



Australian Government

Australian Radiation Protection and Nuclear Safety Agency

REGULATORY GUIDE: APPLYING FOR A FACILITY LICENCE FOR A PRESCRIBED RADIATION FACILITY

This Regulatory Guide is provided to assist Commonwealth entities or Commonwealth contractors who wish to make an application for a facility licence for a prescribed radiation facility under section 32 of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the ARPANS Act). This document provides guidance on how to complete a Facility Licence Application for a Prescribed Radiation Facility and should be read in conjunction with that form. Information is also provided about the licensing decision and appeals process.

All licence applications must be accompanied by the appropriate application fee (ss34(b) of the ARPANS Act). Please refer to the *Australian Radiation Protection and Nuclear Safety Regulations 1999* (the Regulations) for information regarding the calculation of such fees, in particular regulation 40C and Schedule 3B. For further information on the calculation of application fees contact the Regulatory and Policy Branch.

The completed application form, accompanying documentation and appropriate fee should be sent to:

The Director
Regulatory and Policy Branch
ARPANSA
PO Box 655
MIRANDA NSW 1490

Alternatively, applications may be lodged electronically at licenceadmin@arpansa.gov.au. If using this option, arrangements must be made for payment of application fee either by cheque or via electronic banking.

COMPLETING THE FACILITY LICENCE APPLICATION FORM

SECTION A – GENERAL INFORMATION

1. Name of Department or Commonwealth Body

This is the name of the Department or Commonwealth Body on behalf of which the application is being made. It may include further information for ease of identification eg Division, Branch, Section etc.

2. Applicant

The application must be made by:

- a) the Secretary, Chief Executive Officer, or an equivalent person, of the Department or Commonwealth Body (the applicant); or
- b) a person authorised by the applicant to lodge an application.¹

In the case of (b), the application must include a copy of the authorisation.

3. Nominee

If the applicant is sufficiently removed from facility that they cannot demonstrate effective control, the name and contact details of a person more directly in control of the facility (the nominee) must be provided. The nominee must be in effective control of the prescribed radiation facility. Generally the nominee will be the manager of a division or agency's operation at the site of the proposed activity or, in the case of mobile devices, where the devices are usually stored. Other nominees may also be acceptable where the hazards of the activity are low and only minimal control is required. If a nominee is appointed, an organisational chart should be provided, showing the relationship of the nominee to the applicant and end users.

4. Radiation Safety Officer

This is an individual appointed by the applicant to supervise radiation safety in relation to the controlled facility, controlled apparatus and/or controlled material for which the licence is sought. This person must be technically competent in radiation protection matters relevant to the facility and/or sources including any non-ionising sources. Evidence of competency should be included in the application. If there is more than one radiation safety officer, the details of other radiation safety officers should also be provided.

5. Declaration

The declaration must be signed by the applicant or authorised person.

SECTION B – KIND OF PRESCRIBED RADIATION FACILITY

Indicate the kind of prescribed radiation facility for which a facility licence is sought by ticking the appropriate box in the table.

Note: The item numbers are taken from Schedule 3B Part 1 of the Regulations.

SECTION C –TYPE OF AUTHORISATION

Indicate the type of authorisation required by ticking the appropriate box in the table.

Note: These types of authorisation are taken from Schedule 3 Part 1 of the Regulations.

¹ Refer reg 39(4)(ii) of the ARPANS Regulations

SECTION D - KIND OF CONTROLLED MATERIAL AND/OR CONTROLLED APPARATUS (SOURCES)

Sources that are part of, used in connection with, produced by, incorporated in, stored in, or disposed of in, a prescribed radiation facility do not require a separate source licence, but must be authorised by the facility licence.

Indicate the kind of controlled material or controlled apparatus to be dealt with under the facility licence by ticking the appropriate box(es) in the table.

Note: These item numbers are taken from Schedule 3C of the Regulations, but these are not necessarily the only category of source that may be the subject of a licence application. If in doubt, contact the ARPANSA Regulatory and Policy Branch on 02 9541 8333 for advice on ascertaining a category.

