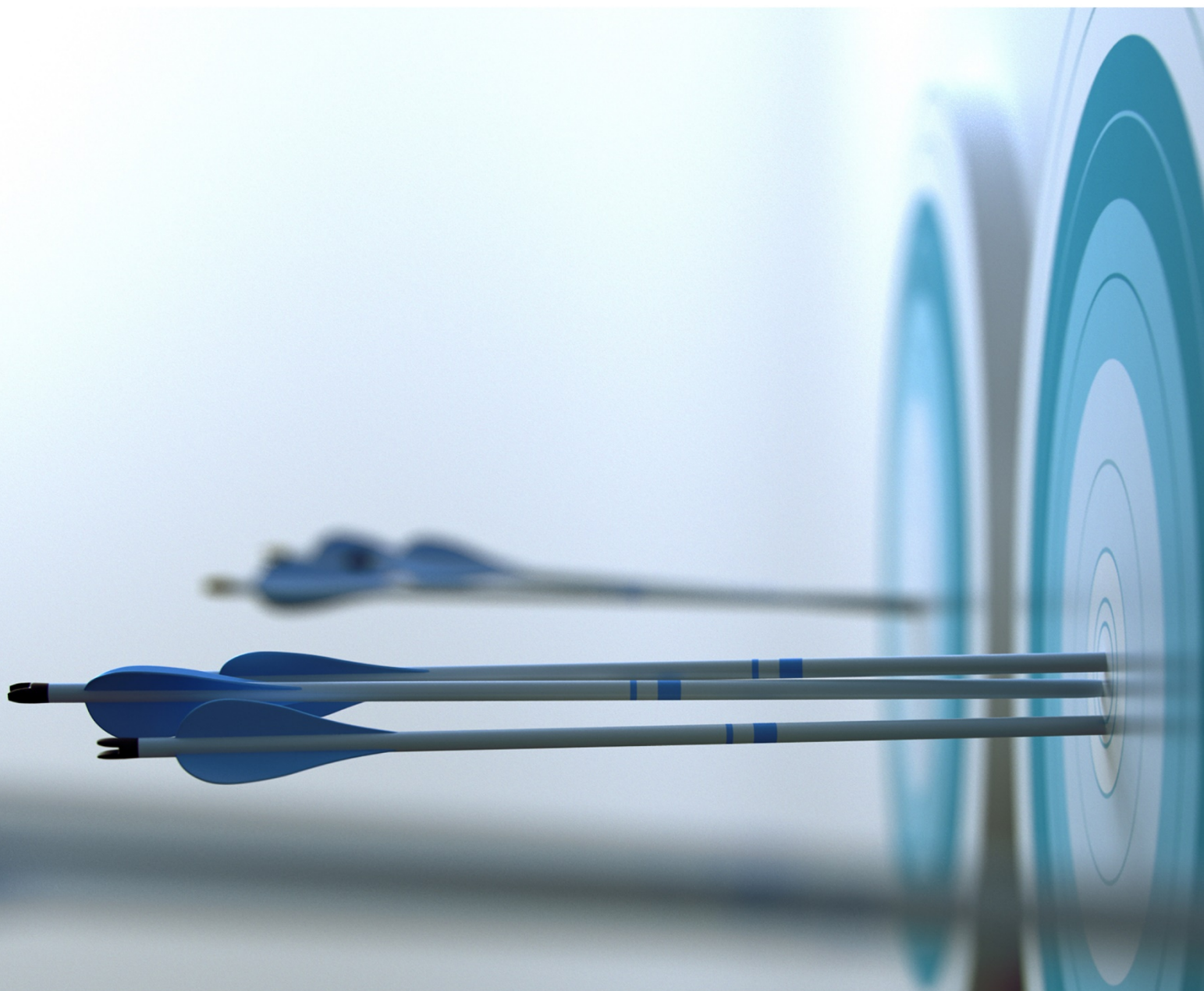




Australian Government
**Australian Radiation Protection
and Nuclear Safety Agency**



Regulator Performance Framework

Self-Assessment Report 2018–19

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Executive summary

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is the Australian Government's primary authority on radiation protection and nuclear safety. ARPANSA protects 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. This includes the regulation of the safety and security of radiation sources¹ and facilities² owned or operated by Commonwealth entities.

This review was undertaken by a team of ARPANSA staff including representatives from the Regulatory Services Branch, the Corporate Office, and the Office of the General Counsel. The team conducted the assessment from 22–26 July 2019. The report was subsequently drafted, validated by the Nuclear Safety Committee and approved by the CEO of ARPANSA as the accountable authority.

The Regulatory Performance Framework (RPF) objectives relate to the efficiency of the regulator. ARPANSA also utilises alternative review mechanisms which look at the effectiveness of the regulatory functions, such as the IRRS which is an international review focusing on effectiveness of regulatory functions and alignment with international standards.

Result

Overall ARPANSA has performed well against the metrics and indicators, and demonstrates a commitment to the RPF objectives. Good performance against the RPF KPIs was observed and, while the rating scale has changed, the results appear consistent with those of previous years.

The report highlights a number of strengths where ARPANSA's performance is highly aligned with the expectations of the RPF. This includes that ARPANSA was open and transparent in dealing with stakeholders and sought feedback and comment regularly. Effective communication and setting clear expectations was seen through a wide range of engagement strategies, ranging from published material on the website to the conduct of inspections and meetings.

The report also highlights some opportunities for improvement, such as the Information management and data systems. ARPANSA has a range of information management needs that are currently being met through a patchwork of, at times, overlapping tools. ARPANSA is progressing an agency-wide project to review our digital systems, with a view to implement improvements which would benefit licence holders and staff through more efficient and enhanced oversight.

¹ Sources include 'controlled apparatus' and 'controlled material' as [defined in the legislation](#).

² Facilities included both 'prescribed radiation facilities' and 'nuclear installations' as [defined in the legislation](#).

Introduction

About 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*.

ARPANSA regulates nuclear installations and prescribed radiation facilities across 33 facility licences, while 58 source licences cover approximately 75 000 radiation sources. The complexity of these licensed activities range from the Open-Pool Australian Lightwater (OPAL) reactor and medical radioisotope production, to the use of low risk equipment such as X-ray baggage scanners and handheld laser pointers.

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. The CEO retains responsibility for all regulatory decisions, but draws on expertise from Regulatory Services Branch (RSB) and other ARPANSA staff as required and where appropriate.

The RSB undertakes regulatory activities such as inspections and assessments. This includes the assessment of licence applications, licence amendments, or changes significant to safety, and compliance monitoring with the Act, Australian Radiation Protection and Nuclear Safety Regulations 2018 (the Regulations) and licence conditions.

The RSB also carries out a range of other activities such as preparing regulatory policy, regulatory publications and promotion of the adoption of international best practice across Australia.

Impacts during the reporting period

International Regulatory Review Service mission to Australia

At the request of the Australian Government, the International Atomic Energy Agency (IAEA) coordinated an International Regulatory Review Service (IRRS) mission. ARPANSA hosted this mission in November 2018. The IRRS reviewed the regulatory framework across Australia against international standards and guidelines, to report on regulatory effectiveness and to exchange information and experience with international counterparts. This provided ARPANSA with opportunities to enhance ARPANSA's regulatory performance and, with State and Territory regulators, to promote nationally consistent radiation safety regulation across jurisdictions. The review included a two week intensive mission phase, as well as substantial prior self-assessment.

