



Australian Government

Australian Radiation Protection and Nuclear Safety Agency

ARPANSA

Protecting people and the environment
from the harmful effects of radiation

Regulator Performance Framework



**Self-Assessment Report
2015-16**

| | |
|---|-----------|
| Executive Summary | 4 |
| <i>Summary of assessment</i> | <i>4</i> |
| <i>Performance Improvement Actions Identified</i> | <i>5</i> |
| 1 Introduction..... | 6 |
| 1.1 <i>The Agency.....</i> | <i>6</i> |
| 1.2 <i>The Report</i> | <i>6</i> |
| 1.3 <i>Methodology.....</i> | <i>7</i> |
| 2 Performance Assessment..... | 9 |
| 2.1 <i>KPI 1 – Regulators do not unnecessarily impede the efficient operation of regulated entities</i> | <i>9</i> |
| 2.1.1 Measures..... | 10 |
| 2.1.2 Approved evidence metrics for KPI 1 | 10 |
| 2.1.3 Other evidence to indicate compliance with KPI 1 | 10 |
| 2.1.4 Analysis of evidence presented | 11 |
| 2.1.5 Conclusion for KPI 1 | 12 |
| 2.1.6 Self-assessed rating of performance against KPI 1 – 2015-16..... | 12 |
| 2.1.7 Actions for improving performance against KPI 1 | 12 |
| 2.2 <i>KPI 2 – Communication with regulated entities is clear, targeted and effective</i> | <i>13</i> |
| 2.2.1 Measures..... | 14 |
| 2.2.2 Approved evidence metrics for KPI 2 | 14 |
| 2.2.3 Other evidence to indicate compliance with KPI 2 | 14 |
| 2.2.4 Analysis of evidence presented | 15 |
| 2.2.5 Self-assessed rating of performance against KPI 2 – 2015-16..... | 16 |
| 2.2.6 Actions for improving performance against KPI 2 | 16 |
| 2.3 <i>KPI 3 – Actions undertaken by regulators are proportionate to the regulatory risk being managed.....</i> | <i>17</i> |
| 2.3.1 Measures..... | 18 |
| 2.3.2 Other evidence to indicate compliance with KPI 3 | 18 |
| 2.3.3 Analysis of evidence presented | 19 |
| 2.3.4 Self-assessed rating of performance against KPI 3 – 2015-16..... | 20 |
| 2.3.5 Actions for improving performance against KPI 3 | 20 |
| 2.4 <i>KPI 4 – Compliance and monitoring approaches are streamlined and co-ordinated.....</i> | <i>21</i> |
| 2.4.1 Measures..... | 22 |
| 2.4.2 Approved evidence metrics for KPI 4 | 22 |
| 2.4.3 Other evidence to indicate compliance with KPI 4 | 22 |
| 2.4.4 Analysis of evidence presented | 23 |

| | | |
|-------------------|---|-----------|
| 2.4.5 | Self-assessed rating of performance against KPI 4 – 2015-16..... | 24 |
| 2.4.6 | Actions for improving performance against KPI 4 | 24 |
| 2.5 | <i>KPI 5 – Regulators are open and transparent in their dealings with regulated entities.....</i> | <i>24</i> |
| 2.5.1 | Measures..... | 25 |
| 2.5.2 | Approved evidence metrics for KPI 5 | 25 |
| 2.5.3 | Other evidence to indicate compliance with KPI 5 | 25 |
| 2.5.4 | Analysis of evidence presented | 26 |
| 2.5.5 | Self-assessed rating of performance against KPI 5 – 2015-16..... | 27 |
| 2.5.6 | Actions for improving performance against KPI 5 | 27 |
| 2.6 | <i>KPI 6 – Regulators actively contribute to the continuous improvement of regulatory frameworks.....</i> | <i>27</i> |
| 2.6.1 | Measures..... | 28 |
| 2.6.2 | Approved evidence metrics for KPI 6 | 28 |
| 2.6.3 | Other evidence to indicate compliance with KPI 6 | 29 |
| 2.6.4 | Analysis of evidence presented | 29 |
| 2.6.5 | Conclusions | 30 |
| 2.6.6 | Self-assessed rating of performance against KPI 6 – 2015-16..... | 30 |
| 2.6.7 | Actions for improving performance against KPI 6 | 30 |
| 3 | Overall Assessment | 31 |
| 3.1 | <i>Analysis of evidence.....</i> | <i>31</i> |
| 3.2 | <i>Overall self-assessed rating of performance – 2015-16.....</i> | <i>31</i> |
| 3.3 | <i>Performance improvement actions identified.....</i> | <i>31</i> |
| 4 | Concluding remarks | 33 |
| Appendix A | | 34 |
| | <i>Facility licence holders:</i> | <i>34</i> |
| | <i>Source licence holders:.....</i> | <i>34</i> |
| Appendix B | | 36 |

Executive Summary

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) regulates safety and security of radiation sources and facilities and nuclear installations owned or operated by Commonwealth Government entities.








Summary of assessment

This review was the first formal assessment of ARPANSA against the Key Performance Indicators (KPIs) outlined in the Government Regulator Performance Framework (RPF).

The assessment found a high level of commitment to the values of the RPF. A number of improvements were identified which may help to further improve the efficient and effective regulation of Commonwealth entities dealing with radiation.

It was found that some of the Performance Indicators (PIs) which formed the agreed metrics did not directly align with the KPIs. It was also found that the KPIs were not broad enough to fully capture regulatory performance against the framework. Considering a broader range of evidence, the team concluded that defining more representative PIs and making targets more realistic may improve ARPANSA's performance against the KPIs.

The results against each KPI are presented in the table below.

| KPI | Summary of analysis | Rating of Performance |
|---|---|---|
| KPI 1 – Regulators do not unnecessarily impede the efficient operation of regulated entities | Inspections are scheduled and notified in advance and timelines are typically set and adhered to. |  Good |
| KPI 2 – Communication with regulated entities is clear, targeted and effective | A number of positive communication initiatives are in place. However, communication including timelines, guidance documents, and skills could be improved. |  Very Good |
| KPI 3 – Actions undertaken by regulators are proportionate to the regulatory risk being managed | ARPANSA has implemented a risk based inspection schedule, and conducts regular site visits and licence holder forums. |  Good |
| KPI 4 – Compliance and monitoring approaches are streamlined and co-ordinated | ARPANSA has implemented a graded approach focusing on performance deficiencies rather than non-compliances and formal enforcement options. Standardisation of inspection and data recording could be improved. The PI used for this KPI may not accurately reflect performance. |  Good |
| KPI 5 – Regulators are open and transparent in their dealings with regulated entities | A significant number of ARPANSA documents including inspection reports are available online. However, transparency of some processes and data could be improved. The PIs may not adequately reflect the intentions of the KPI. |  Good |
| KPI 6 – Regulators actively contribute to the continuous improvement of regulatory frameworks | ARPANSA has a dedicated continuous improvement team that analyses performance regularly and rigorously. The PIs used should be reviewed to ensure alignment with the KPI. |  Very Good |
| Overall Assessment | |  Good |

Performance Improvement Actions Identified

The following actions were recommended for consideration:

- Review ARPANSA's PI targets to ensure that goals are achievable, realistic and align better with the intention of the RPF KPIs.
- Improve standardisation of inspections, outcomes and approaches through training and teamwork strategies.
- Further improve communication with licence holders through increased feedback and improved guidance material.

1 Introduction

1.1 The Agency

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is a portfolio agency of the Department of Health, and is prescribed as a non-corporate Commonwealth entity under the *Public Governance, Performance and Accountability Act 2013*. ARPANSA is the Australian Government's primary authority on radiation protection and nuclear safety.

The *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act) establishes the CEO of ARPANSA as the safety regulator of Commonwealth entities engaged in nuclear or radiation activities. The object of the Act is to protect people and the environment from the harmful effects of radiation.

The Act was amended in late 2015 to improve the clarity of regulatory requirements related to legacy sites and for contractors working with Commonwealth agencies. It also updated the language to be more consistent with nationally and internationally accepted terms, to make minor changes to enhance regulatory administration, and provide additional options to enhance the graded approach to non-compliance.

The CEO has both regulatory and non-regulatory functions. The non-regulatory functions include providing scientific advice, radiation monitoring and calibration services, and undertaking research. The Regulatory Services Branch (RSB) of ARPANSA assists the CEO perform his regulatory functions. The RSB has primary responsibility for regulating the safety and security of Commonwealth facilities and sources. In addition to licensing, compliance monitoring and enforcement, the RSB also investigates accidents and incidents, and prepares regulatory guidance. RSB draws on expertise from other functional units of ARPANSA as required and appropriate.

