|  |  |  |
| --- | --- | --- |
| Complete this form when you can answer ‘Yes’ to the relevant parts of all 3 questions: | YES | NO |
| Q1. | Does the proposed change involve modifying:(a) the controlled facility covered by the facility licence?(b) the controlled apparatus or controlled material covered by the source licence? | [ ] [ ]  | [ ] [ ]  |
| Q2. | Have you completed a risk assessment on the planning and implementation of the proposed change? [AS/NZS IEC 31010:2020: Risk management – Risk assessment techniques](https://www.standards.org.au/standards-catalogue/sa-snz/other/qr-005/as-slash-nzs--iec--31010-colon-2020), [Regulatory Guide - Construction of an item important for safety](https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides/regulatory-guide-construction-item-important) & [IAEA GSR Part 4 Safety Assessment for facilities and activities](https://www.iaea.org/publications/10884/safety-assessment-for-facilities-and-activities) contain relevant information. |[ ] [ ]
| Q3. | Has your assessment shown that the proposed change is significant according to the [Regulatory Guide - When to seek approval to make a change with significant implications for safety](https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides/regulatory-guide-when-seek-approval-make) |[ ]  [ ]  |

REQUEST FOR APPROVAL

FROM THE CEO OF ARPANSA

*To make a change with significant implications for safety*

|  |  |
| --- | --- |
| Licence holder | insert name of licence holder and division or section |
| Licence number | insert licence number |
| Name and position of person making the request | insert name and position of person making the request |
| Contact details of person making the request  | insert contact details |
| Date of request | insert date |

 *Please select an appropriate security classification for this form once completed and adjust the header/footer accordingly.*

**Applicable legislation**

* [*Australian Radiation Protection and Nuclear Safety Act 1998*](https://www.legislation.gov.au/C2004A00383/latest/text) (the Act)
* [Australian Radiation Protection and Nuclear Safety Regulations 2018](https://www.legislation.gov.au/F2018L01694/latest/text) (the Regulations)

# General Expectations

* The information within the submission needs to help the CEO of ARPANSA to decide on whether the implications for safety of your proposed change will be satisfactorily managed.
* The proposed change should be mature, and the submission should be an objective appraisal of the safety of the change.
* The amount of information in your responses should be proportional to the complexity of the change you are proposing, i.e. a change to a major facility will need more detail here than a change to a source licence. If any of the below sections are not relevant or do not need to be considered for this change, explain why in the appropriate section.
* The contents of the submission should follow a ‘claims, arguments, evidence’ structure. Claims and arguments are to be included within the form, while evidence can be referenced out to submitted documents.
* Supporting documentation included within the submission should be clearly referenced within the form.
* If your response references a specific part of a provided document, please reference the specific section/page/paragraph.
* Licence holders can review [*Submission Guide – Section 63 Request for Approval to Make a Change*](https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides/submission-guide-section-63-request-approval-make-change-arpansa-gde-2321) (ARPANSA-GDE-2321) for further information regarding submission content.

# **Part 1: Background Information**

## **What change are you proposing to make?**

* Please provide details on what you are proposing to change. This includes providing context on how things are before the change, and how things are intended to be after the change.
* Where relevant, please provide drawings, instructions, etc. Where drawings contain a proposed change, please highlight or otherwise identify the change.
* Provide information as to why the change has implications for safety.
* Select the primary implication for safety from the drop-down menu below. Explain your selection in your response. If none are relevant, please consult ARPANSA’s [*Regulatory Guide - When to seek approval to make a change with significant implications for safety*](https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides/regulatory-guide-when-seek-approval-make) (ARPANSA-GDE-1751) to ensure your change qualifies as a section 63 change.

Primary implication for safety: Choose an item.

*Enter your response here*

## **Why are you making the change?**

* Please provide details on why you are making the proposed change, so the CEO of ARPANSA can be satisfied that the change has been sufficiently considered.

*Enter your response here*

# Part 2: How will the Proposed Change be Managed?

Please provide information on how the proposed change will be managed and controlled in a safe manner. This part of the form only concerns what is done during the change. Possible aspects to consider are listed below.

* **Radiation Protection**: For example, if a new source will be installed, how will this be done safely?
* **Deviations:** How will unintentional deviations from the plan be managed?
* **Staff Communication:** If you are changing your organisational structure, how will staff know who to report to?
* **Accountability:** Who is accountable for leading the change and how will the organisation make sure this is communicated to those involved?

Answers for this section can be supported by information gathered through safety assessments and technical reports. The length of your answer should be proportional to complexity of the change you are proposing to make.

*Enter your response here*

# Part 3: Effect of Change on Existing Licence Considerations

Please provide details of how the change will affect the criteria listed under sections 53 & 54 of the Regulations:

## Undue risk

* ***Scope:*** *Undue risk is a risk that is unnecessary or excessive. Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm, and that the environment is protected.*
* The submission should demonstrate that the radiation risks arising from the proposed conduct have been considered and managed.
* For example, this may include the probability and magnitude of potential exposures arising from accident scenarios or abnormal occurrences.

*Enter your response here*

## Net benefit

* ***Scope:*** *The submission should show that the proposed activity is warranted by providing a net benefit to individuals or society (in the planned work, the change being made should do more good than harm). That is, the conduct should be justified, considering societal, economic and other relevant factors.*
* Net benefit arguments should weigh up the current state of the controlled activity with the expected state after the change. Arguments should weigh up the benefit of this specific change and not of the controlled activity as a whole, unless this change is absolutely necessary for continuing the controlled activity. If this is the case, explain why in your response. For example, your response can consider the impact if no change is made.
* When activities involving an increase or decrease in radiation exposure or a risk of potential exposure are being considered, the impact this has on potential harm should be explicitly included in the decision-making process.