The IRRS mission concluded that there was good alignment with the international standards, and was positive regarding the overall regulatory effectiveness of ARPANSA. The final report contains four good practices, 23 recommendations, and 12 suggestions for improvement, many of which confirmed or elaborated on the actions identified during the self-assessments. Actions were addressed to the various

Australian governments and regulatory bodies; fourteen (eight recommendations and six suggestions) were specifically addressed to ARPANSA.

Significant events

ARPANSA monitors the safety performance of its licence holders, and requires prompt notification within 24 hours if certain events with safety implications occur. Events, reported or found, which meet the criteria of an incident under the [Australian Radiation Incident Register](#) are also collated nationally and analysed by ARPANSA.

During the financial year there was one accident reported to ARPANSA, in accordance with section 58 of the Regulations. On 21 June, following the accident, in which the hands of three workers were exposed to radiation, production of nuclear medicine at ANSTO Nuclear Medicine (ANM) facility was halted. Two of the workers received a dose that exceeded the statutory annual dose limit for the hands. Under the International Nuclear and Radiological Event Scale (INES) the event is classified as a 'Level 2 Incident'. ARPANSA instructed Australian Nuclear Science and Technology Organisation (ANSTO) not to resume operations until ARPANSA had assessed the causes of the accident and reviewed ANSTO's assessment of the accident, including their proposed controls to keep workers safe.

ANSTO was authorised to recommence with restricted production from 6 July, at a level that can satisfy the domestic demand for nuclear medicine. The decision took into account previous safety events during nuclear medicine production at ANSTO as well as ARPANSA's review of the circumstances of this accident, including the sequence of events and effectiveness of controls.

ARPANSA is continuing its investigation into the causes and contributing factors of the accident. A formal decision on whether there has been a failure on ANSTO's part to comply with conditions of the ANM licence is pending.

ARPANSA is working to identify potential learnings for the regulator from this and other events. ARPANSA has drawn some preliminary conclusions, including that ARPANSA should further engage with its licence holders to ensure that their risk assessments appropriately reflect the risks of all activities or facilities of a hazardous nature. It is important that the risks and the effectiveness of controls are well understood by workers at the organisation and regularly reviewed.

Regulator performance framework

The Australian Government is committed to reducing the cost of unnecessary or inefficient regulation imposed on business, community organisations and individuals. The Regulator Performance Framework (RPF)³ establishes a common set of performance measures for the comprehensive assessment of regulator performance and their engagement with stakeholders. The way regulators administer regulations can have a major effect on the burden imposed, and therefore the framework aims to encourage regulators to undertake their functions with the minimum impact necessary to achieve regulatory objectives.

³ Further information on the Regulator Performance Framework is available at <https://docs.jobs.gov.au/documents/regulator-performance-framework>

The RPF comprises six outcomes-based Key Performance Indicators (KPIs) and associated measures. The KPIs articulate the Government's overarching expectations of regulator performance, namely that:

1. regulators do not unnecessarily impede the efficient operation of regulated entities
2. communication with regulated entities is clear, targeted and effective
3. actions undertaken by regulators are proportionate to the risk being managed
4. compliance and monitoring approaches are streamlined and coordinated
5. regulators are open and transparent in their dealings with regulated entities
6. regulators actively contribute to the continuous improvement of regulatory frameworks.

Under the RPF, regulators are required to undertake an annual self-assessment of regulatory performance against the six KPIs.

The metrics used to assess performance are a mix of qualitative and quantitative measurements that have been agreed through a ministerially approved stakeholder consultation mechanism, and approved by the Minister. ARPANSA has published its [approved metrics](#) online.

The RPF assessment process is not intended to cover the full range of regulatory and policy objectives. 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'*. ARPANSA also measures its performance against its safety objective 'to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation', using a range of indicators. High level indicators are listed in ARPANSA's published [Corporate Plans](#) and reported against in the [annual report series](#). However, ARPANSA considers the RPF measures and review process a useful tool to identify opportunities for improvement and better utilise resources.

When considering the effectiveness of the regulator within the context of the RPF, the review team took into account the OECD Nuclear Energy Agency (NEA) publication ['The Safety Culture of an Effective Nuclear Regulatory Body'](#).

Assessment team and methodology

Each year, ARPANSA selects an assessment team with a broad range of experience and includes at least one member whose functions are not part of the Regulatory Services Branch. In previous years, the team also included one or more members external to ARPANSA, such as another regulator and/or a representative of a regulated entity. This year, the assessment team was scaled down; however, external members may again be considered in the future.

The RPF assessment was carried out by the following team members:

- Chris Nickel, Senior Regulatory Officer, Regulatory Services Branch, ARPANSA (Team Lead)
- Gemma Larkins, Legal Officer, Office of the General Counsel, ARPANSA
- Donovan Ryan, Director Digital Technology (Acting), Digital Technology Section, Corporate Office, ARPANSA.

The assessment focussed on a review of performance against the six KPIs using the 12 approved measures, and the verification of the associated data. The team also considered additional information against the RPF metrics outlined in the RPF framework, to provide a balanced and objective assessment of performance. This includes reviews of documents, interviews with staff and reviewing records and data within the management systems.

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

Rating scale

ARPANSA has adjusted from a five point scale to a three point scale, in accordance with the guidance from the Department of Health. A uniform rating scale enhances comparability across regulatory bodies undertaking this assessment.

Met	Strong performance against all of the measures under the KPI
Substantially met	Strong performance against most of the measures under the KPI
Not met	Poor performance against all of the measures under the KPI

External validation

The results of this self-assessment are required to be validated by the Nuclear Safety Committee as the approved stakeholder consultation mechanism.

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 at arpansa.gov.au/nsc.

Certification by the Accountable Authority

The self-assessment is required to be certified by the Chief Executive Officer of ARPANSA as the Accountable Authority under the *Public Governance, Performance and Accountability Act 2013* and the Act. The CEO is also a member of the Nuclear Safety Committee. In accordance with established practice, the CEO recused himself from the Nuclear Safety Committee’s deliberations on this matter.

Overall assessment

Using the above performance ratings, targets have been met for all six KPIs, and strong performance observed against all of the measures under the KPIs.

Summary of self-assessment results

Regulator Performance Framework KPIs	Ratings for 2018–19	Summary
Regulators do not unnecessarily impede the efficient operation of regulated entities.	Met	ARPANSA demonstrated a commitment to not unnecessarily impede the efficient operation of regulated entities. This included a high level of adherence to the inspection schedule (79%) and the agreed timeframes for regulatory assessments [such as licence applications and change requests] (88%), which assists the licence holder in planning their operations and avoiding unnecessary impediments to business.
Communication with regulated entities is clear, targeted and effective.	Met	ARPANSA maintained effective communication including holding 58 information sharing meetings, conducting 41 site visits, and updating and maintaining a broad range of information on its website, including a range of guidance and standards.
Actions undertaken by regulators are proportionate to the regulatory risk being managed.	Met	ARPANSA applied a graded approach in the application of its regulatory oversight program, proportionate to the risk the controlled activity poses to people and the environment. This was evident in the inspection schedules, enforcement actions taken, and proportion of time spent on higher regulatory priority licences.
Compliance and monitoring approaches are streamlined and coordinated.	Met	ARPANSA collaborated extensively with other regulatory bodies, such as Comcare, and streamlined its compliance monitoring, to promote licence holder practices that align with international best practice.
Regulators are open and transparent in their dealings with regulated entities.	Met	ARPANSA showed an open and transparent approach in publishing its inspection reports and the reasons for significant licensing decisions. ARPANSA also publishes clear guidance and requirements, following consultation with stakeholders and the public.
Regulators actively contribute to the continuous improvement of regulatory frameworks.	Met	ARPANSA demonstrated commitment to reviewing its performance and identifying potential improvements. In this financial year a number of high calibre reviews have been undertaken including an international review and a safety culture assessment. ARPANSA contributes to improving its own performance and that of the radiation and nuclear safety framework across Australia.

