copy of the detailed training manual for operators of the irradiator;

(i) provide written administrative instructions governing use or responsibility for use of the irradiator and supervision of the associated radiation protection program;

(j) include plan and elevation drawings or sketches with sectional details as required to completely characterise the construction of the irradiation facility and surrounding areas;

(k) include drawings and descriptions sufficient to characterise fully the shielding provided for the safe use of the irradiator;

(l) include environmental, geologic and seismic data, as appropriate; and

(m) provide details of any proposed contract with an external security organisation.

12.1.2 The user shall carry but maintenance of the irradiator as prescribed by the supplier, paying particular attention to ensure that all product positioning system components, product boxes or carriers continue to meet design specification. For example, it is important to ensure that the correct product boxes or carriers are used and that they are maintained in a condition that will not cause an irradiator malfunction.

12.2 Modifications to irradiation facility

The user shall notify and obtain approval from the relevant statutory authority prior to any modification which may cause a radiation hazard. Some examples are:

(a) modification of operating procedures;

(b) modification of the safety control system;

(c) modifications of the irradiator; and

(d) source loading, replenishment, removal or redistribution.

12.3 Commissioning and operation of irradiation facility

The user shall be responsible for the safe use of the equipment and shall ensure that:

(a) all safety features required in this code are implemented regularly serviced and maintained in good working order;

(b) all rules and procedures required in this code are established and maintained;

(c) all legislative requirements of the relevant statutory authority are met;

(d) written administrative procedures containing working rules, designed to minimise radiation exposure and other hazards during normal operation, and emergency procedures to be implemented in the event of an incident, are prepared and submitted to the relevant statutory authority for approval;

(e) upon approval, the working rules and emergency procedures are implemented;

(f) the necessary equipment to enable the working rules and emergency procedures to be efficiently carried out is readily available;

(g) radiation monitoring is carried out in accordance with the requirements of this code;

(h) radiation monitoring equipment and any equipment provided to limit radiation exposure is regularly inspected and. maintained;

(i) such tests as required by the statutory authority are carried out;

(j) periodic tests and inspections of control mechanisms are carried out;

(k) periodic tests and inspections to determine the integrity of the source are carried out (section 17);

(l) the results of examinations, inspections and tests are recorded;

(m) the records are maintained and are available for inspection by the relevant statutory authority;

(n) adequate instruction is given to employees concerning any radiation hazards associated with their work, and any precaution necessary to limit radiation exposure of persons and to avoid radiation accidents and injuries;

(o) reinstruction of employees is undertaken at appropriate intervals;

(p) no person is permitted to operate the irradiator until he has been adequately trained and is competent to operate the irradiator in accordance with the approved working rules;

(q) at least one person, in addition to the operator, is also present in the facility when the irradiator is operational; this person shall be capable of maintaining the safety and integrity of the facility in the event of incapacitation of the operator;

(r) trainee operators are under the direct supervision of a fully trained operator at all times when operating the irradiator;

(s) the necessary supervision is provided to all employees in the performance of their work in accordance with the provisions of this code;

(t) access to parts of the irradiator is restricted so that the radiation exposure to any person complies with the recommendations of the National Health and Medical Research Council[3];

(u) in case of actual or suspected overexposure to personnel the relevant statutory authority is informed without delay (clause 16.4);

(v) in case of actual or suspected overexposure, appropriate medical procedures are carried out, medical reports are retained and full details of the incident are reported to the relevant statutory authority as soon as possible;

(w) operation of the irradiation facility ceases while any safety feature is removed, modified or inactivated unless an exception has been specifically approved in writing by the relevant statutory authority;

(x) a radiation safety officer, approved by the relevant statutory authority, is appointed; the person appointed shall have suitable qualifications and experience in radiation safety, which enable him to readily comprehend and carry out duties laid down for the radiation safety officer;

(y) a replacement officer approved by the relevant statutory authority is available to undertake the radiation safety officer duties when the radiation safety officer cannot be available for any reason;

(z) the equipment, procedures and cooperation of employees are provided so that the radiation safety officer can discharge the duties required by this code. However, this requirement shall not preclude use by the radiation safety officer of outside experts and the use of equipment not in the possession of the user in accomplishing his responsibilities and duties;

(aa) the loading, replenishment, redistribution or disposal of sources is carried out only by a person or company approved by the relevant statutory authority;

(bb) installation, repair and service of parts of the facility, which may affect radiation safety, are carried out only by a person or company approved by the relevant statutory authority; and

(cc) the appropriate fire authority is notified of the location of all radiation sources installed and is instructed concerning the potential hazards at the facility.

