

Sale of radiation sources

Management licence holder's obligations

Licence condition M1750

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OFFICIAL

Introduction

The Victorian Radiation Act 2005 (the Act) has the objective of protecting the health and safety of persons and the environment from the harmful effects of radiation. The Department of Health (Department) administers this legislation. The Act seeks to fulfil this objective by establishing a licensing framework to regulate the conduct of radiation practices and the use of radiation sources. Any person who conducts a radiation practice (e.g. selling a radiation source) must hold a management licence that authorises the conduct of that particular radiation practice (unless exempted from that requirement). The management licence holder must comply with every condition of their licence.

Management licence condition M1750 requires compliance with the requirements specified in this document. This document outlines requirements pertaining to the sale of radiation sources. The requirements are divided into the following sections:

1. General requirements for the sale of all radiation sources
2. Requirements for the sale of X-ray apparatus
3. Requirements for the sale of radioactive material (other than sealed sources)
4. Requirements for the sale of radiopharmaceuticals
5. Requirements for the sale of molybdenum-99 / technetium-99m generators
6. Requirements for the sale of sealed source apparatus
7. Requirements for sale of sealed sources
8. Definitions.

Scope

This document forms a condition of licence which applies to all management licence holders authorised to sell radiation sources and where condition M1750 has been imposed on the authorisation.

Management licence holders must comply with all sections of this document that are relevant to the type of radiation source being sold.

Management licence holder's obligations

1. General requirements for the sale of all radiation sources

1.1. A management licence holder must not sell a radiation source to a customer unless the customer either:

- (a) has provided the management licence holder with evidence that the customer holds a management licence issued under the Act; or
- (b) has provided the management licence holder with evidence that the customer is exempt¹ from the requirement to hold a management licence under the Act.

This obligation does not apply where the customer will take possession of the radiation source outside Victoria.

1.2. A management licence holder must as soon as practicable, upon becoming aware of an unacceptable² radiation safety risk associated with a radiation source supplied by the licence holder:

- (a) conduct a risk assessment and identify corrective actions to mitigate the risk;
- (b) notify the Department of the risk and include in the notification³ the risk assessment and corrective actions required by item a); and
- (c) notify all relevant customers of the potential risk and advise them of the corrective actions that need to be undertaken to mitigate the risk.

2. Requirements for the sale of X-ray apparatus

A management licence holder who is authorised to sell X-ray apparatus must comply with the following requirements:

2.1 A management licence holder must, when selling **X-ray apparatus** of any type, ensure that the X-ray apparatus:

- (a) provides a visible signal at the control panel that automatically indicates when the apparatus is producing radiation;
- (b) is clearly labelled with a sign bearing the radiation hazard symbol and the warning "CAUTION X-RAY APPARATUS – produces radiation when energised" (or equivalent); and
- (c) complies with the relevant Australian Standard.

2.2. A Management licence holder must, when selling:

- (a) **a veterinary X-ray unit**, ensure that the veterinary X-ray unit meets the requirements specified in the 'Code of Practice for Radiation Protection in Veterinary Medicine (2009)' as published by the Australian Radiation Protection and Nuclear Safety Agency;

¹ Exemptions from the requirement to hold a management licence are available at: <https://www2.health.vic.gov.au/public-health/radiation> .

² Unacceptable risk means risk that is greater than the level of risk associated with the radiation source when controls consistent with good radiation safety practice are employed.

³ The notification must be submitted via email to: radiation.safety@health.vic.gov.au.