Overall ARPANSA has performed well against the metrics and indicators, and demonstrates a commitment to the Regulator Performance Framework objectives.

Strengths

Multifaceted communication strategy

ARPANSA's broad range of communication tools aim to ensure that ARPANSA communicates with stakeholders and all levels of the licence holder's organisation. For example, the individual 'Liaison' forums target senior staff, the annual 'Licence holder forum' targets mid-level staff and safety officers, while the 'meet the regulator' forums target operational staff.

Encouraging self-assessment and reporting (Self-assessment tool)

ARPANSA has a number of initiatives to assist licence holders to identify and rectify their own issues without undue regulatory intervention. ARPANSA is currently trialling a self-assessment tool, similar to the e-inspection program, to assist licence holders assess their compliance outside of the inspection cycle.

Review of regulatory systems

ARPANSA is committed to reviewing its performance and identifying potential improvements. In this financial year these reviews have included an International Atomic Energy Agency (IAEA) [Integrated Regulatory Review Service \(IRRS\) mission](#) in late 2018 and a [safety culture assessment](#) of ARPANSA's regulatory services in early 2019. These reviews are examples of how ARPANSA critically reviews its performance and seeks out areas where performance can be improved. The outcome of these reviews are available on ARPANSA's website.

Opportunities for improvement

The self-assessment process highlighted opportunities for improvement, and areas of ongoing focus for continuous improvement in regulatory performance.

The key opportunity for improvement was around data management and recording. Currently, information is fragmented across different data sources and management tools. For example, elements of the application, inspection and compliance enforcement process are recorded in the records management platform (HPERM), the Licence Administration Database, SharePoint (ISAAC), and ad hoc tools such as spreadsheets. The system at present does not use workflows that would allow for tracking from an initiating event through to completion, with appropriate oversight. It was difficult in some instances to clearly identify where the relevant information was stored in the management system. This leads to issues in maintaining oversight of current activities, accurate recording of data, and quality control.

An agency-wide project to replace the platforms and systems is underway which will help to address these issues. While contractors are currently preparing a detailed review of our platform and system needs, the project has not yet progressed to the stage where a detailed scope and timeline for implementation can be established. ARPANSA is continuing to work in this space and will prioritise the regulatory management systems as appropriate, and has identified further interim measures that can enhance internal oversight.

2018–19 Performance reporting

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

ARPANSA endeavours to avoid any undue impact on the operations of the licensed entities. The conduct of inspections and assessment of applications are typically the most direct regulatory impacts for licence holders. A risk informed inspection program, and applications assessed in an agreed timeframe, allows licence holders to efficiently plan their operation and resources.

ARPANSA's risk informed inspection program includes:

- an open and transparent baseline schedule that is maintained, covering the next three or more years
- the scope of each inspection which is defined within the [performance objectives and criteria](#) and is available via the ARPANSA website. These were developed based on international best practice to inform licence holders and the public of ARPANSA's safety and security expectations 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
- specific dates for scheduled inspections and scope for inspections, which are discussed with the licence holder in advance of a formal notification two weeks prior to the inspection
- e-inspections and alternative approaches for low risk radiation sources.

ARPANSA strives to assess applications in a timely manner and within a timeframe agreed with the applicant. ARPANSA receives various types of applications including new licences, requests for safety-significant changes, and transfer or disposal of radiation sources. The timeframe for assessment depends on the nature and complexity of the application and takes account of the licence holder's priorities and ARPANSA's workloads. This process of consultation is important to set realistic expectations and ensure sufficient time for a thorough analysis of the application.

Measures/metrics	Evidence (performance in 2018–19)
<p>PI 1.1 Inspections are conducted in accordance with established inspection schedule</p> <p>Eight inspection areas have been identified for licensed facilities or sources to be undertaken at least once during a three-year facility and six year source inspection cycle. The inspection schedule is updated annually and communicated to licence holders. Adherence to the schedule promotes trust, predictability and efficiency. It supports ARPANSA's efforts to deliver quality regulatory services with due consideration of the health and safety of people and the environment, without being disruptive to business.</p> <p>ARPANSA will measure the percentage of inspections conducted in accordance with the risk-informed long term inspection schedule [Quantitative].</p>	<p>Target substantially met</p> <p>A total of 79% (31/39) of inspections were conducted in accordance with the schedule.</p> <p>This is less than the target of 85%, however the measure was met (or close to met) in the last three quarters (86%, 87% and 83%). The first quarter was affected by operational resourcing constraints, due to inspector leave and preparation for the international Integrated Regulatory Review Service mission.</p> <p>The eight (of 39) inspections which were not carried out in accordance with the schedule, were primarily due to operational resourcing reasons. While 13 of 52 originally scheduled inspections were not conducted for reasons beyond ARPANSA's control or moved in accordance with our procedures, 11 additional inspections were conducted which included re-scheduled inspections and augmented inspections.</p>
<p>PI 2.1 Applications are assessed within agreed timeframes.</p> <p>ARPANSA reviews and takes decisions in relation to applications for new licences, amendment of licences, and for other special approvals under the ARPANSA Regulations. The complexity of applications varies widely. Using a risk-informed approach and in consultation with licence applicants or licence holders, regulatory staff will prioritise resources and establish a date for completion of the application assessment. This assists the licence holder in planning, avoiding impediments to business.</p> <p>ARPANSA will measure the percentage of applications which are assessed within this agreed timeframe [Quantitative].</p>	<p>Target met</p> <p>A total of 88% (28/32) of applications assessed (completed) during this reporting period were assessed within the timeframe agreed with applicants. This exceeded the target of 75%.</p> <p>This measure was met for a number of significant applications including:</p> <ul style="list-style-type: none"> - a new facility licence for operational phase of the 'ANSTO Nuclear Medicine' facility - Section 63 changes to enhance the effective utilisation of the OPAL reactor - a new licence for Norfolk Island Health and Residential Aged Care Service, which permits the use of medical X-ray equipment. <p>Applications received priority where there was an impact on licence holders such as delaying commencing operations. This included allocating resources to these applications and prioritising these over routine inspections.</p>
Self-assessed rating: Met	

Further evidence considered

Fees and charges, which are set in the Regulations, can impact licence holder operations. To ensure that financial impact to licence holders is fair and appropriate, ARPANSA has undertaken a cost recovery project to ensure that financial burden on licence holders is proportionate to the cost of regulating that licence holder.