To meet the object of the Act, ARPANSA is responsible for the safety regulation of 50 nuclear and radiation facilities under 37 facility licences and approximately 70,000 radiation sources under 57 source licences. The complexity of these licensed activities range from the 20 megawatt OPAL research reactor to low risk items such as x-ray baggage scanners and handheld radiofrequency and ultraviolet sources. A full list of the 45 Commonwealth entities that held licences as at 30 June 2016 is provided in Appendix A.

Regulatory activities include the assessment and issuing of new licences, amendment of licences, assessment of changes significant to safety, and monitoring compliance with the Act, Regulations and licence conditions.

Resources for compliance monitoring and inspection are allocated using a risk-based graded approach. This includes leveraging short-term contractual arrangements, where appropriate, to ensure the availability of specialist skills and knowledge. Costs of ARPANSA's regulatory operations are recovered through licence application fees and annual licence charges.

1.2 The Report

In October 2014, the Australian Government released the Government Regulator Performance Framework (RPF), ISBN 978-925237-08, as part of the commitment to reduce

unnecessary or inefficient regulation imposed on individuals, business and community organisations. In December 2014, ARPANSA aligned its Regulatory Delivery Model with the RPF to emphasise openness, clarity, reliability, efficiency and effectiveness.

ARPANSA has sought to improve communication and consultation with licence holders while emphasising their prime responsibility for safety. ARPANSA strives to continuously improve the quality and consistency of its regulatory services and implementation of the graded approach to risk. The structure of the RSB was altered creating new functional areas, including a section dedicated to performance monitoring and continuous improvement, and another focusing on regulatory services meeting international excellence, including the promotion and use of trusted international standards in regulatory decision making.

The framework established by the RPF includes a common set of six Key Performance Indicators (KPIs) to allow for a comprehensive assessment of regulator performance and engagement with stakeholders. ARPANSA obtained ministerial approval for a set of 12 quantitative Performance Indicators (PIs) which relate to the six RPF KPIs. Data collection began in March 2015. A list of data sources is provided in Appendix B.

The 12 ARPANSA PIs were developed in parallel with the Regulatory Delivery Model and had not been previously tested. This first self-assessment identified that some PIs are not adequately aligned with the RPF KPIs and some individual targets have been set at inappropriate levels. In these cases, new targets have been implemented for the 2016-17 financial year. The quantitative PIs alone were insufficient to fully assess regulatory performance against the RPF KPIs, therefore additional evidence was considered in the self-assessment.

In March 2016, RSB developed a self-assessment method and plan to meet the requirements of the RPF. The assessment plan sets out to support a continuous improvement cycle by the critical analysis of regulatory performance and identification of good practices and areas for improvement. This report outlines the implementation of the ARPANSA Focussed Self-Assessment Plan 2016 and provides details of the assessment outcomes.

1.3 Methodology

This report is based on the outcomes of a self-assessment audit undertaken from July 24 to July 29, which included fieldwork. It considered all ARPANSA regulatory activities undertaken in the period from 1 July 2015 to 30 June 2016.

Performance against the framework was assessed by a five-person team that included two members external to ARPANSA and one ARPANSA staff member external to RSB.

Team Leader

- John Ward – Manager Continuous Improvement, Regulatory Services Branch, ARPANSA

Team Members

- Alexander Adams Jr – Chief of the Research and Test Reactors Licensing Branch, US Nuclear Regulatory Commission

- Paula Berghofer – Manager Regulatory Affairs, Australian Nuclear Science and Technology Organisation (ANSTO), Lucas Heights NSW
- George Savvides – Chief Financial Officer and Head of Corporate Office, ARPANSA
- Francesca Wigney – Senior Regulatory Officer, Facility Licensing Section, Regulatory Services Branch, ARPANSA

The assessment focussed on a review of performance against the 12 RSB PIs to ensure that the intent of the six RPF KPIs continues to be met and to verify that quantitative data was accurately recorded.

The team set out to identify Areas for Improvement (AFI) to assist ARPANSA improve the accuracy of the PIs as well as regulatory outcomes.

To provide qualitative information on performance, the assessment team also examined underlying data and information by:

- reviewing various data sources (e.g. inspection data and findings, surveys, records)
- reviewing the inspection processes and procedures
- interviewing ARPANSA staff and management
- observing a source licence and a facility licence inspection
- interviewing more than 12 staff and management from two licence holders.

A list of data and documents provided to the assessment team is in Appendix B.

2 Performance Assessment

2.1 KPI 1 – Regulators do not unnecessarily impede the efficient operation of regulated entities

ARPANSA follows the internationally agreed principle that the prime responsibility for protecting people and the environment rests with the licence holder. ARPANSA has developed guidelines that assist licence holders to develop their own plans and arrangements to fulfil this responsibility and to demonstrate compliance with the Act and Regulations.

ARPANSA strives to create a regulatory environment that is risk-informed, proportionate and effective. Regulatory guidance has been increased and enhanced using the ARPANSA website, and through meetings, forums and workshops. ARPANSA has streamlined its risk-based approach to regulation, especially for low hazard activities.

ARPANSA receives various types of applications for nuclear and radiation facilities and sources, including licences for new activities, requests for approval to construct items important to safety, requests for safety-significant changes to activities, transfer or disposal of sources, and transport of radioactive material. The scope and depth of documentation needed to demonstrate safety depends on the risk of the proposed activity. ARPANSA strives to assess applications in a timely manner and within a timeframe agreed with the applicant. The timeframe depends on the nature and complexity of the application and takes account of the licence holder's programs and priorities.

ARPANSA maintains a risk-based inspection program. Inspections of licensed activities follow a three-year schedule for facilities and a five-year schedule for sources. The schedule identifies the scope of each inspection in terms of [Performance Objectives and Criteria](#) made available to licence holders via the ARPANSA website. These were developed based on international best practice to inform licence holders and the public of ARPANSA's safety and security expectations. They provide a comprehensive list of features, controls and behaviours that contribute to safety, arranged into eight baseline modules and three cross cutting modules.

Publishing the performance objectives and criteria increases ARPANSA's transparency and, together with the schedule, allows the licence holder to prepare for an inspection. The specific date for inspections is agreed with the licence holder well in advance of the two-week formal notification period. Conformance to the inspection schedule is monitored.

Fees and charges are set in legislation. To ensure that financial impacts to a licence holder is fair and appropriate, ARPANSA has undertaken a cost recovery project to ensure that financial burden on licence holders is proportionate to the cost of regulation. The project aims to improve implementation of the Australian Government Cost Recovery Guidelines, which establish that those who create the need for regulation should incur the costs.

Phase 1 has seen an effective Cost Recovery Tracker established that allows ARPANSA to account for direct regulatory activities. This led to the introduction of fixed annual licence charges for ARPANSA's three largest licence holders. Phase 1 resulted in a total reduction of \$384,000. Having successfully implemented Phase 1, the ARPANSA Cost Recovery Team is moving into Phase 2 of the project that strives to expand cost recovery to make ARPANSA

more fiscally transparent and to make annual charges reliable and predictable for smaller licence holders.

2.1.1 Measures

Avoid unnecessary intervention in the operations of regulated entities.

2.1.2 Approved evidence metrics for KPI 1

| Indicator | Evidence | Comment |
|---|--|---|
| PI 1.1 Percentage of inspections conducted in accordance with established inspection schedule (schedule adherence). | ● 90% of inspections in accordance with schedule – target (90%) met. | <ul style="list-style-type: none"> All deviations from the schedule were explained. |
| PI 1.2 Percentage of applications assessed within agreed licence holder expectations. | ● 81% of assessments within agreed timeframes – significant progress towards target (90%). | <ul style="list-style-type: none"> Agreed timeframes were considered important, as they provide certainty to licence holders. Information for some applications was not recorded as required and improvement is needed. Some Licence holder representatives reported delays between the receipt of an application and setting a date for completion which is not captured by this PI. The 90% target was too demanding due to uncertainties in the quality of application and assessment process. A target of 75% will be applied in the future. |

2.1.3 Other evidence to indicate compliance with KPI 1

ARPANSA, through alignment with international standards, ensures that best practice regulation informs decision-making and promotes regulatory certainty. The use of international standards is important in meeting community expectations for nuclear and radiation safety and provides confidence in ARPANSA’s regulatory processes and outcomes. It allows a licence holder to adopt emerging technologies and facilitates the movement of knowledge and expertise internationally. To achieve this alignment, ARPANSA works closely with international organisations such as the International Atomic Energy Agency (IAEA) and regulatory agencies in comparable OECD countries. ARPANSA staff are actively involved in the development of international safety standards.

Using this approach, ARPANSA has recently developed guidance such as a regulatory guide on licensing a facility for the disposal or storage of radioactive waste, an accompanying stakeholder information guide, and interpretation of the legislative term ‘significant implications for safety’.

