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

Regulation of Commonwealth Radiation and Nuclear Activities

Australian Radiation Protection and Nuclear Safety Agency

Australian National Audit Office

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Australian National
Audit Office

Canberra ACT
7 May 2014

Dear Mr President
Dear Madam Speaker

The Australian National Audit Office has undertaken an independent performance audit in the Australian Radiation Protection and Nuclear Safety Agency titled *Regulation of Commonwealth Radiation and Nuclear Activities.* The audit was conducted in accordance with the authority contained in the *Auditor-General Act 1997*. Pursuant to Senate Standing Order 166 relating to the presentation of documents when the Senate is not sitting, I present the report of this audit to the Parliament.

Following its presentation and receipt, the report will be placed on the Australian National Audit Office's website—http://www.anao.gov.au.

Yours sincerely

Ian McPhee
Auditor-General

The Honourable the President of the Senate
The Honourable the Speaker of the House of Representatives
Parliament House
Canberra ACT

AUDITING FOR AUSTRALIA

The Auditor-General is head of the Australian National Audit Office (ANAO). The ANAO assists the Auditor-General to carry out his duties under the *Auditor-General Act 1997* to undertake performance audits, financial statement audits and assurance reviews of Commonwealth public sector bodies and to provide independent reports and advice for the Parliament, the Australian Government and the community. The aim is to improve Commonwealth public sector administration and accountability.

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Abbreviations

ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ANAO	Australian National Audit Office
ANSTO	Australian Nuclear Science and Technology Organisation
CEI	Chief Executive Instruction
CEO	Chief Executive Officer
IAEA	International Atomic Energy Agency
IRRS	Integrated Regulatory Review Service
KPI	Key Performance Indicator
OPAL reactor	Open Pool Australian Lightwater reactor
RAR	Regulatory Assessment Report
SOP	Standard Operating Procedure

Glossary

Controlled apparatus	Apparatus that: (a) produces, or could produce, ionising radiation when energised; (b) produces ionising radiation because it contains radioactive material; (c) produces harmful non-ionising radiation when energised, and is prescribed by the Regulations.
Controlled material	Any natural or artificial material, whether in solid or liquid form, or in the form of a gas or vapour, which emits ionising radiation spontaneously.
Controlled person	A Commonwealth entity; a Commonwealth contractor; an employee of a Commonwealth contractor; or a person in a prescribed Commonwealth place.
Facility licence	Required by controlled persons who are engaged in certain conducts in relation to a nuclear installation or a prescribed radiation facility.
Nuclear installation	Includes: (a) a nuclear reactor for research or production of radioactive substances for industrial or medical use; (b) a plant for preparing or storing fuel for use in a nuclear reactor; (c) a nuclear waste storage or disposal facility with an activity that is greater than the activity level prescribed by the Regulations; (d) a facility for production of radioisotopes with an activity that is greater than the activity level prescribed by the Regulations.
Prescribed radiation facility	A facility that is prescribed by the Regulations.
Source licence	Required by controlled persons who deal with controlled material or controlled apparatus.

Summary and Recommendations

Summary

Introduction

1. Radiation and nuclear technologies have a range of uses in Australia, including to diagnose and treat disease. There are however inherent risks associated with radiation and radioactive substances, ranging from acute effects at high exposure to increased risk of cancers, depending on levels of exposure. Given these risks, and broader public sensitivities about the use of these technologies, it is important that their possession and use is managed safely by operators, and subject to an effective regulatory framework.

2. The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) was established in 1998 under the *Australian Radiation Protection and Nuclear Safety Act 1998* (the ARPANS Act).[1] ARPANSA's role, among other responsibilities, is to protect the health and safety of people and the environment from the harmful effects of radiation. This role includes regulating the use of radiation and the safety of nuclear installations by, and for, Australian Government entities.[2]

3. Following an assessment process, ARPANSA may issue a licence authorising an entity's use of specified materials and apparatus (collectively known as 'sources')[3] and facilities (nuclear installations or other radiation facilities). ARPANSA also monitors compliance with the licence conditions through a program of periodic inspections and reporting requirements. Further, ARPANSA may initiate non-compliance and enforcement action, if required, under its legislation.

4. At present, ARPANSA regulates over 40 entities—including departments of state, statutory authorities, and government companies.[4] Existing licences cover approximately 65 000 individual sources (of which over

1 At the time of this audit, the ARPANS Act was under review by the Department of Health in its role as portfolio agency with responsibility for health protection policy and ARPANSA's governance.

2 State and territory governments have also established regulators for related activities by private entities and government organisations within their jurisdiction.

3 Controlled material emits ionising radiation spontaneously, and a controlled apparatus is an apparatus that is capable of producing ionising or harmful non-ionising radiation. An example of a controlled material is Technetium-99, which is commonly used in nuclear medicine, and an example of a controlled apparatus is an X-ray machine.

4 ARPANSA also regulates one private company—Silex Systems Ltd, which operates within a prescribed Commonwealth place.

60 000 belong to the Department of Defence—Defence)[5] and 36 facilities (over half of which are operated by the Australian Nuclear Science and Technology Organisation—ANSTO). The nature of the regulated equipment and the risks associated with its use can vary significantly. Regulated equipment includes: x-ray baggage scanners in office buildings; lasers used for research by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and linear accelerators for examining cargo by the Australian Customs and Border Protection Service (Customs); and ANSTO's nuclear research reactor at Lucas Heights in Sydney.[6]

5. To inform its work, ARPANSA engages with key international organisations involved in nuclear and radiation safety, particularly the International Atomic Energy Agency (IAEA), of which Australia is a member state. The IAEA's role is to promote international cooperation in the safe, secure and peaceful use of nuclear technologies. ARPANSA has adopted the IAEA's *Fundamental Safety Principles* as an internationally-recognised framework for the regulation of nuclear technologies.[7] The IAEA framework establishes key principles, including the assignment of responsibility for the safe management of ionising radiation, which are reflected in ARPANSA's regulatory framework. The first principle is that 'the prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks'. The second principle is that 'an effective legal and government framework for safety, including an independent regulatory body, must be established and sustained'.

5 Defence informed the ANAO that the majority of their sources are used as safety devices for illumination of sights and gauges, with approximately 50 per cent being tritium-based beta lights, and a further 25 per cent being lasers. Defence also noted that less than five per cent of their sources are in the form of solid radioactive material or x-ray apparatus.

6 Australia's only operational nuclear reactor at Lucas Heights in Sydney is used for research purposes and to produce radioisotopes, but not for generation of electricity. In global terms, as a research reactor, its size of 20 megawatts is typical. There are about 240 research reactors operating in 56 countries, ranging up to 100 megawatts. While power reactors are much larger and can generate up to 3000 megawatts, research reactors are typically more complex in design, operation and risk. For more information see http://www.world-nuclear.org/info/Non-Power-Nuclear-Applications/Radioisotopes/Research-Reactors/ [accessed 12 March 2014].

7 IAEA, *Fundamental Safety Principles,* Safety Fundamentals No. SF-1, Vienna, 2006.

Previous ANAO audit

6. The ANAO's 2005 performance audit of the regulation of Commonwealth radiation and nuclear activities[8] found that ARPANSA did not have a systematic approach to planning, undertaking and monitoring its activities. The audit made 19 recommendations. This current ANAO audit is not a direct follow up from the 2005 audit, as it does not focus primarily on the issues and recommendations made in the previous audit. However, in the course of audit fieldwork and analysis, the ANAO has been able to assess the extent to which ARPANSA has implemented the recommendations of the previous audit.

Audit objective, criteria and scope

7. The objective of the audit was to assess the effectiveness of ARPANSA's management of the regulation of Commonwealth nuclear, radiation facilities and sources, including ARPANSA's compliance with its legislative requirements.

8. To assist in evaluating ARPANSA's performance in terms of the audit objective, the ANAO used the following high level criteria:

- ARPANSA has established appropriate governance arrangements to support effective regulation;
- a structured risk management framework is used to assess and manage regulatory risks, and ARPANSA employs a risk-based approach to monitoring compliance; and
- ARPANSA has policies and procedures to support responses to non-compliance, and its responses are proportionate to the risks presented by the non-compliance.

9. The audit focused on ARPANSA's regulatory role, and did not directly examine ARPANSA's other functions, in particular its scientific, advisory and fee-for-service activities and its role in promoting the national uniformity of radiation and nuclear safety policies and practices across the Commonwealth, states and territories. The audit approach was informed by the 2007 ANAO Better Practice Guide *Administering Regulation* and previous ANAO audits into

8 See ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*.

regulatory bodies. A revised Better Practice Guide is scheduled to be released in 2014.

10. The ANAO examined relevant internal and public documents and guidance that support ARPANSA's regulatory role; interviewed key ARPANSA staff; examined a sample of ARPANSA's licence applications and cost recovery arrangements; held discussions with several regulated entities and the former Department of Health and Ageing (now the Department of Health); and accompanied ARPANSA staff on site inspections to observe the inspection process.

Overall conclusion

11. Radiation and nuclear technologies have diverse applications in the government, commercial, health and research sectors, including x-ray scanning for security purposes, the use of lasers for scientific research and the production of radioactive substances at Lucas Heights. While the risks to human health and the environment posed by such technologies have long been recognised, they can be effectively managed through the appropriate use and care of equipment and materials by operators and the application of an effective regulatory framework. Australian Government entities' use of radiation and nuclear technologies[9] is regulated by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), while state and territory based regulators are responsible for administering radiation protection legislation in their jurisdictions, covering operators such as hospitals, universities and industry.

12. ARPANSA has been generally effective in managing key aspects of the regulatory framework applying to the possession and use of radiation and nuclear sources and facilities by Australian Government entities. ARPANSA has developed and implemented procedures for licensing and monitoring regulated entities, supported by a suite of guidance materials for staff and regulated entities. ARPANSA also continues to develop and apply a risk-based approach to regulation which, if further expanded to the assessment of licence applications and its inspection program, could improve the focus and cost-effectiveness of its administration. However, shortcomings identified in an

9 The three largest licence holders are ANSTO (which operates the Open Pool Australian Lightwater (OPAL) reactor at Lucas Heights), CSIRO, and Defence.

earlier (2005) ANAO performance audit[10], relating to the management of potential conflicts of interest and the application of cost-recovery arrangements, have not been fully addressed and have detracted from ARPANSA's overall performance in administering the regulatory framework.

13. To support the administration of its licensing responsibilities under the framework, ARPANSA has, since 2005, published a range of guidance materials, forms, and assessment templates that align with the relevant legislative requirements.[11] The ANAO's analysis of a sample of licence applications indicated that licensing decisions were, with one exception, supported by an appropriate level of evidence. There has also been a significant improvement in the average time taken to assess applications for source licences, from 153 days in 2007–08 to 42 days in 2012–13. However, the licence assessment process could be further improved by providing clear advice to applicants on ARPANSA's expectations relating to supporting information, to avoid repeated ARPANSA requests for additional information and often lengthy delays in the application assessment process.[12] There is also scope for ARPANSA to extend its risk-based regulatory approach to the licence assessment process, to enable staff to focus on the hazard of each source or facility and the applicant's compliance history. Further development of the risk-based approach would help streamline the licensing process, better target available resources and reduce the regulatory impost on applicants.

14. ARPANSA's approach to monitoring entities' compliance with regulatory requirements focuses on regular entity reporting and a periodic schedule of inspections, including unannounced inspections.[13] Since 2005, ARPANSA has established procedures for monitoring entities' compliance with their reporting requirements and assessment of entities' reports, addressing a shortcoming identified in the ANAO's earlier audit. Further, between 2008–09 and 2012–13, ARPANSA has mostly met its target of 60 planned inspections per year, and the inspections observed by the ANAO largely followed the documented procedures.

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10 See paragraph 6.

11 The ARPANS Act and Regulations are discussed in paragraph 2.

12 Conversely, there is an obligation on Australian government entities to submit applications of appropriate quality and to respond to reasonable follow-up requests in a timely way.

13 Unannounced inspections can be a useful regulatory tool to gain insight into an entity's daily operations and compliance with licensing requirements.

15. To address identified non-compliance, ARPANSA applies a graded approach, which requires entities to report on corrective action undertaken to remediate breaches, and which may trigger additional inspections in the event of identified non-compliance. However, aspects of the inspection process, particularly unannounced inspections, are largely driven by geographical convenience rather than risk[14], and ARPANSA's risk-based approach should also be extended to this aspect of its operations.

16. The ANAO observed in 2005 that ARPANSA's legislated functions, including its role as both a regulator and a licence holder[15], create scope for potential conflicts of interest. While ARPANSA continues to exercise functions which may give rise to such conflicts[16], only recently, in 2011, did it formally enter into an arrangement for an outside body to undertake independent inspections of its compliance with its own licence conditions. To date however, only one external inspection has been conducted, and an ongoing program of independent reviews would strengthen confidence in ARPANSA's arrangements for managing potential conflicts of interest and its compliance with licence conditions. ARPANSA has also released a Chief Executive Instruction (CEI) to provide guidance to staff in managing their self-regulatory role and when providing scientific and advisory services, including those on a fee-for-service basis, to regulated agencies—aspects of ARPANSA's work which can also give rise to conflicts of interest. However, there is no evidence that the CEI is actively implemented or monitored, nor is any training provided for staff on conflicts of interest issues. ARPANSA should strengthen its approach to managing conflicts of interest, assisted by its Audit and Risk Committee.

17. While ARPANSA's cost-recovery arrangements have evolved since 2005, several aspects remain inconsistent with better practice. Since 2008–09 ARPANSA has under-recovered its regulatory expenses by almost $4 million,

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14 For example, an entity may be subject to an unannounced inspection due to its proximity to another entity that has a scheduled inspection rather than being linked to its risk ranking.

15 See ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*. In particular, ARPANSA: requires licences under the legislation to conduct some of its non-regulatory functions (a self-regulatory role); provides services on a fee-for-service basis to regulated entities; and provides subject matter expert advice to regulated entities. Officers may also have established relationships with regulated entities or particular personnel (an issue faced by many regulators).

16 ARPANSA currently holds one facility licence (which covers three facilities) and two source licences in order to provide certain services on a fee-for-service basis, and for scientific and advisory services provided by other parts of the organisation.

and has used revenues from its scientific and advisory services functions to cross-subsidise its regulatory function. Further, ARPANSA's calculations indicate that there is cross-subsidisation occurring between licence holders.[17] While intra-government charging is excluded from the *Australian Government Cost Recovery Guidelines* (the Guidelines)[18], ARPANSA has informed stakeholders that it has adopted the Guidelines as a basis for implementing a better practice approach to cost recovery, which includes the avoidance of cross-subsidisation between business activities.[19] In the course of the audit, ARPANSA initiated a review of its cost recovery arrangements to better align them with the Guidelines.

18. The ANAO's 2005 performance audit of ARPANSA's regulatory function[20] made 19 recommendations. Between 2005 and 2007 there was limited work to implement the recommendations, with significant delays experienced. Despite several assessments of progress in recent years and regular monitoring by ARPANSA management and the Audit and Risk Committee, in the course of this audit the ANAO assessed that only 11 recommendations have been adequately implemented, with six partially implemented. By not implementing agreed recommendations in a timely manner, ARPANSA has foregone opportunities to enhance its performance.[21]

19. The ANAO has made four recommendations aimed at strengthening ARPANSA's management of potential conflicts of interest and expanding the risk-based approach to regulation.

17 In effect, the higher fees and charges of some licence holders are being used to reduce the fees and charges of other licence holders.

18 Department of Finance and Administration, *Australian Cost Recovery Guidelines*, Financial Management Guidance No. 4, July 2005.

19 The Guidelines advise that: 'any charges should reflect the costs of providing the product or service' (see p.2) and 'as far as possible, the agency should identify costs against particular activities to minimise the need to distribute costs arbitrarily among activities' (see p. 40).

20 See paragraph 6.

21 The risks of not implementing or inadequately implementing audit recommendations were recently discussed in ANAO Audit Report No.25 2012–13 *Defence's Implementation of Audit Recommendations*, p.13 and 15; and ANAO Audit Report No.53 2012–13 *Agencies' Implementation of Performance Audit Recommendations*.

Key findings by chapter

Governance and Risk Management (Chapter 2)

20. Sound corporate governance arrangements enable a regulator to meet its legislative and regulatory responsibilities, and be accountable for its decisions and actions.[22] Such arrangements should include documented plans that articulate a regulator's objectives and functions for the immediate and longer term. These plans should be supported by policies and procedures on key issues, including managing conflicts of interest. Regulators also require a mature approach to assessing and managing risks, articulated through a risk management framework.

21. ARPANSA has established a corporate planning framework for its regulatory functions that is aligned with its statutory role, is internally consistent, and cascades downwards from high level strategic documentation through to branch-level planning. ARPANSA has also established an information management and quality system to support its regulatory functions, which includes the two yearly review and update of policy and procedural documents, with many of these being publicly available on the ARPANSA website.[23]

22. The roles and responsibilities established under the ARPANS Act create scope for several potential conflicts of interest to arise.[24] In 2005, the ANAO recommended that ARPANSA improve its management of conflict of interest issues. Since then, ARPANSA has put in place a Chief Executive Instruction (CEI) covering ARPANSA's self-regulatory role and providing scientific and advisory services, including those on a fee-for-service basis, to regulated agencies, as guidance to staff. However, a gap in the CEI is the absence of guidance on managing personal conflicts, that is, where an individual's personal interests and relationships could be seen to unduly influence their responsibilities as an ARPANSA officer and an employee under the Public Service Act. Additionally, there is no training provided for staff on conflicts of interest issues, and no evidence that the policy is actively implemented or monitored. There remains scope for ARPANSA to strengthen

22 ANAO Better Practice Guide—*Administering Regulation*, March 2007, Canberra, p. 7.

23 The majority of the regulatory policy documents reviewed by the ANAO during the course of the audit had been updated within the last 18 months.

24 See footnotes 15 and 16.

its approach to managing conflicts of interest, including through staff training and the preparation of annual declarations—assisted by its Audit and Risk Committee.

23. ARPANSA's corporate and regulatory risk management framework exhibits several positive features, including the recent introduction of explicit statements about its risk appetite and tolerance for risk across its various areas of corporate and regulatory responsibilities. There are, however, several areas where improvements could be made, including more clearly defining strategic and operational risks and suitable treatment strategies to address these. ARPANSA could usefully consider reviewing its definition of these risks to provide greater clarity around their rating, priority, and treatment.

24. To support its staff in consistently applying a risk-based approach to their regulatory roles, ARPANSA has developed specific guidance for assessing risks associated with each licence. This guidance, which serves as a useful framework for the initial risk ranking of a licence, could be further enhanced by expanding this guidance material to include advice on how particular risk rankings should inform ARPANSA's ongoing management of each licence, including the use of discretionary regulatory activities (such as frequency of inspections, reporting, and unannounced inspections).

Licence Application Process (Chapter 3)

25. Under the ARPANS Act, entities require a licence from ARPANSA to possess and operate facilities and sources that emit radiation. A well designed licence application process will feature clear guidance material for staff and applicants that facilitates the preparation, submission and assessment of applications in a timely manner, and at reasonable cost to the regulator and applicant.

26. ARPANSA has published a series of guides on the licence application process to assist entities in preparing and submitting their applications, and for its regulatory staff involved in the assessment process. ARPANSA's published guidance, as well as its application forms and internal assessment templates, generally align with and address the statutory requirements set out in

ARPANSA's legislation.[25] Existing guidance materials could usefully be supplemented to include clear advice on the extent and depth of supporting information required as part of the application process. At present, information for applicants is limited to advice that documentation provided in support of an application should be commensurate with the hazard and risk of the application. Entities consulted by the ANAO and the sample of applications examined by the ANAO identified that, as a consequence of applicants' uncertainty over information requirements, ARPANSA is frequently required to make repeated requests for additional information, an iterative approach often resulting in lengthy delays in the application process.

27. Between July 2007 and June 2013, ARPANSA received 81 licence applications, 60 of which were for new or modified source licences. The ANAO's analysis showed there have been significant improvements over this period in the average time taken to assess source licence applications, from 153 days in 2007–08 to 42 days in 2012–13; while the time taken to assess facility applications has remained relatively stable.[26] The ANAO's analysis of 10 licence applications showed that ARPANSA's conclusions on the applications were, except in one case, supported by evidence, although the extent of analysis undertaken in the report to the delegate varied and there was not always a clear correlation with the apparent risk of the application. Further, there were: several cases of unclear or inconsistent communication between the applicant and ARPANSA; frequent information requests from ARPANSA; and application fees routinely did not accompany the applications analysed by the ANAO—contrary to section 34 of the ARPANS Act.

28. To more effectively use ARPANSA's limited resources and create a more efficient and streamlined application assessment process, ARPANSA should adopt a risk-based approach to its internal application assessment process. Such an approach could leverage off the existing risk ranking framework, taking into account applicants' compliance histories, as well as the hazard of the source or facility.

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25 One guidance document—*Regulatory Assessment Principles for Controlled Facilities*—has not been updated since 2001 and does not directly align with statutory requirements and the information required for a facility application. ARPANSA anticipates a review of this document will be completed by December 2015.

26 In 2012–13 it was 144 days for a facility licence. These figures include 'pause' time, that is, following a request for additional information, assessment of the application cannot proceed until this information is supplied by the applicant.

Monitoring and Enforcement (Chapter 4)

29. A key function of a regulator is the ongoing monitoring of regulated entities' compliance with regulatory requirements and, where required, enforcement in cases of non-compliance. A risk-based monitoring framework can help regulators provide assurance to the public and stakeholders that regulated entities are meeting their compliance obligations, while more efficiently targeting the regulator's available resources.

30. Regular reporting by entities, combined with a varied program of inspections[27] are key regulatory tools used by ARPANSA to verify licence holders' compliance with their licence conditions. ARPANSA has developed policies and procedures to support its inspection staff as well as published guidance for licence holders on reporting and inspection requirements. In 2012–13 ARPANSA conducted 59 inspections, with ANSTO being the primary agency targeted for inspections as it operates more than half the licenced facilities regulated by ARPANSA.

31. While ARPANSA's policy documentation establishes the expectation that its inspection program should be risk-based, the ANAO's examination of the inspection program indicated that ARPANSA could not always demonstrate a clear linkage between the risk associated with the licence and the frequency and scheduling of inspections. As discussed earlier (see paragraph 24), the absence of guidance on how to apply the risk ranking of licences in the context of the ongoing licence management and monitoring regime, may have contributed to the lack of alignment between assessed risk and the inspection approach adopted by ARPANSA. In addition, the ANAO found that the use of unannounced inspections, which are intended to give ARPANSA a better understanding of the day-to-day operations of licence holders and to follow up on any incidents or intelligence, is driven mainly by geographical convenience rather than risk. To enhance its risk-based approach to regulation, ARPANSA should establish a more direct link between risk and the inspection program.

32. A challenging area, acknowledged by ARPANSA, is identifying unlicenced activities. These are sources or facilities that ARPANSA is unaware of, but which are nonetheless required to be regulated under the ARPANS Act

27 Inspections can be planned, incident-based or unannounced.

and Regulations. ARPANSA's regulatory officers are expected to be familiar with licensees and able to identify any additional sources that require licensing. ARPANSA also relies heavily on entities self-reporting the acquisition of relevant equipment. There is scope for ARPANSA to periodically approach regulated entities to reinforce their obligations under the ARPANS Act, as a means of proactively seeking to identify unlicenced sources.[28]

33. ARPANSA continues to be both a regulator and a licence holder.[29] The ANAO recommended in 2005 that ARPANSA take action to better manage this conflict of interest. Only recently, in 2011, did ARPANSA formally enter into an arrangement for Queensland Health to undertake independent inspections of ARPANSA's compliance with its own licence conditions.[30] To date, only one external inspection has been conducted, in May 2012, which made 33 recommendations relating to a source licence held by ARPANSA's Medical Radiation Services Branch. A program of independent reviews of ARPANSA licences and the facilities they cover, as well as regulatory decisions regarding its own licence applications and its own Regulation 51 requests, would strengthen confidence in ARPANSA's compliance with licensing conditions and its arrangements for managing its conflict of interest as both a regulator and licence holder.

Regulatory Cost and Cost Recovery (Chapter 5)

34. When establishing ARPANSA in 1998, the Australian Government's intention was that 'Commonwealth entities regulated under the ARPANS Bill should bear the costs of such regulation, ensuring that there will be no additional burden on the Commonwealth or the public purse'.[31] The ARPANS Act authorises ARPANSA to recover costs associated with assessing licence applications and the annual management of each licence, with the fee or charge

28 Another potential source of unlicensed dealings are legacy sites—sites that existed prior to the introduction of the ARPANS Act in 1998. Regulating legacy sites can be problematic as they may contain mixed sources of contamination and responsibility for managing the site may therefore be split between different authorities. For example, the Little Forest legacy site near Lucas Heights contains both radiological and non-radiological material such as heavy chemicals. Additionally, ARPANSA informed the ANAO that the ARPANS Act—currently under review—does not contain explicit provisions for licensing a legacy site.

29 See footnote 15.

30 ARPANSA held initial discussions with the Victorian Department of Human Services in 2007 about the conduct of such inspections, but an agreement was not entered into.

31 House of Representatives Hansard, 11 November 1998, p. 90.

dependent upon the type and number of items covered in the licence. Annual management charges constitute ARPANSA's main source of revenue from regulatory activities, which totalled $4.43 million in 2012–13, the majority of which is collected from ANSTO and Defence as the predominant holders of sources and facilities.

35. While intra-government charging is excluded from the *Australian Government Cost Recovery Guidelines*[32], ARPANSA has informed stakeholders that it has adopted these Guidelines as a basis for implementing a good practice approach. There are, however, several areas where ARPANSA could adopt improvements to better align its cost recovery arrangements with the Guidelines.

36. The ANAO's analysis of ARPANSA's cost recovery datasets indicates that since 2008–09 ARPANSA has under-recovered its regulatory expenses by almost $4 million.[33] Additionally, revenues from its scientific and advisory services functions have been used to cross-subsidise its regulatory function, and ARPANSA's own calculations indicate that there is also cross-subsidisation occurring within the population of licence holders.[34]

37. Accurate cost recovery relies on regularly capturing and monitoring both direct and indirect staff effort and other costs for regulatory activities. The Guidelines set out key principles including that agencies undertake cost recovery on an activity basis where possible[35], so as to avoid cross-subsidisation between activities within an agency. However, ARPANSA does not have a method or system for regularly tracking the cost of its regulatory activities, including at an activity level.

