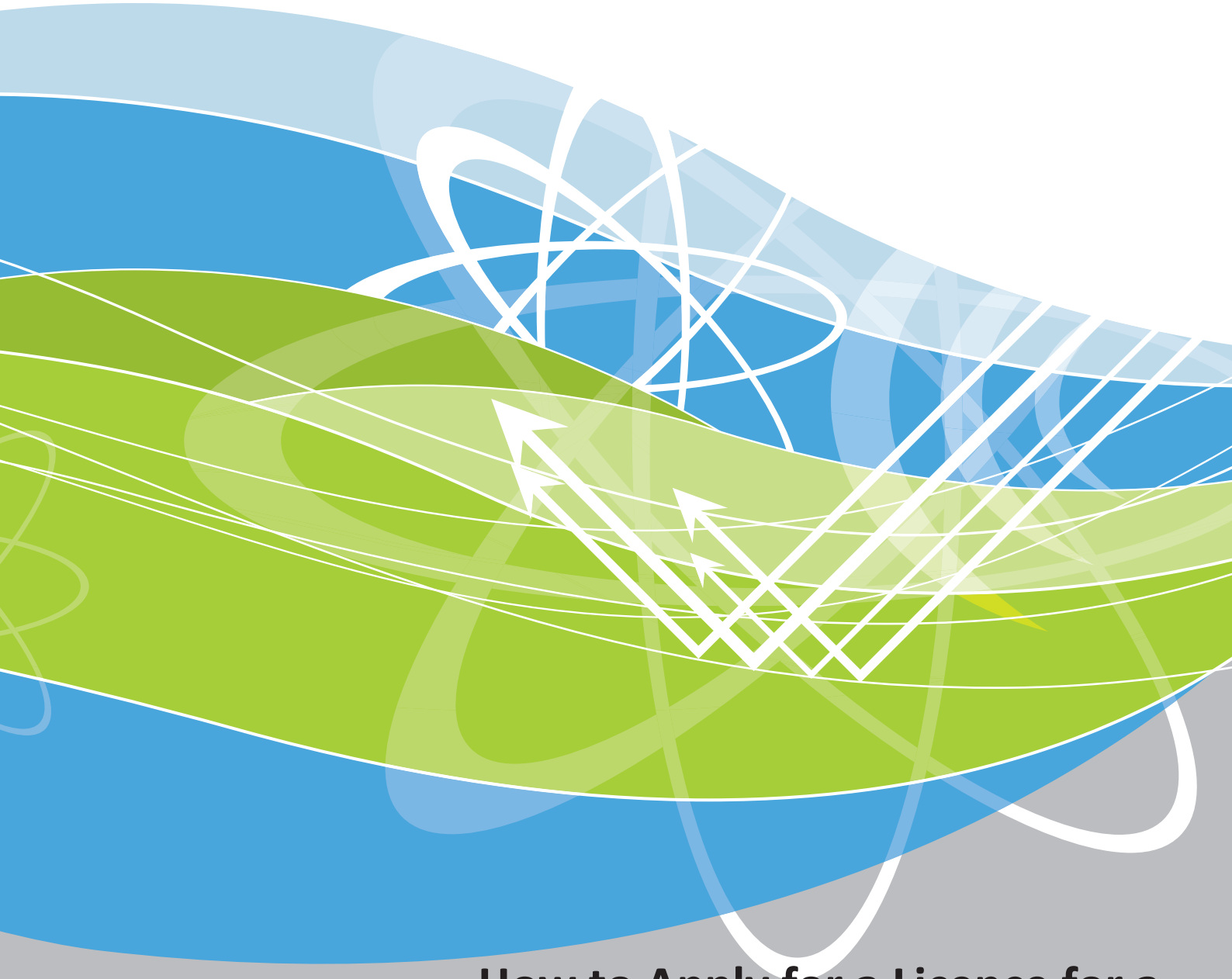
Australian Government
Australian Radiation Protection and Nuclear Safety Agency

ARPANSA

Protecting people and the environment from the harmful effects of radiation

REGULATORY GUIDE



How to Apply for a Licence for a Prescribed Radiation Facility

May 2016

Australian Government

Australian Radiation Protection and Nuclear Safety Agency

REGULATORY GUIDE

HOW TO APPLY FOR A LICENCE FOR A PRESCRIBED RADIATION FACILITY

This Regulatory Guide is provided to assist controlled persons complete a Facility Licence Application for a prescribed radiation facility under section 32 of the *Australian Radiation Protection and Nuclear Safety Act 1998*.

