

Documents required with Management Licence applications and notifications

Radiation Act 2005

Introduction

This document outlines the supporting documents that must be submitted when lodging an application for a new Management Licence, an application to vary a Management Licence or a notification. Where a person is submitting an application for a new Management Licence, an application to vary an existing Management Licence or a notification on behalf of another person or a legal entity that is not a natural person (e.g. company), the person submitting the application or the notification must provide the documents that are specified in the *Evidence of a Legal Entity* section of this document.

Table of contents

Evidence of a Legal Entity	2
Practice Specific Documents	3
Possession of a high consequence sealed source or a high consequence group of sealed sources	3
Medical practices	4
General supporting documents required for medical practices	4
Practice specific supporting documents required for medical practices	4
Dental practices	7
Sale of radiation sources	8
Transport of radioactive material	9
Industrial practices	11
Borehole logging source	11
Fixed radiation gauge	11
Industrial radiography unit	12
Portable nuclear moisture/density gauge	12
Cabinet X-ray unit	13
X-ray analysis unit	13
Veterinary practices	14
Education & research practices (not involving the exposure of humans to ionising radiation)	15

Evidence of a Legal Entity

Where an application is being submitted on behalf of a company

1. Where a person is submitting an application for a new Management Licence, an application to vary an existing Management Licence or a notification on behalf of a legal entity (e.g. company), the person submitting the application or the notification must provide, or have previously provided, the following documents:
 - a) An evidence of identity document that establishes the legal existence of the legal entity (e.g. Certificate of Registration of a Company issued by the Australian Securities and Investments Commission displaying the Australian Company Number).
 - b) Company extract issued by the Australian Securities and Investments Commission or equivalent document showing the name of the Director of the company.
 - c) A letter of authority from the Director of the company that both authorises the person to lodge an application for a management licence on behalf of the legal entity and nominates the person to be the contact in relation to the proposed radiation practice(s). Note: A letter of authorisation is not required if the person submitting the application or notification is a Director of the company and documents specified above have been submitted.

Where an application is being submitted on behalf of another person

2. Where a person is submitting an application for a new Management Licence, an application to vary an existing Management Licence or a notification on behalf of another person, the person submitting the application or the notification must provide, or have previously provided, the following:
 - a) A letter of authority from the proposed licence holder that both authorises the person to lodge an application for a management licence and nominates the person to be the contact in relation to the proposed radiation practice(s).

Practice Specific Documents

Possession of a high consequence sealed source or a high consequence group of sealed sources

Application by a natural person

- Where an application by a natural person involves conducting a radiation practice that includes possession of a high consequence sealed source or a high consequence group of sealed sources, the following documents in addition to the other Practice Specific Documents (e.g. for borehole logging, industrial radiography) must be provided:
 - A copy of an approved security plan and security compliance certificate issued by an approved assessor¹ for that sealed source or group of sealed sources; and
 - Copies of the identification documents which provide evidence of the person's identity.²

Application by a body corporate

- Where an application by a body corporate involves conducting a radiation practice that includes possession of a high consequence sealed source or a high consequence group of sealed sources, the following documents in addition to the other Practice Specific Documents (e.g. for borehole logging, industrial radiography) must be provided:
 - A copy of an approved security plan and security compliance certificate issued by an approved assessor³ for that sealed source or group of sealed sources; and
 - Copies of the identification documents which provide evidence of the person's identity⁴ who is to be responsible for the security of the high consequence sealed source or high consequence group of sealed sources.

¹ A list of approved assessors is available on the Department's website at:

<https://www2.health.vic.gov.au/public-health/radiation/licensing/assessment-security-plans/approved-assessors>

² The evidence of identity that is required can be found in the document with the title 'Guidelines for the verification of identity' located at:

<https://www2.health.vic.gov.au/about/publications/policiesandguidelines/guidelines-for-the-verification-of-identity>

³ A list of approved assessors is available on the Department's website at:

<https://www2.health.vic.gov.au/public-health/radiation/licensing/assessment-security-plans/approved-assessors>

