

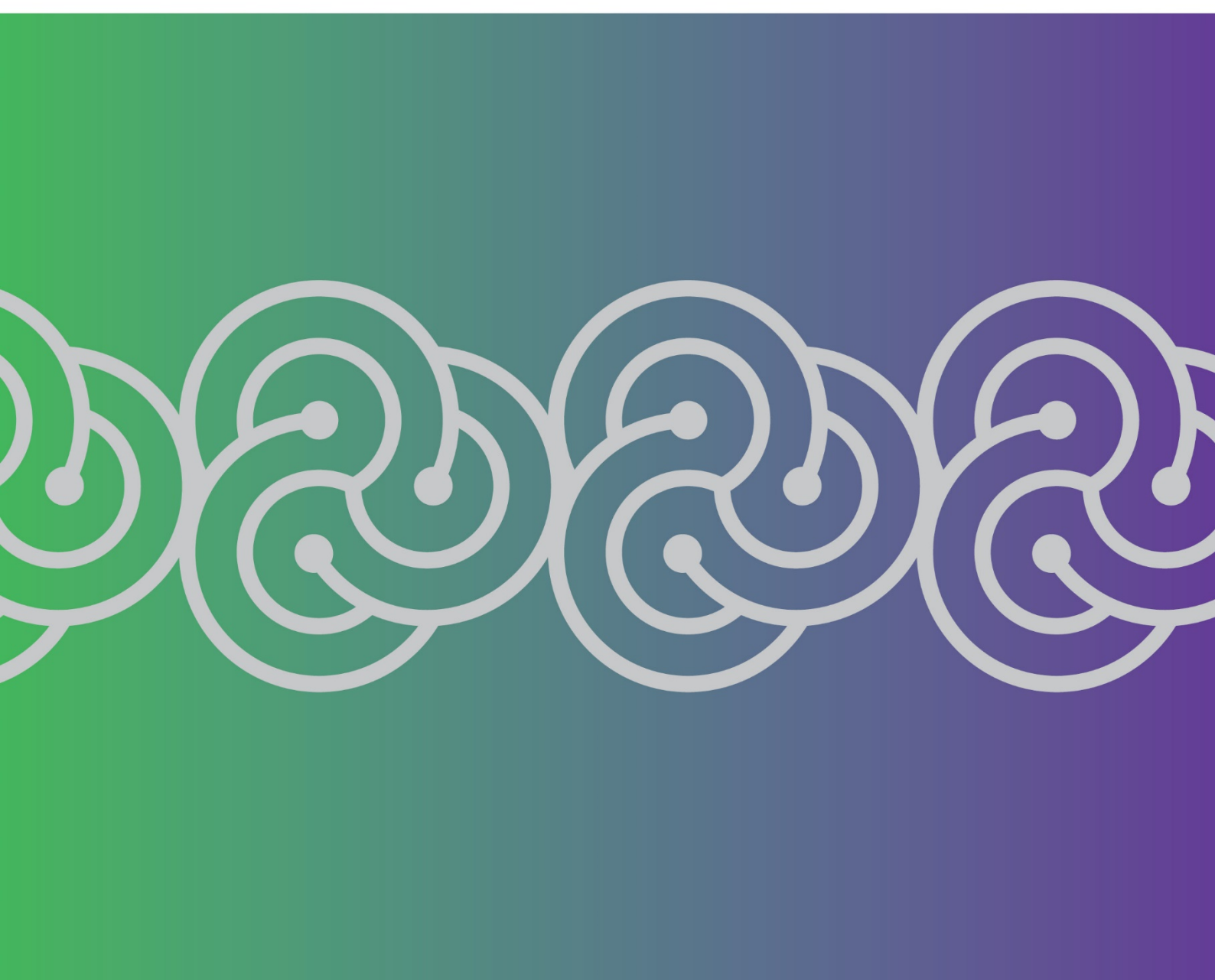


Australian Government
**Australian Radiation Protection
and Nuclear Safety Agency**



Regulatory Guide

Graded approach to dealing with licence holder non-compliance



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REGULATORY SERVICES

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1. Introduction

ARPANSA carries out its functions in accordance with statutory requirements and this guide cannot override those requirements. Nothing in this document should be taken to bind ARPANSA or the government to any particular course of action.

ARPANSA adopts a graded and risk-based approach to compliance and enforcement. When non-compliance is identified, the regulatory response will be commensurate with its significance.

Non-compliance may be reported by the licence holder or identified through an inspection or report to ARPANSA. In all cases, the licence holder is given an opportunity to respond and implement corrective action before a determination of breach is made.

2. Determining the regulatory response

In deciding the most appropriate regulatory response to non-compliance, regulatory officers may take into account the following:

Safety consequences

Whether there were safety consequences such as onsite/offsite releases of radioactivity, on-site/off-site radiation exposures, pollution of the environment, injury, loss of significant safety barriers, loss of shielding, loss of control of radioactive material, or radiological emergency. Situations identified as having the potential to have a negative impact on safety should also be considered.

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 the licence holder to identify and fix its own problems. Such behaviour reflects a healthy and robust safety culture.

For non-compliance reported by the licence holder, considerations may include:

- 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.

For non-compliance identified by ARPANSA, considerations may include:

- 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.

