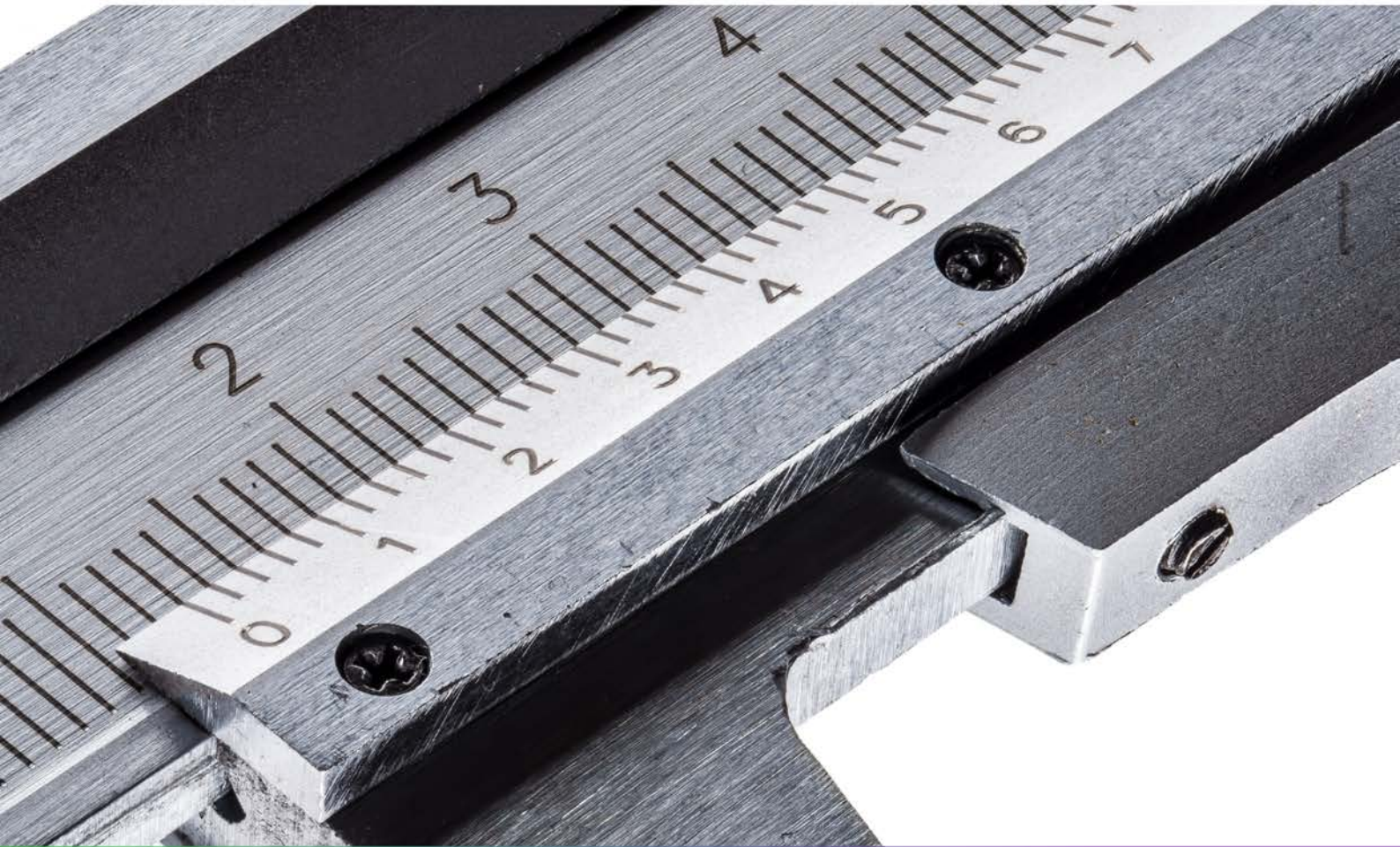**Australian Government**

Australian Radiation Protection and Nuclear Safety Agency

arpansa

Regulator Performance Framework
Self-Assessment Report 2017–18

Contents

Executive Summary

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is the Australian Government's primary authority on radiation protection and nuclear safety. We protect the Australian people and the environment from the harmful effects of radiation through understanding risks, best practice regulation, research, policy, services, partnerships and engaging with the community.

We regulate the safety and security of radiation sources[1] and facilities[2]; owned or operated by Commonwealth entities.

Summary of the self-assessment under the Regulator Performance Framework

This review was the third self-assessment of ARPANSA against the key performance indicators (KPIs) outlined in the Australian Government's Regulator Performance Framework (RPF).

The assessment found a high level of commitment to the RPF. The assessment also identified a number of improvements since the 2016–17 financial year. Overall, ARPANSA's performance as summarised in the table below is rated as 'very good'.

KPI	Rating of performance 2015-16	Rating of performance 2016-17	Summary of analysis	Rating of performance 2017-18
Overall assessment	●●●○○ Good	●●●●○ Very good	Performance against a majority of the KPIs rates as 'very good' or higher.	●●●●○ Very good
KPI 1 Regulators do not unnecessarily impede the efficient operation of regulated entities	●●●○○ Good	●●●●○ Very good	Timeframes for the assessment of applications are agreed with licensees taking into account other priorities and regulatory resources. This assists the licence holder in planning, avoiding impediments to business. ARPANSA establishes a risk informed schedule of inspections; changes to the schedule are clearly communicated.	●●●●○ Very good
KPI 2 Communication with regulated entities is clear, targeted and effective	●●●●○ Very good	●●●●○ Very good	Meetings were held with licence holders to exchange information on regulatory matters such as upcoming legislative changes, new or amended regulatory guides,	●●●●○ Very good

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1   Sources are 'controlled apparatus' and 'controlled material'. These terms have defined meanings from the legislation.

2   Facilities are 'prescribed radiation facilities' and 'nuclear installations'. These terms have defined meanings from the legislation.

KPI	Rating of performance 2015-16	Rating of performance 2016-17	Summary of analysis	Rating of performance 2017-18
			licence applications, or licensing and compliance issues.	
KPI 3 Actions undertaken by regulators are proportionate to the regulatory risk being managed	●●●○○ Good	●●●●○ Very good	ARPANSA applies a graded, risk informed, approach to its inspection program. The vast majority of regulatory time which was recorded against a licence, was spent on licences with medium or higher risk.	●●●●○ Very good
KPI 4 Compliance and monitoring approaches are streamlined and co-ordinated	●●●○○ Good	●●●●○ Very good	ARPANSA collaborated with other regulators, where appropriate, by sharing information or undertaking joint activities. The majority of the areas for improvements identified by ARPANSA were actioned voluntarily by licence holders. This may reflect good safety culture, the effectiveness of non-enforcement actions and ARPANSA's promotion of best practice.	●●●○○ Good
KPI 5 Regulators are open and transparent in their dealings with regulated entities	●●●○○ Good	●●●●○ Very good	A total of 37 inspection reports have been posted on the ARPANSA website[3]. Updates to expectations for licensee plans and arrangements have been published.	●●●●● Excellent
KPI 6 Regulators actively contribute to the continuous improvement of regulatory frameworks and processes	●●●●○ Very good	●●●●○ Very good	Five regulatory initiatives have been implemented during the year.	●●●○○ Good

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[3] ARPANSA conducted 41 inspections during the financial year. At the time the self-assessment was conducted, 37 of these had been published on the ARPANSA website. However, the remaining four reports were subsequently published. Hence, all inspection reports were published on the website.

Strengths

A number of strengths were identified during the review. These highlight the areas where ARPANSA's activities are highly aligned with the RPF. Broadly, the strengths identified are:

Consistency

ARPANSA has prepared policies and procedures describing the organisation's graded/risk informed approach to regulation; and importantly, both staff and management are being seen to be using them.

ARPANSA has developed [Performance Objectives and Criteria (PO&C)](#) that are used to provide structure and predictability in how it undertakes inspections. These are used by inspectors and may be appreciated by licensees for providing a transparent guide to what ARPANSA is looking for during an inspection. The PO&C are aimed at allowing inspectors to assess the safety performance of a licence holder at the appropriate depth based upon the hazard of the source or facility.

Through the establishment and rotation of lead inspectors, ARPANSA has endeavoured to strike a balance between the strengths and efficiencies of a consistent point of contact for regulatory matters with the risk of regulatory capture.

Transparency

The commitment to transparency is demonstrated by the amount of information that is available on the ARPANSA website (regulatory guidance, inspection reports and major licence applications) through to publication of quarterly and annual reports to parliament in a timely and publicly available manner.

ARPANSA is open and available to discuss safety matters with the licence holder and tries to be responsive to the wider community.

Communication

The inspectors have been observed by the team to have a professional rapport with licence holder's representatives. Licence holders respect ARPANSA staff and acknowledge the efforts that have gone into explaining ARPANSA's regulatory requirements.

A mini-licence holder forum initiative has been established. This aims to bring regulatory staff together with those personnel who actually use the radiation sources. Hence, provide for better engagement with staff of the operating organisation on a deeper and more thorough level. This is done by bringing regulatory staff closer to where the operating staff use the sources of radiation. The intention is for future mini-licence holder forums to be held at a variety of cities around the country.

Continuous Improvement

Australia has requested an Integrated Regulatory Review Service (IRRS) from the International Atomic Energy Agency (IAEA). ARPANSA has played a lead role in coordinating the radiation protection regulators in each State and Territory to engage with the IRRS review process and contribute towards an assessment of the Australian radiation protection framework against international standards.

ARPANSA has a high degree of engagement with the international radiation protection and nuclear safety community. This can be used to allow ARPANSA to engage with the latest thinking and consider it for implementation in a timely manner.

ARPANSA participates in the newly re-established working level forum of radiation protection regulators, the Radiation Regulators Network (RRN). ARPANSA has provided the electronic portal and the secretariat support.

Areas for Improvement

A number of Areas for Improvement (AFI) were identified that may help to improve the efficient and effective regulation of Commonwealth entities dealing with radiation. Broadly, the AFIs cover:

Communication
The effectiveness of internal communication and transfer of information, particularly with regard to inspection findings, may be improved through more regular meetings and a more structured approach to communication. The effectiveness of external communication can be improved through better communicating the Inspection Schedule to licence holders, preparing targeted and tailored information for specific licence holders and developing better guidance for inspectors on providing suggestions/advice to licence holders.

Regulatory performance improvement
There were some opportunities for performance improvement that had not been previously identified or actioned. Some examples were:

The relative regulatory priority between source and facility licences has not been thoroughly assessed and documented. Therefore, it is not clear if the same amount of regulatory resources applied to a particular source or facility are protecting against the same level of overall risk.

- ARPANSA can decrease the regulatory burden on some licensees, achieve efficiencies and gain a better understanding of the strengths and weaknesses of safety management at the licensed organisations through more strategic collaboration with other regulators (e.g. Comcare, Australian Safeguards and Non-Proliferation Office (ASNO) and the Therapeutic Goods Administration (TGA)).

- Propagation of self-assessment tools that can be used by the licensees to assess their compliance and be prepared for inspections at any time.

- Framework for sharing national and international experience (beyond the development of Codes/Standards).

Information Management
The Regulatory Services Branch (RSB) has a range of information management needs that are currently being met through a patchwork of, at times, overlapping tools. ARPANSA and its licence holders may benefit from a holistic review of its information management needs leading to an integrated and improved system that reduces duplication and 'red-tape'.

Planning
A review of tasks, and how they are allocated, may be useful to assist in setting appropriate performance targets and priorities. Improved awareness of workforce planning including resource management, defining training and skills needs, and succession planning at a strategic level may also assist in balancing the workload pressures on staff.

Actions associated with all AFIs will be recorded and managed through the ARPANSA Issue Management Register.

1   Introduction

1.1   The agency

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is the Australian Government's primary authority on radiation protection and nuclear safety. 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*.

The powers and functions of the agency are outlined in the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act). The Act establishes the CEO of ARPANSA as the safety regulator of Commonwealth entities engaged in nuclear or radiation activities. The objective of the Act is to '…protect the health and safety of people, and to protect the environment, from the harmful effects of radiation' (section 3 of the Act). ARPANSA aims to achieve this through understanding risks, best practice regulation, research, policy, services, partnerships and engaging with the community.

ARPANSA regulates nuclear installations and prescribed radiation facilities including 35 facility licences and approximately 75 000 radiation sources under 58 source licences. The complexity of these licensed activities range from the 20 megawatt (thermal) OPAL reactor and associated medical radioisotope production to the use of low risk equipment such as X-ray baggage scanners, and handheld radiofrequency and ultraviolet sources. A full list of the 42 Commonwealth entities that held licences as at 30 June 2018 is provided in Appendix A.

