REGULATORY GUIDE

Reporting compliance

REGULATORY SERVICES
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Introduction

Paragraph 7(d)(i) of the Australian Radiation Protection and Nuclear Safety Regulations 2018 requires the CEO to publish guidelines on how licence holders will report their compliance with the Australian Radiation Protection and Nuclear Safety Act 1998 (the Act), the Regulations and licence conditions. This document fulfils that requirement and provides information on when, how and what licence holders must report.

ARPANSA applies a graded approach to compliance reporting. The frequency of reporting is aligned with the regulatory priority of the source or facility. The regulatory priority is risk-based.

➢ When to report

Licence holders are required to report either quarterly, biannually or annually depending on the regulatory priority.

For licence holders who are required to report quarterly, a report must be provided to the CEO of ARPANSA in an approved form within 28 days of the end of each quarter that is, by 28 January, April, July and October, or within such other period as determined by the CEO.

For licence holders who are required to report annually, a report must be provided to the CEO in an approved form within 28 days of the end of the financial year, that is, by 28 July each year, or within such other period as determined by the CEO.

For licence holders who are required to report every six months, a report must be provided to the CEO by 28 January and 28 July each year, or within such other period as determined by the CEO.

An email reminder is sent to licence holders two weeks prior to the end of the reporting period.

➢ How to report

Licence holders must use the appropriate template unless there are other agreed arrangements in place.

- Quarterly Report Template
- Biannual Report Template
- Annual Report Template

Reports must be sent by the licence holder’s Radiation Safety Officer, or other person authorised to provide such information on behalf of the licence holder. Reports should be sent to licenceadmin@arpansa.gov.au with a copy to the licence holder/nominee. Receipt of the report will be acknowledged by ARPANSA.

➢ What to report

The licence holder should address all matters in the report template. Guidance on the information required is provided below.

1. Accidents (section 58 of the Regulations)

The licence holder should provide a summary of any accident that occurred during the reporting period.

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1 The report templates are designed for electronic use; the printed version may not display all data
Under section 58 of the Regulations, the licence holder must tell the CEO about an accident within 24 hours of it happening and give the CEO a written report about the accident within 14 days of it happening.

Guidance on what constitutes an accident for the purposes of section 58 is provided in Regulatory Guide: Reporting an Accident.

2. Other occurrences

Except as otherwise required by a special licence condition, the licence holder should report any other occurrence during the reporting period that had the potential to affect safety but which was not an accident under section 58 of the Regulations.

For example:
- Loss of a Group 1 sealed source
- Minor contamination of laboratory clothing or work area
- Breach of operating limits and conditions
- Deliberate exposure of a personal monitoring device
- Incorrect settings on a safety system
- Sticking shutter mechanism on a radiation gauge
- Laser incident where there is the potential for injury

3. Personal monitoring (Dose limits in sections 77 – 79 of the Regulations)

Division 5.2 of the regulations sets out the practices to be followed by licence holders with respect to dose limits. Any dose received by an individual that exceeds the dose limits is regarded as an accident and must be reported under section 58. Other unusually high doses that required investigation or corrective action should be reported.

4. Acquisition of a source

The licence holder should provide a summary of sources acquired during the reporting period. Import permit numbers should be quoted where relevant.

When changes to the source inventory are reported, ARPANSA will provide the latest version of the SIW (exported from the Licence Administration Database) to be updated by the licence holder and returned.

Before acquiring a source the licence holder should consider which of the following regulatory actions is required:
- New licence application
- Prior approval under section 63 of the Regulations
- Reporting a change to the source inventory under section 64 of the Regulations

For further guidance on the regulatory implications of making changes to the source inventory including acquiring, using, transferring or disposing of sources, see Appendix A.

5. Disposal of a source (section 65 of the Regulations)

The licence holder should provide a summary of any disposals made during the reporting period.
Disposal of sources can only occur with the prior approval of the CEO. Licence holders should refer to the [Regulatory Guide: Disposal of controlled apparatus and controlled material](https://example.com).

Licence holders seeking approval from the CEO for the disposal of a source should use the [Disposal Request Form](https://example.com). Completed forms should be sent to licenceadmin@arpansa.gov.au.

Under subsection 65(5) of the Regulations the licence may make other arrangements with regard to disposal such as where regular source transactions are part of routine operation and seeking prior approval for every disposal would be impractical. An example of such an arrangement is where there is regular disposal of controlled material or controlled apparatus. Any alternative reporting arrangements will be specified in the licence.

Disposal of a controlled facility requires prior approval from the CEO of ARPANSA under subsection 65(4).

