



Australian Government  
Australian Radiation Protection  
and Nuclear Safety Agency



## REGULATORY SERVICES

# COMPLIANCE MANUAL

*Guide for regulatory officers on promoting compliance, managing breaches  
& applying a graded approach to enforcement*

ARPANSA-GDE-1117 v7

January 2023

## Introduction

ARPANSA's [Regulatory Activities Policy \(ARPANSA-POL-0002\)](#) provides the over-arching framework for efficient and effective regulatory activities for the purpose of achieving the object of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act) *to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation.*

The regulatory oversight of controlled persons (in this Manual mainly referred to as *licence holders*) provides ARPANSA with the mechanisms to promote, verify and – as necessary – enforce compliance with the Act, with the Australian Radiation Protection and Nuclear Safety Regulations 2018 (the Regulations), and with licence conditions.

Promotion of compliance involves provision of advice, guidance and identification of areas for improvement (AFI)<sup>1</sup>. ARPANSA may through its regulatory oversight, licence holders' self-reporting, or information from third parties become aware of circumstances that *prima facie* constitute non-compliance with the Act, Regulations or licence conditions. A **non-compliance** will be subject to proper review and assessment while providing the licence holder procedural fairness and an opportunity to submit information and evidence that ARPANSA will take into consideration in the final determination. If a non-compliance is confirmed, the licence holder is found in **breach** of the Act.

A range of regulatory intervention tools are available if it is reasonable to believe or it has been determined that the licence holder has or is likely to contravene the Act, Regulations or licence conditions. These include requests for corrective action, licence decisions and enforcement actions.

Regulatory interventions are made in accordance with a graded approach<sup>2</sup> that take into account the particular circumstances including but not limited to the severity of the breach; impact on health and safety of workers, the public and the environment; mitigating circumstances; and impact of regulatory intervention on third parties. Regulatory interventions must be effective in achieving the desired change in safety and security performance of licence holders. The aim is to ensure that the licence holder returns to compliance and as relevant and required to stop, prevent or deter practices and behaviour that lead to or may lead to undue risk to people or to the environment from the harmful effects of radiation. Regulatory interventions do not remove the licence holder's primary responsibility for safety.

This Manual provides guidance to regulatory officers (RO) about promoting compliance and managing non-compliance. It should be read in conjunction with the aforementioned Regulatory Activities Policy. By making the Manual available on ARPANSA's website, licence holders and interested parties are informed of ARPANSA's approach to compliance. Process descriptions, flow-charts, templates, etc. that form part of ARPANSA's Integrated Management System are not included in the online version of this Manual.

ARPANSA's program for regulatory oversight of the safety and security performance of its licence holders is described in the [Inspection Manual](#) while the [Review & Assessment Manual](#) describes the processes for review and assessment of applications.

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<sup>1</sup> An AFI means an identified opportunity to improve performance to achieve best practice rather than minimal compliance. It is distinct from a non-compliance with the Act, the Regulations or a licence condition.

<sup>2</sup> Graded Approach: For a system of control such as a regulatory system or a safety system means a process or method in which the stringency of the control measures and conditions to be applied is commensurate to the extent practicable with the likelihood and possible consequences of and the level associated with a loss of control.

## In this manual:

1. [Graded approach to promoting & enforcing compliance](#)
2. [Managing non-compliance & breaches](#)
3. [Managing compliance reports](#)
4. [Event notification & management](#)
5. [Issuing an improvement notice](#)
6. [Monitoring personal dosimetry reports](#)

## Management system elements not included in the web version of this manual:

[Appendix A: Dealing with a high dose notification](#)

[Appendix B: Reviewing dose reports](#)

[Appendix C: Event management process](#)

[Appendix D: Convention for citing legislation](#)

[Appendix E: Review and approval of regulatory matters](#)

[Appendix F: Process for publishing licence holder performance](#)

[Attachment 1: Email templates](#)

[Attachment 2: Letter templates](#)

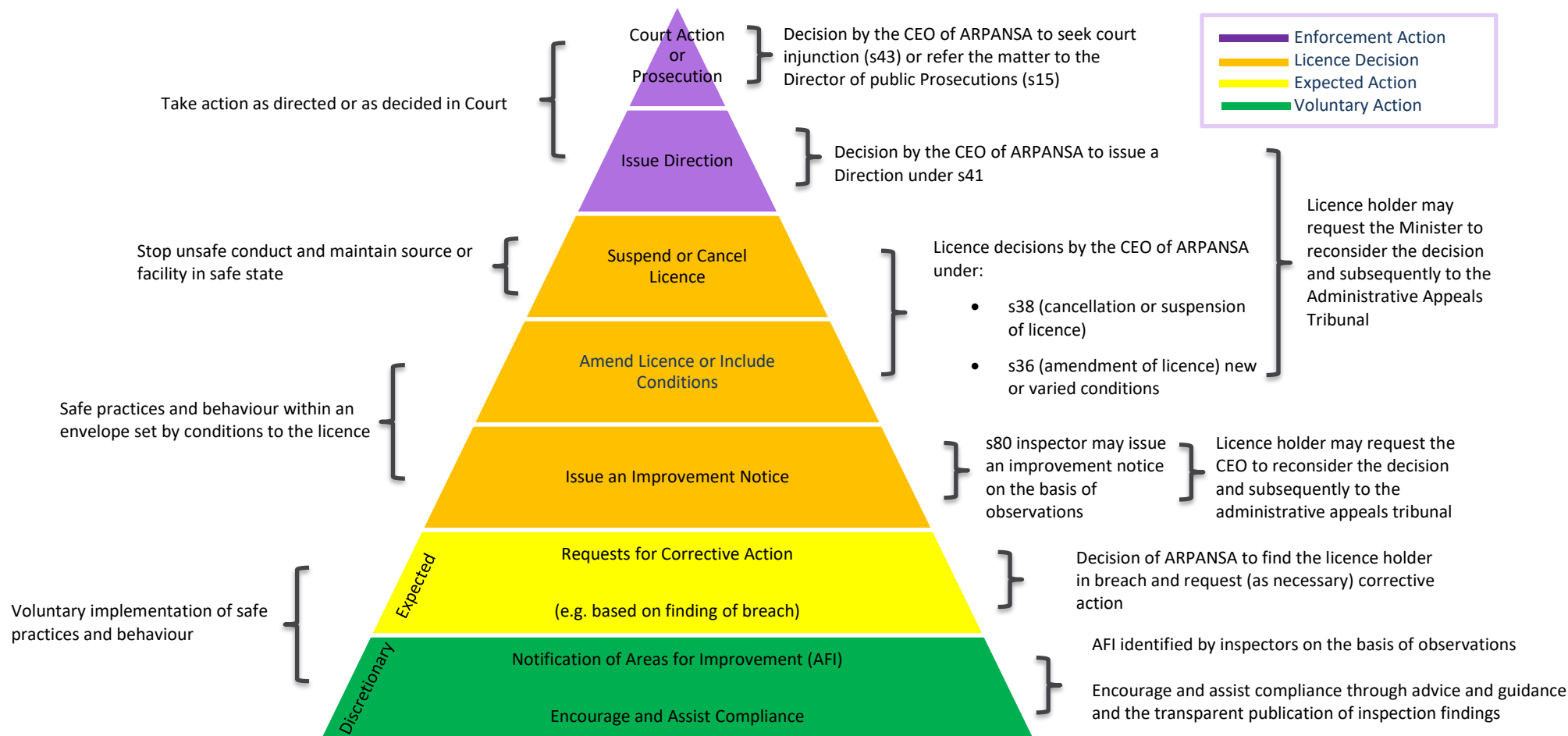
[Attachment 3: Improvement notice template](#)

[Attachment 4: Incident management checklist](#)

[Attachment 5: Sample media statement](#)

## Main changes from the previous version of this manual:

- Improvements to the process for publishing licence holder performance in para 2.5 including a verification step



**FIGURE 1. ARPANSA's graded approach to promoting and enforcing compliance**

# 1. Graded approach to promoting and enforcing compliance

Figure 1 outlines ARPANSA's graded approach to the promotion and enforcement of compliance. There are four general types of interventions:

- **Advice** which includes various actions, formal and informal, to provide advice, information and feedback such as areas for improvement
- **Requests for corrective action** which can ask the licence holder to rectify a breach unless already addressed
- **Licence decisions** which include improvement notices, amendments to the licence and suspension/cancellation of the licence
- **Enforcement** which includes directions and court action

Regulatory interventions should commence at the most appropriate level depending on criteria summarised in section 2. They can be escalated if the initial response does not result in the desired outcome. The different regulatory interventions that may be considered are outlined in detail below.

## 1.1 Advice and requests for corrective action

ARPANSA publishes national codes, standards and guides that make reference to international best practice. ARPANSA aims to promote licence holder compliance to the extent possible; regulatory guides are published to assist this purpose.

ARPANSA engages with licence holders by hosting information sessions such as the annual *Licence Holder Forum* and *Meet the Regulator Forums*; inspectors conduct *site visits* and other meetings to discuss regulatory matters.

ARPANSA also assists compliance through engagement and communication with licence holders to address day-to-day enquiries, noting that none of this advice under any circumstance relieves the licence holder of their responsibility for safety and security.

Areas for improvement (AFI) may be identified during an inspection or assessment that could lead to non-compliance<sup>3</sup> if action is not taken. This pro-active tool helps licence holders avoid breaches.

A finding of breach may result in the CEO (or delegate) requesting corrective action and evidence that such action has been taken. In some cases ARPANSA may accept a written commitment from the licence holder to implement improvements or to take action to rectify or prevent further occurrences within a defined timeframe. Failure to do so will potentially lead to escalated regulatory intervention in accordance with Figure 1.

As a transparency measure to promote compliance and to share lessons learned, ARPANSA publishes inspection reports, good practices, improvement notices and breaches (including their closure) on the website. Breaches are graded on whether or not there are significant implications for safety or security. Security breaches will not be published until the vulnerability has been addressed and in some cases may not be published at all.

Another way ARPANSA shares information and promotes compliance is through the annual reports of the *Australian Radiation Incidents Register*.

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<sup>3</sup> A non-compliance is where the inspector believes the licence holder has failed to comply with a requirement of the Act, Regulations or the licence however only the CEO can determine if it is a breach. Such finding will only be made after considering all the facts and giving the licence holder the opportunity to respond to the alleged non-compliance.

## 1.2 Licence decisions

### ➤ *Improvement notice (see also Section 5)*

Under section 80A of the Act an inspector may issue an improvement notice if the inspector believes that the licence holder is acting or is likely to act in contravention of the Act, Regulations or licence conditions.