REGULATORY SERVICES

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COMPLETING THE APPLICATION FORM

SECTION A: APPLICANT INFORMATION

NAME OF DEPARTMENT OR COMMONWEALTH BODY

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.

PORTFOLIO

Name of the Commonwealth ministerial portfolio in which the Department or Commonwealth Body resides.

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.

The applicant must provide their full name, position and business address.

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 PRF (the nominee) must be provided. The nominee must be in effective control of the PRF. Generally the nominee will be the manager of a division or agency's operation at the site of the proposed activity. If a nominee is appointed, an organisational chart should be provided, showing the relationship of the nominee to the applicant and the operators.

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 any associated 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.

DECLARATION

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

[1] Refer regulation 39(4)(ii) of the ARPANS Regulations

SECTION B: KIND OF PRESCRIBED RADIATION FACILITY

The applicant must indicate the kind of prescribed radiation facility (PRF) for which a licence is sought.

SECTION C: TYPE OF AUTHORISATION

The applicant must indicate the type of authorisation sought.

> Note: Under certain circumstances, the CEO of ARPANSA may exempt an applicant from the need to obtain one or more types of authorisation. For more information on such exemptions, applicants should contact ARPANSA.

SECTION D: FACILITY DETAILS

A detailed description of the facility and information specific to the type of authorisation must be provided. Applicants may include this information in the application form or provide references as to where this information is located in supporting documentation.

> Note: The level of detail should be commensurate with the hazard of the facility. The Regulatory Assessment Principles may provide further guidance.

PREPARE A SITE FOR A PRESCRIBED RADIATION FACILITY

The applicant must provide the following information to support a facility application to prepare a site for a prescribed radiation facility:

- A detailed site evaluation establishing the suitability of the site
- A description of the characteristics of the site, including the extent to which the site may be affected by natural and mad-made events.
- Any environmental impact statement requested or required by a government agency, and the outcome of that environmental assessment.

CONSTRUCT A PRESCRIBED RADIATION FACILITY

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

- The design of the 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.

POSSESS OR CONTROL A PRESCRIBED RADIATION FACILITY

The applicant must provide the following information in support of a facility licence application to possess or control a prescribed radiation facility:

- The arrangements for maintaining criticality safety during loading, moving or storing nuclear fuel and other fissile materials at the controlled facility
- The arrangements for safe storage of controlled material and maintaining the facility.

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

DECOMMISSION A PRESCRIBED RADIATION FACILITY

The applicant must provide a decommissioning plan and a schedule for decommissioning the PRF.

ABANDON A PRESCRIBED RADIATION FACILITY

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

SECTION E: PLANS AND ARRANGEMENTS

The applicant must have plans and arrangements for managing the controlled facility to ensure the health and safety of people and protection of the environment. The plans and arrangements should be a comprehensive program of policies and procedures that demonstrate how radiation safety will be assured. The content of these plans and arrangements will vary depending on the hazard and complexity of the facility.

There is no pre-determined format for supplying this information. The applicant may either describe the plans and arrangements on the application form or may reference suitable organisational documents. If the latter option is taken, the applicant must clearly indicate on the application form where the relevant information can be found within accompanying documents.

A brief description of what is expected in the plans and arrangements is provided below. For more detailed information, applicants should refer to the Regulatory Guide: Plans and Arrangements.

If there are sources associated with the proposed facility, the applicant is required to identify the relevant codes and/or standards and describe how compliance with these documents will be achieved. This may be incorporated into Section E. Codes and/or standards applicable to each kind of source can be found on the ARPANSA website at http://www.arpansa.gov.au/Regulation/LicenceHolders/conditionscodes.cfm.

ARPANSA also maintains a register of Trusted International Standards (TIS) that may be relevant to the proposed facility. Applicants should identify relevant TIS and describe how these will be applied or taken into account.

1. EFFECTIVE CONTROL ARRANGEMENTS

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

2. SAFETY MANAGEMENT PLAN

The applicant must describe the administrative arrangements for managing the safety of the 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.

3. 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 Recommendations for limiting exposure to ionising radiation (RPS 1).