- (b) **a fixed radiation gauge**, ensure that the fixed radiation gauge meets the relevant requirements in the '*Code of Practice for the Safe Use of Fixed Radiation Gauges (2007)*' as published by the Australian Radiation Protection and Nuclear Safety Agency;
- (c) **a cabinet X-ray unit**, ensure that the cabinet X-ray unit meets the relevant X-ray equipment standards described in the '*Statement on cabinet X-ray equipment for examination of letters, packages, baggage, freight and other articles for security, quality control and other purposes (1987)*' as published by the National Health and Medical Research Council;
- (d) **an X-ray analysis unit**, ensure that the X-ray analysis unit meets the relevant X-ray equipment standards described in the '*Code of Practice for Protection Against Ionizing Radiation Emitted from X-ray Analysis Equipment (1984)*' as published by the National Health and Medical Research Council;
- (e) **an enclosed X-ray unit into which articles, products or other materials may be placed**, ensure that the X-ray unit meets the relevant X-ray equipment standards described in the '*Statement on enclosed X-ray equipment for special applications (1987)*' as published by the National Health and Medical Research Council;
- (f) **an industrial radiography X-ray apparatus**, ensure that the industrial radiography X-ray apparatus meets the relevant X-ray equipment standards described in the '*Code of Practice for the Safe Use of Industrial Radiography Equipment (1989)*' as published by the National Health and Medical Research Council;
- (g) **a medical X-ray unit** intended for use on humans, ensure that:
- (i) the X-ray unit is entered in the Australian Register of Therapeutic Goods, or is exempt from this requirement under the Therapeutic Goods Act 1989;
 - (ii) if the unit is a **prescribed radiation source**⁴ as defined by the Radiation Regulations 2017, the X-ray unit can meet the relevant prescribed Radiation Safety Standard⁵;
 - (iii) if clinical protocols are proposed by the manufacturer and preloaded on the X-ray unit, the instructions for use state whether or not the preloaded protocols constitute recommendations to be applied directly so as to allow optimised operation or the protocols are only examples to be replaced by more specific protocols developed by the user;
 - (iv) if there is a possibility in normal use that the patient can be exposed to radiation doses resulting in deterministic effects, the instructions for use address this fact. In this case, the particular modes of operation, configurations and circumstance in which deterministic effects may occur must be listed and the following must be provided:
 - a. the instructions for use must draw attention to the need to reduce the likelihood of high radiation doses and, when applicable, to the availability of selectable settings that can have a significant effect on the radiation quality, the delivered radiation dose, the Air Kerma or Air Kerma Rate, and the image quality;
 - b. the number of exposures or duration of exposure necessary to reach levels where deterministic effects are possible for an average patient and for an obese patient;
 - c. information concerning available settings, technique factors and operating parameters that effect the radiation quality and the radiation dose.
- (h) a dental X-ray unit, ensure that the dental X-ray unit;
- (i) is entered in the Australian Register of Therapeutic Goods, or is exempt from this requirement under the Therapeutic Goods Act 1989;

⁴ Computed Tomography scanners, Fluoroscopic X-ray apparatus, Mammographic X-ray apparatus and Plain Film X-ray units used for human diagnostic purposes have been prescribed.

⁵ Radiation Safety Standard prescribed under the Radiation Act 2005 are available at:
<https://www2.health.vic.gov.au/public-health/radiation>

- (ii) meets the equipment standards in the '*Code of Practice for Radiation Protection in Dentistry (2005)*' as published by the Australian Radiation Protection and Nuclear Safety Agency.

3. Requirements for the sale of radioactive material (other than sealed sources)

A management licence holder who is authorised to sell radioactive material must comply with the following requirements⁶:

3.1. A Management licence holder must, when selling radioactive material other than a sealed source, ensure that the radioactive material is contained in a container or device and the container or device is labelled with:

- (a) batch and/or lot number(s) sufficient to uniquely identify the product
- (b) radionuclide
- (c) activity⁷ and reference time/date;
- (d) chemical form;
- (e) volume or mass of radioactive material;
- (f) sign bearing the radiation hazard symbol and the warning "CAUTION RADIOACTIVE" (or equivalent).

4. Requirements for the sale of radiopharmaceuticals⁸

A management licence holder who is authorised to sell radiopharmaceuticals (including suspensions of radioactive material) must comply with the following requirements:

4.1. A management licence holder must, when selling a radiopharmaceutical, ensure that:

- (a) the radiopharmaceutical is contained in a container and the container is labelled with:
 - (i) batch and/or lot number(s) sufficient to uniquely identify the product;
 - (ii) radionuclide (e.g. Tc-99m);
 - (iii) activity⁹ and reference time/date (e.g. 10GBq @ 0900 12/12/2012);
 - (iv) chemical and/or pharmaceutical form (e.g. 99mTc-HDP);
 - (v) volume or mass of radioactive material (e.g. 4ml);
 - (vi) any restriction on the purpose for which the material is released;
 - (vii) expiry time/date of the radiopharmaceutical;
 - (viii) limitations, if any, in respect of storage and handling (e.g. store below 25C); and
 - (ix) radiation hazard symbol and the warning "CAUTION RADIOACTIVE" (or equivalent).
- (b) the radiopharmaceutical is entered in the Australian Register of Therapeutic Goods or is exempt from this requirement under the Therapeutic Goods Act 1989.
- (c) where the radiopharmaceutical is prepared from precursor products:

⁶ This requirement does not apply to sealed sources as defined by the Radiation Act 2005.

⁷ All measurements of radioactivity must be expressed in SI units (e.g. MBq, GBq, TBq).

⁸ Radiopharmaceutical means radioactive material that is used for the purpose of diagnosing or treating disease.