The improvement notice **may** require the licence holder to:

- remedy the non-compliance
- prevent a likely non-compliance from occurring
- remedy matters or activities contributing to non-compliance
- cease an activity causing non-compliance

An improvement notice **may** also be issued when:

- resolution at a lower level (Figure 1) has failed to result in a return to compliance
- there is multiple or recurrent non-compliance of the same nature
- the licence holder refuses to take action in response to identified AFI that is considered likely to lead to non-compliance

Under section 80C of the Act a licence holder who has been issued an improvement notice may seek a review of the decision.

### ➤ *Amendment of licence*

Under section 36 of the Act the CEO may impose additional licence conditions, remove or vary licence conditions, or extend or reduce the authority granted by the licence. Depending on the nature of the non-compliance, the regulatory officer (RO) may recommend that the CEO amend the licence to facilitate compliance or address any new risks that have been identified.

#### **Example:**

*If the situation warrants it, a condition may be imposed on a licence holder to conduct a self-assessment against all relevant codes and standards every 3 years to ensure compliance. Circumstances where this licence condition may be used include, but are not limited to:*

- *Licence holders who deal with high hazard sources or controlled apparatus*
- *Issues where past regulatory performance is of concern*
- *Number of past incidents is of a concern*
- *Technical competence in respect to the LH's dealing warrants it i.e. an external assessment/review/or assistance by a third party to assist the LH maintain regulatory compliance*
- *Availability of codes and standards pertaining to the actual dealing*
- *Safety culture/HOF or complexities in the dealing that warrants the additional regulatory approach*

Under section 40 of the Act an eligible person who has had their licence amended may seek a review of the decision.

### ➤ *Suspension or cancellation of licence*

Under section 38 of the Act the CEO may decide to suspend or cancel a licence in circumstances where:

- a condition of the licence has been breached (this constitutes a breach of the Act) by the licence holder or by a person covered by the licence
- there are reasonable grounds to believe that an offence has been committed by the licence holder or a person covered by the licence
- the licence was obtained improperly

Suspension or cancellation of a licence could have serious implications for the licence holder's continued business or operations and for third parties. The RO should bear this in mind when recommending such action however the overriding consideration should always be to protect the health and safety of people and the environment.

When recommending the suspension or cancellation of a licence the RO must be mindful of the need to ensure that controlled material/apparatus or the controlled facility remains under regulatory control. A possess or control licence may need to be issued requiring the licence holder to maintain effective control of the facility until the licence suspension is lifted, the facility is disposed of, or a licence to decommission the facility is issued.

When making a recommendation to the CEO about whether or not to reissue a licence that has been suspended or cancelled the RO should take into account the licence holder's compliance history. Where a licence has been cancelled the licence holder will need to submit a new application.

Under section 40 of the Act an eligible person who has had their licence suspended or cancelled may seek a review of the decision.

## **1.3 Enforcement**

### ➤ *Direction by the CEO of ARPANSA*

Sections 41 and 41A of the Act give the CEO the power to issue directions.

Under section 41 before issuing a direction the CEO must believe on reasonable grounds that a controlled person is not complying with the Act or Regulations in respect of a thing and that it is necessary to protect the health and safety of people or to avoid damage to the environment.

Under section 41A the CEO has the power to issue a direction if the CEO believes on reasonable grounds that there is a risk of death, serious illness, serious injury or serious damage to the environment arising from radiation in connection with a controlled facility, controlled material or controlled apparatus and there is an urgent need to minimise the risk.

A copy of any direction issued by the CEO must be provided to the Minister who must table it in each House of Parliament.

Under section 42 of the Act a controlled person who has been given a direction may seek a review of the decision.

### ➤ *Referring matters to the Director of Public Prosecutions*

The laws administered by ARPANSA create a number of offences. The Office of the Commonwealth Director of Public Prosecutions prosecutes these offences. The decision to refer a matter to the Commonwealth Director of Public Prosecutions for prosecution of an offence will be made by the CEO in consultation with General Counsel in light of the facts and the [\*Prosecution Policy of the Commonwealth\*](#).

### ➤ *Injunction*

The CEO can make an application to the Federal Court of Australia for an injunction under section 43 of the Act in circumstances where:

- a person has engaged, is engaging, or proposing to engage in any conduct that would be an offence against the Act
- there has been or is proposed to be a refusal or failure to do a thing where refusal or failure would be an offence against the Act



## 2. Managing non-compliance & breaches

ARPANSA can identify non-compliance through inspection, investigation, or review of licence holder's compliance reports. Non-compliance may also be self-reported by a licence holder or any other party such as a whistle-blower or a member of the public.

The RO will make a recommendation about the level of regulatory response based on the particular circumstances.

When non-compliance is **identified by ARPANSA** the licence holder is given an opportunity to respond before a finding of breach is made<sup>4</sup>. Response is sought in an email accompanying the inspection or investigation report.

The RO will enter any non-compliance into the Licence Administration Database (LAD) and update the linked SharePoint site.

### 2.1 Determining a breach

The RO will consider the licence holder's response to the non-compliance or the licence holder's self-report of non-compliance. The RO will take into account the criteria described in section 2.2 to make a recommendation on whether to find the licence holder in breach and what the regulatory response should be.

The RO will prepare a brief RAR (using the [generic RAR template](#)) to the CEO or delegate to:

- Recommend the licence holder be found in breach and what if any enforcement action should be taken

OR

- Recommend that the licence holder not be found in breach by providing relevant evidence that the non-compliance either did not occur or that there are sufficient mitigating circumstances to satisfy the CEO that all reasonably practicable steps were taken by the licence holder to avoid the breach.

If a breach finding is recommended the RO will also prepare a letter to the licence holder using the appropriate letter template.

### 2.2 Review & Approval

Draft breach letters undergo the following review and approval process in FLOW (as per [Appendix E](#)):

- 1) **Peer review** by another RO (recommended)
- 2) **Director review** - The section directors check that:
  - the correct template has been used
  - the licence holder's submission has been taken into account
  - recommendations for finding a breach are justified and proportionate to the consequences of the non-compliance
- 3) **Quality review** - Advice will be provided on the draft letter to the RO and section director.

NOTE: Requests for quality review should be sent to [\\$ARPANSARegQuality@arpansa.gov.au](mailto:$ARPANSARegQuality@arpansa.gov.au)

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<sup>4</sup> Where a potential breach has been self-reported there is no need to seek further response from the licence holder unless clarification is required

- 4) **Legal review** –Advice will be provided on whether the breach is appropriately worded and any other legal issue.

NOTE: Legal advice may be sought at any time where there is a legal question or issue. Any request for legal advice should be sent to [legal\\_advice@arpansa.gov.au](mailto:legal_advice@arpansa.gov.au) and copied to the relevant director. Advice will usually be provided within 3 working days.

- 5) **Regulatory officer/lead inspector** - Conducts a final check and resolves all comments before ensuring a clean copy is provided for sign off.
- 6) **CRO/CEO approval** - The final determination is made by the Chief Regulatory Officer in consultation with the CEO or by the CEO. The breach letter is signed (electronically) by the Chief Regulatory Officer or the CEO depending on the nature and significance of the breach.

## 2.3 Determining the regulatory response to a breach

The structure of regulatory response depicted in Figure 1 should not be taken to be strictly sequential with regard to severity or approach to escalation. A range of issues and criteria as summarised below must be considered in order to determine the appropriate response and escalation when necessary.

### ➤ *Actual or potential health, safety and security consequences*

Whether there is actual or potential impact on the health and safety of people, impact on the environment, or security implications.

Safety consequences such as onsite/offsite releases of radioactivity, onsite/offsite radiation exposures, contamination of the environment, injury, loss of significant safety barriers (defence in depth), loss of shielding, loss of effective control of controlled material or controlled apparatus, or an actual radiological emergency.

Situations identified as having the potential to negatively impact safety or security should also be considered, as these events effectively introduce a vulnerability in the radiation protection or nuclear safety system which may eventually result in actual consequences for health and safety of people and/or the environment.

Consider any actual/potential impacts on the community or assets.

### ➤ *Nature of discovery*

Whether non-compliance was reported to ARPANSA by the licence holder, discovered by ARPANSA, or revealed as a result of an accident or other occurrence.

ARPANSA encourages licence holders to identify and rectify non-compliance as soon as practicable.

- For non-compliance **reported by the licence holder**, ROs should consider:
  - whether prior opportunities existed to identify the non-compliance and, if so, the time lapsed and the number of those opportunities
  - whether the non-compliance was self-revealing or whether it was reported to ARPANSA as the result of the licence holder's self-monitoring effort
  - whether the licence holder took reasonably practicable steps to prevent the non-compliance
  - whether the licence holder reported the non-compliance as soon as reasonably practicable
- For non-compliance **identified by ARPANSA**, ROs should consider:
  - whether the licence holder is likely to have identified the issue in the same time period even if ARPANSA had not been involved
  - whether the licence holder should have identified the issue and taken action earlier

- the degree of stakeholder initiative or lack thereof in identifying the cause and corrective action
- the responsiveness of the licence holder
- For non-compliance that is self-revealing ROs should consider the ease of discovery, the degree of licence holder initiative in identifying the cause of the non-compliance and the promptness of corrective action.

### ➤ *Cooperation and disclosure*

Whether the licence holder has been transparent and forthright in its interactions with ARPANSA and displayed a willingness to comply with the Act, the Regulations and licence conditions.

Any licence holder action that represents a challenge or barrier to ARPANSA fulfilling its regulatory functions may be significant. Such actions may include failing to provide timely, complete or accurate information, failing to obtain ARPANSA's authorisation or approval where this is required by legislation or licence conditions, failing to keep records, and failing to report an accident or other occurrence that had safety implications. In determining the significance of the non-compliance ROs will consider factors such as:

- whether the failure impeded or undermined regulatory action or ARPANSA's regulatory functions
- the level of responsibility of the individuals involved in the failure and whether the failure was reasonably foreseeable given their position and training

### ➤ *Level of intent*

Whether the non-compliance was intentional or inadvertent. Conscious or careless acts of non-compliance will be regarded as serious breaches. Examples of such acts include deliberate intent to violate, providing false information, or reckless disregard for statutory requirements. Deliberate violations should not be confused with unintentional errors.

The basis for issuing a licence includes the capacity of a licence holder to comply with the legislation and licence conditions. ARPANSA therefore treats a deliberate violation of legislation as being of particular concern.