12.4 Shutdown and decommissioning of a scaled source irradiation facility

12.4.1 Shutdown

Situations may arise where a sealed source may need to be maintained in the shielded condition for periods longer than those envisaged in the application for approval of the facility (clause 12.1). In these circumstances the user shall obtain prior approval from the relevant statutory authority for any proposal to shut the facility down while the sources are retained in the facility. Any proposal shall consider the physical security of the facility and the provisions made for maintaining the integrity of the shielding and source encapsulation. Requirements such as conditioning of the water, maintaining of safety systems and testing for radiation levels and contamination shall be addressed.

12.4.2 Decommissioning

The user shall obtain prior written approval from the relevant statutory authority for any proposal to decommission the facility and dispose of any source(s).

A written proposal shall be made to the relevant statutory authority well in advance of the proposed decommissioning date. The proposal shall:

(a) identify the source(s);

(b) identify the proposed receiver(s) of the source(s);

(c) provide verification that the proposed transfer is agreed to by the proposed receiver(s) and the relevant statutory authorities;

(d) include details of procedures for removal of source(s) from the facility, packaging and transport;

(e) include details of personnel who will be engaged for the procedures described in clause 12.4.2(d), including evidence of competence to carry out such tasks in a safe manner;

(f) include details of proposals for checking the facility after removal of the source(s) to confirm that radiation levels and contamination levels do not exceed limits set by the relevant statutory authority;

(g) include details of procedures for remedial work which might be required to comply with clause 12.4.2 (f); and

(h) include arrangements for the maintenance and ultimate disposal of records described in clause 15.4.

13. Radiation safety officer responsibilities

An officer shall be assigned the responsibility of ensuring that all radiation protection measures are carried out. The radiation safety officer shall:

(a) obtain and maintain knowledge of the principles and practice of protection against radiation and of the potential hazards associated with the operation of irradiation facilities so as to undertake efficiently the routine measurements, investigations and assessments and prepare the reports laid down in this code as the duties of the radiation safety officer;

(b) familiarise him or herself thoroughly with the requirements of the legislation relevant to nonmedical irradiators, the provisions of this code and other relevant codes, the detailed working rules necessary for normal operation and the procedures necessary in the case of actual or suspected overexposure, and the radiation monitoring and protective equipment provided to meet the requirements of this code;

(c) investigate, in consultation with the relevant statutory authority, known and suspected cases of overexposure of personnel to determine the cause, and take appropriate remedial action to prevent any further overexposure;

(d) select, with approval of the relevant statutory authority, radiation monitors to meet the requirements of this code;

(e) ensure that an adequate number of personal monitoring devices and radiation monitors are readily available and are in good working order;

(f) issue and collect any personal radiation monitors and ensure that they are used in a manner approved by the relevant statutory authority;

(g) make available to each employee who may be exposed to radiation appropriate personal monitoring devices for that person's exclusive use and ensure that personal monitoring devices are promptly submitted for assessment after use;

(h) ensure that individual radiation monitoring devices known or suspected to have received a dose equivalent in excess of 10 per cent of the pro-rata limit appropriate for the wearer, whilst being worn, are assessed promptly. If the devices are returned to a -radiation monitoring service for assessment, the service shall be advised of the circumstances of the exposure;

(i) in the event of an interlock tripping, carry out the duties specified in clause 8.7.2;

(j) assess, approve and supervise service and maintenance procedures on systems or in areas where the integrity of the radiation safety might be affected or where the service or maintenance personnel might need to be protected from radiation hazards; these duties include the bypassing of interlocks (clause 8.7.3); and

(k) following the completion of maintenance or repair work, confirm the operational and safety status of the irradiator before permitting it to be put into use.

14. Operator responsibilities

The operator is responsible to the user for ensuring that the operations and procedures are in accordance with the approved working rules.

The operator shall:

(a) at all times carry out established procedures of operation and maintenance;

(b) report to the radiation safety officer all defects in equipment that come to his notice and which he believes may cause a radiation exposure or contribute to one arising;

(c) report to the radiation safety officer any actual or suspected case of unnecessary exposure and assist in determining its cause;

(d) take steps to prevent recurrence of incidents of unnecessary exposure; and

(e) wear personal radiation monitors at such times and in such a manner as directed by the radiation safety officer.

15. Installation and safety related service

15.1 Authorised personnel

Installation and safety related services on an irradiator containing a sealed radioactive source or a machine source shall be performed only by, or under the direct supervision of, an authorised person. The authorised person shall be physically present during any operation involving source loading, replenishment, removal or redistribution.