The CEO has, through delegations, authorised staff of the Regulatory Services Branch (RSB) to take regulatory decisions for, and on behalf of, the CEO. The CEO and the RSB draw on expertise from other functional units of ARPANSA as required and where appropriate. The RSB staff and all other ARPANSA staff that carry out activities supporting such decisions, are ultimately accountable to the CEO; the CEO retains responsibility for all decisions at all times.

In addition to licensing, compliance monitoring and enforcement, the RSB also carries out a range of other activates including preparing regulatory guidance, and investigates incidents and accidents as required. Regulatory activities also include the assessment and issuing of new licences, amendment of licences, assessment of changes significant to safety, and monitoring compliance with the Act, the Australian Radiation Protection and Nuclear Safety Regulations 1999 (the Regulations) and licence conditions.

ARPANSA strives to continuously improve the quality and consistency of its regulatory services and implementation of a graded approach to regulatory management of radiation risk. The structure of the RSB has four functional areas. One section is dedicated to source safety and security; another is facility safety, a third coordinates national codes and standards and the fourth is responsible for safety systems used to conduct ARPANSA's regulatory business.

The CEO and all ARPANSA staff carrying out activities that support the regulatory function are required to take reasonable steps to avoid conflict of interest between the regulatory and other functions; disclose any potential, perceived or real interests; and manage any such situations carefully. The approach to managing the regulatory intersection with other activities is outlined on ARPANSA's website (https://www.arpansa.gov.au/regulation-and-licensing/regulation/our-regulatory-services/regulatory-intersection-other-functions). ARPANSA has published its *Policy for ARPANSA's Regulatory Activities* on the

ARPANSA website (https://www.arpansa.gov.au/regulation-and-licensing/regulation/regulatory-integrity/policy-arpansas-regulatory-activities).

ARPANSA's compliance monitoring activities aim to provide assurance to the Government, and the public, that people and the environment are being protected from the harmful effects of radiation. ARPANSA identifies potential non-compliance through inspection, investigation, or review of licence holder's compliance reports. Non-compliance may also be self-reported by a licence holder. When monitoring compliance, regulatory staff are assisted by the guidance recorded in the Compliance and Enforcement Manual.

ARPANSA undertakes compliance monitoring, inspection, and enforcement as appropriate. Resources for compliance monitoring and inspection are allocated using a hazard- and risk-informed, graded approach. Costs of ARPANSA's regulatory operations are recovered through licence application fees and annual licence charges. When non-compliance is identified, the regulatory response should be appropriate to the circumstances. The minimum response necessary should be used to achieve the desired result, which in most cases, will be a return to compliance.

When a potential non-compliance is identified by ARPANSA, the licence holder is given an opportunity to respond before a finding of breach is made. This is taken into account to determine whether there should be a finding of breach, and the determination of enforcement actions to take.

ARPANSA has established criteria for determining the most appropriate regulatory response. Amongst other things, this considers the actual or potential safety consequences, the nature of the discovery, the impact on the regulatory process, the degree of cooperation and disclosure displayed by the licensee, the compliance history and whether there are any mitigating circumstances.

A range of regulatory enforcement options exist. These include:

- encouraging and assisting the licensee to achieve compliance

- issuing an improvement notice under section 80A of the Act

- issuing a direction under section 41 of the Act

- amending a licence under section 36

- suspending or cancelling a licence under section 38 of the Act

- referring matters to the Director of Public Prosecutions

- seeking an injunction from the Federal Court of Australia.

Guidance for stakeholders is provided in a regulatory guide on the graded approach to dealing with licence holder non-compliance. This is published on the ARPANSA website.

1.2   The Regulator Performance Framework – ARPANSA's experience

In October 2014, the Australian Government released the Regulator Performance Framework (RPF), ISBN 978-1-925237-09-02, as part of the commitment to reduce unnecessary or inefficient regulation imposed on individuals, business and community organisations. In December 2014, ARPANSA applied the RPF to its regulatory processes to emphasise openness, clarity, reliability, efficiency and effectiveness.

The stated aim of the RPF is to '*encourage regulators to undertake their functions with the minimum impact necessary to achieve regulatory objectives and to effect positive ongoing and lasting cultural change within regulators. This can include adapting their approach, for example, to reduce burdens on small business. In turn this will also assist regulators in meeting community expectations, which will help build stakeholder and public confidence*'. The RPF thus addresses the regulatory process from a particular angle, which may not be tightly coupled to achievement of the safety objective to 'protect the health and safety of people, and to protect the environment, from the harmful effects of radiation'. The full range of ARPANSA's regulatory approaches and activities designed to achieve the safety objective are outlined in the *Policy for ARPANSA's Regulatory Activities*.

While the RPF thus does not measure regulatory performance across the whole range of activities covered by the aforementioned policy, it is nevertheless in ARPANSA's experience over the last three years a valuable tool for self-assessment and reflection. It has, among other things, informed a discussion within the agency of meaningful performance indicators and has been a positive driver in promoting a culture of accountability and transparency. It has also been valuable to receive the input and advice from the Nuclear Safety Committee[4] on ARPANSA's performance in relation to the RPF.

A disproportionate focus on the small set of key performance indicators (KPI) prescribed in the RPF may detract from other important activities that relate to achieving the safety objective, or – worst case – a disproportionate focus on strong performance in relation to the RPF could lead to complacency. A regulator, just as regulated entities, cannot afford complacency. ARPANSA measures its performance against a range of indicators outside of the RPF, with the high level indicators listed in ARPANSA's publicly available Corporate Plans. It is important to recognise the limited scope of the RPF key performance indicators and that regulatory efforts to achieve the safety objective need to be more wide-ranging. It is, in fact, stated in the framework that the RPF will '*be a useful tool for regulators to identify opportunities for improvement and better target their resources for greater impact*'.

A measure of regulatory *impact* and safety outcomes is the record of safety performance among the regulated entities. ARPANSA annually evaluates the national incident information collated in the Australian Radiation Incidents Register, and continually monitors the safety performance of ARPANSA's licence holders. During the 2017-2018 financial year, a series of events with safety implications occurred at the Australian Nuclear Science and Technology Organisation (ANSTO), specifically with regard to the operations of ANSTO Health in Building 23 at the Lucas Heights Science and Technology Centre. The first of these events involved a serious skin contamination of a worker, which was reported by ARPANSA as a Level 3 'serious incident' under the International Nuclear and Radiological Event Scale (INES). This event was also reported to Parliament under section 61(1) of the Act. On 29 June 2018, the CEO of ARPANSA issued a direction to ANSTO under section 41(1A) of the Act to take immediate steps to initiate an independent review of safety practices at ANSTO Health and to provide the report to ARPANSA together with ANSTO's response to the reviewers' recommendations and an action plan[5]. While further work is needed to fully take stock of all potential learnings for the regulator from the series of events that occurred at ANSTO

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[4] The Nuclear Safety Committee is established under the Act. Its functions include 'to review and assess the effectiveness of standards, codes, practices and procedures in relation to the safety of controlled facilities'. More information on the Nuclear Safety Committee is available on ARPANSA's website.

[5] ARPANSA received the report, with 85 recommendations, on 5 October 2018. ARPANSA has granted ANSTO 60 days to respond to the recommendations and to present an action plan based on the recommendations for ARPANSA's approval. At the time of preparation of this report, ARPANSA is analysing the findings of the independent review, with the view of identifying opportunities to strengthen the regulatory oversight of licenced entities.

Health, ARPANSA has already drawn some preliminary conclusions which were discussed and endorsed by the Nuclear Safety Committee at its June 2018 meeting, being:

- ARPANSA should engage with its licence holders to ensure that their risk assessments appropriately reflect the risks of any activity or facility of a hazardous nature and that the effectiveness of controls are regularly reviewed

- the ARPANSA inspection program should take a graded approach by identifying moderate or higher consequence scenarios involving activities licensed under each facility and verify that adequate risk control measures are in place and effective. Particular attention should be paid to human factors and their contribution to uncertainties in the risk estimate

- ARPANSA should ensure that licence holders with high-risk activities also investigate near misses and events with low safety significance in order to identify possible trends in potentially triggering events and contributing factors. The analyses should assist in effective implementation of control measures

- ARPANSA should ensure that licence holders preserve the scene, as far as possible, following an event. However, this is subject to making the scene safe to prevent any unnecessary exposure

- a regulatory event response procedure should be developed that provides guidance to regulatory officers and inspectors from time of notification to closure of the incident.

It should be noted that ARPANSA will host an IAEA-coordinated Integrated Regulatory Review Service (IRRS) mission in November 2018. It is anticipated that the IRRS will offer further opportunities to enhance ARPANSA's regulatory performance, including its interaction with State and Territory regulators to promote nationally consistent safety regulation, across all Australian jurisdictions.

While ARPANSA takes into account regulatory experience outside of the RPF, this report summarises ARPANSA's assessment of its performance against the six KPI of the RPF. This assessment supports 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 Self-Assessment 2017–18 and provides details of the assessment and its outcomes.

1.3 Methodology

The framework established by the RPF includes a common set of six KPIs to allow for a comprehensive assessment of regulator performance and engagement with stakeholders. In 2015, ARPANSA obtained ministerial approval for a set of 12 quantitative Performance Indicators (PIs) that relate to the six RPF KPIs. Data collection began in March 2015 and these PIs were used to assess ARPANSA's performance for the first two annual self-assessments. During this time it was concluded that the PIs adopted by ARPANSA were not fully aligned with the six KPIs established by the RPF. Hence, ARPANSA sought, and received, ministerial approval for a revised set of 12 PIs that came into use from July 2017. This is the first year that these PIs have been used.

The revised set of 12 ARPANSA PIs were developed after taking into account the learnings gathered during the last two years. In order to provide as complete a picture of ARPANSA's regulatory performance as possible, additional evidence was used to provide a more informed assessment.

The report is based on the outcomes of a self-assessment undertaken from 22 July to 27 July 2018, and that included fieldwork as well as consideration of the previous assessments. It considered all ARPANSA regulatory activities undertaken in the period from 1 July 2017 to 30 June 2018.

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

- Andrew McCormick – Regulatory Officer, Regulatory Services Branch, ARPANSA.

Team members

- Stephen Newbury – Principal Health Physicist, Department of Health and Human Services, Tasmania

- Robin Foy – Manager, Radiation Protection Services, Australian Nuclear Science and Technology Organisation (ANSTO)

- Jessica Lye – Director, Australian Clinical Dosimetry Service, Medical Radiation Services, ARPANSA

- Chris Nickel – Senior Regulatory Officer, Regulatory Services Branch, ARPANSA.

The assessment focussed on a review of performance against the 12 PIs to ensure that the intent of the six RPF KPIs are met and to verify that quantitative data was accurately recorded. Additional data has been taken into account to provide a balanced and objective assessment of performance.

The team set out to identify Areas for Improvement (AFIs) to assist ARPANSA improve its regulatory outcomes. Strengths were also identified to understand and learn from what ARPANSA does well.

To provide qualitative information on performance, the assessment team 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 14 ARPANSA staff including management

- observing two regulatory inspections

- interviewing seven staff of the licence holders that were associated with the two inspections observed by the self-assessment team.

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

1.3.1   External validation

The Nuclear Safety Committee (NSC) was been appointed by the former portfolio minister as the external validators for the RPF reports. This was after reflecting on the NSC's wide ranging stakeholder representation and expertise in ARPANSA's regulatory role. External validation of a regulator's self-assessment involved the following:

- whether the report appropriately reflects ARPANSA's performance against the KPI over the assessment period[6]

- whether ARPANSA has adopted and is currently working to the Government Regulator Performance Framework to the extent that is reasonably practical

- whether the self-assessment has met the scope of reporting objectively on efforts and progress against administering regulation fairly, effectively and efficiently

- whether relevant continuous improvement actions have been identified to strengthen ARPANSA's performance.

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[6]   Note that it is not intended that external validation should involve an audit of ARPANSA's self-assessment approach or results

2 Performance assessment

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

2.1.1 Overview of KPI 1

ARPANSA endeavours to avoid any undue impact on the operations of the licensed entities. This is by conducting inspections according to an open and transparent schedule and by assessing licence applications in a timeframe as agreed with the licence holder.

ARPANSA maintains a hazard- and risk-informed inspection program. Inspections of licensed activities follow a three-year schedule for facilities and a six-year schedule for sources. These schedules describe the baseline inspection frequency. Unscheduled inspections beyond the baseline may also be conducted. These 'augmented' inspections are likely to occur in response to specific circumstances such as an incident, accident, non-compliance or area for improvement. In such cases, targeted inspections of a defined scope will be planned, scheduled, and communicated to the licence holder. In certain circumstances, it may be necessary to conduct an unannounced inspection. Such inspections are in response to a specific situation or event. The licence holder will typically be notified of the inspection prior to entry.