ARPANSA has a consultative approach to the development of regulatory guides. This is subject to PI 5.2 ([See section 2.5](#)). ARPANSA has published a wide range of regulatory guidance on its [Regulation and Licensing](#) webpages.

Through the IAEA Integrated Regulatory Review Service (IRRS), ARPANSA’s regulatory processes have been subject to international peer review. A second review is scheduled for 2018. ARPANSA staff also participates in the IRRS review of other nuclear and radiation

regulatory bodies. This international cooperation helps to inform and streamline ARPANSA's approach to regulation and embed good regulatory practices.

ARPANSA undertakes regular meetings, forums and site visits to explain regulatory requirements to licence holder representatives and to gain understanding of operational needs. This informs the licence holder how ARPANSA conducts its regulatory business. During the reporting period, 25 information-sharing meetings and 83 site visits were undertaken.

2.1.4 Analysis of evidence presented

These two PIs only partially capture the potential impact of regulation on the efficient operation of regulated entities.

PI 1.1 measures adherence to inspection schedules. A 90% result reflects well on ARPANSA's performance in this area. Deviations from the schedule were communicated to the licence holder in advance with explanation. This is good practice and demonstrates a commitment to the intent of the RPF, in terms of predictability and transparency of regulatory services.

The intent of the original PI covered facility inspections only. In practice, ARPANSA also includes this measure for source inspections. The assessment team considered this extended coverage to be appropriate. The PI stipulates a three-year inspection program which is in place for facilities. The approach to the source inspection schedule was adjusted during the year to take a more graded approach and align with the hazard of the source. Inspection frequencies typically range from once a year for the more hazardous facilities to once every five years for very low hazard sources. While this was considered in the analysis, it was not originally captured by the requirement of the PI.

Licence holder representatives reported that there have been no changes to the inspection schedule in the 18 months following implementation of the current [Regulatory Delivery Model](#). This may be considered a good outcome as it provides consistency for licence holders. However, because facility risks are regularly reviewed, the assessment team expected to find that inspection frequencies for some licence holders had been revised to reflect compliance maturity and reward good performance with reduced regulatory oversight. From the current reporting data it was not clear the extent to which such adjustment of inspection schedules had occurred.

Feedback from post-inspection surveys showed that licence holders greatly value being advised of the inspection schedule and associated performance objectives and criteria in advance. This allows them to plan for availability of staff and documentation and inspector access to premises in order to minimise disruptions to operations.

PI 1.2 seeks to avoid unnecessary impact on the efficient operation of licensed entities by providing timely decisions, be they positive or negative. The current process is for inspectors to discuss the urgency of an application with the applicant and take into account ARPANSA workloads to agree on a decision date. This process of consultation is important to set realistic expectations and ensure sufficient time for a thorough analysis of the application. The PI measures whether the agreed date was met. While not fully meeting the target, results have been consistently high, which suggests that ARPANSA performs well in this area.

However, the metric was initially applied only to new licence applications, which is not consistent with the stated intent of the PI. This was rectified part way through the year to include applications for changes to existing licences. Consequently, the measure did not include all applications to ARPANSA during the reporting period.

Licence holder representatives reported that, on occasions, there was a significant delay between ARPANSA receiving an application and agreeing on a target date. In some cases it was reported that a completion date was not agreed prior to completing the application, or a target date was changed without a satisfactory explanation. The assessment team was unable to verify the full extent of this issue as the agreed completion date, or when it was changed, were not adequately recorded in the Licence Administration Database. Some licence holder representatives expressed the view that agreed timeframes varied depending on the inspector. This could be due to inspector workloads. The reason for delays could not be fully determined but assessors acknowledge that delays in review of an application can occur for a variety of reasons such as incomplete information, technical complexity, availability of specialist expertise, or ARPANSA staff not following procedures.

The evidence presented above demonstrates that ARPANSA is striving for best practice regulation while being mindful of the impact that this has on licensed entities. A good deal of effort is being invested in transparency of the regulatory approach and communication with licence holders. This communication is two-way and appears to be building mutual respect. Without exception, Licence holder representatives confirmed that ARPANSA’s regulatory processes had improved.

2.1.5 Conclusion for KPI 1

Overall, the performance against this KPI was assessed as good. However, taking the additional evidence into account the ‘true’ performance meets the ‘very good’ standard.

2.1.6 Self-assessed rating of performance against KPI 1 – 2015-16

| Excellent | Very Good | Good | Fair | Poor |
|---|--|--|--|---|
| Strong performance against all the measures under the KPI | Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure | Average performance against the measures under the KPI | Poor performance against some measures under the KPI | Poor performance against most of the measures under the KPI |

2.1.7 Actions for improving performance against KPI 1

The team identified the following AFI related to PI 1.1:

- Where changes are made to a risk ranking, the schedule of inspections is required to be updated. To ensure this occurs and is communicated to licence holders, existing procedures should be reviewed.

The team identified the following AFI related to PI 1.2:

- The procedures and arrangements for setting timeframes for licensing decisions should be reviewed with a view to provide greater consistency of service and better data collection.
- Training and reinforcement in the updated procedures may help to improve consistency.

- Other regulatory bodies have specific timeframes for assessment of applications, often based on the complexity of an application (e.g. an expected processing time of 90 days for a complex application). A similar assessment method could be used to establish expectations for applications to ARPANSA. This would require a system to be in place for a RSB manager to assess the completeness and complexity of an application.

2.2 KPI 2 – Communication with regulated entities is clear, targeted and effective

A licence holder has primary responsibility for safety of its activities. Good communication is essential to inform regulated entities how to meet their responsibilities under the Act and Regulations. It is also important to educate regulatory staff of the operating environment, priorities and needs of regulated entities.

ARPANSA's methods of communication include written communication, meetings, site visits and inspections, workshops and licence holder forums. In addition, a licence holder may approach ARPANSA at any management level, at any time, to seek clarification and to provide feedback. Surveys are used to obtain feedback on specific regulatory services.

ARPANSA prepares [regulatory guidance](#) that describes how ARPANSA goes about its regulatory business and what it expects from a licence holder. Development of these guides includes consultation with stakeholders (See section 2.5). This reduces the risk of a licence holder undertaking unfocussed or unnecessary work in order to address regulatory requirements. Regulatory guidance is published on the ARPANSA website and is kept up-to-date and relevant.

As previously discussed, a schedule is provided to a licence holder well in advance of an inspection advises when an inspection will take place and which performance objectives and criteria are to be used. This is the basis for a mutually agreed timetable that details when specific inspection activities will take place, who is involved, what documentation and evidence is needed, and the premises to be visited. A formal entrance meeting is held to ensure that the licence holder understands the purpose, scope and method of the inspection.

A meeting is held at the end of each day and a final exit meeting is held to agree the facts on which the findings of the inspection will be based. The exit meeting provides an opportunity for feedback on how the inspection has been received by the licence holder.

After the inspection report is issued the Office of the CEO sends a survey to the licence holder seeking feedback on how effectively and efficiently the inspection was planned and executed and its impact on operations. To provide licence holder anonymity, this process is independent of RSB. The response options range from 'strongly agree' to 'strongly disagree'. Negative feedback is seen as an opportunity for improvement. If the average response is neutral or better, then the feedback is taken to be favourable. This serves as an indicator of how effective inspectors are at implementing the six KPIs while maintaining positive stakeholder relations.

As discussed in section 2.1 above, in addition to scheduled inspections, inspectors make regular site visits to facilitate two-way communication on regulatory matters. These visits

provide opportunities for inspectors to understand the ongoing operational environment and to share wider regulatory experience with the licence holder. Unlike an inspection, site visits are not planned weeks in advance and no formal report is issued to the licence holder. Instead, observations are discussed with the licence holder before departure.

Regular meetings are held with licence holders to exchange information on regulatory matters such as upcoming legislative changes, licence applications or licensing and safety compliance issues. Examples of such established forums are the Defence-ARPANSA Liaison Forum (DALF) and the annual licence holder forums.

Communication is a two-way process so these meetings are effective in helping ARPANSA understand regulatory impact on a licence holder and provides a forum for discussion of the benefits of regulatory action to the licence holder itself and to community safety more broadly. The number and quality of meetings in a year and the feedback from these meetings will indicate if communication is effective.

2.2.1 Measures

Communicate with regulated entities clearly and effectively.