⁴ The evidence of identity that is required can be found in the document with the title 'Guidelines for the verification of identity' located at:
<https://www2.health.vic.gov.au/about/publications/policiesandguidelines/guidelines-for-the-verification-of-identity>

Medical practices

General supporting documents required for medical practices

1. A **shielding assessment report** that specifies the minimum amount of shielding that is required in the walls, doors, floor, ceiling and windows of the room in which the radiation source is will be installed to ensure that no person receives a radiation dose in excess of the relevant radiation protection limits specified in the Radiation Regulations 2017. This requirement also applies to mobile X-ray units used primarily in one location. The shielding assessment must include the following:
 - a) Floor plan showing the room in which the radiation source will be installed and surrounding rooms.
 - b) Occupancy factors and purpose of surrounding rooms
 - c) Methodology/references used in the assessment
 - d) Shielding required for the operator
 - e) Radiation source workloads for the proposed practice
 - f) The location of any related equipment e.g. X-ray equipment, tables, buckys, controls, protective screens, warning lights

The shielding assessment must take into consideration exposures arising from all aspects of the proposed radiation practice e.g. in the case of Nuclear Medicine the assessment must consider exposure from patients administered with radioactive material as well as radioactive material that is in storage.

2. Details (including thicknesses) of construction/shielding materials used in the walls, doors, floor, ceiling and windows of the room in which the radiation source is will be installed. Where a shielding material is used that is different to the material specified in the shielding report, evidence must be provided of the material used having equivalent shielding properties.
3. Evidence of **personal radiation monitoring** devices being available to staff; or
A dose assessment showing that doses from the proposed practice are not likely to exceed 1 mSv in any one year.
4. Copy of a **Radiation Management Plan** as required by the Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation as published by the Australian Radiation Protection and Nuclear Safety Agency. This Code can be downloaded from:
<http://www.arpansa.gov.au/Publications/codes/rps14.cfm>

Practice specific supporting documents required for medical practices

Radiation source	Information required
Radiography Practices	
Fluoroscopy (fixed apparatus used for image guided interventional procedures)	Either: <ol style="list-style-type: none"> 1. Evidence of devices being available at the proposed practice to: <ol style="list-style-type: none"> a. minimise radiation exposure to the eyes of staff that will be in close proximity of the fluoroscopic apparatus (e.g. shields, lead glasses); and b. monitor radiation exposure to the eyes of staff that will be in close proximity of the fluoroscopic apparatus; or 2. A dose assessment showing that doses to the lens of the eye are not likely to exceed an equivalent dose of 2 mSv in any one year.

Radiation source	Information required
Nuclear Medicine Practices	
Unsealed Radioactive Materials	<p>Provide details regarding surface finishes, ventilation, drains in areas where radioactive material is to be used, and proposed arrangements for storage and disposal of radioactive material.</p> <p>As a guide to good practice it is recommended that the principles contained in the following Standards be adopted for all laboratories in which radioactive substances are used or stored:</p> <p>AS 2243.4-1998 Safety in laboratories Part 4: Ionizing radiations AS/NZS 2982:2010 Laboratory design and construction Australasian Health Facility Guidelines HPU B.0500 – Nuclear Medicine / PET Unit</p>
Sealed Sources	<p>Provide a plan outlining how the radioactive source will be disposed of when it is no longer required. For example, there may be documentation from the manufacture or supplier of the radiation source indicating a disposal option at the end of the working life of the radiation source. The proposed disposal pathway must comply with the following document:</p> <p>http://docs.health.vic.gov.au/docs/doc/Disposal-of-radioactive-material</p>
Radiotherapy Practices	
Linear Accelerators	<p>Linear accelerators intended to be used for radiotherapy must undergo a two stage licensing process.</p> <p>Firstly, the possession of a linear accelerator must be authorised for the purpose of commissioning and testing. This authorisation allows the licence holder to acquire the linear accelerator and perform commissioning and testing on the apparatus.</p> <p>Secondly, once the linear accelerator has been commissioned and tested, an application for the authority to possess the linear accelerator for the purpose of radiotherapy (i.e. clinical use) can be submitted.</p> <p>The supporting documents required with both types of applications are listed below:</p> <p>Documents required with an application for an authority to possession a linear accelerator for the purpose of commissioning and testing:</p> <ol style="list-style-type: none"> 1. A shielding assessment as specified above under the heading <i>General supporting documents required for medical practices</i>. The shielding assessment must be verified by a physicist who is independent of the person who produced the shielding assessment. <p>Documents required with an application for an authority to possession a linear accelerator for the purpose of radiotherapy:</p> <ol style="list-style-type: none"> 1. A radiation survey that demonstrates that the radiation shielding is sufficient to ensure that no person receives a radiation dose in excess of the relevant radiation protection limits specified in the Radiation Regulations 2017. 2. Evidence of the facility having undergone dosimetric audits as required by the document titled <i>Requirements for independent dosimetric auditing of linear accelerators</i> (i.e. evidence of the commissioned linear accelerator having passed a level Ib audit and evidence of at least one linear accelerator at the site having passed a level III audit in the last 4 years).
High Dose Rate Brachytherapy	<p>Documents specified in the section titled “<i>Possession of a high consequence sealed source or a high consequence group of sealed sources</i>”</p>

