Australian Government
Australian Radiation Protection and Nuclear Safety Agency

arpansa

REGULATORY SERVICES

# REVIEW & ASSESSMENT MANUAL

*Guide for regulatory officers on the review and assessment of licence applications, requests for exemption, significant changes, and other activities that require prior approval by the CEO of ARPANSA*

**ARPANSA-GDE-1118 v5**

January 2023

# Introduction

ARPANSA's *Regulatory Activities Policy* (ARPANSA-POL-0002) provides the over-arching framework for efficient and effective regulatory activities to achieve the object of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act) *to protect the health and safety of people the environment from the harmful effects of radiation*. This document should be read in conjunction with that policy.

This manual provides guidance to regulatory officers on how to undertake the review and assessment of licence applications, requests for exemption, changes with significant implications for safety, and other submissions seeking to undertake activities that require prior approval by the CEO of ARPANSA.

ARPANSA's program for regulatory oversight of the safety and security of facilities and sources is described in the Inspection Manual while the Compliance Manual describes how ARPANSA promotes compliance and manages non-compliance. By making these manuals available on ARPANSA's website we are being open and transparent about how ARPANSA conducts its regulatory business.

Process descriptions, flow-charts, templates, and other detailed elements of the management system are not included in the online version.

A risk-informed graded approach is applied to regulatory assessment and decision-making.

## In this document:



## Detailed management system elements that are not part of the online version of this manual:



## Key changes in this version of the manual:

- Section 6 Exemptions updated to align with amendments to Regulations in August 2022
- Section 5 on extension of RWL expanded to align with ARPANSA-GDE-1746

# 1. General considerations

The *review and assessment* of an application for regulatory approval forms the basis for an independent and informed judgement on the adequacy of an applicant's submission. It involves evaluation of the claims, arguments and evidence provided by the applicant against the Act and Regulations, codes, standards, and guides. International best practice and operating experience are also considered. The purpose is to determine whether the applicant has demonstrated compliance with relevant requirements and whether the proposed conduct meets the object of the Act.

The review and assessment of an application is assigned to a regulatory officer (referred to in this document as the *assessor*) on the basis of their experience and expertise and whether the application relates to a facility or source. Depending on the nature and complexity of the assessment the assessor may form a team and may involve technical and scientific experts from other branches, advisory bodies, or in some cases external consultants.

Assessments should be undertaken in a timely manner. In most cases a timeframe for review is agreed with the applicant taking into account existing priorities and the nature and complexity of the application. The scope and depth of an assessment should not be influenced by time pressures that an applicant may seek to impose.

It is expected that the submission has been independently reviewed and approved by the applicant's internal assurance process (safety/security committee or equivalent). The assessor should consider the presentation of information and quality of the submission before commencing the assessment. Factors to consider include:

- Is it comprehensive, coherent, accurate and consistent?
- If not, is the missing information or assumed prior knowledge already to hand?
- Is there sufficient detail?
- Is it adequately structured?
- If a staged submission does the information provided match the scope of the staged submission and when relevant include sufficient information about subsequent stages to allow an informed judgement on the adequacy of the submission?

The review and assessment will evaluate the claims, arguments, and evidence presented by the applicant. The claims represent the applicant's understanding of the safety and security objectives to be met. The evidence is the information and data to support the claims. The arguments link the evidence with the claims to demonstrate that they have been met.

A useful means of hastening the assessor's understanding of complex submissions is by the applicant presenting its case to those who will undertake the assessment.

Guidance for applicants and expectations for the content of submissions is published in Regulatory Guides. Assessors should have a clear idea of the regulatory requirements and expectations for a particular submission. The level of detail and depth of the review and assessment should reflect the hazard and complexity of the facility or activity. The information necessary to conduct a comprehensive review should be identified including the following (where relevant):

- Legal and regulatory requirements, regulatory procedures and guidance specific to review and assessment
- Technical and other documents needed to assess compliance with regulatory requirements and the licence
- Outcomes from other regulatory processes (e.g. inspections, previous assessments)
- National and international best practice as demonstrated in standards, guidance, research and technology, and in operational experience with similar activities/facilities.

When there is an assessment team there should be a clear assessment plan. With multiple assessors there is potential for assessment gaps or duplication to occur so there should be a clear assignment of responsibilities to ensure comprehensive coverage of all requirements. For complex applications and/or applications involving high hazard activities a project may be formally established under ARPANSA's project management framework. Confidential information such as that in the security plan must be managed in accordance with the Australian Protective Security and Policy Framework (PSPF). The assessment plan should include identification of the following:

- Any likely interfaces between specialist assessments (e.g. safety and security) and a clear plan to manage them
- Interfaces with the applicant and who is the primary point of contact
- Any interfaces with other regulatory bodies and an understanding of the scope of their remit

Additional information is requested where necessary to clarify issues and to confirm claims and arguments. Applicants may seek advice or assistance with respect to what needs to be done to satisfy the reviewer's concerns. Licence holders/applicants are responsible for managing safety and security. Assessors should therefore be mindful that any advice they provide should not be prescriptive and any solution should be 'owned' by the applicant.

Areas of regulatory concern/opportunities for improvement may be identified during an assessment. These may require considerable interaction with the applicant to influence the improvements necessary to address shortfalls in the submission. In some cases it may be necessary for improvements to be in place before a decision can be made. In other cases it may be appropriate for the applicant to develop an action plan to address the issues in an agreed timeframe.

To ensure a balanced assessment, good practices should be identified and highlighted where they present learning opportunities for other applicants/licence holders.

Site visits and meetings may be useful to supplement the written submission and verify that procedures and practices match the claims in the application. They provide an opportunity for assessors to extend their understanding of the managerial, engineering and operational aspects of the facility or activity. A site visit is recommended where there are significant safety or security risks and for unusual or complex facilities or activities. Any verbal information provided during site visits or meetings should subsequently be confirmed by supporting evidence. The outcomes of site visits should be recorded using the appropriate report template.

Details of the assessment are recorded in a regulatory assessment report (RAR); relevant templates for this purpose are available in the ARPANSA Management System (AMS). The RAR provides the basis for any conclusions and recommendations to the decision maker (either the CEO or delegate).

The basis for major licensing decisions made by the CEO with respect to a nuclear installation or other significant facility is documented in a *Statement of Reasons* and published on the website.

After the completion of major applications there should be a review to discuss lessons learned for the future and how the processes can be improved. The results of such reviews should be recorded and documents updated accordingly.

Figure 1 presents a process flowchart and Table 1 provides an overview in terms of inputs, outputs and relationships with other regulatory processes. Both can generally be applied to any submission where a regulatory decision is required.