Consideration will be given to the position and level of responsibility of the individuals involved in the action, the significance of the action, and any perceived or actual advantage gained as a result of the action.

### ➤ *Compliance history*

Whether there have been recent non-compliances of a similar nature and enforcement actions taken against the licence holder and if any related areas for improvement have been previously identified which if acted on may have prevented the non-compliance.

Whether the non-compliance or areas for improvement indicate systemic issues that may pose ongoing compliance concerns and any actions which the licence holder has put in place to address these.

### ➤ *Mitigating circumstances*

Whether there were any mitigating circumstances in the facts and circumstances leading to the non-compliance including whether the non-compliance and the result of the non-compliance have been rectified or whether ARPANSA is satisfied with a plan to do so.

Whether the licence holder had taken all reasonably practicable steps to avoid non-compliance.

## ➤ **Consequences of regulatory intervention**

When selecting the most appropriate regulatory response the RO should consider the impact (both positive and negative) on any third parties. The RO should satisfy themselves that the nominated enforcement option is justified and is likely to achieve the desired outcome while not unduly limiting the societal benefit of the conduct or causing other undesired consequences.

### **Examples:**

#### ▪ **1: Radiological exposure of an employee above the statutory limit**

*On face value it might appear that in this circumstance it would be best to recommend to the CEO that a facility should be directed to cease all activities or suspend and cancel a licence to operate. However it might be that this licence holder provides a critical service to society. Therefore it might be more appropriate for the CEO to introduce restrictive licence conditions that limit activity to a level where it can be carried out safely and simultaneously request review and analysis and ultimately rectification of the circumstances that surrounded the exposure.*

#### ▪ **2: Repeated loss of controlled apparatus (bio-safety cabinets)**

*On face value the loss or misplacement of bio-safety cabinets while technically a breach of the Act may not necessarily result in a significant safety concern to people or the environment due to the fact that most of this apparatus is inherently safe by design. In such situations little to no enforcement action would generally be required. However if a particular licence holder was found to have repeatedly lost control of such apparatus then it may be appropriate to escalate the response in order to prevent a recurrence. In this circumstance a net benefit may be demonstrated with the issue of an improvement notice.*

## **2.4 Approval and issue of breach finding**

Following all necessary reviews the final breach letter is signed by the CRO or CEO. The letter should include a timeframe negotiated with the licence holder for corrective actions to be completed unless they are already fully addressed.

The RO must enter the details of the breach into LAD and the corrective action plan must be recorded in the register in [Teams KPIs](#). Once the actions are followed up the RO must update Teams and LAD to close out the matter.

If a non-compliance is determined to not be a breach the RO or Licence Administration Officer (LAO) will update LAD to reflect this.

## **2.5 Publishing licence holder performance**

The compliance performance of licence holders is published on the ARPANSA website. This includes breaches, directions, improvement notices, and inspection reports. All breaches are graded on whether or not there are significant implications for safety or security. The nature of discovery is indicated and good practices and self-reporting are highlighted.

**NOTE: Security breaches are not published until the vulnerability has been addressed to the satisfaction of ARPANSA. In certain cases where there is a security or commercially sensitive concern the breach may not be published at all.**

The lead inspector must ensure that the relevant information is recorded and made available to the Comms Team.

## ➤ **Compliance**

When an inspection report concludes that the licence holder is compliant, this will be noted in

the covering email from Licence Admin to Comms who will create an entry in the performance table with a link to the inspection report.

The LAO uses Quick Parts to provide the required fields. If the LAO is not available the inspector should provide the following information:

1	2	3	4	5	6
Outcome	Licence number	Method of detection	Implications for safety or security	Date identified	Date resolved
Compliant	F/SXXXX	Inspection	N/A	<Date of insp>	N/A

### ➤ **Good Practice**

When good practice has been identified it will be noted in the covering email from Licence Admin to Comms who will create an entry in the performance table with a link to the inspection report. (The LAO uses Quick Parts to provide required fields.)

It is important that good practice be expressed as a clear 'stand-alone statement' in the inspection report so that it is self-explanatory when extracted and published. Preferably no more than 50 words should be used to describe a good practice.

In the event there are multiple findings in a report (eg compliance and good practice) a separate entry is required for each as shown:

1	2	3	4	5	6
Outcome	Licence number	Method of detection	Implications for safety or security	Date identified	Date resolved
Compliant	F/SXXXX	Inspection	N/A	<Date of insp>	N/A
Good practice	F/SXXXX	Inspection	N/A	<Date of insp>	N/A

### ➤ **Breach**

Where the licence holder has been found in breach the lead inspector will:

- Enter all relevant details about the breach in LAD and [SharePoint](#) including the required actions

**NOTE: Care must be taken to ensure that correct data is published particularly the date identified/determined:**

- For self-reported breaches it is the date of notification
- For breaches identified by ARPANSA it is the date the breach is determined by the CRO/CEO (noting this should also be the date of the letter to the licence holder)
- Prepare a **brief media statement** and include in SharePoint entry. This will not be published but will be held by Comms should an enquiry be made about the matter – see sample statement below.
- Assess whether there are security implications associated with the breach. If there is any doubt, seek assistance from an ARPANSA security expert. If there are security implications the breach must not be published until resolved.
- After updating the SharePoint entry, select [Publish to Web](#) to initiate Flow to:
  - Section Director for final review & approval
  - Comms for publishing (with media statement)

### ➤ **Media statement**

Media statements should include:

- What happened & when
- Underlying causes
- Impact on safety / security
- Remedial action
- Next steps / future regulatory action

### **SAMPLE STATEMENT**

*On 6 September 2019, licence holder X experienced a break down when mechanical failure of a component occurred. The failure had no direct impact on safety and was unrelated to recent safety incidents. Following a request on 9 September, ARPANSA approved a modification to the impacted equipment to allow resumption of operations. The modification was successfully completed on 11 September with no significant safety issues. ARPANSA will continue to work with licence holder X to consider any future modification applications that may be necessary in the future.*

### ➤ **Improvement notice**

Where an improvement notice has been issued the lead inspector will:

- Enter all relevant details about the improvement notice in LAD and [SharePoint](#) including a brief media statement
- Assess whether there are security implications associated with the improvement notice. If there are security implications the improvement notice must not be published until resolved. If in doubt seek assistance from an ARPANSA security expert.
- Select 'publish to web' to initiate Flow to:
  - a. Section Director for final review & approval
  - b. Comms for publishing (with media statement)

### ➤ **Closeout of breaches and improvement notices**

When a breach or improvement notice is resolved to ARPANSA's satisfaction the item must be closed out on the webpage by entering the date resolved.

- Go to [SharePoint](#), enter relevant information particularly the date of close out, add any further comments to the notes field, then click 'publish to web'. Make it obvious to Comms to link the breach to the respective inspection report – this request may be added to the notes field.

After section director review, Flow will prompt Comms to update the LH performance table.

NOTE: If an improvement notice is challenged and withdrawn the entire entry must be removed from the webpage, and LAD and SharePoint updated accordingly.

### ➤ **Checking website data**

It is the responsibility of the lead inspector (or RO assigned to the licence) to verify that the correct data has been published on the [Licence Holder Performance page](#) paying particular attention that dates match those in LAD and Sharepoint. The trigger for this check should be the email from Comms confirming that data has been loaded or updated.

## **2.6 Reporting to Parliament**

Sections 59 and 60 of the Act require the CEO to report details of any breach of licence conditions by a licensee to Parliament through the Minister. The report will also contain a link to the ARPANSA website where all breaches will be registered.

NOTE: A licence holder may also be in breach of the prohibitions in section 30 or 31 of the Act. This is often referred to as an unauthorised conduct or dealing. Although the Act does not expressly require the reporting of a breach of prohibitions, ARPANSA will report such breaches as part of reporting the operations of the CEO under paragraph 59(a)(i) and paragraph 60(1)(a) of the Act. Breaches of prohibitions are generally regarded as serious and enforcement actions will reflect this in line with the graded approach.

Section 61 of the Act sets out other provisions for reporting to Parliament:

- Under subsection 61(2) if a serious accident or malfunction occurs at a nuclear installation, the CEO *must* cause a report about the incident to be tabled in each House of the Parliament no later than 3 sitting days after the incident occurs and under subsection 61(3) must give a copy of the report to the Minister.
- Under subsection 61(1) the CEO *may* cause a report to be tabled in Parliament on any matter related to the CEO's functions. Hence the CEO may at any time report an event that occurred in any facility or involving controlled material/controlled apparatus where there are significant safety or security implications.

## 2.7 Record keeping

Details of all breaches must be entered into LAD and Sharepoint and the webpage updated when the required action is completed.

### 3. Managing compliance reports

A condition on all licences requires the licence holder to report periodically on compliance. ARPANSA provides templates for this purpose on the [Regulatory Forms](#) webpage.

The reporting period in most cases is quarterly but to reduce regulatory burden licence holders who meet the following criteria may have their reporting frequency extended to biannually or annually:

- Low hazard source(s)
- Stable source inventory
- Good compliance history
- Facilities that heavily rely on passive safety

A change to the reporting frequency may be made in consultation with the relevant section director. Reasons for the change must be recorded in the licence file.

ROs are responsible for monitoring the compliance of licence holders assigned to them. This includes managing their compliance reports. The RO and the LAO both have responsibilities in the process.

#### 3.1 Reminder notices

Two weeks before the end of the reporting period the LAO sends a first reminder email notice to licence holders with links to the reporting template and related guidance.

If no report is received within a week of the due date a second email reminder notice is sent and the RO alerted.

#### 3.2 Receipt of compliance report

The LAO monitors the licence admin mailbox for licence holder reports. The receipt of a compliance report is acknowledged by email with copy to the relevant RO.

The LAO saves the report and its attachments in the records management system, uploads the report into LAD and updates the licence holder contact list in Outlook as necessary.

The LAO assigns an action to refer the report to the relevant RO for assessment.

#### 3.3 Regulatory assessment

The RO checks that the report was received within the required period. If the report is late the appropriate response is prepared depending on whether this is a one-off or repeated occurrence (refer to compliance history).

The RO checks that any new or amended information is within the scope of the licence holder's authorisation and in compliance with the Regulations including any approvals that should have been obtained or notifications provided.

Compliance with any special licence conditions or actions arising from an inspection is assessed in terms of progress and/or agreed completion schedule.

Any issues or non-compliance requiring follow-up or investigation are identified taking into account the management process in section 4. If the management checklist is not required the RO should create a file note to record this information. Any arising actions such as an inspection or investigation should follow standard operating procedures.