Recommendations

Compliance with the **Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation** as published by the Australian Radiation Protection and Nuclear Safety Agency is a condition of licence for medical practices. Licence holders must be familiar with its requirements. An important requirement of this Code is the development and implementation of a Radiation Management Plan. This Code can be downloaded from: <http://www.arpana.gov.au/Publications/codes/rps14.cfm>

We strongly recommend that applicants become familiar with the Code as well as the following Safety Guide(s) relevant to their practice before lodging an application:

- [Safety Guide 'Radiation Protection in Diagnostic and Interventional Radiology'](#).
- [Safety Guide 'Radiation Protection in Nuclear Medicine'](#).
- [Safety Guide 'Radiation Protection in Radiotherapy'](#).

Dental practices

What do I need to include in my licence application?

You must include the following information with your application. Please note that electronic files can be attached with your application.

1. A **floor plan** of the premises where the dental X-ray equipment will be installed or used. The plan must include the following:
 - a) The location of each X-ray unit and any related equipment e.g. controls, protective screens, warning lights.
 - b) In relation to the room(s) containing X-ray units, include in the floor plan the surrounding rooms, their purposes and their occupancy.
1. For extra-oral X-ray units only (e.g. panoramic, cephalometric, cone beam CT), an assessment of the minimum amount of shielding that is required in the walls, doors, floor and ceiling of the room in which the radiation source is will be installed to ensure that no person receives a radiation dose in excess of the relevant radiation protection limits specified in the Radiation Regulations 2017. This requirement also applies to mobile X-ray units used primarily in one location. The shielding assessment must include the following:
 - a) Floor plan showing the room in which the radiation source will be installed and surrounding rooms.
 - b) Occupancy factors and purpose of surrounding rooms
 - c) Methodology/references used in the assessment
 - d) Shielding required for the operator
 - e) Radiation source workloads used in the assessment
 - f) The location of any related equipment e.g. controls, protective screens, warning lights.
2. **For extra-oral X-ray units only**, the name of the personal radiation monitoring service (PRMS) provider that you will use and the centre number assigned to you by the provider.

For practices that involve **intra-oral X-ray apparatus only**, there is no requirement either for personal radiation monitoring or for shielding additional to that provided by normal plasterboard or similar building material.

Compliance with the **Code of Practice for Radiation Protection in Dentistry** as published by the Australian Radiation Protection and Nuclear Safety Agency is a condition of licence for dental practices and you must be familiar with its requirements. This Code can be downloaded from:

<http://www.arpansa.gov.au/Publications/codes/rps10.cfm>

We strongly recommend that you also read the Safety Guide that accompanies the abovementioned Code of Practice before lodging an application.

Sale of radiation sources

What do I need to include in my licence application?

You must include the following information with your application. Please note that electronic files can be attached with your application.