15.2 Qualifications

The authorised person shall have the training and experience necessary to act responsibly in the event of contingencies arising during the installation or service work.

15.3 Responsibility

15.3.1 The authorised person shall be responsible for the radiation safety of all associated personnel during the installation and service operations and should be accorded full cooperation by the various personnel involved.

15.3.2 The authorised person shall have available all documentation as required by the relevant statutory authority.

15.3.3 The authorised person shall comply with all safety regulations relating to the complete operation and ensure that all personnel associated with the operation are in compliance with the pertinent regulations, such as the wearing of personal monitors.

15.4 Records

Records of all installation and service work shall be maintained by the user. These records shall be made available to the relevant statutory authority on request.

15.5 Underwater tools and servicing for sealed source irradiators

15.5.1 All components used below water level which could compromise the integrity of the radiation shield during procedures such as maintenance, servicing. and source addition or removal should be of material with a specific gravity equal to or greater than that of water. If tubing is used in the pool, such as when the pool floor is vacuumed or hollow tool rods are used for servicing, it shall be fully vented to allow water to flood the tubing as it enters the water.

15.5.2 All tools, vacuum tubing, or equipment which may reduce the shielding provided by the water, shall be monitored during introduction to the storage pool.

15.5.3 All items removed from the storage pool shall be monitored as they are withdrawn.

15.5.4 Continuous monitoring of the area above the storage pool shall be carried out during any source handling or pool vacuuming operation.

16. Administrative procedures

16.1 Written instructions and operational requirements

Administrative instructions and operational requirements shall be submitted to the relevant statutory authority for evaluation and approval. The approved instructions and requirements shall be incorporated into the administrative procedures.

Written administrative instructions governing the use or responsibility for the use of the irradiator, and the associated radiation safety program, shall be provided to all personnel involved in the operation of the irradiator. These instructions shall be fully understood by the personnel and shall include, as a minimum, the following:

1. a description of the safety organisation including the functions, duties, and responsibilities of the radiation safety officer and the operator;

2. the method of implementing the operating instructions and assuring that the facility is being used safely on a continuing basis, including:

   (a) a description and schedule of the inspections and test procedures for ensuring that all safety interlocks, devices, and components associated with the irradiator are functioning properly. Each such safety item and the appropriate tests, checks, and inspections for each should be specified;

   (b) the requirement that at all times when the irradiator is operational it is under the control of an operator approved by the relevant statutory authority (clause 12.3);

   (c) the requirement that, when the radiation safety officer cannot be available, a replacement officer approved by the relevant statutory authority shall be available to undertake the duties (clause 12.3);

   (d) the requirement that at all times when the irradiator is left unattended, the personnel access door shall be closed and secured;

   (e) the requirement that the emergency procedures are conspicuously posted in the control area;

   (f) the requirement that the operating procedures, instruction manuals(s), and log book shall be located in the control area, along with:

   • name and address of irradiator manufacturer;
   • model and serial number of the irradiator;
   • for a sealed source irradiator:
     - name and address of source manufacturer(s);
     - model and serial numbers of all sources;
     - type of radionuclide involved and total activity with date of measurement. This information shall be kept up to date; and
     - maximum design activity, or nominal capacity, of the irradiator;
   • for a machine source irradiator:
     - model and serial number of irradiating apparatus; and
     - type and energy of radiation produced;

3. the method of assuring that operating personnel wear proper radiation monitoring devices and that their results are assessed and recorded; and

4. the method(s) of assuring that only persons approved by the user will use the irradiator or have access to the area. This can include controlling keys to the door into the room containing the irradiator control console, controlling operating console keys, or other positive methods of excluding access.

16.2 Log book

A log book or file shall be maintained to record details of all important irradiator activities, including adjustments, changes or service to mechanisms and circuitry, and those functions performed under the test program. At a minimum, the log shall provide space to record time, date, operation performed, visitors' names, radiation room monitor readings on entry (clause 8.4), and operator performing the task. Each log entry shall be verified by the operator with a signature or initials.

16.3 Malfunction procedure

Written instructions shall be provided covering action to be taken in the event of irradiator malfunction and should include a general outline of the action to be taken by persons who are notified of an irradiator malfunction, correction of which may involve the source. It should be made clear that remedial action in situations involving work around the irradiator shall be controlled only by the radiation safety officer, or another authorised person, as required by the circumstances.

