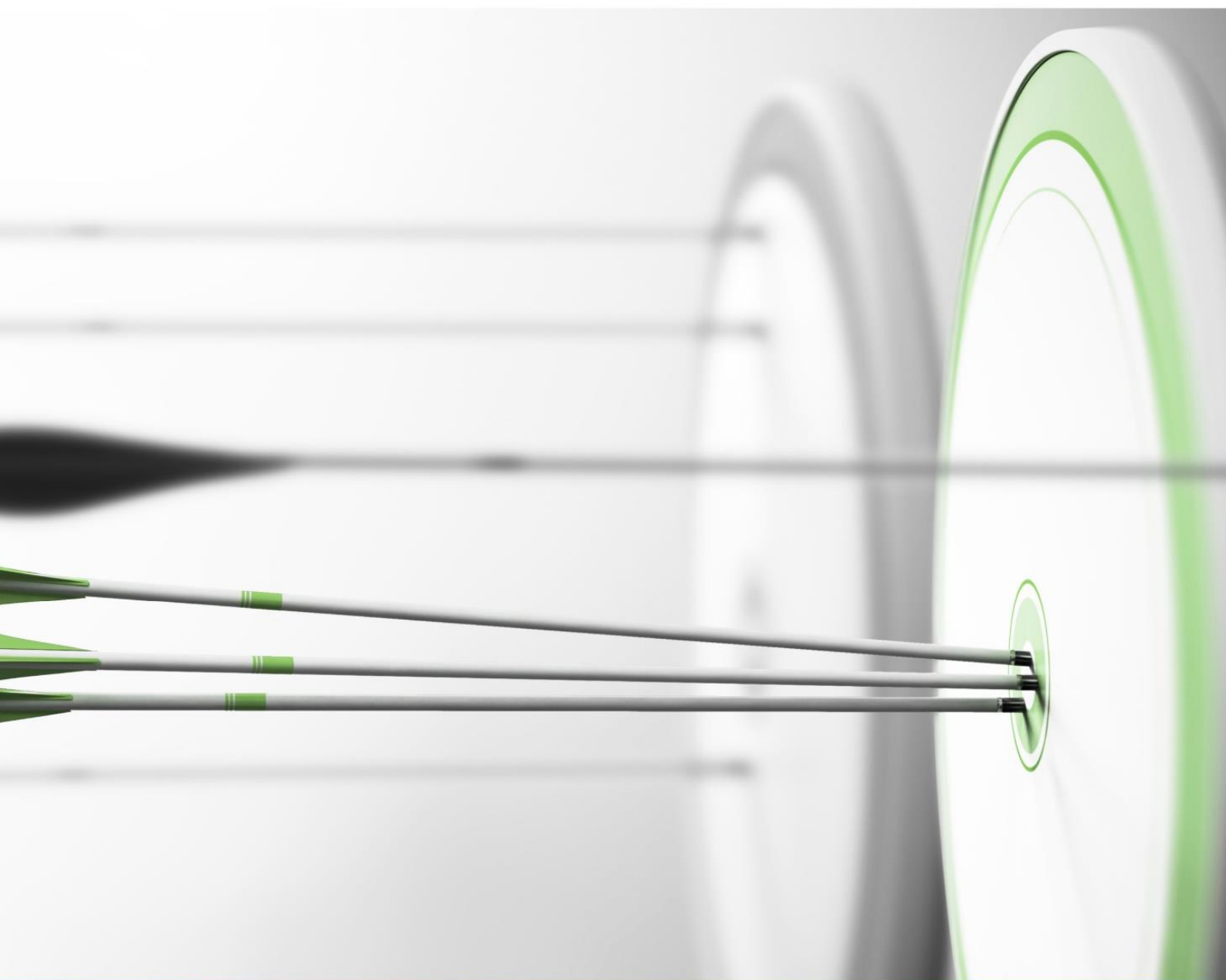




Australian Government
**Australian Radiation Protection
and Nuclear Safety Agency**



Regulator Performance Framework

Self-Assessment Report 2019–2020

Contents

Executive summary	1
Introduction.....	2
About the agency.....	2
Performance Framework.....	2
Assessment team and methodology	3
External validation.....	4
Certification by the Accountable Authority.....	4
Significant events during the reporting period	4
Overall assessment	6
Summary of self-assessment results	6
2019–20 Performance reporting	9
KPI 1 - Regulators do not unnecessarily impede the efficient operation of regulated entities	9
KPI 2 - Communication with regulated entities is clear, targeted and effective.....	12
KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk	15
KPI 4 - Compliance and monitoring approaches are streamlined and co-ordinated	18
KPI 5 - Regulators are open and transparent in their dealings with regulated entities	21
KPI 6 - Regulators actively contribute to the continuous improvement of regulatory frameworks.....	23
Concluding remarks	27
Glossary.....	28

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 from the Regulatory Services Branch of ARPANSA. The team conducted the assessment from 3–10 August 2020 and prepared this report that was subsequently validated by the Nuclear Safety Committee (NSC) 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 efficiency and effectiveness of the regulatory functions, such as the International Atomic Energy Agency Integrated Regulatory Review Service (IRRS) which is an international review focusing on effectiveness of regulatory functions and alignment with international standards. This was last undertaken in Australia in 2018.

Result

ARPANSA continues to perform well against the RPF metrics and indicators, and demonstrates a commitment to the RPF objectives. Despite impact from the COVID-19 pandemic restrictions, the results of this year's self-assessment are similar to previous years indicating that the RPF objectives are essentially "integrated into the regulatory systems and culture of ARPANSA.

Core strengths for ARPANSA are its openness and transparency with licensed entities and wider stakeholder groups through the extensive website publications on how it conducts its business, details of major licence decisions and the availability of inspection reports and outcomes. ARPANSA continues to consult widely with its licence entities, sets clear expectations, seeks regular feedback and reviews its performance with the objective of continuously improving its service to licence holders and the Australian community.

The report identifies opportunities for improvement including in areas where there is already strong performance. Business intelligence needs to be improved through better data management. The approach to and promotion of holistic safety needs to be strengthened. There are also further opportunities to seek feedback from licence holders and to improve the guidance available to them to manage safety. Work on these issues has started as long term projects.