### 3.4 Source Inventory Workbook

If a change to the source inventory is reported the LAO exports a copy of the source inventory workbook (SIW) from LAD and sends it to the licence holder to be updated.

When the SIW is returned it should be cross-checked with any import permits, correspondence, or requests for approval received during the reporting period to ensure the SIW is accurate and complete. The SIW is then imported into LAD to complete the cycle. The RO should follow-up on any highlighted rows that appear during the upload as they show discrepancies between the exported and imported data. Any changes to source details are highlighted; this could be as simple as a room change but may also indicate an unauthorised source or disposal without approval. All discrepancies must be resolved before LAD will accept the updated SIW.

### 3.5 Incident reporting

Where there is an incident that should be reported to the [Australian Radiation Incident Register](#)<sup>5</sup> (ARIR) the RO should complete the online form use the [ARPANSA Connect portal](#)<sup>6</sup> to report the incident online.

The RO should be aware of the reporting requirements in subsection 61(2) of the Act if a serious accident or malfunction occurs at a nuclear installation (see paragraph 2.5) and the more general reporting provision in subsection 61(1).

Where there is an event with significant safety or security consequences the RO should contact the branch INES Officer (or deputy) for assessment of the event on the [International Nuclear & Radiological Event Scale](#) (INES). Events with a rating of INES Level 2 or above are expected to be reported to the IAEA within 24 hours. Events with a rating of INES Level 1 are often reported for information and learning opportunities. Such events should be recorded in LAD and included in ARPANSA's quarterly report to the Minister.

*See also [Section 4 Event notification & management](#)*

### 3.6 Complete action

After completing the regulatory assessment the RO should complete the action raised by the LAO and enter the date of review into LAD.

### 3.7 Failure to submit a report

For a one-off failure to submit a report the RO should send an email to the licence holder reminding them of their statutory obligation. For repeated failure to submit a report an escalated response should be considered - refer to previous sections of the manual.

### 3.8 Information sharing

Any issues or actions arising from compliance reports that present a learning opportunity should be raised with the section director and shared with other ROs via email.

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<sup>5</sup> See Schedule 13 of the [National Directory for Radiation Protection](#)

<sup>6</sup> The RO must be a registered user to access the portal.

## 4. Event notification & management

When notification of an event<sup>7</sup> is received it is managed by assessing the nature and magnitude of the event, potential consequences, and implications for safety and security to determine what regulatory action is required. For information on what constitutes a reportable incident that requires notification within 24 hours see [Regulatory Guide: Radiation incidents](#).

The purpose of the following procedure is to ensure that ARPANSA applies a consistent approach to decision-making and response to a nuclear or radiological event. It aims to ensure that ARPANSA meets public and government expectations in its responsiveness to an event.

The following procedure applies to all regulatory staff who may in the course of their duties receive notice of an event. Note that event information should also be recorded in the regulatory systems such as Content Manager and LAD and distributed where applicable e.g. to the ARIR.

### 4.1 Managing notifications (see flowchart in [Appendix C](#))

- The RO receiving the notification confirms whether it has come from or relates to a controlled person or ARPANSA licence holder. If the event has occurred in another jurisdiction the RO will refer the notification to the relevant authority. Information should be provided to the Chief Regulatory Officer (CRO), CEO and Office of the CEO<sup>8</sup> as soon as possible. Depending on the nature of the event<sup>9</sup> the RO may also consider advising ARPANSA's Monitoring & Emergency Response (MER) Section/or the duty officer in accordance with the [ARPANSA Incident Management Plan](#).
- If the event falls under Commonwealth jurisdiction the RO records details of the event using the [Event Management Checklist](#) then emails it to the CRO as soon as possible with copy to relevant section director and lead inspector.
- The CRO should assess the event and any potential consequences and make a decision on whether regulatory response is required.
- Where appropriate the lead inspector (or alternate) should reinforce the need for the licence holder to preserve the incident site as per [Regulatory Guide: Radiation incident site preservation](#).
- If no regulatory intervention is deemed necessary the lead inspector should monitor the case for further developments or new information until there is a steady state where there are no changes.
- Where action is required the lead inspector should gather any additional information regarding the event including the area affected, injuries, dose estimates, etc and keep the CRO and section director informed.
- In the case of a serious event the lead inspector should refer to [RPS G-3 Guide for Radiation Protection in Emergency Exposure Situations \(2019\)](#) to classify the emergency and determine the appropriate response.
- In the case of a serious event the lead inspector should contact the branch INES Officer for assessment of the event on the [International Nuclear & Radiological Event Scale](#) (INES) and any required reporting – see paragraph 3.5.
- The CRO should convene a Branch Executive (BE) meeting as soon as practicable that includes the lead inspector and a representative from the OCEO and as required from MER. In such cases the

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<sup>7</sup> An event may be an accident reported under section 58 of the Act, an incident or other unplanned occurrence with the potential to affect safety or security

<sup>8</sup> The OCEO will decide whether an issue is likely to be of interest to media or government. Any further detail on an event will be requested as required.

<sup>9</sup> Depending on the significance of the event and its potential consequences, the jurisdiction may request support from MER under the ARPANSA Incident Management Plan

lead inspector should provide a brief dot point summary of basic information to the OCEO at [media@arpansa.gov.au](mailto:media@arpansa.gov.au) or [parliamentary@arpansa.gov.au](mailto:parliamentary@arpansa.gov.au) as background prior to the meeting.

If convened the BE should:

- discuss potential consequences
  - consider any risks to people, the environment, ARPANSA, and the Government
  - make decisions on immediate<sup>10</sup> and longer term<sup>11</sup> regulatory response
  - liaise with OCEO to assist with any possible media enquiries, talking points, or ministerial briefs
  - consider any information sharing with other agencies such as Comcare
  - report the decisions to the CEO or the deputy CEO
  - record all decisions and actions for post event review
- Regulatory actions should commence as soon as appropriate. If a site visit/inspection/investigation is to occur a number of WHS and preparatory actions will be necessary. These actions will proceed in accordance with relevant procedures<sup>12</sup>.
- For any prolonged event the BE may need to consider additional administrative support, business continuity plans, incident management plan, and relief arrangements for personnel directly involved in the event response.

## 4.2 Reporting to Parliament

Under subsection 61(2) of the Act if a serious accident or malfunction occurs at a nuclear installation, the CEO must cause a report about the incident to be tabled in each House of the Parliament no later than 3 sitting days after the incident occurs and under subsection 61(3) must give a copy of the report to the Minister.

The CEO may report any serious event at a facility or involving controlled material/apparatus to Parliament under subsection 61(1) – see paragraphs 2.5 & 3.5.

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<sup>10</sup> This may include augmented inspection, investigation, improvement notice, direction, or some other action necessary to maintain safety such as suspension of licence

<sup>11</sup> This may include a licence amendment to limit the authorisation or impose additional licence conditions

<sup>12</sup> [Inspection Manual](#)

<sup>12</sup> [Investigation Procedure](#) – note *investigation* means a detailed, careful and searching line of inquiry into an allegation of serious wrong-doing or event so as to ascertain the facts, or the likelihood of events and to report findings for decision by the adjudicator (CEO of ARPANSA or General Counsel).

## 5. Improvement notices

It may be appropriate for the lead inspector to issue an improvement notice where a potential or actual non-compliance has been identified such as during an inspection or site visit, reviewing a periodic report from a licence holder, or assessing a request for approval under section 63 of the Regulations.

An improvement notice is useful as a preventative tool to require the licence holder to do something or stop doing something to eliminate a risk to people and/or the environment before a breach occurs.

### 5.1 When & how to issue an improvement notice

An improvement notice may be issued when:

- The inspector reasonably believes an activity is likely to pose an unacceptable risk to the health and safety of people or to the environment if a non-compliance or potential non-compliance is not rectified immediately
- Resolution at the lowest enforcement level (Figure 1) has failed to result in a return to compliance. For example, a non-compliance previously identified has not been rectified in an acceptable time or temporary measures taken by the licence holder to rectify a non-compliance have had a limited effect and stronger measures are necessary
- There are recurrent non-compliances of a similar nature
- It is unlikely that the licence holder will take actions to rectify a non-compliance or likely non-compliance in an acceptable time. Consideration should be given to the licence holder's compliance record, timeliness of investigation, and rectification of previous non-compliance

In the process of making a decision whether to issue an improvement notice the inspector must apply judgment based on knowledge of the licence holder, the licensed activities, and the compliance history. The decision should be based on evidence and facts not on speculation or subjective reasoning.

If no immediate or urgent risk associated with the non-compliance or likely non-compliance is perceived by the inspector enforcement responses other than an improvement notice should be considered.

An improvement notice should be issued as soon as possible when the inspector reasonably believes a delay would create an unacceptable risk to the health and safety of people or the environment.

However an improvement notice need not be issued on the spot. Unless there is an immediate risk of serious harm to people or the environment the inspector should consult the Chief Regulatory Officer, the relevant section director, or seek legal advice before issuing an improvement notice.

An improvement notice should be delivered to a representative of the licence holder either in person (on-the-spot) or via email. The latter should be followed by a phone call. The method chosen depends on the urgency of the matter or the need for discussion with the Chief Regulatory Officer or section director before issuing the improvement notice.

If an improvement notice is issued on the spot, before it is handed to the licence holder the inspector should take a photo of the document for record keeping purposes. Subsequently the photo is to be saved to the ARPANSA records management system.

## 5.2 Form & content of an improvement notice

An improvement notice must be issued using the approved template and may be completed electronically or by hand. The inspector should explain to the licence holder the requirements of the notice and reason for issuing it.

The licence holder is responsible for safety therefore the inspector must NOT tell the licence holder how to remedy or avoid a contravention.

The inspector must ensure that the time nominated for completion of corrective actions is reasonable and takes into consideration the potential impact on safety and/or security.

## 5.3 Compliance with an improvement notice

An improvement notice has the status of a licence condition therefore the licence holder must comply with its requirements within the specified time. The improvement notice does not limit any of the existing provisions of the Act, Regulations or licence conditions.

When the licence holder has adequately demonstrated that the requirements of an improvement notice have been met, the inspector should send an email confirming that the intent of the notice has been satisfied. The email must clearly describe why the requirements of the improvement notice are considered to be met.

Non-compliance with an improvement notice constitutes a breach of licence condition and the inspector must manage it accordingly as per section 2 of this Manual.