Impact on the regulatory process

Any licence holder action that represents a challenge or barrier to ARPANSA fulfilling its regulatory functions may be significant. Such non-compliances 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, regulatory officers will consider factors such as:

- whether the failure impeded or undermined regulatory action or ARPANSA's regulatory functions
- the position of the individuals involved in the failure and the reasonableness of the failure given their position and training.

Cooperation and disclosure

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

Level of intent

Whether the non-compliance was inadvertent or wilful. Acts of wilful violation will be regarded as serious breaches. Examples of such acts include deliberate intent to violate, providing false information, or reckless disregard for statutory requirements. The basis for issuing a licence includes the capacity of a licence holder to comply with the legislation and licence conditions. ARPANSA therefore treats wilful violation of legislation as being of particular concern.

Wilfulness should not be confused with acts of carelessness or inadvertent errors in information provided to ARPANSA. Consideration will be given to the position and responsibilities of the person submitting the information, the significance of the action, and any advantage gained as a result of the action.

Compliance history

Whether there have been other recent non-compliances of a similar nature and enforcement actions taken against the licence holder.

Whether the non-compliance indicates systemic issues that may pose ongoing compliance concerns.

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.

Impact on the community and/or the environment

The degree to which the non-compliance, or the result of the non-compliance, adversely impacted or had the potential to impact on the community or the environment.

3. Regulatory response

There are a range of regulatory responses available to ARPANSA to address non-compliance. The following diagram describes ARPANSA's range of responses.

In general, the enforcement process has three basic steps. The non-compliance must be identified. Next, ARPANSA must evaluate the significance of the non-compliance. Finally, ARPANSA must respond to the non-compliance.



Figure 1: Graded response to non-compliance

Regulatory response will commence at the most appropriate level in Figure 1 depending on the circumstances of the non-compliance, taking into account the criteria in section 2, and will be proportionate to any risks posed by the non-compliance. The initial regulatory response will most often be at the lowest level, but may be escalated if a return to compliance is not achieved.

Encourage and assist compliance

ARPANSA may provide information to encourage and assist a licence holder return to compliance.

ARPANSA may accept a written commitment from the licence holder that action will be taken to rectify non-compliance within a defined timeframe. If resolution efforts prove unsuccessful in achieving a return to compliance, the regulatory response may be escalated.

Improvement notice (s. 80A)

Under section 80A of the Act, an inspector may issue an improvement notice in response to non-compliance or where non-compliance is likely to occur.

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 the lowest level 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 areas for improvement that are considered likely to lead to non-compliance. See *Guide for Regulatory Officers on the use of Improvement Notices*.

Under section 80C of the Act, a licence holder who has been issued with an improvement notice may request that the CEO review the decision.

Direction by the CEO of ARPANSA (s. 41)

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 request that the Minister review the decision.

Amendment of licence (s. 36)

Under section 36 of the Act, the CEO may impose additional licence conditions, remove or vary licence conditions that were imposed by the CEO or extend or reduce the authority granted by the licence. Depending on the nature of the non-compliance, it may be considered appropriate to amend the licence to facilitate compliance or address any new risks that have been identified.

Suspension or cancellation of licence (s. 38)

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 by the licence holder or by a person covered by the licence; where there are reasonable grounds to believe that an offence has been committed against the Act or Regulations by the licence holder or by a person covered by the licence, or where the licence was obtained improperly.

Suspension or cancellation of a licence could have serious implications for the licence holder's continued business or operations. When making decisions about such action, this will be taken into account however the overriding consideration is protecting the health and safety of people and the environment.

When making a decision whether or not to reissue a licence that had been suspended or cancelled ARPANSA will take into account the licence holder's compliance history. Where the licence has been cancelled, the licence holder will be required to make a new application.

Under section 40 of the Act, a licence holder may appeal certain licence decisions made by the CEO including a decision to amend, suspend or cancel a licence.

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 ARPANSA in light of the facts and the [Prosecution Policy of the Commonwealth](#).

Injunction

Under section 43 of the Act, the CEO can make an application to the Federal Court of Australia for an injunction in circumstances where a controlled person has engaged, is engaging, or proposing to engage in any conduct that would be an offence against the Act, or where there has been or is proposed to be a refusal or failure to do a thing, which refusal or failure would be an offence against the Act.

4. Administrative matters

Under sections 59 and 60 of the Act, details of any breach of licence conditions, directions given by the CEO, and improvement notices issued by an inspector must be included in ARPANSA's annual and quarterly reports to the Minister.

A licence holder's non-compliance with a licence condition is a breach of section 30(2) or section 31(2) of the Act and must be reported. However, the way in which such breaches are reported will vary, depending on the circumstances of each particular case. ARPANSA has adopted a graded approach to the reporting of

breaches, similar to the graded response to non-compliance, where the amount of detail reported is dependent on the significance of the breach.

When non-compliance is identified, the licence holder is given an opportunity to respond. The response is taken into account along with the criteria in Section 2 of this guide to determine not only the regulatory response but the safety or security implications of the breach and hence how the breach will be reported.

Where safety and security implications are considered to be minor the breach is reported as part of aggregated statistical data for similar breaches across all licence holders; the nature of the breach is described but the licence holder is not identified. For breaches with significant safety or security implications, the details of the breach include the identity of the licence holder.

Examples of breaches with minor safety or security implications may include late submission of a quarterly report or failure to adhere to a timeframe imposed by a licence condition. However such breaches may be considered of greater significance after taking into account the criteria detailed in Section 2 of this guide. For example, multiple or repeated breaches with minor safety or security implications may result in escalation.

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.