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 ranges 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 regulatory expertise from ARPANSA's Regulatory Services Branch (RSB) and as required from other areas of ARPANSA.

Under the [Regulatory Activities Policy](#), 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. When making regulatory decisions, sections 32(3) and 33(3) of the Act requires ARPANSA to consider international best practice in relation to radiation protection and nuclear safety.

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.

Performance Framework

The Australian Government is committed to reducing the cost of unnecessary or inefficient regulation and associated costs, imposed on business, community organisations and individuals. The [Regulator Performance Framework](#) (RPF)³ establishes a common set of performance measures (see Performance Section below) for the comprehensive assessment of regulator performance and their engagement with stakeholders. The framework aims to encourage regulators to undertake their functions with the minimum impact necessary to achieve regulatory objectives.

Under the RPF, regulators are required to undertake an annual self-assessment of regulatory performance against the six KPIs. ARPANSA uses 12 metrics to assess performance that have been agreed through a

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

ministerially approved stakeholder consultation mechanism. ARPANSA has published its [approved metrics](#) online.

The RPF assessment process is not intended to cover the full range of regulatory and policy objectives. 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'. ARPANSA's published [Corporate Plans](#) and [Annual Report](#) provide further information on its strategies and overall performance.

Assessment team and methodology

Each year, ARPANSA selects an assessment team with a broad range of experience that in previous years included non-agency members. This year, due to restrictions imposed during the COVID-19 pandemic, all team members were from ARPANSA's Regulatory Services Branch. Two staff new to ARPANSA joined the team and provided input that was not biased by any former association with ARPANSA's regulatory activities.

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

- John Ward, Director Safety Systems, Regulatory Services Branch (Team Lead)
- Joy Ho, Senior Regulatory Officer, Regulatory Services Branch, Safety Systems
- Serene Mukattash, Regulatory Officer, Regulatory Services Branch, Facility Safety
- Rodger Tranter, Senior Regulatory Officer, Source Safety and Security.

The assessment focussed on a review of performance against the six KPIs using the 12 approved measures, and the verification of the associated data. To ensure a balanced and objective assessment, the team considered additional information against the RPF metrics outlined in the RPF framework. The assessment includes reviewing records, documents and data within the management systems. Interviews were conducted with both staff members, senior management and licence holder representatives to inform this report.

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

Rating scale

ARPANSA has used a three-point scale, in accordance with 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 validating body.

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.

Significant events during the reporting period

Regulatory Action Arising from an Accident at ANSTO's Nuclear Medicine Facility (ANM).

ARPANSA monitors the safety performance of its licence holders and, in accord with Section 58 of the Regulations requires notification within 24 hours if certain events with safety implications occur.

During the 2019-20 financial year there were no accidents reported to ARPANSA, under section 58 of the Regulations. However, ARPANSA did investigate and take a series of regulatory interventions over an accident that occurred on 21 June 2019 that was reported in the previous RPF report. In this accident, the hands of three workers were exposed to radiation at the ANSTO Nuclear Medicine Facility (ANM) at Lucas Heights, NSW. ANSTO voluntarily suspended its ANM operation. On 25 June 2019, ARPANSA instructed ANSTO not to resume production at ANM without ARPANSA's approval and required it to provide information on the causes of that accident, actions taken to prevent its recurrence, and to update the ANM Facility risk assessment.

ANSTO was authorised by ARPANSA to resume production from 6 July 2019, at a level that would satisfy the domestic demand for nuclear medicine only. This decision took account of previous safety events during nuclear medicine production at ANSTO as well as ARPANSA's review as to the circumstances of the accident, including the sequence of events and effectiveness of controls. The production restriction freed capacity at ANSTO to enable it to enhance its operational safety.

ARPANSA continued its investigation into the causes and contributing factors of the accident. ANSTO was found to have breached the Act by failing to take all reasonably practical steps to prevent accidents and failing to ensure that doses to workers were below statutory limits. Following assessment of ANSTO's safety enhancements, on 27 March 2020, ARPANSA authorised the resumption of a staged return to normal production at ANM.

On 6 September 2019, a mechanical failure of a gate valve occurred at the ANM facility that halted production and caused further disruption to the supply of Mo-99 based radiopharmaceuticals within Australia. ARPANSA expedited the approval process of a s63 change relating to the recovery process. This approval supported an early resumption of ANM operation and minimised further disruption of supply.

Amendment of Regulations

The ARPANS regulations provide a framework for ensuring that licenced entities that use or produce radiation do their work safely. The regulations are updated annually and in November 2019 amendments were introduced that provided further safeguards and clarification of requirements for new licence applications. The changes also incorporated separate dose limits for occupational exposure to ionising radiation for people aged 16 and 17 years of age and referenced new Codes that apply to licence holders including the Code for Disposal Facilities for Solid Radioactive Material (2018) and Code for Disposal of Radioactive Waste by the User (2018).

COVID-19 Impact

ARPANSA took timely action to safeguard its workforce, maintain its critical operations and reduce the health risk to its stakeholders.

In March 2020, shortly before reducing its office presence, ARPANSA launched its ARPANSA Teams system (A-Teams) that was built on a Microsoft Teams platform. This system has been used to maintain high levels of connectivity, communication and a collaborative workspace without the need for staff to physically meet.

ARPANSA made enquiries to all licence holders in order to understand how each was addressing and maintaining nuclear safety and radiation protection under COVID-19 restrictions. Many licence holders suspended their operations and discussed with ARPANSA whether to request a change facility authorisations to possess or control rather than operation licences. Ultimately, licence holders decided that the shutdown period did not warrant a change to authorisations and remained under operating licence arrangements, including maintaining the safety systems as if the facility was operating.

ARPANSA has maintained its international engagement through distance methods such as video conference and webinars. No overseas travel has been undertaken since March 2020. The number of requests for expert support that involved travel have been declined and an international workshop that ARPANSA had planned to host in December 2020 has been postponed.

In consideration of a risk informed approach, ARPANSA's source inspection program was suspended; however, the facility inspection program was maintained predominately through remote inspection practices. Recognising that ARPANSAs safety mission cannot be fully sustained without an active on-site inspection program, ARPANSA decided to resume a limited source inspection program in the first quarter of 2020/21.