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, radiation monitoring of individuals and the workplace and protection of the environment.

Where sources or facilities are to be used for medical purposes, the plans and arrangements should address the requirements of the Code of Practice in the medical applications of ionizing radiation (RPS 14) and associated safety guides for diagnostic and interventional radiology, radiotherapy, and nuclear medicine, in particular, optimisation of exposure and radiation protection of the patient.

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.

4. 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 relevant TIS.

5. SECURITY PLAN

Arrangements for the security of the 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 (RPS 11). Compliance with this code is mandatory for security enhanced sources; in particular, the need for an approved security plan.

6. EMERGENCY PLAN

Emergency arrangements must 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.

7. ENVIRONMENT PROTECTION PLAN

Arrangements should be developed for the protection of wildlife populations and ecosystems in parallel with radiation protection of people, consistent with international best practice. The arrangements should include identification of all potential exposure scenarios and pathways to the environment and affected biota with environmental radiological assessments of wildlife in their natural habitats based on the concept of reference organisms. Applicants should refer to the Guide for Radiation Protection of the Environment (RPS G-1).

SECTION F: ASSOCIATED SOURCES

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

Not all facilities have associated sources but where they do the applicant must indicate the kind of controlled material and/or controlled apparatus in Section F of the application. Common types of sources in facilities are calibration sources. For sealed sources, a copy of any source certificate or special form certificate should accompany the application as per item 5(d) of Part 2 of the Regulations.

SECTION G: SOURCE DETAILS

The details of any sources associated with the facility must be recorded in a Source Inventory Workbook (SIW). The SIW is the form approved by the CEO for maintaining source records. It is an Excel spreadsheet available from the ARPANSA website. An explanation of terms and required information appears in the first worksheet of the SIW. If in doubt, contact ARPANSA for advice. The completed SIW is to be submitted electronically with the application, either on CD-ROM or by email.

Note: For sealed sources, a copy of any source certificate or special form certificate should accompany the application.

SECTION H: MATTERS TO BE TAKEN INTO ACCOUNT BY THE CEO

Under section 32(3) of the Act, the CEO, in deciding whether to issue a facility licence, must take into account matters prescribed in the Regulations and international best practice in relation to radiation protection and nuclear safety. Regulation 41(3) lists the matters that the CEO must take into account and regulation 39(2) prescribes the information that the CEO may require an applicant to provide. Section H of the application form is designed to enable an applicant to provide the information that the CEO needs to take these matters into account. These matters are described below:

INTERNATIONAL BEST PRACTICE IN RADIATION PROTECTION AND NUCLEAR SAFETY

Sub-sections 32(3) and 33(3) of the Act require the CEO to take into account international best practice in relation to radiation protection and nuclear safety when making a decision whether to issue a licence. The applicant should provide information about how international best practice has been considered in relation to the facility, relevant to the type of authorisation sought.

National and international codes and standards are generally based on international best practice and adherence to such documents may be an indication of international best practice. Applicants should refer to the ARPANSA website for further information about International Best Practice.

INFORMATION ASKED FOR BY THE CEO

Under regulation 41(3)(a), the CEO must consider if the application includes all the information asked for by the CEO. For this purpose the CEO will consider if the applicant has provided:

- The information required under Part 1, Schedule 3 of the Regulations, (Note that this is the information that is required under 'Section C – Facility Details' of the Facility Licence Application form.)
- All information required to be provided in the Facility Licence Application form, and
- Any other information that the CEO may have required under regulation 39(2)(b).

UNDUE RISK

Under regulation 41(3)(b) the CEO must consider whether the information provided by the applicant establishes that the proposed conduct can be carried out without undue risk to the health and safety of people and to the environment. For this purpose, the applicant must demonstrate that the radiation risks to people and the environment arising from the proposed conduct have been fully assessed, including the probability and magnitude of potential exposures arising from accident scenarios or abnormal occurrences.

NET BENEFIT

Under regulation 41(3)(c) the CEO must consider whether the applicant has shown that there is a net benefit from carrying out the conduct relating to the controlled facility. For this purpose the applicant must demonstrate that the proposed conduct produces sufficient benefit to individuals or to society to offset the radiation harm that it might cause, taking into account social, economic and other relevant factors, that is, the applicant must justify the conduct and demonstrate a net benefit from the conduct.

