Australian Government
Australian Radiation Protection and Nuclear Safety Agency

arpansa

REGULATORY SERVICES

COMPLIANCE MANUAL

Guidance for regulatory officers on promoting compliance and applying a graded approach to enforcement

ARPANSA-GDE-1117WEB v5

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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)[1]. 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[2] 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 Licensing and Assessment Manual describes the processes for review and assessment of applications.

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[1] 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.

[2] Graded Approach: For a system of control, such as a regulatory system or a safety system, a process or a method in which the stringency of the control measures and conditions to be applied, to the extent practicable, with the likelihood and possible consequences of, and the level of associated with, a loss of control.

In this manual:

Management system elements: *<not included in online version of this manual>*

What's changed from the previous version of this manual?

- Aligned with ARPANSA's Regulatory Activities Policy
- Updated graded approach 'pyramid'
- Included information on how regulatory performance will be published on web
- Removed discretion to not name licence holders for minor breaches
- Self-monitoring and reporting is promoted and will be highlighted on web
- Moved graded approach to non-compliance to new section 1 and renumbered other sections accordingly
- Included event notification and management as new section 4
- Included guidance on issuing an improvement notice as new section 5.

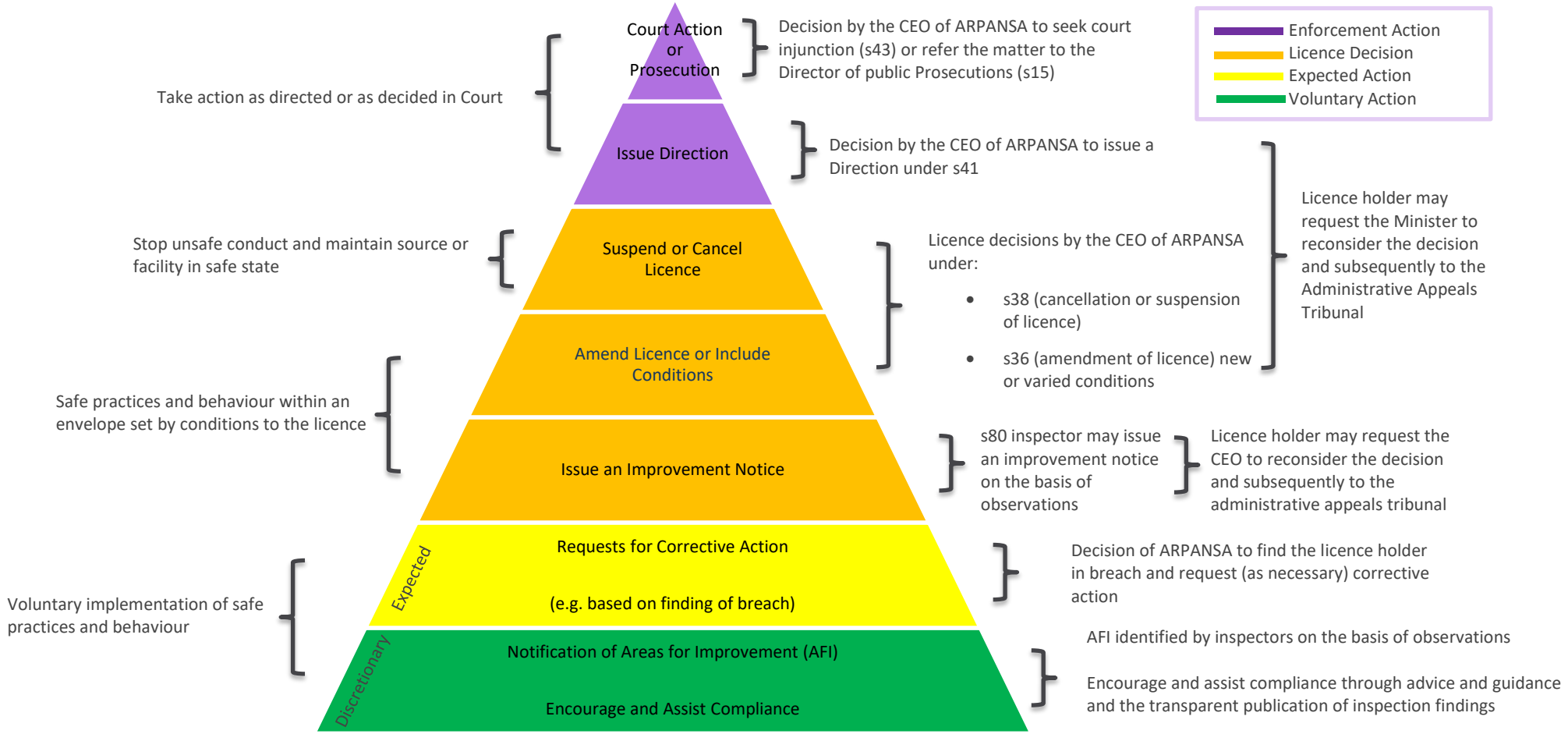

Figure 1. ARPANSA's graded approach to promoting and enforcing compliance.

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 AFIs
- **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 aims to promote licence holder compliance to the extent possible. ARPANSA engages with licence holders by hosting information sessions such as the annual licence holder forum and meet the regulator forums, and conducts 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.

ARPANSA publishes regulatory guides as well as national codes, standards and guides that make reference to international standards. ARPANSA also publishes inspections reports and the annual report of the Australian Radiation Incidents Register on its website all of which contribute to promoting and encouraging compliance.

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

Areas for improvement (AFI) may be identified during an inspection or assessment that could lead to non-compliance[3] 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.

[3] 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.