16.4 Emergency procedures

16.4.1 Emergency procedures shall be submitted to the relevant statutory authority for evaluation and approval and the approved procedures incorporated into the administrative procedures.

16.4.2 Emergency procedures shall be written for each type of emergency that may reasonably be encountered. Foreseeable emergencies should include those resulting from observed or suspected damage to sealed sources or machine sources, observed or suspected malfunctions of safety procedures, fire, flood or other disaster. These should be concise, easily followed instructions. They should describe what will be indicative of a situation requiring emergency action, specify the immediate action to be taken to minimise radiation exposure to persons in the vicinity of the irradiator, and include the name and telephone number of the person(s) to be notified to direct remedial action. Emergency contact information should be kept up-to-date.

16.4.3 Emergency procedures shall include the requirement for the radiation safety officer to:

(a) assess the incident immediately and direct remedial measures designed to: ensure that the source is returned to the fully shielded or de-energized condition; protect or rescue personnel; contain the incident; bring it under control;

(b) as soon as possible after the incident has been brought under control investigate the circumstances and notify the user of actual or suspected exposures of personnel and damage to facilities;

(c) notify the relevant statutory authority without delay, outlining the measures being taken to restore the normal situation; and

(d) within seven days of the incident submit a detailed written account to the relevant statutory authority, and include the steps to be taken to prevent a recurrence.

16.4.4 An emergency exercise shall be held at least annually to test the response of staff to a radiation incident at the irradiator. The exercise should be based on the conditions of a maximum credible accident.

16.5 Controlled access

The radiation room of all irradiators shall be designated as a restricted area, and access to it strictly controlled. Initial access upon return of the radiation source to its fully shielded condition or shut down of a machine source shall be made by an operator who shall use the portable monitor when entering and occupying the radiation room.

16.6 Visitors

When visitors are permitted to enter the irradiator, they shall be escorted by an operator. Visitors entering the restricted area shall be issued a personal monitor. The visitor's name, dosemeter identification, dose received, and name of escort shall be recorded in the log book. In cases where there is a large group of visitors to the restricted area, each of their names shall be recorded in the visitors' log book. However, it will suffice if at least two members of the group have a personal monitor, provided that the two conduct activities representative of the group as a whole.

17. Contamination tests for sealed source irradiators

17.1 General

The purpose of the contamination test program is to detect gross contamination and to evaluate trends so that the presence of unacceptable contamination can be foreseen.

Annexe 3 describes currently acceptable contamination tests required by clauses 17.4.2 and 17.5.3. The contamination test report requirements are described in clause 5.5.

17.2 Authorised personnel

Only authorised personnel shall perform contamination tests.

17.3 Contamination test sensitivity

The test shall be capable of detecting the presence of 1000 becquerel of contamination on the test sample.

17.4 Source transport package tests

All empty or loaded source transport packages shall be tested prior to introducing them into the source storage pool in order to prevent the introduction of radioactive contaminants into the irradiator pool source storage system.

17.4.1 External radiation test

Prior to performing the contamination tests, the authorised person shall verify that the radiation air-kerma rate at one metre from any accessible surface of the transport package does not exceed 100 μGy h^{-1}.

If the air-kerma rate exceeds 100 μGy h^{-1} at one metre, it shall be assumed that the integrity of the package or its contained source has been impaired and transfer of the package into the source storage pool shall not be carried out. Further action shall be taken only in consultation with, and with the approval of, the relevant statutory authority.

17.4.2 Removable contamination test on external surfaces.

The authorised person shall perform a wipe test on the external surface of the source transport package to test for the presence of removable contamination.

If removable contamination in excess of 1000 becquerel per 300 square centimetres of package surface is. found, it shall be assumed that the integrity of the package or its contained source has been impaired and transfer of the package into the source storage pool shall not be carried out. Further action shall be taken only in consultation with, and with the approval of, the relevant statutory authority.

17.4.3 Removable contamination test on internal surfaces.

The authorised person shall test the inside of the source transport package for the presence of removable contamination.

If removable contamination in excess of 2000 becquerel is found on a test sample, it shall be assumed that the integrity of the package or its contained source has been impaired and transfer of the package into the source Storage pool shall not be carried out. Further action shall be taken only in consultation with, and with the approval of, the relevant statutory authority.

17.5 Acceptable test program

For tests where the results are going to be recorded and compared to previous or future test results there must be consistency in the test procedure. It is useful to plot the test results in order to have a simple illustration of trends.

