Australian Government
Australian Radiation Protection and Nuclear Safety Agency

arpansa

Regulatory Guide

Applying for a licence for a radioactive waste storage or disposal facility

Australian Government
Australian Radiation Protection and Nuclear Safety Agency

arpansa

REGULATORY GUIDE

Applying for a licence for a radioactive waste storage or disposal facility

This regulatory guide is designed to assist a controlled person when applying for a facility licence under section 32 of the *Australian Radiation Protection and Nuclear Safety Act 1998*

It should be read when completing the Licence Application Form

Additional information can be found in supplementary document
Radioactive Waste Storage and Disposal Facilities: Information for Stakeholders

REGULATORY SERVICES

REG-LA-SUP-240L v3

May 2017

Contents

1. Introduction

1.1 Purpose and scope

This regulatory guide provides information for controlled persons (referred to as 'the applicant' in this guide) applying for a licence for a radioactive waste storage or disposal facility[1] and associated ancillary facilities under the *Australian Radiation Protection and Nuclear Safety Act 1998* (the ARPANS Act) and the Australian Radiation Protection and Nuclear Safety Regulations 1999 (the ARPANS Regulations). It supersedes the regulatory guide *Licensing of Radioactive Waste Storage and Disposal Facilities* (OS-LA-SUP-240L v2) issued in March 2013.

The guide addresses issues that should be considered when applying for a licence for a controlled facility designed to store large quantities of low and intermediate level radioactive waste including long term storage of such waste, noting that a storage facility may be operational for more than a century; or dispose of similarly large quantities of low level radioactive waste in a near-surface disposal facility. It is applicable to waste generated in activities carried out under a licence issued under the ARPANS Act[2] and only to waste generated in Australia, including waste generated during reprocessing overseas of spent nuclear fuel from nuclear reactors operated in Australia.

The guide is not applicable to:

- short-term storage of small quantities of waste
- disposal of small quantities of low level waste at the point of generation[3]
- management of waste generated during mining and milling of ores
- waste facilities under state or territory jurisdiction.

The guide provides information on documentation, relevant to the type of facility and in line with a graded approach, to be submitted in order for the CEO of ARPANSA to make an informed assessment of whether the proposed facility sufficiently addresses the matters that should be taken into account by the CEO in making a licensing decision that is not in conflict with the object of the Act, which is to **protect the health and safety of people, and to protect the environment, from the harmful effects of radiation**. Failure to provide sufficient and satisfactory information may cause delays in the review of the application, or result in the application being declined.

1.2 General aspects of radioactive waste management

In Australia, radioactive waste is generated from a wide range of activities involving radiation sources, facilities and nuclear installations in the processing, use or generation of radioactive material in medicine, industry and research.

---

1 Near-surface disposal facility; facilities established on or close to the surface.

2 Including, for example, storage and disposal of waste in a National Radioactive Waste Management Facility (NRWMF), should plans to establish a NRWMF currently under development by the Department of Industry, Innovation and Science be pursued.

3 See ARPANSA's website www.arpansa.gov.au for guidance relevant to other types of radioactive waste than covered in this Regulatory Guide.

Effective and safe management of radioactive waste requires an appropriate classification of the waste. An internationally acknowledged scheme for classification of radioactive waste has been developed by the International Atomic Energy Agency (IAEA) in IAEA Safety Series GSG-1 *Classification of Radioactive Waste* (2009), which comprises six classes of radioactive waste. Australia has adopted this classification system through Radiation Protection Series (RPS) 20 *Safety Guide for Classification of Radioactive Waste* (ARPANSA 2010).

The most important factor that determines the classification of the waste is the manner by which it can be safely disposed. This depends on the amounts and concentrations of radioactive substances, their properties including half-life (the time it takes for the activity to decay to half its original level), and other properties such as heat generation and chemical nature of the waste.

Radioactive waste storage and/or disposal facilities are components of a *system* for waste management that also includes transport routes from sites of waste generation or interim storage to the waste management facility. Additionally, radioactive waste from various activities may require predisposal management such as treatment and conditioning in ancillary facilities to ensure that it conforms to the waste acceptance criteria for processing, storage and emplacement into the disposal facility.

Transport of waste to, from and between facilities must conform to requirements in the Transport Code RPS C-2 *Code for the Safe Transport of Radioactive Material* (ARPANSA 2014).

Disposal refers to the emplacement of radioactive waste into a facility or a location with no intention of retrieving the waste. Disposal options are designed to *contain* and *isolate* the waste from the accessible biosphere[4] by means of engineered and natural barriers in a manner that is commensurate with the hazard.

Storage refers to the retention of radioactive waste in a facility or a location with the intention of retrieving the waste for conditioning (if needed) and ultimate disposal. The period of storage may vary depending on the waste and the type of facility. However storage is always an interim measure.

A storage facility may be located at a site where radioactive waste is generated; it may comprise a separate facility or it may be co-located with a disposal facility.

1.3 Structure of this guide and explanation of terms

Sections of this guide deal with the matters in Regulation 41 of the ARPANS Regulations that the CEO must take into account when deciding whether to issue a facility licence. The CEO will require an applicant to provide information to address those matters.

Schedule 3 of the Regulations lists the kinds of documents and information that the CEO may ask for in relation to an application. Depending on the activity to be authorised by the licence, the CEO will require whichever of those documents and information are relevant.

Matters in Regulation 41 are listed below, with an indication as to where they are dealt with in this regulatory guide.

[4] The term biosphere is often used in connection to the assessment of safety of facilities for storage and disposal of radioactive waste, meaning the part of the environment where organisms can be found.

Matters specified in regulation 41 of the Regulations	Relevant section
(a) whether the application includes the information asked for by the CEO	Section 2: Information Requested
(b) whether the information establishes that the proposed conduct can be carried out without undue risk to the health and safety of people, and to the environment	Section 3: Undue Risk
(c) whether the applicant has shown that there is a net benefit from carrying out the conduct relating to the controlled facility	Section 4: Net Benefit
(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	Section 5: Optimisation
(e) whether the applicant has shown a capacity for complying with these regulations and the licence conditions that would be imposed under section 35 of the Act	Section 6: Capacity to Comply
(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	Appendix 2
(g) if the application is for a facility licence for a nuclear installation—the content of any submissions made by members of the public about the application	Not dealt with in this regulatory guide

Section 32(3) of the ARPANS Act requires that in making a decision in relation to an application for a facility licence, the CEO must take into account international best practice in relation to radiation protection and nuclear safety. Information and documents that the CEO asks for in relation to a licence application will include information relevant to international best practice.