Inspections are conducted using PO&C. These were developed based on international best practice to inform licence holders and the public of ARPANSA's safety and security expectations that are assessed during an inspection. They provide a comprehensive list of features, controls and behaviours that contribute to safety, arranged into eight baseline modules and three cross cutting modules.

For sources, and simple facilities, all of the PO&C are addressed in a single inspection. For complex facilities, a series of inspections are used to address all of the PO&C. This is done by focussing each inspection on a single or subset of the PO&C and assessing the performance of the facility at a deeper level. The Inspection Schedule identifies the scope of each inspection in terms of PO&C and is made available to licence holders.

Publishing the PO&C increased ARPANSA's transparency and, together with an inspection schedule that identifies the PO&C areas to be inspected, allows the licence holder to prepare for an inspection. The specific date and a schedule of activities for inspections is then agreed with the licence holder in advance of a two-week formal notification period. Conformance to the Inspection Schedule is monitored.

ARPANSA receives various types of applications for nuclear installations, prescribed radiation facilities and sources. This includes 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 detail 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.

2.1.2   Approved evidence metrics for KPI 1

Indicator	Evidence	Comment
PI 1.1 ARPANSA will measure the percentage of inspections conducted in accordance with the risk-informed long term inspection schedule [quantitative].	⛔ 78% of inspections were conducted in accordance with schedule. This is less than the target of 85%.	• This measure was met in the last three quarters (100%, 92% and 88%). The first quarter was affected by changes in the inspection program that altered the types of sources to be inspected. • 9 of 40 inspections were not carried out in accordance with the schedule. More than three quarters of these occurred in the first quarter. In addition to changes to the inspection program, non-adherence to the schedule was largely due to operational and resource considerations.
PI 1.2 ARPANSA will measure the percentage of applications which are assessed within this agreed timeframe [quantitative].	✅ 84% (22 of 27) assessments were within agreed timeframes. This is better than the target of 75%.	• This result meets the target. • In consultation with licence applicants or licence holders, regulatory staff will prioritise resources and establish a date for completion of the application assessment. • The agreed timeframes assist the licence holder in planning, avoiding impediments to business.

2.1.3   Other evidence to indicate compliance with KPI 1

ARPANSA works to reduce unnecessary regulatory burden for licence applications. Different application forms are available for low, medium and high hazard sources as well as for prescribed radiation facilities and nuclear installations. The different forms require differing levels of detail and reflect a graded approach to safety. Whereby, low hazard sources require less detail to demonstrate safety can be appropriately managed then prescribed radiation facilities and nuclear installations which require substantial detail to demonstrate an acceptable level of safety.

ARPANSA has a comprehensive framework of guidance for licence holder's periodic compliance reporting, incident reporting, how they should review their plans and arrangements, and whether regulatory approval is needed when changes are made to their licences, by providing this guidance ARPANSA minimises the burden on the licence holders. Furthermore, these guidelines are informed by hazard and risk and help licence applicants and holders focus their resources and minimize the burden in addressing these requirements of the legislation.

ARPANSA undertakes meetings and site visits with licensees to explain regulatory requirements to licence holder representatives and to gain understanding of their operational needs. This helps to inform the licence holder how ARPANSA conducts its regulatory business and also informs ARPANSA of specific operational needs of the licence holder. During the reporting period, 37 information-sharing meetings and 70 site visits to facilities and seven site visits to sources were undertaken.

ARPANSA, through alignment with international standards, endeavours to ensure that best practice regulation informs decision-making and promotes regulatory certainty. The use of international standards is important in meeting community expectations for nuclear safety and radiation protection 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 directly involved in the development of international safety and security standards and guidance documents.

Using this approach, ARPANSA published additional guidance in 2017–18 such as the Guide for Radiation Protection in Existing Exposure Situations and guides for determining if Class 1M and Class 2M laser products and UV sources are a controlled apparatus. ARPANSA also published an update on its guide for licence holder plans and arrangements for managing safety, based on international standards.

Through the IAEA Integrated Regulatory Review Service (IRRS), ARPANSA's regulatory processes were subject to an international peer review in 2007 (with follow-up in 2011) that set out to determine how closely ARPANSA's regulatory service meets international standards. Following established international practice that IRRS reviews (or similar peer reviews) should be conducted at approximately ten-year intervals, a second review is scheduled for 2018. ARPANSA staff are currently undertaking a self-assessment of processes and practices against IRRS guidance. ARPANSA staff also participate 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.

2.1.4   Analysis of evidence presented

These two PIs provide a reliable indicator of the potential impact of regulation on the efficient operation of regulated entities.

PI 1.1 measures adherence to Inspection Schedules. Inspection frequencies range from three per year for the most hazardous facilities to once every six years for very low hazard sources. ARPANSA's use of inspection schedules aims to bring efficiency through a transparent predictable program of inspections. If the licence holders know when and where an inspection will be occurring they can better plan to facilitate it by preparing resources and the availability of staff, documentation and inspector access to premises in order to minimise disruptions to operations.

The target of 85% adherence to the schedule is a commitment made under the Parliamentary Budget Statement (PBS) reporting. In this financial year, ARPANSA achieved a result of 78%. Over the course of the year, 9 of 40 inspections were not conducted in accordance with the schedule. While poor performance was seen in the first quarter (46%), the target was met in the second (100%), third (92%) or fourth quarter (88%).

As is evident from the above, the majority of the deviations to the schedule occurred during the first quarter. This followed the implementation of a new source inspection program. The changes to the program were made with the aim of more efficiently using regulatory resources. Two further deviations from the schedule did occur in the later part of the year. Deviations from the schedule were communicated to the licence holder in advance with explanations. ARPANSA has previously met this target. For instance, in the 2016/17 financial year, ARPANSA achieved a result of 92%. As such, this is considered to be a minor variation from the long term performance against the Inspection Schedule. Furthermore, it is considered that the spirit of this KPI is that ARPANSA as a regulator does not unnecessarily impede the operation of the regulated entities. While adherence to the inspection schedule enables licence holders to better plan their activities, it is concluded that some deviations from this schedule does not unavoidably mean that

ARPANSA is being unnecessarily burdensome. Particularly, if the deviations are communicated with the licence holders.

The inspection frequencies are based upon regulatory priority, which is risk informed. For facilities this is based on an assessment of both the hazard of the facility and the observed level of control exercised by the licence holder. For sources the regulatory priority is based on the hazard of the sources, through a graded source categorisation. Additionally augmented inspections of both sources and facilities may be undertaken outside the schedule where warranted by poor licence holder safety performance[7]. The Inspection Manual provides for the option that a simplified inspection approach, such as a limited scope inspection, can be performed in some instances if the licensee has demonstrated excellent performance.

A licence holder's representative commented on the efficient manner of notification being 2–3 months ahead and then confirmed two weeks or so before the date of the inspection. The team was advised that the licence holder was not aware of the long-term schedule, but would greatly value being advised of the long-term Inspection Schedule as this would have assisted the licensee with budgeting and planning purposes. They were not aware that the multi-year inspection schedule was available, or how to obtain a copy.

It was also suggested that some strategic opportunities were being missed. These involve the setting of specific inspection strategies outlining the areas that should be examined in more detail, for example, risk assessments. This can be set at a broad level for all licensees but could also be applied for large licence holders that have multiple facilities (e.g. focus on organisational and human factors). A natural time to consider the inspection strategy could be during hand over from one lead inspector to another occurring approximately every three years. For large licence holders, a small team with a range of expertise covering both safety and security aspects could discuss the strategic focus on various PO&C for the subsequent three years.

The assessment team also examined the workload planning arrangements. In general, the RSB was seen to be performing at a high level in a demanding and important work program. However, it was observed that RSB staff did not have access to specialised task management and project management software. Planning for inspections was frequently interrupted by administrative work matters. The team concluded that there is scope for planning of staff time to be optimised.

RSB is organised around four functional sections that lead and co-ordinate activities shared throughout the entire branch. This is an intentional strategy that takes account of individual's specialisation. This appears to be working as feedback from the licence holder's representatives indicated that ARPANSA staff and management have a good technical grasp and understanding of their operations. However, RSB as a whole has often struggled to break down organisational silos and collaborate beyond performing direct regulatory activities such as inspection and assessments. This may, in part, be due to the high demand work environment. This can affect important non-direct regulatory functions such as codes and standards development and tasks required for quality assurance.

The current information and record systems remain fragmented and inefficient. There is substantial scope for improvements in regulatory efficiency and effectiveness by bringing together a number of record systems and databases and integrating these together more fully. A project has been initiated that is

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[7] During this financial year, three augmented inspections were conducted. Two of these were at ANSTO Health and one of them was at ANSTO's Gamma Irradiator Suite.

looking to replace the existing licensing database and provide a more complete solution capable of supporting the regulatory staff with easily accessible information. This project was identified as being important by ARPANSA staff including management, however the project has not yet received funding and established implementation timelines. The assessment team put high importance on this development as a way of reducing work pressures and freeing up more time to work on core regulatory business. The team recommended that this project be given high priority.

ARPANSA is currently implementing a project to bring its inspection service into conformance with ISO17020 that specifies requirements for the competence of bodies performing inspections. As part of the project ARPANSA is mapping workforce needs and implementing a strategic approach to recruitment, training and education to improve resource depth and flexibility.

During the review, a licence holder's representative indicated they would be interested in the possibility of ARPANSA producing self-assessment tool(s) to enable them to be more 'inspection-ready'. This would be a move towards effective self-regulation and a sign of good safety culture. It also has the potential to greatly improve the efficiency of inspections as the operators will know the type of information the inspectors intend to request and can have it ready. Further, this can improve the effectiveness of the inspections by focussing on the deeper, more important safety management issues. The type of tool that has been suggested would be similar to the e-inspections and supplement the PO&C and the tools to improve holistic safety that are already available on the ARPANSA website. It will be important in the development of such self-assessment tools to avoid encouraging a 'tick the box' mentality to inspections. Rather, it is suggested that this is a way of achieving a higher degree of licensee compliance, and thereby affording, inspectors the capacity to examine licensee performance more deeply and thoroughly.

PI 1.2 seeks to avoid unnecessary impact on the efficient operation of licensed entities by providing timely decisions. The assessment of various applications, alongside inspections, are the most direct regulatory impact to licence holders. The current process is for inspectors to discuss the urgency of an application with the applicant and also taking 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. ARPANSA assessed 22 of 27 applications within agreed timeframes. This is a result of 84% which exceeds the target.

The team concluded that the majority of applications are unique making it difficult to have set timeframes for many applications. However, the high performance against this PI is a remarkable achievement. Failure to meet target dates occurs for a variety of reasons such as incomplete information in an application, technical complexity and the unavailability of specialist expertise to review an application. Conflicts of regulatory resources, especially in the inspection program, can also cause delay.

During interviews with ARPANSA staff and management the team was advised that the lines of decision making could be further streamlined in the review and approval of assessments whilst still maintaining the appropriate amount of oversight.

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.

2.1.5 Self-assessed rating of performance against KPI 1 – 2017–18

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

In the 2015–16 self-assessment report, ARPANSA's performance was judged to be 'good'. In 2016–17, this was judged to be 'very good'. ARPANSA has maintained its performance in this area at the 'very good' level. This has been supported by the continued and the improved use of the PO&C which is appreciated by the licence holders. In regard to the inspection schedule, the team considered that a deviation in one quarter did not indicate overall negative or poor performance when factors discussed above were taken into account.

2.1.6 Actions for improving performance against KPI 1

The team identified the following AFI:

* data management tools are fragmented and inefficient and a review of potential actions to resolve the issues (including consolidation or replacement) should be conducted as soon as possible

* workforce planning (ISO 17020 project currently in progress to address this)

* preparation of a self-assessment tool, similar to the e-inspection program, to assist licence holders to assess their compliance outside of the inspection cycle.

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

2.2.1 Overview of KPI 2

The internationally agreed principle is that the prime responsibility for protecting people and the environment (i.e. for carrying out activities safely and securely) rests with the licence holder. To achieve this, ARPANSA has sought to improve communication and consultation that supports and encourages licence holders to be effective in managing nuclear safety and radiation protection and meet their responsibilities under the Act and Regulations. Likewise, it is also important to inform regulatory staff of the operating environment, priorities and needs of regulated entities. In order to fulfil the former, ARPANSA has developed, and regularly updates, guidelines that assist licence holders to develop their own plans and arrangements to fulfil their responsibilities and to demonstrate compliance with the Act and Regulations. The latter is addressed by consistency in the lead inspectors, two-way communication and site visits to see work being undertaken in practice.