38. The ANAO conducted a small sample test of annual charge payments, which identified an inconsistent approach by ARPANSA to pro-rating[36] and a pattern of late payment of annual charge fees by agencies. These practices are

32 Department of Finance and Administration, *Australian Cost Recovery Guidelines*, Financial Management Guidance No. 4, July 2005.

33 ARPANSA has not updated its methodology for calculating its regulatory cost inputs since 2009.

34 In effect, the higher fees and charges of some licence holders are being used to reduce the fees and charges of other licence holders.

35 The Guidelines advise that: 'any charges should reflect the costs of providing the product or service', p2, and 'as far as possible, the agency should identify costs against particular activities to minimise the need to distribute costs arbitrarily among activities', p. 40.

36 Under the Regulations, there are provisions for the pro-rating of the annual licence charge if the licence has not been held for a full financial year.

inconsistent with the requirements of the Regulations, which require all annual charges to be paid before 31 July of that financial year, or, in the case of a new licence, 30 days after the licence is issued.

39. ARPANSA has made efforts in recent years to progressively recover more of its identified regulatory costs and minimise the estimated level of cross-subsidisation across regulated entities. In the course of the audit, ARPANSA advised the ANAO that it had initiated a further review of its cost recovery model.

Reporting and Relationships (Chapter 6)

40. Well-defined performance indicators enable a regulator to measure, monitor and report on regulatory performance, as well as providing measures to assess the extent to which the regulator is meeting expectations. Over time, ARPANSA's public reporting has reduced to only one Key Performance Indicator (KPI)—the number of safety incidents involving Commonwealth users—as a basis for measuring the effectiveness of the regulatory function. While this measure is appropriate, it does not reflect the breadth of ARPANSA's regulatory work, and ARPANSA could consider developing additional indicators, particularly to reflect its recent focus on promoting holistic safety and a safety culture amongst licensees.[37]

41. The quality of the relationship between a regulator and its stakeholders can affect regulatory outcomes, and establishing open and responsive relationships can increase the level of voluntary compliance by reinforcing confidence and transparency in the regulatory framework. ARPANSA has established a range of channels to enable stakeholder feedback and communication. ARPANSA's own surveys and stakeholder feedback provided to the ANAO during the course of this audit, indicate that stakeholders reported a general level of satisfaction with ARPANSA's regulatory performance; with differing opinions on scope for improvement, particularly in terms of timeliness and consistency. Overall, stakeholders reported that ARPANSA was approachable and professional, and commented on the generally positive working relationship between ARPANSA and its regulated entities.

37 In 2011 ARPANSA established a team to assess and improve the safety culture of licence holders, including developing an assessment tool to conduct safety culture reviews.

42. The ANAO's 2005 performance audit of ARPANSA's regulatory function[38] made 19 recommendations. Between 2005 and 2007, work on implementing the recommendations was limited, leading to significant delays in ARPANSA progressing to an adequate stage of implementation. Notwithstanding regular monitoring by ARPANSA management and its Audit and Risk Committee, as well as several assessments of progress in implementing the recommendations, the ANAO assessed that only 11 of the 19 recommendations from this earlier audit had been adequately implemented, with six assessed as partially implemented.

Summary of agency response

43. The Australian Radiation Protection and Nuclear Safety Agency's (ARPANSA) letter in response to the proposed audit is reproduced at Appendix 1. ARPANSA's response to the proposed audit report is set out below:

> ARPANSA agrees with the recommendations made by ANAO in this performance audit and will continue to: advance the internal framework for managing declaration of interests and the related procedures and processes; advance the internal procedures for licence application assessment to support and promote a risk-informed approach; strengthen the existing risk-informed compliance monitoring program and strategic targeting of inspections; and improve the frequency of our rigorous self-inspection program and explore options for a broader base of suitable organisations for independent review of ARPANSA's own licences.
>
> ARPANSA also agrees with the ANAO's view that it should further improve its alignment with the Australian Government Cost Recovery Guidelines. ARPANSA will continue to advance its cost recovery model in a staged approach in consultation with licence holders. This will be supported by ARPANSA's current review of the regulatory delivery model to reduce regulatory burden.

44. The ANAO provided the Australian Nuclear Science and Technology Organisation (ANSTO), the Department of Defence (Defence), and the Department of Health with extracts of those parts of the report which were relevant to them. The letters from ANSTO and Defence are also included at Appendix 1. The Department of Health did not comment on the report.

38 See paragraph 6.

Recommendations

Recommendation No.1

Paragraph 2.23

To maintain stakeholder confidence in the independence and impartiality of its regulatory operations and decisions, the ANAO recommends that ARPANSA:

(a) periodically conducts training for regulatory staff on identifying and managing conflicts of interest, including personal conflicts; and

(b) obtains written declarations from regulatory staff at annual intervals indicating whether they have any potential, perceived or actual conflicts.

ARPANSA response: *Agreed.*

Recommendation No.2

Paragraph 3.48

To streamline its applications process and more effectively use its limited resources, the ANAO recommends that ARPANSA implements a documented risk-based approach to assessing licence applications, having regard to the:

(a) hazard of the source or facility to workers, the public and environment; and

(b) the applicant's compliance maturity.

ARPANSA response: *Agreed.*

Recommendation No.3

Paragraph 4.30

To strengthen its risk-based approach to monitoring compliance, the ANAO recommends that ARPANSA more directly links its management of licences to risk rankings, focusing particularly on:

(a) clearly aligning its planned inspection program to risk rankings of licences; and

(b) strategic targeting of unannounced inspections.

ARPANSA response: *Agreed.*

Recommendation No.4

Paragraph 4.65

To improve transparency and support continuing public confidence in the regulation of licences held by ARPANSA, the ANAO recommends that:

(a) inspections of its own licences are conducted periodically using inspectors from a state or territory radiation regulator; and

(b) provisions are made for independent review of other regulatory decisions relating to ARPANSA's own licences, particularly licence applications and Regulation 51 approvals.

ARPANSA response: *Agreed.*

Audit Findings

1. Introduction

This chapter provides an overview of government regulation and an explanation of radiation, and then introduces the roles of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), with the primary focus on its regulatory role. The chapter also outlines the audit objective, criteria and related matters.

Background

1.1 The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) was established in 1998 under the *Australian Radiation Protection and Nuclear Safety Act 1998* (the ARPANS Act).[39] ARPANSA's role, is to protect the health and safety of people and the environment from the harmful effects of radiation. This role, among other responsibilities, includes regulating the use of radiation and the safety of nuclear installations by, and for, Australian Government entities.[40]

What is regulation?

1.2 Regulation is any rule endorsed by government where there is an expectation of compliance, including legislation and treaties. It also comprises other means by which governments influence organisations to adopt certain goals, standards or practices which do not form part of explicit government regulation (such as codes of practice and accreditation schemes).[41] Regulation is ultimately about government influencing behaviour to achieve specific outcomes, such as: to promote specific policy objectives; to correct 'market failure'; to improve public confidence; or, pertinently, to reduce the risk of harm to the public.[42]

1.3 A regulator is the organisation that administers the relevant legislation and advises government, controls entry into a regulated market, monitors compliance with regulations, and addresses non-compliance. Regulators come

39 At the time of this audit, the ARPANS Act was under review by the Department of Health in its role as portfolio agency with responsibility for health protection policy and ARPANSA's governance.

40 State and territory governments have also established regulators for related activities by private entities and government organisations within their jurisdiction.

41 See: Australian Government, *Best Practice Regulation Handbook*, June 2010, p. 9.

42 For an explanation of the reasons for regulation, see A Freiberg, *The Tools of Regulation*, The Federation Press, Sydney, 2010, pp. 5-16.

in many different forms and regulate a variety of organisations operating in different industries. Consequently, there is not one approach to regulation or enforcement that suits all situations. Enforcement options need to reflect the seriousness of an offence and may range from a 'light touch' (such as persuasion and providing guidance), to written warnings and financial penalties, up to stronger sanctions such as licence suspension and revocation.[43]

1.4 Regulation does impose costs on business, and poorly administered regulation may constrain investment, innovation and development.[44] To minimise these burdens, regulators should be responsive, flexible and structure their operations using a risk-based approach.

What is radiation?

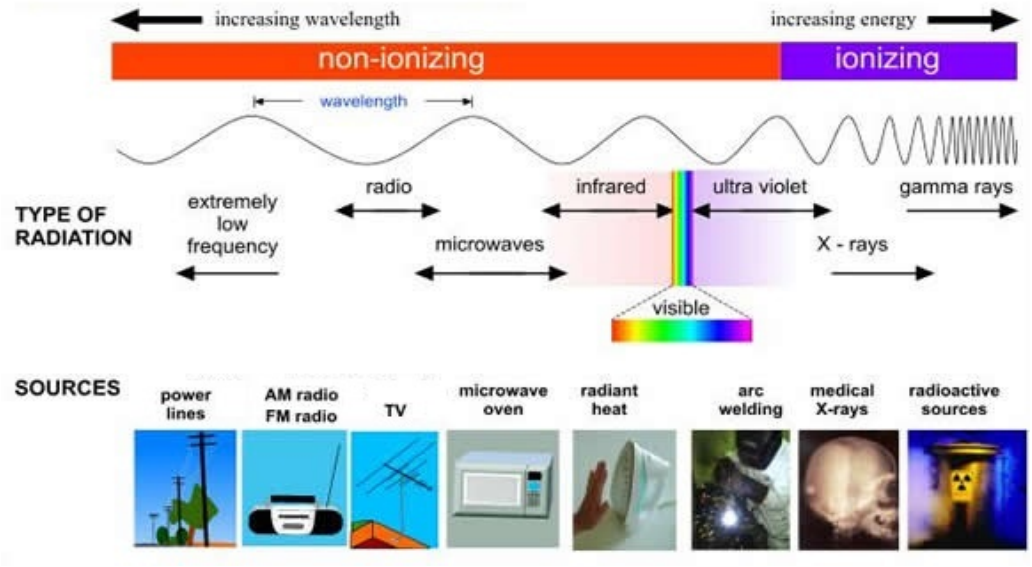
1.5 Radiation is energy travelling as waves or particles. Australians are exposed to radiation every day from a variety of natural and artificial sources. An example of a natural source is the sun, while artificial radiation sources can include x-rays for medical diagnostic tests. Radiation may be either ionising or non-ionising (see Figure 1.1):

- Ionising radiation has enough energy to remove electrons from atoms or molecules, which creates ions. This radiation is associated with nuclear processes, and is the focus of most radiation protection activities. Alpha and beta particles are also sources of ionising radiation. Ionising radiation can damage living tissue.
- Non-ionising radiation has enough energy to move around atoms in a molecule, but not enough to remove electrons and cause ionisation. Non-ionising radiation includes radiofrequency electromagnetic radiation (for example radiowaves) and ultraviolet radiation. High levels of ultraviolet radiation can burn skin on exposure and lead to increased risk of skin cancer.

43 For further discussion, see: I Ayres and J Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate*, Oxford University Press, New York, 1992, particularly chapter 2.

44 Council of Australian Governments Business Regulation and Competition Working Group, *Future COAG Regulatory Reform Agenda Stakeholder Consultation Paper*, 2011, <http://www.finance.gov.au/publications/coag-future-regulatory-paper/docs/future_coag_regulatory_reform_agenda_stakeholder_consultation_paper.pdf> [accessed 25 September 2013].

Figure 1.1: Types of radiation in the electromagnetic spectrum



Source: ARPANSA, 'Radiation Basics—Ionising and Non Ionising Radiation', <http://www.arpansa.gov.au/radiationprotection/basics/ion_nonion.cfm> [accessed 25 September 2013].

Note: Ultraviolet radiation may be either ionising or—more commonly—non-ionising, depending upon the wavelength.

There are benefits and risks associated with the use of radiation

1.6 Naturally occurring radioactivity–mainly from minerals containing radioactive elements, gaseous decay products from natural radioactive decay, and from cosmic rays entering the atmosphere–is often termed 'background radiation'. The average background radiation dose to a person living in Australia is approximately 1.5 millisieverts.[45]

1.7 Radiation and nuclear technology have wide-ranging commercial and health applications, such as:

- Radioisotopes—radioactive variants of an element—are used in the medical sector, for diagnostic and therapeutic purposes. Radiopharmaceuticals and X-ray are used to diagnose and treat

45 Ionising radiation doses are measured in sieverts (Sv). The Sievert is the SI unit of equivalent and effective dose. Dose is often expressed in microsieverts (μSv)–one-millionth of a sievert–or millisieverts (mSv)–which is one thousandth of a Sievert. Dose rates are often expressed in microsieverts per hour (μSv/hr) for example.

diseases such as cancer. Exposure to radiation during medical procedures represents the largest non-natural radiation exposure to the Australian population.[46]

- Radioisotopes may be used in biological and agricultural research, for example to trace how much fertiliser is used by plants, or to determine metabolic processes in animals.
- Industrial radiography uses gamma ray sources to check the integrity of welds, or in gauges to measure material thickness or liquid flow.
- Food irradiation —exposure to high levels of ionising radiation—is used to destroy bacteria and pests in food.
- Nuclear reactors are used to produce radioactive substances, such as radioisotopes, and for generation of electricity (nuclear reactors are not used for electricity generation in Australia).[47]

1.8 It has long been recognised that exposure to ionising radiation can cause adverse health effects. Ionising radiation can cause mutations that may increase the risk of cancer.[48] At high levels of exposure, acute effects (such as acute radiation syndrome), or delayed reactions (such as cataract of the lens of the eye, fibrosis and circulatory disease) may occur. At very high levels of exposure, the outcome may be fatal.

1.9 ARPANSA, through its Radiation Protection Series No 1–implemented in all Australian jurisdictions–has set the following limits[49] for planned

46 For information on the types of radioisotopes Australian Nuclear Science and Technology Organisation (ANSTO) produces, and their medical applications, see <http://www.ansto.gov.au/NuclearFacts/AboutNuclearScience/Radioisotopes/UsingRadioisotopes/index.htm> [accessed 10 October 2013].

47 Australia's only operational nuclear reactor at Lucas Heights in Sydney is used for research purposes and to produce radioisotopes, but not for generation of electricity. In global terms, as a research reactor, its size of 20 megawatts is typical. There are about 240 research reactors operating in 56 countries, ranging up to 100 megawatts. While power reactors are much larger and can generate up to 3000 megawatts, research reactors are typically more complex in design, operation and risk. For more information see http://www.world-nuclear.org/info/Non-Power-Nuclear-Applications/Radioisotopes/Research-Reactors/ [accessed 12 March 2014].

48 ARPANSA advised the ANAO that animal studies have shown that ionising radiation may increase the frequency of heritable health effects, although this has never been demonstrated in epidemiological studies on humans. Cancer is an example of a so-called stochastic effect, its occurrence in a population increases with increasing exposure but the severity of the disease does not.

49 These limits are based on recommendations from the International Commission on Radiological Protection as set out in the *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*, GSR Part 3, IAEA (2011), and Publication 103 of the International Commission on Radiological Protection (2007).

activities giving rise to exposure to ionising radiation (over and above natural background radiation):

- General public: 1 mSv per year.
- Occupational exposure: 20 mSv per year, 100 mSv averaged over a period of five consecutive calendar years, with the further provision that the effective dose shall not exceed 50 mSv in any single year.[50]

An overview of ARPANSA

1.10 ARPANSA is responsible under its legislation for 'protecting people and the environment from the harmful effects of radiation', a goal that largely mirrors the International Atomic Energy Agency (IAEA) fundamental safety objective (see paragraph 1.14). ARPANSA was created with the passage of the *Australian Radiation Protection and Nuclear Safety Act 1998* (ARPANS Act) in December 1998 by combining the Australian Radiation Laboratory (which provided advice and undertook research on radiation) and the Nuclear Safety Bureau (which regulated the nuclear reactors at Lucas Heights in Sydney). ARPANSA is a prescribed agency under the *Financial Management and Accountability Act 1997*, and is part of the Health portfolio.[51] The Department of Health has responsibility for regulatory policy and governance, providing assistance to ARPANSA when required, for example in the development of new policy and budget proposals, and has responsibility for the current review of the ARPANS Act (see paragraph 1.22).

1.11 ARPANSA performs a number of different activities, including:

- advising the Australian Government and the public on nuclear safety and radiation protection (for example in response to the nuclear accident at the Fukushima Daiichi nuclear power station in Japan in 2011)[52];

50 ARPANSA, 'Fact Sheet 17: Ionising Radiation and Health', <http://www.arpansa.gov.au/pubs/factsheets/017is_ionisingRadiationHealth.pdf> [accessed 25 September 2013].

51 The Department of Health and Ageing was renamed the Department of Health (DoH) under the Administrative Arrangements Order, 18 September 2013.

52 For more information from ARPANSA on the Fukushima nuclear accident, and ARPANSA's assessment of the impact of this accident on Australia, see <http://www.arpansa.gov.au/News/MediaReleases/japanadvisory.cfm> [accessed 3 October 2013]. ARPANSA informed the ANAO that there was no need to change its normal regulatory business as a result of the Fukushima accident, although it did provide an increased awareness of, and lessons for, a national regulator's role in a nuclear or radiation emergency.

- undertaking research into radiation protection, nuclear safety and medical exposures to radiation;
- developing standards, codes of practice and guidelines on radiation protection and nuclear safety;
- working with state and territory authorities to promote national uniformity of policies and practices;
- collaborating with international agencies and groups, such as the IAEA[53], and participating in international forums that develop new practices and principles for radiation protection and nuclear safety;
- monitoring and evaluating work environments where workers are exposed to elevated levels of radiation; and
- regulating and monitoring compliance of Commonwealth radiation facilities and sources.

ARPANSA performs other functions beyond its regulatory role

As noted above, ARPANSA provides a number of scientific and advisory services relating to radiation safety, separate from its regulatory role. These other activities are managed by ARPANSA's Radiation Health Services branch and Medical Radiation Services branch and are carried out to fulfil the objective of the ARPANS Act. Funding for these activities is provided through a mix of fee-for-service arrangements and an annual budget appropriation. Some of these activities are:

- Reviewing research and publishing advice on non-ionising radiation exposure, such ultraviolet radiation, and radiofrequency and extremely low frequency electromagnetic radiation.
- Providing a personal radiation monitoring service to monitor worker exposure to ionising radiation in industries such as medicine and mining.
- Operating radionuclide air monitoring facilities as part of Australia's commitment to the Comprehensive Nuclear-Test-Ban Treaty (CTBT).
- Maintaining the Australian National Radiation Dose Register (ANRDR)—the collection, storage and auditing of radiological dose histories for uranium industry workers in Australia.
- The Australian Clinical Dosimetry Service (ACDS)—an audit service for radiotherapy providers to measure whether the radiation dose being delivered to the patient is correct. This service is currently funded until June 2014.

53 The IAEA is a treaty organisation which works with its member states (of which Australia is one), to promote the safe use of radiation and nuclear sources and facilities (also see the shaded box below paragraph 1.13). Australia has international legal obligations that arise from its membership of the IAEA.

In some cases staff from these branches provide expert scientific support to ARPANSA's regulatory function (the type and extent of this assistance is discussed later in the report). These branches also possess radiation facilities and sources that require them to be regulated—ARPANSA's management of this self-regulatory role is described from paragraph 4.58.

1.12 ARPANSA's functions and mandate are set out in the ARPANS Act and associated Australian Radiation and Nuclear Safety Regulations 1999 (ARPANS Regulations). The ARPANS Act also establishes an advisory council and two committees that provide advice to ARPANSA's Chief Executive Officer (CEO) on issues of radiation protection and nuclear safety: the Radiation Health and Safety Advisory Council; the Radiation Health Committee; and the Nuclear Safety Committee.[54] [55]

1.13 ARPANSA has approximately 132 staff. Regulatory staff are primarily located in Miranda, New South Wales, close to the Australian Nuclear Science and Technology Organisation's (ANSTO's) Lucas Heights campus. Other staff are based in Yallambie, Victoria. The agency's budget for 2013–14 is $30.2 million, of which $10 million is funded from fee-for-service revenue and recovery of regulatory costs, with the remainder budget funded.

54 Another Act that has implications for nuclear activity is the *Environment Protection and Biodiversity Conservation Act 1999*. This Act prohibits an organisation undertaking a nuclear action (which includes, amongst other things, establishing or significantly modifying a nuclear installation) that will have 'a significant impact on the environment' unless it obtains Ministerial approval, or otherwise falls into activity categories where approvals are not needed.

55 The ANAO did not examine the council and committees as their activities are not directly relevant to ARPANSA's regulation of Commonwealth entities. The roles of these bodies are primarily to provide expert advice to the CEO on all matters relating to nuclear safety and radiation protection (which may not be directly relevant to the regulation of Commonwealth activities), increase the consistency of regulation across all state/territory regulatory bodies (national uniformity), and assist in developing technical codes of practice and standards on a number of radiation and nuclear matters.

International engagement is a key part of ARPANSA's operations

ARPANSA is represented, and in some cases, represents Australia, on a number of international organisations and committees that deal with matters relating to nuclear and radiation safety, including developing and updating codes of practice, standards and rules which provide the basis for national regimes.

The International Atomic Energy Agency (IAEA), a key international institution, works with member states and other international organisations to promote the safe, secure and peaceful use of nuclear technologies. ARPANSA is represented on IAEA committees that set safety standards in areas of nuclear and radiation safety, waste and transport. Other international organisations and committees that ARPANSA engages with include:

- United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) which reports to the UN General Assembly on sources, effects and risks of exposure to ionising radiation. The CEO of ARPANSA is the current chair of the committee.
- International Commission on Radiological Protection (ICRP) which maintains the international system of radiological protection, used as the basis for radiological protection standards and practices. The CEO of ARPANSA is a member of the Main Commission and chairs one of the sub-committees.
- World Health Organisation (WHO) which is the authority for health matters within the United Nations system. ARPANSA is a WHO collaborating centre for radiation protection (collaborating centres provide support to WHO across its different programs) and participates in WHO's international electromagnetic fields (EMF) project—established to assess health and environmental effects of exposure to electric and magnetic fields.

1.14 ARPANSA operates in a regulatory environment guided by the work of the IAEA. Pertinently, the IAEA has published the *Fundamental Safety Principles*, which contain an overarching safety objective and ten safety principles, written in non-specialist language, to provide a common philosophy for dealing with ionising radiation.[56] Similar to ARPANSA's goal, the IAEA's fundamental safety objective is 'to protect people and the environment from harmful effects of ionizing radiation'. The first two safety principles are listed below, which highlight the need for a regulatory body and, principally, that responsibility for safety rests with those who possess and

56 The IAEA has produced a series of safety standards to provide an international reference for nuclear and radiation safety. The goal of these standards is to promote the safe use of radioactive substances and radiation sources for the benefit of humankind. The safety standards series comprises safety requirements and safety guides, with the primary overarching publication in the series being the IAEA's *Fundamental Safety Principles*. This publication is jointly sponsored by multiple international bodies that have a stake in nuclear and radiation safety, such as the World Health Organisation, the International Labour Organisation, and the Food and Agriculture Organization of the United Nations.

use nuclear and radiation facilities and sources (all principles are reproduced at Appendix 2).

> **Principle 1: Responsibility for safety**
>
> The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give risk to radiation risks.
>
> **Principle 2: Role of government**
>
> An effective legal and government framework for safety, including an independent regulatory body, must be established and sustained.[57]

1.15 These principles are also reflected in ARPANSA's publication *Radiation Fundamentals: Protection Against Ionising Radiation* (published in February 2014), to provide a basis for the management of radiation risks and the protection of people and the environment.

ARPANSA's regulatory role

1.16 ARPANSA is responsible for regulating radiation facilities and controlled material and apparatus (collectively known as sources)[58] used by Australian Government entities—which range from departments of State to government business enterprises—and their contractors.

1.17 ARPANSA regulates over 65 000 individual sources, of which over 60 000 belong to the Department of Defence (Defence).[59] After Defence, the agencies that have the largest inventory of radiation sources are the Australian War Memorial (784 sources)[60], Australian National University (ANU) (666 sources), and ANSTO (392 sources). ARPANSA also regulates 36 facilities, with ANSTO possessing 20 of these. ARPANSA regulates a wide variety of facilities and sources, including: X-ray baggage scanners in government buildings; cargo scanners used by the Australian Customs and Border

57 IAEA, *Fundamental Safety Principles,* Safety Fundamentals No. SF-1, Vienna, 2006, pp. 4, 6, 7.

58 As defined in the ARPANS Act, controlled material is material that emits ionising radiation spontaneously, and a controlled apparatus is an apparatus that is capable of producing ionising or harmful non-ionising radiation. An example of a controlled material is Technetium-99, which is commonly used in nuclear medicine, and an example of a controlled apparatus is an X-ray machine.

59 Defence informed the ANAO that the majority of their sources are used as safety devices for illumination of sights and gauges, with approximately 50 per cent being tritium-based beta lights, and a further 25 per cent being lasers. Defence also noted that less than five per cent of their sources are in the form of solid radioactive material or x-ray apparatus.

60 These sources include: lasers, clocks and watches that have a luminous dial or indicators marked with paint containing radium, or other sources containing thorium, infrared or ultraviolet light.

Protection Service (Customs); lasers used for research by the Commonwealth Scientific and Industrial Research Organisation (CSIRO); and ANSTO's nuclear research reactor (the Open Pool Australian Lightwater reactor—OPAL). As discussed, the prime responsibility for safety rests with the entities responsible for facilities and activities that give rise to radiation risks.

1.18 ARPANSA's regulatory functions are performed by its Regulatory Services Branch[61], with approximately 25 people in the branch dedicated to ongoing regulation.[62] The branch comprises four sections:

- Licensing and Compliance: (established in May 2011) this section has the majority of branch staff, and assesses licence applications and conducts licence inspections;
- Safety Analysis: (established in May 2011) assesses safety culture within regulated entities, through inspections and a holistic safety tool (see from paragraph 4.36);
- National Uniformity and Regulatory Systems: (established in May 2011, realigned July 2013) supports development of radiation protection standards and policies, which are used to promote national uniformity (see from paragraph 1.25); and
- Security and Community Safety: (established May 2011) reviews licence holder security plans, manages ARPANSA's role in emergency preparedness planning, and maintains the National Sealed Source Register (a register of all high level sealed sources in Australia, used by both ARPANSA and state and territory radiation regulatory bodies).