Additional information is provided in the appendices as follows:

- Appendix 1 provides generic information on how to complete and lodge a licence application
- Appendix 2 provides information on how a licensing decision is reached
- Appendix 3 provides information on how an applicant can appeal against a decision.

Terms and their definitions in this guide are the same as in the ARPANS Act and Regulations. To the extent terms that are used here are not found in the ARPANS Act and Regulations, their use is aligned with the IAEA *Safety Glossary 2007*.[5]

Use of the term 'safety' or the phrase 'health and safety' in this regulatory guide refers to radiation, waste, transport and nuclear safety, emergency management, and nuclear security, i.e., actions taken to achieve protection against radiation risks[6]. It does not refer to safety in the sense used in work health and safety legislation, or in other safety legislation.

[5] A 2016 draft version of the Glossary is available from the IAEA website for informational purposes only: https://www-ns.iaea.org/downloads/standards/glossary/iaea-safety-glossary-draft-2016.pdf

[6] Radiation risk means detrimental health effects of exposure to ionising radiation including the likelihood of such effects occurring, and other risks including environmental risks, that might arise from exposure to ionising radiation; the presence of radioactive material (including radioactive waste) or its release to the environment; or a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation; alone or in combination (see RPS F-1, *Fundamentals for Protection Against Ionising Radiation* (ARPANSA 2014)).

Some concepts, principles and processes related to waste management are outlined in a supplementary document, *Radioactive Waste Storage and Disposal Facilities: Information for Stakeholders*. The information document can be read in conjunction with this regulatory guide as a source of explanations and background, but should not be considered a guide.

2. Information requested

Sub-regulation 39(2) of the ARPANS Regulations gives the CEO the power to ask an applicant for some or all of the information and documents mentioned in Schedule 3 Part 1, and other information about the application if appropriate.

This regulatory guide indicates the documents and information from Schedule 3 that the CEO *will* require as part of the application. This regulatory guide also indicates the documents and information that should be submitted by the applicant to enable the CEO to take into account the matters in Regulation 41, as relevant to the type of facility and stage in the licensing process.

Use of 'must' in this guide indicates a mandatory legislative requirement. Use of 'should' statements indicates the CEO's expectations in terms of what would be considered a complete application. A graded approach should be applied by the applicant to ensure that the depth and detail of information is appropriate to the nature of the facility and the activity to be authorised.

Under paragraph 41(3)(a) of the ARPANS Regulations, the CEO must assess whether the application includes all of the information asked for by the CEO, as relevant to the specific stage in the licensing process (see further **Section 2.2**).

A licensing decision will not be made unless and until the information provided by the applicant demonstrates that the proposed conduct can be carried out without undue risk to the health and safety of people and the environment. For facilities, this information will be collated in a safety case. The safety case is the collection of scientific, technical, administrative and managerial arguments and evidence in support of the safety of a facility, covering the suitability of the site and the design, construction and operation, the assessment of radiation risks, and assurance of the adequacy and quality of all of the safety related work that is associated with the facility.

Information provided in the safety case should support the applicant's conclusions in relation to items (a) through (e) in Regulation 41 (**see Section 1.3**) and will, where applicable, support consultation in relation to item (g).

2.1 The safety case

Objective: The applicant should prepare and maintain a safety case that allows for a full understanding of all aspects relevant to the safety of the controlled facility; it should contain references to supporting material. It should be in a form suitable to be used as the basis for consultation[7] with all stakeholders on the safety of a facility for storage or disposal of radioactive waste as well as any ancillary facilities that may be part of the system for waste management.

The safety case should outline all safety-related arguments the applicant draws on in support of the application. It should include information on the consultation activities undertaken by the applicant prior to seeking a licence and during development of the safety case and what conclusions have been drawn from such consultation.

A table outlining the information that the applicant should submit as part of the safety case is at Schedule 1, including references to relevant sections in this regulatory guide. The schedule contains the generic elements applicable to all stages in the licensing process, as well as specific elements that should be introduced at various stages in the licensing process. Note that the safety case is a living document; specific elements will continue to be relevant for subsequent licensing stages and need to be updated in the safety case.

A major component of the safety case is the *safety assessment*, which includes the *safety analysis*. Important elements of the safety assessment are radiological impact on humans and the environment, site and engineering aspects, operational safety, non-radiological impacts, and the management system. Safety should be achieved by applying the principles of defence in depth, optimisation, and, as relevant, through the use of best available technique[8]. The safety analysis is the evaluation of the potential hazards associated with a facility or activity, documented in a safety analysis report (SAR).

The safety case will be the main source of information for stakeholders during the consultation phase[9]. As such, the CEO will require a summary of the safety case in plain non-technical language, to facilitate communication and consultation.

The applicant should take into account the ARPANS Act and Regulations, regulatory guides (http://www.arpansa.gov.au/Regulation/guides.cfm), relevant codes, standards and guides (http://www.arpansa.gov.au/Publications/codes/index.cfm), all available from ARPANSA's website, when preparing the safety case.

The CEO will require information about compliance with other legislation relevant to the protection of health and safety of people and the environment such as the *Environment Protection and Biodiversity Conservation Act 1999* (the EPBC Act) and the *Nuclear Non-Proliferation (Safeguards) Act 1987*. An application may be submitted to ARPANSA even if the environmental impact statement (EIS) or outcomes of the environmental assessment are not available. Assessment work by both agencies may continue in parallel but a licensing decision cannot be made by ARPANSA until the EIS and assessment of the EIS are provided.

---

7 Consultation required under Regulation 40, where the CEO is obliged to consult following receipt of a complete application. This will include publishing a notice in a daily newspaper and in the Gazette, stating his intention to make a decision on the application. The CEO must include in the notice: an invitation to people and bodies to make submissions about the application; a period for making submissions and procedures for making submissions [see Appendix 2]

8 See Section 5, Information for Stakeholders, page 31 or ICRP Publication 122.

9 Refer footnote 7.

As there is an obligation on the CEO to take international best practice into account in regulatory decision-making, it is incumbent on the applicant to demonstrate how international best practice has been considered in the safety case. Information on international risk assessments and standards that are relevant in this context is available at http://www.arpansa.gov.au/Regulation/ibp/index.cfm. A licence application should also draw on relevant design concepts, operational experience, and decommissioning and closure experience from facilities in other countries with an advanced infrastructure for safety.