During the year, ARPANSA has communicated via written communication, meetings, site visits and inspections and a mini-licence holder forum. 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 can include consultation with

stakeholders via the ARPANSA website (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, communication with a licence holder well in advance of an inspection advises when an inspection will take place and the PO&C that are to be used. A condition of all licences allows ARPANSA to undertake an inspection at any time including through the use of unannounced inspections. In, practice, unless there are urgent and unusual circumstances, each inspection is to 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.

For multi-day inspections, meetings are held at the end of each day and for all inspections a final exit meeting is held to agree the facts identified and to outline the preliminary findings. This exit meeting can be conducted via teleconferencing facilities. Exit meetings are seen as a positive practice and provides an opportunity for immediate feedback on how the inspection had been perceived by the licence holder.

After the inspection report is issued, the Office of the CEO (OCEO) 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. Currently to assure the integrity of the process, this process is independent of RSB. The response options range from 'strongly agree' to 'strongly disagree'. Feedback is analysed and is seen as an opportunity for learning and improvement. A score is calculated for overall satisfaction from 0 (strongly disagree) to 100 (strongly agree). This serves as an indicator of how licence holders perceive the effectiveness of the planning and implementation of an inspection.

As discussed in section 2.1.3 above, in addition to scheduled inspections, inspectors can make regular site visits to facilitate two-way communication on regulatory matters. These visits provide opportunities for inspectors to understand the ongoing operational environment of the licence holder and to share wider regulatory experience. 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, and recorded in our Licence Administration Database (LAD).

In addition to site visits, regular meetings are held with many licence holders to exchange information on regulatory matters such as licence applications or licensing and safety compliance issues. Examples of such established forums are the Defence-ARPANSA Liaison Forum (DALF), the CSIRO Liaison Forum, ANSTO OPAL Reactor quarterly meetings and the mini-licence holder forum.

Communication is a two-way process so these meetings are effective in helping ARPANSA understand regulatory impacts 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 of meetings in a year demonstrates the efforts that ARPANSA goes to in communicating with the licensees.

2.2.2 Approved evidence metrics for KPI 2

Indicator	Evidence	Comment
PI 2.1(a) – ARPANSA will measure the number of meetings held in a year [quantitative]; and (b) evaluate the quality, including any feedback received from these meetings, to determine if the communication is effective [qualitative].	✅ 38 information sharing meetings exceeds the target of 20.	• Meetings were held with licence holders to exchange information on regulatory matters such as upcoming legislative changes, new or amended regulatory guides, licence applications, or licensing and compliance issues. • Surveys and feedback from meetings were overall positive and where applicable were used to enhance future meetings.

2.2.3 Other evidence to indicate compliance with KPI 2

ARPANSA promotes a holistic approach to safety that encourages licence holders to consider any human and organisational factors affecting safety of controlled activities that are underlying causes of accidents. A licence holder is expected to improve systems and processes beyond an immediate problem, and carefully consider wide ranging issues of safety and security culture, human performance and performance improvement. ARPANSA has also published information about its inspection process and other guidance on the website to inform licence holders of their regulatory responsibilities and assist and encourage them to identify and rectify their own problems.

The team observed two inspections. It was concluded that both of the inspections were well conducted with the inspectors demonstrating clear communication skills. The feedback from the licence holders is that ARPANSA is open and very available for discussion on matters relevant to safety. This appears to have fostered a culture that encourages licence holders to be willing to discuss issues in a transparent manner. The team observed that there was a respectful relationship between the ARPANSA inspectors and the licence holders.

One of the inspections observed by the team followed-up on the outcomes of a previous inspection. It was observed that the inspector clarified previous communication by identifying what the requirements are and discussing alternative means of achieving compliance without resorting to telling the licensee exactly what to do.

Discussions with regulatory staff and management identified some differences of opinion about what verbal guidance could be given to a licence holder without taking on their responsibility for safety. Some inspectors gave more guidance than others, and some guidance was more appropriately presented. For instance, explaining to the licence holder's representatives what the requirement is and discussing other non-prescriptive means of achieving the same outcomes. On the other hand some inspectors gave specific and direct guidance which caused the licensee to believe that they have to comply with the 'suggestion'. The team considered that, where available, advisory documents could be an aid to discussions with licence holders.

ARPANSA has a 'no surprises' policy when it comes to the reporting of safety concerns back to the licence holder. This was observed to be implemented in a variety of ways; including 'on-the-spot' communication such as the identification of poor practice during a facility walkthrough; a debrief at the end of the day; and the formal exit meeting. ARPANSA then formally reports the issue via the written inspection report. The

team considered that, where achievable, communicating the issue as soon as possible improves the licensee's understanding of what the poor practice is, why it is considered a poor practice, and increases the likelihood that the matter will be properly investigated and robust improvements made.

As described in KPI 1 application timeframes are negotiated and agreed. These timeframes were met in 84% of cases.

ARPANSA has a practice of routinely rotating the lead inspectors responsible for each of the licenses. This aims to balance the desire for inspectors to be knowledgeable in the operations of the facility against the risk that inspectors can become too close to a facility and lose impartiality (regulatory capture). There is the added benefit that introducing the 'fresh eyes' of a different inspector that may identify something that would otherwise be missed. The licence holder's representatives were supportive of ARPANSA's efforts to understand their facilities and their business, and observed that efficiencies are available when there is a consistent point of contact. The three year period was seen as a suitable timeframe to balance the risks and the benefits of the approach.

ARPANSA staff observed that weaknesses in internal communication can sometimes negatively affect their ability to communicate with the licence holders. For instance, when staff have been unaware of changes that have been made to the regulations. Another concern was that the process for the routine review of documents was considered to be too onerous and not always result in as thorough a job as expected, having a negative effect on the quality and substance of ARPANSA's written communications with licence holders.

ARPANSA uses PO&C to guide the structure of inspections. The PO&C are available on the ARPANSA website. The team observed that the PO&C are clearly used by the inspectors and the licence holders indicated that they provide value through clearly identifying areas of inspections.

The licence holder's representatives reported that the ARPANSA website is a useful source of information. It was identified that it would be useful to the licence holders if further information was available on specific topics. It appears that information on the suggested topics is already present. However, it was reported that the website is difficult to navigate in order to find specific information.

The team praised the amount and quality of information that ARPANSA has published. Particularly, the high level codes and guides were considered to be effective. However, it was observed that there was scope to perform further work in tailoring the information to suit the intended audience. For instance, the investigation into a serious accident raised questions about the management of human factors within that organisation. Feedback from the licence holder suggested that there was a lack of clarity on what human factors really meant; how they contributed to holistic safety and how ARPANSA expected the licence holder to address these issues. At the other end of the scale, there is limited clear simple information for low risk/hazard applications (e.g. users of baggage X-ray scanners obligations under the Planned Exposure Code). It was also reported to the team that ARPANSA had been poor at educating licensees on security requirements. It was suggested that ARPANSA could provide licensees with fact sheets and background information to help both with clarification of terms and educating operators.

A licence holder observed that there had been a change in ARPANSA's approach to include an expectation of a holistic approach to safety and consideration of human factors. The licence holder agreed that this was important and represented a maturation of ARPANSA's approach to regulation. However, they expected a grace period to allow time to implement an approach to holistic safety. The licence holder did not appear to be aware that ARPANSA has promoted holistic safety since 2012 through a wide range of media,

meetings, forums and conferences. This suggests that a renewed emphasis needs to be given to communication of regulatory requirements and expectations throughout licensed entities. The ARPANSA website could be improved to achieve this.

ARPANSA has implemented a multifaceted approach to communications. This involves written material ('advisories') on the common findings and issues for source types (e.g. baggage X-ray screening, lasers, etc.) and correspondence, large and small forums for interacting with the licence holders. The use of alternative methods of encouraging compliance (i.e. other than inspections) is seen positively by ARPANSA staff and licence holders. The licence holder's representatives reported that inspectors communicate clearly and that correspondence from ARPANSA is also clear.

ARPANSA updates and communicates its Inspection Schedules to licence holders. 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 PO&C 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 as 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 areas for improvement, 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 inspections was effective. ARPANSA inspectors were reported as well regarded and seen as professional in their work.

Following the 2015–16 self-assessment, RSB now reviews, analyses and compiles survey data, along with other performance metrics, into an internal quarterly report for staff. This highlights where RSB is doing well and where improvements can be made. It also provides information on licence holder performance that can inform inspection planning and improve communications during inspections, site visits and other meetings or correspondence. On a similar theme, RSB published information on inspection outcomes on its website. This can assist licence holders to understand the common safety issues that inspectors encounter.

ARPANSA has historically held a licence holder forum at least on an annual basis. A forum was scheduled for June 2018, however, it was postponed as there was insufficient resources to coordinate and manage the forum. In addition, a key note speaker was unavailable. The absence of the annual licence holder forum for 2017–18 was offset somewhat by the introduction of a new outreach endeavour. This was the concept of mini-licence holder forums conducted with the licence holders in the local regions.

ARPANSA conducted the first mini-licence holder forum in June 2018. This was located in South Australia and aimed to engage with the local licence holder representatives. The mini-forum was targeted towards front-line staff who work with radiation rather than the corporate representatives of the larger licensees. The mini-forum focussed upon sharing the analysis and findings of the inspections of source licence holders between 2016 and 2018, and discussing common issues and challenges faced by licence holders and the regulator. The forum was attended by 11 people from three licence holders. A survey was distributed to the attendees and a small number of responses were received. These responses showed that licence holders thought that the information that was shared was relevant and communicated in an effective manner.

2.2.4 Analysis of evidence presented

Overall, performance against this KPI was assessed as very good. This is based on both PI results and other licence holder feedback.

PI 2.1(a) focuses on the number of information sharing meetings held with licence holders. During the last 12 months, ARPANSA has conducted 38 information sharing meetings with licence holders. This number is substantially greater than the target. It has previously been identified that information-sharing meetings are predominantly undertaken with large licence holders. This has been the case this year again. On top of this, 77 site visits were also conducted. Again site visits were almost exclusively with the large licence holders.

PI 2.1(b) The effectiveness of ARPANSA's communication was judged to be sound, based upon the perceived degree of licensee engagement. As previously identified, information-sharing meetings and site visits are predominantly undertaken with large licence holders. While it is understandable that the large licence holders probably have numerous issues to be discussed, strategies to improve communication with the smaller licence holders should be implemented. Some methodologies, such as video or telephone conferences have previously been identified as supplementing a large licence holder forum. The mini-forum concept has been developed and implemented to enhance communication to smaller licence holders. Improved methods of measuring ARPANSA's performance in this qualitative measure are recommended.

A number of issues were highlighted where internal communications should be improved to drive a culture of openness in safety matters throughout ARPANSA and beyond to licence holders. There was little practice to share information between source and facility inspection areas. It was thought to be a good idea if more regular meetings were set up for this between the general regulatory team as this may lead to improved communication of safety and security issues within the branch that would then flow through to licence holders, particularly in relation to greater consistency of approach by different inspectors.

2.2.5 Self-assessed rating of performance against KPI 2 – 2017-18

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

In the 2015-16 self-assessment report, ARPANSA's performance was judged to be 'very good'. In 2016–17, this was judged to be 'very good'. ARPANSA has maintained its performance in this area at the 'very good' level. This has been supported by the introduction of the mini-licence holder forums[8] and the continued feedback from the licence holders that ARPANSA is open and available. It has also been acknowledged that the use of lead inspectors has had a positive impact on the efficiency of the licensees operations as it allows the clear communication associated with a single point of contact.

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[8]   Although, only one mini-licence holder forum has been held to date, the intention to hold further mini-forums was evident.

2.2.6   Actions for improving performance against KPI 2

The team identified the following AFI:

- more tailored information should be prepared to suit specific situations or practices, such as the advisories recently produced for some common source types

- the structure of the ARPANSA website should be reviewed so that the information that is currently available is easily identified by interested parties

- better guidance should be provided describing the suitable level of guidance for inspectors to provide to licensees

- internal communications and information sharing should be improved to enhance understanding of issues and sharing knowledge across the branch and better outcomes for licence holders.

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

2.3.1   Overview of KPI 3

ARPANSA seeks to ensure that its regulatory oversight program is proportionate to the risk the controlled activity poses to people and the environment. It includes licence holder reporting, inspections, site visits and other meetings or forums. An inspection may identify potential non-compliance, areas-for-improvement or good practices.