Overall assessment

ARPANSA continues to perform well against the RPF objectives. Using the established performance ratings, targets have been met for all six KPIs, and strong performance observed against nearly all the measures under the KPIs.

Summary of self-assessment results

Regulator Performance Framework KPIs	Ratings for 2019–20	Summary
KPI 1 - Regulators do not unnecessarily impede the efficient operation of regulated entities.	Substantially met	<p>ARPANSA is committed to the avoidance of any unnecessary impact on licence holder operations. It has maintained high levels of predictability regarding its inspection schedule (96%) and met agreed timelines on applications (94%). ARPANSA's regulatory staff have good mission awareness and understand the need to be responsive to licence holder priorities and to avoid being unnecessarily prescriptive.</p> <p>Whilst ARPANSA meets its agreed timelines for most applications, there is lower satisfaction in regard to how long the process actually takes as reported in the Post-Assessment Surveys. This is an area for improvement.</p>
KPI 2 -Communication with regulated entities is clear, targeted and effective.	Met	<p>ARPANSA has undertaken 32 information sharing meetings with regulated entities during the year. This meets the target but has been negatively impacted by COVID-19 restrictions.</p> <p>ARPANSA received positive feedback for a range of communication methods and initiatives from its stakeholder surveys. Licence holders reported that inspectors are professional, knowledgeable and accessible. Ideas to strengthen this measure further include the development of remote conference methods and webinars as a substitute for physical forums, staggering the rotation to lead/support inspector appointments (rather than simultaneous changes) and improved recording and encouragement of feedback.</p>
KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk being managed.	Met	<p>ARPANSA's inspection schedule was subject to review and update, albeit there was minor delay arising from consideration of COVID-19 restrictions. ARPANSA spent 73% of its time on medium or higher risk licences. Two potential non-compliances and 137 less safety significant areas for improvement were identified during inspections.</p>

Regulator Performance Framework KPIs	Ratings for 2019–20	Summary
		<p>ARPANSA's most significant regulatory action of the year illustrates a proportionate response to a significant safety issue. After an accident at ANSTO in June 2019, ARPANSA suspended operations for a short period of time whilst causation and urgent mitigations were agreed. From the beginning of July through to March 2020 ARPANSA permitted a limited resumption of operations whilst further improvements were implemented and undertook a series of inspections. A staged return to full operation was authorised in March only when ARPANSA was satisfied that the mitigations were adequately implemented.</p> <p>Areas for improvement for ARPANSA concerned improving the consistency of regulatory approaches by inspectors, improvements to the delivery and promotion of ARPANSA's holistic safety approach and for various aspects of record keeping.</p>
KPI 4 - Compliance and monitoring approaches are streamlined and coordinated.	Met	<p>ARPANSA has collaborated with other regulatory bodies for example Comcare, where each agency has shared approaches and co-ordinated important safety messaging to a shared licence holder.</p> <p>ARPANSA's compliance monitoring goes beyond compliance by emphasising, where appropriate, the importance of meeting best practice as a safeguard for compliance. Review and revision of ARPANSA's Compliance and Enforcement Manual has commenced and is on track for finalisation before the end of 2020.</p>
KPI 5 - Regulators are open and transparent in their dealings with regulated entities.	Met	<p>ARPANSA's leadership and staff are committed to openness and transparency. Its main operating manuals and other information on how it conducts its regulatory business are published on the ARPANSA website. ARPANSA publishes inspection reports, and for large or significant applications, its regulatory assessment reports and the basis for decisions. The basis for all decisions that affect a licence holder are stated to the licence holder.</p> <p>ARPANSA consults during the development of national codes, standards and guides.</p>

Regulator Performance Framework KPIs	Ratings for 2019–20	Summary
KPI 6 - Regulators actively contribute to the continuous improvement of regulatory frameworks.	Substantially Met	<p>ARPANSA seeks feedback from licence holders on its regulatory service. The feedback received is overall positive according to ARPANSA continuous improvement surveys. Increasing the number of responses to inspection and assessment surveys and improving the use from feedback provided in-person at meetings or by telephone is an area for improvement. For this reason the KPI is considered to be only substantially met.</p> <p>ARPANSA is subject to internal and external reviews and is open and transparent in this regard. This year, a safety culture self-assessment was undertaken across the whole of ARPANSA. The assessment report is published on the website. A general review of regulatory guidance was initiated. Improvements identified are recorded in a register and tracked. Some actions arising from an IAEA IRRS mission to Australia in November 2018 have been closed during this year and others are being progressed. The IRRS covered all Australian Radiation Regulators and ARPANSA works actively with each of these to promote the use of international best practice across Australia.</p>

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

2019–20 Performance reporting

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

ARPANSA's Objectives/Claims for KPI 1

ARPANSA's impact on the operations of licensed entities is driven by the safety objective and is based on Act and Regulations that set out its regulatory functions and powers. ARPANSA strives to undertake these functions in a way that is proportionate and does not unduly impact on the operations, while still meeting the safety objective of protecting people and the environment from the harmful effects of radiation. A risk informed inspection program, and applications assessed in an agreed timeframe, provide predictability and allows licence holders to efficiently plan their operation and resources whilst meeting its regulatory responsibilities.

ARPANSA's risk informed inspection program includes:

- an open and transparent baseline schedule that is maintained, covering the next three or more years. The schedule includes mechanisms to elevate or reduce the frequency of inspections based on risk, the adequacy of safety controls and the safety performance of the operator.
- a defined scope of each inspection based on published [performance objectives and criteria](#) (PO&C). The PO&Cs were developed based on the requirements of the Act and Regulations and on international best practice that is most commonly expressed in Australian standards or the IAEA safety standards. 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 for 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 2019–20)
<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 met</p> <p>A total of 96% (26/27) of inspections were conducted in accordance with the schedule. This meets the target of 85% and is above the five-year average of 86%.</p> <p>ARPANSA does not count inspections that were cancelled or postponed for reasons that were outside of its control or for reasons permitted in its procedures. There were 13 inspections in this category. The reasons included restrictions associated with the COVID-19 pandemic, reclassification of items as no longer being controlled apparatus or sources being transferred from the inspection premises and lack of licence holder staff availability.</p> <p>In total 44 inspections were conducted. This number included some deferred from the original schedule and augmented inspections in response to specific safety concerns.</p>
<p>PI 1.2 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 94% (17/18) of applications assessed (completed) during this reporting period were assessed within the timeframe agreed with applicants. This exceeded the target of 75% and is above a five-year average of 85%.</p> <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 or non-urgent work. For example, following a mechanical failure at ANSTO's Nuclear Medicine facility a Section 63 approval to install a blanking plate was granted one day after it was submitted for approval. A later, more complex approval for the dissolution of uranium target plates was approved in 11 working days.</p>
Self-assessed rating: SUBSTANTIALLY MET (Taking account of further evidence)	

Further evidence considered

Fees and charges, which are set in the Regulations, can impact licence holder operations. ARPANSA's regulatory service operates on a cost recovery basis. The resources applied to specific licences and some generic regulatory tasks is recorded and analysed. The data is used to ensure that financial impact to licence holders is fair and appropriate.