2.2.2 Approved evidence metrics for KPI 2

| Indicator | Evidence | Comment |
|--|--|--|
| PI 2.1 – Percentage of stakeholder inspection feedback in which the positive outweighs the negative (customer satisfaction). | ● 100% of surveys positive – exceeds target (75%). | <ul style="list-style-type: none"> • A PI based on a feedback score may be more representative, as negative feedback is unlikely to outweigh positive. • There is no formal system for analysis leading to actions being taken on the feedback. • Some negative feedback on the survey system was reported, such as repetitive, time consuming and a perceived lack of anonymity. |
| PI 2.2 – Number of information sharing meetings with facility Licence holders (effective communication). | ● 25 information sharing meetings held – exceeds target (8). | <ul style="list-style-type: none"> • Licence holder response indicates a growing satisfaction with the communication with ARPANSA. • 83 site visits were also an important tool for communication but are not included in this measure. |

2.2.3 Other evidence to indicate compliance with KPI 2

The ‘no surprises’ policy, as defined in the [Regulatory Delivery Model](#) (RDM), ensures that open and transparent communication takes place. Licence holder representatives reported that since the delivery model was introduced communication with ARPANSA had significantly improved.

ARPANSA updates and publishes its inspection schedules. Dates for inspections are agreed with a licence holder well in advance. A formal notification is sent to the licence holder at least two weeks before the start of an inspection. The notification includes details such as when, who, and what will be inspected, including the [Performance Objectives and Criteria](#) to be used.

Each inspection includes an entrance and exit meeting involving appropriate staff from the licensed entity. There should be no surprises at the exit meeting because any significant findings should be discussed with staff during the inspection. An effective exit meeting will result in agreement on the facts of any potential non-compliance and performance deficiencies, identification of good practices, and clear expectations for both the licence holder and the regulator. During the self-assessment, the team observed two inspections and spoke with licence holder staff who confirmed that communication during and at the close of inspections was effective.

In addition to the inspection environment, without exception, licence holder representatives reported communication and services from ARPANSA had improved since the introduction of the new delivery model in December 2014. The results of inspection surveys and feedback provided to the ARPANSA self-assessment team indicated general satisfaction with the inspection process. Licence holder representatives also welcomed the introduction of the performance objectives and criteria. Responses to a survey following a licence holder forum showed that licence holders appreciated the communication opportunities this had provided, both with ARPANSA and between licence holders.

As demonstrated by PI 5.2, 100% of codes and standards developed in this financial year included consultation with licence holders.

2.2.4 Analysis of evidence presented

Overall, performance against this KPI was assessed as good. This is based on both PIs exceeding the targets as well as licence holder feedback.

PI 2.1 focuses on licence holder feedback received from post inspection surveys, with the indicator being that positive outweighs negative. The team found that it is unlikely that negative feedback will ever outweigh positive in these surveys and therefore this PI is not an ambitious goal and it does not provide useful trend information.

Some licence holder representatives reported that the post inspection surveys were not an efficient use of their time as they have not seen any response or actions resulting from their comments. A number of licence holder representatives expressed a preference for remaining anonymous, and felt that the survey was repetitive and time consuming.

A review of survey results noted a large number of comments from licence holder representatives. While feedback is reviewed when it is received, to date these comments have not undergone a systematic management review. As such, an analysis for learning opportunities and formal feedback to inspectors was not evident.

PI 2.2 focuses on the number of information sharing meetings held with licence holders. The number of meetings recorded has been consistently above the target and indicates that performance in this area is strong.

Other Evidence: The effectiveness of ARPANSA's communication was generally reported as acceptable although the team noted that with the exception of the annual licence holder forum information-sharing meetings are predominantly undertaken only with large licence holders.

Wider distribution of inspection outcomes was identified by licence holder representatives as

a useful area for improvement. The licence holder forums provide an opportunity for licence holder representatives to learn of safety issues commonly identified through the inspection program. It may be desirable to increase the distribution of this information, such as during other types of meetings or through the ARPANSA website and newsletters. Such information could help to improve safety practices by assisting licence holders to learn from the operational experience of others.

ARPANSA staff also reported that information sharing among staff could be improved.

The timeliness of decision-making is further discussed under KPI 1. However, published guidance or clearer communication on timeframes for decisions could improve performance against KPI 2.

2.2.5 Self-assessed rating of performance against KPI 2 – 2015-16

| | | | | |
|---|--|---|---|--|
| Excellent Strong performance against all the measures under the KPI | Very Good Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure | Good Average performance against the measures under the KPI | Fair Poor performance against some measures under the KPI | Poor Poor performance against most of the measures under the KPI |
|---|--|---|---|--|

2.2.6 Actions for improving performance against KPI 2

The team identified the following AFI related to PI 2.1:

- This PI could be refined to reflect a feedback score instead of only positive outweighing negative.
- The survey could be restructured to be less repetitive and include a review of inspector skills that could be fed into any future training needs analyses.
- An internal process could be developed to manage and review feedback in conjunction with other continuous improvement processes.
- An option could be included for respondents not to remain anonymous. This would allow for the follow-up of negative comments by speaking directly to respondents who are willing to be contacted. This change may help to ensure that the respondents feel valued.
- Investigate additional feedback processes, such as telephone interviews with licence holder representatives, or a ‘talk to a regulator’ program for public enquiries similar to ARPANSA’s ‘talk to a scientist’ program. This may support effective communication across a wider range of stakeholders and ensure accurate regulatory advice.

The team identified the following AFI related to PI 2.2:

- Strategies could be developed to provide additional information sharing on operational experience across licence holders and inspection and assessment outcomes (including good practices).
- Improve internal communication on inspection and assessment outcomes.

2.3 KPI 3 – Actions undertaken by regulators are proportionate to the regulatory risk being managed

ARPANSA's regulatory oversight program is proportionate to the regulatory risk of the controlled activity. It includes licence holder reporting, inspections, site visits and other meetings or forums. An inspection may identify potential non-compliance, performance deficiencies or good practices.

Performance deficiencies may occur when a licence holder does not follow accepted best practice or does not meet self-imposed standards. These represent an area where the licence holder could improve their safety systems and practices and are typically actioned voluntarily without regulatory intervention.

Potential non-compliances may arise when inspectors consider that a licence holder does not meet the legislative requirements of the Act and Regulations or specific licence conditions. A formal determination of whether a potential non-compliance is a breach of the Act is made by the CEO of ARPANSA (or his delegate), based on the evidence presented by inspectors and the licence holder.

The CEO has a range of regulatory responses to non-compliance. The level of response is proportionate to the particular circumstance. ARPANSA provides guidance on how the response is determined in regulatory guide [Graded Response to Non-compliance](#). In most cases, ARPANSA's initial response will be to encourage a return to compliance. If this is unsuccessful, the regulatory response may be escalated to more formal action such as an improvement notice or direction through to suspension or cancellation of licence, or court action. Most of these enforcement actions, which are similar to those of other regulatory bodies, have never needed to be used, but are nonetheless important tools to ensure compliance with the Act and provide confidence to stakeholders, including the public, in ARPANSA's ability to protect the people and environment from the harmful effects of radiation. In practice, ARPANSA strives to use the lowest level of regulatory response necessary to assure safety and security.

The Act requires that a licence only be issued to an applicant who is able to demonstrate a capacity to comply with the Act, the Regulations and any licence conditions. Consequently, a finding of non-compliance (breach) almost always results in corrective actions by the licence holder without the need for formal enforcement action.

As discussed under KPI 1, ARPANSA schedules inspections commensurate with risk. Licence holder performance is taken into account when reviewing [risk ranking](#). In the case of facilities, the risk is determined based on the inherent hazard, the effectiveness of critical safety and security controls, and performance history. Where the risk is altered the inspection schedule is adjusted accordingly. Two identical facilities may therefore have a different inspection frequency if the safety and security practices of one are better than the other.

In the case of sources, the method for determining the inspection schedule was altered during the reporting year to recognise the generally less complex nature of sources compared to facilities. The baseline inspection program is now based on the hazard category of the source with additional (augmented) inspections undertaken where a performance issue is identified. For very low risk sources, a remote inspection process (known as an e-Inspection) has been

implemented which does not require inspectors to physically attend the site. This is particularly useful for sources in remote locations or overseas.

The inspection schedules are recorded in the records management system and are updated as required.

Inspectors monitor licence holder performance on a regular basis outside the inspection process through site visits, reports and meetings. Frequent site visits are undertaken to meet with staff and observe operations. Unlike inspections, no detailed advance planning is required and observations are shared verbally with the licence holder. Frequent site visits improve regulatory understanding and oversight and increase the visibility of the regulator. They also contribute to minimising the incidence of potential non-compliances through enhanced communication of regulatory requirements and experience.

2.3.1 Measures

Take action proportionate to the regulatory risks being managed.