Any apparent change in radioactive contamination levels which cannot be attributed to known causes requires that further action be taken to determine the cause. Such further action may include:

(a) verifying that the test instrumentation is functioning properly;

(b) repeating the tests to verify the apparent change in radioactive contamination levels;

(c) performing more frequent source wipe tests to verify source integrity; and

(d) consulting with the source supplier.

While each radiation safety officer is responsible for developing his own specific program, the following tests shall be included as a portion of the total program.

17.5.1 Weekly test

Each filter bed in the water conditioning system shall be checked weekly with a portable survey meter and results recorded. An accumulation of radioactivity in the filter or resin beds will most likely be the first evidence of source leakage.

In addition to the contamination check of the water conditioning system, the system may be equipped with a continuous radiation monitoring device - with an alarm - which will stop all pool water recirculation should the radiation reach the preset alarm level.

17.5.2 Monthly test

An irradiator wipe test shall be carried out on selected surfaces inside the radiation room on which one would expect contamination to accumulate if there were to be leak-age of radioactive material. The wipes shall be evaluated and the results recorded.

Typical areas where contamination may accumulate are ventilation ducts, floor surfaces between the ventilation ducts and the radiation source, and parts of mechanisms that are adjacent to the radiation source when it is in its source-in-use position.

17.5.3 Semi-annual test

On a semi-annual schedule, a contamination test shall be performed on the radiation sources (annexe 3). Particular attention should be given to source surfaces in the immediate vicinity of encapsulation welds and submerged surfaces of the pool and its components on which one would expect contamination to accumulate if there were to be leakage. Examples of the latter would be the floor of the pool, the source holder and source guides.

If the test indicates the presence of contamination in excess of that specified in section 17.5.4, then discrete tests shall be performed on individual source elements to establish the origin of the contamination.

17.5.4 Detection of removable contamination

The results of the tests of clauses 17.5.2 and 17.5.3 are considered negative if less than 2000 becquerel of removed radioactive material is detected on the test sample. When the test results are negative, no action other than record keeping is required.

Tests which reveal the presence of 2000 becquerel or more of total removed radioactive material on the test sample shall be considered as evidence that the sealed source is leaking. In this event, the irradiator shall be immediately withdrawn from service and appropriate action taken to prevent exposure of personnel and further dispersal of radioactive material. The responsible user shall immediately notify the relevant statutory authority and should notify the manufacturer or supplier of the equipment that an incident has occurred which might have caused or threatens to cause a radiation hazard Under no

circumstances shall unauthorised or untrained persons attempt to examine or decontaminate the irradiator.

18. Safety tests and checks

18.1 Tests at installation

18.1.1 Contamination test for sealed source irradiators

After installation of the sealed source, a contamination test shall be performed to confirm compliance with section 17 of this code before the start of routine operations.

18.1.2 Radiation survey

Immediately after installation of the source, a radiation survey of the irradiator shall be conducted in accordance with section 5 to confirm compliance with clauses 7.2 and also 7.3 if appropriate. The survey shall be performed with the irradiator free of materials or objects for irradiation.

18.2 Routine checks and tests

18.2.1 Interlock testing

To ensure that all interlocks and critical components remain operable and continue to provide the personnel safety for which they were intended, periodic or systematic testing shall be performed using a formal checklist. If the interlocks do not function properly, the irradiator shall not be used until repairs are accomplished. At a minimum, the checks and tests shall include the following:

- *Indicator and system checks*

  Verification of visual indicators and general system operation prior to each radiation room entry.

- *Weekly tests*

  Critical systems such as the emergency stop button on the control console, emergency stop device(s) inside the radiation room, door interlock, water level control, low pool water interlock, and water treatment system shall be tested. Attempts should also be made to operate the irradiator after deliberately violating the approved start-up procedure to ensure that the interlocks and sequential controls are functioning correctly.

- *Monthly tests*

  (a) All irradiators

  The radiation room monitor shall be tested for correct functioning by exposing the monitor probe to a check source until the alarm sounds. With the monitor alarm sounding, the personnel access door shall be checked to see that it cannot be opened from the outside.

  Tests and checks of less critical but important items such as the source exposure mechanism, the ventilation system, and similar hardware which contribute to the safe operation of the irradiator and its related product positioning mechanism.

  (b) Sealed source irradiators

  With the irradiator operating, tests for proper functioning shall be performed on the product exit monitor by exposing the monitor probe to

a check source until the alarm sounds. The exit product conveyor shall stop and the source shall return automatically to the fully shielded position.

18.3 Additional contamination tests for sealed source irradiators

Tests shall also be performed when sealed sources have been loaded, replenished, removed or redistributed in an irradiator, or when contamination is suspected, before the irradiator is returned to routine operation.