### Examples

#### ▪ Example 1

*A licence holder was found to have breached a licence condition by failing to comply with an operating limit and condition. The facility was found to be operating outside the set safety limits during the inspection and no action was taken by the licence holder.*

*The inspector issued an improvement notice based on the serious nature of the breach and because the licence holder had failed to take remedial action. The improvement notice required operations to cease immediately and not resume until a return to compliance was confirmed.*

#### ▪ Example 2

*An area for improvement (AFI) was identified during an inspection. A piece of equipment placed in front of a radiation monitor blocked the detector and therefore reduced its functionality. During a site visit two months later, an inspector found that another piece of equipment was placed in front of another radiation monitor in a similar way. Despite the licence holder's initial commitment to address the problem immediately, no learning from the AFI was evident.*

*Considering the licence holder's approach to the risk highlighted in the previous inspection and the time available to address the matter, the inspector issued an improvement notice on the spot. The improvement notice required immediate removal of equipment obstructing radiation monitors and improvement in communication across the organisation to raise awareness and prevent recurrence.*

#### ▪ Example 3

*A non-compliance was identified because training of an operator was not up to date. An inspection three months later identified that the non-compliance had not been rectified. However, there was evidence that the operator had been temporarily reassigned to other duties not requiring that particular training. Refresher training for the operator had been scheduled for the following month.*

*In this case, the inspector did not issue an improvement notice because the licence holder demonstrated that corrective action had been initiated as soon as reasonably practicable and the operator had been removed until the training could be completed.*

#### **5.4 Publishing information about improvement notices**

Information about an improvement notice and its close out is published as per [paragraph 2.4](#).

#### **5.5 Record keeping**

Information about the improvement notice must be saved in the records management system, LAD and Sharepoint. The inspector should also ensure that the required information is provided to update the website.

## 6. Monitoring personal dosimetry reports

An agreement is currently in place with ARPANSA's Personal Radiation Monitoring Service (PRMS) where they will inform RSB as soon as possible if any of its licence holders receive a dose in excess of the occupational dose limits as set out in the [Planned Exposure Code RPS C-1](#) or in excess of a pro-rated dose limit.

PRMS will also inform RSB of any recorded dose which exceeds the annual dose limits pro-rated for the dosimeter wearing period e.g. 5 mSv whole body effective dose in a three monthly wearing period or 125 mSv to the hands or feet in a three month wearing period.

Dose reports are routinely provided on a quarterly basis. An annual report of cumulative dose is also provided.

Some licences have a condition requiring them to provide personal occupational radiation dose records of persons covered by the licence to ARPANSA for inclusion in the Australian National Radiation Dose Register (ANRDR). All such dose records will be subject to review.

The Chief Regulatory Officer will delegate the review of dosimetry reports to an appropriate RO. This officer will review the report and direct the report to the relevant sections director/inspector to undertake appropriate enquiries as required.

### 6.1 High dose notification

When a high dose report is received from the licence holder or PRMS, the reviewer should initiate an enquiry and follow the actions shown in the flow chart at [Appendix A](#).

The reviewer should initially establish the nature of the dose through PRMS and check the exposure is consistent with the sources used by the licence holder, viz.

- Type of radiation recorded on the dosimeter
- Energy range of radiation
- Magnitude of radiation exposure recorded
- Any other factors e.g. possible exposure during medical procedures, accidental exposure via airport security screening.

### 6.2 Review of quarterly dose reports

Quarterly dose reports should be reviewed in accordance with the procedure in [Appendix B](#). Any doses exceeding the threshold should be brought to the attention of the lead inspector and relevant section director.

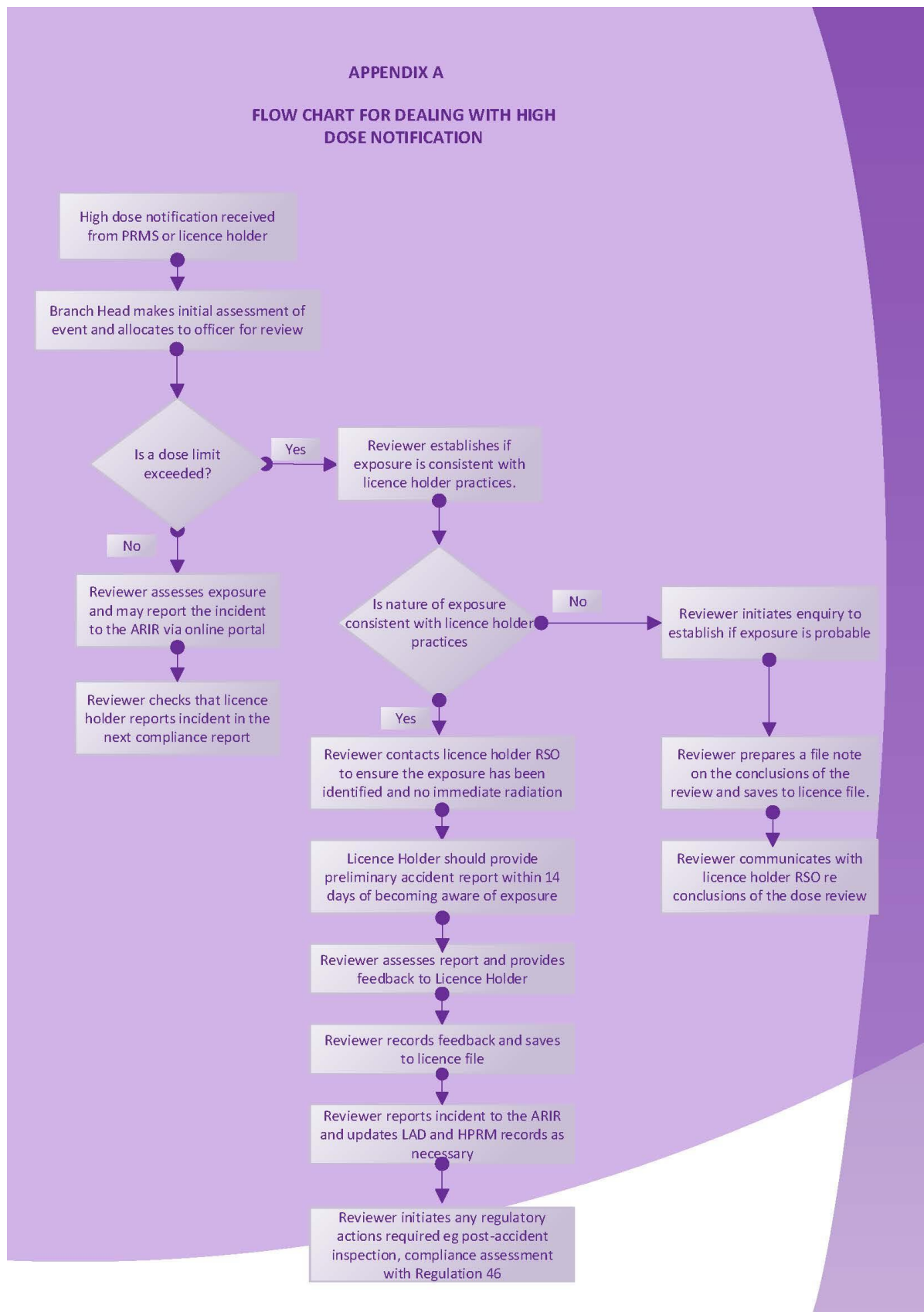
### 6.3 Review of annual dose reports

Annual dose reports should be reviewed and any doses exceeding the threshold brought to the attention of the lead inspector and relevant section director.

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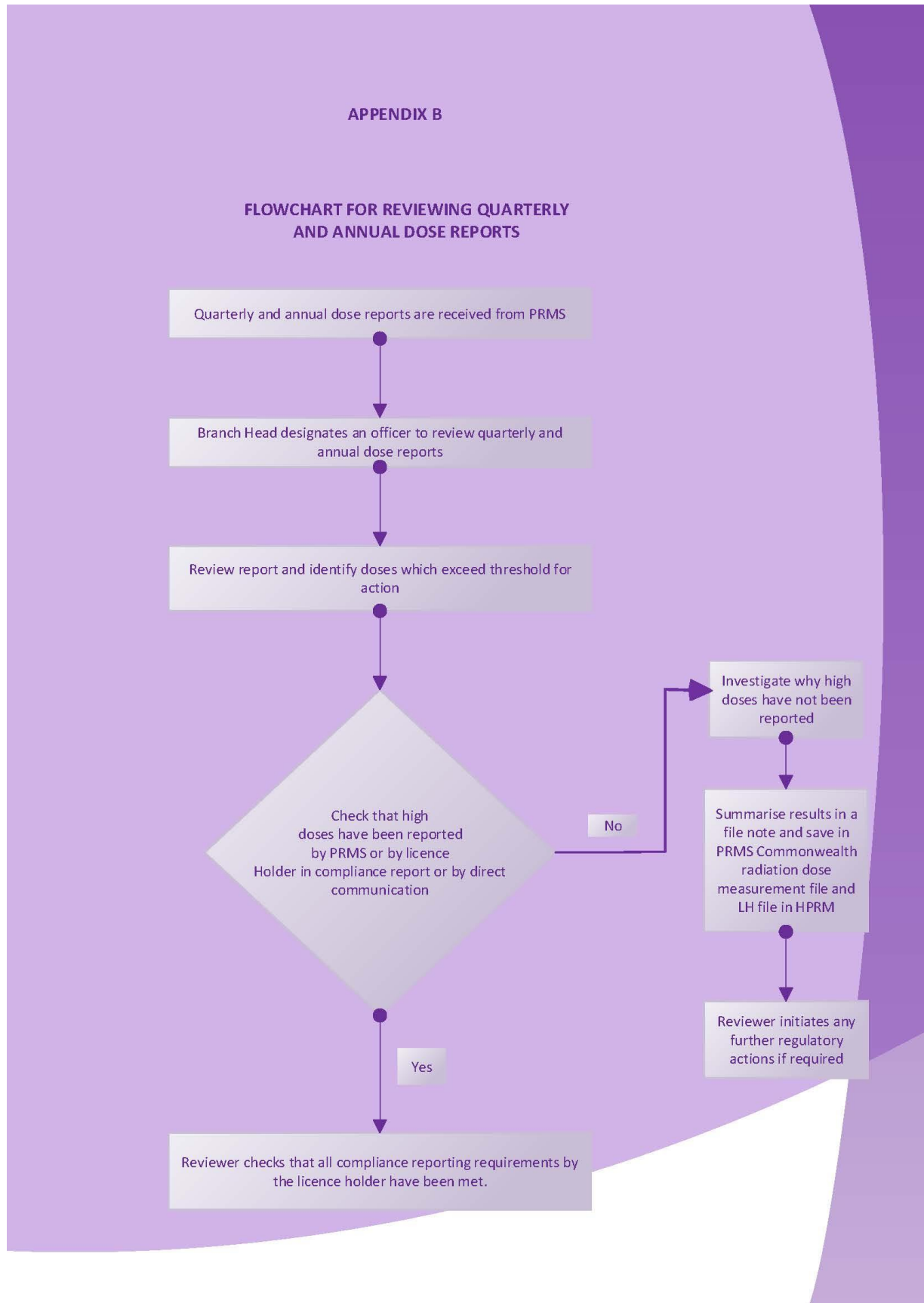
**NOTE: The web version of this manual ends here - please delete appendices and attachments before publishing**