1. Detailed description of all **types of radiation sources** that you are seeking authority to sell.
2. When radioactive material will be stored for the purpose of sale, provide details both of the type of radioactive material and of the maximum activity of the radioactive material,
3. Where radioactive material will be stored for any period of time, provide details of the construction and **shielding** in the walls, doors, floor and ceiling of the storage facility or premises in which the radiation sources will be stored to ensure that no person receives a radiation dose in excess of the relevant radiation protection limits specified in the Radiation Regulations 2017. These details must include shielding calculations.
4. Where radioactive material will be handled, provide the name of the **personal radiation monitoring service** (PRMS) provider that you will use and the centre number assigned to you by the provider.
5. Where radiation sources will be handled, provide details of **training of staff** that will be involved in the radiation practice. Note: A separate authorisation will be required if the intention is to also service and/or maintain the radiation sources to be sold, along with training of staff that will be involved in the servicing of the sources.
6. In the case of radioactive material, details of the company that will be **transporting** the material. For applicants seeking authority to transport radioactive material, please refer to "[Transport of Radioactive Material](#)".

Where the proposed radiation practice will involve possession of a high consequence sealed source or a high consequence group of sealed sources as defined by the Radiation Act 2005, you will need to provide the documents specified in the section titled "*Possession of a high consequence sealed source or a high consequence group of sealed sources*".

Transport of radioactive material

What do I need to include in my licence application?

The Department of Health has published '**Regulation of Transport of Radioactive Material**' to provide more detail about the Victorian approach to regulating this practice. It is strongly recommend that you read this document. A copy of the document is provided below:

 [Regulation of the transport of radioactive material \(112kb, pdf\)](#)

You must include the following information with your application. Please note that electronic files can be attached with your application.

1. A description of the types of radioactive materials that you are seeking authority to transport and in what capacity. For example, do you wish to transport radioactive material for other people as a 'contract carrier' or do you wish to transport radioactive material that you are authorised to possess?
2. The name of the **personal radiation monitoring service** (PRMS) provider that you will use and the centre number assigned to you by the provider.
3. Details of your quality assurance systems. For example the tracking system used to locate consignments or chain-of-custody procedures.
4. Details of the **training in radiation safety** provided to all workers involved in the transport of radioactive material.
5. Where radioactive material will be stored for any period of time, provide details of the construction and shielding of the storage facility or premises that will ensure that no person will receive a radiation dose in excess of the relevant radiation protection limits specified in the Radiation Regulations 2017. These details must include shielding calculations.
6. For applications seeking authorisation to transport a high consequence sealed source or a high consequence group of sealed sources as defined by the Radiation Act 2005 please provide the following:
 - a. a generic Transport Security Plan endorsed by an Approved Assessor. A list of approved assessors is available on the department's website: <https://www2.health.vic.gov.au/public-health/radiation>
 - b. a copy of a Certificate of Compliance issued in respect of the Transport Security Plan by an Approved Assessor.
7. Emergency procedures in the event of transport accidents.

Compliance with the **Code for the Safe Transport of Radioactive Material** (2014) as published by the Australian Radiation Protection and Nuclear Safety Agency is a condition of licence for transport of radioactive material and you must be familiar with its requirements. This Code can be downloaded from:

<https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/codes-and-standards/rpsc-2>

Additional documentation if the transport involves a high consequence sealed source or a high consequence group of sealed sources

If you are a natural person (not a body corporate), then you must provide evidence of your identity. The evidence of identity that is required can be found in the document with the title 'Guidelines for the verification of identity' located at:

<https://www2.health.vic.gov.au/about/publications/policiesandguidelines/guidelines-for-the-verification-of-identity>

If you are a body corporate, then you must provide evidence of the identity of the person who is responsible for the security of the high consequence sealed source or high consequence group of sealed sources. The evidence of identity that is required can be found in the document with the title 'Guidelines for the verification of identity' located at:

<https://www2.health.vic.gov.au/about/publications/policiesandguidelines/guidelines-for-the-verification-of-identity>

We strongly recommend that you read the following documents before lodging an application:

-  [Load restraint guidelines \(30kb, pdf\)](#)
- [Safety Guide for the Safe Transport of Radioactive Material.](#)

Industrial practices

What do I need to include in my licence application?

You must include the following information listed in the table below with your application. Please note that electronic files can be attached with your application.