SECTION E – SOURCE DETAILS

Section E is the Source Inventory Workbook (SIW), a separate section of the licence application form. The SIW is the form approved by the CEO for maintaining records of all sources to be dealt with under the licence. The details of all sources must be provided in the SIW. An explanation of terms and required information appears in the first worksheet of the SIW. The completed SIW is to be submitted electronically with the application, either on CD-ROM or via email.

Note: For sealed sources, a copy of any sealed source certificate or special form certificate should be provided.

SECTION F – OTHER INFORMATION

In deciding whether to issue a facility licence for a prescribed radiation facility under subsection 32(1) of the ARPANS Act, the CEO must take into account the matters specified in the Regulations, and must also take into account international best practice in relation to radiation protection and nuclear safety. Your application must address the following:

1. Purpose of the Prescribed Radiation Facility

Give a detailed description of the purpose of the prescribed radiation facility.

2. Description of the Prescribed Radiation Facility and its Site

Give a detailed description of the prescribed radiation facility and its site.

3. Net Benefit

Provide a statement describing the net benefit for the conduct and dealings intended to be carried out under the facility licence.

4. International Best Practice in Radiation Protection and Nuclear Safety

The applicant may wish to include details of relevant national/international standards and codes of practice that are adhered to in relation to the prescribed radiation facility and when dealing with associated sources. The Applicant must provide a description on how the proposed dealings meet international best practice.

5. Dose Information

Provide information to show that the magnitude of individual doses, the number of people exposed, and the likelihood that exposure will happen, are as low as reasonably

achievable, having regard to economic and social factors. This could include actual dose information (including dosimeter readings and surveys) and/or sample dose calculations.

6. Plans and Arrangements

The organisational plans and arrangements should form a comprehensive program of policies and procedures that are necessary to control radiation exposure. The content of these plans and arrangements will vary depending on the hazard and complexity of the prescribed radiation facility, controlled apparatus and/or controlled material.

The format for supplying this information is not prescribed. The applicant may either describe the plans and arrangements on the application form or may reference suitable organisational documents (to be supplied with the application). Where a consolidated document exists that covers all of the plans and arrangements, the applicant should cross-reference the plans and arrangements with the applicable sections of the consolidated document. A copy of all referenced documents must be provided with the application.

A brief description of the plans and arrangements is given below. For more detailed information, applicants are advised to refer to the [Regulatory Guide on Plans and Arrangements](#).

(a) Effective Control Arrangements

The applicant must demonstrate how he/she or the nominee will maintain control over the prescribed radiation facility. This should cover issues such as organisational arrangements, management systems and resources.

(b) Safety Management Plan

The applicant must describe the administrative arrangements for managing the safety of the prescribed radiation facility and any associated sources. This should cover issues such as safety culture, safety of premises and equipment, competency and training, incidents and accidents, auditing and record keeping.

(c) Radiation Protection Plan

Radiation protection policies and procedures should be set out in a radiation safety manual and in specific operating procedures. Guidance on the content of such a manual is provided in the [Recommendations for limiting exposure to ionising radiation \(1995\) – ARPANSA Radiation Protection Series 1 – republished 2002](#).

The radiation protection plan should cover issues such as principles of radiation protection, planning and design of the workplace, classification of work area, local procedures and radiation monitoring of individuals and the workplace.

In addition, the applicant is responsible for ensuring that arrangements are implemented for the appointment of a suitably qualified radiation safety officer and/or radiation safety committee as appropriate. The applicant must provide information about the qualifications and experience of such persons and the arrangements in place for their continued competency.

Applicants who propose to undertake dealings with unsealed sources under the facility licence must also demonstrate how the environment will be protected.

(d) Radioactive Waste Management Plan

A full description and anticipated amounts of any radioactive wastes, including discharges arising from the proposed conduct and the arrangements for the safe handling, treatment,

storage and disposal of any such waste should be set out in a radioactive waste management plan.

