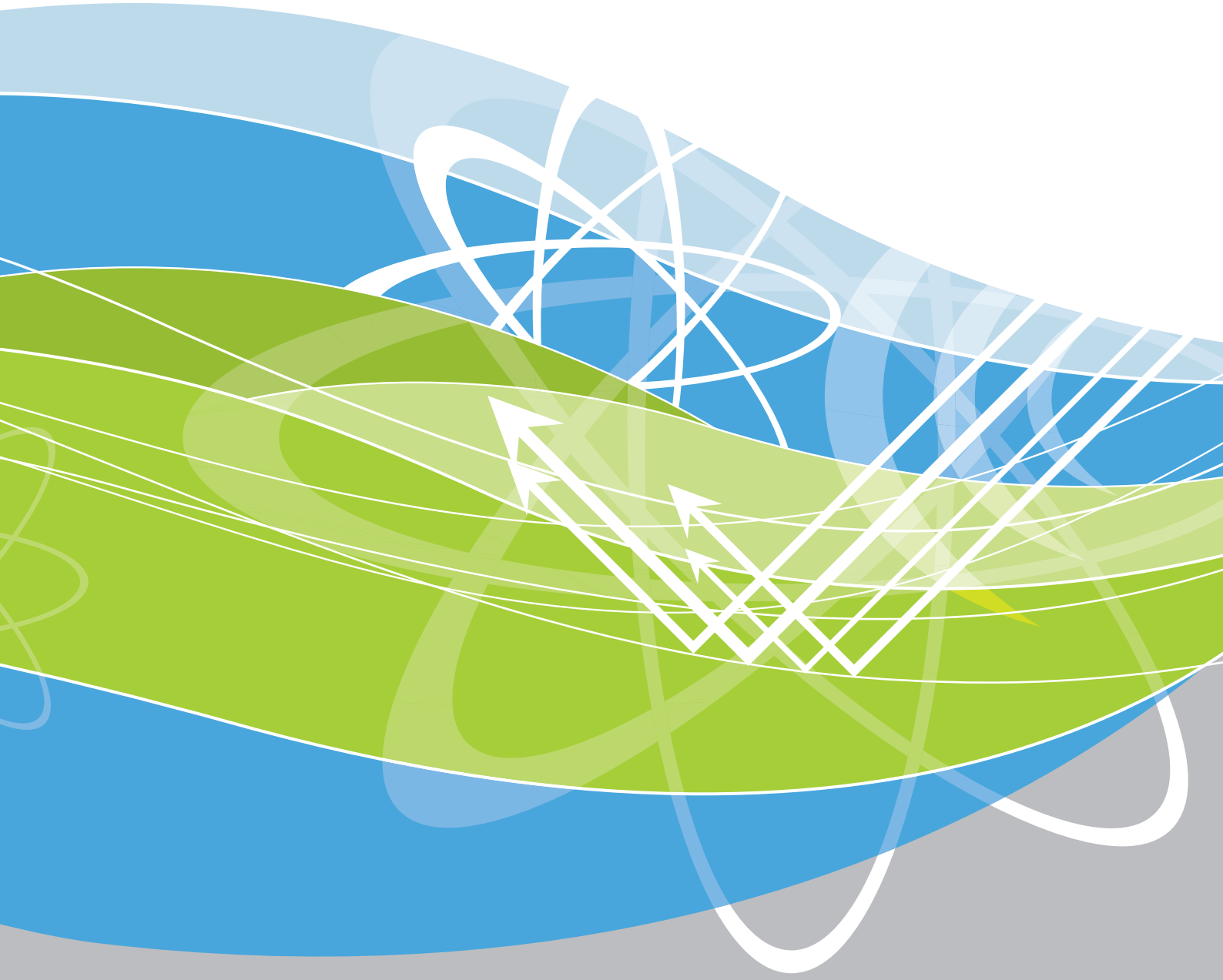
Australian Government

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 Source Licence

May 2016

Australian Government

Australian Radiation Protection and Nuclear Safety Agency

REGULATORY GUIDE

HOW TO APPLY FOR A SOURCE LICENCE

This Regulatory Guide is provided to assist controlled persons apply for a source licence under section 33 of the *Australian Radiation Protection and Nuclear Safety Act* and to assist licence holders apply for an amendment to an existing source licence.