ARPANSA applies a risk informed approach to the allocation of its regulatory resources for inspections. The precise methods, which are described in the ARPANSA [Inspection Manual](#), varies between source and facility licences. For radiation sources the allocation of resources is associated with the inherent risk of the source and expressed by the categorisation in the Act. Additional, augmented inspections may be undertaken where it is considered that safety performance needs further assessment or be improved. For facilities, which are generally more complex and subject to more regulatory oversight than a source, the number of inspections is determined from the inherent risk of the controlled activity, the operating organisation's safety arrangements and its operational safety performance. Facility operators with comprehensive safety controls and good safety performance will downwardly influence the regulatory charges that they must pay and conversely those with poorer safety performance will pay higher charges as they are subject to more oversight. ARPANSA's inspection program is subject to annual review which includes the review of any factors that affect regulatory prioritisations.

ARPANSA published a range of guidance. [Regulatory publications](#) include radiation safety codes and standards that are used by all Commonwealth, State and Territory jurisdictions. ARPANSA also publishes its own [Operating Manuals](#) and [Regulatory Guides](#) to provide information on how it works and its expectations in regards to safety, compliance and applications.

Strengths

Mission awareness

Interviews with ARPANSA's regulatory staff indicated that they have good self-awareness, consciousness and understanding of ARPANSA's objectives and are outcomes focussed and not unnecessarily prescriptive. Stakeholders reported that Inspectors were professional, approachable and responsive to the operational needs of licence holders.

Self-assessment tool

As reported in the previous self-assessment report, 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. During this reporting year the tool has been tested, three further software licences purchased, to be used by licence holders, and the range of controlled activities covered has been increased to include LASER safety. The ultimate objective of this tool is to empower licence holders to identify and improve safety themselves and, in doing so, free ARPANSA's resources to concentrate on areas of greater regulatory priority.

Identified opportunities for improvement

Processing of Applications

Data indicates that, as in previous years, ARPANSA performs strongly in meeting agreed decision dates for applications. However, data from post assessment surveys indicated only a 64% overall satisfaction rate in regard to the timeliness of assessment decisions, i.e. about a third of respondents think ARPANSA takes too long to process applications. The reasons that assessments take a long time vary widely and include technical complexity, the availability of specialist expertise, and the completeness of applications. It is recommended that ARPANSA investigate ways to streamline the assessment process and to better understand the reasons underlying the expectations on timeliness are not more closely matched in practice. Two ARPANSA projects are currently underway that may assist this. ARPANSA has commenced a review of its guidance material to ensure its scope, depth and applicability meets the needs of regulatory officers and licence holders or applicants. A major project is also underway to build a modern information

technology platform and systems framework. A module of this project will include administrative tools to improve the efficiency of ARPANSA's regulatory service.

Data management and management of workflow

As reported in previous self-assessment reports, regulatory data is fragmented across different data sources, including records management, SharePoint and ad hoc tools such as spreadsheets and databases. Whilst not outwardly visible, regulatory staff regard the current arrangements as inefficient, making workflow management difficult and increasing the risk of administrative error through the multitude of reporting protocols. The use of regulatory data for business intelligence purposes such as identifying trends or common safety issues is sub-optimal. To address these issues ARPANSA is progressively improving its platforms and systems. ARPANSA is investing heavily into an upgrade of its platforms and systems over several years into which its regulatory systems will be integrated. Until these systems are designed, developed and implemented a level of fragmentation will remain.

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

ARPANSA's Objectives/Claims for KPI 2

ARPANSA communicates with licenced entities by a range of methods to collect information and to consult and inform licence holders of regulatory matters. These include:

- Dedicated Lead Inspectors are allocated to each licence to build up detailed knowledge and understanding of the licensed activity and understand the impact of ARPANSA's regulatory approach. They are the licence holder's main point of contact with ARPANSA and the focus of communication.
- Licence Administrator to distribute, collect and collate important licence data. The Licence Administrator is the focus of communication involving any administrative regulatory questions between ARPANSA and the regulated entity.
- Information sharing meetings. These range from working level meetings between inspectors and frontline operational staff to meetings between the senior executives of each organisation.
- Annual conferences (licence holder forums) are held where topical radiation safety issues are discussed. These forums also allow for networking between licenced entities for the purpose of sharing operational experience relating to safety
- Meet the regulator forums. These are mini licence holder forums and are aimed at a front-line, operational level, workers that would not otherwise attend the main licence holder forum that is a Canberra-based conference.
- ARPANSA website. The website provides a range of information on how ARPANSA conducts its business, guidance on the expected safety standards to be met and a range of reports including statement of reasons for key decisions, significant regulatory analysis reports and the analysis of common safety problems.
- Meetings with prospective licence holders and the general community that may be affected by licensed activities. These meetings provide information on regulatory expectations and confidence to stakeholders that ARPANSA's processes achieve its regulatory purpose.

- All licensing decisions are communicated in writing and include a statement of reasons that formed the basis for the decision. Major licence decisions and regulatory assessment reports are published on the ARPANSA website.
- Inspection reports are provided to each licence holder individually. Unless containing security sensitive information all inspection reports are published on the ARPANSA website.