Regulation is based upon issuing licences

1.19 Australian Government entities that use radiation facilities and sources must be granted a licence by ARPANSA. Over 40 entities hold licences for the reasons outlined in Table 1.1. There are two types of licences:

61 In May 2011, ARPANSA underwent a significant organisational restructure with a view to improving the operation of the agency. The restructure created two new areas within the branch responsible for regulation (then Operations Services branch): the Security and Community Safety section and the Safety Analysis section. In 2013, the Operations Services branch was renamed the Regulatory Services Branch.

62 Staff from other areas of ARPANSA are used to supplement the expertise within the branch on a case-by-case basis.

- Facility licences—for nuclear installations and prescribed radiation facilities. For nuclear installations, different licences authorise different stages in the installation's life cycle, from preparing a site and construction to de-commissioning and disposal. Individual licences cover a defined number of facilities, and in many cases there is one facility per licence. ANSTO holds 20 of the 36 facility licences currently issued.
- Source licences—for the possession, use and disposal of sources. Individual licences cover varying numbers of sources. ARPANSA regulates 63 source licences, with the majority of entities holding only one source licence, although CSIRO holds 12 source licences, organised according to its internal divisions.

Table 1.1: Reasons Australian Government entities have licences

Reason for licence	Examples of Commonwealth entities that have licences
Scientific research	Australian National University CSIRO
Security and border protection	Australian Defence Force Australian Quarantine and Inspection Service
Medical and biomedical activities	ANSTO Australian Sports Commission
Cultural institutions (which may have items containing radiation)	Australian War Memorial National Museum of Australia
Building and personal security (these are primarily baggage X-ray machines)	Department of Parliamentary Services (DPS) High Court of Australia

Source: ANAO analysis of ARPANSA information.

1.20 The majority of licence holders are Commonwealth departments of state, prescribed agencies and statutory authorities. Other types of licence holders include:

- wholly owned subsidiaries of government bodies (for example PETNET Australia Pty Ltd: a wholly owned subsidiary of ANSTO, which operates two medical cyclotrons for radiopharmaceutical production);
- Australian Submarine Corporation Pty Ltd (a Commonwealth company that designs, builds and maintains naval ships and submarines);

- Decipha Pty Ltd (a subsidiary of Australia Post that provides information management services, including x-ray mail security screening); and
- Silex Systems Ltd (a private company, operating in a prescribed Commonwealth place, which deals with nuclear energy, solar energy and advanced materials and instrumentation).[63]

1.21 Table 1.2 illustrates the types of items that ARPANSA is required to regulate (as specified in the Regulations), and provides some examples of their use by licencees.

Table 1.2: Types of items ARPANSA regulates

Number of different types	Examples from Regulations	Examples of use in Australia
Nuclear installations		
5(A)	A research or production nuclear reactor(B)	ANSTO OPAL Research Reactor
	A nuclear waste storage facility	ANSTO Interim Waste Storage facility (a current licence application)
Prescribed radiation facilities		
8	Particle accelerator	ANU high energy implanter accelerator
	Irradiator	ARPANSA teletherapy laboratory
De-commissioning or disposing of certain prescribed radiation facilities or sites		
4	Decommissioning, disposing of or abandoning a controlled facility, being a nuclear reactor	MOATA research reactor (licence was surrendered in June 2011(c)
Sources		
45	Baggage inspection X-ray unit (ionising example)	DPS baggage X-ray machine
	Sealed source for calibration purposes of activity of more than 40 MBq (ionising example)	ANSTO Caesium-137 sealed source (used to calibrate radiation detection equipment)

63 People required to be regulated under the ARPANS Act include those operating in a prescribed Commonwealth place (as prescribed by the Regulations). The Regulations prescribe one such place: a site at Lucas Heights in Sydney that houses Silex Systems Ltd, and ARPANSA regulates Silex System's use of laser technology for the enrichment of non-nuclear material.

Number of different types	Examples from Regulations	Examples of use in Australia
	Optical source, other than a laser product, emitting ultraviolet radiation, infrared or visible light (harmful non-ionising example)	CSIRO ultraviolet water treatment system
	Laser product with an accessible emission level more than the accessible emission limit of a Class 3R laser product (harmful non-ionising example)	Customs forward looking infrared camera/imager (for maritime night surveillance)

Source: ANAO analysis of ARPANS Regulations 1999 and ARPANSA licence information.

Note A: There are also five stage licences for each nuclear installation that cover its life cycle: site preparation; construction; possession/control; operation; and de-commissioning/disposal.

Note B: The ARPANS Act prohibits the construction or operation of the following nuclear installations: a nuclear fuel fabrication plant; a nuclear power plant; an enrichment plant; and a reprocessing facility.

Note C: MOATA was the first research reactor acquired by ANSTO (then the Australian Atomic Energy Commission). It began use in 1961 and was shutdown after 34 years of operation. MOATA has now been removed and the site it was on restored.

The Department of Health is developing proposed amendments to the ARPANS Act

1.22 In May 2011, the (then) Parliamentary Secretary for Health and Ageing requested that the (then) Department of Health and Ageing review ARPANSA's regulatory powers under the ARPANS Act to ascertain the adequacy of the powers and whether the legislation should be updated.

1.23 The review was conducted by an external consultant and completed in August 2012. ARPANSA made a detailed submission to the review. The review found that overall, the broad objective of the ARPANS Act was appropriate and provided a reasonable framework for the regulation of radiation and nuclear use by Commonwealth agencies. The report also noted a number of areas where the legislation could be improved or updated, making 15 recommendations. Some key recommendations were that:

- The regulatory framework be reviewed every five years.
- The ARPANS Act be amended to provide greater flexibility to ARPANSA to issue licences for processes or sites where this is the most appropriate way to manage risk.
- Following any Act amendments, ARPANSA review all licence conditions with a view to: identifying a hierarchy of licence conditions

that are risk-based and outcomes-focused wherever possible; removing unnecessarily prescriptive detail from licence conditions; and removing references to outdated Codes and Standards.

1.24 The Department of Health is responsible for developing proposed amendments to the ARPANS Act, taking into account the review's findings. In the 2013–14 Budget, the department received funding to progress the proposed legislative changes, and anticipates that this will be completed by June 2014.

National regulatory arrangements

1.25 Separate state and territory legislation governs the regulation of radiation protection in each jurisdiction, with separate state and territory bodies administering their own legislation, which prescribes the type of equipment covered[64], the regulator's powers, and the licensing and inspection regime. These arrangements have resulted in a diversity of powers and inspection regimes across the country. State and territory regulatory bodies are usually established within an environment protection authority or department of health, and hospitals, universities and industries using radioactive sources are the entities most commonly regulated. This means that, unlike ARPANSA, state and territory regulators deal more regularly with private sector organisations, as well as public hospitals and universities.

1.26 Against the inter-government background discussed above, one of the ARPANSA CEO's functions under the ARPANS Act is:

> To promote uniformity of radiation protection and nuclear safety policy and practices across jurisdictions of the Commonwealth, the States and the Territories.

1.27 ARPANSA's Radiation Health Committee and Radiation Health and Safety Advisory Council assist the CEO in performing this function, supported by ARPANSA's Regulatory Services Branch and the Office of the CEO. The Committee includes representatives from each state and territory, and one of its roles is to develop codes of practice and other publications to promote

64 There are some differing levels of coverage across each jurisdiction, in that some items regulated at the Commonwealth level are not required to be licensed by certain state/territory regulators, as the state/territory regulators consider that the items pose insufficient risk to people to be worth regulating. The extent of this practice, and the type of items that do not require a licence, varies across Australia.

uniform national standards for radiation protection. The Council advises the CEO on the publication program and endorses documents for publication.

1.28 The promotion of national uniformity relies on building a consensus for change amongst jurisdictions. ARPANSA advised the ANAO that measures to implement national uniformity have not been adopted as extensively and consistently as they envisaged, and there have been problems with the timely implementation of agreed standards. Additionally, some sections of the *National Directory for Radiation Protection*—an important national uniformity publication which provides an agreed framework for radiation safety, with regulatory statements to be adopted by jurisdictions—remain incomplete many years after it was first published.[65] ARPANSA is planning to conduct a review of national uniformity during 2013–14, with a report to be published by the end of 2014.

1.29 National uniformity was not a focus area of this audit, particularly as the implementation of relevant initiatives is a state and territory responsibility and therefore beyond ARPANSA's direct control.

Previous ANAO audit of ARPANSA

1.30 ARPANSA was last the subject of a performance audit in 2005, when the ANAO published Audit Report No. 30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*, in March 2005. The audit findings demonstrated that ARPANSA did not have a systematic approach to planning, undertaking and monitoring its activities, and the audit made 19 recommendations. ARPANSA's implementation of the audit's recommendations is discussed in Chapter 6.

1.31 In addition, ARPANSA has been the subject of a number of reviews since the ANAO audit, as shown in Table 1.3.

65 For more information on the *National Directory for Radiation Protection*, see http://www.arpansa.gov.au/Publications/Codes/rps6.cfm [accessed 1 October 2013].

Table 1.3: Reviews of ARPANSA's regulatory role since 2005

Year of review	Title of review	Organisation that undertook the review
August 2006	*Report 407—Review of Auditor-General's Reports tabled between 18 January and 18 April 2005*	Joint Committee of Public Accounts and Audit
July 2007	*Integrated Regulatory Review Service (IRRS)– Full Scope—to The Commonwealth Government of Australia, Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)*[66]	IAEA
June 2011	*Report into ARPANSA's handling of the Yttrium 90 and Molybdenum 99 incidents at the ANSTO radiopharmaceutical site with specific regards to matters relating to impartiality*	Department of Health and Ageing
November 2011	*Integrated Regulatory Review Service (IRRS)—Follow Up Mission—to The Commonwealth Government of Australia, Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)*	IAEA

Source: ANAO analysis.

Audit objective, criteria and approach

1.32 The audit objective was to assess the effectiveness of ARPANSA's management of the regulation of Commonwealth nuclear and radiation facilities and sources, including ARPANSA's compliance with its legislative requirements.

1.33 To assist in evaluating ARPANSA's performance in terms of the audit objective, the ANAO used the following high-level criteria:

- there are appropriate governance arrangements to support effective regulation;
- a structured risk management framework has been developed to assess and manage regulatory risks;

66 'The IAEA IRRS is designed to strengthen and enhance the effectiveness of the national regulatory infrastructure of States for nuclear, radiation, radioactive waste and transport safety and security of radioactive sources whilst recognising the ultimate responsibility of each State to ensure safety in the above areas. This expressed purpose of the IRRS is to be accomplished through consideration of both regulatory, technical and policy issues, with comparisons against IAEA safety standards and where appropriate, good practices elsewhere.'
International Atomic Energy Agency, 'Integrated Regulatory Review Service' http://www.ns.iaea.org/review/rs-reviews.asp [accessed 28 March 2013].

- a risk-based approach to monitoring compliance by regulated entities is established and implemented, enabling ARPANSA to target priority risks and use resources effectively; and
- responses to non-compliance are supported by policies and procedures, and are proportionate to the risks presented by the non-compliance.

1.34 The audit focused on ARPANSA's regulatory role, and did not directly examine ARPANSA's other functions. The audit methodology included:

- examining relevant documents and guidance that support ARPANSA's regulatory role;
- interviews with key ARPANSA staff;
- discussions with staff of several regulated entities and the former Department of Health and Ageing (now Department of Health); and
- observing the site inspection process.

1.35 The approach to this audit has been informed by the 2007 ANAO Better Practice Guide *Administering Regulation* and previous ANAO audits into regulatory bodies. A revised Better Practice Guide is scheduled to be released in 2014.

1.36 The audit was conducted in accordance with ANAO auditing standards at a cost to the ANAO of approximately $490 000.

Report structure

1.37 The structure of the report is set out in Figure 1.2.

Figure 1.2: Report Structure

Chapter 2 **Governance and Risk Management**	Examines ARPANSA's governance and risk management arrangements for its regulatory function, including governance documentation, information and quality management, the management of conflicts of interest and maintaining appropriate training and skills.
Chapter 3 **Licence Application Process**	Examines ARPANSA's licence application process. It examines the legislation, policies and procedures that guide ARPANSA's assessments, guidance material that informs preparation of an application, and includes an analysis of a sample of licence applications.
Chapter 4 **Monitoring and Enforcement**	Examines ARPANSA's approach to monitoring agency compliance with licence conditions and legislation as well as the process for managing non-compliance. The chapter also includes an examination of ARPANSA's self regulatory role.
Chapter 5 **Cost Recovery**	Examines ARPANSA's recovery of its regulatory costs from regulated Australian Government entities.
Chapter 6 **Performance Measurement and Stakeholder Relationships**	Examines ARPANSA's key performance indicators, and also how regulated agencies provide feedback. The chapter concludes by reviewing ARPANSA's implementation of the recommendations from the previous ANAO audit.

2. Governance and Risk Management

This chapter examines ARPANSA's governance and risk management arrangements for its regulatory function, including governance documentation, information and quality management, the management of conflicts of interest, and maintaining appropriate training and skills.

Introduction

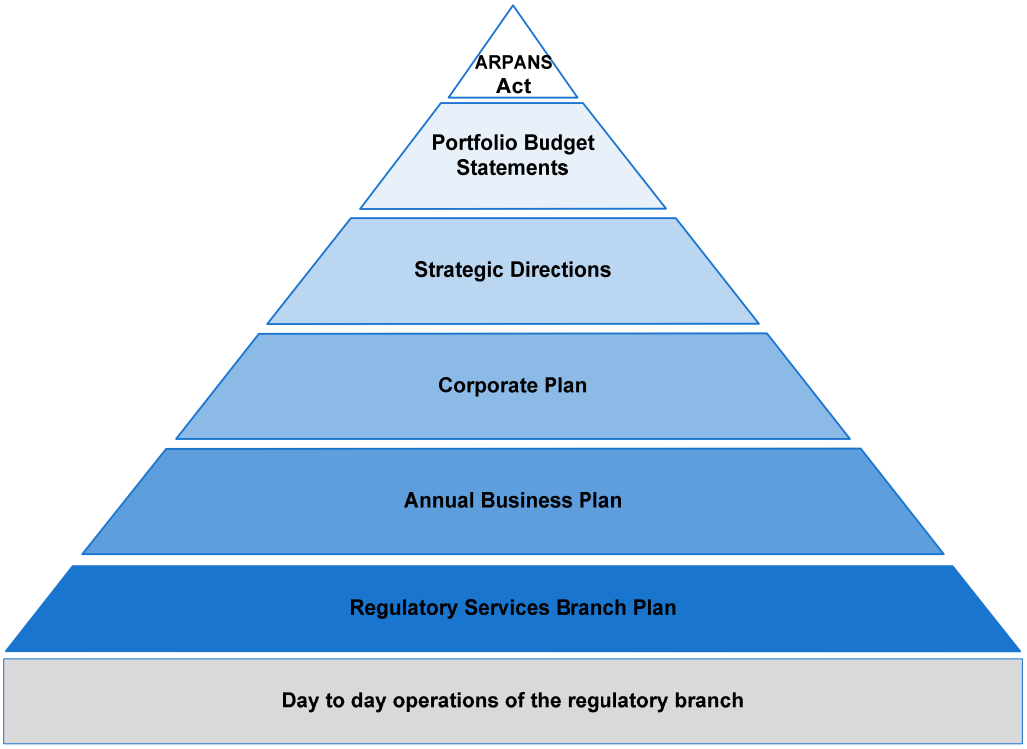
2.1 Sound corporate governance arrangements enable a regulator to meet its legislative and regulatory responsibilities and be accountable for its decisions and actions.[67] Such arrangements should include documented plans that articulate a regulator's objectives and functions for the immediate and longer term. These plans should be supported by detailed guidance, particularly on managing conflicts of interest and developing a workforce with the required skill set. Importantly, regulators also require a mature approach to assessing and managing risks, articulated through a risk management framework.

Corporate governance and planning arrangements

2.2 To support it in fulfilling its regulatory mandate under the ARPANS Act, ARPANSA has: established governance and planning arrangements to guide the regulatory function; prepared documents that set out its legal obligations, strategic objectives and operational responsibilities; and developed performance measures and targets for its regulatory role. ARPANSA's broad corporate planning framework for regulation is illustrated in Figure 2.1.

67 ANAO Better Practice Guide—*Administering Regulation*, March 2007, Canberra, p. 7.

Figure 2.1: ARPANSA's corporate planning framework



Source: ANAO.

2.3 The ANAO analysed ARPANSA's corporate planning documents relating to the regulatory function to consider the extent to which they aligned and were consistent in communicating ARPANSA's statutory role. There is generally a logical and consistent linkage between the regulatory responsibilities in the ARPANS Act, how ARPANSA's regulatory objectives are articulated in strategic level governance documentation (down to the Corporate Plan), and how these goals are operationalised (through the Branch Plan and relevant parts of the Business Plan).

2.4 ARPANSA could consider reflecting, in the sections of its high level corporate documentation that relate to ARPANSA's regulatory role, the first IAEA fundamental safety principle for protecting against radiation risks: 'the prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks'.[68] This

68 IAEA, *Fundamental Safety Principles*, Safety Standards Series No. SF-1, 2006, Vienna, p. 6.

principle establishes the context within which a regulatory body for nuclear and radiation safety operates.

2.5 To streamline and simplify its high level planning arrangements, it would be beneficial for ARPANSA to consider whether the *Corporate Plan* and *Strategic Directions* documents serve clearly defined purposes, as they currently contain very similar—often identical—information.

Information and quality management

2.6 Sound information management and quality systems are central to the effective and accountable administration of regulatory activity. To be effective, information and quality management systems rely on the development and maintenance of appropriate management documentation, a robust records management system[69], information systems that support regulatory activities, quality review systems, and detailed policies and procedures to guide regulatory work.

2.7 The Regulatory Services Branch is responsible for the development and review of regulatory policies and procedures and improvements to quality management documentation. ARPANSA maintains an internal schedule as an aid to tracking when documentation is scheduled for periodic quality review (generally two years from the date it was previously issued). ARPANSA's Committees and the Council (see paragraph 1.12) review regulatory policy and guidance when requested, and the Radiation Health Services Branch is also consulted where its specialist expertise is required. Additionally, ARPANSA's Legal Office has assigned a dedicated legal officer to advise Regulatory Services Branch, including in the development of its regulatory guidance.

2.8 Overall, ARPANSA is managing the update of its quality management documentation effectively, as the majority of the regulatory policy and procedural documents the ANAO examined during the audit had been reviewed by ARPANSA in the last 18 months, and, in line with good regulatory practice, many are publicly available on ARPANSA's website.

2.9 While ARPANSA has an established system for records management, the one component of a well developed information and quality management system it has historically lacked was a management system to provide

69 ARPANSA uses TRIM as its electronic records management system to store all regulatory documents.

operational support for regulatory activities. The absence of, and need for, such a system was identified in the ANAO's 2005 audit[70], and in October 2013, during the course of this audit and approximately eight and a half years later, the Licence Administration Database—was first implemented by ARPANSA. The Database is intended to assist the application and licensing process, the development of an inspection program, and the management of various types of reporting.

Management of potential conflicts of interest

2.10 The effective management of conflicts of interest contributes to the integrity of regulation. Conflicts of interest, which can be real or perceived, can affect the quality and reliability of decisions, harm working relationships with regulated entities and damage the reputation of the regulator.

2.11 ARPANSA's roles and responsibilities established under its legislation, create scope for several potential conflicts of interest to arise:

- ARPANSA requires licences because it possesses and uses several sources and facilities in order to conduct its scientific and advisory functions.[71] In the absence of another designated Commonwealth regulator, ARPANSA regulates its own licences (self-regulation is discussed further from paragraph 4.58);
- ARPANSA's scientific and advisory area provides a range of services, on a fee for service basis, to various public and private sector organisations, including the entities it regulates[72];
- ARPANSA, through its regulatory and scientific and advisory areas, may provide subject matter expert advice (for example on radiation safety and protection) to the entities it regulates; and
- in the context of a highly specialised regulatory environment, regulatory officers may establish long-term relationships with

70 ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*, p. 59.

71 ARPANSA has three licences (two sources and one facility) that cover over 260 different types of sources and three facilities: two linear accelerators and a teletherapy laboratory.

72 As noted in the shaded box below paragraph 1.11, ARPANSA provides a number of services that are separate from its regulatory services, for which it often charges a fee (for example workplace radiation monitoring services and equipment calibration and testing). Clients for these services can be regulated entities.

> regulated entities, or may have personal or other connections to a regulated entity. These are issues facing many regulators.

2.12 The ARPANS Act states that: 'The CEO must take all reasonable steps to avoid any conflict of interest between the CEO's regulatory functions and the CEO's other functions'.

2.13 The 2005 ANAO audit found that ARPANSA's management of conflicts of interest was insufficient to meet the conflicts of interest requirements outlined in the ARPANS Act and Regulations. The relevant Chief Executive Instructions were not fully implemented, and did not explicitly address issues such as self-regulation. The audit recommended that ARPANSA develop adequate documentation of all perceived or potential conflicts of interest, and that all instructions be implemented and complied with.[73]

The Chief Executive Instruction on conflicts of interest has not been implemented to the extent envisaged

2.14 ARPANSA has in place a 2011 Chief Executive Instruction (CEI) on conflicts of interest that provides the framework for identifying and managing conflicts of interest. The CEI's primary focus is on conflicts between ARPANSA's advisory roles and regulatory decision making. It provides a number of examples of potential conflicts, one being:

> Advice by ARPANSA officers involved in the regulatory functions of ARPANSA on how an entity should meet regulatory requirements.

2.15 Interaction between regulatory officers and their licence holders, at both a formal and informal level, occurs regularly as part of normal business. Given this, it may be difficult to distinguish when regulatory officers provide information on regulatory requirements as opposed to advice on how to meet the regulatory requirements. It is therefore important that ARPANSA officials are aware of limits in the advice they can provide.

2.16 The CEI states that the best way to deal with a possible conflict of interest is to fully disclose and record the conflict of interest. However, except in cases of possible conflicts around specific types of advice, the CEI does not

73 ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*, p. 42.

provide guidance on how declared personal conflicts should be managed, or the process for managing actual conflicts of interest should they arise. The CEI also states that the legal adviser of ARPANSA will conduct conflicts of interest training at least once a year. Training records since 2012 do not include this training, and the responsible area of ARPANSA was unable to advise the ANAO of the last time such training was provided to staff.

2.17 Table 2.1 summarises how the CEI addresses the potential conflicts of interest mentioned at paragraph 2.11, and the ANAO's findings of how ARPANSA has implemented these measures.

Table 2.1: ARPANSA's management of conflicts of interest

Sources of potential conflict	How the CEI addresses these potential conflicts	How these measures have been implemented in practice
Self-regulation	Participation of Victorian radiation regulator in inspections of ARPANSA licences at least once per year.	No inspections conducted with Victorian regulator. Current MOU with Queensland regulator has resulted in one inspection (see also paragraphs 4.61 to 4.64). No provision made for other matters, such as assessing licence applications from ARPANSA.
Scientific and advisory services to regulated agencies, including on a fee-for-service basis	Complete a *Notice of Possible Conflict of Interest*, which will be referred to Regulatory Services branch head. All advice with a possible conflict to be kept in a Register and forwarded to CEO. All payments received relating to such advice to be audited at least every six months.	No such notices completed, conflict of interest register empty as at June 2013.ARPANSA informed ANAO in December 2013 that they were aware of one conflict of interest being noted within ARPANSA, however it was not managed consistently with the CEI.
Personal conflicts of interest	Limited to: 'this is dealt with under the APS Code of Conduct'. No further guidance.	No record of any personal declarations.

Source: ANAO analysis of ARPANSA information, including *Chief Executive Instruction 6—Conflict of Interest*.

2.18 For two of the three areas noted in Table 2.1 relating to self-regulation and the provision of advice and services on a fee-for-service basis to regulated entities, ARPANSA has a policy in place to manage potential conflicts of interest, although the implementation of this policy has not been evidenced and does not appear to be actively monitored as set out in the CEI. In addition, ARPANSA does not have any active arrangements or specific guidance in place to manage personal conflicts, relying instead on regulatory officers to

self-identify and declare potential conflicts as issues or concerns arise. Further, the lack of training around conflict of interest issues does not support staff in meeting their obligations. While the CEI does reference the APS Code of Conduct, it does not elaborate on the implications of the Code in the context of working in ARPANSA.

2.19 The CEI does not address a number of other potential conflicts of interest arising in respect of ARPANSA's self-regulation of its own facilities and holdings of controlled sources, specifically:

- Assistance provided by ARPANSA's scientific branches to Regulatory Services Branch for licence application assessments and inspections (as these branches operate under a licence issued by Regulatory Services Branch).
- The periodic need for the Regulatory Services Branch to assess licence applications and Regulation 51 requests from the scientific and advisory branches of ARPANSA (Regulation 51 requests are discussed from paragraph 3.50).
- The CEO granting exemptions to ARPANSA from the need to seek a licence, as allowed under the ARPANS Regulations (see paragraph 3.9).

2.20 As a small organisation with unique, highly specialised expertise, it is important that Regulatory Services Branch makes best use of the skills and knowledge within ARPANSA's other branches where necessary, and this should be encouraged, provided conflicts of interest are declared, and where necessary, managed.

2.21 The potential conflicts of interest noted in paragraphs 2.11 and 2.19, arise from the requirements of the ARPANS Act. The tensions in the Act are long-standing and well known within ARPANSA. While ARPANSA has revised its CEI and expanded its scope since the ANAO's 2005 audit, it does not cover the range of potential conflicts of interest potentially arising from the operation of the ARPANS Act, and ARPANSA has not fully implemented the revised CEI. There is also a lack of guidance on how to manage personal conflicts of interest, as well as a lack of monitoring and training to support the implementation of the other elements of the CEI.

2.22 ARPANSA assisted by its Audit and Risk Committee, should strengthen its current approach to managing potential conflicts of interest, to provide assurance to regulated entities and other stakeholders of the impartial operation of the regulatory function. This should include regular, mandatory

training on identifying potential conflicts of interest, in line with ARPANSA's policy, and guidance to managers and employees on strategies to avoid or manage conflicts. Regulatory staff should also declare on an annual basis whether they have any potential conflicts of interest, and if any are declared, a management plan should be put in place and monitored.

Recommendation No.1

2.23 To maintain stakeholder confidence in the independence and impartiality of its regulatory operations and decisions, the ANAO recommends that ARPANSA:

(a) periodically conducts training for regulatory staff on identifying and managing conflicts of interest, including personal conflicts; and

(b) obtains written declarations from regulatory staff at annual intervals indicating whether they have any potential, perceived or actual conflicts.