As a result of this work, more than half of source licence holders' fees were reduced, while the fees of licence holders with the most complex facilities were increased in proportion to the effort spent on regulation of these licence holders. This helps to ensure that ARPANSA does not place an unnecessary financial burden on licence holders, particularly licence holders with low numbers of sources.

As discussed under KPI 5, ARPANSA publishes a range of guides, codes and other publications. Clear guidance and requirement documentation assist the licence holder in preparing an appropriate application, which can reduce unnecessary burden and improve processing times. These set out clear expectations, such as [how to apply](#) for a licence and the information and [documentation required](#).

Strengths

Self-assessment tool

ARPANSA has developed a self-assessment tool, similar to the e-inspection program, to assist licence holders in assessing their compliance outside of the inspection cycle. This tool is currently being tested by small and medium sized licence holders, prior to release of the tool. Making the tool available to licence holders and the public can have a significant potential benefit to licence holders, as it allows for organisations to 'self-regulate' more effectively, decreasing the regulatory burden associated with regulatory inspections.

Application timeframes

The majority of applications (e.g. licence applications, or requests for other approvals) are unique which presents difficulties in setting general timeframes for applications. However, the high performance against this KPI is a significant achievement. Failure to meet target dates can occur for a variety of reasons such as incomplete information in an application, technical complexity and the availability of specialist expertise to review an application.

Identified opportunities for improvement

Data management

Data available to regulatory staff are fragmented across different data sources and management tools. For example, elements of the application, inspection and compliance enforcement process are recorded in the records management system (HPERM), the Licence Administration Database, SharePoint (ISAAC), and ad hoc tools such as spreadsheets. It was difficult in some instances to clearly identify where the relevant information was stored in the management system, such as to identify when or how a timeframe for an application had been established. An agency-wide project to replace the platforms and systems is underway which could address these issues. This project presents an opportunity to significantly add to ARPANSA's regulatory oversight capability. However, the project has not yet progressed to the stage where a detailed scope or timeline for implementation could be provided. It is recommended that this project be appropriately prioritised. Some of the costs associated with the implementation of this system may be eligible for cost recovery as part of annual charges.

Management of workflow

Following interviews with ARPANSA staff, the team identified that approval and review processes were not considered to be streamlined and that gaps in the current oversight and tracking of these processes, at times, led to inefficiencies and delays. A workflow that tracks from an initiating event through to completion, with appropriate oversight, was considered as a significant potential improvement. It is recommended that options to enhance this process and oversight be investigated and implemented as appropriate.

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

ARPANSA uses a wide range of communication tools to facilitate effective communication with licence holders.

Communication practices include the use of information sharing meetings and site visits, which enhance compliance monitoring, build inspector knowledge, and foster an open relationship with the licence holder. Information-sharing meetings include:

- licence holder meetings to discuss a topic such as quarterly reporting or a specific regulatory issue
- meetings with prospective licence holders such the Department of Industry, Innovation and Science on the proposed National Radioactive Waste Management Facility
- periodic 'liaison forums' to discuss issues affecting licence holders at a senior level
- the annual Licence Holder Forum which provides licence holders with an opportunity to interact as well as receive updates on ARPANSA's activities and regulatory findings
- 'meet the regulator' forums which are similar to the annual forum but smaller and typically held in regional areas with operational level staff.

As communication is a two-way process, meetings are effective in helping ARPANSA understand regulatory impacts on a licence holder and provide forums for discussion of regulatory issues facing licence holders. The number of meetings in a year, and an evaluation of their effectiveness, was selected as an indicator of the resources ARPANSA devotes to maintaining clear communication.

Measures/metrics	Evidence (performance in 2018–19)
<p>PI 2.1 Information sharing meetings are held with licence holders</p> <p>Meetings are 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. Examples of such established forums are the Defence-ARPANSA Liaison Forum (DALF), the newly instituted ANSTO-ARPANSA Liaison Forum (AALF) and ARPANSA Licence Holder Forums. Regular information exchange on regulatory matters reduces uncertainties about regulatory expectations, ultimately improving compliance rates and removing unnecessary regulatory burden.</p> <p>ARPANSA will measure the number of meetings held in a year [Quantitative], and evaluate the quality, including any feedback received from these meetings, to determine if the communication is effective [Qualitative].</p>	<p>Target met</p> <p>A total of 58 information sharing meetings were held over the year as well as 41 site visits.</p> <p>Examples of meetings held in the period include:</p> <ul style="list-style-type: none"> liaison forums with Defence, CSIRO and ANSTO two ‘meet the regulator’ forums in Hobart and Perth the annual Licence Holder Forum (LHF) quarterly meetings with major licence holders Twenty survey responses were received for the LHF held in September 2018. A total of 75% of respondents felt the forum was ‘excellent’ or ‘above average’. Participants’ responses demonstrated that many enjoyed the panel discussions and coffee corner discussions.
Self-assessed rating: Met	

Further evidence considered

Examples of communication practices, in addition to the meetings above, include:

- leading and alternating inspectors assigned to each licence to help build a professional relationship and familiarity with a licence. These inspectors are periodically rotated
- ARPANSA having a ‘no surprises’ policy for regulatory actions. In addition to pre-inspection activities discussed under KPI 1, at the start of inspections an entrance meeting is held to clearly discuss the scope of the inspection, and an exit meeting discusses any findings before the preparation of the inspection report. The inspection report is also reviewed by the licence holder for factual accuracy and comment is sought on any potential non-compliance prior to determining if a breach has occurred
- written correspondence including notifications, letters outlining potential non-compliances, breaches of the Act, licence amendments or reviews, and other regulatory matters
- online publishing of [inspection reports](#) for all inspections (except where this is not possible due to security implications), and regulatory assessments and statement of reasons on a licence decisions, which are published for [major assessments](#)
- publishing of [inspection outcomes](#), including advisories on the common findings and issues for a type of source (e.g. baggage X-ray screening, lasers)
- publishing of [regulatory publications](#) and [forms](#) on the website and providing transparent, comprehensive and consistent advice on licensing applications and reporting, and regulatory requirements, expectations, guidance and standards.

In the [*Fundamentals for Protection Against Ionising Radiation \(2014\)*](#), ARPANSA places the prime responsibility for protecting people and the environment from the harmful effects of radiation (i.e. for carrying out activities safely and securely) with the licence holder. Taking a less prescriptive approach to regulation requires clear, targeted guidance and effective communication to set clear expectations and ensure successful outcomes.

ARPANSA prepares [regulatory guidance](#) that establishes expectations, requirements and provides clarity on how ARPANSA conducts its regulatory operations. This is in addition to the development of codes and standards for adoption across Australian jurisdictions. Development of these guides includes consultation with stakeholders via the ARPANSA website; stakeholders are also consulted on revision of guides where there are significant changes. Regulatory guidance is published on the ARPANSA website and is kept up-to-date. For example a [new guide for decommissioning of facilities](#) was published in February 2019, and nine other guides were reviewed or updated. However, in some instances it was not clear how these changes were communicated to licence holders. This is further discussed in this report under KPI 5.

Strengths

Multifaceted communication strategy

ARPANSA's broad range of communication tools aim to ensure that ARPANSA communicates effectively with all levels of licensed organisations. For example, the [Liaison forums](#) target senior staff at major licence holders, the annual [LHF](#) targets mid-level and safety officers, while 'meet the regulator' forums target operational staff. Similarly, correspondence is sent to licence holder nominees, safety officers, or senior staff depending on the circumstances. The website offers guidance on a large number of [regulatory topics](#), as well as sharing information on [inspection outcomes](#), [international best practice](#) and [holistic safety](#) approaches.