'Areas for improvement' may occur when a licence holder does not follow accepted best practice or does not meet self-imposed standards but are not contravening a legal requirement. These represent an area where the licence holder should improve their safety and security systems and practices and are typically actioned voluntarily without further 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 an escalating range of available 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 the Regulatory Guide _Graded Response to Dealing with Licence Holder 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. These enforcement powers are common for regulatory bodies. While rarely required, they are necessary tools to ensure compliance with the Act in cases of acute risks to the safety of people and the environment; and to 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 ensure appropriate levels of 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, the frequency and intensity of the Inspection Schedule is informed by regulatory priority. Different systems are in place for facility and source licences. In the case of facilities, the regulatory priority is determined on the basis of the inherent hazard, the effectiveness of critical safety and security controls, and performance history. The regulatory priority for each facility is recorded in LAD in the section on risk ranking. Where the regulatory priority is altered, the inspection schedule is adjusted accordingly. Two similar 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 recognises the generally less complex nature of sources compared to facilities. The baseline inspection program is based on the hazard category of the source with additional (augmented) inspections undertaken where a performance issue is identified. The Inspection Manual specifies the regulatory priority for each type of source. ARPANSA has decided not to routinely inspect very low risk sources on the proviso that the licensee is reporting safety matters on at least a six monthly basis. ARPANSA has committed to performing more information-sharing and educational activities instead. If compliance reporting raises any regulatory concerns, additional oversight can be implemented. This can be a physical inspection or a remote inspection process (known as e-Inspection) which does not require inspectors to physically attend the site.

The inspection schedules are recorded in the record management system and are updated annually or as required by changes in licence holder performance.

Inspectors monitor licence holder performance on a regular basis outside the inspection process through site visits, licence holder reporting and meetings. Frequent site visits are undertaken to meet with licence holder staff and observe their operations. Unlike inspections, no detailed advance planning is required and observations are shared verbally with the licence holder at the time of the site visit. 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.

Fees and charges are set in legislation. To ensure that any financial impact to a licence holder is fair and appropriate, ARPANSA is undertaking a cost recovery project so that financial burden on licence holders is proportionate to the cost of regulation and that regulatory services are streamlined, efficient and effective. The project aims to more closely meet the goals of the Australian Government Charging Framework, which establishes that those who create the need for regulation should incur the costs. The project has identified areas for improvement to the business and costing models of ARPANSA's regulatory functions. The new cost recovery model aims to improve the transparency of ARPANSA's charging regime and make annual charges more reliable and predictable for small and large licence holders.

2.3.2 Approved evidence metrics for KPI 3

Indicator	Evidence	Comment
PI 3.1 – ARPANSA will measure the conformance to this scheduling and risk review processes [qualitative].	✅ This measure indicates ARPANSA's ability to apply its regulatory resources efficiently and proportionately where needed.	• Source and Facility licences were reviewed annually, and 14 facility licences were reviewed after significant regulatory events. • ARPANSA applies a graded, risk informed, approach to its inspection program.
PI 3.2 – ARPANSA will measure conformance with the policies for inspection outcomes and non-compliance, and the general proportion of effort applied to areas of greatest safety risk [qualitative].	✅ This measure indicates ARPANSA's ability to apply its regulatory policies in the event of non-compliance and in a graded manner.	• 86% of regulatory time which was recorded against a licence, was spent on licences with medium or higher risk. • The inspection program identified 113 Areas for improvement and six potential non-compliances. • ARPANSA has considered the significance of the non-compliances that have been identified. When reporting details of the non-compliances the licence holders involved are not identified by name due to the low safety significance of the issues.

2.3.3 Other evidence to indicate compliance with KPI 3

Policies and guidance on assessing regulatory risks and the effects on Inspection Schedules are clearly documented. However, there is no specific document outlining the implementation of the risk informed approach. As such there is variation (internally, nationally and internationally) on what is a task requiring high or low levels of resourcing due to its risk level. It has previously been identified that ARPANSA has a method of assessing the regulatory priority of sources and a separate method of assessing the regulatory priority of facilities. However, there was no assessment of how the two systems align and whether the appropriate regulatory resources were being applied in the correct areas.

The team observed that there was strong commitment to the graded/risk informed approach to regulation. Policies and procedures exist within the regulatory management system and both staff and management have a common understanding of how this is implemented within ARPANSA's regulatory activities.

ARPANSA uses PO&C in the conduct of inspections. This provides a consistent and transparent approach to the areas that ARPANSA will examine regarding licence holder performance. The PO&C provide a structure for inspections, with a scope and depth proportionate to the risk of the controlled activity, and at an appropriate frequency. The team observed that a graded approach existed in the planning of inspections. The areas that were assessed were the same, however, a less onerous approach applied for low risk sources. As an inspection tool, the PO&C were judged to be effective for providing consistency across the licence holders. However, some staff proposed that they should be reviewed to ensure all areas are appropriately assessed (e.g. security) in a relevant manner. The PO&C could be further improved by providing clarity on approach for low hazard sources. This work has been started.

ARPANSA's application process requires an applicant to demonstrate their capacity to meet regulatory requirements under the Act and Regulations. Where it is necessary, ARPANSA undertakes a regulatory intervention graded in accordance with the Enforcement Policy in the Compliance and Enforcement Manual. ARPANSA's policies have effectively emphasised that the prime responsibility to identify and rectify safety or security issues rests with the licence holder.

The risk-informed inspection program is designed to direct regulatory resources to licences presenting the highest risk. For sources this means an allocation of a regulatory priority and a minimum inspection frequency based upon the hazard of the source. For facilities, the regulatory priority takes into account the hazard of the facility and the assessed level of control implemented by the licensee. Amongst other things, the assessment of the licensee's level of control is based upon their compliance history, the frequency of incidents/accidents, the robustness of their defence in depth and plans and arrangements, their monitoring of safety performance and effectiveness of changes, and other holistic safety aspects. The regulatory priority for facilities should be reviewed annually, after an inspection, after an incident or accident and after changes to the facility.

The methodologies describing how the regulatory priority for facilities and for sources are assessed were previously published on the ARPANSA website. However, it was removed when the regulatory management system underwent a strategic restructure. ARPANSA is endeavouring to publish the information in the near future on its website.

2.3.4 Analysis of evidence presented

PI 3.1 relates to how well ARPANSA applies a graded approach to its risk review processes. The regulatory priority of 14 facility licenses were reviewed after regulatory events such as non-compliance, incidents and accidents.

Inspections use a holistic safety approach which means looking at human and organisational factors such as safety culture. An observation from inspections was that baseline inspections do not always have a clear line of sight of what is happening 'on the ground'. The team was advised that augmented inspections, and site visits, more frequently observe a process performed by an operator. Baseline inspections that watch actual workflow or dry runs may see improved understanding of underlying licensee's operations, their risks, and how they are being managed. The Inspection Manual suggests that observing work in practice should routinely occur where possible.

A potential area of uncertainty is the comparative regulatory priority between sources and facilities, i.e. does a source having an inspection frequency of once a year present the same risk as a facility having an inspection frequency of once a year? It was suggested that this should be an area that ARPANSA should resolve to assist the balance of workload and resourcing throughout RSB.

PI 3.2 relates to how well ARPANSA applies a graded approach to regulatory intervention. The team observed that formal enforcement action is only initiated where there is, or is likely to be, a non-compliance of a high safety significance or the licence holder fails to solve its own problems. The Compliance and Enforcement Manual contains a diagram showing the graded response to non-compliance. It reflects the ability to escalate the regulatory action if the initial response does not achieve a return to compliance. Regulatory response should commence at the most appropriate level depending on the circumstances. ARPANSA has a range of options when dealing with non-compliance. Whilst it is preferred to encourage and assist the licence holder to return to compliance, further actions including improvement

notices and directions are used. Additionally matters may be referred to the Director for Public Prosecution or for the Federal Court of Australia to grant an injunction where considered appropriate.

This is an effective approach that helps to avoid direct interference in the operations of a licence holder unless necessary. It indicates that ARPANSA is mindful of the need to be proportionate and predictable in its regulatory response.

During the reporting period, almost a third of all regulatory time was spent on activities that are related to licence holders, of this, 85% of time was on licence holders with a medium to high risk.

The team observed the use of both areas for improvement and potential non-compliances in the appropriate circumstances. However, the team was concerned that there can be grey-areas in some circumstances and encouraged the development of greater guidance to assist regulatory staff in differentiating the two concepts. It is recommended that there should be a written procedure with guidance on some common criteria (e.g. safety significance). However, one of the licence holder's representatives indicated that the areas for improvement that are identified by inspectors are generally useful and appropriate.

Overall performance against this KPI was assessed as very good. This takes into account the work that ARPANSA has performed in assessing regulatory risk. However, the previously identified shortcoming associated with the comparative risk of sources and facilities has not been addressed. Until this has been resolved, it is difficult to know whether ARPANSA is efficiently using the available resources and managing regulatory risk.

2.3.5   Self-assessed rating of performance against KPI 3 – 2017–18

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

In the 2015–16 self-assessment, ARPANSA's performance was rated as 'good'. In 2016–17 this was considered to be 'very good'. This assessment has concluded that the current rating is still 'very good'. Potential exists for ARPANSA to be considered 'excellent' in this area in future years. Areas for improvement that may assist ARPANSA in achieving this have been highlighted.

2.3.6   Actions for improving performance against KPI 3

The team identified the following AFI related to KPI 3:

- comparative safety risks between source and facilities licences have not been assessed and should be considered with a view to providing consistently proportionate levels of resources aligned to risk across both areas.

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

2.4.1 Overview of KPI 4

ARPANSA's compliance monitoring program comprises performance reporting by the licence holder, regulatory inspections and a range of communication practices that collectively provide regulatory oversight of licence holder compliance. Together, these approaches enable ARPANSA to assess licence holder performance against international best practice and to justify the need for any safety and security improvements identified. ARPANSA strives to be non-intrusive in its regulation wherever possible.

Each licence holder must report on its operations to ARPANSA. These reports keep ARPANSA informed of any significant safety matters. Reporting is typically conducted at quarterly intervals. However, this has been extended to periods of up to a year for low hazard and passive sources and facilities. The information required by reports should provide information that is readily available from internal conformance and business management systems. 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. To minimise administrative burden, 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. All sources and facilities are inspected against published PO&C that aim to deliver a consistent, predictable and transparent inspection service across the entire range of licence holders[9]. Importantly, to minimise disturbance to the licence holders, much of the inspection is undertaken through the detailed planning phase through research and review of documents before physically inspecting premises. The PO&C are available to licence holders on the ARPANSA website. All areas of the PO&C are examined in at least a three year cycle for facilities. Likewise, for sources, all areas of the PO&C are examined in at least a six year cycle[10]. Higher risk facilities and sources are inspected more frequently. The frequency and depth of each inspection is informed by risk. Currently, a typical particle accelerator is inspected across all PO&C every two and a half years whereas the more complex OPAL reactor is inspected six times over two years. Each of these OPAL inspections has a limited scope and addresses a small number of PO&C. This is so each area of the PO&C can be assessed in greater depth than a full scope inspection (i.e. against all PO&C). All inspections include the licensee's performance in three cross cutting areas: safety culture, human performance and performance improvement. These modules have a greater focus on human and organisational factors for safety and, together with the baseline modules, are consistent with ARPANSA's promotion of holistic safety that recognises the interacting importance of technological, human and organisational factors to safety and security.

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.

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[9] Although, it was observed in section 2.1.4 that there seems to be some variation in how inspectors implement the PO&C. Some inspectors strictly adhered to the structure of the PO&C while others used them more as a starting point to work from.

[10] Where a source licence holder has a large number of sources, a sample or subset of their sources are inspected within six years.

As described in KPI 3, ARPANSA streamlines its compliance activities by informing inspection frequency with risk. The regulatory priority ranking methodology was previously published on the ARPANSA website. However, it was removed when the regulatory management system underwent a strategic restructure. ARPANSA is endeavouring to publish the information in a public manner in the near future. Re-establishing a transparent and planned inspection program which is informed by risk will provide a platform for 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 their own AFIs and potential non-compliances. Commencing 1 July 2017, ARPANSA introduced an internal target to strive towards more self-reported non-compliance compared with those identified during inspections. The purpose of this target is to provide an indication of the maturity of safety culture at a licence holder. ARPANSA's ambition is that its processes are encouraging mature cultures[11] rather than less safe reactive and calculative models that require heavier and more intrusive regulatory practices. ARPANSA strives for licence holders that are increasingly able to manage their accountabilities for safety, and increased trust that permits a gradual reduction in necessary regulatory oversight and intervention. Three of the 16 breaches that were determined during the year were self-reported by the licensees. This shows a degree of self-management amongst the licence holders. This is an area ARPANSA may wish to examine further so that a greater proportion of breaches are identified, reported and rectified by the licensee. Improvements in licensee safety management and culture would be expected to improve self-reporting rates.

In the case of identified AFIs, there is an expectation that the licence holder will take corrective action in a timely fashion. ARPANSA anticipates that the licence holder correct or initiate corrective actions within 3 months. The objective of identifying AFIs is to encourage the improvement of safety and security and the adoption of best practice. The licence holder voluntarily taking actions following the finding of an AFI may be an indicator of the influence, transparency and effectiveness of ARPANSA's inspection/compliance monitoring program. It may also be an indicator of the safety culture of a licensee.