ARPANSA response:

2.24 *ARPANSA agrees and accepts the recommendation and will continue to advance staff understanding of conflicts of interest (as have been done through ARPANSA requested external reviews, inspector training, general code of conduct training and procedural updates) and specifically review the training program for regulatory staff for opportunities for further inclusion of managing conflicts of interest, update the relevant Chief Executive Instructions to ensure they adequately address conflicts of interest, and ensure a system for regular update and assessment of declarations of interest is implemented.*

Training and skills

2.25 Developing a workforce with the required level of skill enables the effective delivery of regulatory services. The 2007 IAEA IRRS mission found that ARPANSA did not have a well-defined training program for technical regulatory issues. The 2011 follow-up mission found progress had been made in addressing this issue, through the development of a training policy and conduct of technical training courses.

2.26 Regulatory inspectors are appointed by the CEO under the ARPANS Act. ARPANSA's training policy—*Requirements and Competencies for ARPANSA Inspectors*—sets out the requirements and skills that inspectors should have, including formal qualifications and the number of inspections regulatory

inspectors should undertake. In accordance with the policy, inspectors should also be familiar with ARPANSA's regulatory regime, including the legislation and codes of practice, and be familiar with relevant licences and the agency's relevant systems.

2.27 ARPANSA's training register for 2012 to 30 June 2013 shows regulatory staff have undertaken a range of corporate and technical training.

ARPANSA has some specialist skill shortages

2.28 In its 2007 report, the IRRS mission noted that ARPANSA did not have sufficient technical and regulatory staff to cover all possible areas of expertise required to fulfil its regulatory function.[74] To compensate for this shortage ARPANSA was using contractors and consultants in areas such as geology, seismology, civil engineering, fire engineering, welding science and specialist reactor physics. The report also noted that around 70 years of nuclear experience had already been lost and another 35 would be lost in the next few years due to the retirement of staff. A subsequent 2011 mission noted some planning to address workforce development, although more work remained to be done.[75]

2.29 During audit fieldwork, ARPANSA informed the ANAO that the agency has low staff turnover, an ageing workforce and difficulty recruiting suitably qualified staff. Skills shortages arose particularly in nuclear physics and control engineering, and ARPANSA is currently managing this shortage with the use of external consultants, while planning to recruit suitably qualified staff in the future. In December 2013, ARPANSA's Strategic Management Committee approved the extension of a workforce succession planning trial completed in the Radiation Health Services Branch to the other Branches and Offices across ARPANSA.

ARPANSA's risk management framework

2.30 Effectively managing risk (uncertainty) is central to achieving an agency's outcomes, and should inform organisational strategy, program delivery and resource allocation. A risk management framework, tailored to the

74 IAEA, *Integrated Regulatory Review Service Full Scope to the Commonwealth Government of Australia, Australian Radiation Protection and Nuclear Safety Agency*, Sydney, August 2007, p. 30.

75 IAEA, *Integrated Regulatory Review Service Follow-Up Mission to the Commonwealth Government of Australia, Australian Radiation Protection and Nuclear Safety Agency*, Sydney, November 2011, p. 20.

agency's requirements, provides the policies, procedures and organisational arrangements to allow risk to be managed throughout an organisation.[76]

2.31 For regulatory agencies, a regulatory approach informed by risk management principles allows for a targeted and proportionate approach that can contribute to maximising effectiveness within available resourcing.

Past reviews identified weaknesses but also improvement over time

2.32 The ANAO's 2005 audit found that ARPANSA's risk management framework did not identify risks to key regulatory responsibilities (for example unlicenced activity or non-compliance), and recommended that ARPANSA address key operational risks to achieving regulatory outcomes (including mitigation and monitoring strategies).[77] Further external reviews between 2007 and 2011 concluded that ARPANSA had made progress in strengthening its risk management process, although several areas required improvement, including follow-up action to ensure that activities outlined in the risk framework were followed in practice.

There remain opportunities to improve ARPANSA's risk management framework

2.33 The need for a risk based approach is a consistent theme in ARPANSA's corporate planning documents. ARPANSA's *Strategic Directions 2012–2016* states that effective organisational governance is to be achieved by, amongst other things, 'ensuring risk management is effective and embedded in the agency', while its regulatory outcomes will be achieved by 'employing a risk-based approach to inspections and compliance monitoring'. There are also multiple references to adopting a risk based approach to regulation in ARPANSA's regulatory policies, procedures and guides for inspections (including in respect to resource allocation, inspections and responses to non-compliance).

2.34 ARPANSA's risk management framework was last revised in September 2013, and comprises: a high level risk management policy and plan; a statement on its risk appetite and risk tolerance across its corporate and

76 Australian/New Zealand Standard, *Risk Management—Principles and guidelines*, AS/NZS ISO 31000:2009.

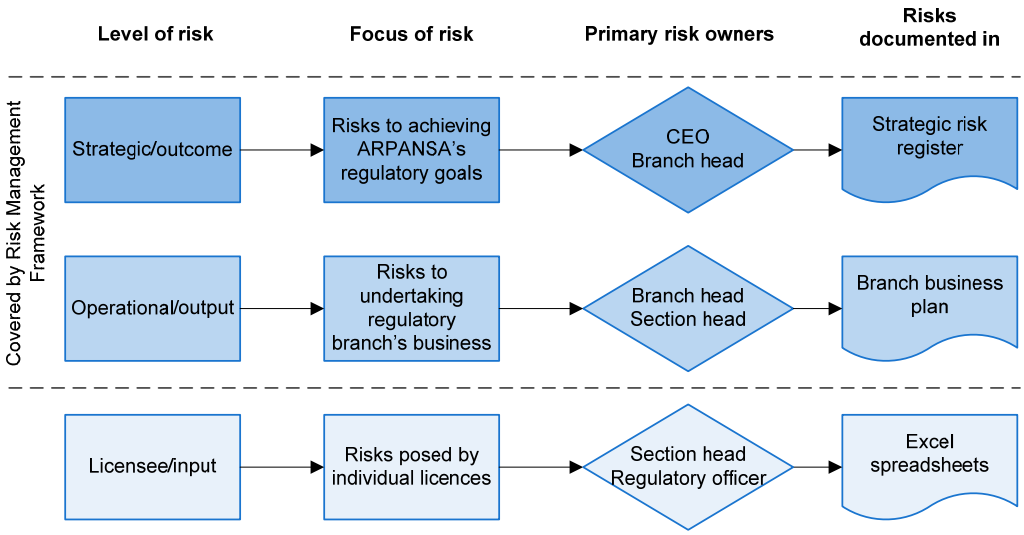
77 ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*, p. 41.

regulatory functions; and a risk management methodology (the methodology for assessing risks of individual licences is discussed from paragraph 2.41). The risk management plan is supported by a strategic risk register. ARPANSA's strategic risk register 2012–2013 includes seven risks relevant to regulation, similar to those in the *Regulatory Services Branch Plan 2013–14*. Regulatory Services Branch review the relevant strategic risks quarterly. This has resulted in the addition of new risks and adjusting the likelihood of a risk in response to mitigation measures.

2.35 The *ARPANSA Annual Business Plan 2013–14* lists ARPANSA's various activities under each of the 10 key areas, and the *Regulatory Services Branch Plan 2013–14* identifies both strategic and business risks to the Branch.

2.36 The ANAO's interpretation of ARPANSA's approach to risk management, as it pertains to ARPANSA's regulatory function, is outlined in Figure 2.2.

Figure 2.2: ARPANSA's approach to risk management



Source: ANAO interpretation.

2.37 The ANAO examined ARPANSA's risk management framework and noted areas of sound practice as well as several opportunities for improvement, which are outlined in Table 2.2.

Table 2.2: ANAO review of ARPANSA's risk management framework

Areas of sound practice[(A)]
The risk management policy is endorsed by the CEO as evidence of management commitment.
There is guidance on how to define risk measures (likelihood and consequence).
The policy outlines the broad responsibilities of different officials and offices (including the Audit and Risk Committee), and the strategic risk register identifies those responsible for specific risks.
There are documented reviews and evaluation points of strategic risks and controls, including by senior management.
The policy states that training in risk management will be provided, which ARPANSA advised occurs periodically as part of branch review workshops.
The statements on risk appetite and risk tolerance describe in general terms the extent to which ARPANSA is willing to accept risk for its various organisational activities.
Areas requiring improvement
The risk management policy, methodology and strategic risk register should be aligned to organisational goals, specifically ARPANSA's legislative mandate and the *Strategic Directions* 10 key areas.
There is no guidance on how particular rankings (moderate, extreme etc) should then be managed (such as frequency of review).
For strategic risks in the register relevant to ARPANSA's regulatory role: • risk descriptions are limited and it is not always clear what the actual risk is; • mitigation strategies/treatments descriptions are limited and not documented (and not listed in the Branch Business Plan); and • there is no resource allocation or prioritisation.
Conflicts of interest management is not listed as a risk nor mentioned in the risk management policy.
The risk management methodology could be further developed by providing practical guidance on each step in the process.

Source: ANAO analysis of ARPANSA Risk Management Framework.

Note A: Sound practice is based on the ANAO Better Practice Guide *Administering Regulation*, and the Australian/New Zealand Standard, *Risk Management—Principles and guidelines*, AS/NZS ISO 31000:2009.

2.38 A risk register is a useful tool to document identified risks and facilitate their monitoring and management. A risk register should contain an assessment of the likelihood, consequence and impact should the risk occur, as well as a treatment strategy for addressing the risk, and the assignment of responsibility to manage the risk. The ANAO's review of risk documentation suggests that three risks are absent from ARPANSA's strategic risk register, which could be considered and assessed:

- ARPANSA not complying with the ARPANS Act and Regulations;

- non-compliance with the legislation and licence conditions by regulated entities; and
- ARPANSA not adequately addressing unlicenced activity (unlicenced activity is discussed in detail from paragraph 4.39 and covers entities possessing sources and facilities that are not licenced).

2.39 Further, operational risks to the regulatory role are not clearly defined. The ANAO's review of risk documentation indicates that the *Regulatory Services Branch Plan 2013–14* lists five 'risks to business delivery', which are issues that could affect the regulatory business process producing its outputs, such as workload and cooperation from stakeholders.[78] This plan contains: a limited description of the risk topic (for example 'large number of simultaneous applications'); and frequently unclear mitigation strategies (for example 'planning and contingency arrangements'). The risks listed are poorly articulated and unclear, the treatment/controls are not elaborated, and are not ranked in terms of likelihood and consequence.

2.40 More fundamentally, there is scope to expand the application of ARPANSA's risk-based approach to regulation to the assessment of licence applications and the inspection program, to improve the focus and cost-effectiveness of its administration. This issue is discussed below.

Expanding the risk-based approach to the management of licences

2.41 The ANAO's 2005 audit observed that ARPANSA did not have a systematic approach to the risk ranking of licence holders, which considered the likelihood and the consequences of non-compliance, to be used as a basis for deciding on the compliance effort to be directed to particular entities or sources. The ANAO recommended that ARPANSA implement a documented compliance framework, based on an analysis of the risk posed by a licencee, which targeted compliance effort in accordance with these licence risk assessments.[79]

2.42 The *Guide for Regulatory Officers: Risk Ranking Methodology*—available on ARPANSA's website[80]—provides the basis for regulatory officers to rank the

78 Regulatory Services Branch does not maintain a separate risk register for operational risks.

79 ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*, pp. 64-65.

80 The Guide was updated in January 2013 (having been originally released in 2008) and last revised in June 2013.

risk of licences. Under the Guide, risks are ranked on the basis of 'hazard' and 'control': with 'hazard' the consequence of potential harm and 'control' the demonstrated ability to maintain safety. The Guide contains a useful table to assist officers determine a 'control' level against several criteria (such as the number of inspections over time, history of compliance and the adequacy of a licence's approach to holistic safety (holistic safety is discussed from paragraph 4.36).

2.43 The 'hazard' ratings developed using the Guide are based on risk of dose or injury to the public/outside the facility, while some hazard descriptions for sources focus on public dose limits. Given the nature of the sources and the facilities regulated, workers are those most at risk from injury and excessive dosage (noting that people that work with radiation have higher annual dose limits), and this should be acknowledged in the guide.

2.44 Further, the Guide does not provide any advice on assessing risks to the environment, something that should be explicitly covered, consistent with the object of the ARPANS Act: 'to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation'.

2.45 The Guide provides a useful framework for regulatory officers to determine a risk rating for a licence, and helps take into account the full spectrum of risks related to a licence. However, the Guide understates the potential value of risk rankings, describing them as an input to planning the inspection program:

> The resulting risk [*ranking of a licence*] will be a useful tool in planning inspections and directing regulatory effort, enabling resources to be allocated to areas of higher risk. Other factors such as geographic location, specific issues arising, timing of previous inspections etc are also taken into account when planning the inspection program.

Further, the methodology set out in the Guide is not connected to ARPANSA's risk management framework, and does not employ the same terminology or risk matrix as the broader framework.

2.46 One key area where the methodology could be improved relates to the inclusion of guidance on how particular rankings should influence ARPANSA's management of a licence, having regard to discretionary regulatory activities and strategies such as:

- frequency of inspections;
- frequency of licence holder reporting;

- use of unannounced inspections (acknowledging that incidents or accidents may occur that necessitate unplanned inspections);
- inspections targeting a particular condition/process of the licence; and
- the level of evidence/verification required during standard inspections for particular conditions.

2.47 Other areas where the methodology could be strengthened include:

- Providing guidance on possible risk treatment options—if there are strategies ARPANSA can implement, for example, to reduce a high risk rating.
- Formalising the need for periodic review of risk rankings.
- Implementing a peer review arrangement where another regulatory officer examines a risk rating, to promote the 'consistent and transparent risk ranking' that is the objective of the guide. In any event, the head of the Licensing and Compliance section should periodically review rankings as a consistency and quality control.

The Audit and Risk Committee and internal audits form part of the risk management framework

2.48 ARPANSA's Audit and Risk Committee considers risk management during its meetings, and provides input into the risk management framework, such as on the risks in the register, including frequency of review and prioritisation, and the need to incorporate risk treatment plans into business plans.

2.49 The use of audit is an important risk management tool. The last internal audit relating to the regulatory function was conducted in 2004.[81] The IAEA conducted two IRRS reviews of ARPANSA in 2007 and 2011, both at ARPANSA's request. The 2007 mission was a peer review of ARPANSA's regulatory framework and its effectiveness against IAEA safety standards, with a follow up mission conducted in 2011. ARPANSA informed the ANAO that these IRRS reviews were used in place of internal audits. ARPANSA's internal audit program schedule, which states that it intends to 'cover all risks

81 An October 2010 internal audit examined ARPANSA's progress in implementing recommendations and suggestions from the 2005 ANAO audit, subsequent JCPAA inquiry, and the 2007 IRRS mission.

to some level with a focus on higher rated risks', lists two planned audits relating to ARPANSA's regulatory role, both scheduled for 2014–15:

- 'administering regulation—inspection and incident investigations'; and
- 'ARPANS Act Compliance (including Licence Processing)'.

2.50 The schedule does not indicate which regulatory risks these audits will address; the ANAO suggests ARPANSA clearly links the design of such audits with key strategic risks.[82]

Conclusion

2.51 Sound corporate governance arrangements enable a regulator to meet its legislative and regulatory responsibilities, and be accountable for its decisions and actions.[83] Such arrangements should include documented plans that articulate a regulator's objectives and functions for the immediate and longer term. These plans should be supported by policies and procedures on key issues, including managing conflicts of interest. Regulators also require a mature approach to assessing and managing risks, articulated through a risk management framework.

2.52 ARPANSA has established a corporate planning framework for its regulatory functions that is aligned with its statutory role, is internally consistent, and cascades downwards from high level strategic documentation through to branch-level planning. ARPANSA has also established an information management and quality system to support its regulatory functions, which includes the two yearly review and update of policy and procedural documents, with many of these being publicly available on the ARPANSA website.[84]

2.53 The roles and responsibilities established under the ARPANS Act create scope for several potential conflicts of interest to arise.[85] In 2005, the ANAO recommended that ARPANSA improve its management of conflict of interest issues. Since then, ARPANSA has put in place a Chief Executive

82 As noted in paragraph 2.38, compliance with legislative requirements is an important risk currently absent from the strategic risk register.

83 ANAO Better Practice Guide—*Administering Regulation*, March 2007, Canberra, p. 7.

84 The majority of the regulatory policy documents reviewed by the ANAO during the course of the audit had been updated within the last 18 months.

85 See footnotes 15 and 16.

Instruction (CEI) covering ARPANSA's self-regulatory role and providing scientific and advisory services, including some provided on a fee-for-service basis to regulated agencies, as guidance to staff. However, a gap in the CEI is the absence of guidance on managing personal conflicts, that is, where an individual's personal interests and relationships could be seen to unduly influence their responsibilities as an ARPANSA officer and an employee under the Public Service Act. Additionally, there is no training provided for staff on conflicts of interest issues, and no evidence that the policy is actively implemented or monitored. There remains scope for ARPANSA to strengthen its approach to managing conflicts of interest, including through staff training and the preparation of annual declarations—assisted by its Audit and Risk Committee.

2.54 ARPANSA's corporate and regulatory risk management framework exhibits several positive features, including the recent introduction of explicit statements about its risk appetite and tolerance for risk across its various areas of corporate and regulatory responsibilities. There are, however, several areas where improvements could be made, including more clearly defining strategic and operational risks and suitable treatment strategies to address these. ARPANSA could usefully consider reviewing its definition of these risks to provide greater clarity around their rating, priority, and treatment.

2.55 To support its staff in consistently applying a risk-based approach to their regulatory roles, ARPANSA has developed specific guidance for assessing risks associated with each licence. This guidance, which serves as a useful framework for the initial risk ranking of a licence, could be further enhanced by expanding this guidance material to include advice on how particular risk rankings should inform ARPANSA's ongoing management of each licence, including the use of discretionary regulatory activities (such as frequency of inspections, reporting, and unannounced inspections).

3. Licence Application Process

This chapter examines ARPANSA's licence application process. It examines the legislation, policies and procedures that guide ARPANSA's assessments, guidance material that informs preparation of an application, and includes an analysis of a sample of licence applications.

Introduction

3.1 Controlling entry into a market, through a mechanism such as a licence, allows a regulator to manage risks, enhance the achievement of policy objectives, and communicate expectations directly to an entrant.[86] Under the ARPANS Act, Commonwealth agencies require a licence from ARPANSA to possess and operate facilities and sources that emit radiation.

3.2 A well designed licence application process supported by clear, published guidance facilitates the preparation, submission and assessment of applications in a timely manner, at minimum cost to the regulator and the applicant. Consistent with good practice and administrative law principles, a regulator's licensing decisions should be documented and transparent.[87]

Legislative requirements for licencing

3.3 The ARPANS Act provides the CEO of ARPANSA with authority to issue, amend, suspend and cancel licences that authorise Australian Government entities and employees to possess and use nuclear installations, prescribed radiation facilities or radiation sources. Entities cannot possess or use such facilities or sources unless the CEO of ARPANSA has issued a licence for this purpose.

3.4 Under the ARPANS Act and Regulations, in deciding whether to issue a licence, the CEO (or the CEO's delegate) must take into account:

- A number of matters specified in the Regulations, such as whether the dose levels and exposure are 'as low as reasonably achievable', and

86 ANAO Better Practice Guide, *Administering Regulation*, March 2007, p.43.

87 For more information on Regulatory better practice in controlling entry to a regulated market, see: ANAO Better Practice Guide, *Administering Regulation*, March 2007, pp. 43-49.

whether the applicant has shown a capacity to comply with statutory requirements and licence conditions.

- International best practice in relation to radiation protection and nuclear safety.[88]

3.5 In addition, the CEO may request information, such as: an applicant's plans and arrangements that describe how the applicant proposes to manage the facility or source; and specific information that relates to a particular facility licence stage. ARPANSA's application forms and guides require this information. There are also procedural requirements under the legislation, such as the need for an application to be in an approved form and accompanied by the prescribed fee.

3.6 Between 2007–08 and 2012–13, ARPANSA received 81 licence applications, the majority (60) of which were for source licences (the possession and use of controlled material and apparatus—see paragraph 1.16). Forty four of the 81 applications were to amend an existing licence (such as adding a new type of source onto an existing licence) and the remaining 37 were for new licences.

3.7 Once issued, licences have no expiry dates. They remain in force until suspended—if the CEO deems a breach of licence conditions serious enough to warrant suspension (which has not occurred)—or cancelled (when a facility stage licence has been superseded, or the items covered by a licence are disposed of).

88 International best practice is not defined in the ARPANS legislation.

Licence format

Licences issued by ARPANSA:

- Refer to the provisions of the legislation that apply. These cover various compliance, reporting and dose limit requirements.
- List the items covered. Facility licences provide detail on the actual item, including its location, while source licences only list the kind of item (as defined in the Regulations). A licence's source inventory workbook contains supporting details such as the source location, purpose, and maximum activity.
- Contain a standard set of conditions. These cover the need to:
  - keep an accurate inventory of sources;
  - report compliance at periodic intervals;
  - have appropriate training for users and maintainers; and
  - have documented work practices, records and procedures.

Many licences list additional standards and codes of practice that must be complied with. Standardised conditions are applied to particular facilities, such as reporting the discharge of radioactive waste (used for the OPAL Reactor licence). Non-standard conditions may also be added, however, the rationale for these needs to be made clear, and such conditions should not be used to overcome deficiencies in a licence application.

The CEO has granted some exemptions for facilities and sources

3.8 Under ARPANS Regulation 37(1), the CEO can exempt the need for a facility licence (at any licence stage) if the CEO considers that the facility does not, or will not, pose an unacceptable potential hazard to the health and safety of people or the environment. The CEO can also declare a source exempt, under ARPANS Regulations 38(5) and 38(6), using criteria and dose limits set in the Regulations.[89] These exemptions must be published in the *Commonwealth Government Gazette*, and the CEO must also publish an intention to make an exemption for a facility licence prior to publishing the actual exemption.[90]

89 The Regulations list specific requirements (such as limits of particular activity levels for certain nuclides) that allow particular sources to be exempted by default, without the need for the CEO's intervention. Conversely, the CEO can declare that these items are not exempted, if the CEO considers that the dose during operation, in the event of an accident or misuse or to the broader population, would likely exceed the set limits.

90 Exemptions may be granted, for example, if the CEO considers that the radiation dosage of an item, even in the event of an accident or misuse, would not exceed set limits; or if a facility does not require a particular stage licence (for example a construction licence is not needed for an item purchased off-the-shelf, or if there is an existing site then a site preparation licence is not needed, such as when new equipment is replacing existing equipment).

3.9 Between July 2007 and June 2013, ARPANSA granted five exemptions for sources and 10 exemptions for a facility stage licence, three of which were for ARPANSA's own licences.[91] For two of the facility licence exemptions, including in relation to one ARPANSA licence, notices of intention to make a declaration were published but, in an administrative oversight, the actual exemption was not, despite legal requirements to do so. The most common exemption was for a licence to prepare a facility site (because an existing site already existed), followed by the need for a licence to construct a facility (because equipment was procured off-the-shelf).

An example of a licence exemption granted to a facility

In 2010 CSIRO applied for, and received, an exemption from the need to obtain site preparation and construction licences for a mobile deuterium-tritium neutron generator used for borehole logging. ARPANSA considered that site preparation and construction authorisation was not relevant for this piece of equipment as it had a relatively low hazard level and was an off-the-shelf product.

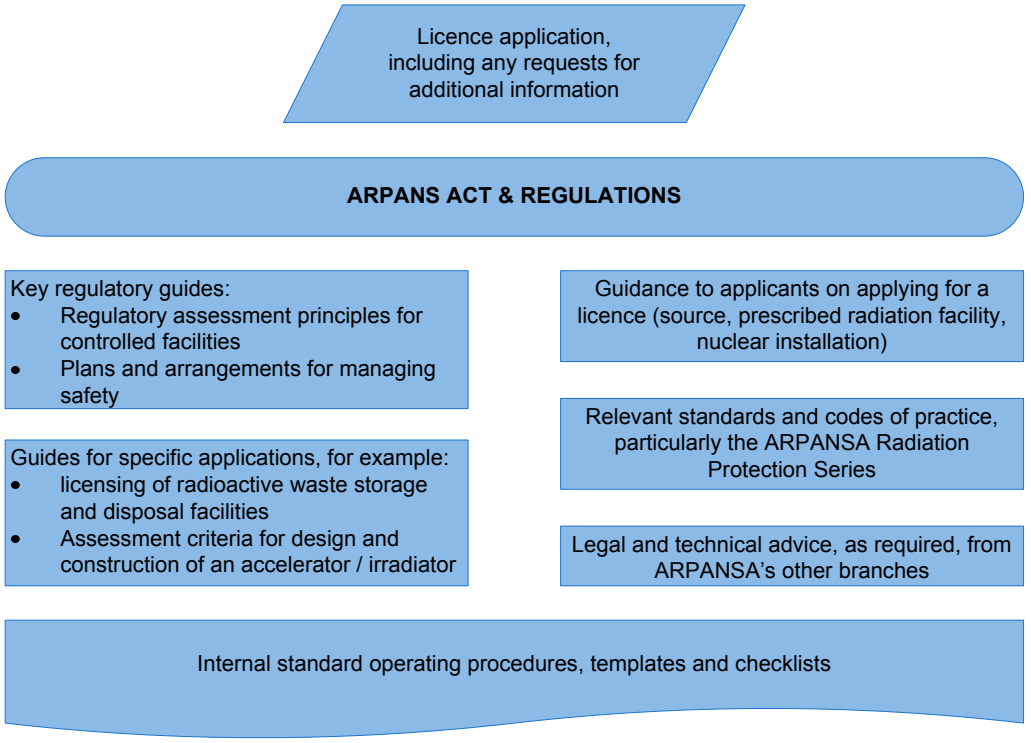
3.10 ARPANSA does not have an established exemption application process or standardised form for seeking an exemption. Its website contains information on exemptions that lists the relevant parts of the Regulations, and also contains the regulatory guide *How to seek an exemption from a source licence (ionising radiation)*. There is no guidance on how to seek an exemption for a facility licence, nor for harmful non-ionising radiation sources (under Regulation 4(3)). To better inform regulated entities seeking an exemption, there would be benefit in ARPANSA expanding its guidance to cover facility and non-ionising source exemptions.

Requirements and guidance for licence applications

3.11 To assist entities' understanding of statutory requirements, ARPANSA has published a number of guides to inform applicants on what should be included in an application, and how ARPANSA assesses applications. Figure 3.1 outlines the various inputs into ARPANSA's assessment process.