The Codes of Practice listed under each radiation source are a condition of licence with respect to the radiation source. You must be familiar with the requirements of the Code of Practice applicable to the radiation source you are seeking authority to possess. The Codes of Practice can be downloaded from the following website: <http://www.arpansa.gov.au/publications/codes/index.cfm>

Radiation source / Code of Practice	Information required
<p>Borehole logging source</p> <p>NHMRC Code of Practice for the safe use of sealed radioactive sources in borehole logging (1989), RHS No. 28</p> <p>Code of Practice for the Safe Transport of Radioactive Material (20014), RPS No. 2</p>	<ol style="list-style-type: none"> 1. A detailed plan showing the areas within the premises where the radiation source will be stored. 2. The name of the personal radiation monitoring service (PRMS) provider that you will use and the centre number assigned to you by the provider. 3. Details of the training in radiation safety provided to all workers involved in the radiation practice. 4. Please also provide the information specified under "Transport of Radiation Sources". 5. Provide a plan outlining how the radioactive source will be disposed of when it is no longer required. For example, there may be documentation from the manufacture or supplier of the radiation source indicating a disposal option at the end of the working life of the radiation source. The proposed disposal pathway must comply with the following document: http://docs.health.vic.gov.au/docs/doc/Disposal-of-radioactive-material 6. Where the radiation source is a <i>high consequence sealed source as defined under the Radiation Act 2005</i> documents specified in the section titled "<i>Possession of a high consequence sealed source or a high consequence group of sealed sources</i>" must be provided.
<p>Fixed radiation gauge</p> <p>Code of the Practice & Safety Guide for the Safe Use of Fixed Radiation Gauges (2007), RPS No. 13</p>	<ol style="list-style-type: none"> 1. Description of how the radiation gauge will be used. 2. A detailed floor plan showing the areas within the premises that the radiation sources will be installed or used. 3. The name of the personal radiation monitoring service (PRMS) provider that you will use and the centre number assigned to you by the provider. 4. Details of the training in radiation safety provided to all workers involved in the radiation practice. 5. Provide a plan outlining how the radioactive source will be disposed of when it is no longer required. For example, there may be documentation from the manufacture or supplier of the radiation source indicating a disposal option at the end of the working life of the radiation

Radiation source / Code of Practice	Information required
	<p>source. The proposed disposal pathway must comply with the following document: http://docs.health.vic.gov.au/docs/doc/Disposal-of-radioactive-material</p> <p>6. Where the radiation source is a <i>high consequence sealed source as defined under the Radiation Act 2005</i> documents specified in the section titled “<i>Possession of a high consequence sealed source or a high consequence group of sealed sources</i>” must be provided.</p>
<p>Industrial radiography unit</p> <p>NHMRC Code of practice for the safe use of industrial radiography equipment (1989), RHS No. 31</p> <p>Code of Practice for the Safe Transport of Radioactive Material (20014), RPS No. 2</p>	<ol style="list-style-type: none"> 1. A detailed floor plan showing the areas within the premises where the radiation sources will be used or stored. 2. Indicate whether the industrial radiography practice will be conducted in the field (mobile) or in a dedicated exposure bay. 3. In the case of an exposure bay, provide details of the construction and shielding of the exposure bay that will ensure that no person receives a radiation dose in excess of the relevant radiation protection limits specified in the Radiation Regulations 2017. These details must include shielding calculations. 4. The name of the personal radiation monitoring service (PRMS) provider that you will use and the centre number assigned to you by the provider. 5. For applicants seeking authority to transport mobile industrial radiography equipment which utilises radioactive source(s), please provide the information specified under “Transport of Radiation Sources”. 6. Details of the training in radiation safety provided to all workers involved in the radiation practice. 7. Provide a plan outlining how the radioactive source will be disposed of when it is no longer required. For example, there may be documentation from the manufacture or supplier of the radiation source indicating a disposal option at the end of the working life of the radiation source. The proposed disposal pathway must comply with the following document: http://docs.health.vic.gov.au/docs/doc/Disposal-of-radioactive-material 8. Where the radiation source is a <i>high consequence sealed source as defined under the Radiation Act 2005</i> documents specified in the section titled “<i>Possession of a high consequence sealed source or a high consequence group of sealed sources</i>” must be provided.
<p>Portable nuclear moisture/density gauge</p>	<ol style="list-style-type: none"> 1. A detailed plan showing the areas within the premises where the radiation sources will be stored. 2. With regards to the transport of gauges, a brief description of the method for achieving

Veterinary practices

What do I need to include in my licence application?