Identified opportunities for improvement

Recording and encouraging feedback (information sharing meetings)

A significant number of meetings (58) were recorded in the meeting register. This register also provides a mechanism for recording any feedback received or evaluation of meetings. However, this was not routinely completed and only the annual LHF had evidence of a qualitative analysis of the effectiveness of the meeting based on survey feedback.

Communication of changes affecting licence holders

A significant amount of correspondence as well as guidance is prepared by ARPANSA. However, it was not always clear how information, particularly updates to the website, was distributed to licence holders and individuals. For example, emails of notification to licence nominees would be saved within the records management system, but it is not clear who should be, or was, notified. This was particularly relevant to updates of the Regulations and applicable codes and standards. An email distribution list, which people can subscribe to, may improve the dissemination of updates.

KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk

ARPANSA seeks to ensure that its regulatory oversight program is proportionate to the risk the controlled activity poses to people and the environment. Oversight includes licence holder reporting, regulatory inspections, site visits by regulatory officers and other meetings or forums.

The risk-informed inspection program is designed to direct regulatory resources to areas of most risk. The regulatory priority determines the minimum inspection frequency based on the hazard of the source or the risk of the facility to people and the environment. The regulatory priority for facilities should be reviewed annually, after an inspection, after an incident or accident and after changes to the facility. These assessments consider licensee compliance history, the frequency of incidents/accidents, the robustness of their defence in depth and safety controls described in plans and arrangements, their monitoring of safety performance, effectiveness of changes, and other holistic safety aspects.

An inspection may identify three types of findings:

- ‘good practice’ which identifies where the licence holder has a practice which is considered superior to that observed elsewhere and goes beyond the fulfilment of requirements or expectations. This helps to highlight and share good practices
- ‘areas for improvement’ (AFI) which identifies when a licence holder does not follow accepted best practice or does not meet self-imposed requirements, but the licence holder is not contravening a legal requirement. These represent an area where the licence holder should improve their safety and security systems and practices. AFIs are typically actioned voluntarily and therefore do not require further regulatory intervention
- ‘potential non-compliances’ (PNC) which identifies where inspectors consider that a licence holder does not meet the legislative requirements of the Act, Regulations or specific licence conditions. A formal determination of whether a PNC 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.

ARPANSA has a 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. ARPANSA is currently reviewing this compliance and enforcement strategy to determine its effectiveness to drive safe behaviours. This review will take into account the outcomes of reviews of other regulatory bodies, such as the [*Royal Commission into Misconduct in the Banking, Superannuation and Financial Services Industry*](#).

Measures/metrics	Evidence (performance in 2018–19)
<p>PI 3.1 Inspection schedule is risk informed and reviewed annually.</p> <p>ARPANSA applies a graded, risk informed approach to its inspection program. This measure indicates ARPANSA's ability to apply its regulatory resources efficiently and proportionately where needed.</p> <p>For source licences a six-year baseline inspection program based on the source (hazard) category is used. For efficiency, the inspection program also takes account of the geographical location of the sources so that regions with multiple sources may be inspected together.</p> <p>Inspection schedules for facility licences are reviewed annually and after any significant regulatory events such as non-compliance, incidents and accidents. The structured review takes account of the inherent risks presented by the facility, the level of safety controls and performance of the operator. The outcome of this review is used to determine the overall proportion of regulatory resources applied to each facility.</p> <p>This balanced approach recognises good performance of the operator with reduced regulatory effort and allows regulatory resources to be applied where they have most safety benefit.</p> <p>ARPANSA will measure the conformance to this scheduling and risk review processes [Qualitative].</p>	<p>Target met</p> <p>The facility inspection schedule was last reviewed in January 2019; the source schedule in October 2018.</p> <p>A total of 23 facility reviews were recorded as part of either periodic or post-inspection reviews. This resulted in a number of augmented inspections, including of the ANSTO Nuclear Medicine facility following a reported event.</p>
<p>PI 3.2 A graded approach is applied to compliance monitoring and enforcement actions.</p> <p>ARPANSA applies a graded, risk informed, approach to compliance monitoring and non-compliance in accordance with published policies. When potential non-compliance is identified, the regulatory response is commensurate with its significance and ARPANSA will use the minimum response required to achieve the desired result, which, in most cases will be a return to compliance. Good safety performance characterised by a good safety (and security) culture will be taken into account when determining the response. The baseline inspection schedule is supplemented by augmented inspections where there are concerns about the licensee's safety performance.</p> <p>ARPANSA will measure conformance with the policies for inspection outcomes and non-compliance, and the general proportion of effort will be applied to areas of greatest safety risk.</p>	<p>Target met</p> <p>Regulatory time recorded against licences with medium or higher regulatory priority (risk-informed) totalled 82%.</p> <p>A range of options are regularly used to ensure effective control in a graded manner. For example, in the 42 inspections performed 114 AFIs, nine PNCs, and five good practices were found.</p> <p>In accordance with the published 'graded approach to non-compliance', the safety significance of the non-compliance is taken into account. Of the 25 confirmed non-compliances, 21 were considered non safety-significant and the licence holders were not named. ARPANSA is currently reviewing its compliance and enforcement strategy.</p> <p>In line with the published approach there was a clear preference for the use of lower order controls such as AFIs and non-named breaches.</p>
Self-assessed rating: Met	

Strengths

Graded Approach

ARPANSA's internal and publicly available guidance on the graded approach such as for inspection and enforcement were clearly visible and well utilised by regulatory officers. ARPANSA clearly prioritised and resourced a number of applications and regulatory actions that had both a high impact to licence holders and a high regulatory priority. For example, ANSTO Nuclear Medicine and ANSTO Health. This aligns well with the figure of 82% of the effort on licence holders being spent on licences with medium or higher regulatory priority.

Identified opportunities for improvement

Data management

As identified under KPI1, data are fragmented across various business systems. Inspections (recorded in LAD) that deviate from the schedule (Spreadsheet in HPERM) are recorded in a register (ISAAC - internal SharePoint site). Some facilities and source sites have not been inspected as frequently as they should have been, given their regulatory priority. This may be due, in part, to the difficulty of maintaining management oversight across these systems.

Record keeping

Related to data management, a number of instances of poor record keeping were identified. For example, when reviewing the regulatory priority of licenced activities, it was observed that LAD reporting indicated that less than half of the facilities had their regulatory priority reviewed in the last twelve months. However, when the individual records were checked it was found that these had been done more frequently, but this had been either recorded only in HPERM or only in LAD. This is important as if a regulatory priority is not recorded correctly it has the possibility to affect the inspection frequency.

Another example of record keeping issues was the breach follow-up register. While there was evidence of actions required in breach letters and followed up during inspections this was not always recorded in the register.

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

ARPANSA's compliance monitoring program includes review of reporting from the licence holder, regulatory inspections and a range of communication practices that collectively provide regulatory oversight of licence holders. These approaches enable ARPANSA to assess licence holder performance against regulatory requirements and international best practice and to evaluate the need for any safety and security improvements. ARPANSA strives to be non-intrusive in its regulatory oversight to the extent practicable.