A periodic analysis of AFIs, potential non-compliances, and good practices is performed. This monitors trends and is able to identify emerging issues. Outcomes of analysis are made available to licence holders through the ARPANSA website so that they may review their operations for similar problems.

ARPANSA oversees the Commonwealth's use of radiation sources and nuclear facilities. However, many of the entities that hold a licence issued by ARPANSA must also simultaneously work within other regulatory frameworks. Examples of other regulators are Comcare, ASNO, and TGA.

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[11] Details of the culture maturity model are available at https://www.safeworkaustralia.gov.au/moving-culture-ladder-professor-patrick-hudson.

2.4.2 Approved evidence metrics for KPI 4

Indicator	Evidence	Comment
PI 4.1 – ARPANSA will measure the percentage of time an action is initiated within 3 months of an area for improvement being formally identified to a licence holder [quantitative].	✅ 57% of time an action is implemented within 3 months of finding an AFI. Target of 50% exceeded.	• 64 of 113 AFIs were actioned. • The target was met showing licence holders voluntarily implement corrective action following the finding of an area for improvement. • This may demonstrate good safety culture, the effectiveness of non--enforcement actions and ARPANSA's promotion of best practice.
PI 4.2 – ARPANSA licence holders are also regulated by other regulatory agencies. ARPANSA will collaborate with other regulators, where appropriate, by the sharing of information or undertaking joint activities. The objective of collaboration is to co--ordinate work in common areas of interest so as to avoid duplication and unnecessary disruption to the licence holder, and in so doing reduce regulatory burden [qualitative].	✅ ARPANSA collaborated with ASNO, Comcare and TGA.	• ARPANSA collaborated with other regulators, where appropriate, by sharing information or undertaking joint activities.

2.4.3 Other evidence to indicate compliance with KPI 4

ARPANSA collects regulatory information about the safety performance of licensees. This information is stored in a record management system, a purpose built database (LAD), the branch intranet page and a number of spreadsheets. It was observed that data for regulatory activities are not always easily available and have to be sought out. The team was informed that LAD stores 90% of the relevant regulatory information but that this information was not always easily accessible. Regulatory staff did not consider they had adequate tools to do their jobs efficiently. Further, LAD does not provide data to help managers see strategic issues.

LAD was developed in-house within ARPANSA and rolled-out several years ago but with only minor upgrades in the previous few years. The interviews with ARPANSA staff and management identified some frustration around this system which has not been kept up-to-date with ARPANSA's evolving regulatory management needs. Specifically, that it is not capturing all required information and that the usability is not in line with regulatory officer's expectations, and, as such, officers expressed a desire for the database to be improved. While data entered into LAD can be used with some difficulty to help inspectors do their jobs, it does not provide management with the tools they need to see strategic issues. This makes it difficult to make informed strategic decisions (evidence based) and creates the risk that something could be

overlooked. The LAD system does not meet the standards of a modern business intelligence system. For example, it does not provide for the calculation of fees, generation of licences, review of inspection outcomes, identification of what is where, etc. without manual intervention and the use of additional programs (e.g. spreadsheets). When a deficiency is identified there is a tendency to implement a stop-gap solution outside of LAD. However, this tends to complicate the matter further. A single, integrated, piece of software that not only stores information but also flags issues, helps to achieve regulatory oversight of current activities and feeds improvements back into the regulatory system is desirable. ARPANSA has invested in customer relations software with the aim of using this as the platform to house ARPANSA's regulatory data, amongst other things. However, while this was identified as a high priority project that offers the promise of good efficiency improvements, this has not been implemented at this time due to a lack of resources.

While the current system, which relies heavily on humans talking to each other, works as an oversight and management system, technology could facilitate data gathering, storage and retrieval. Currently, there is no direct upload of information, rather there is reliance on a shared email account, then manual load to ARPANSA's record management system. Such enhancements may also improve the data collected which is assessed against PI 4.1.

ARPANSA has a wide ranging, but limited, pool of resources within the regulatory branch. RSB may request assistance from the other parts of ARPANSA and also externally. RSB staff were unaware that a strategic approach to the resourcing of the branch exists. Likewise there was no awareness of a skills matrix or minimum training requirements being specified at the branch level. Training generally occurs 'on the job'. The formal sign-off of competencies through the Qualcard modules is currently being developed. There is reliance on the experience of each individual inspector, which may lead to a lack of consistency in regulation between different inspectors, which is mitigated through initiatives such as the PO&C. The interviews identified concerns among some staff that resources were not always utilised efficiently, and that the upskilling of staff in specialist areas is often performed in an ad-hoc manner.

The team was advised that some staff thought that internal lines of approval were too restrictive and that delegation level is not clearly linked to outcomes. This causes delays such as when applications for small changes need to be reviewed by too many people. This was countered by the managerial perception that although, it sometimes seems excessive, these checks identify necessary changes and as such the existing delegation structure is necessary.

2.4.4   Analysis of evidence presented

PI 4.1 relates to the percentage of AFIs identified during ARPANSA inspections that are initiated within three months. During the year, ARPANSA inspectors identified 113 AFIs, 64 of these had some type of actions initiated within 3 months. This is an action rate of 57%. Only two AFIs were rejected by the licensees. However, for 47 of the AFIs there is no indication whether action will be taken. This is a percentage of 42%. A single licensee represents 24% of the AFIs identified by ARPANSA. The management system tracks whether AFIs are initiated (this can be as little as lodging the AFI in a database), it does not record whether the licensee has adopted these AFIs. However, all AFIs are eventually reviewed in subsequent inspection(s) to determine if and how they are addressed.

PI 4.2 relates to how well ARPANSA collaborates and shares information with other regulators. ARPANSA is tasked with overseeing radiation protection and nuclear safety within the Commonwealth of Australia. The licensed entities are commonly also regulated by other bodies such as ASNO, Comcare and TGA. The team observed that collaboration and information sharing occurs on a regular basis with some regulators, but it

does not appear to be conducted in an extensive and coordinated fashion with others. Hence, it was concluded that more joint activities would be beneficial, especially on regulatory guidance and inspections. For instance, some incidents are investigated by both ARPANSA and Comcare, while it is perceived from a licence holder that certain incidents, such as lasers, are only investigated by Comcare.

ARPANSA has signed MOU with other regulatory agencies such as Comcare. ARPANSA reported holding 13 meetings with other regulators. The team observed that collaboration with ASNO appeared to be good with multiple meetings held to discuss security arrangements. Improved collaboration with Comcare offers potential benefits as Comcare and ARPANSA have common interests in underlying safety matters. During this reporting period ARPANSA has particularly worked with Comcare in the sharing of knowledge, information and expertise following an accident at one licence holder. ARPANSA and Comcare are currently updating an MOU between the two organisations. ARPANSA's relationship with the TGA has substantial room for improvement. However, broadly speaking, it is recommended that ARPANSA, pursue stronger relationships with all other relevant Commonwealth regulators.

One aim of the RPF is that regulators should be working together to minimise the burden on the regulated community. It was concluded that improvements are achievable in this regard. ARPANSA is encouraged to make greater efforts to reach out to the other regulators.

The team concluded that ARPANSA could improve in the engagement with State and Territory regulators to share more information. This would streamline regulation through the adoption of a consistent approach to radiation protection nationally. For instance, improved information flow from the Radiation Health Committee and Radiation Regulators Network on developing protection requirements for new technologies.

The team was advised that regulatory staff believe they do not always have easy access to all of the available information on regulatory matters. The document management system is considered to not be ideal for handling regulatory records or be well suited to performing higher level functions such as lessons learned from analysis of metadata.

Some staff and management considered that further work is needed to balance the available skills and the depth of those resources. The team concluded that cross-pollination and improvements in two-way communication internally could also improve ARPANSA's effectiveness by streamlining ARPANSA's regulatory activities.

Overall performance against this KPI was assessed as good.

2.4.5   Self-assessed rating of performance against KPI 4 – 2017–18

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

The 2015–16 self-assessment found ARPANSA's performance in this area to be 'good'. In 2016–17, this had improved to be 'very good'. However, this self-assessment rated performance to be 'good'.

2.4.6   Actions for improving performance against KPI 4

The team identified the following AFI related to PI 4.1:

- develop a strategic approach to collaboration with other regulators to minimise the burden on licensees and maximise the effectiveness of the compliance monitoring techniques

- develop better systems to help staff and managers do their jobs (e.g. task and project managers, a replacement for LAD, etc.)

- continue to develop the formal training program to improve overall consistency of regulation.

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

2.5.1   Overview of KPI 5

ARPANSA has endeavoured to become increasingly open and transparent in its approach to regulation and regulatory outcomes. This is important to promote consistent and high standards of regulation and to stay connected and maintain an honest and respectful dialogue with all licence holders.

ARPANSA has published a range of information on its website describing how it implements a risk-informed 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, a very small amount of content may be redacted or a report withheld for security or confidentiality reasons.

As discussed in previous sections, ARPANSA publishes guides, codes and standards on a range of regulatory topics that describes how ARPANSA carries out its regulatory business and sets out expectations for licence holders with respect to safety and security of sources and facilities. These guides, codes and standards aim to reflect international best practice; hence their requirements and expectations are predictable and in keeping with the international framework for safety and security. 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, assessment of applications, and enforcement activities. As regulation is a core business activity, time spent on direct regulatory activities is expected to enhance ARPANSA's understanding of licence holder operations, resulting in better compliance outcomes. Recording time spent on regulatory activities increases transparency, as it provides the basis on which licence charges are determined. Hence, enables ARPANSA to move towards a position that is consistent with the Australian Government Charging Framework which establishes the principle that those who create the need for regulation should incur the costs.

2.5.2 Approved evidence metrics for KPI 5

Indicator	Evidence	Comment
PI 5.1 – Appropriate feedback from a range of interested parties requires transparency in the regulatory decision framework and decision making. ARPANSA will use its website as the primary mechanism to improve transparency [qualitative].	✅ Information on the website is kept up to date.	• A total of 37 inspections have been posted during the year. • Updates to expectations for licensee plans and arrangements have been published. • The pages describing training requirements and compliance reporting have been updated.
PI 5.2 – ARPANSA will consult with licence holders for feedback on the development or significant amendment of guides and codes so as to improve transparency in regulation and support continuous improvement [quantitative].	✅ 100% of guides, codes and standards were open for consultation which exceeded the target of 90%.	• ARPANSA has published draft versions of a code and a guide and consulted with licence holders for feedback to improve transparency in regulation and support continuous improvement.

2.5.3 Other evidence to indicate compliance with KPI 5

ARPANSA endeavours to be open and transparent. For instance, the team that undertook this self-assessment included the Principal Health Physicist from the Tasmanian radiation safety regulator and a senior manager with responsibility for radiation protection at a large licence holder.

The Act establishes the Radiation Health and Safety Advisory Council (RHSAC), the Radiation Health Committee (RHC) and the Nuclear Safety Committee (NSC) to advise the CEO of ARPANSA. Each of these groups provides independent advice and assistance to the CEO of ARPANSA in regard to emerging issues, safety standards and practices and regulatory approaches relating to radiation protection and nuclear safety. The roles and expectations for members of the advisory bodies have been defined. The minutes from the meetings of these advisory bodies are available on ARPANSA's website.

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

In accordance with international best practice in the communication and consultation with interested stakeholders, ARPANSA is required to publish a notice of the intention to make a decision on an application for a facility licence. If the facility is a nuclear installation, the notice must include an invitation to the public to make submissions along with the period and procedure for making the submissions. This provides transparency and openness for interested parties when assessing licence applications.

A decision was made by the CEO of ARPANSA to authorise the operation of the ANSTO Nuclear Medicine (ANM) Facility on 24 April 2018. This decision was made after publishing notices and inviting submissions on the application from the public and major stakeholders. These notices were placed in the Australian Government *Gazette*, in The Australian newspaper and on the ARPANSA website. A public meeting was

held in the Engadine Community Centre in June 2017. The licence application was also published on the ARPANSA website which provided access to interested parties.

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

2.5.4 Analysis of evidence presented

Overall performance against this KPI was assessed as excellent. 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.

PI 5.1 is a measure of the transparency of ARPANSA's regulatory decision framework and decision making. The team was satisfied with the commitment to transparency and observed that ARPANSA is open and responsive to licence holders and the wider community and applauded the volume of material published on the ARPANSA website. These range from the high level examples, like the timely publication of quarterly and annual reports in a public manner, to the request for an IRRS review which will result in a publicly available report, and to operational examples, like the transparent way the inspectors conduct themselves, the publication of inspection reports and the quick response to enquiries.