The safety case should acknowledge the existence of any unresolved issues and should provide information on work proposed to resolve these issues in future stages of the licensing process. Issues that have been resolved with ARPANSA and other stakeholders should be documented and form part of the safety case.

The safety assessment should also consider the safety implications of any proposed co-location of different types of radioactive waste management facilities. In the case of co-location, each facility would in most cases require a separate application and safety case, addressing the relevant requirements for each stage of facility development. The safety of transport to, from and between radioactive waste management facilities should also be considered noting that the responsibility for transport of waste to a storage or disposal facility lies with the waste owner. This may require prior approval of a transport safety and/or security plan by ARPANSA.

It is expected that the safety case will be updated for each stage of licensing or otherwise as required by the CEO of ARPANSA. For each stage, it should provide enough information about the subsequent licensing stages to allow for an informed decision on the feasibility of the storage and/or disposal concept, as well as of the system for radioactive waste management.

With each new licensing stage, the safety case will become increasingly informed by experience gained during previous stages and by safety and security reviews, if any such review has been performed. For a storage facility, the safety case should outline plans for the final management of the waste in storage, including its disposal.

The IAEA requirements for a safety case are outlined in:

- *IAEA GSR Part 5 Predisposal Management of Radioactive Waste*
- *IAEA SSR-5 Disposal of Radioactive Waste*

Guidance from IAEA on how to prepare a safety case and the typical components can be found in:

- *IAEA GSG-3 The Safety Case and Safety Assessment for the Predisposal Management of Radioactive Waste*
- *IAEA SSG-23 The Safety Case and Safety Assessment for the Disposal of Radioactive Waste*

The applicant is encouraged to implement a graded approach and direct efforts and resources to the matters that are most significant for protection of the health and safety of people, and of the environment.

2.2 Information specified in the ARPANS Regulations

Schedule 3 Part 1 of the ARPANS Regulations outlines information that *may* be requested by the CEO.

For a facility covered by this regulatory guide, the information below *will be required* by the CEO as part of the application and should form part of the safety case.

The schedule differentiates between the different stages of licensing; however, as stated earlier, an application should also go into some detail about subsequent licensing stages. That is, the level of detail of information required at the various stages of licensing will vary and should be proportionate to the particular stage. For example, an emergency management plan is not expected to be as detailed in the application to site a facility as in the application to operate the facility.

General information

The CEO will require the following information as part of the safety case before a licensing decision can be made	
Item 1	The applicant's full name, position and business address
Item 2	A description of the purpose of the facility that is to be authorised by the facility licence
Item 3	A detailed description of the controlled facility and the site for that facility
Item 4	Plans and arrangements describing how the applicant proposes to manage the controlled facility to ensure the health and safety of people and the protection of the environment

Note that further details relevant to Item 4 are outlined in Sections 3 and 5, and in Appendix 2, of this regulatory guide.

Prepare a site for a controlled facility

The CEO will require the following information as part of the safety case before a licensing decision can be made	
Item 5	A detailed site evaluation establishing the suitability of the site
Item 6	The characteristics of the site, including the extent to which the site may be affected by natural and man-made events
Item 7	Any environmental impact statement requested or required by a government agency, and the outcome of the environmental assessment[10]

The selection of a site for a controlled facility requires that the conceptual design has been established so that the suitability of the site can be adequately assessed in relation to the general safety features of the facility. The performance of the barriers (engineered and natural) that separate the waste from the biosphere should be well understood and documented in the safety assessment and through the first iteration of a safety analysis report (preceding the preliminary safety analysis report required in the construction stage). The characteristics of the site as well as its evolution in terms of such things as geology, hydrology, biology, demography and land use should be well characterised.

Apart from a detailed site characterisation, all information may not be developed in full detail at the time the siting application is submitted and will be gradually refined as the safety case evolves. However, the application should provide sufficient information to demonstrate that the facility can provide protection of the health and safety of people and of the environment under all reasonably foreseeable circumstances at the time of application.

[10] An environmental impact assessment can be conducted in parallel with the licence application however a licensing decision will not be made until the EIS and its outcomes have been submitted to ARPANSA (see p7).

Construct a controlled facility

The CEO will require the following information as part of the safety case before a licensing decision can be made	
Item 8	The design of the controlled facility, including ways in which the design deals with the physical and environmental characteristics of the site
Item 9	Any fundamental difficulties that will need to be resolved before any future authorisation is given
Item 10	The construction plan and schedule
Item 11	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
Item 12	The arrangements for testing and commissioning safety-related items

The safety case for the construction phase should include a preliminary safety analysis report (PSAR) that takes into account the detailed design of the facility and demonstrates that the safety issues have been satisfactorily resolved. The safety case should demonstrate that construction will result in a facility that has the potential to be licensed to operate and be decommissioned or closed (as appropriate) while providing for the protection of health and safety of people and the environment.

Possess or Control

The CEO will require the following information as part of the safety case before a licensing decision can be made	
Item 14	The arrangements for safe storage of controlled material and maintaining the controlled facility

The safety case for the possess or control phase should detail arrangements for maintaining the facility in the event that such a licence is required before radioactive waste is received by the facility. This could eventuate if there is a delay between the construction and operation phases.

Operate a controlled facility

The CEO will require the following information as part of the safety case before a licensing decision can be made	
Item 15	A description of the structures, components, systems and equipment of the controlled facility as they have been constructed
Item 16	A final safety analysis report that demonstrates the adequacy of the design of the controlled facility, and includes the results of commissioning tests
Item 17	The operational limits and conditions of the controlled facility
Item 18	The arrangements for commissioning the controlled facility
Item 19	The arrangements for operating the controlled facility

Following construction, the PSAR should be updated to address the design information for the facility including the operational limits and conditions within which the facility must operate. The term 'final SAR'

(FSAR) is used for the updated version that must be submitted to ARPANSA with an application for a licence to operate a facility as part of the updated safety case.

Decommission or close a controlled facility

The CEO will require the following information as part of the safety case before a licensing decision can be made	
Item 20	The decommissioning plan for the controlled facility
Item 21	The schedule for decommissioning the controlled facility
Item 22	The results of decommissioning activities at the controlled facility
Item 23	Details of any environmental monitoring program proposed for the site

Decommissioning is applicable to a radioactive waste storage facility and to ancillary infrastructure necessary for predisposal management including infrastructure associated with a disposal facility before closure of the facility.