ARPANSA encourages licence holders to proactively manage safety by identifying and managing their own areas for improvement (AFI) and self-reporting any potential non-compliances. There is an expectation that the licence holder will investigate and take appropriate corrective action following the identification of inspection outcomes including AFIs. ARPANSA anticipates this action would be initiated, if not completed, within three months. The licence holder voluntarily taking actions following the finding of an AFI may be an indicator of the influence and effectiveness of ARPANSA's inspection and compliance monitoring program. It may also be an indicator of the safety culture of a licensee.

ARPANSA oversees the Commonwealth's use of radiation sources and facilities. However, many of the entities that hold a licence issued by ARPANSA are also subject to other regulatory frameworks. Examples of other regulators include Comcare, the Australian Safeguards and Non-proliferation Office (ASNO), and the Therapeutic Goods Administration (TGA).

Measures/metrics	Evidence (performance in 2018–19)
<p>PI 4.1 Actions are initiated within three months of the identification of an area for improvement.</p> <p>When an Area For Improvement (AFI) is identified as a result of an inspection or other monitoring, there is an expectation that the licence holder will take corrective action in a timely fashion. The objective of identifying areas for improvement is to reduce regulatory burden by improving safety through a light touch, without the use of enforcement actions. Typically, an AFI represents a situation that could lead to a non-compliance or in which safety practice could be improved. As such, where licence holders voluntarily implement corrective action following the finding of an AFI it demonstrates good safety culture, the effectiveness of non-enforcement actions and ARPANSA's promotion of best practice.</p> <p>ARPANSA will measure the percentage of AFIs identified where an action is initiated by the licence holder [Quantitative].</p>	<p>Target met</p> <p>In 82.5% of AFIs an action is initiated within three months. A total of 94 out of 114 AFIs had actions initiated ranging from placing the issues into action register to updating procedures and processes.</p> <p>The target (50%) was exceeded, showing licence holders voluntarily implement corrective actions following the identification of an area for improvement. This demonstrates good safety culture, the effectiveness of non-enforcement actions and ARPANSA's promotion of best practice.</p>
<p>PI 4.2 Information is shared with collaborating regulatory agencies.</p> <p>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].</p>	<p>Target met</p> <p>ARPANSA collaborated extensively with Comcare in this reporting period, including several joint meetings with licence holders on shared regulatory issues and investigations. This collaboration avoids duplication and leads to improved understanding of the respective requirements of Comcare and ARPANSA, which reduces regulatory burden on the licence holders.</p> <p>ARPANSA also collaborated with other state and Commonwealth regulators, as appropriate, sharing information and participating in events. This included regulators such as Australian Safeguards and Non-proliferation Office, and members of the Regulatory Science Network and Radiation Regulators Network.</p>
Self-assessed rating: Met	

Further evidence considered

ARPANSA collects regulatory information about the safety performance of licensees. This information is stored in one or more of the following: the record management system (HPERM), a purpose-built access database (LAD), the branch intranet page (ISAAC) and ad hoc tools such as spreadsheets. Functionality such as dashboards, which would assist officers and managers to maintain oversight, are not currently available. The LAD system does not have a full range of features desirable to staff. For example, it is not able to calculate fees, generate licence documents, review inspection outcomes, or generate reports and inventory updates without the use of additional programs (e.g. via spreadsheets).

A quarterly and annual analysis of Inspection findings (AFIs, potential non-compliances, and good practices) is sent to staff via email. This helps to monitor trends and identify emerging issues. The outcomes of this analysis is made available to licence holders through the ARPANSA website, and discussed at forums, so that they may review their operations for similar issues.

ARPANSA has signed MOUs with other regulatory agencies, such as Comcare. ARPANSA has been working closely with Comcare in this reporting period including joint inspections or site visits, meetings and close co-operation on the outcomes of reported incidents/accidents. This is a benefit to licence holders as there is a single clear message from both regulators without duplication of effort, while maintaining the independence of the regulators.

ARPANSA has a broad range of skills and experience within the regulatory branch. Further assistance from the other parts of ARPANSA, and external contactors, is available and was used this reporting period. A strategic approach to training such as skills matrix, or job specific training requirements beyond inspection competence were not evident at the branch level. Training generally occurs 'on the job' and through attendance at technical meetings or workshops, as well as a small amount of formal training. The formal sign-off of competencies for new inspectors, through the Qualcard modules, has been developed but has not yet been formally adopted within the quality framework.

Identified opportunities for improvement

Data management

As identified under KPI1, data are fragmented across different sources and management tools. It is recommended that the project to replace the platforms and systems and to address these issues be appropriately prioritised.

Training and competence

A formal training and qualification program, such as through ISO17020, may assist in the identification of any current or future gaps. These could then be addressed, for example, through the utilisation of formal training programs or secondments to local or international peer organisations.

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

ARPANSA has endeavoured to be open and transparent in its approach to regulation and regulatory outcomes. This is important to promote consistent high standards of regulation, and to build 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. Information includes how to apply for a licence, inspection approaches, the promotion of international best practice and outcomes of reviews and inspection programs. ARPANSA publishes its [inspection reports](#), except where they are redacted or withheld for security 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. Consultation with licence holders on the development of such documents improves transparency in regulation.

Measures/metrics	Evidence (performance in 2018–19)
<p>PI 5.1 ARPANSA's risk framework, the basis for regulatory decisions, and the outcomes of compliance monitoring are published on the web.</p> <p>To provide confidence to regulated entities and the wider community, ARPANSA publishes a range of reports and information on how it goes about its business. This information includes, whenever possible, the prompt publication of inspection reports and the 'statement of reasons' for any significant licensing decisions. Information relating to ARPANSA's approach to risk and many of the processes used to manage the regulatory business are also published. These communication practices are part of ARPANSA's no-surprise, evidence-based approach to regulation that provides trust from licensed entities and the wider community.</p> <p>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].</p>	<p>Target met</p> <p>A total of 32 inspections were posted this FY, as of June 2019.</p> <p>Information is maintained on the website including updates to webpages and reporting on compliance. Publications in this period include:</p> <ul style="list-style-type: none"> • Statement of Reasons for ANM which were published for the limited operation (commissioning), routine production (operate), and restricted (following an incident) licences • ARPANS Regulations 1999 and ARPANS Licence Charges Regulations 2000 which were repealed and remade. This required a significant number of guidance documents and updating of website content. • a direction, issued in the previous financial year, which was published following tabling in parliament.
<p>5.2 Stakeholders, including the public, are consulted on the development of codes and guidance publications.</p> <p>ARPANSA publishes guides, codes and standards on a range of regulatory topics which set out expectations for ARPANSA's licence holder with respect to safety of sources and facilities. This includes national documents such as the Regulatory Protection Series and local documents such as Regulatory guides. These documents typically reflect international best practice. 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].</p>	<p>Target met</p> <p>ARPANSA consulted with licence holders for feedback on the development or significant amendment of guides and codes to improve transparency in regulation and support continuous improvement.</p> <p>These included:</p> <ul style="list-style-type: none"> • <i>Code of Radiation Protection Requirements for Industrial Radiography</i> (2018) • <i>Code for Disposal Facilities for Solid Radioactive Waste</i> (2018) • <i>Guide for Radiation Protection in Emergency Exposure Situations</i> (2019) • <i>ARPANSA Regulatory Guide: Decommissioning of Controlled Facilities.</i>
Self-assessed rating: Met	

Further evidence considered

Evidence of other consultation was observed, for example during the consultation for the cost recovery project (see KPI 1), several licence holders provided input which was responded to and actioned as appropriate. Consultation was also undertaken for other publications such as the recent *Australian Radiation Incident Register Annual Report*, for which professional bodies and State/Territory regulators were consulted. This shows a commitment to seeking and listening to feedback from stakeholders.