For further guidance on the regulatory implications of making changes to the source inventory including acquiring, using, transferring or disposing of sources, see [Appendix A](https://example.com).

### 6. Transfer of a source (section 65 of the Regulations)

The licence holder should provide a summary of any source transfers made during the reporting period.

Transfer provisions also apply to infrequent sales, hires, loans, gifts, or donations within Commonwealth jurisdiction. Licence holders should notify the CEO about the transfer of a source using the [Transfer Notice Form](https://example.com). Completed forms should be sent to licenceadmin@arpansa.gov.au.

Transfers under subsection 65(3) must generally be reported within 7 days unless the source is in security category 1, 2 or 3. In such cases, the CEO of ARPANSA must approve the transfer regardless of the jurisdiction to which it is being transferred.

Under subsection 65(5) of the Regulations the licence may make other arrangements with regard to source transfers such as where regular source transactions are part of routine operation and seeking prior approval for every transfer would be impractical. An example of such an arrangement is where there are regular sales of controlled material or controlled apparatus. Any alternative reporting arrangements will be specified in the licence.

Transfer of a controlled facility requires prior approval from the CEO under subsection 65(4) of the Regulations.

For further guidance on the regulatory implications of making changes to the source inventory including acquiring, using, transferring or disposing of sources, see [Appendix A](https://example.com).

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2 Refer to [Radiation Protection Series No. 11 - Code of Practice for the Security of Radioactive Sources](https://example.com) which is a statutory licence condition under section 59 of the Regulations.
7. **Corrective action arising from an inspection**

The licence holder should report progress on any corrective actions arising from an inspection in accordance with any reporting requirements specified in the inspection report or covering letter.

8. **Changes with significant implications for safety (section 63 of the Regulations)**

The licence holder should provide a summary of any approvals sought and received under section 63 during the reporting period.

For guidance on how to categorise a change, licence holders should refer to Regulatory Guide: How to determine when a change has significant implications for safety.

9. **Changes unlikely to have significant implications for safety (section 64 of the Regulations)**

Under section 64, licence holders must report any change that is unlikely to have significant implications for safety at least once every three months. Licence holders reporting quarterly will include this information in their quarterly report. However, licence holders reporting biannually or annually must inform ARPANSA of the change within three months.

10. **Review of plans and arrangements (section 61 of the Regulations)**

Licence holders are required to review their plans and arrangements at least once every three years and keep and maintain records of the review.

When conducting the review, licence holders should refer to the Regulatory Guide: Plans and Arrangements for Managing Safety.

11. **Compliance with special licence conditions**

The licence holder should report progress against any special licence condition. Any such conditions will be removed when compliance has been adequately demonstrated.

12. **Breaches of licence conditions (section 57 of the Regulations)**

ARPANSA encourages licence holders to find and fix their own non-compliances. Such behaviour reflects a healthy and robust safety culture. Whenever a potential breach is encountered, the licence holder has a responsibility under section 57 to investigate and rectify the breach including any consequences of the breach as soon as reasonably practicable.

The licence holder must tell the CEO as soon as reasonably practicable if a breach of a licence condition is identified. The quarterly/biannual/annual report must also include a summary of any breach reported during the reporting period.

Common breaches relate to:

Section 60: A licence holder not taking all reasonably practicable steps to comply with their plans and arrangements.
Section 61: A licence holder not reviewing and updating plans and arrangements at least once every three years/not keeping records of the review.

Section 63: A licence holder not seeking the CEO’s prior approval to make certain changes that have significant implications for safety.

Section 65: A licence holder not seeking prior approval from the CEO or telling the CEO about movement of a source or facility in particular failure to obtain prior approval before disposing of a source.

In many cases, the licence holder will be expected to perform a cause analysis to fully investigate the non-compliance. An investigation that involves a root cause analysis (to prevent recurrence) may take considerable time.
Appendix A: Regulatory implications of changes to the source inventory

Under section 62 of the Regulations the licence holder must keep an accurate inventory of sources its deals with. The approved form for maintaining this information is the Source Inventory Workbook (SIW). The licence holder must consider the regulatory implications of making any change to the source inventory after the licence is issued.

Licence holders intending to acquire, relocate, transfer, dispose of, or modify a source or facility should refer to sections 63-65 of the Regulations and licence conditions to identify what regulatory action is required. It is particularly important to identify whether a proposed change requires the prior approval of the CEO of ARPANSA or in some cases, whether a new application for licence is necessary.

Licence holders should also refer to Regulatory Guide: When to seek approval to make a change with significant implications for safety to determine whether a proposed change requires prior approval.