The decommissioning plan should be part of the safety case from the outset and will be refined until such time an application to decommission the facility is submitted. It will at that time also be informed by operational experience including information about any events that might be relevant to the safety of decommissioning.

A final decommissioning report should summarise:

- decommissioning undertaken
- dismantling of the facility
- waste management including clearance of radioactive materials or objects from regulatory control
- the final status of the site at the time of release from regulatory control or of conversion to other use
- any remaining restrictions on the site.

The final decommissioning documentation should show, as far as practicable, that all radioactive materials present at the beginning of decommissioning are accounted for and their ultimate destination is confirmed.

Release of the site or facility from regulatory control may be achieved progressively for parts of the facility or site or with restrictions to ensure protection of people and the environment. A plan for ongoing control, maintenance and surveillance of any area released with restrictions should be prepared by the licence holder and approved by ARPANSA. Legal and financial arrangements should be made for implementation of the plan.

For a disposal facility the safety case for operation of the facility should consider the safety after closure of the facility. The safety of the disposal facility after closure should take into account the expected range of possible developments affecting the disposal system and events that might affect its performance including those of low probability. Further details of the post-closure phase are described in Section 5.2.2 of this document and specific requirements for the final closure plan are presented in Schedule 1.

The CEO's consent must be obtained before a licence can be surrendered and a site released from regulatory control.

3. Undue risk

Under paragraph 41(3)(b) of the ARPANS Regulations, 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 should 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 abnormal occurrences.

Guidance on optimisation of protection in terms of radiation doses and risks are given in Section 5 of this regulatory guide. The systematic approach to achieve the appropriate level of protection is captured under *Plans and arrangements for managing safety* as outlined below.

3.1 Plans and arrangements for managing safety

Objective: The applicant should demonstrate effective systems and processes that provide assurance that the controlled facility can be sited, constructed, operated, decommissioned and closed in a way that does not pose undue risk to the health and safety of people and to the environment.

The management system is key to establishing a system for leadership and management for safety; it should provide assurance that the operator has systems and procedures in place to identify, characterise and manage all safety issues including ranking the relative importance of risks so that available resources are deployed efficiently and effectively.

The management system should be designed to foster and promote a culture of safety which takes into account human factors such as attitudes and behaviour as well as the general mindset by which all workers including senior management approach safety. These factors should interact with the technological and organisational factors in a way that promotes *holistic safety* (often referred to as systems safety) which is considered a best practice approach to safety management. A holistic approach to safety ensures the technology is safe to use, people perform tasks safely, and the organisation overall is managed safely.

ARPANSA has developed a Holistic Safety Guideline on the implementation of holistic safety to which applicants may refer.

Guidance on what the CEO would expect to be included in plans and arrangements is provided in *REGULATORY GUIDE: Plans and arrangements for managing safety (2017)*.

The applicant should include in the safety case information that demonstrates leadership and management for safety, relevant to all safety aspects and licensing phases, documented in a management system

The management system should define how the applicant proposes to manage the controlled facility to ensure health and safety of people and protection of the environment. The applicant should provide the following information as per Schedule 3 Part 1 Item 4 of the ARPANS Regulations:

- the arrangements for maintaining effective control of the facility
- the safety management plan for the controlled facility
- the radiation protection plan for the controlled facility
- the radioactive waste management plan for the controlled facility
- the security plan for the controlled facility
- the emergency plan for the controlled facility
- the environment protection plan for the controlled facility.

The interdependencies between different components of the waste management system and their collective contribution to the over-all safety of the facility should be considered.

In the case of co-located facilities, the management system should address the elements which are common to these facilities and their interrelationships as well as the safety implications of co-location.

The management system should address holistic safety, that is, the human, organisational and technical elements, and their interrelations in managing the facility safely.

4. Net benefit (Justification)

Objective: the applicant should demonstrate that the controlled facility provides an overall net benefit.

The principle of *justification* in the internationally adopted system for radiological protection states that any activity which introduces a radiation source or exposure must do more good than harm, that is, there is net benefit.

Under regulation 41(3)(c) of the ARPANS Regulations, the CEO must consider whether the applicant has shown that there is a net benefit from carrying out the conduct related to the controlled facility.

For radioactive waste storage or disposal facilities, the analysis of justification should take into consideration the conduct relating to the controlled facility including any predisposal management as well as the risks and benefits of the activities and facilities that generate further waste. For waste that already exists, justification cannot be assessed; however, any decision to manage it should consider optimisation of protection (see Section 5).

The risks associated with the continuation of current practices (the ‘zero option’) and with reasonable alternatives to the proposed system should be considered by the applicant.

It is acknowledged that in many cases, decisions relating to benefit and risk are taken at the highest levels of government[11]. In other cases, a regulator, such as the CEO of ARPANSA, may determine whether proposed facilities and activities are justified.

The applicant should include in the safety case information that demonstrates that the proposed facility is justified

The applicant should provide:

- information on current and future activities generating waste destined for the facility and the benefits and risks associated with the generation of waste that contribute to such waste streams
- an analysis of potential alternative technologies than the ones currently generating the waste or other ways by which the same benefit can be achieved with less risks
- an analysis of alternative options for managing (predisposal management including storage, and disposal) the current waste inventory and projected waste streams including the option of continuing current practices and the associated risks.

5. Optimisation

Under regulation 41(3)(d) of the ARPANS Regulations, the CEO must consider whether the applicant has shown that the magnitude of individual doses, the number of people exposed, and the likelihood that exposures will happen, are as low as reasonably achievable, having regard to economic and social factors. This internationally adopted principle for radiological protection is referred to as *optimisation*.

Dose limits have been set in Part 5, Division 5.2 of the ARPANS Regulations at levels that provide a high level of protection for individuals from detrimental effects of radiation exposure. The dose limits and provisions regarding averaging times and calculations of committed dose outlined in Division 5.2 apply in their entirety to facilities covered by this regulatory guide.

Optimisation ensures that the dose limits are very rarely exceeded as exposures are normally optimised far below such limits. Optimisation is often guided by a dose constraint which is set at a fraction of the dose limit and is specific to the activity or facility (the 'source') that is the cause of the exposure. Planning, design and management should be such that exposures over this constraint are not expected to occur but are maintained as low as reasonably achievable where economic and social factors are taken into account.