## Appendix A: Dealing with a high dose notification

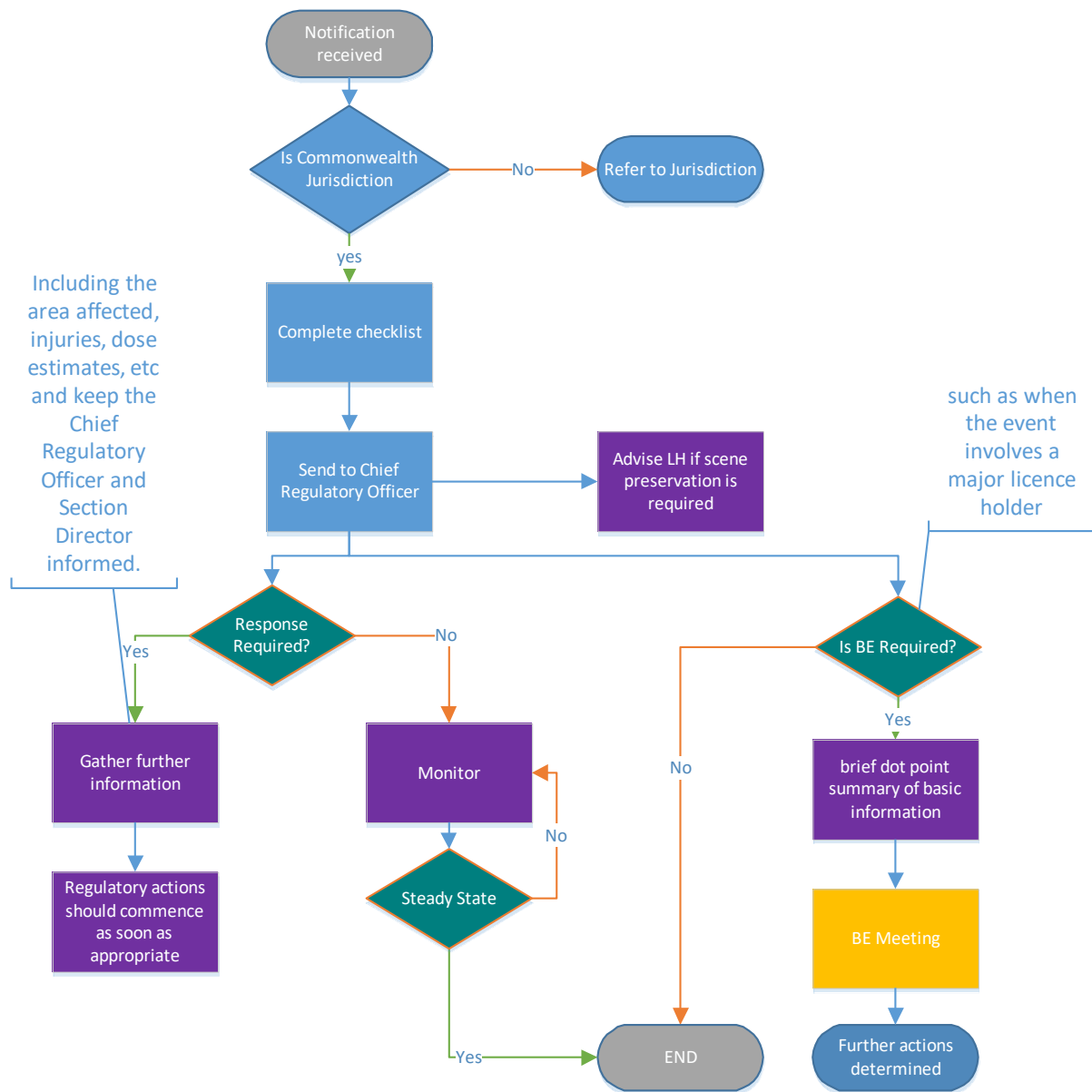




## Appendix B: Process for reviewing dose reports



## Appendix C: Event management process



## Appendix D: Convention for citing legislation

### ➤ Acts

The title of an act is italicised. The first time the title appears in a document the full title is used followed by ('the Act' or 'the ARPANS Act', as appropriate). This abbreviation is then used for the remainder of the document. For example:

*Australian Radiation Protection and Nuclear Safety Act 1998* (the Act)

Citing parts of an act - examples:

Full text	Shortened form
Section 36 of the Act	s36
Subsection 36(1) of the Act	s36(1)
Paragraph 36(1)(a) of the Act	s36(1)(a)
Subparagraph 36(1)(a)(i) of the Act	s36(1)(a)(i)

### ➤ Regulations

The title of regulations is not italicised. The first time the title appears in a document the full title is used followed by ('the Regulations' or 'the ARPANS Regulations', as appropriate). This abbreviation is then used for the remainder of the document. For example,

Australian Radiation Protection and Nuclear Safety Regulations 2018 (the Regulations)

Citing parts of regulations – examples:

Full text	Shortened form
Section 4 of the Regulations	r4
Subsection 4(2) of the Regulations	r4(2)
Paragraph 4(2)(a) of the Regulations	r4(2)(a)
Subparagraph 4(2)(a)(i) of the Regulations	r4(2)(a)(i)

If you are setting out the words in full such as in a formal letter, use those examples on the left; for less formal communication such as emails, memos or file notes, the shortened form may be used.

## Appendix E: Review & approval of regulatory documents

The table below shows the reviews required for regulatory documents prior to approval by the CRO, CEO or other officer with the appropriate delegation.

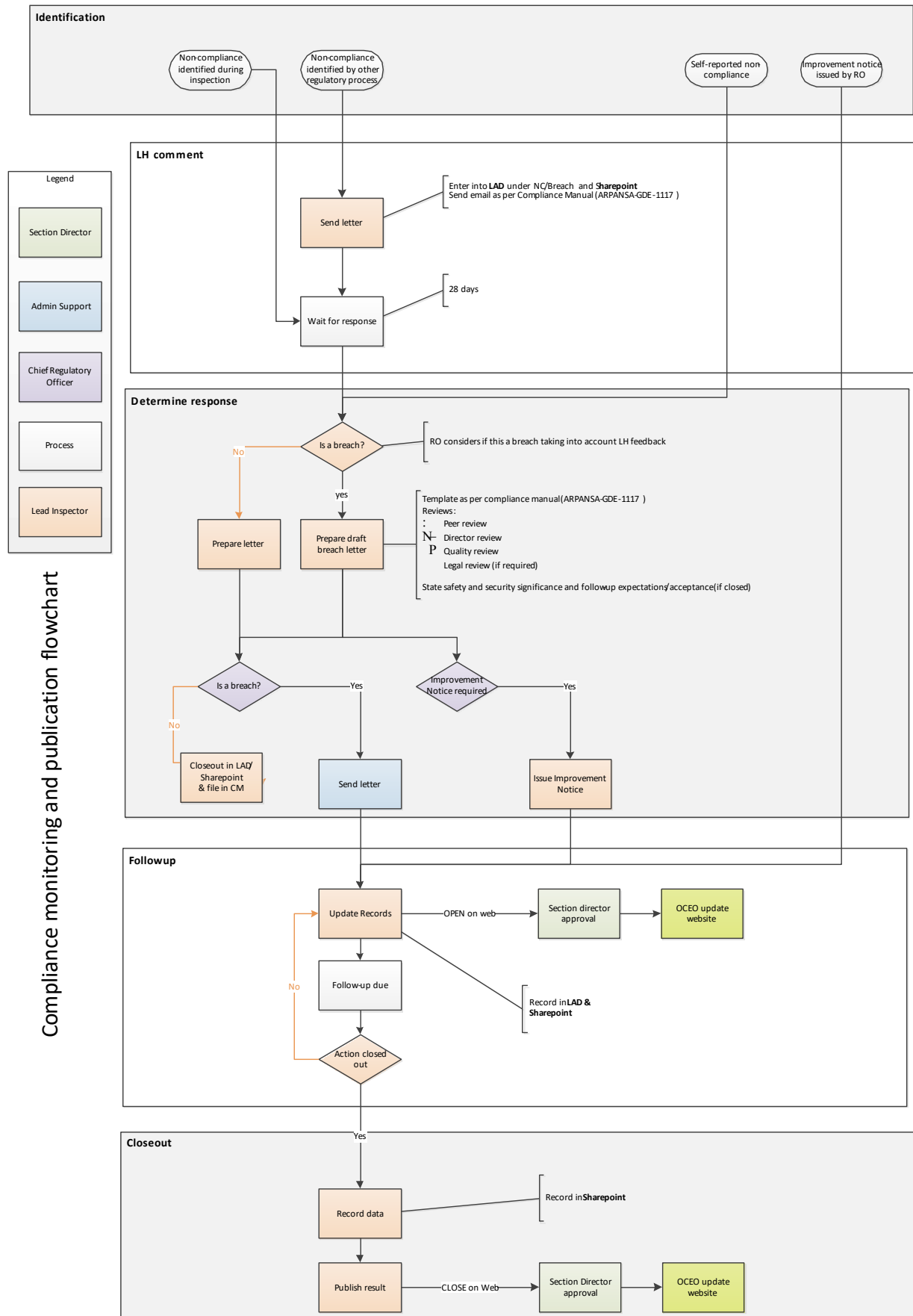
Matter	Peer review	Director	Quality	Legal
New licences <ul style="list-style-type: none"> <li>- Licence</li> <li>- Letter</li> <li>- RAR</li> </ul>	Yes	Yes	Yes	Yes Licence & letter only
Licence amendments <ul style="list-style-type: none"> <li>- RAR (where relevant<sup>13</sup>)</li> <li>- draft licence</li> <li>- justification for any special licence conditions</li> </ul>	Yes	Yes	Yes	No unless special licence conditions are added
Requests for exemption	Yes	Yes	Yes	No unless specific legal question
Section 63 changes with no licence amendment <ul style="list-style-type: none"> <li>- RAR</li> <li>- letter</li> </ul>	Yes	Yes	No Yes	No
Inspection reports & covering letter	Recommended	Yes	Yes	No unless these is non-compliance
Non-compliance letters	Recommended	Yes	Yes	Yes
Findings of breach <ul style="list-style-type: none"> <li>- letter to LH</li> </ul>	Recommended	Yes	Yes	Yes
Regulatory content for website	Optional	No unless content is new	Recommended	No unless specific legal question
Any matter with legal implications such as application of codes or standards (excluding matters of national security or personnel in confidence)	Optional	Recommended	Recommended	No unless specific legal question
Enforcement actions such as improvement notice, seizure, direction	Optional	Recommended	Recommended	No unless specific legal question