91 The ARPANSA exemptions were for licences relating to: preparing a site for a medical linear accelerator (in 2008); constructing a medical linear accelerator (in 2008); and de-commissioning and disposing of a Vickers linear accelerator (in 2013).

Figure 3.1: Inputs into ARPANSA's assessment of a licence application



Source: ANAO interpretation of ARPANSA licence assessment process.

3.12 The 2005 ANAO audit observed that guidance provided to applicants did not explicitly ask applicants to address the statutory matters against which they will be assessed. As a result, applications often correlated poorly with legislative requirements, requiring ARPANSA to seek clarification during the assessment process. The ANAO made a recommendation that ARPANSA enhance its guidance to better reflect the requirements of the ARPANS Act and Regulations.[92] In response, ARPANSA made amendments to its guidance and application templates, which are discussed below.

Guides are provided for each type of licence application

3.13 The main sources of guidance for applicants are regulatory guides provided for each type of application (source, prescribed radiation facility and nuclear installation). These guides describe the requirements under the Act

92 ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*, p. 53.

and Regulations, although in some places the description of requirements is very high level. For some requirements the guides provide links to more detailed guides and codes, particularly the *Regulatory Guide: Plans and Arrangements for Managing Safety*. The three guide documents have been updated over time to more accurately reflect the statutory requirements.

3.14 In some areas, the guides advise that the information required will vary according to the hazard and complexity of the items in the application. However, the guides do not elaborate on how this should be applied. To illustrate:

> The plans and arrangements should be a comprehensive program of policies and procedures that demonstrate how radiation safety will be assured. The content of these plans and arrangements will vary depending on the hazard and complexity of the [*facility/sources to be dealt with*].
>
> There is no pre-determined format for supplying this information.

3.15 The ANAO reviewed two key guidance documents: *Regulatory Assessment Principles for Controlled Facilities* (October 2001) (RAPs)—which is relevant for facility applications—and *Regulatory Guide: Plans and Arrangements for Managing Safety*.[93]

3.16 The RAPs document is based on the IAEA nuclear safety principles, and articulates areas where ARPANSA places high importance, based on the principles. In the 2005 ANAO audit, it was noted that the document did not specifically describe the extent of information required, and did not align with statutory requirements or information sought in facility application guides and forms. The RAPs document has not been updated since 2001, notwithstanding the ANAO's recommendation that guidance to staff be enhanced to explicitly address statutory matters the CEO must take into account when assessing a licence. The document should be reviewed for alignment with statutory requirements and other guidance.[94]

93 There are also other guides for specific types of applications, such as radioactive waste storage and disposal, or to determine whether a non-ionising radiation apparatus needs to be covered by a licence.

94 ARPANSA informed the ANAO that a review of the RAPS began in late 2012, but has been delayed due to resourcing issues. ARPANSA anticipates the review will be completed by December 2015.

ARPANSA has an internal standard operating procedure

3.17 ARPANSA's *Standard Operating Procedure: Licence Application Assessment v5* is an internal document that outlines the process involved in receiving, assessing and deciding on applications. However, it does not provide guidance on how to assess applications. Similar to the other guidance documents, the procedure contains a statement that 'the level of detail for this review should be commensurate with the hazards and risks associated with the proposed conduct or dealing'. There is no further guidance on this point to support ARPANSA staff in applying a consistent approach as part of the assessment process.

ARPANSA's template application forms and assessment reports align with legislative requirements

3.18 The 2005 ANAO audit found that guidance for ARPANSA staff reviewing applications was not explicitly aligned with the legislative matters the CEO must take into account in making a decision. The ANAO made a recommendation that guidance explicitly address these statutory matters.[95]

3.19 Older versions of the application form did not directly align with requirements in the Regulations and the assessment criteria in the Regulatory Assessment Report (RAR—discussed below). This was addressed in early 2012, some seven years after the ANAO's 2005 audit. The current application form templates align with the supporting guidance provided to applicants.

3.20 RARs are the reports provided to the officer that approves an application—the branch head or the CEO—and contain the regulatory officer's assessment of the application. ARPANSA's RAR templates are aligned with statutory requirements, although the source template could be improved by specifying the requirement that the reviewing officer conclude that each requirement was adequately addressed.

Guidance and templates align and address statutory requirements

3.21 Overall, the ANAO found ARPANSA's guidance (with the exception of the RAPs document), application templates and assessment templates align

95 ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*, p. 57.

with and cover the requirements of the ARPANS Act and Regulations. This is an improvement compared with the findings of the previous ANAO audit.

3.22 However, the guidance material does not make clear the scope and level of detail expected in supporting information, nor any approach to scale the information requirements in proportion to the risk of the source or facility.[96] The lack of guidance on these matters can give rise to an iterative assessment process with long processing times for some applications. This view was also reflected by some stakeholders.

Stakeholder feedback on the application process

3.23 Stakeholders interviewed by the ANAO expressed generally positive views about their relationship with ARPANSA. However, some stakeholders raised concerns about the application process, primarily that ARPANSA requests a large amount of additional information during the assessment process, often highly technical, that is not clearly specified in the guidance material. This iterative approach means that ARPANSA information requests may be made a long time after an application is submitted, slowing down the application process. Other concerns included:

- long processing times for some applications; and
- inconsistent advice across officers (particularly differing views over whether a new application or Regulation 51 request was required—see from paragraph 3.50).

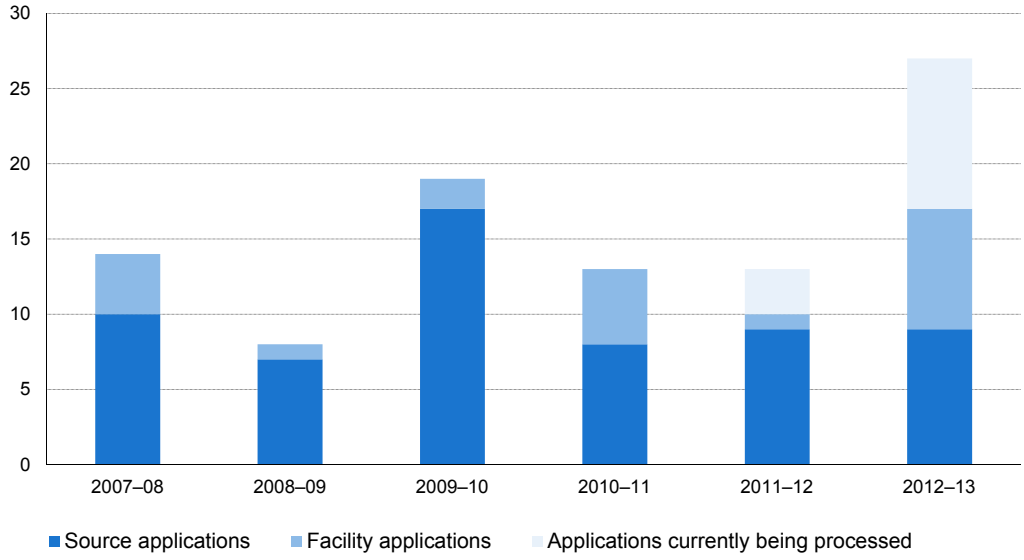
3.24 The timeliness of ARPANSA's application processing is discussed below.

Number of applications over time

3.25 The ANAO examined quantitative data on all (81) applications from July 2007 to June 2013 (excluding Regulation 51 requests, which are discussed from paragraph 3.50). The number and type of applications received by ARPANSA during this period is outlined in Figure 3.2.

96 This is also known as the proportionality principle, which relates to tailoring requirements in a manner commensurate with the risk and complexity of an activity.

Figure 3.2: Number of licence applications over time



Source: ANAO analysis of ARPANSA data.

Note: The financial years relate to when the application was received. Applications being processed are as at August 2013.

3.26 ARPANSA informed the ANAO that it has not rejected any applications. ARPANSA's assessment approach is to continually seek more information and work with the applicant until an application is acceptable or the applicant withdraws. This approach may have informed some of the stakeholder comments about information requests and the length of the application process, noted at paragraph 3.23.

ARPANSA sets internal indicators for processing and reports results

3.27 The ANAO's 2005 audit observed that ARPANSA did not monitor its timeliness in assessing applications, nor did it report timeliness in its annual report. The 2005 audit recommended that ARPANSA monitor its timeliness and report this in its annual report.[97] The lack of timeliness standards for the application process was also noted in the 2007 IRRS mission report.[98]

97 ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*, p. 62.

98 IAEA, *Integrated Regulatory Review Service Full Scope to the Commonwealth Government of Australia, Australian Radiation Protection and Nuclear Safety Agency*, Sydney, August 2007, p. 36.

3.28 ARPANSA does not indicate in its guidance to applicants the expected time for assessing an application, and there are no processing time frames set out in its Act or Regulations. However, ARPANSA has established internal performance indicators for assessing licence applications. The July 2013 *Regulatory Services Branch Plan 2013–14* included the following targets, with the 2012–13 results, as reported in ARPANSA's annual report, indicated in brackets:

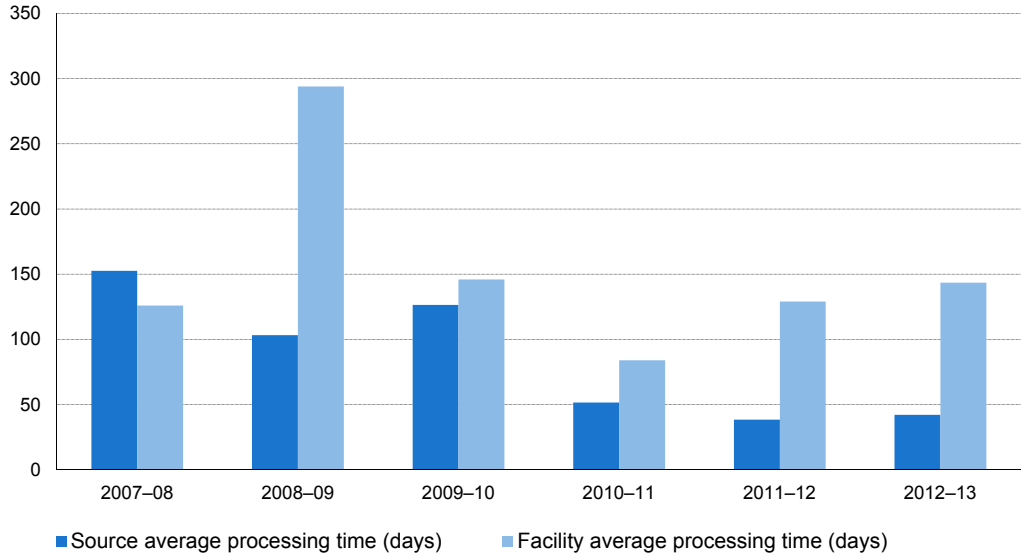
- 30 days for sources (17.3 days actual);
- 30 days for small facilities; and
- 60 days for large facilities (the 2012–13 Annual Report states for facility licences 'an average completion time of 59.5 days against a target of 60 days'; it does not distinguish between small and large applications).

3.29 The results reported in the Annual Report exclude 'pause' time, which relates to waiting for additional information when the application could not proceed. The reporting also excludes weekends and public holidays. The actual elapsed time involved in assessing applications may therefore be longer than the times reported in the annual report.

Time taken to assess source applications has decreased over time, and has been reasonably constant for facility applications

3.30 The average time taken to assess applications over time is listed in Figure 3.3. Time taken to assess source applications is on a downward trend, from a high of 153 days in 2007–08. The time taken to assess facility applications has remained relatively stable, with the exception of 2008–09.

Figure 3.3: Total average time taken to assess applications over time



Source: ANAO analysis of ARPANSA data.

Notes: These results are based on the date an application was received and the date it was approved, and exclude 'pause' time (see paragraph 3.29), which is taken into account when ARPANSA reports on the average time taken in its annual report.

The financial years relate to when the application was received. Only one facility licence application was received in 2008–09 and 2011–12.

Analysis of a sample of licence applications

3.31 The ANAO examined in more detail 10 licence applications, including for compliance with statutory requirements, the extent of information requested by ARPANSA, communication during the application process, and timeliness. The ANAO focused on the process, and did not assess the technical information in the submissions, nor conclude on the merits of ARPANSA's decisions. A summary of the applications examined, is at Appendix 3. The sample represents 10 per cent of source applications and 14 per cent of facility applications since July 2007.[99]

99 The sample included two ongoing applications, and the seven completed applications covering both source and facility licences, applications for new licences and licence amendments, and applications that took varying times to process (from eight days to 16 months). One of these applications related to ANSTO's Interim Waste Storage Facility, was withdrawn and subsequently re-submitted as two separate applications. Both these applications were approved on 29 November 2013, after ANAO analysis was completed.

Regulatory Assessment Reports addressed requirements

3.32 In the 2005 audit, the ANAO found that many Regulatory Assessment Reports (RARs) did not provide a clear analysis of the extent to which the application satisfied statutory requirements. The ANAO made a recommendation that ARPANSA ensure its regulatory assessment reports explicitly address the extent to which an application addressed statutory requirements.[100]

3.33 In this audit, the ANAO analysed the seven completed RARs. The ANAO found that the analysis undertaken by regulatory officers was supported by an appropriate level of evidence provided by the applicant, except in one case where this information was limited.[101] All RARs addressed relevant requirements (although as noted at paragraph 3.19, some older application templates did not align with the RARs in use). The extent of information and analysis in the RARs varied: such as the extent to which the RAR addressed the numerous parts in the *Plans and Arrangements* guide. These differences did not clearly correlate to the apparent risk of an application.

3.34 All seven sample RARs made an overall conclusion and recommended the granting of a licence. In four cases, plans and arrangements were described without directly concluding that the arrangements were satisfactory. While it was usually apparent from the description that the reviewing officer found the arrangements satisfactory, ARPANSA should adopt a consistent approach across all RARs and form conclusions on whether the applicant satisfactorily addressed each matter.

3.35 In some cases the assessment officer was the same officer normally in charge of monitoring the relevant licence.[102] Ideally, different staff members should assess applications and monitor ongoing compliance, however resource limitations or need for specialist expertise can limit the ability to separate these roles. When these roles are not separated, there must be strategies to mitigate risks of capture and conflicts of interest, such as peer review and monitoring

100 ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*, p. 57.

101 This case involved an urgent request from Defence which was supported by less supporting documentation than usually required. ARPANSA advised that it expected further supporting documentation to be provided by Defence in its application to 'use' the equipment. However, ultimately the equipment was not acquired, so further analysis did not proceed.

102 ARPANSA informed the ANAO that, due to the technical nature of its work, there is value in having application assessment and compliance monitoring for an entity done by the same regulatory officer.

by senior management. All seven completed RARs were signed by at least the section manager; in three cases the branch director signed off, and in three cases another regulatory officer also signed as a reviewing officer. There was no indication in the RARs of the reasons the additional sign offs were required.

3.36 All seven completed RARs examined by the ANAO added extra licence conditions in addition to the standard conditions. As required, these extra conditions made reference to relevant standards and codes of practice applying to the type of equipment (for example, adding a reference to a standard relevant for laser products for laser sources).

Fees did not accompany most applications in the sample analysed by the ANAO

3.37 Section 34 of the ARPANS Act requires a licence application to be accompanied by the prescribed fee. The ANAO found that this requirement was routinely breached. In six cases examined by the ANAO the fee was not paid when the application was submitted. In two of these cases ARPANSA approved the application and issued a new licence without receiving the fee. The RAR in each case incorrectly advised that the application 'was accompanied by the appropriate fee'.[103]

3.38 The acceptance of applications without a fee was an issue identified in the 2005 ANAO audit, and was the basis of the recommendation that ARPANSA introduce appropriate systems to ensure its application processing complies with statutory requirements. Despite ARPANSA developing an internal procedure on managing the application process, which provides that assessment cannot proceed until the correct fee is received, the acceptance of applications without a fee continues to be an ongoing source of statutory non-compliance.[104]

103 In the case of the withdrawn ANSTO Interim Waste Storage combined site preparation and construction application (discussed at Appendix 3), ARPANSA informed ANSTO that only one fee (the greater of the two) would be required for both licences because it was one application. However, this was in breach of the Act and was subsequently overturned.

104 ARPANSA informed the ANAO that it estimates that over 95 per cent of application fees are paid within 30 days of the application being submitted.

Large and numerous information requests were commonly made, and communication was not always clear

3.39 ARPANSA requested additional information (to that accompanying the application) in all cases. In two cases, these requests were relatively minor, or clarifications. In another case, most of the requests related to information clearly required as part of the application process; but for later requests in this case, and in the remainder of cases, the pattern was for numerous, detailed requests for information. Often ARPANSA would seek additional information after a significant period of time had elapsed after receipt of the application. Some requests sought detailed technical information, with the requirement for this level of detail not clear from guidance documentation.

3.40 There were also several cases of unclear or inconsistent communication between ARPANSA and the applicant. These often, but not always, related to additional information requests, highlighting the need for clear communications and advice to avoid a gap arising between ARPANSA's and applicants' expectations and understandings of the information required to support the application process.

Additional information requests were a key reason for long application processing times

3.41 The ANAO's examination of three sample applications which took the longest assessment time found that:

- One application was delayed primarily due to the applicant taking several months to provide information in response to follow-up requests from ARPANSA, most of which related to basic information missing from the original application.
- One application was affected by additional ARPANSA information requests and subsequent delays in receiving outstanding information. It took ARPANSA two months to ask for additional information in the first instance, while the responding agency took four months to provide the last of its outstanding information.
- One application encountered three distinct periods of delay:
  - initially, ARPANSA took three months to inform the applicant the original application was not adequate;
  - the applicant subsequently took five months to address these concerns; and

– ARPANSA took approximately 8.5 months to inform the applicant that the additional information was sufficient to approve the proposal.

3.42 While acknowledging the sometimes iterative character of the application assessment process, which may require additional information requests and further information exchanges between the parties, in a resource-constrained environment there would be benefit in ARPANSA reviewing the scope to streamline its processes to minimise delays and related costs for both applicants and ARPANSA. Conversely, there is an obligation on Australian Government entities to submit applications of appropriate quality and to respond to reasonable follow-up requests in a timely way.

ARPANSA could improve the application process by adopting a risk-based approach

3.43 As noted earlier, ARPANSA's guidance material and procedures for licence applications, as well as its internal application assessment standard operating procedure, state that information required, and 'the level of detail' of review, should be commensurate with the hazard. There is no further guidance on these points, and the ANAO's examination of a sample of applications indicated that a risk-based approach is not adopted. There are potential benefits for ARPANSA in adopting a risk-based approach to streamline its application assessments, specifically:

- more effectively using its limited resources by applying a proportionate level of effort commensurate to the risk posed by the application;
- improving processing times for some applications, minimising disruption to the applicant's business and creating efficiencies within ARPANSA;
- providing greater certainty for applicants on information requirements and expected processing times; and
- reducing the potential for miscommunication and delays by minimising the number of additional information requests.

3.44 A risk-based approach could utilise ARPANSA's existing risk ranking methodology (discussed from paragraph 2.42), and in particular could consider the:

- hazard of the source or facility to workers, the public and environment (if applicable), for both normal usage and in the event of misuse or an accident, taking into account the intended use of the equipment; and
- applicant's compliance maturity (history of compliance together with the strength of its internal controls).

3.45 Placing greater emphasis on an organisation's compliance maturity would be consistent with the first IAEA fundamental safety principle:

> The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks...
>
> The licencee retains the prime responsibility for safety throughout the lifetime of facilities and activities, and this responsibility cannot be delegated.[105]

3.46 Consistent with a more streamlined and risk-based approach, potential applicants could be encouraged to establish initial contact with ARPANSA to discuss plans to apply for a licence through a 'pre-lodgement meeting' (the adoption of such an approach may first require legal advice). In this way, ARPANSA could gain sufficient understanding of the potential application and, informed by the applicant's compliance maturity, determine the risk of the application, and subsequently use this as a further basis for communicating information requirements.

3.47 A risk-based approach, based on clear, documented expectations that are communicated to agencies, would help focus ARPANSA's effort on applications that represent the greatest risk, with potential benefit to applicants and ARPANSA.

Recommendation No.2

3.48 To streamline its applications process and more effectively use its limited resources, the ANAO recommends that ARPANSA implements a documented risk-based approach to assessing licence applications, having regard to the:

(a) hazard of the source or facility to workers, the public and environment; and

(b) the applicant's compliance maturity.

105 International Atomic Energy Agency, *IAEA Safety Standards: Fundamental Safety Principles*, Safety Fundamentals No. SF-1, 2006, p. 6 (original emphasis).

ARPANSA response:

3.49 *ARPANSA agrees and accepts the recommendation and will advance the internal procedures for licence application assessment to support and promote a risk-informed approach.*

Regulation 51 requests

3.50 Under Regulation 51 of the ARPANS Regulations, the holder of a licence must seek approval from the CEO of ARPANSA before making a relevant change to facilities or sources that will have significant implications for safety. Historically, there has been uncertainty about the triggers and scenarios for when a Regulation 51 request applies, as opposed to submitting a new licence application or simply notifying ARPANSA of a relevant change under Regulation 52 (see Table 3.1).

Table 3.1: ARPANS Regulations 51 and 52

Regulations	Definition of 'relevant change' (from ARPANS Regulations Dictionary)
51 CEO approval for relevant changes The holder of a licence must seek the CEO's prior approval to make a relevant change that will have significant implications for safety. **52 Holder of a licence must tell CEO about other changes** (1) The holder of a licence may make a relevant change that is unlikely to have significant implications for safety without the CEO's approval. (2) However, the holder of a licence must, at least once every 3 months, tell the CEO about any changes mentioned in subregulation (1). (3) However, subregulation (2) does not apply to the extent that the licence makes other arrangements for a matter mentioned in the subregulations.	***relevant change,*** for regulations 51 and 52, means a change to: (a) the details in the application for the licence; or (b) a modification of the source or facility mentioned in the licence.

Source: Australian Radiation Protection and Nuclear Safety Regulations 1999.

3.51 It has been observed by both ARPANSA and stakeholders that Regulation 51 requests can involve as much effort as a regular licence application. The Regulation 51 application form, for example, requests the same information as a licence application, including international best practice.

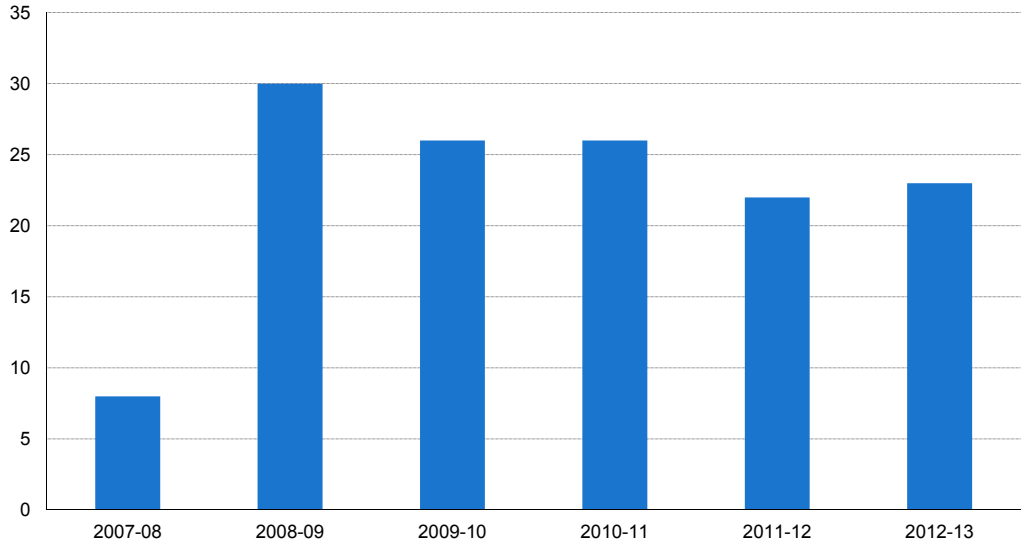
3.52 The 2007 IRRS mission report noted that ARPANSA did not have a procedure or guide that described what is meant by 'significant implications

for safety' under the regulations, nor what information a licence holder is required to provide when seeking such an approval. The mission recommended ARPANSA prepare a guide to address these matters. The 2011 mission found that a guide had yet to be prepared, but at the time ARPANSA planned to produce one by June 2012. As discussed below, guidance was released in January 2013.

There are normally more Regulation 51 requests than licence applications in a given year

3.53 The number of Regulation 51 requests between July 2007 and June 2013 is displayed in Figure 3.4. Since 2008–09, the number of requests has been reasonably consistent and more numerous than licence applications (except for 2012–13—see Figure 3.2). ANSTO (46 per cent) and CSIRO (27 per cent) account for almost three quarters of all the Regulation 51 requests since 2007–08.

Figure 3.4: Number of Regulation 51 requests over time



Source: ARPANSA data.

3.54 ARPANSA has recently established an internal performance target of 30 days to process Regulation 51 requests (the same target as new source and small facility licence applications). In 2012–13, ARPANSA reported that it took 17.6 days on average to assess such requests. ARPANSA did not record this data in previous years, and the information supplied by ARPANSA to the

ANAO does not indicate the length of time taken to process these earlier requests. As Chapter 5 notes, ARPANSA spends a similar amount of time assessing Regulation 51 requests as it does assessing licence applications, (see paragraph 5.37).

Stakeholder feedback on Regulation 51 is similar to that for licence applications

3.55 Some stakeholders raised concerns about a lack of clarity of what constitutes a Regulation 51 change (including inconsistencies across ARPANSA officers) and the timeliness of Regulation 51 approvals. Stakeholders acknowledged that the recent publication of guidance (discussed from paragraph 3.56) helps, although there were concerns that this guidance does not accurately reflect the amount of information ARPANSA requires in practice.

ARPANSA published guidance in 2013

3.56 In January 2013, ARPANSA published the *Regulatory Guide: Regulation 51—How to determine when a change has significant implications for safety*.[106] ARPANSA informed the ANAO that the guide is intended to limit the risk of licence holders improperly categorising changes as a Regulation 52 (see Table 3.1). The guide focuses on the potential consequences of a change, both properly and improperly implemented:

> ARPANSA considers that an implication for safety is a suggested or inferred effect on safety which, even if it is not easily derivable, possesses some degree of probability. A significant implication is one which is important, notable, or of consequence, having regard to its context or intensity.