*Enter your response here*

## Optimisation of protection

* ***Scope:*** *Optimisation refers to the processes for managing the magnitude of individual doses, the number of people exposed, and the likelihood of exposure, being As Low As Reasonably Achievable (ALARA), taking into account economic and societal factors.* The applicant should outline all reasonable efforts that have been made to reduce each of these factors.
* For example, the licence holder should demonstrate that protection will continue to be optimised during and after the proposed change, i.e. radiation risks will be as low as reasonably achievable and there will be an adequate margin of benefit over harm.

*Enter your response here*

## Technical, human & organisational factors

* ***Scope:*** *The submission should acknowledge interactions between people, technology and the organisation in relation to safety.*
* The licence holder should demonstrate that leadership for safety, and management of safety, are integrated into a holistic approach in which the interactions between technical, human, and organisational factors are adequately managed.
* Appropriate use of human factors methodologies and assessments should show that human capability and limitations are being considered in the management of safety. To support the licence holder, ARPANSA’s [*Regulatory Guide - Holistic Safety*](https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides/regulatory-guide-holistic-safety-arpansa-gde) (ARPANSA-GDE-1753) has useful information on the organisational behaviours and attributes.
* Review the [section 63 Submission Guide’s](https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides/submission-guide-section-63-request-approval-make-change-arpansa-gde-2321) section on technical, human, and organisational factors for further detail on these factors and their specific relevance to section 63 changes.

*Enter your response here*

## Capacity to comply

* ***Scope:*** *Capacity to comply refers to the licence holder’s ability and willingness to comply with all legislative requirements under the Act, the Regulations and licence conditions. In making a change, considerations of whether licence holders have the resources, organisational support, and willingness to comply are of relevance.*
* The licence holder should demonstrate that the proposed change will not affect their capacity or willingness to comply with the Act, the Regulations and licence conditions.
* Any self-assessment by licence holders regarding compliance history, etc. should be brief and objective.

*Enter your response here*

## International Best Practice

* ***Scope:*** *This submission should demonstrate that all aspects of the change are in line with current best practice, as evidenced by international standards, collaboration or precedent.*
* The licence holder should demonstrate that international best practice has been considered in relation to the proposed change (e.g. compliance with international codes and/or standards).
* If there are aspects of the change which do not require the consideration of international best practice, explain why not.
* Citing instances where identical or similar work has been conducted internationally would be appropriate for this section.
* Highlighting where respected international counterparts have developed or collaborated on aspects of the change would be appropriate for this section.

*Enter your response here*

# Part 4 Ongoing Management of Safety and Security

* All information provided in this part of the form should detail the impacts of this change upon ongoing safety and security maintenance. Full plans (e.g. safety management plans) need not be provided, and instead only the aspects of these plans which are changed as a result of the change being proposed need to be provided.
* There may be no change to ongoing safety and security maintenance for some of the below headings. In this case, provide a brief justification to explain why this aspect will not be impacted by the change being proposed.
* Where the proposed change will impact matters under the below headings, please provide sufficient detail of how you will maintain effective control and how the change will impact plans (including details of whether any changes made within the plan are temporary or permanent).
* Describe impacts to safety and security maintenance during and after the proposed change, and specify which relate to during the change and which relate to after the change.
* Please consider and detail what physical changes to structures, systems and components, as well as the work environment, will be needed during and after the proposed change. Systems can be organisational as well as physical.
* For example, if a new source is to be installed, how will it be managed and controlled so that its ongoing safety is assured?
* Licence holders may wish to consult the [*Regulatory Guide - Plans and Arrangements for Managing Safety*](https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides#plans-and-arrangements-for-managing-safety) (ARPANSA-GDE-1735) for best practice principles for managing sources and facilities under the headings below.

## **Effective control**

*Enter your response here*

## **Safety management plan**

*Enter your response here*

## **Radiation protection plan**

*Enter your response here*

## **Radioactive waste management plan**

*Enter your response here*

## **Plan for:**

* 1. Ultimate disposal or transfer (source licences)
	2. Decommissioning plan (facility licences)

*Enter your response here*

## **Security plan**

*Enter your response here*

## **Emergency plan**

*Enter your response here*

## **Environment protection plan**

*Enter your response here*

## **Safety analysis report (facility licences only)**

*Enter your response here*

## Document History

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Version** | **Issue Date** | **Prepared/Reviewed by** | **Approved by** | **Amendment Details** |
| 1 | Oct 2012 | D Harrison | R Evans | Original issue |
| 2 | Dec 2014 | J LockA McCormickS Sarkar | J Scott | Revision of format, font, layout, fields removed, checkboxes and initial questions added *[Reviewed Oct 2016 – no change]* |
| 2.1 | Jun 2017 | M Partridge | N/A | Rebranding |
| 2.2 | Nov 2018 | C Nickel | N/A | Rebranding in correct template |
| 2.3 | Dec 2018 | D Harrison | N/A | Updated to align with new Regulations |
| 2.4 | May 2020 | D Harrison | N/A | Moved to IMS – changed doc ID from REG-RC-FORM-250F |
| 2.5 | Feb 2021 | D Harrison | N/A | Updated references in Q2; slight change to wording in Q1; added Environment protection plan  |
| 2.6 | Sep 2021 | D Harrison | N/A | Added expectations for the ‘matters’ in Part 5 |
| 2.7 | May 2023 | D Harrison | N/A | Added HOF to matters in Part 5 as per Regulations |
| 2.8 | Mar 2025 | L Whittle J Ward | J Scott | Periodic review |