5.1 Protection of workers

Objective: The applicant should demonstrate that systems, structures and components, and the management of the controlled facility provide optimised protection of workers during operation and decommissioning and that worker protection is optimised during monitoring and remedial works including in the post-closure phase of a disposal facility.

The applicant should propose a *dose constraint* for workers below which protection will be optimised. The expectation is that the constraint would not normally be set higher than 5 mSv effective dose per year[12] for workers in a facility for storage or disposal of radioactive waste.

[11] IAEA Safety Fundamentals SF-1 paragraph 3.19.

Dose limits apply and optimisation of worker protection should also be implemented during remedial work whether this work takes place during the operation, decommissioning or post-closure phases.

Dose records provide a means of verifying that efforts to optimise radiation protection have been effective.

5.2 Protection of the public

Objective: The applicant should demonstrate that systems, structures and components, and the management of the controlled facility provide optimised protection of the public during operation, decommissioning and post closure.

The engineered barriers should be designed and maintained, and for the long term the natural barriers should be of a nature so that the containment of the radioactive waste will be effective and will withstand reasonably foreseeable disruptive events over the time period the waste poses radiation risks of concern.

The applicant should demonstrate the protective capability of the facility by carrying out exposure modelling based on a set of clearly defined and explained assumptions[13]. This includes defining and using a representative person, affected by reasonably foreseeable exposures from the facility, or reasonably foreseeable exposures resulting from handling, including transport, of the waste (see ICRP Publication 101a Assessing Dose of the Representative Person for the Purpose of the Radiation Protection of the Public (2006) for details on the representative person).

5.2.1 The operational phase

The applicant should demonstrate that the protective capability is optimised including how different design alternatives have been considered in the optimisation process and support the analysis by exposure modelling.

For a storage facility, the design and maintenance during the operational phase should aim to permit abandonment of the site and unrestricted access after decommissioning ('green field') or – if so authorised – use for different purposes including for activities that may require management of radiation risks.

5.2.2 Post-closure phase

The post-closure phase for a disposal facility includes the normal and natural evolution of the systems, structures and components that contribute to safety and disruptive natural events that may impact on safety, either immediately or in the future.

---

[12] The effective dose is a risk-related quantity used for radiation protection purposes (not risk assessments) that integrates current knowledge of biological effectiveness of different types of radiations, and the likelihood of developing disease in different organs. It is measured in units with the special name sievert (Sv). For further specifics of radiation and tissue weighting factors, and other matters that relate to dosimetry and radiation risks, information in ICRP Publication 103 *The 2007 Recommendations of the International Commission on Radiological Protection*, Annals of the ICRP 37 (2-4) serves as the main reference.

[13] A prudent approach could be to use reasonably cautious, yet realistic, assumptions in deterministic assessments; the use of overly pessimistic assumptions in successive iterations provides little information on actual safety performance and protective capability. In a probabilistic approach, a comprehensive analysis is made of failure scenarios to quantify risks. The applicant may chose the approach or a combination of approaches, but must provide justification for the chosen methodology and define the assumptions made.

Disruption may also be caused by inadvertent and planned intrusion, accidents and reckless activities, and intrusion with malicious intent.

Normal evolution of the facility and its surroundings

Processes that govern the performance of the barriers can be foreseen with reasonable certainty and are linked to the *features* of the facility. The period during which ongoing control of the facility will take place should be defined by the applicant. During this phase, and taking reasonably foreseeable natural *events* into account, the protective capability of the facility is expected to be at least similar to the protective capability during the operational phase (features, events and processes are commonly referred to as FEPs).

Following termination of controls, or for time periods beyond several tens to a few hundred years (depending on the type of facility), it is reasonable to analyse the facility's protective capability in terms of risk rather than in terms of exposure or dose.

The concept of radiation risk as used in this regulatory guide considers the probability of an event occurring with the probability of harm (the implications for the health of people) should the event occur. A high probability event with a low probability of harm may thus pose the same risk as a low probability event with high probability of harm. The applicant should define the scenarios that govern the risk estimates. This can be done deterministically by defining likely scenarios and assigning parameter values to FEPs. The analysis can be supplemented by performing a number of realisations in a probabilistic approach to the assessment. Information should be provided on the time frames within which the risk is assessed.

For normal evolution including reasonably foreseeable natural disruptive events, optimisation and use of best available technique should aim at reducing the annual risk for health detriment[14] for a member of the public to in the range 10^{-5} to 10^{-6} or less (one in a hundred thousand to one in a million). This range takes into account the various means (and inherent uncertainty) in predicting the characteristics, including behaviour and land use of future populations including the representative person, over time periods of centuries and beyond. The applicant should provide information on how the risk may vary over time.

Accidents and severely disruptive natural events

Severely disruptive events include accidents and natural events of a magnitude that is well outside of the ordinary, e.g. seismic events outside the range of what has been recorded or can be reasonably expected or flooding caused by similarly extreme weather conditions. The consequences of multiple and simultaneous events should be analysed as well as the long term consequences of such events for the protective capability of the facility.

The applicant should separately and deterministically assess and record a suite of scenarios that involve accidents and severely disruptive natural events that may result in an annual dose of ≥1 mSv effective dose (annually or in immediate association with the event) if such scenarios exist and explain the rationale for identifying the scenarios.

Human intrusion

Planned intrusion may result from any future attempt to alter the engineered barriers or retrieve the waste or any other reason that today can only be speculated. They would be considered planned actions. The

[14] The detriment adjusted nominal risk coefficient at low dose rates, applicable to the whole population and to stochastic effects (all cancers and heritable effects); of 5.7% per sievert, given in Table 1 of ICRP Publication 103, must be used.

framework for institutional control and preservation of information should be developed with the potential for such future planned actions in mind.

Any design features aimed at facilitating retrieval of waste should not reduce the protective capability of the facility.

The applicant should address possible scenarios involving inadvertent human intrusion into the disposal facility in the post-closure phase. The consequence of intrusion for the protective capability of the facility should be analysed.

If such intrusion is expected to lead to an annual dose of less than 1 mSv effective dose to the intruder or those living close to the site then efforts to reduce the probability of intrusion or to limit its consequences are likely not warranted.

Where it is calculated that inadvertent human intrusion could result in doses of between 1 and 10 mSv effective dose for any human associated with the intrusion (annually or in immediate association with the intrusion) further evaluation of the particular scenario is needed and reasonable efforts may be warranted to reduce the probability of intrusion or to reduce the consequences.