PI 5.2 relates to the level of consultation with licence holders on the development of ARPANSA's regulatory guides, codes and standards. During the year, draft versions of the following documents were published on the ARPANSA website for comment:

- the Existing Exposure Guide - Guide for Radiation Protection in Existing Exposure Situations (RPS G-2)
- the Code for Disposal of Solid Radioactive Waste (RPS C-3).

ARPANSA's public consultation via the ARPANSA website is the method for consulting with affected licensees on Radiation Protection Series documents. The team was advised that extensive consultation with states and territories, public (via website) and peak bodies was undertaken.

In addition to the above documents, public consultation was also undertaken for other publications with peak professional bodies (including the Australian and New Zealand Society for Nuclear Medicine, Australasian Radiation Protection Society, The Royal Australian and New Zealand College of Radiologists, etc.), and State/Territory regulators on the Australian Radiation Incident Register Annual Report.

During the reporting period, ARPANSA held 38 information-sharing meetings and 77 site visits to promote clarity and transparency.

With regard to siting of potentially contentious facilities, in particular waste storage and disposal facilities, international experience demonstrates that early visibility of the regulator in the local debate is imperative to build trust in the licensing process. This outreach must commence well before a licence application is received and respond to legitimate concerns and requests for information on the role of the regulator in the process. ARPANSA has taken the approach to reach out to stakeholders in South Australia regarding the proposed National Radioactive Waste Management Facility. ARPANSA has carried out several visits to relevant communities and engaged with a wide range of stakeholders. This in no way pre-empts a regulatory decision, but contributes to the establishment of a regulatory process that is characterised by rigour and transparency, and is well known by stakeholders.

2.5.5 Self-assessed rating of performance against KPI 5 – 2017–18

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

The 2015–16 assessment characterised ARPANSA's performance as 'good'. In 2016–17, ARPANSA was rated as 'very good'. ARPANSA has continued to improve in this area. This assessment has concluded that ARPANSA's performance is 'excellent'.

2.5.6 Actions for improving performance against KPI 5

The assessment team did not identify any specific improvement measures for KPI 5.

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

The regulatory environment ARPANSA operates is constantly evolving as knowledge of the hazards are better understood and the philosophies and techniques for safely managing them mature. Developments in the science, technology and systems that are available to, or developed by, ARPANSA's licence holders support a continual re-evaluation of all aspects of nuclear safety and radiation protection. ARPANSA must be adaptable to meet the needs of regulated entities while assuring compliance with the Act and Regulations and maintaining high levels of nuclear safety and radiation protection. A program of continuous improvement is recognised as being important to building a resilient regulator that is able to know what to expect, monitor its regulatory environment, adapt to any challenges, and learn from its experience. To help facilitate this, RSB has four functional areas, including one focusing on regulatory codes and standards and another on safety systems and continuous improvement.

Areas for improvement in the regulatory framework are identified via various methods including this annual self-assessment. Additional opportunities include performance and governance processes, routine reviews of the regulatory management system, stakeholder feedback surveys, external audits including peer review missions by international teams of comparable regulators, international, national and stakeholder 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 domestic stakeholders, and the international community. See Section 2.2 for more information on communication.

ARPANSA is active in international standards development and risk assessments through, for example, active participation in safety standards committees of the IAEA and the International Commissions on Radiological Protection (ICRP) and Non-Ionizing Radiation Protection (ICNIRP). ARPANSA works to ensure that international standards fully meet Australian safety and security interests and that risk assessments are relevant in the Australian context. This is important for ARPANSA's work to promote the use of international standards, rather than developing local documents. International fora are an important source of new ideas and initiatives in regulatory policy and practices.

2.6.1 Approved evidence metrics for KPI 6

Indicator	Evidence	Comment
PI 6.1(a) – A survey score is used to trend ARPANSA's performance [Quantitative]. (b) The survey format provides the opportunity to add specific comments on the service provided. Feedback is an opportunity to identify improvements and enhance consistency of good practices. ARPANSA will analyse results to help gauge how effective regulatory staff is in putting the six KPIs into practice [qualitative].	✅ 87% overall satisfaction exceeds the target of 75%.	• 43 post inspection surveys received from 196 invitations. Feedback included praise on the knowledge and professionalism of inspectors.
PI 6.2 – The number of regulatory improvements identified and implemented will measure ARPANSA's actions to continuously improve the regulatory framework [qualitative].	✅ 5 regulatory improvements were identified and implemented in the financial year	• ARPANSA's efforts to continuously improve the regulatory framework has been observed. • Information sharing mini-licence holder forums have been designed to share the common results of inspections with licence holders. • A register was established for the tracking of actions associated with confirmed non-compliances. • A survey has been developed to obtain feedback on the process for the assessment of licence applications.
PI 6.3 – ARPANSA's regulatory activities should meet national and international standards of good practice. To achieve this, ARPANSA will cooperate with national and international bodies in the development of best practice radiation regulation including in the development of international	✅ ARPANSA co-operates with national and international bodies in the development of best practice radiation regulation including in the development of international standards and recommendations.	• ARPANSA has worked with state and territory regulators to support an upcoming IRRS mission to Australia that will review how well aligned Australia's regulatory framework is with international standards. • ARPANSA held three NSC and RHC meetings during the year. The NSC provides expert

Indicator	Evidence	Comment
standards and recommendations [qualitative].		independent advice to the CEO in regard to regulatory policy standards and practices with regards to safety of nuclear facilities both in a general sense and in regard to certain specific matters. The RHC develops national codes and standards. • ARPANSA hosted an IAEA workshop on inspection of research reactors.

2.6.2 Other evidence to indicate compliance with KPI 6

ARPANSA has good international engagement and participates in multiple IAEA safety committees. Interviews suggested there was a good communication loop which feed learnings from international engagement to the development of codes and standards. There was also positive feedback on ARPANSA's contribution to IRRS missions, both as participant and as peer reviewer. Room for improvement was potentially identified with international engagement leading into regulatory practices. Some staff considered that the selection of what international engagements ARPANSA participate in should be reviewed so that it more appropriately covers ARPANSA's areas of responsibility. Also the team considered that an annual review of the regulatory manuals could include consideration of international practice.

The sharing of information internally, particularly from international engagements was identified as an area for improvement. The team was advised that, there was the perception that, when ARPANSA staff from outside the RSB participated in international events, there was a link from these meetings to Australia's codes and standards development. However, it was unclear whether the current approach to international engagement within RSB led to clearly visible regulatory outcomes.

ARPANSA has nine bi-lateral agreements to provide for information and resource sharing with international radiation protection and nuclear safety regulators. These are established by MOU. There has been active communication with Norway and the US Nuclear Regulatory Commission and weeklong visits to ARPANSA from Indonesian colleagues have occurred. However, this practice has not translated into ARPANSA staff visiting other regulators internationally, observing inspections, collaborating and learning from other similar agencies.

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 of a newly published document is the Guide for Radiation Protection in Existing Exposure Situations, which was published during the year.

ARPANSA also promotes national uniformity of radiation regulation through the Radiation Health Committee. ARPANSA has recently worked collaboratively with the State and Territory radiation safety regulators to reinvigorate the national uniformity program through active participation in the newly established Radiation Regulator's Network (RRN). Feedback on this was very positive. ARPANSA has volunteered the electronic portal and secretariat support. The RRN has the potential to progress a nationally uniform approach to radiation protection in Australia; particularly, for new or novel activities

involving radiation. This can have a positive effect on radiation users through the implementation of nationally consistent positions.

The team concluded that the use of the targeted liaison forums with large licence holders such as the CSIRO-ARPANSA Liaison Forum (CALF) and Defence-ARPANSA Liaison Forum (DALF) provides specific avenues for high level communication with those licensees. The team concluded that the number of these forums could be expanded. Similarly, the team supported the concept of mini-licence holder forums to provide targeted information and communication to smaller groups of licence holders. In particular, this type of forum seeks to engage with the actual users of the radiation sources. The team encouraged greater use of this concept.

ARPANSA has a regulatory management system. This cascades from three key manuals that describe the majority of the branch's activities. The team was advised that it performs well but is an administrative burden which could be made to be more efficient. Some staff indicated that there was no holistic approach to quality. A survey of the RMS was recently performed. This provided varying results. Some staff and management were happy with it, while others identified that it could add more value to the organisation. The team observed that it is difficult to perform higher level functions like automating tasks or alerts and data mining in the current system, with the tools currently available. ARPANSA is currently developing an overarching integrated management system that is expected to bring benefits to its regulatory services.

2.6.3   Analysis of evidence presented

PI 6.1 is a measure of licensee opinion on ARPANSA's performance of inspections.

ARPANSA has used surveys as a method of judging performance and identifying areas for improvement for several years. Following the 2015-16 self-assessment, the inspection survey was revised to make it simpler to complete, allow for anonymity and to provide a 'score' that may be trended. This has now been implemented. Quarterly results from the survey ranged from 79% to 98% for 2017–18 year. The overall satisfaction value for the entire year was 87%. The results of inspection surveys and feedback provided to the ARPANSA self-assessment team indicated a high level of satisfaction with the inspection process. Feedback included praise on the knowledgeability and respectfulness of inspectors. It has previously been identified that the number of survey responses had declined significantly for unknown reasons. A lower than desired participation rate remains with 43 responses received from 196 invitations (22%). These surveys provide a quick and easy way for licence holders to voice concerns and for ARPANSA to reflect on its service. It is presumed that when survey invitations go uncompleted the licence holder's representatives were either neutral or satisfied with the inspection.

An analysis of the aforementioned customer survey process is circulated in an internal quarterly and annual inspection outcomes report. While most responses were positive some indicated areas for improvement. However, it was unclear how much improvement can be directly related to these reports.

PI 6.2 represents the number of improvements formally identified and implemented. ARPANSA has a section within RSB that works toward promoting continuous improvement in regulatory policies, procedures and practices.

Improvements have included the revised set of ARPANSA PIs. The implementation of information sharing mini-licence holder forums that have been designed to share the common results of inspections with licence holders and the creation of a register was established for the tracking of actions associated with confirmed non-compliances.

The target was met indicating good performance in this area despite a highly demanding environment in terms of tight regulatory resources. Work continues on the actions identified in the previous self-assessments. These are recorded in a database. As of the end of June 2018, 16 of 35 actions identified in the 2016/17 report have been completed. However, it was noted that a significant number of the actions previously identified are quite substantial and require significant resources and effort to be implemented. Progress was observed on a number of these initiatives, some of which are anticipated to be achieved during 2018-19.

The current Licence Administration Database (LAD) remains a significant system to improve. It is a tool for the management of crucial licence information, yet it is lacking a number of useful features, as its development has not kept pace with changes in regulatory services or the expectations of staff. Due to the current limitations of LAD, alternative methods are used to record data and a supplementary reporting system has been created to bring this and LAD data together where possible. This could be described as a 'Band-Aid' approach whereas a more efficient holistic licensing information system would offer significant benefits to the management of licence holder data and performance reporting. ARPANSA has recently invested in Customer Relationship Management (CRM) software and the LAD system is one of a number of projects to be transitioned to this system in the future. The RSB has undertaken some initial scoping for the system and is in a position to develop and implement the system once resources are available. A delay in the CRM project initiation is expected to delay the transition to a more efficient system. A new system will offer significant benefits to ARPANSA and its regulated community including direct access to data. This observation was also made in the previous self-assessment.

ARPANSA has adopted the use of PO&C for inspections. Two versions of the PO&C exist; one for facilities and one for sources. The PO&C are available on the ARPANSA website. The team observed some variation in how the PO&C were used. Some ARPANSA staff suggested that the PO&C are quite prescriptive without much room to be streamlined. Others suggested that the PO&C are a starting point but that it was up to the inspector's judgement on how the PO&C is interpreted. The team identified room for improvement in the use of multi-expertise approach to planning and scoping the inspection. This can avoid gaps in assessment and use the different strengths and expertise of the team.

The team concluded that, particularly for facilities, the PO&C are useful and it was acknowledged that the ability to use them in a graded manner was a positive practice. It was observed that some ARPANSA staff and management, considered that the PO&C are excessive for sources. The team suggested that the PO&C be better tailored to specific practices with clear guidance on what is 'applicable' to that practice. The assessment team was advised that a review of the PO&C had been initiated to determine if the current source licence PO&C could be better aligned with the requirements of low hazard sources.

PI 6.3 relates to ARPANSA's cooperation with national and international bodies in the development of best practice regulation including the development of international standards and recommendations. ARPANSA is one of nine radiation regulators that share responsibility for overseeing the safe use of radiation in Australia. These are the eight States or Territories of Australia and the Commonwealth itself. The team concluded that ARPANSA has achieved significant improvement in the collaboration and co-ordination with the State and Territory regulators. It was identified that this could be strengthened through better cross-pollination between State and Territory Regulators and ARPANSA.