⁹ All measurements of radioactivity must be expressed in SI units (e.g. MBq, GBq, TBq).

- (i) the precursor products are entered in the Australian Register of Therapeutic Goods, or are exempt from this requirement under the Therapeutic Goods Act 1989; and
 - (ii) the radiopharmaceutical is produced in accordance with the Product Information document approved by the Therapeutic Goods Administration (TGA) or a validated protocol approved by the Department
- (d) a quality control report is provided to the customer that certifies:
- (i) the radionuclidic purity of the radiopharmaceutical;
 - (ii) the radiochemical purity of the radiopharmaceutical; and
 - (iii) the radiopharmaceutical is produced in accordance with the Product Information document approved by the Therapeutic Goods Administration (TGA) or a validated protocol approved by the Department.
- (e) the quality control report required by part d) includes:
- (i) the name of the person who verified that the quality of the product met the required standards;
 - (ii) test results;
 - (iii) date of tests;
 - (iv) batch number of the radiopharmaceutical;
 - (v) Name of test methods; and
 - (vi) the standards that the radiopharmaceutical meets.

4.2. A management licence holder must, upon becoming aware of a radiopharmaceutical that the management licence holder supplied not complying with relevant specifications or there being doubts as to the quality, safety, efficacy or presentation of the radiopharmaceutical:

- (a) immediately contact customers by telephone or email to prevent the use of the radiopharmaceutical;
- (b) seek customers' acknowledgment that they have quarantined unused radiopharmaceutical; and
- (c) notify¹⁰ the Department of the affected radiopharmaceutical.

5. Requirements for the sale of molybdenum-99 / technetium-99m generators

A management licence holder who is authorised to sell molybdenum-99 / technetium-99m generators must comply with the following requirements:

5.1 A management licence holder who is authorised to sell molybdenum-99 / technetium-99m generators must ensure that:

- (a) the performance of the generator meets the criteria specified in Table 1 prior to the generator being dispatched,
- (b) a quality control report is provided to the customer that certifies that the performance of the generator meets the criteria specified in Table 1,
- (c) the quality control report required by part b) includes:

¹⁰ The notification must be submitted via email to: radiation.safety@health.vic.gov.au

- (i) date of test;
- (ii) batch number of the generator;
- (iii) results of tests specified in Table 1.

Table 1: Quality control tests and criteria

Test	Criteria
1. Molybdenum-99 breakthrough	The activity of molybdenum-99 in any 1 MBq of technetium-99m must not exceed 1 kBq.
2. Aluminium breakthrough	The concentration of aluminium ions must not exceed 5 µg/mL.
3. Radiochemical purity	$^{99m}\text{TcO}_4^- > 95\%$ (hydrolysed-reduced <5%)
4. pH of eluate	The pH must be in the range 4.0 to 8.0

6. Requirements for the sale of sealed source apparatus

A management licence holder who is authorised to sell sealed source apparatus (apparatus containing a radioactive sealed source e.g. portable density/moisture gauge) must comply with the following requirements:

6.1 A management licence holder must, when selling a sealed source apparatus, ensure that:

- (a) the sealed source contained within the apparatus is firmly bonded within metal or sealed in a capsule or similar container of adequate strength to prevent dispersion of the active substance into the surroundings under foreseeable conditions of use and wear;
- (b) the sealed source complies with a recognised quality standard, such as ISO 2919:2012;

6.2 A management licence holder must, when selling a sealed source apparatus, ensure that the apparatus is clearly and permanently labelled with:

- (a) a serial number or other identifier sufficient to uniquely identify the apparatus;
- (b) a sign bearing the radiation hazard symbol and the warning "CAUTION RADIOACTIVE APPARATUS – contains radioactive material" (or equivalent);
- (c) the number of sealed sources contained within the apparatus; and
- (d) for each sealed source within the apparatus:
 - (i) serial number of the sealed source;
 - (ii) radionuclide (e.g. Cs-137); and
 - (iii) activity and reference date.

6.3. A management licence holder must, when selling:

- (a) a **fixed radiation gauge containing a sealed source**, ensure that the fixed radiation gauge meets the relevant standards described in the '*Code of Practice for the Safe Use of Fixed Radiation Gauges (2007)*' as published by the Australian Radiation Protection and Nuclear Safety Agency.