If doses of greater than 10 mSv effective dose associated with the intrusion are calculated for an individual from a plausible but inadvertent human intrusion scenario (annually or in immediate association with the intrusion) additional controls should be put in place to further limit the possibility of intrusion or to limit the consequences to below that dose figure. This may involve re-design of the facility, changes to the waste acceptance criteria or segregation of the radioactive substances giving rise to the higher dose.

Deliberate intrusion may also arise from acts with malicious intent. The concern here is primarily with the safety of those indirectly affected by the intrusion. The arrangements for safety should reduce the worker, public and environmental risks associated with such intrusion to levels that are as low as reasonably achievable where economic and social factors are taken into account.

Remediation preparedness

For any remedial actions that are deemed justified following reckless actions, accidents and disruptive events including human intrusion a reference level of 10 mSv annual effective dose or less should be applied for protection of the public. Remedial actions should be planned and optimised so that the resulting annual effective dose is below the selected reference level. Worker exposures must be below the dose limit for workers and should be optimised. Information on remediation preparedness should include the following, as relevant:

- division of responsibilities for remediation
- the role of stakeholders
- approaches to defining remediation targets and end states as well as generic waste management plans
- potential methods and technology available for environmental remediation.

Time frames

The applicant may impose a time cut-off in the assessment of passive safety. The reason for the cut-off should be explained.

In the case of time frames beyond several hundreds of years, increased attention needs to be placed on analysis of implications for safety of long-term climatic and other environmental trends in order to form a view on the appropriateness of the protective capability of the facility.

The applicant should include as part of the safety case information that demonstrates that all reasonable steps have been taken to ensure that protection of workers and the public is optimised

The applicant should optimise the protection of workers and in doing so:

- establish dose constraints to guide optimisation efforts
- optimise worker protection during any monitoring or remedial work

The applicant should optimise protection of the public in the operational phase of a storage or disposal facility and in doing so:

- model exposures of representative individuals and define what assumptions that have been made about exposure pathways and their characteristics, and about the characteristics of the exposed groups including the representative individuals.

The applicant should optimise protection of the public and apply best available technique to the design and to the safety of the post-closure phase of a disposal facility and in doing so:

- aim for reducing risks of detriment to between 10^{-5} and 10^{-6} per annum or less, including during reasonable foreseeable natural disruptive events, using the nominal risk coefficients in ICRP Publication 103 and provide information on the assumptions used in the risk calculations
- identify scenarios including disruptive events, accidents, and intrusion (inadvertent or with malicious intent) that may lead to effective doses over 1 mSv annually or in association with the event
- for intrusion scenarios leading to effective doses in excess of 10 mSv (annually or in association with the event) consider alternative designs or methods to segregate the waste
- for planned remedial actions, comply with dose limits for workers and optimise protection against a reference level of 10 mSv effective dose per year or less.

The applicant should carry out calculations demonstrating the protective capability of a disposal facility in the future and in doing so:

- analyse the features, events and processes governing the protective capability of the engineered and natural barriers over a time period that is commensurate with the hazard of the disposed waste.

5.3 Protection of the environment

Objective: The applicant should demonstrate that the systems, structures and components, and the management of the controlled facility provide protection of the environment and that the facility does not adversely impact an area that has special environmental attraction or appeal, is of notable ecological significance, or is the known habitat of rare fauna or flora.

In order to assess the impact of a proposed radioactive waste storage or disposal facility on the environment the applicant should undertake a screening assessment of exposures to wildlife. If a screening assessment that uses a cautious approach indicates that incremental exposures to relevant wildlife in the natural environment are likely to be below a dose rate of 10 microGy per hour, no further assessment will

be deemed necessary[15]. If the assessment indicates higher dose rates, further assessments should be performed to estimate the potential level of impact on wildlife. Guidance is provided in ARPANSA RPS G-1 *Guide for Radiation Protection of the Environment (2015)*.

An environmental management plan should be established for the disposal site prior to commencement of construction and operation. The purpose of the plan is to set out management objectives and practices which will provide for the safe and environmentally sound management of the facility during its construction, operational and post-operational phases.

Time frames and scenarios used for the analysis of long-term protection of people should be applied also when analysing long-term protection of the environment.

The applicant should include as part of the safety case information that demonstrates that the environment is protected

The applicant should characterise the environment, including any unique features requiring particular attention in terms of conservation that may influence the feasibility of the site.

The applicant should, before the construction of a facility, establish baseline information of the site regarding its radiological characteristics, to inform the development of the environment management plan and environmental monitoring.

The applicant should, as parallel to the optimisation of protection of people, consider exposures of organisms in the natural environment using scenarios and time frames that have been used when analysing long-term protection of people and in doing so:

- analyse the characteristics of the natural and semi-natural environment in the facility's surroundings
- take into consideration that dose rates incurred by wildlife in such environments below 10 µGy per hour and determined or predicted using cautious approaches and methodologies may serve as an indicator that wildlife is adequately protected.

5.4 Security

Objective The applicant should demonstrate that systems are in place to prevent unauthorised access, theft and acts with malicious intent including actions that would contribute to proliferation of nuclear material considering the security vulnerabilities of the controlled facility and entire system for waste management.

The approach to security should be guided by the optimisation principle and be benchmarked against the dose and risk reduction strategies outlined above. The interaction and interface between measures to ensure safety on one hand and security on the other, should be taken into consideration so that actions taken to ensure security do not inadvertently impact on safety and *vice versa*.

If radioactive waste that is also nuclear material is to be managed then the security systems and infrastructure protecting the nuclear material will need to comply with the requirements under the Amendment to the *Convention on the Physical Protection of Nuclear Material* and the IAEA *Nuclear Security*

[15] There is no risk-related quantity for radiation protection of organisms in the natural environment; hence the physical quantity absorbed dose is used. The absorbed dose is measured in units of joule per kg of absorbing matter, with the special name gray (Gy).

Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities. This is managed through permits issued under the *Nuclear Non-Proliferation (Safeguards) Act 1987* by the Australian Safeguards and Non-Proliferation Office (ASNO).

The applicant should include as part of the safety case information that demonstrates that people, property, society and the environment is protected from malicious intent

The applicant should:

- submit a security plan that covers security issues including transport of waste where relevant
- assess and manage any conflicts or tension between security and safety.

6. Capacity to comply

Objective: The applicant should demonstrate that adequate capacity is sustained for the full life-cycle of the controlled facility and records are established and preserved for the future.