The team was advised that historically the development of radiation protection documents in Australia has sometimes been driven by the existence of an international document and the desire to create an 'Australian' version of it. However, new codes and guides are developed based on a need in the community

in consultation with the RHC. ARPANSA also promotes a range of documents which have been assessed as being international best practice on ARPANSA's website.

Overall performance against this KPI was assessed as good. This is based on the meetings of the NSC and RHC, the implementation of the mini-licence holder forum and the publication of draft codes and guides on the ARPANSA website.

2.6.4 Self-assessed rating of performance against KPI 6 – 2017-18

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

This rating in the 2015-16 and 2016-17 self-assessment was 'very good'. The current assessment of ARPANSA's performance is 'good'.

2.6.5 Actions for improving performance against KPI 6

The team identified the following AFI related to KPI 6:

- the effectiveness of internal communication and transfer of information, particularly with regard to inspection findings, may be improved through more regular meetings and a more structured approach to communication

- the effectiveness of external communication can be improved through better communicating the inspection schedule to licence holders, preparing targeted information on specific subjects that are suitable for specific licence holders and developing better guidance for inspectors on suggestions/advice

- the source licence PO&C should be reviewed and updated. It should be considered whether improvements could be made to the applicability of the PO&C for the range of radiation sources, particularly low hazard sources

- implementation of a framework for sharing national and international experience (beyond codes/standards development).

3 Overall assessment

3.1 Analysis of evidence

This was the third annual self-assessment under the Regulator Performance Framework (RPF). The review assessed regulatory performance against previously approved metrics as well as established processes and procedures, and through discussions with staff and stakeholders. Some of the interviews demonstrated to the team that there is a deep-seated desire to improve the effectiveness and efficiency of its regulatory service.

Section 2 of this report considers specific evidence against individual KPIs, while the section summarises the data more holistically to provide an overall picture of how ARPANSA meets the aims and objectives of the RPF. This same approach is used in discussing broad themes and recommendations to strengthen performance through a cycle of continuous improvement.

Despite some specific aspects to address, overall the standard of communication between ARPANSA, its licence holders and the wider stakeholder community was professional. ARPANSA is seen as approachable and uses the website to consult on changes that may affect licence holder operations. A range of information sharing meetings were held, predominately with large licence holders. However, ARPANSA has recently instigated the mini-licence holder forum to engage more directly with the users of radiation.

Licence holders reported high satisfaction levels for the inspection processes and appreciated the regulatory guidance available to them. The structure and planning of inspections that was introduced in 2015 was continuing to drive improved consistency in the delivery of this service. The transparent 'no-surprises' approach to inspections is appreciated as is the opportunity to provide feedback, including face to face, during the inspection exit meeting. Inspectors were reported as professional, helpful and well regarded. Licence holders appreciate that inspections are an opportunity to identify and bring about improvements rather than just a regulatory compliance assessment.

3.2   Overall self-assessed rating of performance – 2017-18

Last year ARPANSA was assessed as 'very good' in five areas and 'good' in another. This year, the performance rating of three KPIs is rated as 'very good'. One area that previously was 'very good' has now been graded as 'excellent'. This area was 'openness and transparency'. This is the first time ARPANSA has been considered 'excellent' and is an achievement that shows improvement is occurring. Although this is countered somewhat as two areas that previously were 'very good' are now rated 'good'. This is 'streamlined and coordinated compliance' and 'continuous improvement'. Areas for improvement have been identified and if ARPANSA actively works in these areas it is expected that future self-assessments will acknowledge this. ARPANSA's performance was assessed to be 'good' in the 'contribution to continuous improvement of the regulatory framework'. This previously was regarded as 'very good'. ARPANSA is encouraged to maintain constant and continual improvement of its regulatory framework.

Based upon the above, ARPANSA's overall performance has been rated 'very good'.

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

3.3   Strengths

The assessment team identified the following strengths.

Consistency

ARPANSA has prepared policies and procedures describing the organisation's graded/risk informed approach to regulation; and importantly, both staff and management are being seen to be using them.

ARPANSA has developed Performance Objectives and Criteria (PO&C) that are used to provide structure and predictability in how it undertakes inspections. These are used by inspectors and may be appreciated by licensees for providing a transparent guide to what ARPANSA is looking for during an inspection. The PO&C are aimed at allowing inspectors to assess the safety performance of a licence holder at the appropriate depth based upon the hazard of the source or facility.

Through the establishment and rotation of lead inspectors, ARPANSA has endeavoured to strike a balance between the strengths and efficiencies of a consistent point of contact for regulatory matters with the risk of regulatory capture.

Transparency

The commitment to transparency is demonstrated by the amount of information that is available on the ARPANSA website (regulatory guidance, inspection reports and major licence applications) through to publication of quarterly and annual reports to parliament in a timely and publicly available manner.

ARPANSA is open and available to discuss safety matters with the licence holder and tries to be responsive to the wider community.

Communication

The inspectors have been observed by the team to have a professional rapport with licence holder's representatives. Licence holders respect ARPANSA staff and acknowledge the efforts that have gone into explaining ARPANSA's regulatory requirements.

A mini-licence holder forum initiative has been established. This aims to bring regulatory staff together with those personnel who actually use the radiation sources. Hence, provide for better engagement with staff of the operating organisation on a deeper and more thorough level. This is done by bringing regulatory staff closer to where the operating staff use the sources of radiation. Future mini-licence holder forums are anticipated to be held in different places around Australia.

Continuous Improvement

Australia has requested an Integrated Regulatory Review Service (IRRS) from the International Atomic Energy Agency (IAEA). ARPANSA has played a lead role in coordinating the radiation protection regulators in each state and territory to engage with the IRRS review process and contribute towards an assessment of the Australian radiation protection framework against international standards.

ARPANSA has a high degree of engagement with the international radiation protection and nuclear safety community. This can be used to allow ARPANSA to engage with the latest thinking and consider it for implementation in a timely manner.

ARPANSA participates in the newly re-established working level forum of radiation protection regulators, the Radiation Regulators Network (RRN). ARPANSA has provided the electronic portal and the secretariat support.

3.4 Performance improvement actions identified

The assessment team identified the following broad areas for improvement. These should be read in conjunction with the actions for improving performance previously identified throughout Section 2 of this report.

Communication
The effectiveness of internal communication and transfer of information, particularly with regard to inspection findings, may be improved through more regular meetings and a more structured approach to communication. The effectiveness of external communication can be improved through better communicating the Inspection Schedule to licence holders, preparing targeted and tailored information for specific licence holders and developing better guidance for inspectors on providing suggestions/advice to licence holders.

Regulatory performance improvement
There were some opportunities for performance improvement that had not been previously identified or actioned. Some examples were:

- the relative regulatory priority between source and facility licences has not been thoroughly assessed and documented. Therefore, it is not clear if the same amount of regulatory resources applied to a particular source or facility are protecting against the same level of overall risk

- ARPANSA can decrease the regulatory burden on some licensees, achieve efficiencies and gain a better understanding of the strengths and weaknesses of safety management at the licensed organisations through more strategic collaboration with other regulators (e.g. Comcare, Australian Safeguards and Non-Proliferation Office (ASNO) and the Therapeutic Goods Administration (TGA))

- propagation of self-assessment tools that can be used by the licensees to be more 'inspection-ready'

- framework for sharing national and international experience (beyond the development of codes/standards).

Information management
The Regulatory Services Branch (RSB) has a range of information management needs that are currently being met through a patchwork of, at times, overlapping tools. ARPANSA and its licence holders may benefit from a holistic review of its information management needs leading to an integrated and improved system that reduces duplication and 'red-tape'.

Planning
A review of tasks, and how they are allocated, may be useful to assist in setting appropriate performance targets and priorities. Improved awareness of workforce planning including resource management, defining training and skills needs, and succession planning at a strategic level may also assist in balancing the workload pressures on staff.

Actions associated with all AFIs will be recorded and managed through the ARPANSA Issue Management Register.

4 Concluding remarks

This was the third self-assessment performed under the Government Regulatory Performance Framework. It was observed that approximately half of the AFIs that had previously been identified had been

implemented. The identification of AFIs through these reviews highlights the culture within ARPANSA to improve the effectiveness and efficiency of its regulatory service. ARPANSA is encouraged to continue working towards the implementation of the AFIs as part of its continuous improvement cycle. In particular it is recommended that ARPANSA establish a timetable for the implementation of AFIs. This timetable can span several years for completion of substantial projects.

This self-assessment followed a similar approach to the first two self-assessments and aims to provide a consistent, thorough and robust examination of regulatory performance for the period 1 July 2017 to 30 June 2018. In the interests of openness and transparency, the self-assessment team included a senior manager from one of ARPANSA's largest licence holders (ANSTO). This year the team also included the Principal Health Physicist from the Tasmanian radiation safety regulator. This provided insight from a senior manager within a regulatory body charged with a similar mandate and similar challenges.

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

The assessment team concluded that ARPANSA has been an effective regulator during the reporting period and that the structure and consistency of its services is improving. The team found that ARPANSA has a good regulatory culture. The team noted that without exception, licence holder representatives also consider that ARPANSA is open and transparent in dealing with them and has an effective graded approach to regulation.

Several areas for improvement were identified for consideration. Addressing the issues will improve ARPANSA's performance.

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.

ARPANSA has chosen to provide a high level of resources, including external members, to the RPF review team to enable it to carry out a detailed assessment each year. The team noted that as improvements identified in the RPF reviews may take time to develop, implement and review, ARPANSA may consider carrying out more detailed reviews at a set frequency such as every second or third year.

Appendix A
ARPANSA licenced entities as at 30 June 2018

Facility licence holders:

- Australian National University
- Australian Nuclear Science and Technology Organisation (ANSTO)
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)
- Department of Defence/Australian Defence Force
- Department of Home Affairs
- Department of the Environment and Energy – Director of National Parks

Source licence holders:

- ASC Pty Ltd and ASC AWD Shipbuilder Pty Ltd
- Attorney-General's Department
- Australian Criminal Intelligence Commission
- Australian Federal Police
- Australian Institute of Marine Science
- Australian National Maritime Museum
- 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 and Investment Commission
- Australian Transaction Reports and Analysis Centre
- Australian War Memorial
- Commonwealth Bureau of Meteorology
- Commonwealth Scientific and Industrial Research Organisation
- Decipha Pty Ltd
- Department of Agriculture and Water Resources
- Department of Defence/Australian Defence Force
- Department of Foreign Affairs and Trade
- Department of Home Affairs
- 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, Regional Development and Cities – Indian Ocean Territories Airports
- Department of Infrastructure, Regional Development and Cities – Indian Ocean Territories Health Service
- Department of Parliamentary Services
- Department of the Environment and Energy – Australian Antarctic Division
- Department of the Environment and Energy – Australian Antarctic Division, Polar Medicine

- Department of the Environment and Energy – Supervising Scientist
- Department of the Prime Minister and Cabinet
- 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 Limited

Appendix B
Information sources and documents provided to the assessment team

1. Australian Government - Regulator Performance Framework – ISBN 978-1-925237-07-8

2. ARPANSA Regulator Performance Framework – Self-Assessment Report 2015-2016 (HPE document R16/09670)

3. ARPANSA Regulator Performance Framework – Self-Assessment Report 2016-2017 (HPE document R17/09687)

4. ARPANSA Evidence metrics for the regulator performance Framework

5. Reporting on Performance Indicators – 2017-18 (HPE document D1828504)

6. The Auditor-General Audit Report No.29 2013–14 Performance Report No.29 2013–14

7. Facility Licence for ANSTO Health (HPE document F0262)

8. Source Licence for Australian Federal Police (HPE document S0056)

9. ARPANSA Performance Objectives and Criteria (PO&C)

10. Three Year Facility Inspection Schedule – January 2017 (HPE document R16/12363)

11. Three Year Facility Inspection Schedule – January 2018 (HPE document R18/01076)

12. Six Year Source Inspection Schedules – August 2017 (HPE document R17/10311)

13. Inspection Reports 1 July 2017 to 30 June 2018

14. Post Inspection Survey Results 2017-18 (HPE document D1828666)

15. Performance Indicators/Inspection Outcomes – Quarterly Reports from July 2017 to June 2018 (HPE documents R17/11161, R18/00378, R18/04590, R18/08831)

16. ARPANSA Regulatory Services - Licensing and assessment Manual (HPE document R15/08566)

17. ARPANSA Regulatory Services - Inspection Manual (HPE document R15/08057)

18. ARPANSA Regulatory Services - Compliance and Enforcement Manual (HPE document R15/08485)

19. ARPANSA Organisational Charts

20. NEA/CNRA/R(2014)3 - The Characteristics of an Effective Nuclear Regulator OECD 2014