Identified opportunities for improvement

Management of workflow

As described in KPI1, approval and review processes were not considered streamlined. During interviews, staff identified that this contributed to the majority (75%) of inspections not being posted within the internal target timeframes. However, an analysis of the deviations to the timeframes was not available and was not performed during this review. As this timeframe is a target, not a requirement, this is not considered a non-conformance with the management system.

Management of website content

Internally ARPANSA uses 'quality documents' which are maintained in the records management system HPERM. In some instances, information on the website was found to be out of date or inconsistent with the version in the quality system. Website management follows a separate process from quality documents.

For example, the information on one webpage was found to discuss a previous licence stage, but included content from the current licence stage. This may be confusing to the reader and the entire page should have been updated. It was also not clear to the team when the page was last reviewed, or would next be reviewed.

Differences observed between these quality documents and the documents on the website was limited to formatting and minor variations, however it highlights the possibility for incorrect content to be on the website. For example, one instance was observed of a form from the quality system being provided to a licence holder. This contained internal information (the document change register) and was not formatted the same as the website version. A reconciliation between the website and quality documents is recommended, and improvements to the system in capturing and controlling web content.

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

ARPANSA strives to be adaptable to meet the needs of the community and regulated entities, assuring compliance with the Act and Regulations and high levels of nuclear safety and radiation protection.

A program of continuous improvement is recognised as being important to building a resilient regulator that knows what to expect, monitors its regulatory environment, adapts to challenges, and learns from experience.

The regulatory framework is reviewed, and potential improvements identified, via various methods. This includes this annual self-assessment, internal audits, stakeholder forums, periodic reviews of the regulatory management system, stakeholder feedback surveys, external audits and peer review missions. A list of potential improvements including all areas for improvement from reviews is maintained and updated such as when an action is closed following completion.

Measures/metrics	Evidence (performance in 2018–19)
<p>PI 6.1 Feedback from licence holders is encouraged and feedback received is positive, constructive and drives improvement.</p> <p>Soon after the completion of an inspection, licence application, change request (section 63 of the Regulations) or construction request for an item important for safety (section 66 of the Regulations), the Office of the CEO will administer a survey independent of the Regulatory Services Branch, to ask for feedback on the service provided. The options for response from the licence holder range from 'strongly agree' to 'strongly disagree'.</p> <p>A survey score is used to trend ARPANSA's performance [Quantitative].</p> <p>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 are in putting the six KPIs into practice [Qualitative].</p>	<p>Target met</p> <p>A total of 36 post-inspection surveys were received, with an average overall satisfaction score of 87%. This is consistent with previous year's results of 87%, and 88%.</p> <p>Four post-assessment surveys were received, with an average overall satisfaction score of 86%. This is the first year this measure has been used.</p> <p>The comments are also analysed for improvement opportunities. The comments received indicate an overall positive perception of the delivery of regulatory services.</p>

Measures/metrics	Evidence (performance in 2018–19)
<p>PI 6.2 - Improvements identified through internal or external reviews, self-assessment or feedback, are implemented effectively.</p> <p>Areas for improvement in the regulatory framework can be identified via various routes such as annual self-assessments. Additional opportunities include internal procedure and policy reviews as part of the Regulatory Services Branch Quality Management System, staff suggestions, external audits of ARPANSA including international peer review missions, and stakeholder feedback from surveys and licence holder forums.</p> <p>The number of regulatory improvements identified and implemented will measure ARPANSA's actions to continuously improve the regulatory framework [Quantitative].</p>	<p>Target met</p> <p>A list of potential improvements is maintained and updated as actions are completed. Improvements implemented this financial year included:</p> <ul style="list-style-type: none"> • two changes made to the LAD database to enhance application and non-compliance management • enhanced transparency by publishing the manuals for assessment, inspection and enforcement on the website • improved efficiency of the annual cost charging process and integration with finance. <p>Reviews in this period have included:</p> <ul style="list-style-type: none"> • an Integrated Regulatory Review Service mission in November 2018 • a safety culture assessment of regulatory functions in early 2019 • an internal audit of the management system in March 2019 • the Regulatory Performance Framework review in July 2019.
<p>PI 6.3 - Promote the use of international best practice across Australia.</p> <p>ARPANSA's regulatory activities should meet national and international standards of good practice. To achieve this, ARPANSA will co-operate with national and international bodies in the development of best practice radiation regulation including in the development of international standards and recommendations [Qualitative].</p>	<p>Target met</p> <p>ARPANSA demonstrated strong international engagement including working with international regulators, IAEA standards committees, and participation in IRRS missions.</p> <p>ARPANSA promoted best practice across Australia through the Radiation Health Committee and initiatives such as the Radiation Regulators Network, the Australian National Radiation Dose Register, the Australian Radiation Incident Register and working collaboratively with the Environmental Health Standing Committee (enHealth), comprising senior health officials from all Australian jurisdictions and reporting to the Australian Health Protection Principal Committee (AHPPC).</p>
Self-assessed rating: Met	

Further evidence considered

ARPANSA has strong international engagement, which helps to ensure that best practice in regulation can be adopted in Australia and reduces potential barriers to licence holders adopting international best practice. ARPANSA participates in multiple IAEA safety committees and has nine bi-lateral agreements for information and resource sharing with international radiation protection and nuclear safety regulators. Activities have included visits by the Dutch regulator (ANVS) and the Vietnamese regulator (VARANS), a two-week technical cooperation visit to ARPANSA from the Thai regulatory body (OAP), and ARPANSA participation in IRRS missions to Spain, Norway and Germany.

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 the newly established Radiation Regulator's Network (RRN). The RRN is currently working on national issues such as exemptions, equipment testing, and transport security requirements. Nationally uniform requirements can significantly reduce regulatory burden on persons working in more than one jurisdiction.

ARPANSA has recently introduced a series of informal communication measures including 'morning tea information sessions', where an officer provides updates on recent regulatory and international matters. This is a positive initiative which was developed as a result of improvement opportunities identified in previous RPF reports.