2.3.2 Other evidence to indicate compliance with KPI 3

| Indicator | Evidence | Comment |
|--|--|---|
| PI 3.1 – Ratio of performance deficiencies to non-compliances during inspections (graded approach). | ● 42 performance deficiencies to each non-compliance – target (5:1) exceeded. | <ul style="list-style-type: none"> • 169 performance deficiencies (PDs) & 4 potential non-compliances (NCs). • There appeared to be some inconsistencies in categorisation of PDs and NCs. • Percentage of PD to NC as an indicator was not considered to be an effective indicator of the graded approach. • AFI – Consider developing a PI that is a better quantitative indicator of performance related to the graded approach. |
| PI 3.2 – Ratio of site visits (monitoring) to inspections at licensed facilities (performance monitoring). | ● 3 site visits per inspections at licensed facilities – target (5:1) not met. | <ul style="list-style-type: none"> • 83 site visits & 30 inspections of licensed facilities. • The current measure of site visit/inspection ratio may not fully reflect the adequacy of oversight for many facilities. The current ratio is dominated by a few licence holders that receive many site visits. • Sources are not included in PI, but may benefit from a similar arrangement. • AFI – Consider revising the PI so that it is an indication of an acceptable visit ratio for individual facilities rather than an overall ratio being met. |

ARPANSA’s application process requires an applicant to demonstrate their capacity to meet regulatory requirements under the Act and Regulations. ARPANSA strives to avoid direct regulatory intervention wherever possible. Its policies have effectively emphasised that the prime responsibility to identify and rectify safety or security issues rests with the licence holder.

ARPANSA promotes an [holistic approach to safety](#) that encourages licence holders to consider any human and organisational factors affecting safety of controlled activities. A licence holder is expected to improve systems and processes beyond an immediate problem,

and carefully consider wide ranging issues of safety culture, human performance and performance improvement.

The risk informed inspection program is designed to direct regulatory resources to licences presenting the highest risk. Inspections are undertaken using [Performance Objectives and Criteria](#) (PO&Cs) as described under KPI 1. The PO&Cs provide a structure for inspections, with a scope and depth proportionate to the risk of the controlled activity, and at an appropriate frequency. During the reporting period, 69% of inspections were of licence holders with a medium to high risk (See Section 2.4 - KPI4). Policies and guidance on assessing risks and the effects on inspection schedules are clearly documented and published where appropriate.

The [risk ranking methodology](#) used to allocate regulatory resources is available to stakeholders on the ARPANSA website. Facility risk ranking is reviewed annually and after any significant change or inspection finding such as non-compliance.

2.3.3 Analysis of evidence presented

Overall performance against this KPI was assessed as good. This is based on evidence that a range of enforcement options are available, and risk assessment and management policies and procedures are in place and available to stakeholders. Performance against the PIs was reasonable, but they are not closely aligned with KPI 3.

PI 3.1 shows that ARPANSA applies a graded approach to regulatory intervention. Formal enforcement action will only be initiated for findings of non-compliance where the licence holder fails to solve its own problems. This is an effective approach which helps to avoid direct interference in the operations of a licence holder. It indicates that ARPANSA is mindful of the need to be proportionate and predictable in their regulatory response. The measured value for this PI was 42:1 against a target of 5:1.

The ratio of performance deficiencies to non-compliance may not be the best measure of how well the graded approach is implemented, i.e. a change in the PI from 5:1 to 10:1 may not indicate an increase in the degree to which the actions taken by ARPANSA are proportionate to the risk being regulated (KPI 3).

To ensure this indicator is accurate, the team reviewed how performance deficiencies, non-compliances and good practices were categorised. The review found some inconsistencies in the categorisation process. Some 'good practices' were not sufficiently different from expected standards to warrant the term. Several performance deficiencies appeared as though they may have been down-played from potential non-compliance. These inconsistencies appear to have lessened after training was provided in February 2016, suggesting that the problem may have been associated with a 'bedding-in' period while inspectors became familiar with the revised inspection process. As such, the indicator was considered representative of performance.

PI 3.2 measures the ratio of site visits to inspections. This measure indicates the level of involvement, oversight and presence of ARPANSA outside of scheduled inspections.

The 2015/16 data shows that the target of five site visits to each inspection was not met for many facilities. The result is also positively skewed because the high number of site visits to the OPAL research reactor.

There was mixed opinion from licence holder representatives regarding site visits. Some considered that the ratio of visits to inspections could be more risk informed and five visits was excessive in some cases. Other licence holder representatives welcomed the regular contact by ARPANSA. The assessment team noted that the requirement for site visits is, in practice, risk informed. A higher risk site will have more inspections, which will increase the required number of site visits.

A number of inspectors expressed the view that the required ratio of inspections to site visits for some low level facilities was an inefficient use of their time. A phone call was suggested as a suitable alternative for communicating with low risk facilities.

This PI does not currently apply to source licences, however the assessment team believe that the general benefits offered by the graded use of site visits, or a suitable alternative, would complement communication and oversight for source licence holders.

Other Evidence supporting KPI 3 indicates that the Act and supporting policies and procedures have been effective to emphasis the responsibility of licence holders to rectify their own problems without the need for regulatory intervention. ARPANSA’s approach to [holistic safety](#) emphasises the importance of safety culture, human performance and performance improvement. Applying this approach may result in improvements made by licence holders having a wider effect than may otherwise be the case. ARPANSA has published regulatory guidance about its [inspection process](#) on the website to inform licence holders of their regulatory responsibilities and empower them to identify and rectify their own problems.

2.3.4 Self-assessed rating of performance against KPI 3 – 2015-16

| Excellent | Very Good | Good | Fair | Poor |
|---|--|--|--|---|
| Strong performance against all the measures under the KPI | Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure | Average performance against the measures under the KPI | Poor performance against some measures under the KPI | Poor performance against most of the measures under the KPI |

2.3.5 Actions for improving performance against KPI 3

The team identified the following AFI related to PI 3.1:

- This PI could be refined to reflect more directly the use of risk based approaches at ARPANSA.
- Consistency could be improved by increasing guidance or training material for inspectors on the use of discretion when categorising non-compliance, performance deficiencies and good practices.

The team identified the following AFI related to PI 3.2:

- The scope of this PI could be expanded to include sources.
- The PI could be developed so it more accurately reflects performance of all licence holders, and is not as influenced by the larger licence holders. For example, the indicator could be the proportion of licences for which the desired ratio is met.
- A site-visit to inspection ratio could be determined for each facility commensurate to its risk.

- Evaluate the use of phone calls or alternatives to replace some site visits for low risk licence holders.

2.4 KPI 4 – Compliance and monitoring approaches are streamlined and co-ordinated

ARPANSA's compliance monitoring program comprises performance reporting, regulatory inspections and a range of communication practices that collectively provide effective regulatory oversight of licence holder compliance. Together, these approaches also enable ARPANSA to assess licence holder performance against international best practice and to justify the need for any safety and security improvements identified.

Each licence holder must report on its operations to ARPANSA. These reports keep ARPANSA informed of any significant operational matters. The usual interval for reporting is quarterly however this was streamlined in 2013 to annual reporting for low hazard activities. Reports include any self-identified potential non-compliance; acquisition, transfer or disposal of radiation sources; occurrence of any incidents; any changes that affect the basis on which the licence was issued; and updates on actions associated with inspection outcomes. Reporting is via a simple, standardised form and is a non-intrusive approach to regulatory oversight.

ARPANSA's inspection program is described under KPI 1 and KPI 3. Facilities and sources are inspected against published [Performance Objectives and Criteria \(PO&C\)](#) available to licence holders on the ARPANSA website. Each PO&C is examined at least every three years in the case of facilities and five years for sources. Higher risk facilities and sources are inspected more frequently. The frequency and depth of each inspection is determined by risk. For example, a typical particle accelerator is inspected once a year across all performance objectives and criteria whereas the more complex OPAL research reactor is inspected quarterly on a single baseline module. All inspections examine performance in three cross cutting areas: safety culture, human performance and performance improvement. These modules are consistent with ARPANSA's promotion of [holistic safety](#) that recognises the importance of human and organisational factors to safety.

Inspectors monitor licence holder performance on a regular basis outside the formal compliance reporting and inspection processes through site visits, meetings and forums. Frequent site visits are undertaken to enhance communication.

As described in KPI 3, ARPANSA streamlines its compliance activities by basing inspection frequency on risk. The [risk ranking methodology](#) is published online. Establishing a transparent and planned inspection program based on risk allows ARPANSA to streamline its compliance monitoring program as necessary and reduce regulatory burden where appropriate.

ARPANSA encourages licence holders to proactively manage safety by identifying performance deficiencies and potential non-compliance. When a performance deficiency is identified there is an expectation that the licence holder will take corrective action in a timely fashion. The object of identifying performance deficiencies is to encourage the improvement of safety and security. The time taken for a licence holder to address corrective actions

following the finding of a performance deficiency is an indicator of the influence, transparency and effectiveness of ARPANSA’s inspection/compliance monitoring program.

A periodic analysis of performance deficiencies, potential non-compliances, and good practices is performed to ensure that resources are appropriately allocated and to monitor trends or emerging issues.

Although not during the reporting period, ARPANSA has previously undertaken joint activities with other Commonwealth regulators; namely the Australian Safeguards and Non-Proliferation Office (ASNO) and Comcare.