REGULATORY SERVICES

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CONTENTS

SELECTING THE APPLICATION FORM

There are two application forms; the choice of form depends on the hazard of the source – see below:

ITEM	KIND OF CONTROLLED MATERIAL OR CONTROLLED APPARATUS	APPLICATION FORM
1	Sealed source for calibration purposes of activity of 40 MBq or less	LOW HAZARD
2	Sealed source in a fully enclosed analytical device	
3	Sealed source with activity of 400 MBq or less in a fixed gauge	
4	Sealed source in a blood irradiator	
5	Sealed source in a bone densitometer	
6	Sealed source that:(a) is in storage and awaiting disposal; and (b) has a nuclide with a maximum activity of not more than 10^9 times the amount mentioned in column 4 of Part 2 of Schedule 2 for that kind of nuclide	
7	Unsealed source, or sources, in a laboratory or premises, having nuclides amount mentioned in column 4 of Part 2 of Schedule 2 for that kind of nuclide	
8	Unsealed source, or sources, in a laboratory or premises, having nuclides such that when the maximum activity of each nuclide in the source, or sources, is divided by the amount mentioned in column 4 of Part 2 of Schedule 2 for that kind of nuclide, the total of the results for all nuclides in the source, or sources, is not more than 100	
9	Mammographic x-ray unit	
10	Conventional dental x-ray unit	
11	X-ray unit used for bone densitometry	
12	X-ray unit used for veterinary radiography	
13	Fully enclosed x-ray analysis unit	
14	Baggage inspection x-ray unit	
15	Mobile or portable medical x-ray unit	
16	Magnetic field non-destructive testing device	
17	Induction heater or induction furnace	
18	Industrial radiofrequency heater or welder	
19	Radiofrequency plasma tube	
20	Microwave or radiofrequency diathermy equipment	
21	Industrial microwave or radiofrequency processing system	
22	Optical source, other than a laser product, emitting ultraviolet radiation, infra-red or visible light.	
23	A laser product with an accessible emission level more than the accessible emission limit of a Class 3R laser product as set out in AS/NZS IEC 60825.1:2011 *Safety of Laser Products – Equipment classification and requirements*	
24	An optical fibre communication system exceeding Hazard Level 3R as defined by AS/NZS IEC 60825.2:2011 *Safety of Laser Products – Safety of optical fibre communications systems (OFCS)*	
24A	Sealed source of controlled material not mentioned in another item of Schedule 3C, part 1 of the Regulations, dealings with which have the potential for accidental exposure but the exposure would be unlikely to exceed the dose limits mentioned in regulations 59 and 62. (1) Sealed source for training and education purposes of activity 40 MBq or less (2) Manufactured item or component containing thorium (3) Clock, watch, heritage object, luminous dial or indicator with paint containing radium 226 of activity of 1 MBq or less and no other controlled material (4) Clock, watch, heritage object, luminous dial or indicator with paint containing promethium 147 of activity of 1 GBq or less and no other controlled material (5) Clock, watch, heritage object, military device or electronic component with paint containing tritium of activity of 100 GBq or less and no other controlled material	
24B	Controlled apparatus that produces ionising radiation not mentioned in another item of Schedule 3C, Part 1 of the Regulations, dealings with which have the potential for accidental exposure but the exposure would be unlikely to exceed the dose limits mentioned in regulations 59 and 62. (1) Fully enclosed x-ray unit (radiography for special purposes) (2) Portable handheld dental x-ray apparatus (3) Optical source, other than a laser product, emitting ultraviolet radiation, infrared or visible light – solar tower array (4) Ion beam etching unit (5) CT scanner (for inspection of baggage/freight etc.) (6) Dual energy x-ray absorptiometry (DEXA) unit for veterinary studies	