18.4 Additional radiation surveys

A radiation survey shall be performed to confirm continued compliance with section 7 when changes to the irradiator have been made such as:

(a) an increase in the amount of activity above the previous maximum in a sealed source irradiator;

(b) scaled source rearrangement in a sealed source irradiator;

(c) an increase in the performance specifications, such as energy or beam current, of a machine source above the previous maxima.

(d) a decrease in shielding; or

(e) any other chance which may have increased the leakage radiation levels.

If the survey indicates the need for corrective action, another survey shall be performed after appropriate modifications have been made.

The survey shall be performed with the irradiator free of materials or objects for irradiation if it is calculated that in this condition the leakage radiation levels may exceed those specified in clause 7.2.

19. Removal of sources and contaminated material from sealed source irradiators

19.1 Removal of sealed sources

Removal, transfer or disposal of the sealed source may become necessary or desirable. These procedures shall only be performed by, or under the supervision and in the physical presence of, an authorised person and the radiation safety officer.

19.2 Removal of damaged or leaking source

The appropriate method of removal, transfer or disposal of a damaged or leaking source will be dictated by circumstances, but the following procedure is generally applicable.

If an actual or suspected source leak has occurred, terminate use of the irradiator and close down its water circulation and air ventilation systems to prevent the spread of contamination and exposure of personnel. Isolate the area and contact for assistance:

(a) the relevant statutory authority;

(b) the manufacturer of the device;

(c) the supplier and the installer of the source (if different from the manufacturer of the device); and

(d) a person authorised to remove the defective source. Special permission to remove and transport the source shall be obtained from the relevant statutory authority.

Removal of the defective source should be prompt once the decision is made and shall be performed by, or under the supervision and in the physical presence of, an authorised person.

19.3 Removal of contaminated material

Contaminated material generally results from a leaking source. Under no circumstances shall any contaminated material such as water, filter medium, resin or components be removed, transferred or disposed of without the express written permission of the relevant statutory authority. Disposal of contaminated material shall be performed by, or under the supervision and in the physical presence of, an authorised person.

Glossary of terms

Accessible surface - that surface of the irradiator to which human access is possible without the use of tools or without penetration of the structural radiation shield.

Authorised person - see clause 2.7.

Capsule - protective envelope used for prevention of leakage of radioactive material.

Contaminated material - any material or object other than a sealed source that contains a radioactive substance (or substances) in average concentration or total quantity such that disposal procedures must be approved by the relevant statutory authority.

Exposed or energized - the condition in which a sealed source or a machine source is not fully shielded or de-energized.

Fully shielded or de-energized - the condition in which a sealed source is stored, or a machine source is deactivated, so that the radiation level in the radiation room does not exceed the levels specified in clause 7.2.2 of this code.

Fully vented - a design characteristic of hollow tools, tubes, or control rods, that allows air to escape from the tool at a rate sufficient to allow water to flood the immersed section as it enters the water.

Installation of irradiator - the construction, source loading (where applicable), and commissioning of an irradiator.

Irradiator - a device or facility designed for the irradiation of objects or materials and containing sources of ionizing radiation, shielding and other provisions for safeguarding personnel and the environment from hazards associated with such sources.

Leakage radiation - that radiation emitted by the source at the accessible surface of the radiation room shield and by a sealed source at the surface of the source storage pool.

Machine source - an irradiating apparatus producing electrically generated radiation.

Machine source irradiator - a controlled human access irradiator incorporating a machine source; the ionizing radiation is produced within a radiation room which is maintained inaccessible during use by interlocked controls.

Operator - see clause 2.7.

Personal monitor - a radiation sensitive device that is worn by an individual and is used for the measurement of radiation dose.

Primary beam - that part of the radiation from a source which is intended for use in irradiating product.

Product - the objects or materials which are intentionally irradiated in a commercial or research process.

Product positioning system - the means by which the product to be irradiated is conveyed around the source under the source-in-use condition.

Radiation loom - that region of the irradiator which is enclosed by radiation shields and which is made inaccessible when the source is in use.

Radiation safety officer - see clause 2.7.

Radiation shields - the materials which have as their primary function the attenuation of radiation emitted by the source to acceptable levels.

Radiation worker - see clause 2.7.

Restricted area - that region of the irradiator to which human access is controlled for radiation safety purposes.

Safety interlock - a device for precluding exposure of an individual to a hazard either by preventing entry to the hazardous area or by automatically removing the hazard.