2.4.1 Measures

Compliance and monitoring approaches are streamlined and coordinated.

2.4.2 Approved evidence metrics for KPI 4

| Indicator | Evidence | Comment |
|--|---|---|
| PI 4.1 – Percentage of inspections on licence holders with a medium to high risk ranking (risk informed regulation). | ● 69% of inspections conducted on medium to high risk licence holders – target (80%) not met. | <ul style="list-style-type: none"> • ARPANSA’s performance against this PI may be under-represented due to the introduction of new strategies to improve the efficient allocation of resources to high and medium risk licence holders. • The introduction of e-inspections, which require less ARPANSA and stakeholder resources, increased the frequency of inspection for some low risk licence holders. |
| PI 4.2 – Percentage of time that actions are initiated within three months of the issuance of a performance deficiency (light touch regulation). | ● 35% of time that action is initiated within 3 months – target (50%) not met. | <ul style="list-style-type: none"> • The actual percentage of actions initiated may be higher than the recorded figure. Developing the process for the recording of the data could address this issue. However, no data is available were inspectors did not follow up on whether an action has been initiated within three months. • Improvement in this PI is seen as a management priority. Improvements could be achieved through an increased focus on inspectors following up with licence holders. • Use of the term performance deficiency is unpopular with licence holder representatives. |

2.4.3 Other evidence to indicate compliance with KPI 4

A review of facility risk ranking takes place at least annually and following an inspection. The risk ranking determines inspection frequency and monitoring strategies. As such, facilities with a high level of control and demonstrated good performance can earn a higher level of autonomy. Source inspection frequencies are determined primarily on the inherent hazard of the source.

Feedback from a licence holder is acted on to streamline regulatory performance. For example, licence holders with more than one type of licence have requested that inspections of sources and facilities be combined. ARPANSA has now implemented combined source and facility inspections to streamline the inspection process for those licence holders.

2.4.4 Analysis of evidence presented

Overall performance against this KPI was assessed as good. This is based on evidence that there was a high level of transparency of inspection and monitoring arrangements, feedback mechanisms in place to seek stakeholder views on the inspection and monitoring regimes, and monitoring and enforcement strategies that allow for a range of regulatory responses.

While the PIs relate to the KPI, the measures used may not provide sufficient information to fully and accurately assess performance.

PI 4.1 relates to the number of inspections performed on higher risk licences compared to the lower risk licences. This PI represents how well ARPANSA targets resources to higher risk licence holders.

The team noted that since the establishment of this PI, the risk ranking method for source licences was adjusted. A large proportion of source licences are in the lower risk categories. These graded strategies help to meet the intention of the PI. However, the introduction of less resource-intensive inspections may result in an increased number of low risk inspections which may require an adjustment of the PI target.

The revised source inspection schedule retains the option to undertake more inspections when poor safety performance is identified. However, there is no system in place to reward good performance with reduced regulatory oversight, in line with the ‘earned autonomy approach’ described in the RPF. Implementing a formal system for source licences may result in more appropriate resource allocation to meet this PI.

The requirement for regular review of monitoring and compliance strategies, including reduced regulatory oversight where appropriate, was seen as very positive. However, there was insufficient evidence for the team to determine whether risk ranking of facilities and sources is being consistently reviewed.

In addition, there was no evidence that the inspection schedule was changed to reflect changes in risk ranking. The team could not determine if this was due to poor data recording practices, or that the changes had not been made.

PI 4.2 relates to initiation of action to address a performance deficiency within three months. The PI shows the effectiveness of light touch regulation, allowing a licence holder to address issues with reduced regulatory interference.

There was some evidence that inspectors may not always follow up on performance deficiencies to determine if actions are taken in a timely manner. Therefore, the performance against this PI may be better than that recorded.

There appeared to be some differences in how inspectors interpreted the term ‘action initiated’ which may also affect the PI. Training was provided on this issue in February 2016 which has helped to clarify the term.

The use of the term ‘performance deficiency’ is unpopular among licence holder representatives who have indicated that it implies a more severe issue than has often been identified. There were also concerns raised that there is variation in how individual inspectors find and determine a performance deficiency. It was not clear if this is due to changes in processes or differences of approach between inspectors. For example, some source

inspections were not based on the PO&Cs, instead using internal checklists that are not available to a licence holder.

2.4.5 Self-assessed rating of performance against KPI 4 – 2015-16

| Excellent | Very Good | Good | Fair | Poor |
|---|--|--|--|---|
| Strong performance against all the measures under the KPI | Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure | Average performance against the measures under the KPI | Poor performance against some measures under the KPI | Poor performance against most of the measures under the KPI |

2.4.6 Actions for improving performance against KPI 4

The team identified the following AFI related to PI 4.1:

- The PI could be reviewed to ensure efficient allocation of resources to high and medium risk sources.
- Arrangements around risk ranking for source licences could be reviewed to ensure that good performance can influence risk and inspection frequency.
- Data recording processes could be strengthened to provide evidence of regular risk ranking review.

The team identified the following AFI related to PI 4.2:

- The PI may not reflect actual performance. Consider an increased focus on ensuring that actions identified are followed-up.
- The system for reporting and recording that performance deficiencies have been actioned could be clarified and improved.
- The term ‘performance deficiency’ should be substituted with another term.

2.5 KPI 5 – Regulators are open and transparent in their dealings with regulated entities

ARPANSA has endeavoured to become increasingly open and transparent in its approach to regulation and regulatory outcomes. This policy is important to promote consistent and high standards of regulation and to build trust and mutual respect with a licence holder.

For the purposes of openness and transparency, ARPANSA has published on its website a range of information on how it implements a risk-based approach to regulation. The [Regulation and Licensing webpages](#) are the starting point for this information. Information includes how to apply for a licence; details about the inspection program; and the promotion of international best practice. ARPANSA publishes the majority of its [inspection reports](#), however content may be redacted or a report withheld for security reasons.

As discussed in previous sections, ARPANSA publishes guides, codes and standards on a range of regulatory topics that set out expectations for a licence holder with respect to safety and security of sources and facilities. These guides, codes and standards reflect international best practice, hence their requirements and expectations are predictable and in keeping with the international framework for safety. Consultation with licence holders on the development

of such documents improves transparency in regulation and supports continuous improvement.

ARPANSA appoints a ‘lead inspector’ for each licence. As the title suggests, the lead inspector is responsible for co-ordinating inspection and compliance monitoring activities. The lead inspector is also the main point of contact for communication between ARPANSA and the licence holder, and plays an important role in ARPANSA’s open and transparent approach to regulated entities.

ARPANSA tracks the amount of time spent on direct regulatory activities attributed to a particular licence holder. Activities include inspections, site visits, compliance monitoring, application assessments, and enforcement activities. As regulation is a core business activity, time spent on direct regulatory activities is likely to enhance ARPANSA’s understanding of licence holder operations, resulting in better compliance outcomes. Recording direct regulatory activities increases transparency, as it provides the basis on which licence fees are determined under the cost recovery framework.

2.5.1 Measures

Remain open and transparent in dealings with regulated entities and the public.

2.5.2 Approved evidence metrics for KPI 5

| Indicator | Evidence | Comment |
|---|--|--|
| PI 5.1 – Percentage of RSB time devoted to regulatory activities (core business efficiency). | ● 32% of RSB time spent on regulatory activities – target (60%) not met. | <ul style="list-style-type: none"> • The PI measures only the time spent working directly on individual licences. It was considered to be a good indicator of performance. However, the target may have been set too high. • The indicator includes all RSB personnel but does not account for all types of regulatory activity or staff leave. • This target is a major input into a transparent cost recovery tool, from which the allocation of licence charges can be determined. |
| PI 5.2 – Percentage of instances in which Licence holders are consulted on the development of Guides, Codes and Standards (transparent development of standards). | ● 100% of guides codes and standards consulted on – target (90%) exceeded. | <ul style="list-style-type: none"> • Licence holder representatives have sometimes not been consulted on, or informed of, revisions to regulatory guides. • Licence holder representatives do not typically receive explanatory feedback when their comments and suggestions have not been actioned. |

2.5.3 Other evidence to indicate compliance with KPI 5

ARPANSA publishes a large number of reports and guidance on its [Regulation and Licensing](#) webpages.

As discussed above, ARPANSA conducts regular meetings, forums and site visits to improve transparency of its regulatory requirements and processes. Similar opportunities are provided during inspections.

The Act establishes a Nuclear Safety Committee (NSC) to provide advice to support the CEO of ARPANSA. The NSC is an independent group of senior national experts drawn from nuclear and other high reliability industries and regulatory bodies. Any matters of interest in ARPANSA's regulatory environment, its approach to regulation, and its operational performance, is referred to the NSC for information or discussion. The NSC also reviews any significant guidance under development.