- (b) an **industrial radiography apparatus containing a sealed source**, ensure that the apparatus meets the relevant standards described in the '*Code of practice for the safe use of industrial radiography equipment (1989)*' as published by the National Health and Medical Research Council.
- (c) a **portable density/moisture gauge** ensure that the apparatus meets the relevant standards described in the '*Code of Practice for Portable Density/Moisture Gauges containing Radioactive Sources (2004)*' as published by the Australian Radiation Protection and Nuclear Safety Agency.
- (d) an **irradiator containing a sealed source**, ensure that the irradiator meets the relevant sealed source standards described in the '*Code of practice for the design and safe operation of non-medical irradiation facilities (1988)*' as published by the National Health and Medical Research Council.
- (e) a **sealed source apparatus** intended for therapeutic¹¹ use on humans, ensure that the apparatus is entered in the Australian Register of Therapeutic Goods, or is exempt from this requirement under the *Therapeutic Goods Act 1989*.

7 Requirements for sale for sealed sources

A management licence holder who is authorised to sell sealed sources¹² (radioactive material that is permanently sealed in a capsule or closely bound in solid form) must comply with the following requirements:

7.1 A management licence holder must, when selling a sealed source, ensure that:

- (a) the radioactive material is permanently sealed in a capsule or is closely bound in solid form to prevent dispersion of the radioactive material into the surroundings under foreseeable conditions of use and wear; and
- (b) the sealed source complies with a recognised quality standard, such as ISO 2919:2012.

7.2 A management licence holder must, when selling a sealed source, ensure that the source is held in a suitably shielded container or device and the container or device is labelled with:

- (a) the number of sealed sources held within the container or device;
- (b) for each sealed source within the container:
 - (i) serial number of the sealed source;
 - (ii) radionuclide (e.g. Cs-137); and
 - (iii) activity and reference date.

7.3. A management licence holder must, when selling a sealed source intended for therapeutic use on humans, ensure that the sealed source is entered in the Australian Register of Therapeutic Goods, or is exempt from this requirement under the *Therapeutic Goods Act 1989*.

7.4. A management licence holder must, when selling a sealed source intended for use in:

- (a) a **fixed radiation gauge** ensure that the sealed source meets the relevant standards described in the '*Code of Practice for the Safe Use of Fixed Radiation Gauges (2007)*' as published by the Australian Radiation Protection and Nuclear Safety Agency.

¹¹ Therapeutic use includes preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury.

¹² Not including radioactive material held within a container (e.g. a vial or syringe containing a suspension of radioactive material/sources).

- (b) an **industrial radiography apparatus** ensure that the sealed source meets the relevant standards described in the '*Code of practice for the safe use of industrial radiography equipment (1989)*' as published by the National Health and Medical Research Council.
- (c) a **portable density/moisture gauge** ensure that the sealed source meets the relevant standards described in the '*Code of Practice for Portable Density/Moisture Gauges containing Radioactive Sources (2004)*' as published by the Australian Radiation Protection and Nuclear Safety Agency.
- (d) an **irradiator** ensure that the sealed source meets the relevant sealed source standards described in the '*Code of practice for the design and safe operation of non-medical irradiation facilities (1988)*' as published by the National Health and Medical Research Council.
- (e) a **sealed source apparatus** intended for therapeutic¹³ use on humans, ensure that the sealed source is entered in the Australian Register of Therapeutic Goods, or is exempt from this requirement under the *Therapeutic Goods Act 1989*.

8 Definitions

Radioactive Material means:

- (a) any material that spontaneously emits ionising radiation that:
 - (i) has an activity concentration equal to, or greater than, the amount prescribed by the Radiation Regulations 2017; and
 - (ii) consists of, or contains, an activity equal to, or greater than, the amount prescribed by the Radiation Regulations 2017; or
- (b) any material that spontaneously emits ionising radiation that:
 - (i) has an activity concentration, or consists of, or contains, an activity, less than the amount prescribed by the Radiation Regulations 2017; and
 - (ii) occurs in prescribed circumstances:

but does not include:

- (c) raw material with unmodified concentrations of radionuclides unless that material is prescribed by the regulations to be radioactive material;
- (d) material that is:
 - (i) prescribed by the Radiation Regulations 2017 not to be radioactive material; or
 - (ii) declared not to be radioactive material under section 4 of the Radiation Act 2005.

Radiopharmaceutical means radioactive material that is used for the purpose of diagnosing or treating disease.

Sealed Source means radioactive material that is:

- (a) permanently sealed in a capsule; or
- (b) closely bound and in solid form.

¹³ Therapeutic use includes preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury.

Sealed Source Apparatus means an apparatus that produces ionising radiation because it contains a sealed source but does not include an apparatus that is:

- (a) prescribed by the Radiation Regulations 2017 not to be a sealed source apparatus; or
- (b) declared not to be a sealed source apparatus under section 4 of the Radiation Act 2005

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