Licensing decisions are subject to review as per section 86 of the Regulations.

### *Disruptions to regulatory operations*

In the case disruptions affecting functions in society or specifically ARPANSA's ability to deliver in accordance with its functions, ARPANSA's regulatory functions may be significantly hindered or interrupted. A variety of scenarios are possible including those experienced over the 2011-2020 decade, for example the nuclear accident in Japan following the 2011 earthquake and tsunami (which significantly affected ARPANSA staff for a period of several months) and the COVID-19 pandemic (where lockdowns, quarantine, physical distancing and travel restrictions impeded agency activities).

Under such circumstances RSB will be guided by the Business Continuity Plan and the decisions of the CEO and the Business Continuity Group and will consider alternative arrangements to maintain effective regulatory activities.

In the specific case of the pandemic, alternative arrangements include:

- Limiting physical visits to facilities and sources with medium-high radiological risks including reactive inspections or investigations in response to safety and security events
- Carrying out virtual inspections including the use of video facilities for interviews, photographs and videos taken by the licence holder and collecting information electronically for review
- Introducing additional reporting requirements such as self-assessment of compliance with regulations and licence conditions and conducting a desktop review of information submitted by licence holders
- Maintaining regular communication with licence holders during any lockdown period to understand any changes in the risk profile and offer guidance where required.

It is expected that applicants and licence holders will consider disruptions in their risk assessments and develop appropriate management plans.

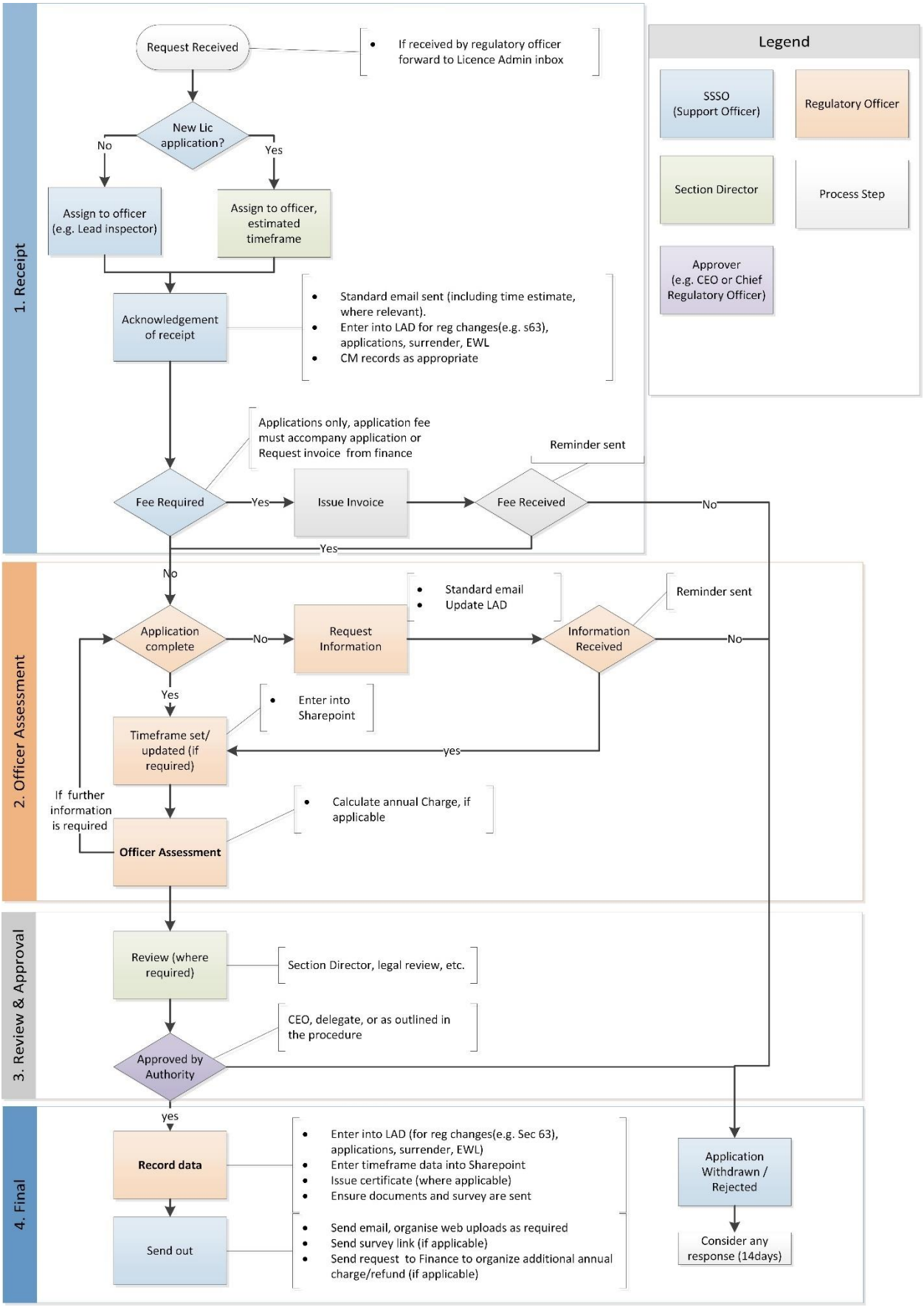


FIGURE 1: PROCESS FLOW CHART

TABLE 1. REVIEW AND ASSESSMENT PROCESS OVERVIEW

| | |
|---|---|
| **Purpose** | **To independently review and assess technical and other information to verify the adequacy of safety and security arrangements & determine whether the proposed conduct or dealing complies with regulatory requirements and meets the object of the Act** |
| **Inputs** | ➢ Legal and regulatory requirements, guidance and regulatory procedures specific to review and assessment<br>➢ Application forms and other documents submitted in support of applications for licence or other approvals<br>➢ Technical and other documents required to assess compliance with the regulatory requirements and the licence (where applicable)<br>➢ Feedback on operating experience<br>➢ Developments in international standards, guidance, research & technology<br>➢ Outputs of other regulatory processes (e.g. inspection outcomes, previous assessments) |
| **Process** | ➢ Identify relevant information from inputs<br>➢ For complex applications establish a review and assessment plan (a project plan under the project management framework when relevant). Identify key issues and tasks, milestones and assigned resources (both internal and external)<br>➢ Request additional information as necessary<br>➢ Conduct review and assessment activities, including site visits, meetings, etc<br>➢ Conduct stakeholder consultation for nuclear installations & other significant applications as required by legislation<br>➢ Collect and integrate conclusions<br>➢ Document the review and assessment<br>➢ Propose licence conditions (where applicable)<br>➢ CEO's statement of reasons (where applicable)<br>➢ Review the process and provide feedback on the process (on complex applications where appropriate) |
| **Outputs** | ➢ Reports and documents covering review and assessment results (i.e. granting or refusing a licence or request for approval), licence[1] with mandatory and additional (where relevant) conditions, areas for improvement (if not already actioned) |
| **Interfaces** | ➢ Compliance reporting<br>➢ Inspection of facilities and sources<br>➢ Enforcement<br>➢ Event reporting<br>➢ Document control<br>➢ Communication and consultation with interested parties<br>➢ Periodic licence review |
| **Performance criteria** | ➢ Review completed with planned resources and within set time frame<br>➢ Successful communication with the applicant or licence holder and other interested parties<br>➢ Constructive feedback from post-assessment survey to contribute to continuous improvement |