Safety related service - any service work which could affect the radiation safety of an irradiator such as sealed source loading, replenishment, removal or redistribution; machine source service and maintenance; bypassing any of the safety interlocks; or modification to the radiation shields which could result in radiation levels in excess of those specified in section 7 of this code.

Scaled source - radioactive material sealed in a capsule, the capsule being strong enough to prevent dispersion of the radioactive material under the conditions of use for which it was designed. Also an assemblage of sealed sources in an array utilised in an irradiator.

Sealed source irradiator - a controlled human access irradiator in which the sealed source is contained in a storage pool (usually containing water), and the sealed source is fully shielded when not in use; the sealed source is exposed within a radiation room which is maintained inaccessible during use by interlocked controls.

Shall - indicates that the particular requirement is necessary to ensure protection from radiation.

Should - indicates a procedure or precaution which is to be applied, whenever practicable, in the interests of minimising hazards.

Source holder - that component of the irradiator into which the sealed source is positioned, including any retaining screws, pins, clips, etc.

Source-in-use - that status of an irradiator during which a sealed source is not fully shielded or a machine source is energized.

Supplier - see clause 2.7.

Unrestricted area - any region to which human access is not controlled for radiation safety purposes.

User - see clause 2.7.

Visible indication - a visual signal provided as an indication of the status of an irradiator component.

References

1. Commonwealth Department of Health (1983*) Code of good manufacturing practice for therapeutic goods*, Appendix A, 'Radiation sterilization', Canberra.
2. National Health and Medical Research Council (1987) 'Model food standards regulation S3, Irradiation of food', in *Report of the 101st session*, Appendix XVI, AGPS, Canberra.
3. National Health and Medical Research Council (1981) *Recommended radiation protection standards for individuals exposed to ionising radiation*, AGPS, Canberra
4. Standards Association of Australia (1985*) Maximum exposure levels Radio-frequency radiation-300 kHz to 300 GHz,* Australian Standard AS2772-1985, North Sydney.
5. International Organization for Standardization (1980) *Sealed radioactive sources-Classification*, International Standard ISO 2919, Geneva.
6. National Health and Medical Research Council (1983) *Occupational health guide-threshold limit values*, Canberra.
7. Standards Association of Australia (1979) *Design of earthquake resistant buildings*, Australian Standard AS2121-1979, North Sydney.
8. Standards Association of Australia (1984) *SAA Fire door code. Part 1: Fire resistant door sets*, Australian Standard AS1905-1984, North Sydney.

ANNEXE 1

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

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 humans 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

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

**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.

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.

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, nonmalignant 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 μSv). In certain circumstances, it is possible that only partial exposure of the body occurs or that single organ exposure occurs. In these circumstances, limits a 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 μSv per week (or 4000 μSv 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 1 mSv, 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 dose not exceed 1 mSv. The non-stochastic dose equivalent limit for the skin and the lens of the eye is 50 mSv 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 2

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) 410560

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 3724
Fax (09) 381 1423

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

ANNEXE 3

Ionizing radiation measurements

For the purpose of this code, the objective of radiation measurements is to provide adequate information for protection of personnel.

When making a survey of exposure rates through the radiation shields of an irradiator, the monitoring instrument should be properly calibrated. This becomes particularly important as radiation levels approach the limits specified in section 7. The measured levels will determine what action is necessary.

In many cases, the detection of radiation above the normally expected levels may be as important as accurately determining the amount of radiation present. This is illustrated by the following examples.

(a) When entering the radiation room with a survey meter, a reading which increases steadily above the expected background level should be taken as an indication that a problem exists and additional investigative action should be taken before further entry is made.

(b) If the reading on material used in a wipe test on the sources in the pool is significantly greater than previous measurements made under similar conditions, it should be taken as an indication of potential contamination and more accurate measurements should be made to determine the extent of the problem.

These examples illustrate the two most common types of radiation measurements performed on irradiators: exposure rate (or dose rate) and activity.

A3.1 Instrument selection

In all cases an instrument should be selected which will measure the radiation quantity under consideration to the required accuracy. Exposure measurements are usually performed with survey meters whereas more accurate measurement of a particular radiation quantity may have to be made using sophisticated instruments or laboratory equipment. This annexe only addresses selection criteria for survey instruments. Additional information can be found in ANSI N323-1978*, Radiation protection instrument test and calibration.*[1] Some of the most important considerations in the selection and use of survey instruments include:

A3.1.1 Energy dependence

Energy dependence of an instrument is its observed response as a function of radiation energy when placed in a field of known exposure (or exposure rate). The response should be known at several energies over the operating energy range of the instrument so that appropriate correction factors may be applied.