### NOTES:

1. Independent review is required for all matters where ARPANSA is the applicant/licence holder
2. A risk based graded approach should be applied where review is optional or recommended
3. If there is disagreement over advice provided by the reviewing officer, the officers should discuss their differing opinions with the intent of resolving them. Where differences remain, the basis and evidence should be documented in line with [ARPANSA-SOP-1774](#) Differing Professional Opinions and the matter referred to the CRO. The CRO may seek advice from any source considered appropriate in addressing the matter. This may involve staff anywhere in the agency or even outside the agency if appropriate.
4. The reason for any departure from this procedure must be recorded in CM
5. A Review & Approval workflow should be initiated in Teams by the RO.
6. Legal advice can be requested at any time but should **only** be sought where there is a real legal issue ie the request should contain specific questions on which legal advice is sought rather than a general request for 'review'. Requests should be sent to [legal\\_advice@arpansa.gov.au](mailto:legal_advice@arpansa.gov.au) and copied to the relevant director.

<sup>13</sup> There will only be a RAR when a LH has applied for an amendment. Under s36 of the Act, the CEO may amend a licence at any time in which case there should be a file note explaining the reason for the amendment in addition to a letter to the LH.

## Appendix F: Publishing licence holder performance



## Attachment 1: Email templates

### A1. Compliance Report Reminder Notice

Dear Licence Holder Representative

This is a reminder that you will soon be required to submit your **quarterly/annual/biannual** report for the period **XXXX** to **XXXX**.

Completion and submission of such reports is an important demonstration of compliance with your licence conditions.

Please ensure that your report is submitted by **cob 28 XXXX**.

Where unforeseen circumstances may prevent you from meeting this deadline, please contact ARPANSA to seek an extension of time for submission of the report.

Please also note that failure to submit a compliance report in accordance with licence conditions may result in a finding of breach. Under the Act, the CEO is obliged to report breaches of licence conditions to the Minister in ARPANSA's quarterly and annual reports and the Minister is in turn required to provide the reports to Parliament.

Click on the links for [Quarterly Report Template](#) / [Annual Report Template](#) and [Regulatory Guide: Reporting Compliance](#).

Please send reports to [licenceadmin@arpansa.gov.au](mailto:licenceadmin@arpansa.gov.au).

If you report changes to your source holdings ARPANSA will provide the latest version of your SIW to be updated.

Sent on behalf of

<name>

Chief Regulatory Officer

### A2. Compliance Report Reminder - Second Notice

Dear Licence Holder Representative

Your **quarterly/annual/biannual** report for the period **XXXX** to **XXXX** was due by 28 **XXXX** and despite an earlier reminder has not yet been received.

All licence holders have certain statutory reporting obligations under the Act and Regulations. This includes reporting of certain changes to the CEO of ARPANSA under section 64 of the Regulations on a quarterly basis.

This email has been addressed to the key contact person for each source licence and prescribed radiation facility and copied to the licence holder or nominee. If you consider it the responsibility of someone else to respond, please forward this email to them with a copy to [licenceadmin@arpansa.gov.au](mailto:licenceadmin@arpansa.gov.au).

Please give this matter your immediate attention.

Sent on behalf of

<name>

Chief Regulatory Officer

### A3. Receipt of Compliance Report

This email acknowledges receipt of your **quarterly/annual/biannual** report for the period **XXXX** to **XXXX 20XX** which has been referred to the relevant Regulatory Officer for review.

## Attachment 2: Letter templates

<Copy & paste onto ARPANSA letterhead>

### A4. Non-compliance – fail to comply with a licence condition

< insert record # >

Date

Name

Title / position

Organisation

Address line 1

Address line 2

Suburb STATE POSTCODE

Dear

**S/FXXXX Non-compliance with section X of the Regulations/licence condition #**

Section XX of the Australian Radiation Protection and Nuclear Safety Regulations 2018 (the Regulations) OR Condition # of source/facility licence S/FXXXX requires the licence holder to <summarise requirement or if quoting - use italics (no inverted commas required)>.

<Describe how the licence holder has not met the requirement>

Subsection 31(2)/30(2) of the Act requires compliance with licence conditions. Failure to do so can result in a finding of breach and lead to enforcement action being taken. Where a licence holder is found to be in breach of the Act, the CEO is obliged to report the breach to Parliament under sections 59 and 60 of the Act.

Before deciding whether there has been a breach, you are invited to respond to this matter and describe any corrective action you propose to take and a timeframe in which to complete it. If you believe no action is required please provide justification.

You are also reminded of your responsibility under section 57 of the Regulations which requires a licence holder to investigate and rectify breaches of licence conditions.

Please provide your response within 28 days of this request. If you fail to respond within this time, the CEO may make a decision on the evidence available.

Yours sincerely

<name>

Chief Regulatory Officer

#### A5. Non-compliance – prohibited activity by a controlled person

< insert record # >

Date

Name

Title / position

Organisation

Address line 1

Address line 2

Suburb STATE POSTCODE

Dear

**Non-compliance with subsection 31(1)(a) of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act)**

I refer to a site visit conducted by my inspectors at your <suburb> premises on <date>. During the site visit evidence was collected which indicated that <controlled person> was in possession of controlled apparatus/controlled material in the form of <description>.

Paragraph 31(1)(a) of the Act requires controlled apparatus/controlled material to be authorised under a source licence if held by a controlled person. Failure to have an ARPANSA licence is likely to result in a finding of breach of the Act and may result in enforcement action.

<Organisation/Controlled person> which is a controlled person for the purposes of the Act (*Commonwealth entity*) does not hold a source licence issued by ARPANSA.

Before a decision is made on whether there has been a breach of the Act I invite you to respond to this matter.

Please provide your response within 28 days of the date of this letter. If you fail to respond within this time the CEO may make a decision on the evidence available.

Yours sincerely

<Name>

Chief Regulatory Officer



## A6. Finding of breach – failure to comply with licence condition

< insert record # >

Date

Name

Title / position

Organisation

Address line 1

Address line 2

Suburb STATE POSTCODE

Dear < name >

<Licence holder> - <Facility/Source licence F/SXXXX> - Breach of licence condition

### Decision

On the matter of <nature of breach - eg safe management of sources> I find <licence holder> in breach of <subsection 60(1)/(2) of the Australian Radiation Protection and Nuclear Safety Regulations (2018) which requires the licence holder to take all reasonably practicable steps to manage the safety of the facility/source.>

### The issue

Whether the licence holder has breached <subsection XX of the Regulations/condition X in Schedule 2 of the licence> as it relates to <the matter>

### Statement of reasons

As identified in inspection report RXX/YYYYY the licence holder has not <state details – eg effectively managed safety or stayed within the facility's safety case as it relates to Lu-177>.

On <date> I wrote to you regarding this matter requesting that you make any submissions you believe appropriate.

Your response to this request was received on <date>. I have considered your response however you have not provided any evidence relevant to the matter to persuade me that a breach of <subsection 60(1)/(2) of the Regulations> has not occurred.

### Next steps

This breach will be included in ARPANSA's annual and quarterly report to the Minister and the Parliament in accordance with sections 59 and 60 of the Act. The breach will also be published on the ARPANSA website. Further information on the reporting of breaches is available in ARPANSA's [Compliance Manual](#).

I do not intend to pursue any formal enforcement action in regard to this matter at this time as <state reasons – eg I am aware that you have recently made a submission for approval of changes to the OLCs. This is currently being assessed by ARPANSA.>

Yours sincerely

Name of Decision Maker (no titles)

Position/CEO of ARPANSA

## A7. Finding of breach – prohibited activity by a controlled person

< insert record # >

Date  
Name  
Title / position  
Organisation  
Address line 1  
Address line 2  
Suburb STATE POSTCODE

Dear < name >

### Breach of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act)

#### Decision

On the matter of dealing with <type of source> without a licence, I find <controlled person> in breach of paragraph 31(1)(a) of the Act.

#### The issue

Whether there has been a breach of the Act by undertaking prohibited activity in relation to a <controlled apparatus / controlled material>.

#### Statement of reasons

During a site visit on <date>, <controlled person> was found in possession of <controlled apparatus / controlled material> in the form of <description> without a licence authorising such dealing.

However, I note that <insert any mitigating circumstances>.

On <date> I wrote to you regarding this matter requesting that you make any submissions you believe appropriate.

Your response to this request was received on <date>. I have considered your response however you have not provided any evidence relevant to the matter to persuade me that a breach of paragraph 31(1)(a) has not occurred. **OR** Since you have not disputed this matter I have determined that <controlled person> has failed to comply with paragraph 31(1)(a) of the Act.

#### Next steps

This breach will be reported to the Minister and the Parliament, and published on the ARPANSA website. For further information on the reporting of breaches see ARPANSA's [Compliance Manual](#).

I do not intend to pursue any formal enforcement action in regard to this matter as I am aware that the apparatus/material is appropriately secured and not in use. I am also advised that you are taking steps to apply for a licence.

Yours sincerely

Name of Decision Maker (no titles)  
Position/CEO of ARPANSA

## A8. Finding of breach – self-reported

<insert record # >

Date

Name

Title / position

Organisation

Address line 1

Address line 2

Suburb STATE POSTCODE

Dear < name >

**<Licence holder> - <Facility/Source licence F/SXXXX> - Breach of licence condition – subsection XX of the Australian Radiation Protection and Nuclear Safety Regulations 2018 (the Regulations)**

### Decision

On the matter of <insert details> I find <licence holder> in breach for failing to comply with <relevant section of the Regulations or licence condition # in S/FXXXX>

### Statement of reasons

Your <letter or email or compliance report> dated <date> identified a potential breach of <insert details>. I agree with your assessment that this constitutes a breach of licence condition X for the following reasons: <insert details>

Accordingly, I find <licence holder> in breach of subsection 60(1)/(2) of the Regulations/licence condition X. However, <discussion of mitigating circumstances where appropriate>

Further, I am satisfied with <licence holder's> prompt reporting of the breach under subsection 57(3) of the Regulations and the subsequent corrective action taken/proposed and the timeframe in which action is to be completed.