ALARA

Under regulation 41(3)(d), the CEO must consider 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. For this purpose, the applicant could provide actual dose information, including dosimeter readings and surveys or sample dose calculations or both.

CAPACITY TO COMPLY

Under regulation 41(3)(e), the CEO must consider 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. For this purpose, the applicant should provide a statement that demonstrates its capacity to comply with the Regulations and any conditions that may be imposed if a licence is issued.

An applicant may provide evidence of compliance with similar legislation such as that administered by Comcare or the Australian Safeguards and Non-Proliferation Office (ASNO) in order to demonstrate its capacity to comply. A current ARPANSA licence holder may provide details of its compliance history.

An applicant should also demonstrate that it has or will have sufficient financial and human resources to safely undertake the proposed dealing.

AUTHORISED SIGNATORY

Under regulation 41(3)(f), the CEO must be satisfied that the application has been signed by an office holder of the applicant or a person authorised by an office holder of the applicant. For this purpose, the applicant must ensure that the application is signed by an office holder or a person authorised by an office holder. An office holder is

the Secretary, Chief Executive Officer or an equivalent person of the Department or Commonwealth Body that is named as the applicant in the application. Where a person authorised by an office holder of the applicant signs the application, an instrument of authorisation must be provided with the application.

CHECKLIST

A checklist is provided as final confirmation that the application is complete and in a form acceptable to the CEO of ARPANSA.

APPLICATION FEE

The licence application must be accompanied by the appropriate fee. Applicants should refer to regulation 40B and the table in clause 1 of Schedule 3B of the Regulations to determine the fee.

SUBMITTING THE APPLICATION

The completed application form, all supporting documentation, CDs and appropriate fee should be sent to:

The CEO of 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 the application fee either by cheque or electronic funds transfer.

HOW AN APPLICATION IS DECIDED

Once an application has been submitted to ARPANSA, the application will be examined to ensure that all necessary information has been included and that it is properly signed and that the application fees have been paid. If so, the applicant will receive a letter of acknowledgment. However, if any of the basic information is not included, the applicant may be contacted for further information or the application and application fee may 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. The CEO will also include in the notice:

- an invitation to people and bodies to make submissions about the application
- a period for making submissions
- procedures for making submissions

Applications are then forwarded to a Regulatory Officer for assessment. Where matters require clarification, the Regulatory Officer will contact the applicant or nominee. The Regulatory Officer may also consider that an inspection or site visit is necessary and may contact the applicant to make arrangements.

Once the Regulatory Officer has reviewed and assessed all the information provided, a Regulatory Assessment Report (RAR) is produced. This report will address the matters to be taken into account by the CEO of ARPANSA in accordance with subsection 32(3) of the Act, namely international best practice in relation to radiation protection and nuclear safety and the matters specified in the regulations. Regulation 41 specifies those matters. They are:

(a) whether the application includes the information asked for by the CEO

(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

(c) whether the applicant has shown that there is a net benefit from the proposed

(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

(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

(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

(g) In the case of a nuclear installation, the content of any submissions made by members of the public about the application

The Regulatory Assessment Report will make a recommendation to the CEO (or Delegate) about whether to issue a licence and may recommend the licence conditions to be imposed under section 35 of the Act. All relevant documentation is sent to the decision maker. The applicant will be advised in writing of the decision. The CEO (or Delegate) may also publish a 'statement of reasons' for the decision on the ARPANSA website.

Under section 37 of the Act, a licence may be issued for an indefinite period or for a period specified in the licence. Once issued a licence remains in force until it is cancelled or surrendered or the specified period has elapsed.

APPEALING A LICENCE DECISION

Section 40 of the Act describes the rights of review available to eligible persons in respect of licence decisions made by the CEO. The following decisions are reviewable:

a. to refuse to grant a licence
b. to impose conditions on a licence
c. to suspend a licence
d. to cancel a licence
e. to amend a licence
f. not to approve the surrender of a licence
g. to issue a licence for a particular period, rather than for a longer period or indefinitely
h. not to extend the period for which a licence was issued

An *eligible person* in relation to a decision to refuse to grant a licence means the person who applied for the licence, and in relation to any other licence decision, it is the licence holder.

REVIEW BY THE MINISTER

Should an applicant wish to have a licence decision reviewed, the applicant may request the Minister for Health to review the decision. The request must be in writing and be given to the Minister within 28 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 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.