Under regulation 41(3)(e) of the ARPANS Regulations, 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.

The applicant should demonstrate that it has the capacity of managing safety over the life-time of the facility. It should demonstrate adequate human and financial resources, the necessary skills for leadership and management of safety, and long-term sustainability. It should also provide information of its record of managing similar facilities or relevant information that provides confidence in its ability and capacity to do so.

The approximate timing and conditions for termination of the responsibility of the operating organisation should be defined for example, after decommissioning or closure. Where relevant, the terms and conditions for continued institutional control should be clarified.

Records relevant to safety should be established and arrangements should be made for their long-term maintenance including determining locations where the records are to be kept. Commonwealth government agencies must comply with the requirements of the *Archives Act 1983 (Cth)*.

The applicant should demonstrate adequate capacity to sustain safety over the life-cycle of the facility

The applicant should, unless the information is already available to ARPANSA, demonstrate that:

- it is adequately resourced financially
- possesses the necessary competencies, skills and experience
- it is able to sustain its activities including safety during the expected time of ongoing control of the facility.

Safety-related records should be established and arrangements made for their long-term maintenance.

Schedule 1: Information that should be submitted as part of the safety case

General information relevant to all stages of a controlled facility
The applicant should submit a safety case with the licence application that includes: - the information requested under Schedule 3 Part 1 of the ARPANS Regulations relevant to the specific licensing stage (**see Section 2.2**) - all safety-related arguments the applicant draws on in support of the application. A safety case *document* may reference detailed supplementary documentation but should be comprehensive enough to allow all stakeholders to form a view on the safety of the facility - a summary in plain language to facilitate communication during the consultation process.[16] The safety case should be updated for each new stage in the licensing process, drawing on input during consultation and experience gained during establishment of the facility, include information on remaining unresolved issues and the plan towards their resolution. It should contain enough information on future licensing stages to allow for an informed decision on safety during the facility's life-cycle.
Compliance with legislative and regulatory requirements - these include the Act and Regulations, other Acts as relevant, codes (RHS and RPS) as relevant, and to take into account ARPANSA regulatory guides as relevant.
Approach to international best practice - the radiation protection, and nuclear safety and security objectives as a part of the siting, design, operation, decommissioning and closure; compared with those laid out in the international framework for safety, security and radiation protection documented in international standards (e.g. IAEA safety standards and nuclear security guidance) - technical standards for construction, materials and other features, relevant to safety - experience from siting, construction, operation, decommissioning and closure of similar facilities in countries with an advanced infrastructure for safety.
Protection of the health and safety of people and of the environment - demonstration that the application meets the health and safety objectives of relevant legislation - justification for the application in terms of net benefit, i.e. that there is more good than harm (**see Section 4**) - demonstration that protection is optimised and that the environment is protected (**see Section 5**) - a safety assessment including an iteration of the safety analysis report (SAR) relevant to the licensing stage - an analysis of long-term safety taking into account foreseeable natural events and severely disruptive events including reckless action, accidents and events associated with human intrusion (**see Section 5**) - a management system outlining the interdependencies between safety factors within the controlled facility and within the system for waste management including systematic consideration of human factors and the human-machine interface to promote holistic (or system) safety (**see Section 3**).

[16] Refer footnote 7.

Specific information relevant to an application to prepare a site for a controlled facility
Conceptual design of the facility and information on the waste management system including: - design characteristics of the proposed facility and information on how the facility interacts with the site so that any introduction of unreasonable design requirements to compensate for a less favourable site can be avoided - descriptions of the considered disposal options and the considerations leading to the applicants preferred option including choice of site and design of the facility - waste management system including: facilities for storage and disposal; waste inventory and future waste streams destined for the facility; transport arrangements and likely paths; any ancillary facilities for predisposal management, e.g. for conditioning of waste - potential safety and security issues from co-location of facilities at new or existing sites, where applicable - for a storage facility: the operational life span, plans covering final disposal including transport to the disposal facility, necessary ancillary facilities for predisposal management and contingency planning for delays in the establishment of a disposal facility - for a disposal facility: the intended period of institutional control - the availability of resources over the lifetime of the proposed waste facility including for decommissioning or closure as appropriate.
Description of the radioactive waste to be managed in the facility - the waste (form, volume, radionuclide inventory, chemical composition, toxicity, stability and all other physical, chemical and radiological characteristics that are relevant for reviewing the safety of the facility) currently in store that is destined for the facility - the waste and its characteristics (see above) anticipated for the facility during its operational life-time and whether the facility is a store or a disposal facility - the waste acceptance criteria including the characteristics of the waste (e.g. mobility), waste form and the containment system; design and construction of packages; provisions for retrievability of packages; design provisions for criticality safety where nuclear materials are present.
Site characteristics - characteristics of the proposed site including seismology, meteorology, hydrology, geology, demography, biology, hazards and human actions, and the environment's ability to serve as a barrier that provides protection for the facility and retards migration of radionuclides - assessment of the site taking into account the implications of the site characteristics for the radiological impact of the facility on the surrounding population and the environment during normal operation and anticipated natural events.
Reference accident - the identification of a severe hypothetical event beyond the design basis of the facility (design extension conditions) and assessment of its radiological consequences and mitigation.

Specific information relevant to an application to construct a controlled facility
Engineered barriers for a storage or disposal facility - the approach to defence in depth including a multi-barrier approach to ensure containment and the use of redundancy, independence and diversity in the design of the safety system to ensure that the design is balanced i.e. that safety at defence in depth level 3 is not relegated unduly to defence in depth levels 4-5 - selection and optimisation of a system of engineered barriers including consideration of best available technology as appropriate including the waste containers, the waste conditioning materials and matrix, the use of vaults or trenches made from materials with specific properties, drainage systems, cover layers, and other barriers - design features to facilitate waste handling, storage and transport as well as inspection, and if considered appropriate, retrieval of waste from a disposal facility - design consideration (for a waste store) of aspects that may facilitate subsequent extension of the life of the facility and eventual decommissioning.
Items important for safety - items important to safety are designed to a standard and quality that is commensurate with their categorisation by safety significance according to the appropriate national and international standards taking into account effects of ageing during operational states and accident conditions.
Access control, physical security and surveillance - design provisions for physical security and access control appropriate for the radioactive material present in the facility - design provisions for monitoring and surveillance.
Verification and validation - a program for design verification and validation to confirm that the design is adequate and is in accordance with the design specifications including the closure features - a program for managing uncertainties including their characterisation with respect to their source, nature and importance - the process for validation and verification of computer codes.
Design-basis accident - provisions that the design ensures that the safety systems accommodate design-basis accidents and there are provisions to ensure that for design-basis accidents, the radiological consequences if any, would be minor and within prescribed limits and that no off-site emergency response would be required following any design-basis accidents - design-basis safety limits are not exceeded in the event of a design-basis accident - likelihood is extremely small of any beyond-design-basis accident (design extension conditions) that could have serious radiological consequences - design provisions for limiting the progression and mitigating the consequences of beyond design basis accidents.