Applicants should refer to the following codes of practice:

- [Code of Practice for the disposal of radioactive waste by the user](#) (NH&MRC, 1985)
- [Code of Practice for the near surface disposal of radioactive waste](#) (NH&MRC, 1992)
- [Safety Guide for Classification of Radioactive Waste](#) (ARPANSA 2010)
- [Safety Guide for the Predisposal Management of Radioactive Waste](#) (ARPANSA 2008)

Note: Where the application is for a radioactive waste management facility, the applicant should also refer to the [Regulatory Guidance for Radioactive Waste Management Facilities: Near Surface Disposal Facilities; and Storage Facilities.](#)

(e) Security Plan

Arrangements for the security of the prescribed radiation facility, and any associated sources, to prevent theft, damage or unauthorised use must be provided. These arrangements should ensure that control of the facility and any associated sources is not relinquished without compliance with any requirements of the regulations and conditions of licence, and provide for periodic inventories to confirm that all sources are in their assigned locations and are secure.

Applicants should refer to the [Code of Practice for Security of Radioactive Sources – ARPANSA Radiation Protection Series No 11.](#)

NOTE: An ARPANSA approved security plan may be required under the requirements of RPS11.

(f) Emergency Plan

Emergency arrangements should be developed for all foreseeable emergencies such as dispersion of materials, over-exposure of operators, or theft or loss of controlled material. The arrangements should include the responsibilities of all parties in the event of an emergency, contact arrangements, emergency procedures, emergency equipment and reporting arrangements. Where necessary, arrangements for involving external agencies such as police and other emergency services should be included.

The plan should include arrangements for testing the emergency arrangements through regular reviews and exercises, and rectifying any deficiencies found in the emergency plans.

(g) Environmental management plan

Arrangements, including a policy statement on how the environment will be protected and monitored.

7. Authorisation-specific Information

Depending on the type of authorisation required, further information must be submitted with the application as required by Schedule 3 Part 1 of the Regulations. Applicants should provide references as to where this information is located in the documentation, and provide copies of the documentation with the application.

Note: The level of detail should be commensurate with level of hazard of the conduct undertaken at the prescribed radiation facility. The [Regulatory Assessment Principles](#) may provide further guidance.

Authorisation for preparing a site for a prescribed radiation facility

The applicant must provide a detailed site evaluation establishing the suitability of the site, as well as a description of the characteristics of the site. The applicant must also provide any environmental impact statement requested or required by a government agency, and the outcome of that environmental assessment. The *Criteria for the Siting of Controlled Facilities* may provide further guidance.

Authorisation to construct a prescribed radiation facility

The applicant must provide:

- The design of the controlled facility, including ways in which the design deals with the physical and environmental characteristics of the site.
- Any fundamental difficulties that will need to be resolved before any future authorisation is given.
- The construction plan and schedule.
- A preliminary safety analysis report that demonstrates the adequacy of the design of the facility and identifies structure, components and systems that are safety related items.
- The arrangements for testing and commissioning safety related items.

The [Regulatory Assessment Criteria for the Design of New Controlled Facilities and Modifications to Existing Controlled Facilities](#) may provide further guidance.

Authorisation to possess or control a prescribed radiation facility

The applicant must provide a detailed safety analysis report in support of their application to possess and control a prescribed radiation facility. The applicant must also provide details of the arrangements for safe storage of controlled material and maintenance of the prescribed radiation facility.

Authorisation to operate a prescribed radiation facility

The applicant must provide the following information in support of the application to operate a prescribed radiation facility:

- A description of the structures, components, systems and equipment of the controlled facility as they have been constructed.
- A final safety analysis report that demonstrates the adequacy of the design of the prescribed radiation facility, and includes the results of commissioning tests.
- The operational limits and conditions of the prescribed radiation facility.
- The arrangements for commissioning the prescribed radiation facility.
- The arrangements for operating the prescribed radiation facility.