[1] After issuing a licence, follow-up of review and assessment results should be conducted through regulatory compliance monitoring activities as per Compliance Manual

# 2. Licence application or amendment[2]

## 2.1 Receiving the application

All applications should be received by LicenceAdmin@arpansa.gov.au. If an officer receives a direct request it should be forwarded to the LA mailbox.

When the application is received in the shared inbox the Regulatory Support Officer (aka Licence Admin Officer or LAO) saves the application in Content Manager (CM) and enters details into the Licence Administration Database (LAD).

For licence applications or amendments the LAO conducts an initial check (using checklist template) to determine whether all sections of the application have been completed and the following information provided:

- details of person submitting the application
- person's signature
- licence nominee details (if applicable)
- contact person's details
- details of radiation safety officer
- description of conduct or dealing

For an application or amendment associated with a specific licence or licence holder, the LAO will usually assign it to the lead inspector. For a new application, the relevant section director will assign it to an appropriate assessor.

If the application contains the required information as per the checklist the LAO will arrange for Finance to issue a debtor invoice.

The LAO acknowledges receipt of the application (using appropriate email template) with copy to the assessor.

## 2.2 Public notice & consultation

Section 48 of the Regulations requires that as soon as practicable after receiving an application for a facility licence the CEO must publish a notice in a daily national newspaper and on the ARPANSA website stating the CEO's intention to make a decision on the application. If the application is for a nuclear installation the notice must invite public comment and provide the procedure for doing so.

The assessor must complete a Notice of intention to make a decision on a facility licence application and indicate the preferred publication date. This is reviewed by the Chief Regulatory Officer (CRO) and sent to the LAO who will arrange for it to be published in the newspaper and on the website. A copy of the notice must be saved in CM.

[2] Under s36 of the Act, the CEO may at any time amend a licence. For example, a licence may be amended to impose additional licence conditions, remove or vary conditions already imposed, or extend or reduce the authority granted by the licence. A decision to amend a licence may be at the request of the licence holder or may be taken by ARPANSA as, for example, enforcement action (refer ARPANSA-SOP-1776 *Compliance Manual*). An application for amendment of a source licence is submitted using the appropriate source licence application form. Applications for amendment of a facility licence are less common and generally take the form of a written request. The assessment of an amendment generally follows a similar process to that for a licence application. Changes with significant implications for safety under section 63 of the Regulations are assessed using a similar process (see section 3) but may not necessarily result in a licence amendment.

## 2.3 Assessing the application

NOTE: The assessor must confirm receipt of the application fee with the LAO or Finance before starting the assessment

### ➢ Agreed assessment time

After confirming payment of the appropriate fee, the assessor should agree a timeframe for completing the assessment with the applicant. This should be done by email and must be recorded in Sharepoint. The level of assessment hence the time taken should be commensurate with the hazard of the source or facility taking into account the adequacy of information in the application for example, the assessment of an application for a low hazard source should not take more than 2 working days, however the assessment of a complex facility application may take in the order of 60 - 90 days or more.

No agreement is required if the assessment is expected to take 5 working days or less and be approved within 2 weeks.

### ➢ Assessment criteria

The assessor reviews the application against the criteria relevant to the particular facility or source. The regulatory guides on applying for a licence set out the information that an applicant is expected to provide in their application; this includes the information and documents specified in sections 46 & 47 of the Regulations and the matters in sections 53 & 54 of the Regulations which now require the applicant to consider interactions between technical, human and organisational factors in the management of safety.

The assessment criteria and expectations must be clearly stated by the assessor (under appropriate headings) followed by a review of the claims, arguments and evidence provided by the applicant. The assessor makes a conclusion about whether the expectations have been met. The assessor considers whether all regulatory requirements have been appropriately addressed and demonstrate that the proposed conduct or dealing can be carried out in a manner that meets the object of the Act. Sound reasoning must be provided for conclusions and recommendations; these should reflect international best practice and be clearly referenced. If professional judgement is used it should be stated as such and fully explained.

Relevant codes and standards are available at https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/licence-conditions.

Links to international best practice can be found at https://www.arpansa.gov.au/regulation-and-licensing/regulation/international-best-practice.

### ➢ Further information & site visits

Where required the assessor will request further information[3] using the appropriate email template.

Additional information may also be obtained by the assessor undertaking one or more meetings or site visits. Site visits allow face to face clarification of issues as well as to acquaint the assessor with the source or facility. Details of site visits should be recorded using the appropriate template and must be recorded in LAD.

[3] The power to request additional information comes from sections 46 & 47 of the Regulations.

This process continues until the assessor is satisfied that the information provided is sufficient to make a recommendation to the CEO/CRO. The level of detail should be commensurate with the nature of the hazards and risks associated with the proposed conduct or dealing. Facilities that are inherently more hazardous and have the potential to pose a greater risk require more detailed information.

A graded approach should also be applied to expectations around the provision of additional information by the licence holder. A reasonable timeframe for providing information relating to low or medium sources is 1-2 weeks; for high hazard sources and basic prescribed radiation facilities (PRFs) a reasonable time is 2-3 weeks; and for complex facilities it may take 4-6 weeks or more depending on the nature of information requested. The timeframe for provision of additional information may be renegotiated as necessary and records updated.

If there is no response to the request for further information after 6 weeks the assessor should confirm whether the licence holder wishes to proceed with the application. If there is still no response after two months the application may be considered withdrawn and the applicant advised accordingly.

### ➢ Expert advice

Where appropriate the assessor should discuss with their director/CRO the need to seek expert advice on any specialised aspects of the application from other sections of ARPANSA or external consultants. In such cases the terms of reference and deadlines should be clearly stated.