	(7) Fully enclosed x-ray biological irradiator (low power) (8) CT, SPECT/CT or PET/CT scanner for imaging of small animals (9) Klystron amplifier for radio communication or radar (10) Laser used on animals (11) Handheld backscatter x-ray security inspection system	
25	Sealed source for calibration purposes of activity of more than 40 MBq	**MEDIUM – HIGH HAZARD**
26	Sealed source in a partially enclosed analytical device	
27	Sealed source of activity of more than 400 MBq in a fixed gauge	
28	Sealed source in a mobile gauge	
29	Sealed source for medical or veterinary diagnostic nuclear medicine use	
30	Unsealed source, or sources, in a laboratory or premises, having nuclides of 1 kind only with a maximum activity of more than 100, but not more than 10 000, times the amount mentioned in column 4 of Part 2 of Schedule 2 (of the Regulations) for that kind of nuclide	
31	Unsealed source, or sources, in a laboratory or premises, having nuclides such that when the maximum activity of each nuclide in the source, or sources, is divided by the amount mentioned in column 4 of Part 2 of Schedule 2 (of the Regulations) for that kind of nuclide, the total of the results for all nuclides in the source, or sources, is more than 100 but not more than 10 000	
32	Unsealed sources used for tracer studies	
33	Industrial radiography x-ray unit	
34	Fixed medical x-ray unit, including a unit used for fluoroscopy, tomography and chiropractic radiography	
35	Partially enclosed x-ray analysis unit	
36	Medical therapy simulator	
37	CT scanner	
37A	Sealed source of controlled material not mentioned in another item of this Schedule, dealings with which have the potential for accidental exposure that is likely to exceed a dose limit mentioned in regulations 59 and 62 but that is unlikely to result in acute effect	
37A(1)	Sealed source for training and education purposes of activity more than 40 MBq	
37A(2)	Clock, watch, heritage object, luminous dial or indicator with paint containing radium 226 of activity of more than 1 MBq and no other controlled material	
37A(3)	Clock, watch, heritage object, luminous dial or indicator with paint containing promethium 147 of activity of more than 1 GBq and no other controlled material	
37A(4)	Clock, watch, heritage object, military device or electronic component containing tritium of activity of more than 100 GBq and no other controlled material	
37B	Controlled apparatus that produces ionising radiation not mentioned in another item of this Schedule, dealings with which have the potential for accidental exposure that is likely to exceed a dose limit mentioned in regulations 59 and 62 but that is unlikely to result in acute effects	
37B(1)	Mobile backscatter x-ray security inspection system	
37B(2)	Mobile fluoroscopic x-ray apparatus	
37B(3)	CT scanner for imaging of non-human objects	
37B(4)	Fixed medical x-ray unit used for research purposes, including a unit designed for fluoroscopy, tomography, mammography and chiropractic radiography	
37B(5)	Personnel security screening system using backscatter x-rays	
37B(6)	Orthopantomogram (OPG) (dental panoramic x-ray unit)	
37B(7)	Fully enclosed x-ray biological irradiator	
37B(8)	Personnel anti-smuggling screening system using transmission x-rays	
38	Sealed source for industrial radiography	
39	Sealed source for medical and veterinary radiotherapy	
40	Sealed source in a bore hole logger	
41	Sealed source of controlled material not mentioned in another item of this Schedule, dealings with which have the potential for accidental exposure that is likely to exceed a dose limit mentioned in regulations 59 and 62 and that is likely to result in acute effects	
41(1)	Reactor start-up source	
42	Unsealed source, or sources, in a laboratory or premises, having nuclides of 1 kind only with a maximum activity of more than 10 000, but not more than 1 000 000, times the amount mentioned in column 4 of Part 2 of Schedule 2 (of the Regulations) for that kind of nuclide	
43	Unsealed source, or sources, in a laboratory or premises, having nuclides such that when the maximum activity of each nuclide in the source, or sources, is divided by the amount mentioned in column 4 of Part 2 of Schedule 2 (of the Regulations) for that kind of nuclide, the total of the results for all nuclides in the source, or sources, is more than 10 000 but not more	

	than 1 000 000
44	Veterinary or medical radiotherapy unit
45	Controlled apparatus that produces ionising radiation not mentioned in another item of this Schedule, dealings with which have the potential for accidental exposure that is likely to exceed a dose limit mentioned in regulations 59 and 62 and that is likely to result in acute effects
45(1)	Industrial irradiator containing less than 100 TBq of a controlled material
45(2)	Neutron Beam Instrument
45(3)	Low Energy Implanter
45(4)	Deuterium-tritium or deuterium-deuterium neutron generator
45(5)	Industrial irradiator containing >=100 TBq but < 1 PBq of a controlled material

COMPLETING THE APPLICATION FORM

SECTION A: APPLICANT INFORMATION

DEPARTMENT OR COMMONWEALTH BODY

This is the name of the Department of State 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 applicant must provide their full name, position and business address. The applicant must be:

(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 the source dealing that they cannot demonstrate effective control, the name and contact details of a person more directly in control of the source dealing (the nominee) must be provided. The nominee must be in effective control of the controlled material and/or controlled apparatus (sources). 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.

RADIATION SAFETY OFFICER[2]

This is an individual appointed by the applicant to supervise radiation safety in relation to the sources for which the licence is sought. This person must be technically competent in radiation protection matters relevant to all sources, including non-ionising radiation sources if these are part of the application. Evidence of competency should be included. 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.

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[1] Refer regulation 39(4)(ii) of the Regulations
[2] In some cases a RSO may not be required. Applicants should refer to Regulatory Guide: Plans and Arrangements or contact ARPANSA

SECTION B: DESCRIPTION OF THE SOURCE AND PROPOSED DEALING

The applicant should indicate the kind of controlled apparatus and/or controlled material in the table provided. If there is any doubt about the hazard category or description of a source the applicant should seek advice from Regulatory Services on 02 9541 8333.