Under section 40 of the Act an eligible person who has had their licence suspended or cancelled 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 and 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[4]. Response is sought either in an email accompanying the inspection or investigation report or using the appropriate email template.

The RO will enter any non-compliance into the Licence Administration Database (LAD).

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 an explanatory email to the CEO or delegate to either:

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

Draft breach letters undergo the following review and approval process prior to sign-off:

1) **Peer review** by another RO (recommended).
2) **Director review –** The directors of Source Safety and Security and Facility Safety are responsible for checking 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 –** After the draft is cleared by the section director the RO seeks a quality review. The request and links to relevant documents are sent to reg_quality@arpansa.gov.au. Advice will be provided on the draft letter to the RO and section director. Acceptance of advice is at the discretion of the section director.
4) **Regulatory officer/lead inspector –** Conducts a final check to make sure the original intent and facts of the matter are correct.

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

5) **Director/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.

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 and copied to the relevant director. Advice will usually be provided within 3 working days.

2.2 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 and safety consequences

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

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 as soon as practicable to rectify non-compliance.

- 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 themself 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 cause other undesired consequences.

2.3 Approval and issue of breach finding

Following all necessary reviews the final breach letter is signed (electronically) by the Chief Regulatory Officer or the CEO. The letter should include a timeframe negotiated with the licence holder for corrective actions to be completed unless the licence holder has already fully addressed them.

The RO must enter the details of the breach into LAD and the corrective action plan must be recorded in the register in ISAAC[5]. Once the actions are followed up the RO must update ISAAC and LAD to close out the matter.

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

2.4 Publishing compliance performance

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

Should the licence holder identify and report a breach this will be color-coded to highlight proactive practices in contrast to breaches identified by ARPANSA through an inspection or other means or from information shared by a third party.

Security breaches will not be published until the vulnerability has been addressed to the satisfaction of both ARPANSA and the licence holder. In some cases the breach may not be published.

[5] ISAAC is the ARPANSA intranet

The following information will be published about breaches:

- The nature of the breach in terms of which section of the Regulations
- The nature of discovery – i.e. inspection, self-reported, third party – these will be colour-coded to highlight self-identified breaches
- Whether or not there are significant implications for safety or security – these will be colour-coded to highlight the difference
- Type of intervention or enforcement action taken by ARPANSA as a result of the breach
- The resolution or status of corrective action – these will be colour-coded to differentiate between open and closed actions.

Table 1 presents an example of how compliance performance *may* be presented on the web.

Table 1: Publishing performance on the web

Licence Holder	Finding	Regulation breached	Nature of discovery	Significant implications for safety or security?	Licence decision or enforcement action	Resolution or status of action	Resolution or close out date
Licence holder A	Good practice	n/a	Inspection (details)	n/a	n/a	n/a	n/a
Licence holder B	Breach	s60(1)	Self-identified	Yes	Improvement notice issued	Closed (details)	DDMMYYYY
Licence holder C	Breach	s76(1)	Self-identified	No	n/a	Open	n/a
Licence holder D	Breach	s65(2)(a)	Third-party	Yes	Imposed additional licence conditions	Closed (details)	DDMMYYYY

Note: purple text indicates a hyperlink to the inspection report or a paragraph describing the resolution or implementation status

2.5 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. Thus 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.

2.6 Record keeping

Details of all breaches must be entered into LAD and the ARPANSA Intranet and the web updated when the licence holder closes out the required action.

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; however, 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 and copied 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[6] (ARIR) the RO should complete the online form use the ARPANSA Connect portal[7] 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 consequences the RO should contact the branch INES Officer (or deputy) for assessment of the event on the International Nuclear and Radiological Event Scale (INES). Events with a rating of INES Level 2 or above are expected to the 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 and 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.

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.

[6] See Schedule 13 of the National Directory for Radiation Protection

[7] The RO must be a registered user to access the portal.

4. Event notification and management

When notification of an event[8] 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 an accident and which requires notification within 24 hours see *Regulatory Guide: Reporting an Accident*.

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.

This 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 Notification management process (see flowchart in Appendix C)

a) 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[9] as soon as possible. Depending on the nature of the event[10] the RO may also consider advising ARPANSA's Monitoring and Emergency Response (MER) Section/or the duty officer in accordance with the ARPANSA Incident Management Plan.

b) 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.

c) The CRO should assess the event and any potential consequences and make a decision on whether regulatory response is required.

d) Where appropriate the lead inspector (or alternate) should advise the licence holder of the need to preserve the incident site as per Regulatory Guide: Radiation incident site preservation.

e) 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.

f) 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.

g) 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.

h) 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 and Radiological Event Scale (INES) and any required reporting – see paragraph 3.5.

i) The CRO should convene a Branch Executive (BE) meeting as soon as practicable that includes the lead inspector and a representative from the Office of the Chief Executive Officer (OCEO) and as

[8] 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.

[9] 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.

[10] Depending on the significance of the event and its potential consequences, the jurisdiction may request support from MER under the ARPANSA Incident Management Plan.

required from MER. In such cases the lead inspector should provide a brief dot point summary of basic information to the OCEO at media@arpansa.gov.au or 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[11] and longer term[12] 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.

j) 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[13].

k) 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) 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 and 3.5.

[11] This may include augmented inspection, investigation, improvement notice, direction, or some other action necessary to maintain safety such as suspension of licence

[12] This may include a licence amendment to limit the authorisation or impose additional licence conditions

[13] Inspection Manual

[13] 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 and 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 and content of 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 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.

5.4 Publishing information about improvement notices

Information about an improvement notice and its close out will be published as per paragraph 2.4 and Table 1.

5.5 Record keeping

Information about the improvement notice must be saved in the records management system and LAD. 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.

Notification of a high dose

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.