Measures/metrics	Evidence (performance in 2019–20)
<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 CSIRO-ARPANSA Liaison Forum (CALF), 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 32 information sharing meetings were held over the year as well as 18 site visits. This number represents a good number of meetings although it is down on a five-year average of 37. From March 2020 the number of meetings held reduced to four in recognition of COVID-19 physical distancing restrictions. ARPANSA, has reached out to licence holders by telephone and video conference to maintain regular contact. This is effective as an interim measure but cannot replace, only supplement physical meetings in the long term.</p> <p>Examples of meetings held in the period include:</p> <ul style="list-style-type: none"> • liaison forums with Defence, CSIRO and ANSTO • quarterly meetings with major licence holders • 21 survey responses were received for the 2019 LHF with all respondents rating it as 'excellent' or 'above average'. The responses indicated that the panel discussions and coffee corner discussions are particularly useful including by providing opportunities for networking.
Self-assessed rating: Met	

Further evidence considered

ARPANSA's approach to regulation was found to be open and transparent, a feature that is recognised from the results of surveys and feedback from licence holders including interviews undertaken for this assessment. ARPANSA's philosophy is to publish information wherever feasible, unless there is a reason not to publish.

The allocation of a Lead Inspector for each licence was singled out as being particularly useful. Lead inspectors were said to be readily available, open and consistent in their messaging regarding regulatory expectations. There were high levels of licence holder satisfaction regarding the accessibility, knowledge and professionalism of inspectors.

Written communication was reviewed and found to be targeted and clear. Correspondence regarding applications and any non-compliance provide clear statements of regarding the basis of the decision. The licence holders are consistently provided the opportunity to review the factual basis for decisions.

Inspection reports and information on major regulatory decisions is published on the ARPANSA website.

Strengths

Multifaceted communications

As stated above, ARPANSA employs a wide range of communication tools with the purpose of protecting people and the environment. There is no single focus to these tools and instead they are intended to deliver messages for safety from various angles. The results of surveys and from discussion with licence holders, ARPANSA is recognised as an effective communicator. However, despite this recognition, ARPANSA continues to review its processes in the interest of continuous improvement. Current projects in this space include a review of its guidance material to ensure that its scope, depth and applicability meets the needs of regulatory officers and licence holders. For this review, which examines the entirety of available guidance, ARPANSA is actively reaching out to licence holders to properly understand what is needed to assist them to maintain safety and meet compliance requirements.

Identified opportunities for improvement

Impact of COVID-19 Restrictions

From March 2020 ARPANSA's regulatory activities have been impacted by Commonwealth, State and Territory restrictions aimed at limiting the spread of COVID-19. It was found that this had impacted certain aspects of communication between ARPANSA and its licensed entities that are normally undertaken physically. For example, planning for the next Licence Holder Forum was suspended, no "Meet the Regulator" forums have been held and ARPANSA's inspection program has been impacted with those remaining inspections being undertaken mostly using remote methods (for example, document correspondence and video methods). Whilst these methods have been effective as an interim and temporary arrangement, the assessment team recommends that other, alternative methods of interacting are explored and implemented. These must be able to support and independently verify the safety performance of licensed entities.

Lead Inspectors and Inspector Rotation

The allocation of a Lead Inspector for each licence was singled out as being particularly useful. Lead inspectors were said to be readily available, open and consistent in their messaging regarding regulatory expectations. There were high levels of licence holder satisfaction regarding the accessibility, knowledge and professionalism of inspectors.

Lead inspectors are rotated periodically from one licence to another, a practice undertaken to spread operational knowledge and experience throughout the inspection team and to reduce the potential for 'regulatory capture'. Licence holder representatives reported that the transition from one lead inspector to another should be improved to allow more time for the incoming lead to learn the licence holder operation. Licence holders reported that they must invest time to bring the incoming inspector's knowledge of its operations up to speed, especially where there are novel uses for radiation such as those used in scientific research.

Recording and encouraging feedback (information sharing meetings)

As reported in previous self-assessments, a mechanism for recording feedback received from meetings is under-utilised. Forums for sharing approaches and knowledge within RSB was also identified as an area which should be further developed. This suggests that there have been missed opportunities to improve regulatory actions.

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

ARPANSA's Objectives/Claims for 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. Oversight includes an inspection program where depth and frequency of inspections are determined by the overall risk of the controlled activity that includes an assessment of the safety controls in place and the safety performance of the operator. Outside of the inspection program, site visits by regulatory officers, other meetings, forums and self-reporting requirements are used to maintain effective oversight of safety and compliance.

An inspection may result in 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 ARPANSA may monitor, advise and encourage actions, but will not intervene.
- 'Potential non-compliances' (PNC), which identify 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 which are described in the [Compliance and Enforcement Manual](#). The level of response is proportionate to the particular circumstance. ARPANSA's most common response to non-compliance will be to encourage a voluntary return to compliance. If this is unsuccessful or if the matter is particularly serious, the regulatory response may be escalated to formal enforcement action such as the imposition of additional licence conditions, an improvement notice or direction, through to suspension or cancellation of licence, or court action. ARPANSA is currently updating its compliance and enforcement manual to ensure its policies are outcomes focussed and drive protective behaviours and practices. This update takes into account the findings of reviews of other regulatory bodies, such as the [Royal Commission into Misconduct in the Banking, Superannuation and Financial Services Industry \(2019\)](#).

Measures/metrics	Evidence (performance in 2019-20)
<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 and updated in March 2020. The review of the source inspection program completed in July 2020 having been delayed allowing adjustments arising from the COVID-19 pandemic.</p>

Measures/metrics	Evidence (performance in 2019-20)
<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 73%. This year's figure matches the average for the previous four years (73%) but is the lower than the previous two years (86% and 82%).</p> <p>A range of options are available to ensure effective control. ARPANSA will use an appropriate response to non-compliance and any performance concerns that considers the risk to safety. For example, in the 44 inspections performed 137 AFIs, two PNCs, and three good practices were found during inspections.</p> <p>In accordance with the published 'graded approach to non-compliance', the safety significance of the non-compliance is considered. Of the 12 confirmed non-compliances, 11 were considered not to be of high significance to safety and the licence holders were not named.</p> <p>In line with the ARPANSA's published approach there was a clear preference by ARPANSA to use lower order controls such as non-named breaches and or AFI's in place of very minor examples of non-compliance.</p>
Self-assessed rating: Met	

Assessment of Objectives/Claims

ARPANSA's claims against KPI 3 were largely found to be fulfilled. The prioritisation of regulatory resources accurately follows the approach described in the inspection manual that is published on the website and this is supported by data showing most time is spent on licences with highest inherent risk. Although this does not extend to the RPF concept of "earned autonomy", recognition of good safety performance is built into the allocation of regulatory resources. An example of where this is clearly demonstrated is the ARPANSA [Inspection Manual](#).