For applications involving medical sources or facilities the assessor should liaise with Medical Radiation Services to determine whether there are any special considerations with regard to medical exposure, for example regarding occupational and patient protection. Similarly, if there is a need for expert advice on radioactive waste, dose assessments or environment and public protection issues, the assessor should liaise with Radiation Health Services.

### ➢ Endorsement of security plan

The security plan for a nuclear installation, PRF or security enhanced source must be endorsed by an accredited assessor[4]. The security plan for a nuclear installation, PRF and security enhanced source cannot be endorsed without a site visit unless it has been previously approved and the new application has no impact on the current security arrangements.

### ➢ Public consultation

If the application is for a nuclear installation public consultation must be undertaken. This requires the assessor to liaise with the Office of the CEO to arrange for the required information to be published on the website and to arrange public meetings, media releases, etc. This may be a lengthy process and will need to be factored into the agreed assessment time mentioned above.

In accordance with paragraph 53(h) of the Regulations the CEO must take the content of any public submissions into account when making a decision on whether to issue a licence. The assessor must ensure that the regulatory assessment report (RAR) includes a comments resolution table in which all comments are addressed.

[4] See list of accredited assessors

## 2.4 Documenting the assessment

The assessor records their assessment of the application in a RAR using the appropriate template. The template provides a framework for recording the assessment.

Each RAR must:

- clearly describe the assessment criteria and expectations
- include an analysis of the claims, arguments and evidence provided by the applicant and whether the applicant has met the expectations
- cover all matters that the CEO is required to take into account in making a decision on the issue of a licence as per subsections 32(3) or 33(3) of the Act and sections 53 & 54 of the Regulations
- include a comments resolution table if public consultation has been conducted
- contain a recommendation on whether a licence should be issued
- contain justification for recommending any licence condition in addition to those in the licence template or amending or deleting any condition in the licence template
- be signed by the assessor and a peer reviewer (usually the section director)
- be independently reviewed[5] and signed where ARPANSA is the applicant
- be saved in the licence file in CM

## 2.5 Preparing the licence

If a licence or amendment to a licence is recommended, the assessor should use the latest licence template from the AMS. The amended licence and accompanying letter to the applicant (using appropriate template) are prepared by the assessor.

All details on the licence especially the licence holder's name must match LAD exactly. Where the type of dealing in the application does not match an existing item in Schedule 1 of the licence template, consult the section director and branch quality officer to determine whether an additional item is required.

A licence is subject to all relevant conditions in the Act and Regulations as listed in Schedule 2 of the licence template along with other standard conditions including a link to relevant codes and standards on ARPANSA's website. Any additional special licence conditions are based on circumstances specific to a particular application.

All special licence conditions require legal review to ensure they are lawful and appropriately worded. Special licence conditions are not to be used to overcome deficiencies in the application.

### ➢ Applicable codes and standards

Codes and standards applicable to sources and PRFs as licence conditions are published on the web. The assessor should check that the relevant codes and standards are current.

If a code or standard has been superseded the assessor should advise the Director, Safety Systems to have the necessary amendments made to the website and the change communicated to licence holders.

[5] Independent review should be arranged in consultation with the Chief Regulatory Officer or section director

## 2.6 Review & approval

The RAR, draft licence and covering letter undergo the following reviews prior to final sign-off:

**[1] Peer review** by alternate inspector or other RO

Applications with high risk should be peer reviewed prior to submission to the section director. For other applications, the need for a peer review should be discussed with the director on a case-by-case basis.

**[2] Director review**

The directors of Facility Safety and Source Safety and Security are responsible for the quality of RARs. They should check the following:

- correct template is used
- assessment and recommendations are clearly described
- basis for any special licence conditions including those under subsections 64(2) and 65(5) are clearly described

Directors will determine whether a factual check is required by other expertise in ARPANSA and seek as necessary.

**[3] Quality review**

After the section director clears the draft the assessor seeks a quality review. The reviewing officer will provide advice on the documents to the assessor and section director. Acceptance of advice is at the discretion of the section director.

**[4] Legal review**

Legal review is required when the licence deviates from the approved template eg where a special licence condition is proposed.

**[5] Independent review**

Where ARPANSA is the applicant there must be an independent review of the assessment by a state or territory radiation regulator.

A review & approval workflow should be initiated in Teams taking care to attach all relevant documents.

After all reviews are completed links to the RAR, licence, and covering letter are emailed to the CEO/CRO for approval and sign-off.

## 2.7 Issuing the licence

When approved an electronic copy of the signature of the CEO/CRO is added to the licence and letter.

The approved licence and covering letter are converted to pdf, saved over the Word drafts in CM then emailed to the applicant or licence holder and copied to LicenceAdmin@arpansa.gov.au.

## 2.8 Calculate annual licence charge

The licence charges from the month of licence issue may be pro-rated as per section 70 of the Regulations. Where appropriate the assessor calculates the annual charges taking into account the month in which the licence is issued.

The assessor will advise the LAO of the licence charges and the LAO will arrange for Finance to issue a debtor invoice.

## 2.9 Record keeping

The LAO will:

- save the notification email in the relevant licence file
- close the application file and raise a licence file
- create new licence holder in LAD (if applicable)
- enter relevant information in LAD

## 2.10 Post-assessment survey

A link to the post-assessment survey is included in letter & email templates.

Responses should be periodically analysed to identify opportunities for improvement.

## 2.11 Statement of reasons

The CEO may document the reasons for the decision to issue a licence (using appropriate template). A statement of reasons is prepared and published for all major facilities and any other significant facilities as determined by the CEO.

## 2.12 Post-assessment review

After finalising the assessment of a major application the assessment team should conduct a review of the process to discuss lessons learned and identify changes that may be required to drive continuous improvement. The outcomes of such reviews should be recorded and saved appropriately in CM.

# 3. Request for approval to make certain changes

Applications may be made by a licence holder seeking approval to:

- make a change with significant implications for safety under section 63 of the Regulations
- construct an item important for safety under section 66 of the Regulations
- load nuclear fuel under section 67 of the Regulations

## 3.1 Receiving the application

All requests should be received by LicenceAdmin@arpansa.gov.au. If an officer receives a direct request it must be forwarded to the LA mailbox.

When the application is received in the shared mailbox the LAO:

- saves the application into CM
- enters the required information into LAD
- assigns the application to an assessor (usually the lead inspector)
- acknowledges receipt of the application with a copy to the assessor

## 3.2 Assessing the application

Assessment of a change follows similar processes to that for a licence application in section 2.

### ➢ Agreed assessment time

If no further information is required the assessor should agree a timeframe for completion of the assessment with the applicant. This should be done by email and must be recorded in Sharepoint. No agreement is required if the assessment is expected to take 5 working days or less and be approved within 2 weeks.