Authorisation for decommissioning a prescribed radiation facility

The applicant must provide a decommissioning plan and a schedule for decommissioning the prescribed radiation facility

Authorisation for abandoning a prescribed radiation facility

The applicant must provide the results of decommissioning activities at the prescribed radiation facility, as well as any environmental monitoring programs proposed for the site.

CHECKLIST

A checklist is provided to ensure that the application is complete and in a form acceptable by the CEO.

HOW AN APPLICATION IS DECIDED

Once an application has been submitted to ARPANSA, the application will be examined to ensure that all the necessary information has been included (eg correct signature, application fees etc). If this has been provided, the applicant will then receive a letter of acknowledgment. However, if any of the basic information is not included, the application and application fee will be returned with a covering letter describing the omission.

As soon as practicable after receiving an application for a facility licence, and once it has been determined to be complete, regulation 40 requires the CEO to publish a notice in a daily newspaper and in the *Gazette*, stating his intention to make a decision on the application. If the application relates to a nuclear installation, the CEO must also include in the notice:

- (a) an invitation to people and bodies to make submissions about the application; and
- (b) a period for making submissions; and
- (c) procedures for making submissions.

Applications are forwarded to a Regulatory Officer for assessment. Where matters require clarification, the Regulatory Officer will contact the applicant. The Regulatory Officer may also consider that an inspection is necessary and may contact the applicant to arrange such an inspection.

Once the Regulatory Officer has reviewed and assessed all the information provided, a Regulatory Assessment Report will be produced. This report will address the matters to be taken into account by the CEO of ARPANSA, as well as international best practice in relation to radiation protection and nuclear safety (as per ss33(3) of the ARPANS Act and regulation 42).

The matters to be taken into account include:

- a) whether the application includes the information asked for by the CEO; and
- b) whether the information establishes that the controlled apparatus or material can be dealt with without undue risk to the health and safety of people, and to the environment; and
- c) whether the applicant has shown that there is a net benefit from dealing with the controlled apparatus or material; and
- d) whether the applicant has shown that the magnitude of individual doses, the number of people exposed, and the likelihood that exposure will happen, are as low as reasonably achievable, having regard to economic and social factors; and
- e) whether the applicant has shown a capacity for complying with the regulations and the licence conditions that would be imposed under section 35 of the Act; and
- f) whether the application has been signed by an office holder of the applicant, or a person authorised by an office holder of the applicant.

In the case of a nuclear installation, the Regulatory Assessment Report will also take into account any submissions made about the application.

The Regulatory Assessment Report will make a recommendation to the CEO of ARPANSA as to whether to issue a facility licence, and may include recommended licence conditions. This will then be forwarded to the CEO who will decide whether to issue a facility licence and what additional licence conditions (if any) should be imposed.

The applicant will be advised in writing of the CEO's decision. Once a licence is issued it remains in force until it is suspended, cancelled or surrendered.

APPEALING A LICENCE DECISION

Section 40 of the ARPANS Act describes the rights of review available to eligible people following decisions by the CEO. The following decisions are reviewable:

- to refuse to grant a licence;
- to impose conditions on a licence;
- to suspend a licence;
- to cancel a licence;
- to amend a licence; and
- not to approve the surrender of a licence.

An *eligible person* in relation to a decision to refuse to grant a licence means the person who applied for the licence.

Review by the Minister

Should an applicant wish to have a licence decision reviewed, the applicant may request the Minister for Health and Ageing to review the decision. The request must be in writing and be given to the Minister within 90 days of the making of the licence decision.

Once a request for review has been lodged the Minister must reconsider the licence decision and confirm, vary or set aside the decision.

The Minister is taken to have confirmed the licence decision if the Minister does not give written notice of the Minister's decision within 60 days of the request.

Review by the Administrative Appeals Tribunal (AAT)

An application may be made to the AAT for review of a decision of the Minister within 28 days of receiving notification of that decision.