The team that undertook this self-assessment included a representative from a large licence holder and another from an international regulator. This is another demonstration of openness and transparency.

2.5.4 Analysis of evidence presented

Overall performance against this KPI was assessed as good. This is based on evidence such as the amount of information publicly available online, including the enforcement strategy and risk approaches, regulatory guides, and inspection outcomes. Although performance against the PIs was taken into account, the team considered that they might not accurately reflect the intent of the KPI.

PI 5.1 is a measure of the proportion of time regulatory staff spend on direct regulatory activities. These are activities associated with a specific licence such as application assessments, inspections, compliance monitoring, and enforcement. This measure was primarily introduced to assist the determination of annual licence charges. However, there is considerable indirect regulatory work that this PI does not measure. This should be included to make the PI reliable.

Indirect regulatory work includes administration of the licensing framework, including the database; managing the development of codes and guides; promotion of national uniformity, education and training; reporting; implementing measures for continuous improvement; and managing the regulatory management system. Much of this indirect regulatory work is required to establish and maintain the systems that support direct regulatory activities. For example, forms and guides must be in place before a licence application can be made. Applicants must understand the regulatory framework in order to prepare an application. After a licence is issued, licence holders must understand compliance and enforcement.

The indirect activities are important to ARPANSA's approach of enabling and supporting licence holder ownership and management of safety and security, to avoid direct regulatory intervention.

The assessment team recognised ARPANSA's effort to identify potentially inefficient regulatory activities through the tracking and promotion of time spent on direct regulatory work. The team noted that the target for 2016-17 has been revised down to 40% which is seen to represent a more realistic target based on the 2015-16 performance and taking into account the volume of valuable indirect regulatory activities.

PI 5.2 relates to the level of consultation with licence holders on the development of ARPANSA's regulatory guides, codes and standards.

Licence holder representatives have indicated that in the past there have been occasions where they were not aware of any consultation on the development of a guide, code or standard. The current consultation arrangements have improved, however some licence holder representatives commented that where feedback has been provided no advice on how their comments were considered or addressed was provided, particularly if no changes to the document were deemed necessary.

Other evidence: Two significant ARPANSA guides on Regulation 51 and Regulation 54 identified as being ambiguous or providing no additional value compared to IAEA Safety Standards. One licence holder reported that it continues to use its own interpretation of Regulation 51 rather than ARPANSA’s guide. Both regulatory guides were subject to consultation during development and licence holder views taken into account. The review team believes that choosing not to use the guides represents a lack of ‘buy-in’ by a licence holder rather than problems with the guides. Additional justification and reinforcement of the approach may improve uptake of the guides.

During the reporting period, ARPANSA held 25 information-sharing meetings and 83 site visits to promote clarity and transparency.

2.5.5 Self-assessed rating of performance against KPI 5 – 2015-16

| Excellent | Very Good | Good | Fair | Poor |
|---|--|--|--|---|
| Strong performance against all the measures under the KPI | Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure | Average performance against the measures under the KPI | Poor performance against some measures under the KPI | Poor performance against most of the measures under the KPI |

2.5.6 Actions for improving performance against KPI 5

The assessment team did not identify any improvement measures for KPI 5.1, but noted that the target for 2016-17 has been revised to 40% which was considered to be more realistic.

The team identified the following AFI related to PI 5.2:

- Consider developing this PI to include a measure of the frequency of feedback to a licence holder on its comments. The management system could be amended to encourage and record two-way communication with a licence holder during the feedback process.
- A consultative review of guidance could be undertaken to improve understanding and agreement between ARPANSA and its stakeholders, particularly in relation to guidance material on Regulations 51 and 54.

2.6 KPI 6 – Regulators actively contribute to the continuous improvement of regulatory frameworks

ARPANSA operates in a dynamic regulatory environment with many of its licence holders operating at the cutting edge of science and technology. ARPANSA must be adaptable to meet the needs of regulated entities while assuring compliance with the Act and maintaining high levels of nuclear and radiation safety and security. A program of continuous

improvement is recognised as being important to building a resilient regulator that is able to monitor its regulatory environment, adapt to any challenges, and learn from its experience. To help facilitate continuous improvement a restructure of RSB was undertaken in mid-2015 creating a new section to focus on performance monitoring and supporting continuous improvement.

Areas for improvement in the regulatory framework are identified via various methods including this annual self-assessment. Additional opportunities include routine reviews of procedures and policies as part of the regulatory management system, external audits including peer review missions by international teams of comparable regulators, stakeholder feedback from surveys and licence holder forums.

Effective communication is one of the keys to continuous improvement. ARPANSA strives for efficient and effective communication internally between its staff, and externally with Licence holder representatives, other stakeholders, and the international community. See Section 2.2 for more information on communication.

Opportunities for improvement can come from external sources. The inspection program uses external experts with experience in a particular field and/or regulation of particular sources or facilities. Judicious use of certain expertise promotes efficiency and improves regulatory outcomes. The use of external experts provides a valuable source of independent advice in specialised areas and can actively contribute to improvements in the regulatory framework. In addition, the use of external personnel for inspection of sources and facilities held by ARPANSA’s scientific branches is a means to maintain impartiality and avoid any conflicts of interest.

Members of the Nuclear Safety Committee (NSC) have diverse regulatory experience in high reliability industries, such as aviation, and advise the CEO on such matters. The NSC contributes to the development of regulatory documents such as codes, standards, guides and operating procedures.

ARPANSA is active in international standards development through the IAEA. This is part of ARPANSA’s work to promote the use of trusted international standards where possible, rather than developing local documents.

2.6.1 Measures

Perform frequent self-assessments in order to improve our delivery model.

2.6.2 Approved evidence metrics for KPI 6

| Indicator | Evidence | Comment |
|--|--|--|
| PI 6.1 – Number of improvements, identified through self-assessment or external reviews, that were implemented (continuous improvement). | ● 4 improvements identified – target (3) exceeded. | <ul style="list-style-type: none"> It is evident that innovation and continuous improvement are highly valued and promoted. |

| Indicator | Evidence | Comment |
|--|---|---|
| PI 6.2 – Percentage of facility inspections in which expertise external to RSB was utilised (judicious use of regulatory expertise). | ● 23% of facility inspections conducted with external expertise – target (30%) not met. | <ul style="list-style-type: none"> This target was not reached due to lower performance during initial implementation in the first quarter. A renewed focus resulted in the target being exceeded in the next two quarters (33%, 43%) and close in the last quarter (25%). |

2.6.3 Other evidence to indicate compliance with KPI 6

ARPANSA participates, and is frequently a driver, in the development and promotion of national and international codes and standards covering radiation protection, nuclear safety and security, transport of radioactive material, and management of radioactive waste. An example is the new ‘Code for Radiation Protection in Planned Exposure Situations (RPS C-1)’.

ARPANSA also promotes national uniformity of radiation regulation through the Radiation Health Committee.

2.6.4 Analysis of evidence presented

PI 6.1 represents the number of improvements formally identified and implemented. The target was exceeded indicating strong performance in this area. More improvements are anticipated during 2016-17 as areas for improvement identified by this self-assessment are implemented.

The reporting and assessment of RSB performance indicators are integral to the continuous improvement objective of the branch. A continuous improvement agenda that is based on accurate, complete and timely data supports recommendations that will lead to improved branch and inspector performance. However, through the interview and data-gathering process, it became evident that there are issues with data recording in the Licence Administration Database (LAD). While LAD is an effective tool for the management of licence information, it is lacking a number of necessary features, as its development is still incomplete. Due to the current limitations of LAD, spreadsheets are used to record data. This can sometimes create conflict when collating information and makes management oversight more difficult.

PI 6.2 relates to the number of facility inspections where a consultant external to ARPANSA was included on the inspection team. No issues were found with this KPI or ARPANSA’s performance in this area.

Other evidence: To drive continuous improvement, ARPANSA benchmarks its performance against comparable regulatory agencies through external audits including international peer reviews.

Performance against the PIs was taken into account, however, they may not accurately reflect the intent of the KPI.

The team observed ARPANSA’s commitment to continuous improvement, which fits well with the aims expressed in the RPF. Importantly the team noted that without exception,

licence holder representatives consider that ARPANSA’s performance has improved. Licence holder representatives and ARPANSA staff reported that over the previous 18 months, RSB has become more transparent and consistent in its approach to regulatory activities. This corresponds with the introduction of a new regulatory delivery model in December 2014. This delivery model emphasised openness, clarity, reliability, and efficiency, and was designed to meet the requirements of the RPF.

The assessment team noted that the approach to both source and facility inspections was professional and mindful of the licence holder’s time and operations. The assessment noted that the ARPANSA staff interviewed displayed a strong regulatory culture and were committed to continuous improvement. The team noted that there had been no unexplained deviation from the inspection schedules during the review period. This contributes to transparency and clear communication.