Strengths

Open and transparent review of performance

ARPANSA is committed to reviewing its performance and identifying potential improvements. A number of reviews have taken place this financial year:

- ARPANSA hosted an International Atomic Energy Agency (IAEA) coordinated [Integrated Regulatory Review Service \(IRRS\) mission](#) in November 2018 (report is published online). The review included 15 international experts, three IAEA staff, and two observers. The team reviewed Australia's national, legal and governmental framework for nuclear and radiation safety against the IAEA's Safety Standards. The mission was opened by the Deputy Director General for Nuclear Safety and Security of the IAEA, Mr Juan Carlos Lentijo, in the presence of ARPANSA's Minister, Senator The Hon Bridget McKenzie. This two week mission and preparation of a summary report of over 200 pages was a considerable commitment by ARPANSA and jurisdictional regulators, demonstrating commitment to international best practice regulation. This was the first IRRS mission to undertake a comprehensive multi-jurisdictional review, including all six states, two territories and the Commonwealth, and this was identified as a good practice by the IRRS team. The IRRS report also noted Australia's robust national safety framework and detailed several other good practices, while also identifying areas for improvement.
- In early 2019, ARPANSA conducted a [safety culture assessment](#) of its regulatory functions and then developed an action plan based on the outcomes (report and action plan are published online). This assessment is about the core values, beliefs and behaviours of ARPANSA and how they affect not only ARPANSA's safety but also that of licence holders through our regulatory dealings. The results showed an overall positive safety culture ranging in maturity from 'individual commitment' to 'cooperative' levels.
- ARPANSA conducted an assessment in March 2019 as part of an internal audit program to evaluate the compliance of the management system to applicable standard or requirements.
- The Regulatory Performance Framework reviews, FY 2017–18 report (published online), which found a high level of commitment to the RPF and overall assessed ARPANSA's performance as 'very good' and identified a number of opportunities for improvement.

These reviews are examples of how ARPANSA critically reviews its performance and seeks out areas where performance can be improved.

Identified opportunities for improvement

Recording and encouraging feedback (post-assessment)

ARPANSA conducts a large number of assessments including applications (11), significant changes (22), disposals (105) and transport approvals. ARPANSA has a system to seek feedback, which includes a survey link on emails. It was noted that the system is new, however, the number of post-assessment survey responses received was low (4). Strategies to enhance the response rate should be investigated and implemented where appropriate.

Concluding remarks

This was ARPANSA's fourth self-assessment performed under the Australian Government Regulatory Performance Framework. It was observed in the [previous year's review](#) that, a number of the opportunities for improvement identified appear over multiple years. A major reason for this is that a number of these issues have a long timeframe for implementation which can span several years and require significant financial and human resources.

In line with the recommendation of the previous year, this self-assessment followed a more streamlined approach to the previous assessments, focusing more closely on the core requirements of the Regulator Performance Framework. It included interviews with staff and review of data but did not include external participants or observations of work performed. ARPANSA may consider carrying out more detailed reviews at a set frequency such as every third year. However, the team felt the streamlined process was appropriate for evaluation against the Regulator Performance Framework.

The assessment team concluded that ARPANSA has been an efficient regulator during the reporting period and that the structure and consistency of its services is improving, as evidenced by improvements made in this period and the feedback reviewed. 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, and were open in their regulatory conduct.

Successive self-assessments carried out under the Regulator Performance Framework have been instrumental in promoting the efficiency of ARPANSA's regulatory processes, and contributed to a generally good and respectful relationship between the agency and the licence holders. However, as pointed out in the introduction to this report, the object of the Act is to *protect people, and the environment, from the harmful effects of radiation*. Efficient operation of regulatory activities should allow for increased focus on achieving the object of the Act; ARPANSA must therefore consider how *effective* its regulatory actions have been when measured against the object of the Act.

The report for 2017–18 highlighted that a direction had been issued to one licence holder following a series of events of safety significance. The licence holder was directed to initiate an independent review of safety practices at its premises. This report is available at [ARPANSA's website](#) and includes 85 recommendations, some of them also directed to ARPANSA or shared with the licence holder.

ARPANSA has responded to, or is addressing, the recommendations from the independent review that are relevant to the agency. A project has been established to monitor progress of the licence holder's implementation of the recommendations and to take stock of learnings that are relevant for ARPANSA. However, a second contamination event took place at the same licence holder during the year covered by this report. This highlights the need for deeper understanding of the approaches to safety among licence holders, including leadership and management for safety (broadly captured under the umbrella term 'safety culture') and how human factors contribute to events with safety significance. This will help ARPANSA to have an increasing impact on the safety practices among licence holders and in doing so improve the *effectiveness* of its regulatory work.

The values underpinning good safety culture of a licence holder and of a regulator are fundamentally the same. The safety culture survey carried out at ARPANSA's regulatory branch is therefore useful for improved understanding of, not only the approaches to safety of the agency's staff, but the approaches taken by the licence holders. ARPANSA is planning to roll out the safety culture survey across the whole agency during 2019–2020, noting that ARPANSA is also a licence holder under the Act.

The IRRS mission conducted in November 2018 found a high degree of alignment with international standards and was positive on the overall regulatory effectiveness of ARPANSA. However, the IRRS identified that protection may not be equally applied and achieved across jurisdictions. This is related to the ‘functions of the CEO’ laid out in section 15 of the Act, on the promotion of nationally uniform policies and practices for radiation protection across Commonwealth, the states and the territories. The preparation for, and conduct of, the IRRS mission has contributed to an increased attention to both safety outcomes and procedural arrangements for achieving uniform outcomes. This includes the commitment to a seamless experience for individuals and businesses moving across jurisdictional borders to carry out safe radiation practices.

While the Regulator Performance Framework provides a lens by which regulatory activities can be viewed and assessed, ARPANSA’s regulatory activities are broad and go beyond the metrics developed under the Framework. The publically available [Policy for ARPANSA’s Regulatory Activities](#) provides an overview.

ARPANSA is striving to continuously improve the safety outcome for the Australian community, through regulation and otherwise, while not unduly impeding on justified practices carried out safely and responsibly by holders (or applicants) of licences issued under the ARPANS Act. This takes into account events among licence holders, and other sources of information such as the [Royal Commission into Misconduct in the Banking, Superannuation and Financial Services Industry](#), and the report of the [South Australian Independent Commissioner Against Corruption \(ICAC\) on regulatory practices of SafeWork SA](#).

Glossary

Acronym	Description
AFI	Areas for Improvement (inspection outcome, suggested improvement rather than a non-compliance)
ANM	ANSTO Nuclear Medicine (Facility)
ANSTO	Australian Nuclear Science and Technology Organisation
ARPANS Act/Regulations	<i>Australian Radiation Protection and Nuclear Safety Act 1998/Regulations 2018</i>
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ASNO	Australian Safeguards and Non-Proliferation Office
Comcare	Comcare is the Commonwealth agency with regulatory responsibility for work health and safety for the Commonwealth Government.
HPERM	Hewlett Packard Enterprise Records Manager (records management platform)
IAEA	International Atomic Energy Agency (an independent Agency in the United Nations system)
INES	International Nuclear and Radiological Event Scale (used by IAEA for reporting of incidents)
ISAAC	ARPANSA's intranet
KPI	Key Performance Indicator (as defined in the RPF)
LHF	Licence holder forum
OECD	Organisation for Economic Co-operation and Development
OPAL	Open-Pool Australian Lightwater (reactor)
PI	Performance Indicator (a metric set by ARPANSA)
PNC	Potential non-compliance (regulatory finding prior to the CEO's determination of whether a breach of the Act has occurred).
PO&C	Performance objectives and criteria
RHC	Radiation Health Committee, established under the ARPANS Act consisting mainly of radiation control officers from the states and territories, advising the CEO on policies and standards for national adoption
RPF	Regulator Performance Framework
RRN	Radiation Regulators' Network (a working group of radiation regulators from across Australia tasked with improving national uniformity in regulation)
RSB	Regulatory Services Branch (of ARPANSA)
TGA	Therapeutic Goods Administration