### ➢ Assessment criteria

The RAR template provides the framework for recording the assessment. The headings in the template guide the assessor through the assessment criteria. Other criteria may be added as required. The expectations under each criteria must be clearly stated. The assessor should analyse the claims, arguments and evidence provided by the applicant to determine if they meet the expectations. Sound reasoning must be provided for conclusions and recommendations; these should reflect international best practice and should be clearly referenced. If professional judgement is used it should be stated as such and a detailed explanation provided.

### ➢ Further information & site visits

Where required, the assessor requests further information as described in paragraph 2.3.

If there is no response to the request for further information after 6 weeks the assessor should confirm whether the licence holder wishes to proceed with the application. If there is still no response after 2 months the application may be considered withdrawn and the applicant advised accordingly.

### ➢ Expert Advice

Where appropriate, the assessor should seek expert advice on any specialised aspects of the application either from other branches of ARPANSA or an external consultant. For applications involving medical sources or facilities the assessor will liaise with Medical Radiation Services to determine if there are any special considerations with regard to medical exposure and patient protection. Similarly, for advice on

radioactive waste or environment protection issues the assessor should liaise with Radiation Health Services.

Where the change impacts an endorsed security plan, re-endorsement of the plan must be obtained.

## 3.3 Documenting the assessment

The assessor will complete (as appropriate):

- RAR using the appropriate template
- email to the CRO summarising the request and recommended action
- amended licence (if necessary) following the process in section 2

## 3.4 Review & approval

The review and approval process is the same as for a licence application in paragraph 2.6 of this manual, noting that legal review is not required for approvals under section 63 where reissue of the licence is not required.

The section director should check that all conclusions and recommendations are justified.

The CRO will make a decision in accordance with the powers delegated by the CEO. In some circumstances particularly regarding nuclear installations, decisions are made by the CEO. See Delegation relating to Regulatory Functions and Powers for details.

The assessor will advise the applicant about the outcome of the assessment using one of the following templates and with relevant documents attached:

- Section 63 approval no licence amendment
- Section 63 approval with licence amendment
- Section 63 refusal

## 3.5 Record keeping

The assessor must update LAD, record agreed timeframe in Sharepoint and ensure all documents are saved in CM.

## 3.6 Post-assessment survey

The assessor should arrange for the post-assessment survey to be sent (using appropriate email template) if the assessment notification did not include the survey link.

Responses should be periodically analysed to identify opportunities for improvement.

## 3.7 Post-assessment review

After finalising the assessment of a major application the assessment team should conduct a review of the process to discuss lessons learned and identify changes that may be required to drive continuous improvement. The outcomes of such reviews should be recorded and saved appropriately in CM.

# 4. Disposal or transfer

## 4.1 Receiving the application

All requests should be received by LicenceAdmin@arpansa.gov.au. If a RO receives a direct request it should be forwarded to the LA inbox.

The LAO acknowledges receipt of the application (using appropriate email template) then refers the application to an assessing officer (AO). The AO may be a RO or another officer supporting the role.

The AO saves the application in CM; the record number becomes the application number.

## 4.2 Assessing the application

The information required for disposal varies depending on whether it is a controlled apparatus or controlled material. For disposals of apparatus containing controlled material, the assessment should be based on the controlled material.

The AO will:

- check that all the details on the Transfer/Disposal Request Form have been completed
- check the details of the described disposal are appropriate
- confirm with the relevant regulatory authority that any licence number provided belongs to the person/organisation quoted and is relevant for the sources concerned (for transfers outside the Commonwealth)
- assess the request to ensure that the pathway is appropriate and there is minimal hazard to persons or the environment relating to the disposal
- recommend approval (or otherwise) by forwarding the request via email to an appropriately delegated RO with a brief description of the assessment
- save relevant emails in CM with any other relevant information and ensure the request and decision are recorded in LAD

Where necessary, the AO requests further information. The relevant RO should be contacted if the AO is uncertain about any of the requirements.

## 4.3 Review & approval

Only ROs with written delegation[6] from the CEO can approve disposals and transfers.

The delegate will:

- check that the AO has provided an appropriate statement regarding their assessment of the request and taken relevant information into account
- send it back to AO if not satisfied with the assessment or information provided giving suggestions for follow up

[6] Under section 18 of the Act the CEO may only delegate powers to persons at senior executive (SES) or executive level (Senior Regulatory Officer - EL1 or EL2)

- make their decision based on the AO's comments (and licence holder details if necessary) and sign to approve
- emails the signed request to the AO

NOTE: 'Delegate of the CEO of ARPANSA' should be included in the signature block below the officer's name and position.

- set out reasons for declining a request in an email to the AO if applicable

## 4.4 Notifying the applicant

The AO will notify the licence holder that the application has been approved by attaching a pdf copy of the signed request.

If the request is declined the AO will notify the licence holder setting out the reasons why and giving them an opportunity to respond within 14 days. Any response will be forwarded to the delegate who may reconsider the request.

# 5. Extension of sealed source working life

## 5.1 Receiving the application

All requests should be received by LicenceAdmin@arpansa.gov.au. If an officer receives a direct request it should be forwarded to the LA inbox.

The LAO:

- saves the application in CM
- records it in LAD
- assigns it to an assessor (usually the lead inspector)
- acknowledges receipt of the request with copy to the assessor.

## 5.2 Assessing the application

ARPANSA allows continued use of a Group 1 sealed source for one additional recommended working life (RWL) without the need for prior approval subject to the conditions in Wipe testing of sealed sources and use beyond recommended working life:

- Wipe or smear tested at 12-month intervals (6 months for portable density/moisture gauges)
- Results of wipe or smear tests must be recorded and retained with the source records
- If contamination of more than 200 Bq is detected the sealed source is not considered leak tight and must be withdrawn from use[7].
- If contamination is detected that does not exceed 200 Bq then action should be taken to establish whether this is from source leakage. More frequent testing will indicate whether leakage is increasing over time.
- Where access to the sealed source is neither possible nor desirable because of the unjustified exposure of personnel, a wipe or smear test may be carried out on the nearest accessible surface to the sealed source. Under these circumstances, if contamination is detected in excess of 20 Bq[8] the sealed source is not considered to be leak tight and must be immediately withdrawn from use and the nature and extent of the contamination must be investigated.
- Extension must be recorded in source inventory workbook (SIW)

ARPANSA also allows continued use of the following types of Group 2 sealed sources beyond the RWL - up to a period of one additional working life **without the need for prior approval**:

- portable density/moisture gauges containing sealed sources
- fixed radiation gauges containing sealed sources

This extension of RWL is subject to the following conditions:

[7] ISO9978: 1992 Radiation protection – Sealed radioactive sources – Leakage test methods

[8] The specified level of contamination (20 Bq) has been derived on the assumption that there will likely be a loss during transfer of radioactivity from a leaking sealed source to the nearest accessible surface. ARPANSA is aware that this value is consistent with NSW Environment Protection Authority *Radiation Guideline 3 – Recommendations for minimum standards and safety requirements for fixed radiation gauges (sealed source devices)*

- For **portable density/moisture gauges** containing sealed sources - the source, or its housing at a point of closest approach to the source, must be wipe or smear tested at 6 monthly intervals in accordance with Annex F of RPS13. (Note that the relevant code of practice for portable density/moisture gauges, RPS 5[9] does not provide specific guidance on this matter.)