The instrument selected should have the smallest practical energy dependence for the radiation energies being measured.

A3.1.2 Sensitivity

The instrument should have the capability to respond to all types and levels of radiation expected during the survey, and should have the capability to respond to minimum changes of 10 per cent of radiation levels being measured.

A3.1.3 Response time

Survey instruments do not respond instantly to changes in radiation levels but have a finite response time. The response time is the time required for the instrument to reach 90 per cent of its final reading when the radiation sensitive volume of the instrument system is exposed to a step change in radiation level. Response time may be different for the various ranges covered by a given instrument.

A3.1.4 Directional response

The response of the instrument may depend on the orientation of the detector chamber with respect to the incident radiation. Readings should be taken in the orientation in which the instrument has been calibrated.

A3.1.5 Environmental effects

Temperature and pressure can have a significant effect on the indicated radiation levels. Correction factors should be applied to indicated readings to establish the actual radiation levels. Radiofrequency fields can affect some monitors giving false readings. This is of particular concern with machine source irradiators.

A3.1.6 Calibration

The procedure used to calibrate the survey instrument will depend on the radiation quantity being measured. The considerations addressed here are for exposure rate and activity measurements made with survey instruments.

(a) *Exposure rate*. An acceptable procedure for calibrating survey instruments for exposure rate measurements is to use a point source of radiation whose exposure rate at a given distance is known, and to compare the observed instrument response in a particular geometry with the expected response using appropriate correction and conversion factors. The instrument should be calibrated at two points on each scale with the two points separated by at least 50 per cent of the scale. For a properly calibrated instrument, the readings are within ±10 per cent of the known or calculated values for each. point, or the readings are within ± 20 per cent if a calibration chart or graph is prepared and provided with the instrument. The survey instrument should be calibrated in a known radiation field which is traceable to a national standard.

(b) *Activity.* The instrument used for measuring activity should be calibrated with a radioactive source having a known amount of activity on material of the same type

used in the contamination test. All measurements should be performed using the same source-instrument geometry which was used for the calibration. All conversion and correction factors used in the measurement process should be recorded. If the survey instrument has suitable sensitivity, it is acceptable to use the same instrument for both activity measurements and exposure rate measurements required by this code. In this case, the recommended calibration procedure is:

- calibrate the instrument for exposure rate measurements;
- determine the activity on the contamination test sample using appropriate conversion factors.

A3.1.7 Saturation and duty factor effects

In the presence of high radiation fields, some types of survey instruments may 'fold back' due to saturation effects, that is, they may indicate levels which are progressively lower than the actual levels as the level increases. In general, instruments free from this characteristic are preferred. If an irradiation facility uses a machine source with a pulsed beam then duty factor effects on the instrument should also be taken into account.

A3.2 Contamination tests

Several clauses of section 17 specify tests to be performed to detect contamination.

A3.2.1 Source transport package - interna1

An acceptable test method for transport packages fitted with vent holes and drain lines is to fit a 10 micron-pore filter on both the container vent and drain lines to prevent the release of any unfiltered steam/water into the atmosphere during the test. Using a radiation survey instrument, continuously monitor the vent-line filter while filling the source storage cavity with clean water; the water is fed by gravity through the drain line from an elevated water container. Lower the water container to ground level and continuously monitor the drain line filter while all the water from the cavity is flowing back into the water container. During the draining process, the radiation exposure rate at the drain line filter may increase due to displacement of water in the source storage cavity. Both filters and the water shall be taken to a low radiation (background) area and monitored for contamination.

During the test, should the exposure rate at either filter increase beyond the level directly attributable to the displacement of the water shielding, it shall be assumed that the integrity of the contained sources has been impaired and the test shall be terminated. If the measured contamination is below the allowable limit, the contamination test may be resumed.

A3.2.2 Radiation sources

An acceptable contamination test on the radiation sources is to perform a gross wipe test using a foamed plastic wipe sample not exceeding 100 cm^2 in area. Attach the wipe to a rod or tube for wiping the suspect surfaces under water. Care should be taken to ensure that the tubing used as the sample holder is fully vented to allow water to flood the tubing and avoid the risk of a direct unattenuated beam to personnel during the test.

Measure the test sample in a low radiation (background) area with a suitable instrument and record the result.

Reference

1. American National Standards Institute (1978) *Radiation protection instrument test and calibration,* ANSI N323-1978, New York.