3.57 The initial decision on whether a change fits this definition is placed on the licence holder: the guide expects licence holders to undertake a risk assessment of potential consequences, and if the assessment exceeds 'consequence thresholds' outlined in the guide, then the proposed change would trigger the need for a Regulation 51 approval by ARPANSA (if not exceeded, a Regulation 52 notification would be sufficient). ARPANSA informed the ANAO that it receives all such risk assessments of potential Regulation 51 scenarios. The guide further states that:

106 The guide was published five and a half years after the 2007 IRRS mission recommended its production.

> Where the risk assessment demonstrates, to the satisfaction of the CEO of ARPANSA, that the likelihood of occurrence is not credible, no further regulatory assessment will be undertaken.

3.58 The guide contains six categories of thresholds where a change has a potential to trigger the need for a Regulation 51 application. Some are clear (such as the release of radiation above discharge authorisations, or changes to an approved operating limit or condition), while others may be more difficult to define (for example the potential to introduce a risk of an accident not previously considered). The guide also contains a number of examples of changes with significant implications for safety, ranging from replacing a safety interlock system, to relocating a radioactive waste store, to changing work hours.

3.59 ARPANSA informed the ANAO that, when determining the difference between a Regulation 51 and 52 (see Table 3.1), its key aim is that agencies initially undertake their own risk assessments in order to consider the safety implications of any changes. While this approach is consistent with the first IAEA safety principle that the prime responsibility for safety rests with the organisation responsible for the facility or source, there remains a risk that agencies could self-assess changes as a Regulation 52 to avoid the additional level of scrutiny. ARPANSA informed the ANAO that assessing the consequence of a change or failure of a product is usually able to be clearly established, whereas there is good evidence that estimating the likelihood of failure, is in practice less reliably determined. Hence the reason for their approach which is focussed on providing clear thresholds for consequence and then reviewing all proposed changes beyond that. Licence holders are still required to report all Regulation 52 changes in their quarterly reports to ARPANSA; this provides ARPANSA an opportunity to verify the categorisation of changes, albeit after the change is implemented.

3.60 The ARPANSA guide attempts to provide clarity in an area where relevant changes are not always clear cut, and is a positive development recognised by stakeholders. Where ambiguity exists (as the above example illustrates), there remains a degree of judgement still to be exercised by ARPANSA as to what changes constitute a Regulation 51.

3.61 Clear guidance can assist both ARPANSA and applicants to make soundly-based decisions on the application of Regulations 51 and 52.

Conclusion

3.62 Under the ARPANS Act, entities require a licence from ARPANSA to possess and operate facilities and sources that emit radiation. A well designed licence application process will feature clear guidance material for staff and applicants that facilitates the preparation, submission and assessment of applications in a timely manner, and at reasonable cost to the regulator and applicant.

3.63 ARPANSA has published a series of guides on the licence application process to assist entities in preparing and submitting their applications, and for its regulatory staff involved in the assessment process. ARPANSA's published guidance, as well as its application forms and internal assessment templates, generally align with and address the statutory requirements set out in ARPANSA's legislation.[107] Existing guidance materials could usefully be supplemented to include clear advice on the extent and depth of supporting information required as part of the application process. At present, information for applicants is limited to advice that documentation provided in support of an application should be commensurate with the hazard and risk of the application. Entities consulted by the ANAO and the sample of applications examined by the ANAO identified that, as a consequence of applicants' uncertainty over information requirements, ARPANSA is frequently required to make repeated requests for additional information, an iterative approach often resulting in lengthy delays in the application process.

3.64 Between July 2007 and June 2013, ARPANSA received 81 licence applications, 60 of which were for new or modified source licences. The ANAO's analysis showed there have been significant improvements over this period in the average time taken to assess source licence applications, from 153 days in 2007–08 to 42 days in 2012–13; while the time taken to assess facility applications has remained relatively stable.[108] The ANAO's analysis of 10 licence applications showed that ARPANSA's conclusions on the applications were, except in one case, supported by evidence, although the extent of

107 One guidance document—*Regulatory Assessment Principles for Controlled Facilities*—has not been updated since 2001 and does not directly align with statutory requirements and the information required for a facility application. ARPANSA anticipates a review of this document will be completed by December 2015.

108 In 2012–13 it was 144 days for a facility licence. These figures include 'pause' time, that is, following a request for additional information, assessment of the application cannot proceed until this information is supplied by the applicant.

analysis undertaken in the report to the delegate varied and there was not always a clear correlation with the apparent risk of the application. Further, there were: several cases of unclear or inconsistent communication between the applicant and ARPANSA; frequent information requests from ARPANSA; and application fees routinely did not accompany the application—contrary to section 34 of the ARPANS Act.

3.65 To more effectively use ARPANSA's limited resources and create a more efficient and streamlined application assessment process, ARPANSA should adopt a risk-based approach to its internal application assessment process. Such an approach could leverage off the existing risk ranking framework, taking into account applicants' compliance histories, as well as the hazard of the source or facility.

4. Monitoring and Enforcement

This chapter examines ARPANSA's approach to monitoring agency compliance with licence conditions and legislation, as well as the process for managing non-compliance. The chapter also includes an examination of ARPANSA's self-regulatory role.

Introduction

4.1 A key function of a regulator is the ongoing monitoring of regulated agencies and, where required, enforcement in cases of non-compliance. A risk based approach to monitoring compliance provides a basis for focusing regulatory effort and cost-effectively deploying limited resources.

ARPANSA's policies, procedures and guidance

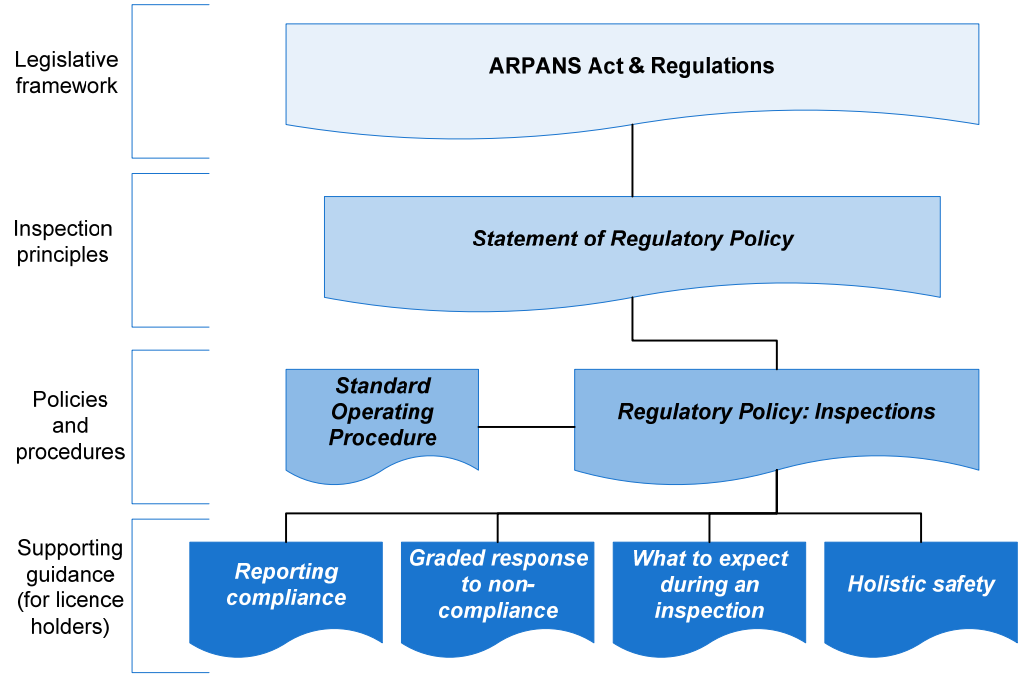
4.2 A monitoring strategy defines the type and frequency of activities to be undertaken to confirm compliance. It should be risk-based and conscious of the cost both to the regulator and regulated entity. One benefit in clearly documenting the monitoring strategy's underpinning rationale is to provide assurance to stakeholders that regulatory risks are appropriately managed.[109]

4.3 ARPANSA's monitoring strategy is focused largely on conducting inspections, supported by regular reporting from entities. The key elements of ARPANSA's compliance monitoring and enforcement framework are outlined in Figure 4.1 below.[110]

109 ANAO Better Practice Guide—*Administering Regulation*, March 2007, Canberra, pp. 52, 56.

110 All of these documents are publicly available on ARPANSA's website.

Figure 4.1: ARPANSA's compliance monitoring and enforcement framework



Source: ANAO.

Notes: ARPANSA's *Statement of Regulatory Policy* describes the high level framework for ARPANSA to undertake its regulatory activities: the independent monitoring of compliance with clear requirements, in a risk based and transparent manner.

ARPANSA's *Regulatory Policy: Inspections* outlines the broad focus areas of the inspection program, as well as the intent of unannounced inspections.

The *Standard Operating Procedure: Regulatory Inspections* describes the process of an inspection and the preparation or inspection reports.

The supporting guidance for licence holders is published on the ARPANSA website.

4.4 Stakeholders interviewed were generally satisfied with the guidance on inspections and compliance requirements provided by ARPANSA, and indicated it had improved over time.

Inspections

4.5 Inspections are a key regulatory tool, providing opportunities to monitor and verify entity compliance with licence conditions. The nature of ARPANSA's inspections varies—some are general inspections of licence conditions, while others focus on a specific aspect of the licence or a specific issue/process, for example how an entity reports on safety issues internally. Inspections can also be in response to an incident or an accident, and may be announced or unannounced.

4.6 The ANAO observed four inspections as part of its fieldwork, involving: ANSTO (ANSTO Health), ANSTO (OPAL), the Department of Parliamentary Services (DPS) and the Australian National University (ANU). The ANAO's observations of these inspections are discussed at paragraphs 4.25 and 4.33.

4.7 One of ARPANSA's deliverables listed in its Portfolio Budget Statements is 60 inspections per year. Table 4.1 illustrates ARPANSA's achievement of its target in recent years. ARPANSA informed the ANAO that the target is based on the number of inspections needed to provide a meaningful sample of licensee dealings, within available resources, while also accommodating for incidents requiring follow up.

Table 4.1: Number of inspections conducted per year against target

	Annual target	Result 2008—09	Result 2009—10	Result 2010—11	Result 2011—12	Result 1012–13
Inspections	60	66	40[(A)]	49[(B)]	62	59[(C)]

Source: ARPANSA Annual Report 2011–12, p. 51, and ARPANSA Annual Report 2012–13, p. 45.

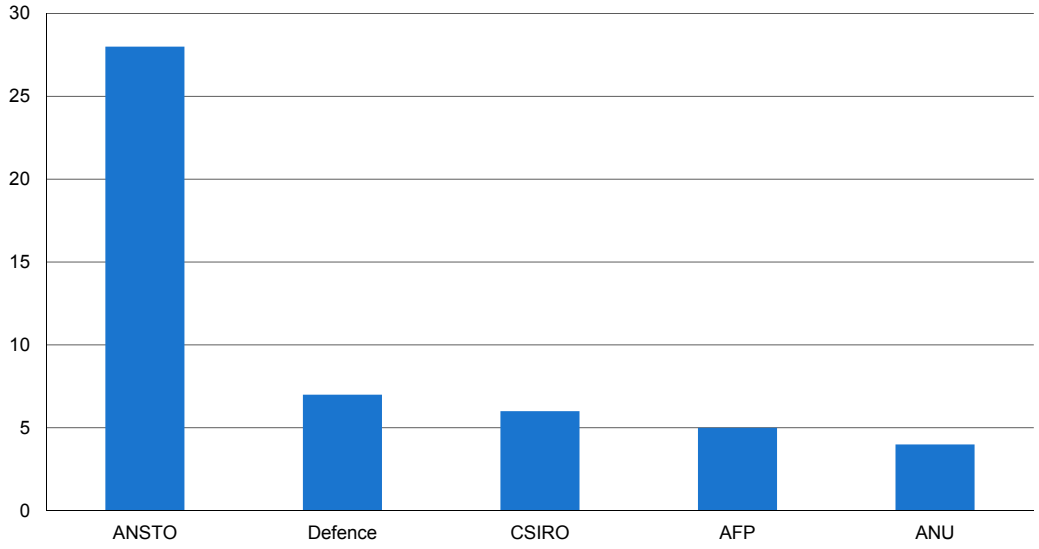
Note A: In its 2009–10 Annual Report, ARPANSA stated it did not meet its target in 2009–10 as staff were instead focused on improving ARPANSA's regulatory quality management.

Note B: In its 2010–11 Annual Report, ARPANSA stated it did not meet its target in 2010–11 as regulatory staff were directed to involvement in monitoring and advising the Australian Government after the Fukushima nuclear accident in Japan.

Note C: ARPANSA informed the ANAO, that the 2012–13 figure includes site visits. This is the first year that site visits have been counted. In 2012–13 there were 49 regulatory inspections, nine site visits, and one accident investigation.

4.8 The 59 inspections in 2012–13 were spread across 13 entities. The five entities subject to the most inspections are noted in Figure 4.2. Cumulatively, 50 inspections were conducted on these five entities, approximately 85 per cent of the total inspections. Twenty eight regulated entities did not receive an inspection.

Figure 4.2: The five most inspected entities in 2012–13



Source: ANAO analysis of ARPANSA information.

Note: The numbers include inspections of both facilities and sources. All the entities listed in the figure, except the Australian Federal Police (AFP) possess several separate licences: ANSTO has the most with 23 separate licences.

The figure for ANSTO includes nine site visits.

4.9 ARPANSA also advised that outcomes and lessons learnt from inspections are routinely discussed and shared.

4.10 The 2007 IRRS mission contained a suggestion that ARPANSA consider a systematic periodic assessment of the inspection program to evaluate its continued effectiveness, informed by previous inspections. The 2011 mission noted that this suggestion had not been implemented[111], and there was no evidence during the current ANAO audit that such a systematic assessment had been undertaken.

ANSTO and Defence are managed differently

4.11 The two largest agencies regulated by ARPANSA, by size and value of the licences, are Defence and ANSTO. Due to the large number of sources and high risk of the facilities these agencies possess, ARPANSA has adopted some

111 IAEA, *Integrated Regulatory Review Service Follow-Up Mission to the Commonwealth Government of Australia, Australian Radiation Protection and Nuclear Safety Agency*, Sydney, November 2011, pp. 28-29.

different management arrangements for these licence holders, such as regular meetings between ANSTO and ARPANSA to discuss the Quarterly Report which outlines how they manage compliance with the Act and Regulations.[112] The ANAO observed one of these meetings, which provided a useful opportunity for ARPANSA to examine responses in more detail, particularly to seek elaboration on information presented in the Quarterly Report.

4.12 Defence presents a regulatory challenge for ARPANSA due to its dispersed nature, the size of the organisation, and the large number of sources it possesses. As a proactive mechanism to assist in meeting its licence requirements, Defence has developed its own internal controls for managing radiation safety (see box below). ARPANSA does not provide any formal accreditation for Defence's internal management arrangements and ARPANSA continues to conduct its own independent inspections of Defence.

Defence adopts a self-regulatory approach to its sources and facilities

Defence has five facility licences and a source licence that covers over 60 000 individual items. Its licences cover two radioactive waste storage facilities, and sources such as lasers, X-ray machines, and bomb disposal equipment.

In 2009 Defence created the Directorate of Radiation Safety and Assurance, within Joint Logistics Command, as a single point of accountability for the ongoing management and oversight of its radiation facilities and sources. One of the main roles of the directorate is to undertake inspections of Defence's facilities and equipment licenced under the ARPANS Act. Defence provides these inspection reports to ARPANSA, increasing ARPANSA's level of oversight over the Defence licences.

Defence captures most of its radiation sources in its inventory management system (MILIS). Some items are not able to be stored in MILIS so are tracked separately using an Excel spreadsheet. ARPANSA does not conduct sample testing on Defence's inventory, and ARPANSA advised that Defence does this regularly as part of its internal inspection process.

The Defence ARPANSA Liaison Forum (DALF) was established in 2003–04 to facilitate strategic level communication on compliance, and meets twice a year.

4.13 Resource limitations and the scale of Defence's holdings has led to ARPANSA placing a degree of reliance on Defence's internal controls. While Defence accepts primary responsible for the safety of such equipment, this does not relieve ARPANSA of its regulatory responsibilities. ARPANSA informed the ANAO that its approach is to work with Defence to support the

112 Entity reporting is further discussed from paragraph 4.45.

department's internal regulatory management, while also maintaining independent oversight through its own inspection program.

Inspection reports are completed by ARPANSA for each inspection

4.14 Once an inspection has been completed, ARPANSA prepares an inspection report using a reporting template.[113] Reports are then sent to the licence holder for comment on the factual content of the report. Final reports are published on the ARPANSA website, although Defence inspection reports are currently not available.[114] Inspection reports outline the purpose of the inspection and contain a brief description of the inspection process. A number of observations and a conclusion are made based on analysis of information and evidence collected during the inspection. If warranted, recommendations are made or good practice is noted. If any non-compliance is identified during the inspection, this is also noted in the report.

4.15 The 2007 IAEA IRRS report suggested that ARPANSA should consider an appropriate mechanism for the timely dissemination of feedback gained from inspections to regulatory staff. While ARPANSA informed the ANAO that inspection feedback is regularly discussed at fortnightly team meetings, it is not the more formal process suggested by the IAEA. Feedback from inspectors provide good learning opportunities for ARPANSA to gain insight into regulatory trends, changes or difficulties licence holders may be encountering, as well as any good practice that may be observed.

Licences are risk assessed, but this does not always link to the inspection program

4.16 A risk-based inspection program allows regulatory effort to be directed to areas of greatest risk in a cost-effective manner. The ANAO's 2005 audit found that ARPANSA did not have an overall program of inspections that took into account the relative risk of each licence. The ANAO made a

113 According to ARPANSA's inspection procedure, if non-compliance has not been identified during the inspection, the report should be completed within 10 working days and signed off by the Licensing and Compliance section head. In cases where non-compliance is identified, reports should be completed within 30 working days and sent to ARPANSA's legal area before being signed by the Regulatory Services Branch head.

114 Defence advised the ANAO that publication of its inspection reports would take place once classified, sensitive or identifying information has been removed from previous and current inspection reports. ARPANSA expects the reports to be available on the website by mid 2014.

recommendation that ARPANSA establish a systematic, risk-based framework for compliance inspections.[115]

4.17 ARPANSA inspection policy states that it has a risk-based inspection program, with the frequency of inspections determined by the licence holder's risk ranking. Risk rankings of individual licences are documented individually (with separate rankings for different sites), and would commonly (but not always) include other information: the dates the ranking was last revised and the licence last inspected, as well as notes on the source/facility. These individual risk rankings are then consolidated into a single document, with a new one created annually.

4.18 Risk rankings for each licence are reviewed annually by the responsible regulatory officer, and represent ARPANSA's assessment of the risks relating to sources and facilities, and the likelihood and consequences of those risks. As the risk ranking methodology has recently changed, risk rankings are currently being reviewed by the head of the Licensing and Compliance section. Chapter 2 examined the methodology, and noted that while it provides a useful framework for determining a risk rating, it lacked guidance on how the licence should be managed once it is allocated a risk ranking, such as the frequency of ARPANSA inspections and agency reporting.

4.19 This lack of guidance on management strategies flowing from risk rankings has resulted in the inspection program not always linking to allocated risk rankings. To illustrate, Table 4.2 shows one source licence belonging to a large licence holder, that is spread over eight different sites, with each site assigned its own risk ranking. ANAO analysis indicates that four of the seven medium risk sites have been inspected, while the other three medium risk sites and the high risk site have not. Under a risk-based approach, the site with the highest risk ranking would receive priority.

115 ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*, pp. 75, 78.

Table 4.2: Risk rankings and last inspection date of sites covered by one source licence

Location	Risk ranking	Risk category	Date of last inspection (since 2008)
Location A	4	Medium	October 2010
Location B	4	Medium	March 2012
Location C	4	Medium	March 2012
Location D	6	Medium	No inspection
Location E	6	Medium	No inspection
Location F	6	Medium	No inspection
Location G	6	Medium	November 2012
Location H	9	High	No inspection

Source: ANAO analysis of ARPANSA risk information.

4.20 To further illustrate, Table 4.3 provides a comparison of four similarly ranked licence holders and their previous inspections, indicating significant variability in the inspection intervals.

Table 4.3: Comparison of similarly ranked licence holders and their previous inspections

Licence holder	Current risk ranking	Date of last inspection	Date of previous inspections
Agency A	High	May 2013	August 2006
Agency B	High	November 2013	October 2010
Agency C	High	November 2013	October 2010, October 2005
Agency D	High	September 2008	-

Source: ANAO analysis of ARPANSA risk information.

Notes: Agency B's licence was issued in 2010.

The risk ranking methodology changed in 2013. The new risk ranking methodology increased the risk ranking matrix from a 3x3 matrix to a 3x5 matrix, and resulted in all these licences being revised from medium to high risk.

4.21 A well designed risk-based inspection regime can instil confidence in the regulatory framework by targeting risks. While efficiencies can be gained in leveraging off planned inspections, particularly for entities that are geographically dispersed, it is important to be aware of the regulatory burden which can be placed on certain licence holders, particularly those assessed as low risk, from frequent inspections. There is scope for ARPANSA to provide

additional supporting guidance on the alignment of the inspection program, including the program of unannounced inspections, with the assessed risk of licences.

Risk rankings remain relatively stable

4.22 While risk rankings are reviewed annually, they do not often change (with the exception of changes resulting from the revised methodology). Rankings can also be changed by a regulatory officer in response to an inspection or an incident. Former risk rankings are not stored in one consolidated document, and individual risk ranking spreadsheets do not track the history of changes over time. Identifying trends from risk rankings over time requires accessing multiple spreadsheets, meaning it is difficult to determine how often and for what reasons an entity's risk ranking changes.

4.23 ARPANSA informed the ANAO that the new Licence Administration Database will assist in tracking changes over time and permits staff to run change reports on risk ranking data in the database.[116] However, the ANAO notes that the database's functionality with respect to risk rankings is limited to manually entering a numeric rank.

Unannounced inspections are not always used strategically

4.24 In accordance with ARPANSA's regulatory policy on inspections, approximately 10 per cent of inspections should be unannounced—that is, no more than 24 hours notice of the inspection given to the licence holder. The aim of unannounced inspections is to provide ARPANSA with a 'realistic snapshot of licence holders' day-to-day operations'.[117]

4.25 Inspectors exercise discretion in determining which inspections are to be unannounced. Three of the four inspections the ANAO attended during fieldwork were unannounced. One inspector chose to do an unannounced inspection as the licence holder had reported an incident, while in the other two cases geographical convenience[118] and meeting ARPANSA's annual quota

116 ARPANSA informed the ANAO in December 2013 that the database was officially launched in October 2013, and is currently undergoing testing and data validation.

117 ARPANSA, *Regulatory Policy: Inspections*, 2012, p.3.

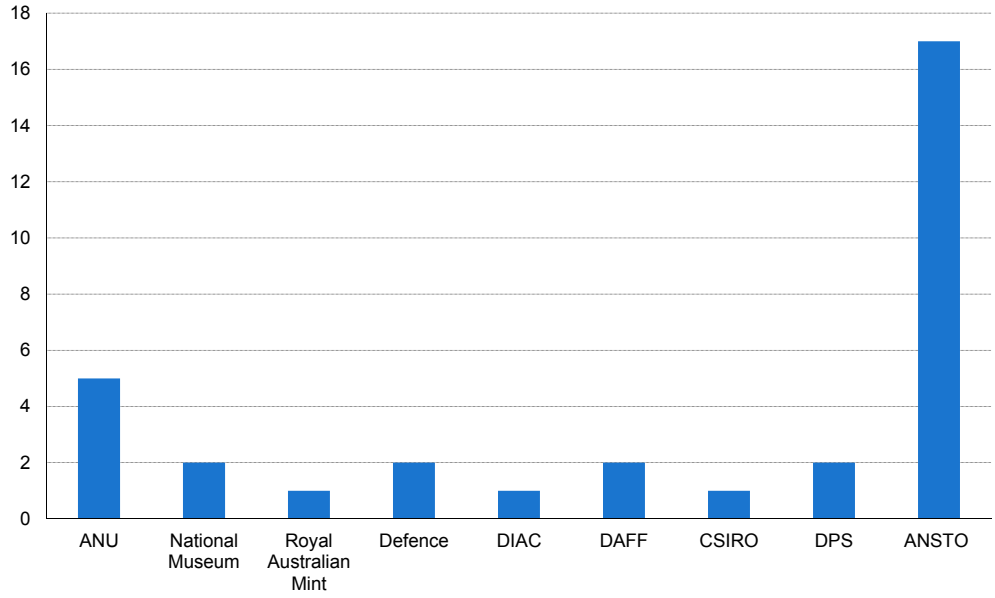
118 ARPANSA advised that it uses its planned inspection program for determining unannounced inspections that are to be conducted interstate. This reduces the risk of travel being undertaken and no successful inspection taking place due to the absence of key personnel.

of unannounced inspections appeared to be key drivers for conducting the inspections.

4.26 ARPANSA also informed the ANAO that, particularly for inspections conducted interstate, inspectors will often undertake additional unannounced inspections in the area. ARPANSA acknowledged that this approach means that there is no guarantee that interstate unannounced inspections will be of medium to high risk licences. These additional inspections may also be undertaken on behalf of another regulatory officer who has responsibility for that entity. While geographical location is a legitimate driver for leveraging some inspections, ARPANSA's scheduling of unannounced inspections does not clearly align to the risk ranking assigned to the individual licences.

4.27 The ANAO analysed the unannounced inspections undertaken between September 2009 to 30 June 2013. During this period, 31 unannounced inspections were undertaken on 10 different licence holders—almost a quarter of the total agencies regulated. As illustrated in Figure 4.3, ANSTO received over half of the total unannounced inspections. The CSIRO, which is one of the three biggest licence holders with a number of medium to high risk sources spread across Australia, was only subject to one unannounced inspection, while DPS is a low risk licence holder with a good compliance history and had two unannounced inspections. All inspections conducted on DPS, the Royal Australian Mint, the National Museum, and the then Department of Immigration and Citizenship (DIAC) during the period were unannounced.

Figure 4.3: Number of unannounced inspections conducted between September 2009 and June 2013



Source: ANAO analysis of ARPANSA *RegInfoTool*.

Note: Some agencies have multiple licences. All different areas of ANSTO are grouped together, comprising: the Bragg Institute, OPAL Reactor, High Flux Australian Reactor (HIFAR—decommissioning), ANSTO Health and ANSTO Waste Operations.