A1. Adding to the source inventory

If the licence holder intends to acquire a kind of source that is not authorised by the existing licence (or any other source licence that the licence holder might have) then a new application must be submitted with the appropriate fee and the licence must be amended and re-issued by ARPANSA before taking possession of the source. Failure to do so may result in a breach of sub-section 31(1) of the Act.

Acquiring additional sources of a kind that is already authorised by the licence does not require prior approval but this is a change for the purpose of section 64 and should be reported within three months or in the next quarterly report.

Occasionally licence holders discover sources in their possession that are not listed in their SIW. These are often ‘legacy’ radioactive sources or sometimes non-ionising apparatus such as Class 3B lasers or UV sources.

If a kind of source not covered by the licence is identified it may be necessary for the licence holder to apply for an authorisation to continue to possess, have control of, or use it. Advice should be sought from ARPANSA if there is any doubt about the status of a newly identified source.

A2. Removing a source from the SIW

Under section 63 of the Regulations a licence holder must have prior approval from the CEO of ARPANSA to:

(i) dispose of a controlled apparatus or controlled material (source)
(ii) transfer a source to another jurisdiction (outside of the Commonwealth)

Transfers under subsection 65(3) must generally be reported within 7 days unless the source is in security category 1, 2 or 3 in which case the transfer must have the prior approval of the CEO of ARPANSA. This requirement comes from the Radiation Protection Series No. 11 - Code of Practice for the Security of Radioactive Sources which is a statutory licence condition under section 59 of the Regulations. Failure to comply with sections 59 or 65 of the Regulations may result in the licence holder being found in breach of sub-section 31(2) of the Act.

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3 Refer to Licence holders with multiple divisions and/or multiple sites
4 The definition of a ‘change’ for the purposes of sections 63 & 64 is a change to (a) the details described in the application for the licence; or (b) a modification of the source or facility
5 Disposal of controlled apparatus for the purpose of subsection 65(1) includes destruction
Following transfer or disposal of a source, its **status should be changed** in the SIW accordingly. The SIW is submitted to ARPANSA and uploaded into the LAD. The source will no longer appear in the next SIW generated by LAD.

When an item no longer meets the definition of a controlled apparatus or controlled material the licence holder should change its status in the SIW and provide further details where relevant, for example: the source has decayed below the exemption limit or changes to the apparatus mean that it no longer meets the definition of a controlled apparatus. The source will no longer appear in the next SIW generated by LAD.

**A3. Licence holders with multiple divisions and/or multiple sites**

Some licence holders have a number of divisions at one location or occupy premises spread over multiple sites. Each division may have a separate source licence and separate source inventory. The licence holder may also have one or more facility licences.

If a licence holder wants to undertake a new dealing in a particular division, the licence holder must determine whether section 63 applies or whether a new application is required. If the new dealing is not authorised by any existing source licence held by that organisation then a licence application is required. If the new dealing is authorised by an existing source licence, held elsewhere in the organisation, then section 63 applies.

If a licence holder wants to relocate a source from one division to another, from one site to another, or from one licence to another, the licence holder must determine whether a licence application is required or whether section 63 or 64 of the Regulations applies.

- **a) Relocation of a source within the same division at the same site**
  
  Section 64 applies; the licence holder must report the change to the source inventory within three months or in the next quarterly report.

- **b) Relocation of a source within the same division but at a different site**
  
  Section 64 applies if the source is to be used for the same purpose at the new site, otherwise section 63 applies.

- **c) Relocation of a source to a different division at the same site**
  
  Section 64 applies if the division receiving the source is authorised for the dealing, and provided there are no implications for safety, otherwise section 63 applies (see Scenario 3). Note that subsection 65(3) also applies as the transfer of a source from one licence to another must be reported to ARPANSA within 7 days, except for security-enhanced sources that require prior approval.

- **d) Relocation of a source to a different division at a different site**
  
  As for (c) above

- **e) Transfer of a source from a facility licence to a source licence**
  
  A licence application is required unless the dealing is authorised by an existing source licence. If authorised, then section 64 applies. Section 65(3) also applies - see (c) above.

- **f) Transfer of a source from a source licence to a facility licence**
  
  If the facility licence already authorises dealing with this kind of source then section 64 applies. If not, then section 63 applies and the CEO must approve the transfer. Note that dealing with the source must be included in the safety assessment report for the facility.