- For **fixed radiation gauges** - the sealed source, or its housing, at or immediately adjacent to the gauge shutter or source control mechanism, must be wipe or smear tested at 12 monthly intervals in accordance with Annex F of RPS13.

- For both types of gauge, all results of wipe or smear tests must be recorded and retained with the source records.

Continued use of other higher hazard sealed sources in Group 2 or 3 beyond one RWL or **any** source beyond a second RWL (whether Group 1, 2 or 3) will be considered on a case-by-case basis, taking into account:

- activity of the source
- toxicity of the radionuclide and its half life
- source construction
- type of dealing
- environment in which the source has been/will be used
- details on source use
- any other inspections or examinations that have been performed (e.g. 6 monthly or annual wipe tests)

A written submission must be made to ARPANSA in such cases.

### ➢ Assessment criteria

Continued use of sealed sources beyond one RWL other than in accordance with the above, or beyond a second RWL will be considered on a case-by-case basis taking into account:

- activity of the source
- toxicity of the radionuclide and its half-life
- source construction
- type of dealing
- environment in which the source has been/will be used
- details of source use
- any other inspections or examinations that have been performed (eg 6 monthly or annual wipe tests)

### ➢ Further information & site visits

Where appropriate, the assessor requests further information using the appropriate email template. Meetings or a site visit may also be considered.

[9] ARPANSA Radiation Protection Series No.5 *Portable Density/Moisture Gauges Containing Radioactive Sources*

- **Expert Advice**

Where the change impacts an endorsed security plan, re-endorsement of the plan may be necessary.

## 5.3 Documenting the assessment

The assessor prepares an email to the CRO with their recommendation.

## 5.4 Approval

The CRO approves an extension of RWL. The assessor sends the approval using the appropriate template.

## 5.5 Record keeping

The lead inspector saves the relevant documents in CM and updates LAD.

# 6. Application for exemption

## 6.1 Receiving the application

All requests should be received by LicenceAdmin@arpansa.gov.au. If an officer receives a direct request it should be forwarded to the LA inbox.

The LAO:

- saves the application into CM
- enters the required information into LAD
- forwards request to the relevant section director who will assign it to an assessor
- acknowledges receipt of the application with a copy to the assessor

## 6.2 Assessing the application

### ➢ Agreed assessment time

If no further information is required the assessor should agree a timeframe for completing the assessment with the applicant. This should be done by email and must be recorded in Sharepoint. No agreement is required where the assessment is expected to take 5 working days or less.

### ➢ Assessment criteria

The assessor will consider each application on its merits to determine whether the required statutory tests have been met. Decisions should be based on international best practice taking into account studies published by scientific and technology-based organisations or other regulatory bodies to substantiate conclusions. The implications of unregulated disposal should also be considered. The required statutory tests are described below.

#### *Apparatus that produces harmful non-ionising radiation*

Under subsection 9(2) of the Regulations the CEO may declare in writing that a particular apparatus producing non-ionising radiation is not a controlled apparatus thereby removing the requirement for a licence.

Under subsection 9(3) the CEO must not declare a non-ionising radiation apparatus exempt unless satisfied that:

*a) the apparatus does not pose an unacceptable potential hazard to the health and safety of people or to the environment; or*

*b) it would be inappropriate for the apparatus to be a controlled apparatus.*

The assessor must be satisfied that the applicant has provided sufficient evidence for the CEO to conclude that the apparatus meets the criteria under paragraph (a) **or** (b) in normal conditions as well as under all reasonably foreseeable abnormal events or conditions.

#### *Prescribed radiation facilities (PRF)*

Under subsection 13(2) of the Regulations the CEO may declare in writing that a facility is not a prescribed radiation facility thereby removing the requirement for licensing of that facility.

The CEO must not declare a PRF exempt unless satisfied that:

a) *the facility does not pose an unacceptable potential hazard to the health and safety of people or to the environment; and*
*b) it would be inappropriate for the facility to be a prescribed radiation facility.*

The assessor must be satisfied that the applicant has provided sufficient evidence for the CEO to conclude that the apparatus meets the criteria under paragraphs (a) **and** (b) in normal conditions as well as under all reasonably foreseeable abnormal events or conditions.

### *One or more conducts in relation to a controlled facility*

Subsection 43(1) gives the CEO the power to exempt any of the conducts mentioned in paragraph 30(1)(a), (b), (c), (d), (e) or (ea) of the Act provided it does not or will not pose an unacceptable potential hazard to the health and safety of people or to the environment.

Applications for an exemption in relation to a controlled facility occur infrequently. The majority of exemptions declared to date have been to decommission a particle accelerator but there have also been exemptions granted to site and construct a particle accelerator – see exemptions log 2020/01080 for details. In all requests for a siting/construction exemption the applicant proposed to replace an existing particle accelerator so no site preparation was necessary and the required structural features/shielding were already in place.

The assessor should consider the claims, arguments and evidence provided by the applicant to decide whether it is reasonable to conclude that the activity will not pose an unacceptable potential hazard to the health and safety of people and the environment. This should be considered under both normal conditions as well as under all reasonably foreseeable abnormal events or conditions. This will usually be in the form of a risk assessment and may include health physics surveys, dose estimates, etc.

Matters to consider for a siting or construction exemption should include whether:

- an existing facility is being replaced and if so whether it is like-for-like replacement
- existing structures and/or safety features such as shielding or interlocks need upgrading

Matters to consider for a decommissioning exemption should include:

- energy of the accelerator to determine the likelihood of activation products within components or shielding material
- potential for contamination
- construction materials (noting that some older accelerators used depleted uranium as shielding)
- how the accelerator has been rendered permanently inoperable
- operational history including any modifications
- plan for decommissioning including dismantling activities, decontamination and disposal, and radioactive waste management considerations as necessary

The assessor's review must provide sufficient evidence to support a recommendation that the CEO approve the exemption.