ARPANSA's response to a contamination accident that occurred on June 2019 is described in the significant events section on page 4 of this report. This provides a useful example of a response to a significant action, in this instance taken by the imposition of a special licence condition in July 2019 together with a series of augmented inspections. The licence condition limited ANM production so that ANSTO was able to continue to supply essential medicines to the Australian market while redirecting necessary resources to address the safety weaknesses identified by the investigations into the accident. This, together with a series of targeted augmented inspections and an ARPANSA initiated survey of ANSTO's culture for safety allowed ARPANSA to relax this restriction in March 2020. A detailed [statement of reasons](#) regarding this regulatory response is available on the ARPANSA website

Strengths

Graded Approach

As noted in previous RPF reports, ARPANSA's internal and publicly available guidance on the graded approach such as for inspection and enforcement is clearly visible and well utilised by regulatory officers. ARPANSA continues to expend the majority of its regulatory resources (73%) on medium or higher risk licences. The approach is outcomes focussed and not prescriptive.

Identified opportunities for improvement

Variability of Service Approach

ARPANSA has a structured framework and management system that guides its approach to regulation. The framework has flexibility to contend with the wide variety of types of controlled activities that it regulates. This assessment found differences in the applied approach (e.g. a mixture of compliance vs guidance approaches) should be better understood and used to inform regulatory systems and training.

Approach to Holistic Safety

For a number of years ARPANSA has promoted a best practice systemic approach to safety management known as holistic safety. The approach examines the interaction of human and organisational contributors to safety together with technological factors. It is a principle now embedded in international safety standards. This assessment identified a wide variety of attitudes to the holistic approach and the appropriateness of ARPANSA's work in this space. The assessment team was told by some licence holder staff that the approach was not helpful and that ARPANSA should concentrate on front-line workplace assessment of safety. Some inspectors are also less comfortable examining holistic safety than other aspects of safety. It is recommended that ARPANSA reviews the effectiveness of its promotion and oversight of holistic safety and the training provided to the inspection team.

It was noted that ARPANSA has recently recruited to further enhance its capabilities in human and organisational factors and has initiated a review of regulatory guidance.

Record keeping

Data management continues to be a challenge as reported in previous years. This is partly due to the fragmented data systems being used for regulation (See KPI 1). While improvements have been noted, a number of instances of poor record keeping were identified particularly in regard to the Licence Administration Database. For example, despite significant resources invested in the planning and conduct of an inspection, it was noted again that the breach follow-up register is in most cases not completed. As stated previously this hinders ARPANSA's ability to use the data it receives for business intelligence purposes.

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

ARPANSA's Objectives/Claims for KPI 4

ARPANSA's compliance monitoring approach is built on a well-documented framework. It includes review of reporting from the licence holder, a risk informed inspection program and a range of communication practices that collectively provide regulatory oversight. An internal management system supports the consistent delivery of its regulatory service through approaches that enable a balanced approach between coercive and softer, persuasive, regulatory practices. ARPANSA strives to limit regulatory burden and not

unduly impede on justified and safe practices involving radiation, emphasising that the primary responsibility for safety rests with the licence holder, and to direct resources to where they are most needed.

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. The ARPANS Regulations require a licence holder to investigate and rectify any suspected instances of non-compliance. To avoid future non-compliance, ARPANSA encourages the adoption of international best practice in nuclear safety and radiation protection as articulated in established international standards such as those of the ICRP and UN IAEA. ARPANSA is involved in the development of these standards through its international engagement program. In its decisions ARPANSA considers the safety implications where a licence holder does not adopt international best practice. The safety implications where a licence holder did not meet international best practice is analysed during licensing assessments and can affect its authorisation to conduct controlled activities. During inspections a licence holder may be notified of an area for improvement where it is found that best practice is not practised.

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). Where appropriate ARPANSA engages with other regulators to share information and approaches.

Measures/metrics	Evidence (performance in 2019-20)
<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 actions 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 68% of AFIs an action is initiated within three months. This compares to a five-year average of 60%. A total of 127 out of 187 AFIs had actions initiated.</p> <p>The target (50%) was exceeded. The voluntary correction of AFIs indicates that licence holders understand the safety benefits and reflects well on the culture of the licence holders and influence of ARPANSA.</p>

Measures/metrics	Evidence (performance in 2019-20)
<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 collaborates regularly with Comcare and met on three occasions (October, February and May) to discuss joint licence holders and shared interests such as the management of human and organisational factors. Comcare also contributed a training session at the Regulatory Services annual training day. ARPANSA also continues to maintain close links with Australian Safeguards and Non-proliferation Office. This collaboration avoids some duplication of requirements, facilitates the delivery of a shared message for safety and leads to improved understanding of respective requirements.</p> <p>ARPANSA also works with and shares information with state and territory radiation regulators and regulatory groups such as the Commonwealth Regulatory Science 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 (Content Manager), a purpose-built database (Licence Administration Database), the branch intranet page (ISAAC) and ad hoc tools such as spreadsheets. The limited functionality of the current system has been identified as an area for improvement. Functionality such as dashboards, would reduce the reliance on individual memory and assist officers and managers to efficiently maintain oversight. Desired features include a licence holder interface for self-reporting, automated calculation of fees, generation of licence documents, analysis of 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 outcome of this analysis is made available to licence holders through the [ARPANSA website](#), and is discussed at forums, so that they may review and compare their operations for similar issues.

ARPANSA has established MOUs with other regulatory agencies, such as Comcare and state and territory radiation regulators. ARPANSA has been working with Comcare in matters of shared interests and regularly meets to discuss specific information on incidents and accidents and the outcomes of regulatory oversight generally. 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 introduced an improved system for on-boarding of regulatory staff that is designed to ensure that each has the necessary baseline administrative and wide-ranging technical knowledge to undertake inspections. Staff need to demonstrate this knowledge before they are appointed as inspectors.