I do not intend to pursue any formal enforcement action that may be available to me under the Act. However, the breach will be included in ARPANSA's annual and quarterly report to the Minister and the Parliament in accordance with sections 59 and 60 of the Act. The breach will also be published on the ARPANSA website. OR

Under sections 59 and 60 of the Act I am required to report details of breaches of licence conditions to the Minister and the Parliament. The breach will also be published on the ARPANSA website.

For further information on the reporting of breaches see ARPANSA's Compliance Manual.

Yours sincerely

Name of Decision Maker (no titles)

Position/CEO of ARPANSA

## A9. Decision to not find a licence holder in breach

< insert record # >

Date

Name

Title / position

Organisation

Address line 1

Address line 2

Suburb STATE POSTCODE

Dear < name >

**Licence holder – Source/Facility licence S/FXXXX – Non-compliance with a licence condition**

### Decision

In the matter of <description> I find that there has not be a breach of subsection 60(1)/(2) of the Australian Radiation Protection and Nuclear Safety Regulations 2018 (the Regulations).

### Statement of reasons

On <date>, I wrote to you regarding <insert description>

Your response was received on <date>.

After considering your response and the advice provided to me by ARPANSA's General-Counsel, I am of the opinion that <licence holder> <insert reasons eg took all reasonably practicable steps to avoid non-compliance/acted in good faith...>. Therefore, I have decided that on this occasion <licence holder> is not in breach.

Should a similar situation occur in the future a different outcome may result. For further information on ARPANSA's regulatory response see our [Compliance Manual](#).

Yours sincerely

Name of decision maker (no titles)

Position

## A10. Decision to amend a licence under s36 of the Act – impose additional licence condition

<insert record # >

Date

Name

Title / position

Organisation

Address line 1

Address line 2

Suburb STATE POSTCODE

Dear

**Re: Amendment of Facility/Source Licence F/SXXXX**

### Decision

Under section 36 of the *Australian Radiation Protection and Nuclear Safety Act* (the Act) I have decided to amend facility licence F/SXXXX to include the following licence condition:

<state condition>

### Statement of reasons

<Why the additional condition is being imposed>

I have also taken into account the key issues and background information provided to me by my Regulatory Officers; this is enclosed as Attachment A.

### Administrative matters

Your amended facility licence is attached. You should make arrangements to update all records which refer to the licence previously issued on <day/month/year> and replace with the current version. Please ensure that all relevant personnel are made aware of the licence amendment. Please acknowledge receipt of the licence by email to [licenceadmin@arpansa.gov.au](mailto:licenceadmin@arpansa.gov.au).

### Right of appeal

As my decision to amend the facility licence is reviewable under section 40 of the Act, please note that you may make a request to the Minister to reconsider my decision. Any such request must be made in writing and submitted to the Minister within 28 days of the date of this letter. The Minister must reconsider the decision and confirm, vary or set aside the decision. If a response from the Minister is not received within 60 days of the request, this is deemed to be confirmation of my decision. A request for review of the Minister's decision may, in turn, be made to the Administrative Appeals Tribunal.

Yours sincerely

Name of decision maker (no titles)

Position

Cc: **Attachment A - Issues and Background** <subject>

## Attachment 3: Improvement notice template

<Cut & paste onto letterhead from Word shared stationery templates>

# Improvement Notice

Issued under section 80A of the  
*Australian Radiation Protection and Nuclear Safety Act 1998 (the Act)*

**Licence holder:** Click or tap here to enter text.

**Licence Number:** Click or tap here to enter text.

**Location:** Click or tap here to enter text.

**Facility/Source:**

**ARPANSA reference number:** Click or tap here to enter text.

**Date of issue:** Click or tap to enter a date.

**(a) Condition the inspector believes is contravened or is likely to be contravened**

sXX of the ARPANS Act/sXX of the Regulations/Licence condition X of licence F0XXX requires  
<describe the condition>

**(b) Briefly, how the condition is contravened or is likely to be contravened**

<Describe how the condition is contravened or is likely to be contravened>

**(c) Remedy the matters or activities causing the contravention or likely contravention**

<name of licence holder> must take appropriate action to remedy/avoid the contravention and ensure a return to/ongoing compliance.

<NOTE: The LH has prime responsibility for safety; in general the inspector must not tell the licence holder what action to take. However in some cases some specificity may be needed.>

**(d) Time by which the licence holder must comply with this notice**

This notice must be complied with by <Day Month Year>

**(e) Inspector issuing this notice**

<signature>

<insert name>

Inspector appointed by the CEO of ARPANSA  
under section 62 of the Act

## Licence Holder's review rights

### *Review of improvement notice decisions under Section 80C of the Act*

- (1) A licence holder to whom an improvement notice has been given may request that the CEO reconsider a decision made by an inspector under section 80A in relation to the improvement notice (the ***improvement notice decision***).
- (2) The request must be:
  - (a) in writing; and
  - (b) given to the CEO within 28 days of the making of the improvement notice decision.
- (3) The CEO must reconsider the improvement notice decision and confirm, vary or set aside the improvement notice decision.
- (4) The CEO is taken to have confirmed the improvement notice decision under subsection (3) if the CEO does not give written notice of the CEO's decision under that subsection within 28 days of the request.
- (5) Applications may be made to the Administrative Appeals Tribunal for review of a decision of the CEO under subsection (3) to confirm, vary or set aside the improvement notice decision.

## Attachment 4: Event Management Checklist

<b>Date &amp; time of notification</b>				
<b>Date:</b>		<b>Time:</b>		
<b>Commonwealth entity/licence holder</b>				
<b>Licence holder:</b>			<b>Licence number:</b>	
<b>Location:</b>				
<b>Person providing the notification</b>				
<b>Name:</b>				
<b>Position:</b>				
<b>Phone number:</b>			<b>Email:</b>	
<b>Date &amp; time of event</b>				
<b>Date:</b>			<b>Time:</b>	
<b>Radionuclide/s involved:</b>				
<b>Security Category: (aggregate)</b>				
<b>Apparatus involved:</b>				
<b>Description of event</b>				
<b>Site of event (include division, school, building number, street address as relevant)</b>				
<b>Considerations</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Actions taken</b>
Does the event qualify as an accident under ARPANSA Reg Guide?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Has the area been rendered safe and any evidence preserved <sup>14</sup> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Were there any injuries?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Has there been a release of radioactivity into the environment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<sup>14</sup> See [REGULATORY GUIDE: Radiation Incident Site Preservation](#)



Are dose estimates available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Who else has been notified (eg. police, emergency response, Comcare)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>In the event of a transport accident:</b>				
<b>Package Description:</b> <b>Type – Material – Form</b>				
<b>Activity per package:</b>				
<b>Transport category:</b>	Choose an item			
<b>Transport index:</b>				
<b>ACTION TAKEN</b>				
<p>&lt;Summary of actions/refer to CM records/ensure event has been recorded in LAD/reported in quarterly report etc&gt;</p>				

## Document History

**Please note: The web version of this document has appendices, attachments & doc history removed**

	Issue Date	Prepared/Reviewed by	Approved by	Amendment Details
1	July 2015	D Harrison, S Kumar, A Kalaiziovski; J Scott	J Dillich	Original issue (incorporating: REG-MAN-270 v2; REG-COM-SOP-270 v5; REG-COM-SOP-272 v2; REG-COM-SUP-270F v3)
2	Dec 2017	D Harrison, S Kumar, C Nickel, V Mottl, L Castle A Kalaiziovski	J Scott	Document rebranded; risk ranking renamed and relocated into Inspection Manual; reversed order of first two chapters; review process described; timeframe to address breach to be negotiated with LH added to para 1.4; note added to para 1.5 re breaches by controlled persons that are not licence holders; letter and email templates included in attachments; templates added for decision not to find LH in breach, potential breach of prohibitions & finding of breach of prohibition by controlled person; email reminder notices made generic to cover biannual reporting requirement for RP 5&6 sources ; flowcharts in Appendix A & B updated
3	June 2018	C Nickel	J Scott	P3 – section 1 paragraph1: The Regulatory Officer (RO) will enter any non-compliance into LAD under the Breach section. P8 - Section 1.4 insert: The RO must enter the details of the breach into LAD, the corrective actions plan must be recorded in the register on <u>ISSAC</u> . If a PNC is found not to be a breach, the LAO will update LAD to reflect this. Once the actions are followed up, the RO must update the Register to close out the action.
4	Sept 2018	J Scott A Kalaiziovski	J Scott	Section <i>Monitoring Personal Dosimetry Reports</i> has been made an appendix - Appendix A. The document was reviewed in preparation for publication on the ARPANSA website (web-version ARPANSA-REG-COM-MAN-270W)
4.1	March 2019	D Harrison	N/A	Updated to references 2018 Regulations; reformatted
4.2	May 2020	D Harrison	N/A	Moved to IMS – changed doc ID from REG-MAN-270
5	Feb 2021	L Castle; D Harrison; A Kalaiziovski; A McCormack; V Mottl; C Nickel	J Scott	Aligned with Regulatory Activities Policy; Updated to remove discretion to report breaches; Updated to include guidance on how to publish regulatory performance on the web; Updated to include graded approach pyramid; Moved <i>graded approach to non-compliance</i> as new section 1 & renumbered other sections accordingly; guidance on issuing an improvement notice (prev REG-ENF-SUP-290B) included as new section 5; Incident notification & management process included as new section 4, workflow as Appendix C and event checklist as Attachment 4; Review and approval included as Attachment 5; guidance on citing legislation (formerly REG-DC-SUP-150A) added as new Attachment 6; changes to when legal advice should be sought - advice on how and when to seek it; slight change to title; the term 'potential' dropped from non-compliance
5.1	Nov 2021	D Harrison	N/A	Added sentence to letter templates that the breach will be published on the ARPANSA website
6	May 2022	D Harrison	J Scott	Enhanced instructions in section 2.4 for publishing licence holder performance including sample media statement
7	Jan 2023	D Harrison	S Sarkar	Improvements made to process for publishing licence holder performance in para 2.5 including a verification step