2.6.5 Conclusions

Overall performance against this KPI was assessed as very good. This is based on the evidence presented including a high level of involvement in the development of documentation and regulatory frameworks, the number of stakeholder events, the frequent interactions with Licence holder representatives, and inputs from external experience and expertise.

2.6.6 Self-assessed rating of performance against KPI 6 – 2015-16

| Excellent | Very Good | Good | Fair | Poor |
|---|--|--|--|---|
| Strong performance against all the measures under the KPI | Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure | Average performance against the measures under the KPI | Poor performance against some measures under the KPI | Poor performance against most of the measures under the KPI |

2.6.7 Actions for improving performance against KPI 6

The team identified the following AFI related to PI 6.1:

- The scope of the next stage of enhancements to LAD should be workshopped, and business requirement specifications developed. This will help to identify additional learning opportunities and improve workflow. For example, LAD could benefit from the introduction of improved reporting or reminder prompts for key tasks such as Regulation 51 assessment status.
- While using the existing systems external to LAD, a process map could be created that links the data required by a branch performance indicator to the data location (database field, screen, file name etc.).
- Evaluate the roles and responsibilities of administration officers to support data entry into the LAD, including functions such as quality assurance.

3 Overall Assessment

3.1 Analysis of evidence

This review assessed regulatory performance against previously agreed metrics as well as established processes, procedures and through discussions with staff and stakeholders. In some cases it was noted that the metrics did not closely align with the intention of the KPI. However, the team found that the use of the current metrics has led to performance improvement that is consistent with the aims of the RPF. Improvements to data collection could be made in some areas, such as agreed timeframes for assessment and follow up on performance deficiencies.

3.2 Overall self-assessed rating of performance – 2015-16

This review assessed overall performance against agreed metrics as good. However, it is acknowledged that problems associated with the PIs and PI alignment to KPIs undervalues ARPANSA’s regulatory performance against the aims of the RPF.

| Excellent Strong performance against all the measures under the KPI | Very Good Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure | Good Average performance against the measures under the KPI | Fair Poor performance against some measures under the KPI | Poor Poor performance against most of the measures under the KPI |
|---|--|---|---|--|
|---|--|---|---|--|

3.3 Performance improvement actions identified

The review highlighted a number of potential improvements that could enhance regulatory performance or the assessment of performance. These areas for improvement are listed throughout section 2 of this report. The key areas for improvement are summarised below.

Review the ARPANSA’s Performance Indicators (PI) targets to ensure that goals are achievable, realistic, and align with the RPF KPI

Some targets may not be realistic as they were exceeded by a large margin, for example PI 3.1 was 840% of the target. Conversely, some targets may not be achievable, such as PI 5.1 which was half of the target. To meet PI 5.1 ARPANSA would need to double the amount of time spent on direct regulatory activities, which is neither realistic nor practical and would negatively impact the indirect regulatory activities which are necessary and important to establish standards and operator ownership for safety and security.

Some PIs may not align well with the KPIs. For example KPI 3.1, the proportion of performance deficiencies to non-compliances may not be a good indicator of how a graded approach is applied. In addition, the ‘Percentage of inspections of licence holders with a medium to high risk ranking (risk informed regulation)’ may more closely align with KPI 3 (Actions undertaken by regulators are proportionate to the regulatory risk being managed) than KPI 4 (Compliance and monitoring approaches are streamlined and co-ordinated).

The process should also map how performance data is captured, stored, and reported.

Improve communication with licence holders through increased feedback and improved guidance material

In general, ARPANSA has very effective communications, however, a number of issues were identified where Licence holder representatives felt improvement was desired. This includes inspection timeframes, recognition of feedback from consultations such as survey results, the website, and regulatory guides.

Improve standardisation of inspections, outcomes and approaches

A number of inconsistencies were identified in the approach of inspectors and in the categorisation of inspection outcomes. Training and improved inspector guidance/teamwork approaches may improve consistency. This could include training on performance deficiencies, actions taken, data recording, and information sharing strategies.

4 Concluding remarks

This was the first self-assessment performed under the Government Regulatory Performance Framework. It was undertaken shortly after a major restructure of the Regulatory Services Branch and recent changes to regulatory functions, particularly the inspection process. The team acknowledged that the new arrangements were being 'bedded-in' during the reporting period.

The self-assessment represents a thorough and robust examination of regulatory performance for the period 1 July 2015 to 30 June 2016. In the interest of openness and transparency, the self-assessment team included a representative from an ARPANSA licence holder (ANSTO). To promote international best practice, the team included a senior manager from an international counterpart organisation (U.S. Nuclear Regulatory Commission).

The team set out to review current regulatory performance against previously agreed metrics. They undertook a qualitative review based on established processes, procedures, and data. Interviews and discussions were held with more than half the RSB staff and managers, and twelve staff and managers from two major licence holders.

The team found that use of the current metrics has led to performance improvement consistent with the aims of the RPF. Some metrics need to be further developed and a number of targets adjusted to present realistic targets for 2016-17.

The assessment team concluded that ARPANSA has been an effective regulator during the reporting period and that the structure and consistency of its services has improved. The team found that ARPANSA has a good regulatory culture with appropriate responsibilities and accountabilities. Staff demonstrated a commitment to continuous improvement consistent with the aims expressed in the RPF. Importantly, the team noted that without exception, licence holder representatives also consider that ARPANSA's performance has improved, particularly in its openness, transparency and graded approach to regulation.

However, the team did identify several areas for improvement. The assessment team has not set out to direct these improvements but has made a number of suggestions to consider. Addressing the issues will significantly improve branch performance. The team recommended that a corrective action program be established for this purpose.

Throughout the self-assessment, the team found RSB staff to be open and responsive. This was an indication that staff are engaged in the process of continuous improvement which is commendable.

Appendix A

ARPANSA Licensed Entities as at 30 June 2016

Facility licence holders:

Australian Defence Force /Department of Defence
Australian National University
Australian Nuclear Science and Technology Organisation (ANSTO)
Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)
Department of Immigration and Border Protection
Department of the Environment – Parks Australia

Source licence holders:

ASC Pty Ltd
Attorney-General's Department
Australian Crime Commission
Australian Defence Force /Department of Defence
Australian Federal Police
Australian Institute of Marine Science
Australian National University
Australian National University Enterprise Pty Ltd
Australian Nuclear Science and Technology Organisation
Australian Postal Corporation
Australian Radiation Protection and Nuclear Safety Agency
Australian Securities and Investments Commission
Australian Sports Commission
Australian Trade Commission
Australian Transaction Reports and Analysis Centre
Australian War Memorial
Bureau of Meteorology – Cape Grim
Commonwealth Scientific and Industrial Research Organisation
Decipha Pty Ltd
Department of Agriculture and Water Resources
Department of Foreign Affairs and Trade
Department of Immigration and Border Protection
Department of Industry, Innovation and Science
Department of Industry, Innovation and Science – Geodesy and Seismic Monitoring Branch,
Geoscience Australia
Department of Industry, Innovation and Science – Geoscience Australia
Department of Industry, Innovation and Science – National Measurement Institute
Department of Infrastructure and Regional Development
Department of Parliamentary Services
Department of Regional Australia, Regional Development and Local Government – Indian
Ocean Territories Health Service
Department of the Environment – Australian Antarctic Division
Department of the Environment – Australian Antarctic Division, Polar Medicine

Department of the Environment – Supervising Scientist
Department of the Prime Minister and Cabinet
Family Court of Australia
Federal Court of Australia
High Court of Australia
Law Courts Limited
National Archives of Australia
National Gallery of Australia
National Museum of Australia
Note Printing Australia
Reserve Bank of Australia
Royal Australian Mint
Silex Systems Ltd

Appendix B

Information sources and documents provided to the assessment team.

1. KPI Data – TRIM document R16/03919 and TRIM document R16/01258
2. The Auditor-General Audit Report No.29 2013-14 Performance Report No.29 2013-14
3. ARPANSA Closure Report of ANAO Audit No.29 2013-14, February 2015
4. NEA/CNRA/R(2014)3 – The Characteristics of an Effective Nuclear Regulator OECD 2014
5. ARPANSA Performance Objectives and Criteria
6. Post-Inspection Surveys, 2015-2016
7. Internal employee surveys, 2015
8. Report to the Australian Communications and Media Authority on the Regulatory Performance Framework (RPF), June 2015
9. Regulator Performance Framework ISBN 978-1-925237-08-5
10. Inspection reports – March 2015 to present
11. Three year facility and five year source inspection schedules
12. ARPANSA Annual Report, 2016
13. Work and meeting schedules
14. Operating experience information
15. Organisation charts
16. Internal complaint mechanism input
17. Area for Improvement Development Form
18. In-house IT systems including the Licence Administration Database (LAD)