NOTE: Although section 43 relates to nuclear installations it is hard to contemplate a case where the CEO would approve an exemption relating to such a facility. However, should an application be received, subsection 43(5) of the Regulations requires the CEO to invite people and bodies to make submissions on the proposed exemption. The period for submissions and the procedure for making submissions must be included in the notice of proposed declaration made under subsection 43(4). If comments are received on the proposed declaration, the RO must resolve them using the appropriate comments resolution template.

ARPANSA-GDE-1737 *Regulatory Guide: Seeking an exemption* contains guidance on exemptions for low energy particle accelerators.

#### *Dealing with controlled apparatus or controlled material*

Dealing with controlled apparatus or controlled material prescribed in subsection 44(1) of the Regulations is exempt unless declared otherwise under subsection 44(2) because of the risk of non-trivial dose.

If a controlled apparatus or controlled material is not listed in subsection 44(1) the CEO can exempt it provided he/she is satisfied it meets the criteria of a *low-dose* or *low-risk* dealing in subsections 44(4) & 44(5) of the Regulations.

Under subsection 44(4) the applicant must demonstrate that for the particular dealing:

a) *The annual effective dose to an individual during normal operations is not likely to exceed 10 µSv; or*

b) *An accident, misuse or exceptional circumstance affecting the dealing is not likely to produce a dose greater than the effective dose limits. That is, for occupational exposure - not greater than 20 mSv per year averaged over 5 consecutive calendar years for a person who is at least 18, and not more than 50 mSv in one year; and for the public not greater than 1 mSv annually. The limit on effective dose for occupational exposure of a person who is 16 or 17 is 6 mSv annually.*

The CEO has determined that the more restrictive of these two tests must be met. The assessor must ensure there is sufficient information to satisfy the more restrictive requirements before making a recommendation to the CEO or delegate. *[See R20/05299 for example]*

Any submission for an exemption under paragraph 44(4)(a) should address annual effective doses for:

- normal use
- accident scenarios
- ultimate disposal scenarios
- routine maintenance scenarios
- source repair scenarios

Under subsection 44(5) the Regulations there are certain low risk dealings that the CEO may declare are exempt:

- a radiological emergency or its after-effects
- the after-effects of a previous dealing
- naturally occurring materials
- bulk material with a mass of more than 1000 kg

The applicant must demonstrate that the magnitude of individual doses, the number of people exposed and the likelihood that potential exposure will actually occur justifies the dealing being exempt.

#### ➢ Further information & site visits

Where necessary, the assessor will request further information (using appropriate email template). Meetings or site visits may also be considered.

## 6.3 Documenting the assessment

If satisfied that the applicant has addressed the relevant statutory criteria, the assessor prepares a RAR using one of the following templates setting out the basis for recommending the exemption.

- IR source ARPANSA-TMP-1900
- NIR source ARPANSA-TMP-1730
- Facility ARPANSA-TMP-2083

## 6.4 Preparing public notices

For exemptions relating to **sources** the assessor prepares the relevant declaration:

- Declaration of exemption under s44(4)/44(5)
- Declaration of exemption under s9(2)

For declarations relating to a **facility** under subsection 43(2) of the Regulations the assessor prepares:

- Notice of proposal to make a declaration which the CEO must publish in a daily newspaper circulating nationally and on the ARPANSA website **BEFORE the declaration is published**.
- Declaration of exemption which the CEO must publish on the ARPANSA website as soon as practicable after making the exemption. NOTE: The declaration must **NOT** be published until **at least 7 days AFTER** the proposal.

## 6.5 Review & approval

For **source exemptions** the RAR, declaration and letter to the applicant are subject to the review and approval process described in paragraph 2.6 of this manual.

For **facility exemptions** the RAR, notice of proposal to make a declaration, declaration of exemption, and letter to the applicant are subject to the review and approval process.

## 6.6 Publishing the declaration

For **sources** the assessor should send the approved declaration to the LAO with a request to publish. The LAO will liaise with Comms to have the notice published on the website.

For **facilities** the assessor should:

1. Send the approved **notice of proposal to make a declaration** to the LAO with a request to publish. The LAO will liaise with Comms to have the notice published on the website and in a national newspaper.
2. Send the approved **declaration** to the LAO **at least 7 days after** the proposal notice has been published. The LAO will liaise with Comms to have the notice published on the website and the proposal notice removed.

## 6.7 Notifying the applicant

The notification of an approved exemption should be sent to the applicant via the licence admin mailbox. This will usually be done by the LAO but if unavailable should be done by the assessor and copied to licence admin.

## 6.8 Record keeping

All documentation must be saved in CM and LAD updated accordingly. The assessor should ensure a copy of the declaration is saved in the exemptions log 2020/01080 noting that this is often done by the LAO.

## 6.9 Revocation of exemption

A declaration issued under subsections 9(2), 13(2), 43(2), 44(4), or 44(5) may be revoked by the CEO if the circumstances under which it was issued have changed in such a manner that the controlled person can no longer satisfy the statutory criteria on which it was based.

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**References**


[1] International Atomic Energy Agency, Nuclear Energy Series No. NW-T-2.9 *Decommissioning of Particle Accelerators (*2020)

[2] European Commission, Nuclear Safety and the Environment, *Evaluation of the radiological and economic consequences of decommissioning particle accelerators* EUR19151 (1999)

[3] International Atomic Energy Agency, Technical Report Series No. 414 *Decommissioning of Small Medical, Industrial and Research Facilities* (2003)

# 7. Request to surrender a licence

## 7.1 Receiving a request

All requests should be received by LicenceAdmin@arpansa.gov.au. If an officer receives a direct request it should be forwarded to the LA inbox.

Such requests will be either:

- seeking approval to surrender a licence and release from regulatory control OR
- seeking approval to surrender a licence and reissue of another licence

The LAO:

- saves the application into CM
- enters the required information into LAD
- assigns the application to an assessor (usually the lead inspector)
- acknowledges receipt of the application by sending the standard email template to the applicant with a copy to the lead inspector.

## 7.2 Assessing the application

To assist the CEO decide whether to accept the surrender of a licence, the assessor will assess whether the applicant has provided sufficient evidence that they will no longer undertake activities that require a licence and all resulting waste is being appropriately managed.

### ➢ Assessment criteria

Where the request is to surrender a source licence, the assessor must be satisfied that the applicant will no longer undertake dealings that require a licence noting that sources must be transferred or disposed of in accordance with section 65 of the Regulations.