The applicant should describe the source, the proposed dealing, and provide the full street address where the sources will be used or stored.

SECTION C: SOURCE DETAILS

Items 5, 6, 7 & 8 of Part 2 of the Regulations set out the information that must be provided about the sources to be dealt with under the proposed licence. This information must be recorded in a Source Inventory Workbook (SIW) which is an Excel spreadsheet available from the ARPANSA website. The SIW is the form approved by the CEO for maintaining source records. An explanation of terms and required information appears in the first worksheet. The completed SIW is to be submitted electronically with the application either on CD-ROM or email attachment.

> Note: 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 D: PLANS & ARRANGEMENTS

The applicant must have plans and arrangements for managing the controlled apparatus or controlled material 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 sources to be dealt with.

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 plans and arrangements is provided below. For more detailed information, applicants should refer to the Regulatory Guide: Plans and Arrangements.

Applicants are required to identify the codes and/or standards relevant to the proposed dealing and describe how compliance with these documents will be achieved. This information may be incorporated into this section.

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.

ARPANSA also maintains a register of Trusted International Standards (TIS) that may be relevant to the proposed dealing. 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 particular dealings for which a licence is sought. The arrangements should cover such things as organisational arrangements, management systems and resources.

2. SAFETY MANAGEMENT PLAN

The applicant must describe the administrative arrangements for managing safety. These arrangements may be minimal, where only low hazards are involved, but will be more extensive for dealings of higher complexity or hazard. The safety management plan should cover things 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 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 dealing 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.

5. ULTIMATE DISPOSAL OR TRANSFER PLAN

The applicant must provide a plan for the ultimate transfer or disposal of sources. Copies of documented undertakings by other organisations to accept sources when no longer required should be provided where possible. Applicants should note that after a licence is issued, regulation 53 applies to the disposal and transfer of sources.

> Note: Stricter requirements apply to security enhanced sources[3] - applicants should refer to the Code of Practice for Security of Radioactive Sources (RPS 11).

6. SECURITY PLAN

Arrangements for the security of sources to prevent theft, damage or unauthorised use must be provided. These arrangements should ensure that control of 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.

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3 A security enhanced source is a radioactive source or aggregation of sources assigned Security Category 1, 2 or 3 when using the methodology set out in Schedule B of RPS 11.

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.

7. EMERGENCY PLAN

Emergency arrangements must be developed for all foreseeable emergencies such as dispersion of materials, overexposure 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.

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

Under section 33(3) of the Act, the CEO, in deciding whether to issue a source licence, must take into account matters prescribed in the Regulations and international best practice in relation to radiation protection and nuclear safety. Regulation 42(3) lists the matters that the CEO must take into account and regulation 39(3) prescribes the information that the CEO may require an applicant to provide. Section E of the application form is designed to enable an applicant to provide the information that the CEO needs to take these matters into account. The matters are described below:

NOTE: Section E only needs to be completed for medium or high hazard sources; it is optional for low hazard sources.

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.

Adherence to national codes and standards and trusted international standards is generally an indication of international best practice. The ARPANSA website provides guidance on International Best Practice.

INFORMATION ASKED FOR BY THE CEO

Under regulation 42(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 2, Schedule 3 of the Regulations
- All information required to be provided in the Source Licence Application form
- Any other information that the CEO may have required under regulation 39(3)(b)

A. UNDUE RISK

Under regulation 42(3)(b) the CEO must consider whether the information provided by the applicant establishes that the proposed dealing 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 dealing have been fully assessed, including the probability and magnitude of potential exposures arising from accident scenarios or abnormal occurrences.

B. NET BENEFIT

Under regulation 42(3)(c) the CEO must consider whether the applicant has shown that there is a net benefit from carrying out the proposed dealing. For this purpose the applicant must demonstrate that the dealing 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 dealing and demonstrate a net benefit from the dealing.

C. ALARA

Under regulation 42(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.

D. CAPACITY TO COMPLY

Under regulation 42(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.

E. AUTHORISED SIGNATORY

Under regulation 42(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 application must be accompanied by the appropriate fee. Applicants should refer to regulation 40B and the table in clause 1 of Schedule 3C of the Regulations to determine the fee.

SUBMITTING THE APPLICATION

Electronic applications are preferred. The completed application form and all supporting documentation should be emailed to 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.

Alternatively, the completed application, supporting documents and application fee may be sent to:

The CEO of ARPANSA

PO Box 655

MIRANDA NSW 1490

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 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.

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.

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.