You must include the following information with your application. Please note that electronic files can be attached with your application.

1. An assessment of the minimum amount of shielding that is required in the walls, doors, floor and ceiling of the room in which the radiation source is will be installed to ensure that no person receives a radiation dose in excess of the relevant radiation protection limits specified in the Radiation Regulations 2017. This requirement also applies to mobile X-ray units used primarily in one location. The shielding assessment must include the following:
 - a) Floor plan showing the room in which the radiation source will be installed and surrounding rooms.
 - b) Occupancy factors and purpose of surrounding rooms
 - c) Methodology/references used in the assessment
 - d) Shielding to the operator's console
 - e) Radiation source workloads used in the assessment
 - f) The location of any related equipment e.g. X-ray equipment, tables, controls, protective screens, warning lights.
2. The name of the **personal radiation monitoring service** (PRMS) provider that you will use and the centre number assigned to you by the provider.
3. For **veterinary nuclear medicine** practices, please also provide details regarding surface finishes, ventilation, drains in areas where radioactive material is to be used, and proposed arrangements for storage and disposal of any radioisotopes, radiopharmaceuticals or sealed sources. As a guide to good practice it is recommended that the principles contained in the following Standards be adopted for all laboratories in which radioactive substances are used or stored: AS 2243.4-1998 Safety in laboratories Part 4: Ionizing radiations and AS/NZS 2982:2010 Laboratory design and construction.
4. For radioactive sources, provide a plan outlining how the radioactive source will be disposed of when it is no longer required. For example, there may be documentation from the manufacture or supplier of the radiation source indicating a disposal option at the end of the working life of the radiation source. The proposed disposal pathway must comply with the following document:

<http://docs.health.vic.gov.au/docs/doc/Disposal-of-radioactive-material>

Compliance with the **Code of Practice for Radiation Protection in Veterinary Medicine (2009)** as published by the Australian Radiation Protection and Nuclear Safety Agency is a condition of licence for veterinary practices and you must be familiar with its requirements. An important requirement of this Code is the development and implementation of a Radiation Management Plan. This Code can be downloaded from:

<http://www.arpana.gov.au/Publications/codes/rps17.cfm>

Before lodging an application, we strongly recommend that you read the Safety Guide which is attached with the abovementioned Code of Practice.

Education & research practices (not involving the exposure of humans to ionising radiation)

What do I need to include in my licence application?

You must include the following information with your application. Please note that electronic files can be attached with your application.

1. A detailed description of the radiation practice you seek authority to conduct.
2. An assessment of the minimum amount of shielding that is required in the walls, doors, floor and ceiling of the room in which the radiation source is will be installed to ensure that no person receives a radiation dose in excess of the relevant radiation protection limits specified in the Radiation Regulations 2017. This requirement also applies to mobile X-ray units used primarily in one location. The shielding assessment must include the following:
 - a) Floor plan showing the room in which the radiation source will be installed and surrounding rooms.
 - b) Occupancy factors and purpose of surrounding rooms
 - c) Methodology/references used in the assessment
 - d) Shielding to the operator's console
 - e) Radiation source workloads used in the assessment
 - f) The location of any related equipment e.g. X-ray equipment, tables, controls, protective screens, warning lights.
2. The name of the **personal radiation monitoring service** (PRMS) provider that you will use and the centre number assigned to you by the provider.
3. Proposed arrangements for the storage of radioisotopes, of radiopharmaceuticals, and of sealed sources.
4. For radioactive sources, provide a plan outlining how the radioactive source will be disposed of when it is no longer required. For example, there may be documentation from the manufacture or supplier of the radiation source indicating a disposal option at the end of the working life of the radiation source. The proposed disposal pathway must comply with the following document:

<http://docs.health.vic.gov.au/docs/doc/Disposal-of-radioactive-material>

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