Where the request is to surrender a decommissioning licence, the assessor must be satisfied that the applicant has demonstrated the following:

a) The remaining structures, systems components and the environment at the location of the facility no longer contain controlled material or the activity concentrations of the remaining material(s) are exempt from regulatory control.

b) The full inventory of non-exempt waste arising from the decommissioning process is accounted for.

c) All non-exempt waste is being appropriately managed.

d) Remaining radioactivity levels associated with the facility (i.e. above natural background) do not pose an ongoing danger.

e) The effective dose to a member of the public at the facility's location is 10 µSv per year or less[10] and justification provided to deviate from this objective.

[10] IAEA Safety Standards – Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards IAEA General Safety Requirements GSR Part 3 – 2014 (Schedule I, Item I.2)

### ➢ Further information & site visits

Where appropriate, the assessor requests further information using the email template provided. Meetings or site visits may also be considered.

Where appropriate, the assessor should seek expert advice (see section 2).

## 7.3 Documenting the assessment

The review of the application should be documented in a RAR using the generic template. If satisfied that the applicant has addressed the guiding principles in Regulatory Guide: Surrender of a licence and release from regulatory control and/or demonstrated that the source inventory has been appropriately disposed of, the assessor will recommend the CEO/CRO consent to the surrender of the licence.

## 7.4 Review & approval

The application is subject to the review and approval process in paragraph 2.6 of this manual.

Only the CEO/CRO may approve the surrender of a licence.

## 7.5 Notification

The assessor will send an email notification to the licence holder consenting to the surrender. The licence holder may also be entitled to a refund of the annual licence charge. This should be confirmed with the relevant section director or CRO and the licence holder advised accordingly. The assessor should contact Finance to arrange for the refund to be processed.

## 7.6 Record keeping

The assessor must update CM and LAD records.

# 8. Transport safety approvals[11]

## 8.1 Receiving an application

All requests should be received by LicenceAdmin@arpansa.gov.au. If an officer receives a direct request it should be forwarded to the LA inbox.

The LAO:

- saves the application into CM
- enters the required information into LAD
- forwards request to the relevant section director who will assign it to an assessor
- acknowledges receipt of the application with a copy to the assessor

## 8.2 Assessing the application

ARPANSA is one of several competent authorities responsible for assessment and approval of applications to transport radioactive material in accordance with the Code for Safe Transport of Radioactive Material, Radiation Protection Series No.C-2 (RPS C-2). This includes approval of low dispersible radioactive material, special form radioactive material, design of packages, validation of packages, shipment of radioactive material, radiation protection program for special use vessel and calculation of basic radionuclides value.

### ➢ Assessment criteria

The assessment should be graded in terms of the available information. For example, the safety analysis report (SAR) is a key requirement for certification of design approval for a package and must be provided. However, for validation of a package, if the SAR is not available in English then a synopsis of the SAR and the regulatory assessment of the competent authority in the country of origin may be acceptable depending on the type of package and the availability of supplementary information.

See AMS for guidance and application checklists.

### ➢ Further information & site visits

Where necessary, the assessor requests further information using the appropriate email template. Meetings or site visits may also be appropriate.

If no further information is required the assessor should agree a timeframe for completing the assessment with the applicant. This should be done by email and must be recorded in the Sharepoint Teams site. No agreement is required if the assessment is expected to take 5 working days or less.

## 8.3 Documenting the assessment

The assessor prepares an assessment report and makes recommendations to the CEO about whether to approve the application. A draft approval certificate is prepared – see AMS for appropriate template.

[11] Does not include endorsement of transport security plans as persons must be accredited for this purpose. Contact Source Safety & Security for further information.

## 8.4 Approval

The CEO must sign all transport approvals as the competent authority. Transport approval is granted for a specific period, for example:

- *Package Design* is generally approved for a period of 5 years with a possibility of recertification, subject to application
- *Special Arrangements* are approved for a nominated period depending on the type of transport activity
- *Validation* of a package is granted for the period specified in the original certificate and subject to the conditions of the original certificate.

## 8.5 Final notification

The assessor sends the approval to the applicant.

## 8.6 Record keeping

The assessor saves all records in CM and updates LAD as necessary.

# 9. Periodic licence review

Licences are reviewed periodically to ensure they remain current. The review should occur at least once every 3 years, when the licence template is updated, or if there is a substantial change to licence conditions or template.

## 9.1 Review

The lead inspector should complete the Licence Review Checklist in conjunction with this procedure.

The following items should be checked as part of the review:

### ➢ Licence template

Check that the licence is in the current format. Licence templates are subject to change as part of continuous improvement within the AMS.

### ➢ Name of licence holder

The name of the licence holder may change over time due to restructure or merger events.

The correct names of Australian Government Departments and Agencies can be found on the Australian Government Online Directory at http://www.directory.gov.au. Details of registered companies may be verified by checking the Australian Securities & Investment Commission internet page at http://www.asic.gov.au.

### ➢ Licence holder primary contact details

The details of the licence holder's primary contact should be checked and updated in LAD as required.

### ➢ Currency of source inventory

Confirm that the SIW on file is current and has been imported into LAD. In cases where an updated SIW has not been received within the last 12 months, a current copy may be requested from the licence holder.

### ➢ Cross check SIW with licence

The SIW should be cross-checked with the authorised dealings in Schedule 1 of the licence. This may involve checking the description of the item to ensure that it matches the classification in the SIW.

### ➢ Currency of special licence conditions

Any special licence conditions should be verified and their validity confirmed. Removal of any special condition must be justified with evidence that the condition has been satisfied.

### ➢ Applicable codes and standards

Confirm the status of all codes and standards relevant to the licence. If a code or standard has been superseded, the RO should advise the Director, Safety Systems to have the necessary amendments made to the website and the change communicated to licence holders.

## 9.2 Documenting the review

The lead inspector should use the checklist to show that they have reviewed the licence file and checked each item. A comment may be placed in the box provided against each item. Where changes are required, other relevant documents should be referenced.

## 9.3 Approval

If any changes are made the lead inspector should follow the relevant parts of the procedure to assess a section 63 change in section 3 of this manual.

Should the requirement to reissue the licence arise as a result of this review the lead inspector should follow the process described in paragraphs 2.5 - 2.7 of this manual and advise the licence holder the reason for reissuing the licence in the accompanying letter.

## 9.4 Record keeping

The lead inspector should:

- save the checklist to the licence file in CM
- update LAD and CM as necessary
- update the CLB if required

## 9.5 Further regulatory action

Should the review identify a need for further action the lead inspector should undertake additional actions in consultation with their director.