Identified opportunities for improvement

Approach to leadership and management for safety

In 2012, ARPANSA adopted a holistic approach to safety that considers human and organisational aspects to safety alongside technical factors. This approach is consistent with international standards and is recognised as an effective approach in addressing the underlying issues that are needed to support safe operations. However, it was found that there are varying approaches and abilities in the regulatory team in the application of the human and organisational factors. There was also a range of opinions amongst the staff of licence holders with some suggesting that ARPANSA should deal with front line issues rather than higher level human and organisational factors. The assessment concluded that further work is needed to improve the delivery of ARPANSA's holistic approach to safety and to inform licensed entities of its importance. It was noted that ARPANSA has recently employed additional specialist resources to this area.

Data management

As identified under KPI1 and reported in previous self-assessments, data is fragmented across different sources and management tools. A project to replace the ARPANSA platforms and systems framework is now underway but work on the regulatory administration aspects of this has not started.

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

ARPANSA's Objectives/Claims for KPI 5

ARPANSA is open and transparent in its approach to regulation and regulatory outcomes. This is important to promote consistent high standards of regulation, to build and maintain an honest and respectful dialogue with all licence holders and to provide confidence to the public.

ARPANSA's website provides extensive information on how it operates its regulatory activities. At a top level its publications include its [Corporate Plan](#), [Annual Report](#) and [Regulatory Activities Policy](#). Published information on its regulatory processes includes its main [operating manuals](#) (Licensing and Assessment, Inspection and Compliance and Enforcement). What ARPANSA looks for during inspections is described in its [Performance Objectives and Criteria](#) and information needed for any applications and safety standards is provided on its [Regulatory Guides](#) page. These guides are supported by published [national safety codes and standards](#) and [international safety standards](#). Any new or significantly amended regulatory guidance is subject to consultation with licence holders before publication.

ARPANSA publishes its [inspection reports](#), except where they are redacted or withheld for security reasons. It also publishes a range of information on major applications and the basis for major decisions.

Measures/metrics	Evidence (performance in 2019–20)
<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 34 inspection reports were posted this FY, as of July 2020.</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 an amendment to the ANM facility authorising it to return to normal operations. • ARPANSA approves ANSTO implementation plan following safety review <p>ARPANSA also provides information on regulatory actions in its quarterly and annual reports which are also published on its website</p>
<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. National Codes and Standards are available for wide consultation on ARPANSA's 'have your say' webpage. Consultation on regulatory guides for licence holders are sometimes targeted to licence holders only.</p> <p>Documents undergoing consultation, or finalised after consultation during 2019-20 included:</p> <ul style="list-style-type: none"> • <i>Radiation Protection Standard: Maximum Exposure Levels to Radiofrequency Fields</i> • <i>Code of Radiation Protection In Planned Exposure Situations. (RPS-C-1)</i> • <i>Regulatory Guide: Safety Analysis Report for Controlled Facilities</i>
Self-assessed rating: Met	

Further evidence considered

All regulatory decisions include a statement to explain, to licence applicants/holders, the basis for any decision made regarding them. Significant applications and regulatory decisions that normally concern

major nuclear facilities are published on the ARPANSA website. ARPANSA consults with the applicant or licence holder where it is unable to authorise an activity or where conditions on the activity are imposed.

ARPANSA has initiated a review of the scope and depth of its regulatory guidance to licence holders that will include consultation. The objectives of the review are to support and enhance safety performance by identifying and filling any gaps in current guidance and to assist in the development of plans and arrangements for managing safety by clearly explaining ARPANSA's expectations and how ARPANSA arrives at its decisions.

Identified opportunities for improvement

Website content

ARPANSA posts a large amount of information on its website including information on applications and inspections. It was reported by staff and licence holders that the search engine on the website is effective when people know what they are looking for. Feedback suggests that the structure and hierarchy of the regulatory webpages is not intuitive and is confusing. As a result information and regulatory guidance can be difficult to find. An example is the regulatory guides for which there is no link from the regulatory publications page or the information for licence applicant's page.

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

ARPANSA's Objectives/Claims for KPI 6

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 self-assessment, internal audits, stakeholder forums, periodic reviews of the regulatory management system, stakeholder feedback surveys, safety culture self-assessments, 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 satisfactory completion.

Measures/metrics	Evidence (performance in 2019–20)
PI 6.1 Feedback from licence holders is encouraged and feedback received is positive, constructive and drives improvement. 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	Substantially met A total of 47 post-inspection surveys were received, with an average overall satisfaction score of 94%. This is marginally higher than previous years that averaged 87%. Three post-assessment surveys were received, with an average overall satisfaction score of 75% compared with 83% in the previous year. The

Measures/metrics	Evidence (performance in 2019–20)
<p>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>comments are also analysed for improvement opportunities. The comments received indicate an overall positive perception of the delivery of regulatory services, however, an audit of approvals found that the request to participate in the post inspection survey had not been issued in seven of the 18 approvals.</p> <p>ARPANSA lacks an effective mechanism to collect feedback from other licence holder interactions such as telephone calls or meetings including inspection exit meetings. This is an opportunity for improvement and the reason that this measure is only substantially met.</p>
<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"> • Introduction of a data dashboard to assist in the management of regulatory oversight • Introduction of a new form for laser safety for use in ARPANSA developed safety assessment tools. These allow licence holders to assess their own compliance. Further forms will be progressively added to cover other controlled activities • The formulation of arrangements for independent oversight of ARPANSA's regulation of its own licenced (under the ARPANS Act) activities (to address issues of conflict of interest) • Actions resulting from the 2018 IAEA IRRS review (see below) <p>Reviews in this period have included:</p> <ul style="list-style-type: none"> • a whole-of-agency safety culture assessment • a review of the scope and depth of regulatory guidance (ongoing)
<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 liaising with international regulators, IAEA safety standards committees, and participation in IRRS missions. During the COVID-19 pandemic this work has continued where possible by remote methods.</p> <p>ARPANSA promoted best practice across Australia through the Radiation Health Committee and</p>