DAFF is Department of Agriculture, Fisheries and Forestry.

4.28 The ANAO's analysis indicates that risk ranking and compliance history are not the main drivers for undertaking unannounced inspections. The risk rankings for licences covered by the agencies in Figure 4.3 varied from 2 (negligible risk) to 12 (high risk for facility licences, very high risk for source licences).

4.29 The concept of unannounced inspections is sound and provides useful information for ARPANSA on the daily processes and practices of a licence holder. It is also a useful tool for a regulator, as it allows prompt access to people and premises in response to intelligence or an incident. However, there does not appear to be a consistently applied rationale for the selection of unannounced inspections (other than in response to an incident). As discussed in paragraph 4.21, there would be benefits to all parties in providing clear guidance to ARPANSA inspectors on unannounced inspections, focusing on the alignment of inspections with risk rankings. A revised approach would: help maximise the benefit of unannounced inspections; apply the

proportionality principle; and potentially reduce the impost on regulated entities.

Recommendation No.3

4.30 To strengthen its risk-based approach to monitoring and compliance, the ANAO recommends that ARPANSA more directly links its management of licences to risk rankings, focusing particularly on:

(a) clearly aligning its planned inspection program to risk rankings of licences; and

(b) strategic targeting of unannounced inspections.

ARPANSA response:

4.31 *ARPANSA agrees and accepts the recommendation and will continue to strengthen the risk-informed compliance monitoring program and strategic targeting of unannounced inspections.*

The nature of inspections vary

4.32 ARPANSA's publicly available guidance, *What to expect during an inspection* and the *Inspection procedure*, outlines the inspection process, notification and reporting requirements. This guidance provides a list of documents that inspectors may need to review as part of the inspection, however it does not elaborate on the scope and level of detailed evidence required to make findings (for example, in respect to training, whether an inspector needs to cite training records or if written advice from management is sufficient).

4.33 The ANAO observed four inspections during fieldwork; two of these were inspections of licence conditions; one was in response to an issue reported by the licence holder; and one was a combination of the two factors. These inspections largely followed the documented procedures, although the level of evidence required by the inspectors varied, with inspections of licence conditions being more of a 'desktop' inspection. However, the verification of entity compliance with codes of practice and standards included in the licence conditions and Regulations was not clearly covered. ARPANSA informed the ANAO that compliance with codes and standards is not systematically examined as part of an inspection, but relevant aspects may be examined.

4.34 Feedback from stakeholders indicated they were generally satisfied with the conduct of inspections. Stakeholders noted that ARPANSA generally

followed a set procedure for inspections, had good technical knowledge and was accommodating of an agency's schedule/time commitments. Larger stakeholders, which have multiple inspectors, raised concerns over the differing levels of evidence required by different inspectors, making it difficult for them to gain a consistent understanding of ARPANSA's requirements and educate their staff on how to prepare for an inspection. An example raised by stakeholders was of a similar inspection conducted at an entity across two areas by two different inspectors. One inspector wanted to physically sight all evidence while the other was satisfied with the entity's advice that evidence existed.

4.35 There may be legitimate reasons for differences in the approach adopted for inspections, as inspections can serve different purposes and therefore vary in their focus. For instance, an inspection in response to an incident may require more detailed verification than would otherwise be required in the absence of a problem. Nonetheless all inspections should provide a level of assurance, and even routine compliance inspections of licence conditions should be informed by an appropriate level of detail and evidence calibrated to the risk of the licence. While ARPANSA's guidance provides clarity on the process for an inspection, it does not extend to the levels of relevant and appropriate evidence necessary to satisfy verification.

Holistic safety is a new and developing focus

4.36 During ARPANSA's 2011 organisational restructure, a new 'holistic safety' focus was adopted with a Safety Analysis section created within the Regulatory Services Branch to assess and improve the safety culture of licence holders.[119] ARPANSA's 'holistic safety' approach to safety management, considers technological, human, and organisational factors as well as the interaction and interdependence between them.

4.37 To assess the extent of an entity's safety culture, ARPANSA has developed an assessment tool based on internally developed 'holistic safety' guidelines. The basis of the tool is a self assessment questionnaire, supported by interviews, workplace observation and management system review. An

119 ARPANSA has produced guidelines on holistic safety that outline its expectations and provide guidance on the key technological, human, and organisational aspects that are necessary to create and maintain optimal safety. The key principles of holistic safety are arranged into seven characteristics. Within each characteristic are attributes that provide a more specific outline of the ways to achieve the key principles of holistic safety

assessment of ARPANSA's Medical Radiation Services Branch has recently been completed, and similar reviews into ARPANSA's Radiation Health Services Branch and ANSTO OPAL are underway.

4.38 ARPANSA's work to undertake safety culture analysis, particularly through the safety assessment tool, is potentially a useful tool that directly contributes to ARPANSA's mission of ensuring the health and safety of people and the environment. There remains scope for ARPANSA to develop a clear strategy for how the results will shape its broader regulatory approach.

Unlicenced activities are a challenging area for regulators

4.39 The ARPANS Act and Regulations require all sources and facilities that can emit ionising radiation or harmful non-ionising radiation to be covered by a licence.[120] As part of the inspection process, inspectors are expected to be familiar with the licence and identify any additional sources. ARPANSA has acknowledged that identifying unlicenced activities is a challenging area of regulation, but considered the amount of unlicenced activities to be quite small.

4.40 There are two main categories of potential unlicenced activities:

- sources and facilities that are covered by the ARPANS Regulations that ARPANSA is not aware of[121]; and
- sources and facilities with mixed responsibility, for example some legacy sites (see appendix 4).

4.41 The ANAO's 2005 audit found that ARPANSA did not have an explicit strategy or framework for identifying prohibited activity by non-licenced entities.[122] ARPANSA still does not have a documented strategy for dealing

120 Seventy one kinds of controlled material or apparatus can be covered by a source licence. Forty five are directly listed in the ARPANS Regulations (covering both ionizing and harmful non-ionising radiation). An additional 26 are listed in ARPANSA's source application form template, which represent variations on those specified in the Regulations.

121 Additionally, there may be cases where certain types of equipment are not covered by the ARPANS Regulations yet may have the potential to emit harmful radiation. During stakeholder consultations, one licence holder noted that it possessed some very powerful radiofrequency transmitters—capable of producing non-ionising radiation—that were not covered by the Regulations and therefore not regulated by ARPANSA (which was nonetheless aware of these sources). ARPANSA informed the ANAO that radiofrequency transmitters are regulated by the Australian Communications and Media Authority (ACMA) and a member of ARPANSA's Radiation Health Committee (RHC) was appointed as an ACMA representative to advise ACMA on radiation issues.

122 ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*, p. 64.

with potential unlicenced activities, which would include activity by non-licenced entities. ARPANSA generally relies on licence holders to self-report any unlicenced activities, but may receive information from equipment suppliers.

4.42 Suppliers of equipment that can emit radiation are licenced and regulated by the relevant state or territory body. Five of the eight states and territories specifically require that those authorised to sell/distribute radiation equipment only sell/distribute such equipment to those licenced to use it. ARPANSA advised the ANAO that manufacturers will often confirm an entity's licensing status with them, thereby giving ARPANSA some oversight of equipment its licence holders are acquiring. Since July 2009 ARPANSA has identified at least 16 breaches across a number of entities relating to accurately reporting the acquisition of relevant sources.

4.43 ARPANSA advised that when entities possess unlicenced sources, it is generally due to a lack of understanding of the Regulations, for example not realising a piece of equipment needed licensing. One stakeholder interviewed by the ANAO commented that not all equipment suppliers were aware of the Commonwealth regulatory requirements.

An example of an entity self-identifying and unlicenced source

In 2011–12, ARPANSA reported that Customs had received a breach for the possession of a Class 4 laser contained in a forward looking infrared device which was not covered by a licence at that time. Customs self-reported the breach and subsequently submitted a licence application for the device.

4.44 As noted in paragraph 2.38, the risk associated with unlicenced sources is not listed in ARPANSA's strategic risk register. In order to address this risk ARPANSA has previously considered writing to agencies to confirm their listing of sources, but did not proceed with this approach. A proactive approach of this sort, to reinforce entities' obligations under the ARPANS Act, could also assist in identifying unlicenced sources.

Reporting by regulated agencies

4.45 The ARPANS Act requires the CEO of ARPANSA to publish guidelines on how licence holders should report their compliance with the ARPANS Act, the Regulations and licence conditions.[123] Together with an inspection program, these are important elements of ARPANSA's regulatory monitoring regime. The Act also requires the CEO to provide quarterly reports to Parliament, and these reports are based on licence holder self-reporting.

4.46 Depending on its risk ranking and compliance history, a licence holder may be required to report to ARPANSA quarterly or annually. In November 2012, ARPANSA wrote to 18 licence holders notifying them they were now only required to report annually to ARPANSA. ARPANSA advised licence holders that this decision is based on the low hazard of sources held, inventory stability and compliance history. This initiative, which promises to reduce the compliance burden on entities, could be given a firmer basis by more directly aligning the reduced reporting arrangements with agency risk rankings; consistent with the proportionality principle.[124] At present, reduced reporting has been granted to four licences with a 'medium' risk ranking.

4.47 The ANAO's 2005 audit found that ARPANSA's reporting requirement guidelines did not include all the relevant information required to be provided by licence holders, and recommended that ARPANSA strengthen its reporting guidelines.[125] ARPANSA's current regulatory guide, *Reporting Compliance*, does set out the detailed and procedural requirements for agency reporting to ARPANSA, as an aid to transparency and entities seeking to comply with those requirements. Licence holders are required to report the following types of information:

- any accidents, incidents, abnormal occurrences or unusual personal monitoring results;
- the acquisition, disposal or transfer of any sources;
- any corrective action taken as a result of an inspection;

123 This is done through *ARPANSA's Reporting Compliance Regulatory Guide*.

124 That is, that the reporting burden placed on an entity is commensurate with the risk being reported on.

125 ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*, pp. 71-72.

- any relevant changes during the reporting period that may constitute Regulation 51 or Regulation 52 changes;
- if the plans and arrangements for the licence has been reviewed;
- any actions required by special licence conditions;
- any breaches of licence conditions during the period; and
- any other matters that the licence holder wishes to report.[126]

4.48 The ANAO's 2005 audit also found that ARPANSA did not monitor or assess the extent to which licence holders were meeting their reporting requirements, and there was no guidance for managing reports or monitoring trends across licensees.[127] To address these issues, ARPANSA has developed a standard operating procedure for managing licence holder quarterly reports, which includes recording of reports that are received and checklists to assess the reports. However, insights gained across the quarterly reports are not centrally recorded and trends across licensees are not identified, a limitation identified in the previous ANAO audit.[128]

Non-compliance and enforcement

4.49 When non-compliance is found, the responsible agency and the regulator must initiate action to address the risks posed by the non-compliance, with the seriousness of the non-compliance and the regulated entity's compliance history informing the regulatory response.[129] Part of a regulatory agency's role is to take action to address non-compliance.

4.50 The ANAO's 2005 audit found that ARPANSA did not have structures in place to manage its enforcement response, including a process for escalating its enforcement response. The ANAO recommended that ARPANSA: develop internal systems, policies and procedures to support a consistent approach to defining non-compliance and breaches; have a robust framework to support a

126 As noted in paragraph 4.11, due to the complexity of their quarterly report, and being a high risk licence holder, ANSTO OPAL and ARPANSA conduct quarterly meetings to discuss the quarterly report.

127 ANAO Audit Report No.30 2004-05, *Regulation of Commonwealth Radiation and Nuclear Activities*, pp. 71-73.

128 ARPANSA informed the ANAO in March 2014 that licence holder reports are now uploaded into LAD which will allow analysis of data.

129 ANAO Better Practice Guide—*Administering Regulation*, March 2007, Canberra, p. 63.

graduated approach to enforcement action; and maintain a database of non-compliance and enforcement actions taken and their resolution.[130]

4.51 ARPANSA's *Regulatory Guide: Graded Response to Non-compliance*, first published in 2012, states that it provides for a graded, risk-based approach to non-compliance, with the response to any non-compliance commensurate with its severity. The Guide lists a number of matters to be considered when determining a response to non-compliance, such as how the non-compliance was discovered, the safety significance, and cooperation of the licence holder.[131]

Enforcement and reporting provisions under review

4.52 Under the ARPANS Act, a controlled person—a Commonwealth entity or contractor—faces a maximum penalty, on conviction, of 2000 penalty units (currently $340 000) for not obtaining a licence when required or not complying with the conditions of the licence.[132] Further, Section 41 of the ARPANS Act allows the CEO to give written directions to a person/licence holder to take steps to rectify a non-compliance within a specified time period if they believe that it is necessary to protect people or the environment (with a maximum penalty, on conviction, of 30 penalty units). Should a licence holder fail to act on the written directions, the CEO may arrange for the steps to be taken to rectify the non-compliance, with the licence holder liable for any costs. Sections 43 and 44 of the ARPANS Act provide for injunctions to be issued or for items to be forfeited (court action). Additionally, ARPANSA has devised its own graded regulatory response and enforcement options to address non-compliance (see paragraph 4.51).

4.53 The ARPANS Act requires the CEO to include details of any breach by a licence holder in the relevant period in ARPANSA's quarterly and annual reports to Parliament. The Act does not provide the CEO of ARPANSA any discretion in determining what constitutes a breach, or whether a breach should be publicly reported. Currently, ARPANSA reports all breaches, but

130 ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*, pp. 80-82.

131 Other considerations that are taken into account are: the impact on the regulatory process, the level of intent, any mitigating circumstances, any corrective actions taken to address the non-compliance, and any impact on the community and/or the environment.

132 Section 4AA of the *Crimes Act 1914* sets the value of a penalty unit in Commonwealth law. As at October 2013 the penalty was $170 per unit.

does not specifically identify the entities responsible for breaches with 'minor or no safety implications'. ARPANSA's submission to the ARPANS Act review proposed that the legislation only require breaches with significant safety implications to be reported. The review report, however, recommended that the ARPANS Act should not be amended; instead ARPANSA should include more detail about the nature of the breach, the significance of the breach and the action taken to rectify the breach in its public reporting.

Most breaches have no or minor safety implications

4.54 ARPANSA has recently adopted a graded approach to reporting breaches to Parliament, with a view to reporting at a level of detail commensurate with the severity of the breach.

4.55 Table 4.4 shows the breaches as reported in ARPANSA's annual reports for the period 2009–10 to 2012–13.

Table 4.4: Breaches as reported in ARPANSA's annual report

	Annual target	Result 2009–10	Result 2010–11	Result 2011–12	Result 2012–13
Breaches	<20	31	23	2	5

Source: ARPANSA Annual Report 2011—12 and ARPANSA Annual Report 2012–13, p. 75.

Note: During 2011–12 ARPANSA changed its policy for reporting breaches (see paragraph 4.53). Breaches that ARPANSA considers minor (for example failure to comply with a licence condition such as the colour of a light or wording of a sign, where there are no safety implications) are no longer counted in these aggregated totals. As a result, the number of breaches reported from 2011–12 decreased significantly and this number cannot be accurately compared with past numbers. There was one minor breach recorded for 2011–12.

4.56 Of the breaches reported in the period 2009–10 to 2011–12, approximately 86 per cent related to a failure to comply with licence conditions. Approximately 27 per cent of these were for failing to submit a quarterly report on time or not keeping the Source Inventory Workbook up to date.[133] During the period ARPANSA also identified nine breaches for agencies possessing sources not authorised by a licence. In 2012–13, ARPANSA reported five breaches with safety implications in its annual report, four of

133 The ARPANS Act requires that licence holders are to provide their quarterly report, in a form acceptable to the CEO, within 28 days of the end of each quarter. The amended standard licence conditions add that reports must be provided within 28 days of the quarter 'or such other period as determined by the CEO of ARPANSA'. ARPANSA informed the ANAO that it has amended a standard licence condition so that agencies are not automatically breached if they deliver reports late, as this was a large source of breaches over time. This change, approved in June 2012, allows for unexpected delays in the submission of quarterly reports.

these were for a breach of licence conditions, while one entity was breached for possession of equipment without the appropriate licence. Eight minor breaches were also recorded in 2012–13.

4.57 Coercive enforcement responses, for example written directions or penalties, has not been a feature of ARPANSA's approach to regulation, which has focused on taking administrative action, in particular written letters, and public reporting. Between 2009–10 and 2012–13 no enforcement action was required for any breach as ARPANSA considered that appropriate corrective action had being taken by the licence holder. ARPANSA informed the ANAO that it has never suspended a licence or cancelled a licence because of non-compliance. Action taken in response to non-compliance in the past has included formal written notifications of breaches, and the public reporting of non-compliance.[134] ARPANSA does not have a set process for following up breaches, and ARPANSA informed ANAO that a licence holder that receives a breach may receive additional inspections, depending on the severity of the breach and if there is a change to their risk ranking. Further, licence holders are also required to report on corrective action undertaken to remediate issues identified during inspections as part of their quarterly reports.[135]

Self regulation

4.58 As well as being the radiation and nuclear regulator, ARPANSA itself holds one facility licence (which covers three facilities) and two source licences which are used for its scientific and advisory activities, including in some cases on a fee-for-service basis.[136] All the ARPANSA licences are currently ranked as a medium risk. In the past ARPANSA's regulatory branch inspected these licences, and Table 4.5 below records the number of inspections that have been conducted on ARPANSA's licences.

134 ARPANSA informed ANAO that the strongest enforcement action taken to date was the issuing of a written Direction in 2004. This was withdrawn a week later following representations by the licence holder.

135 Ad hoc investigations are also undertaken from time-to-time. One such case, involving ARPANSA's regulation of ANSTO, is discussed in Appendix 5.

136 One source licence and the facility licence are held by the Medical Radiation Services Branch, the other source licence is held by the Radiation Health Services Branch. Chapter 1 provides an overview of the functions of each branch.

Table 4.5: Number of inspections conducted on ARPANSA's licences

Licence	Date of inspection		
Medical Radiation Branch (S0003) [Licence issued September 2002]	August 2005	May 2010	May 2012[(A)]
Non-ionising Radiation Branch (S0002) [Licence issued September 2002]	June 2004	May 2010	
Linear Accelerator and Teletherapy Laboratory (F0046) [Licence issued November 2002]	June 2007	June 2009	

Source: ANAO analysis of ARPANSA documentation.

Note A: This inspection was conducted by Queensland Health—see paragraph 4.63. All other inspections were conducted by ARPANSA.

4.59 ARPANSA has received two breaches, one in 2009 for not having an up-to-date source inventory workbook and one in 2010 for non-compliance with the conditions of its licence. In 2010, the risk profile for one of ARPANSA's licences was increased because it was determined that a safety culture was lacking. As indicated in the table, there is substantial variation in the number and frequency of the inspections. In ARPANSA's future inspection program—out to 2015—no future inspections of ARPANSA are scheduled.

Avoiding conflicts of interest in ARPANSA's self-regulatory role

4.60 The ANAO's 2005 audit recommended that ARPANSA, as part of strengthening its conflicts of interest management, 'tak(e) action to better manage the conflict of interest arising from its regulatory role in respect of its own sources and facilities'.[137] The 2007 IRRS mission also suggested that:

> The CEO of ARPANSA should consider an expedited implementation of the arrangement that has been put in place to utilise inspectors from the State of Victoria to inspect ARPANSA's own compliance with the ARPANS Act in relation to its regulated sources and facilities.[138]

4.61 To improve the integrity of its self-regulatory role, in 2007 ARPANSA held initial discussions with the Victorian Department of Human Services

137 ANAO Audit Report No. 30 2004-05, *Regulation of Commonwealth Radiations and Nuclear Activities*, p.42.

138 International Atomic Energy Agency, *Integrated Regulatory Review Service (IRRS)—Full Scope—to The Commonwealth Government of Australia—Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)*, 2007, p. 26.

(DHS) to conduct inspections of ARPANSA's sources and facilities and provide advice on compliance issues. This agreement did not eventuate and DHS Victoria did not undertake any inspections of ARPANSA.

4.62 In November 2011, ARPANSA signed a MOU with Queensland Health (QLD Health) (Radiation Health Unit) to undertake regulatory inspections of ARPANSA facilities. The MOU provides for up to six inspections to be conducted over the two years of the agreement. The MOU was due to expire in October 2013 and ARPANSA informed the ANAO that it intended to extend it for a further two years and include reviews of ARPANSA licence applications.

4.63 To date, QLD Health has conducted only one inspection of ARPANSA, in May 2012, in conjunction with ARPANSA regulatory officials. The inspection report listed 33 recommendations.[139] The detailed inspection report noted that, 'it was questionable whether the licence holder has adequate systems in place to determine whether a breach has occurred'. The report suggested ARPANSA, as the licence holder, conduct its routine internal inspections in a similar way to how it would conduct external inspections as a regulator.

4.64 There have been no further inspections of any ARPANSA licence, either by ARPANSA's Regulatory Services Branch or QLD Health, since this May 2012 inspection. ARPANSA informed the ANAO that there had been difficulties engaging QLD Health to conduct further inspections, potentially due to staffing shortages in QLD Health. As at September 2013 only one independent inspection has been conducted of ARPANSA, notwithstanding the benefit of periodic independent inspections having been identified in the ANAO's 2005 audit report and the 2007 IRRS report. The external review of ARPANSA's licence applications would further strengthen arrangements to manage potential conflicts of interest.

139 A summary version of the inspection report is available on the ARPANSA website. See Queensland Health, *Inspection Report—Summary: Independent inspection conducted by inspectors from Queensland Health under a Memorandum of Understanding with ARPANSA,* May 2012, Available at <http://www.arpansa.gov.au/pubs/regulatory/inspections/Q001-S.pdf> [accessed 24 October 2013].

Recommendation No.4

4.65 To improve transparency and support continuing public confidence in the regulation of licences held by ARPANSA, the ANAO recommends that:

(a) inspections of its own licences are conducted periodically using inspectors from a state or territory radiation regulator; and

(b) provisions are made for independent review of other regulatory decisions relating to ARPANSA's own licences, particularly licence applications and Regulation 51 approvals.

ARPANSA response:

4.66 *ARPANSA agrees and accepts the recommendation and will look to advance the frequency of the rigorous self-inspection program and will also continue to participate in the newly developed holistic safety approach. ARPANSA will explore options for a broader base of suitable organisations for independent review of ARPANSA's own licences (beyond the current agreement with Queensland Health).*

Conclusion

4.67 A key function of a regulator is the ongoing monitoring of regulated entities' compliance with regulatory requirements and, where required, enforcement in cases of non-compliance. A risk-based monitoring framework can help regulators provide assurance to the public and stakeholders that regulated entities are meeting their compliance obligations, while more efficiently targeting the regulator's available resources.

4.68 Regular reporting by entities, combined with a varied program of inspections[140] are key regulatory tools used by ARPANSA to verify licence holders' compliance with their licence conditions. ARPANSA has developed policies and procedures to support its inspection staff as well as published guidance for licence holders on reporting and inspection requirements. In 2012–13 ARPANSA conducted 59 inspections, with ANSTO being the primary agency targeted for inspections as it operates more than half the licenced facilities regulated by ARPANSA.

4.69 While ARPANSA's policy documentation establishes the expectation that its inspection program should be risk-based, the ANAO's examination of

140 Inspections can be planned, incident-based or unannounced.

the inspection program indicated that ARPANSA could not always demonstrate a clear linkage between the risk associated with the licence and the frequency and scheduling of inspections. As discussed earlier (see paragraph 24), the absence of guidance on how to apply the risk ranking of licences in the context of the ongoing licence management and monitoring regime, may have contributed to the lack of alignment between assessed risk and the inspection approach adopted by ARPANSA. In addition, the ANAO found that the use of unannounced inspections, which are intended to give ARPANSA a better understanding of the day-to-day operations of licence holders and to follow up on any incidents or intelligence, is driven mainly by geographical convenience rather than risk. To enhance its risk-based approach to regulation, ARPANSA should establish a more direct link between risk and the inspection program.

4.70 A challenging area, acknowledged by ARPANSA, is identifying unlicenced activities. These are sources or facilities that ARPANSA is unaware of, but which are nonetheless required to be regulated under the ARPANS Act and Regulations. ARPANSA's regulatory officers are expected to be familiar with licensees and able to identify any additional sources that require licensing. ARPANSA also relies heavily on entities self-reporting the acquisition of relevant equipment. There is scope for ARPANSA to periodically approach regulated entities to reinforce their obligations under the ARPANS Act, as a means of proactively seeking to identify unlicenced sources.[141]

4.71 ARPANSA continues to be both a regulator and a licence holder. The ANAO recommended in 2005 that ARPANSA take action to better manage this conflict of interest. Only recently, in 2011, did ARPANSA formally enter into an arrangement for Queensland Health to undertake independent inspections of ARPANSA's compliance with its own licence conditions.[142] To date, only one external inspection has been conducted, in May 2012, which made

141 Another potential source of unlicensed dealings are legacy sites—sites that existed prior to the introduction of the ARPANS Act in 1998. Regulating legacy sites can be problematic as they may contain mixed sources of contamination and responsibility for managing the site may therefore be split between different authorities. For example, the Little Forest legacy site near Lucas Heights contains both radiological and non-radiological material such as heavy chemicals. Additionally, ARPANSA informed the ANAO that the ARPANS Act—currently under review—does not contain explicit provisions for licensing a legacy site.

142 ARPANSA held initial discussions with the Victorian Department of Human Services in 2007 about the conduct of such inspections, but an agreement was not entered into.

33 recommendations relating to a source licence held by ARPANSA's Medical Radiation Services Branch. A program of independent reviews of ARPANSA licences and the facilities they cover, as well as regulatory decisions regarding its own licence applications and its own Regulation 51 requests, would strengthen confidence in ARPANSA's compliance with licensing conditions and its arrangements for managing its conflict of interest as both a regulator and licence holder.

5. Cost Recovery

This chapter examines ARPANSA's recovery of its regulatory costs from regulated Australian Government entities.