Further guidance is provided in the scenarios and examples below. If there is any uncertainty about the regulatory implications of a proposed change to the source inventory, please contact ARPANSA.
Scenario 1: A licence holder wants to acquire a source for a dealing that is already authorised by the licence

In this situation a licence application is not required and the existing licence does not need to be amended. This is because the licence holder’s plans and arrangements for managing that type of source have already been assessed as satisfactory for the particular dealing. The change is regarded as unlikely to have significant implications for safety and therefore subject to section 64 of the Regulations.

Example 1: A licence holder is authorised to deal with a fully enclosed x-ray analysis unit (Group 1 Item 13). The licence holder wants to acquire another fully enclosed x-ray analysis unit.

No amendment to the licence is necessary. Section 64 applies: acquisition of the source must be reported within three months. For most licence holders this will be in the next quarterly report. The licence holder will be requested to updated their SIW accordingly.

Scenario 2: A licence holder wants to acquire a source for a purpose not authorised by the licence

In most cases, a licence application will be required.

Example 2: A licence holder is authorised to deal with a fully enclosed x-ray analysis unit (Group 1 Item 13). The licence holder wants to acquire a partially enclosed x-ray analysis unit (Group 2 Item 11).

The licence holder must apply for a licence amendment to add Group 2 Item 11 before the apparatus is acquired.

Scenario 3: A licence holder wants to relocate source from the location specified in the source inventory

This is a proposed change to details provided in the licence application (or subsequently approved) and therefore a change relevant to either section 63 or 64. The licence holder must decide which applies, that is, whether the relocation is likely to have significant implications for safety.

Prior to moving a source, the licence holder must consider such things as shielding, storage, security, and transport. If there are significant implications for safety in the process of relocation or at the new location, then prior approval is required under section 63. If there are unlikely to be any significant implications for safety, prior approval is not required but relocation of the source must be reported under section 64 within three months or in the next quarterly report.

Example 3: A fixed industrial x-ray unit located in Building A is to be relocated to Building B

This may have a significant effect on safety in terms of protective shielding, interlocks, warning lights, etc. Such a change would require the prior approval of the CEO under section 63.

Example 4: The source inventory shows an unsealed source is being used in Laboratory C

If the licence holder relocates this source to Laboratory D with the same policies and procedures and with equivalent or better storage and handling, then the change is unlikely to have significant implications for safety. Such a change would fall under section 64 with no prior approval required. The change or location should be reported within three months or in the next quarterly report. The SIW will also need to be updated.
Scenario 4: A licence holder wishes to deal with a source that belongs to another organisation

There are certain situations where a licence holder may wish to use a source owned by another organisation. For example, a source may be leased, hired or borrowed or a controlled person may be required to use another organisation’s source at that organisation’s premises.

Under the Act, dealing includes possession or having control of. Therefore use of a source belonging to another organisation may only be undertaken if authorised by a source licence. In such circumstances the licence holder must consider whether the existing authorisation covers the proposed activity or whether an amendment to the licence or further licence application is required.

Example 5: Licence holder (Y) wants to lend a sealed source to another Commonwealth licence holder (Z) for a particular project

Licence holder Z must be authorised for the proposed dealing. The transfer of possession is covered by paragraph 65(2)(b) of the Regulations and must be reported to the CEO within seven days. In this case, the source inventory of licence holder Y should be amended to indicate that the source is temporarily on loan. The source inventory of licence holder Z should also be amended to include the source until it is returned. In any case the temporary transfer should also be reported in accordance with section 64. Similarly, the return of the source should also be reported and the SIW amended as appropriate.

Note: Changes to the SIW are only relevant if the loan is for an extended period, ie more than 3 months. Short-term loans should still be reported in the compliance report to ARPANSA.

Example 6: A source licence authorises the licence holder to deal with baggage x-ray unit. The licence holder leases an additional baggage x-ray unit from an equipment supplier

The licence holder must report the additional source within three months or in the next quarterly report. Eventual return of the sources to an organisation outside the Commonwealth’s jurisdiction requires prior approval.

Example 7: A source licence authorises dealings with a fully enclosed analytical x-ray unit. In a collaborative venture with a university, it is proposed that a controlled person covered under the source licence will use a fully enclosed analytical x-ray unit owned by the university at the university’s premises.

This dealing is authorised under the source licence. The CEO should be advised of this dealing under section 64. The conditions attached to the licence with respect to this kind of controlled apparatus are still applicable. Where direct compliance with these conditions is outside the control of the licence holder (as in the case of equipment maintenance) it is the responsibility of the licence holder to be satisfied that the conditions have been met and to provide supporting evidence to ARPANSA if required. For example, the licence holder may be required to provide ARPANSA with the licensing or registration information from the relevant State/Territory regulatory authority.