Measures/metrics	Evidence (performance in 2019–20)
	initiatives such as the Radiation Protection Network (formerly names Radiation Regulators Network but renamed to illustrate that the network could be accessed by non-regulatory organisations), 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).
Self-assessed rating: Substantially met	

Further evidence considered

ARPANSA has strong international engagement, both regionally and further afield that informs its approach to its own licence holders. ARPANSA participates in IAEA safety standard committees as well as in the Commission on Safety Standards, which helps to ensure that standards address Australian needs. ARPANSA staff are well regarded with many having senior roles in international forums for safety and risk assessments and are requested to support IAEA missions and consultancy groups. Some international engagement has been curtailed in this year due to travel restrictions arising from the COVID-19 pandemic. However, ARPANSA has continued to be actively engaged by video or other methods where possible. Activities this year have included hosting an IAEA regional workshop on regulatory management systems, supporting an IAEA mission to the Philippines on the regulations for research reactors, supporting an IAEA IRRS mission to Norway, attendance of various IAEA safety standards meetings and technical meetings and meetings with the Dutch regulator (ANVS) regarding regulation of construction of a new research reactor. ARPANSA also has nine bi-lateral agreements for information and resource sharing with international radiation protection and nuclear safety regulators. The CEO of ARPANSA led the follow-up mission to Indonesia and was the Deputy Team Leader for the follow-up mission to Japan. ARPANSA was asked and undertook an Inspection of the New Zealand Institute of Environmental Science and Research.

ARPANSA co-hosted, with the Australian Radiation Protection Society (ARPS), the fifth International Symposium on the System of Radiological Protection, in October 2019 in Adelaide. The Symposium attracted over 400 radiation protection specialists from around the world.

ARPANSA also promotes national uniformity of radiation regulation through the Radiation Health Committee and the Radiation Protection Network (RPN). Nationally uniform requirements can significantly reduce regulatory burden on persons working in more than one jurisdiction. To strengthen cooperation between ARPANSA and other radiation regulators MOUs have been signed or are currently being finalised with environmental protection or health authorities in New South Wales, South Australia and Tasmania.

ARPANSA has introduced a series of informal internal communication measures including ‘morning tea information sessions’, where an officer provides updates on recent regulatory and international matters. This is aimed at sharing information within the regulatory team to raise awareness of broad issues and approaches and support a consistent regulatory service.

ARPANSA's on-line learning platform is being upgraded to allow ARPANSA to create bespoke annual training programs.

A comprehensive review of regulatory guidance is being undertaken to determine whether the current guidance is optimised for current and future needs. ARPANSA also continues to conduct individual review and updates to its existing guidance.

Of ten recommendations relating to ARPANSA's regulatory service from the November 2018 IRRS mission three have been closed and work is progressing on seven.

Strengths Open and transparent review of performance

ARPANSA is committed to the continuous review and improvement of its regulatory service. ARPANSA subjects itself to internal and external scrutiny and has a culture of self-reflection that leads to regular improvements to its regulatory service.

International Engagement

ARPANSA is actively engaged internationally. The engagement helps to ensure that ARPANSA's interests are represented in standards development and informs its regulatory approach and the safety standards it expects of licence holders.

Identified opportunities for improvement

Inspection and Assessment Feedback

At completion, an inspection feedback survey is issued to the main licence holder participants with the objective of gauging the level of service provided by ARPANSA and identifying and driving improvements. ARPANSA has not been successful at increasing the response rate from post inspection surveys which for this reporting period averaged just one response per inspection. The feedback rate for assessments is also poor but it is partly attributed to ARPANSA assessors not sending the feedback survey request to licence holders. Consideration should be given into utilising alternative feedback such as telephone calls or recording of feedback during inspection exit meetings.

Concluding remarks

This was ARPANSA's fifth annual self-assessment performed under the Australian Government Regulator Performance Framework (RPF). The Regulator Performance Framework provides a lens through which important elements of ARPANSA's regulatory service can be viewed. ARPANSA uses the RPF to help it determine its efficiency and effectiveness in meeting its core mission of protecting people and the environment from the harmful effects of radiation. ARPANSA's publicly available [Regulatory Activities Policy](#) provides an overview of its approach.

A clear finding of this report is that ARPANSA's regulatory services undertaken are generally efficient and in accordance with the objectives of the RPF. The results are similar to previous years suggesting that ARPANSA's regulatory culture is now well aligned to the RPF. Core strengths include professionalism of ARPANSA staff, openness and transparency, and a willingness to examine how ARPANSA operates in the spirit of self-reflection and continuous improvement.

ARPANSA fulfils its regulatory function, using a risk informed approach that enables stakeholders to function without undue interference. ARPANSA's response to a contamination accident at the ANSTO Nuclear Medicine Facility is an example of proportionate regulatory action with focus on safety and with due consideration of consequences for third parties. This permitted the supply of nuclear medicine to the Australian community whilst also freeing up licence holder resources to make necessary safety improvements. ARPANSA also responded rapidly to two requests for approvals associated with a subsequent mechanical fault at the facility in order to minimise further disruption to the supply of medicines.

This year has been challenging for ARPANSA. It has met its mission objectives under restrictions imposed by the response to the COVID-19 pandemic. Its response to COVID-19 has demonstrated adaptability to service delivery. Longer term consequences, including border closures and restrictions introduced after the resurgence of COVID-19 cases in Victoria will not be known until next year.

As in previous years a number of opportunities for improvement have been identified. This assessment found that many opportunities for improvement are multiyear projects that are being addressed or are planned to be addressed once underlying infrastructure issues have been addressed and rectified.

The assessment found that efficiency savings and performance improvements can be achieved through consolidation of currently fragmented data systems. This is being progressively addressed within an ongoing project to upgrade ARPANSA's platforms and systems.

ARPANSA's approach to and promotion of holistic safety also needs to be enhanced. The assessment found that there was variability in the approach and perceived value of the holistic approach. Recent recruitment will assist this in this area.

Other opportunities for improvement include a reduction on the time to make regulatory decisions and improvement of stakeholder feedback mechanisms regarding the application process. Understanding these issues is complex and it is noted that a review of one aspect, the adequacy and effectiveness of regulatory guidance, has been initiated.

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.
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)
LAD	Licence Administration Database
LHF	Licence holder forum
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
RPN	Radiation Protection 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