Specific information relevant to an application to possess or control a controlled facility

- None except as specified in Schedule 3 part 1 of the ARPANS Regulations.

Specific information relevant to an application to operate a controlled facility

Final waste acceptance criteria (for a disposal facility)

- the final waste acceptance criteria; these will inform ARPANSA whether the characteristics of the waste are aligned with the operational and long-term safety features of the facility.

Operating procedures and arrangements

- operating procedures and arrangements for the facility including details of operational limits and conditions derived from the safety analysis of the facility
- results from tests of items important for safety and commissioning tests.

Confirmed hazard categorisation

- Hazard category F1: where there is no potential for significant consequences outside the facility
- Hazard category F2: where there is potential for significant consequences on the site outside the facility but not outside the site
- Hazard category F3: where there is potential for significant consequences outside the site.

Specific information relevant to an application to decommission a storage facility

Final decommissioning plan

- final decommissioning plan addressing the strategy and processes as well as the justification for selecting a particular strategy
- results of radiological characterisation of structures, systems and components that will be dismantled and the results of the hazard analysis
- provisions for handling, treatment, packaging and transport of waste generated from decommissioning activities
- final decommissioning report demonstrating that the site or the facility can safely be released for the purpose stated in the decommissioning plan
- post decommissioning radiological survey reports demonstrating that the radiation doses specified in the decommissioning plan are not exceeded.

Specific information relevant to an application to close a disposal facility

Final closure plan

- final closure plan describing the institutional controls (restrictions, monitoring and surveillance, maintenance and any remedial actions, and information preservation) for the post-closure period
- a radiological impact assessment for the post-closure period, using deterministic and probabilistic analyses as appropriate.

Appendix 1: Completing the application form

This section is designed to guide an applicant through the licence application form

Section A: Applicant information

Name of department or Commonwealth body

Provide the name of the Department or Commonwealth Body on behalf of which the application is being made. Further information may be included for ease of identification e.g. Division, Branch, Section etc.

Portfolio

Provide the 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 the 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 facility. 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 must 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 must be included with the application. If there is more than one radiation safety officer, the details of other radiation safety officers must also be provided.

[1] See sub-paragraph 39(4)(b)(ii) of the ARPANS Regulations.

Declaration

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

Section B: Kind of nuclear installation and type of authorisation

The applicant must indicate the kind of nuclear installation and type of authorisation for which a licence is sought.

Section C: Facility details

The applicant must provide a detailed description of the facility and its site including the site address. The purpose of the facility must be described and specific information relevant to the type of authorisation sought must be provided. Applicants may include this information in the application form or provide references as to where this information can be found in supporting documentation.

Type of authorisation

The applicant must complete the section relevant to the type of authorisation sought (**see Section 2)**. References as to where this information can be found in the accompanying documentation may be provided.

Section D: 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 must be a comprehensive program of policies and procedures that demonstrate how safety and security will be assured. A brief description of what is expected in plans and arrangements is provided below. For more detailed information, applicants must refer to the *Regulatory Guide: Plans and Arrangements for Managing Safety*.

1. Effective control arrangements

The applicant must describe arrangements for maintaining effective control over the facility. This must address issues such as organisational arrangements, resources and management systems.

2. Safety management plan

The applicant must describe the administrative arrangements for managing the safety of the facility. Issues such as safety culture, safety of premises and equipment, competency and training, incidents and accidents, auditing, and record keeping must be addressed.

3. Radiation protection plan

Radiation protection policies and procedures must be set out in a radiation safety manual or management plan and in specific operating procedures.

The radiation protection plan must 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.

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 must be set out in a radioactive waste management plan.

5. Security plan

Arrangements for the security of the facility and any associated sources to prevent theft, damage or unauthorised use or access must be provided. These arrangements must demonstrate how the security of the facility and any associated sources will be maintained and how periodic inventory checks will be undertaken to confirm that all sources are in their assigned locations and are secure. See also **Section 5.4**.

6. 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 must 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 must be included.

The plan must 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 must be developed for the protection of wildlife populations and ecosystems in parallel with radiation protection of people, consistent with international best practice. The arrangements must 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. See also **Section 5.3**.

Section E: 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 the 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 E 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 Schedule 3, Part 2 of the Regulations.

Section F: 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 sealed source certificate or special form certificate should be provided.

Section G: Matters to be taken into account by the CEO[2]

Under subsection 32(3) of the Act, the CEO, in deciding whether to issue a facility licence, must take into account certain matters prescribed in the Regulations and international best practice in relation to radiation protection and nuclear safety. Sub-regulation 41(3) of the ARPANS Regulations lists the matters that the CEO must take into account. Section G of the application form is where an applicant must provide this information.

Undue risk – **see Section 3**

Net benefit – **see Section 4**

Optimisation – **see Section 5**

Capacity to comply – **see Section 6**

Application fee

Applicants should refer to regulation 40B and the table in clause 1 of Schedule 3A of the Regulations to determine the appropriate application fee.

The application is not valid without the appropriate fee. Assessment of the application cannot begin until the fee is received.

Submitting the application

Electronic applications are preferred and should be lodged at licenceadmin@arpansa.gov.au. Arrangements should be made for electronic payment of the application fee.

Alternatively, the completed application form, all supporting documentation, CDs, and the appropriate fee may be sent to:

The CEO of ARPANSA
PO Box 655
MIRANDA NSW 1490

[2] Under regulation 42 of the Australian Radiation Protection and Nuclear Safety Regulations 1999, the CEO will also take into account the content of any submissions made by members of the public about the application, under a notice issued under regulation 40.

Appendix 2: How an application is decided

Once an application has been submitted it 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. 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 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 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 conduct

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 RAR 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) will 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 specified period. Once issued a licence remains in force until it is cancelled or surrendered or the specified period has elapsed.

Appendix 3: 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

If an applicant wishes 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.