Introduction

5.1 In 2002, the Australian Government adopted a formal cost recovery policy to improve the consistency, transparency and accountability of Commonwealth cost recovery arrangements and promote the efficient allocation of resources. The *Australian Government Cost Recovery Guidelines* (the Guidelines) provide a framework to assist agencies in designing and implementing cost recovery arrangements that comply with the cost recovery policy.[143] Key points made in the Guidelines include:

- Agencies should set charges to recover all the costs of products or services where it is efficient to do so or for explicit government policy purposes.
- Any charges should reflect the costs of providing the product or service.
- All recovery arrangements need clear legal authority.
- Cost recovery should be undertaken on an activity basis where possible.[144]

5.2 The Guidelines state that many arrangements are not considered cost recovery for the purposes of the policy. One arrangement specifically excluded is 'any form of intra-agency or inter/intra-government charging'.[145] As a consequence, ARPANSA is not formally required to comply with the Guidelines. However, where Australian Government agencies have in place cost recovery arrangements with other government agencies, the Guidelines state that: 'these guidelines should be complied with to the greatest possible

143 Department of Finance and Administration, *Australian Government Cost Recovery Guidelines*, Finance Circular No.2005/09, p. 1; Department of Finance and Administration, *Australian Government Cost Recovery Guidelines*, Financial Management Guidance No.4, July 2005, pp. 2, 10.

144 Department of Finance and Administration, *Australian Government Cost Recovery Guidelines*, Finance Circular No.2005/09, pp. 2-3.

145 Department of Finance and Administration, *Australian Government Cost Recovery Guidelines*, Financial Management Guidance No.4, July 2005, p. 10.

extent, depending on other government requirements'.[146] ARPANSA has implemented cost-recovery arrangements for its activities, and has informed stakeholders that it follows the Guidelines in order to adopt a best practice approach to cost recovery.[147]

5.3 The introduction of cost-recovery arrangements reflects government intentions as expressed in the November 1998 second reading of the Australian Radiation Protection and Nuclear Safety (Licence Charges) Bill, that:

> Commonwealth entities regulated under the ARPANS Bill should bear the costs of such regulation, ensuring that there will be no additional burden on the Commonwealth or the public purse.[148]

5.4 Cost recovery can help make a regulator more conscious of the costs its services impose on regulated entities. To avoid the risk of cost recovery being considered a tax, cost recovery arrangements need to consider 'linking the charge or charges as closely as possible to the activity or product to be cost recovered'[149], and should be based upon the accurate capture of direct costs and apportioning reasonable indirect costs. Good practice also entails eliminating cross-subsidies, specifically:

- the regulatory function of ARPANSA being subsidised by, or subsidising, ARPANSA's other functions; and
- some regulated entities cross-subsidising other entities.

5.5 Figure 5.1 illustrates a normative model of the requirements and benefits of an effective cost recovery system in ARPANSA.

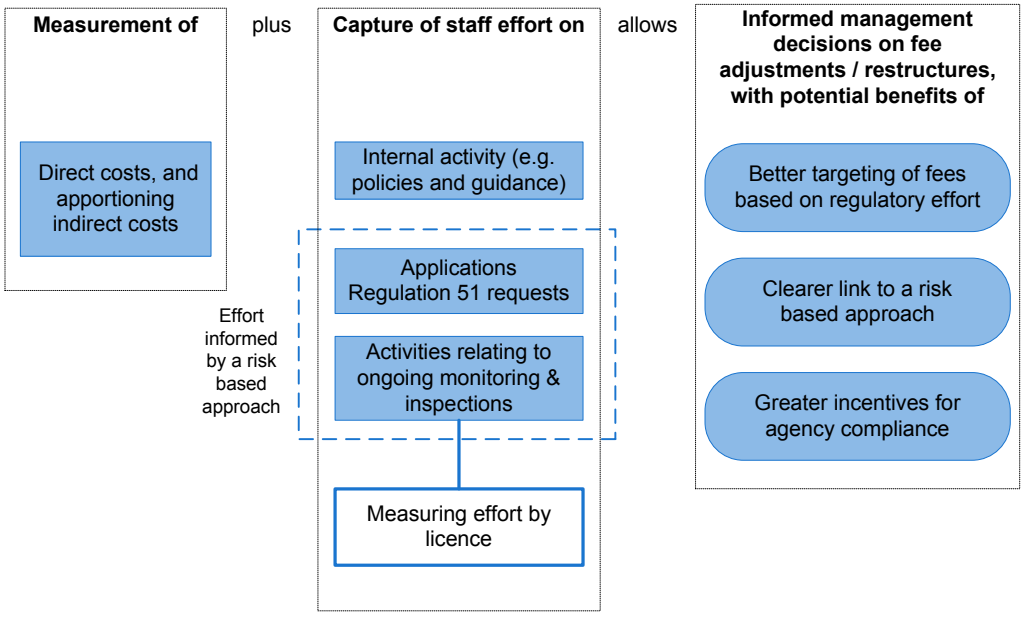
146 Ibid, p.11.

147 The small scale of ARPANSA's cost recovery activity has meant that it has not been required by the Department of Finance to prepare Regulation Impact Statements or Cost Recovery Impact Statements in accordance with the Guidelines. For further information on these Statements, see Department of Finance and Administration, *Australian Government Cost Recovery Guidelines*, Financial Management Guidance No.4, July 2005, pp. 7, 52, 54, 55.

148 House of Representatives Hansard, 11 November 1998, p. 90.

149 Department of Finance and Administration, *Australian Government Cost Recovery Guidelines*, Financial Management Guidance No.4, July 2005, p. 40.

Figure 5.1: A normative approach to effective cost recovery in ARPANSA



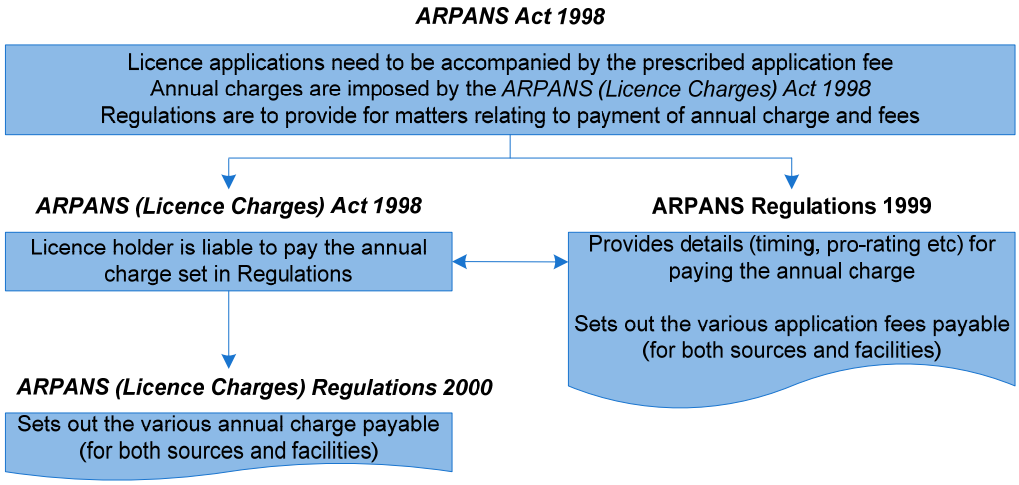
Source: ANAO.

ARPANSA's framework for cost recovery

5.6 The legal framework for ARPANSA to cost recover for its regulatory activities is established by the ARPANS Act, as illustrated in Figure 5.2. The two sources of revenue are:

- licence application fees, for processing and assessing an application for a licence; and
- an annual charge for each licence, for ARPANSA's ongoing management of licences.

Figure 5.2: Statutory framework for ARPANSA's cost recovery



Source: ANAO.

5.7 The fees and charges payable depend upon:

- the facility licence stage; and
- for a source:
  - the type of source (the Regulations organise sources into three groups for fee purposes, broadly based on their hazard); and
  - the number of sources held at the same location.

5.8 The ANAO's 2005 audit found that ARPANSA did not have a documented cost recovery policy or other guidance addressing cost recovery, and recommended that ARPANSA develop such a policy.[150] ARPANSA first issued its *Cost Recovery Policy* in March 2006, which remains in place without revision. This brief document states that ARPANSA is committed to full cost recovery, including that the arrangements:

> are linked as closely as possible to the regulatory activity required by the hazard represented by the activity being carried out by the licence holder.

5.9 The policy states that ARPANSA will establish and maintain a central regulatory management information system, and a time tracker to record the amount of staff time allocate to each licence holder.

150 ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*, pp. 45, 50.

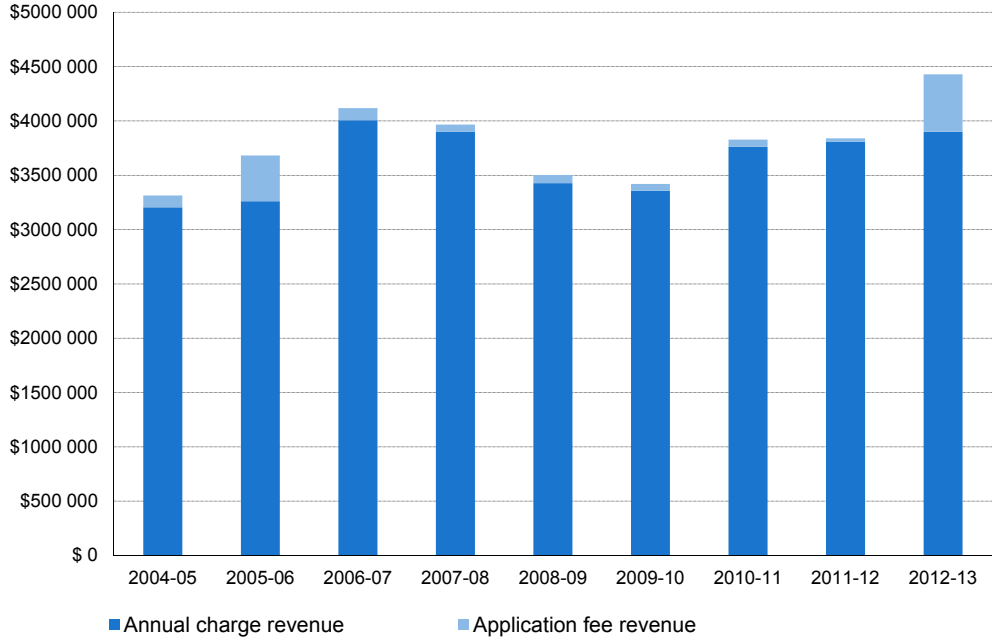
5.10 Further, ARPANSA's 2011 *Statement of Regulatory Policy* states that, in order to operate in a cost-effective manner, ARPANSA will:

> Ensure that the costs of regulation are measured and allocated to licence holders on a fair and equitable basis and that there are regular reviews to ensure that regulatory costs are appropriate.

Income from fees and charges

5.11 ARPANSA's income from licence application fees and annual charges over time are presented in Figure 5.3.

Figure 5.3: ARPANSA's regulatory income, 2004–05 to 2012–13



Source: ANAO analysis of ARPANSA financial statements. Note that these figures do not include income from ARPANSA's own licences.

5.12 The Figure 5.3 shows that the annual charge is the primary source of cost recovery revenue from regulated agencies[151]: in 2011–12 application fees constituted only $0.03 million of the $3.84 million total, and $0.53 million of the $4.43 million total in 2012–13.

5.13 A breakdown of the annual charge by agency is in Table 5.1.

Table 5.1: Regulatory revenue from annual charge by entity

Licence holder	2011–12 annual charge paid	2012–13 annual charge paid
ANSTO	$2,279,911	$2,303,211
Defence	$793,365	$836,685
CSIRO	$260,907	$271,344
CUSTOMS	$101,871	$107,112
ARPANSA	$68,717	$75,997
ANU	$53,864	$56,020
Other licences	$298,608	$325,936
Total	**$3,857,243**	**$3,976,305**

Source: ARPANSA analysis.

5.14 The table shows that over three quarters of the annual charge amount is collected from ANSTO and Defence.

5.15 The regulatory officer/s responsible for each licence calculates the amount owed based on the number and type of facility licences held, and the agency's most recent Source Inventory Workbook for the number and type of sources. ARPANSA informed the ANAO that these calculations are verified by another officer, although this is not documented. ARPANSA's finance area will then use these figures as the basis for invoicing licence holders.[152] Calculating charges for ANSTO, Defence and CSIRO is more straightforward, as they pay a flat source fee regardless of the number and type of sources.

151 ARPANSA also earns revenue from its fee-for-service and other non-regulatory services. In 2011–12, ARPANSA generated a total of $10.55 million in own-source income (excluding the government's budget appropriation), $3.84 million of which came from licence fees. The other $6.71 million came from scientific services such as the Personnel Radiation Monitoring Service (PRMS), and operation and maintenance of monitoring facilities as part of the Comprehensive Nuclear-Test-Ban-Treaty (CTBT)—these other services are discussed in chapter 1.

152 All annual charges are scheduled to be collected before 31 July of that financial year, or 30 days after the issuing of a new licence. The Regulations contain provisions for pro-rating (should a licence not be held for an entire financial year) and refunding of the annual charge if required.

Application fees and annual charges align despite different levels of effort involved

5.16 The ANAO's previous audit noted that ARPANSA's fees and charges were not based on robust analysis of the cost of regulation.[153] This situation has persisted to the present, as demonstrated by a comparison of the application fee and annual charge for each source and facility (excluding nuclear installations), which are exactly the same—see Table 5.2 for two examples.

Table 5.2: Illustration of alignment between application fee and annual charge in 2013–14

Item	2013–14 Application fee	2013–14 Annual charge
Prescribed radiation facility example: An irradiator containing more than 10^{13} Bq of a controlled material but not including shielding as an integral part of its construction	$11 967	$11 967
Source example: 6 Group 3 sources (for example, a sealed source for industrial radiography)	$15 956	$15 956

Source: ARPANS Regulations 1999 and ARPANS (Licence Charges) Regulations 2000.

Note: A becquerel (Bq) is the unit of radioactivity, equal to one disintegration per second.

5.17 The precise alignment of application fees and annual charges raises questions about the robustness of ARPANSA's approach to cost recovery, as it is unlikely that the rate of effort involved in assessing an application fee is identical to that of annual monitoring of a licence.

Establishing the cost of ARPANSA's regulatory role is based on outdated data

5.18 The previous ANAO audit found that ARPANSA's cost recording practices are not activity based and do not support recovery of all regulatory costs.[154] In this audit, the ANAO found that ARPANSA still did not have an activity based approach to recording its costs.

153 ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*, p. 49.

154 Ibid, p.47.

5.19 In 2009, ARPANSA developed a detailed spreadsheet to calculate its regulatory costs for 2009–10, based upon:

- regulatory staff salaries and on costs (for example leave and overtime);
- consumables (such as training, photocopying and furniture); and
- overheads.

5.20 However, ARPANSA has not updated this spreadsheet since its development in 2009. While system capacity and resource limitations may inhibit regular review of cost calculation data, it should be subject to periodic review, and should be reviewed, if possible, in conjunction with other relevant agency reviews. ARPANSA informed the ANAO that the spreadsheet is evidence of its calculations of regulatory cost, and post 2009–10 the regulatory cost was derived by using the 2009–10 data and applying the same annual percentage increases used to amend the Regulations (see paragraph 5.25). Given the age of the original data inputs, the significant organisational restructure in May 2011, and subsequent policy and practice changes effected by the Regulatory Services Branch since the re-structure, it may be problematic to rely on this approach to determine contemporary cost estimates.

5.21 The ANAO's 2005 audit also found that the cost of staff from other areas of ARPANSA that engage in or contribute to regulatory work is not attributed to the regulatory function.[155] Similarly, ARPANSA's current approach does not account for the involvement of staff from its non-regulatory areas in regulatory work, particularly licence applications and inspections. As a consequence, ARPANSA's non-regulatory activities continue to cross-subsidise its regulatory functions.

ARPANSA's regulatory function is subsidised by ARPANSA's other functions

5.22 The ANAO's previous audit found that, between 2000–01 and 2003–04, there was an under-recovery of approximately $1.55 million of regulatory costs.[156] Based on the cost recovery datasheet, estimates of regulatory expenses and under recovery since 2008–09 are listed in Table 5.3.

155 Ibid, p. 47.
156 ibid, p.48.

Table 5.3: ARPANSA's regulatory expenses and revenue

Year	Estimated expenses[(A)]	Revenue	Estimated under recovery (%)
2008–09	$4,740,000	$3,502,000	$1,238,000 (26%)
2009–10	$4,257,000	$3,420,000	$837,000 (20%)
2010–11	$4,449,000	$3,828,000	$621,000 (14%)
2011–12	$4,600,000	$3,839,000	$761,000 (17%)
2012–13	$4,784,000	$4,429,000	$355,000 (7%)
5 year totals	**$22,830,000**	**$19,018,000**	**$3,812,000 (17%)**

Source: ANAO analysis of ARPANSA cost recovery spreadsheet and annual financial statements.

Note A: Estimated expenses for 2008–09 to 2010–11 were included in the regulatory cost spreadsheet (the 2009–10 and 2010–11 figures were draft projections). To establish estimated expenses for future years, the indexation increase for the financial year (see paragraph 5.25) was applied to the 2010–11 estimated expenses total.

5.23 In October 2013, in the course of this audit, ARPANSA undertook a preliminary analysis of its 2012–13 expenses using a simplified costing model. It estimated that its regulatory expenses were significantly higher than the estimates in Table 5.3, as there had been under-counting of regulatory staff costs and 'with these additional costs taken into account it appears the under recovery is greater than previously reported'. ARPANSA informed ANAO in December 2013 that it has begun a more detailed review of its regulatory cost recovery model and costing inputs.

5.24 In any event, the discrepancy between estimated expenses and revenue received demonstrates that cross-subsidisation continues within ARPANSA, with the regulatory function being subsidised by ARPANSA's other functions.

Fees and charges have increased over time, particularly in 2010

5.25 Between 2005 and 2013, there were four separate indexation increases to the various application fees and annual charges (totalling 24.7 per cent) in order to recover ARPANSA's increased labour costs, which has had a cumulative effect of increasing these costs by 26.6 per cent[157]:

- a 14 per cent increase in 2010 (the first increase since 2004);

157 A one-off increase to one type of facility licence is not captured in the bullet points: in 2007, the fee for possessing or controlling a nuclear reactor (facility licence) was increased fivefold (from $21 000 to $105 000) on the basis of: the costs of the public submission process, and the engagement of an international peer review team to assist the CEO take into account international best practice in radiation protection and nuclear safety, as required by the Regulations.

- a 3.4 per cent increase in 2011;
- a 4 per cent increase in 2012; and
- a 3.3 per cent increase in 2013.

5.26 Stakeholders were consulted on the 2010 increase, but were not consulted regarding later changes. ARPANSA was informed by the (then) Department of Finance and Deregulation's Office of Best Practice Regulation that such increases, based on indexation, are machinery in nature, and do not require consultation (in accordance with Section 18(2a) of the *Legislative Instruments Act 2003*).

5.27 The explanatory statements for the 2010 increases stated that the 14 per cent increase represented 'only a part of the 22 per cent actual cumulative wage cost increases from 2005 to 2009'. ARPANSA informed the ANAO that the fees and charges were not increased to take into account the 22 per cent real cost increase because certain regulated entities were concerned at the prospect of such a substantial increase. ARPANSA therefore decided to absorb the eight per cent difference between the 22 per cent actual cost increase to ARPANSA and the 14 per cent increase to fees and annual charges.

5.28 The explanatory statement for the 2010 increases also stated that a full review of ARPANSA's regulatory costs, to address an entity's concerns, would commence in 2010–11. Additionally, ARPANSA informed the then Parliamentary Secretary in 2010, when seeking approval for the 14 per cent increase, that 'a full cost recovery review will commence in 2010–11'. However, this review did not commence until 2012 (discussed at paragraph 5.35).

Application fees were not reviewed

5.29 As noted earlier, licence application fees account for a small fraction of ARPANSA's regulatory cost recovery. Because of this, ARPANSA elected not to include them in the 2012–13 cost review, despite identifying the following 'structural anomalies' with application fees:

- some fees appeared to be quite large given the expected review and approval, while others seemed 'remarkably low'; and
- licence modifications—particularly Regulation 51 requests—are not charged for even though, according to ARPANSA, 'in many cases these applications to change a licence are as time consuming and require a similar level of assessment as many new licence applications'.

5.30 As the cost of processing applications or Regulation 51 requests is not tracked, ARPANSA is unable to quantify these discrepancies. As highlighted in paragraph 5.16 and Table 5.2, the precise alignment between prescribed radiation facility and source application fees with their respective annual charges indicates that ARPANSA's cost recoveries do not relate to the cost of services.

5.31 In 2013, ARPANSA trialled a tool allowing the time taken in days to process applications and Regulation 51 requests to be recorded, for use in reporting against its time performance indicators. A more precise tool, recording staff hours, additional costs (such as site visits) and a proportion of overheads would provide a stronger basis for informing future management decisions on charging for Regulation 51 requests and the alignment of regulatory fees and charges.

Annual charge arrangements in the Regulations are not structured to reflect regulatory effort

5.32 The arrangements set out in the Licence Charges Regulations for levying annual charges is based on the number and type of items in each agency's inventory (see also paragraph 5.7). This approach limits more accurate targeting of the annual charges for sources based on regulatory effort. For the three agencies that pay the largest annual charges—Defence, ANSTO and CSIRO—the Regulations establish an alternative arrangement, involving a flat fee which covers the annual charges relating to their source inventory.

Annual charge payment testing

5.33 The ANAO conducted a small sample test of annual charge payments, in selected entities for the period 2011–12 and 2012–13. The aim was to confirm that payments occurred in accordance with the Regulations, specifically:

- the amount ARPANSA invoiced the licence holder was correct;
- the entity paid the correct amount on time; and
- pro-rating was applied where relevant (under the Regulations, the CEO may decide to pro-rate the annual charge amount if a licence is not held for a whole financial year).

5.34 For five of the six entities in the sample, the correct amounts (not including any pro-rating, discussed below), based on the entity's Source Inventory Workbook, were invoiced and paid. In one case, the amount

invoiced did not align with the relevant Source Inventory Workbook for 2011—12. The ANAO's sample results also showed a pattern of late payment: almost half the payments were received after the statutory time of 31 July, ranging from two days to almost three weeks late.[158] Four new licences were issued during the period for the sample that could have been subject to pro-rating. The ANAO identified an inconsistent approach to pro-rating: two licences were pro-rated, one was not, while in one case no annual charge was applied due to an apparent administrative oversight.[159]

2012—2013 review of cost recovery

5.35 In January 2012 ARPANSA initiated an internal review of its cost recovery arrangements. Regulatory staff were surveyed to estimate the time they spent by task (such as application assessment and inspections) and by licence holder for the previous 12 months. A summary of the survey results is shown in Table 5.4 (for tasks) and Table 5.5 (for licence holders).

5.36 There was a considerable discrepancy in the survey results relating to how much time staff estimated they spent on internal/non-licence holder activity: staff apportioned twice as much effort to such activity when asked to estimate time spent by task (40 per cent, as shown in Table 5.4), compared to time spent by licence holder (19 per cent, as shown in Table 5.5).

158 Late payments were also made for licence applications—see paragraph 3.37.

159 ARPANS Regulation 55 provides that an annual charge for a new licence must be paid within 30 days after the licence was issued. The CEO may decide to pro-rate the amount of the annual charge for a licence not held during the whole of a financial year (in proportion to the number of months the licence is held during the year).

Table 5.4: Estimated ARPANSA staffing time spent by task

Task	% of total staff time	Full time equivalent
Licence applications	7	1.3
Regulation 51 requests	8	1.4
Ongoing monitoring and inspection activity	25	4.6
Imports and exports	6	1
Quarterly and annual reports to Parliament	8	1.4
Other services (such as Reg 52 notifications, requests for disposal of equipment)	6	1.1
ARPANSA internal activity, such as developing and maintaining documentation, training and education, and liaising with other regulatory bodies	40	7.2
TOTAL	**100%**	**18**

Source: ANAO analysis of ARPANSA information.

Note: Totals may not add up because values have been rounded.

5.37 Table 5.4 shows that assessing Regulations 51 requests represents a similar commitment of total staff time as ARPANSA's work on licence applications; however Regulation 51 work is not cost-recovered. Not recovering these costs means that ARPANSA is either not fully cost recovering all its regulatory work, or is cross-subsidising it through other fees and charges.[160] The non-recovery of Regulation 51 costs encourages regulated entities to advise ARPANSA of all changes to licences; it may also create incentives to seek Regulation 51 approvals in lieu of paying for a new licence application.

5.38 The licence holder survey listed 19 entities specifically and put the other licence holders into one category. Staff did not allocate any time to nine of the 19 entities listed. Table 5.5 highlights the six entities representing the highest proportion of staff time. The results have some linkage to total cost, as ANSTO, Defence and CSIRO have the highest annual charges, although ARPANSA itself is a large financial contributor and was not on the list while DSEWPAC—now the Department of the Environment—is proportionally a small financial contributor.

160 Only a small number of entities regularly apply for Regulation 51 requests, with ANSTO and CSIRO accounting for almost three quarters of total Regulation 51 requests between July 2007 and June 2013.

Table 5.5: Estimated ARPANSA staffing time spent by licence holder

Licence holder	% of total staff time	Full time equivalent
ANSTO (OPAL, Health and other licences)	37.7	6.8
CSIRO	8	1.4
Defence	5.9	1.1
ANU	3.9	0.7
Customs	2.6	0.5
DSEWPAC	2.4	0.4
TOTAL—top six licence holders	**60.5%**	**10.9**
Other Licence holders	20.6	3.7
TOTAL—all licence holders	**81.1%**	**14.6**
Time spent on non-licence holder activity	18.9	3.4
TOTAL	**100%**	**18**

Source: ANAO analysis of ARPANSA information.

5.39 Using the time by licence holder data (the basis of Table 5.5), and spreading non-licence holder activity proportionally across all licence holders, ARPANSA compared the results with the annual charge fees to identify discrepancies between effort and cost (based on the 2011–12 charge). The results are reproduced in Table 5.6.

Table 5.6: ARPANSA's estimates of licence holder burden and revenue

Licence holder	Agency's % of total 2011–12 annual charges paid	% of total ARPANSA staff time spent on agency
ANSTO	60	47
Defence	21	7
CSIRO	7	10
Customs	3	3
ARPANSA	2	1
ANU	1	5
Other	7	27
Total	**100%**	**100%**

Source: ARPANSA information.

Note: Totals may not add up because values have been rounded.

5.40 Informed by the 2012 review, ARPANSA considered that a revised approach to annual charge arrangements, outlined below, would eliminate cost under-recovery and reduce the level of cross-subsidy across licence holders:

- leave facility licence annual charges unchanged;
- reduce Defence's and ANSTO's flat source fee costs—Defence's by 33 per cent over the two years (from the 2012–13 amount to the 2014–15 amount), and ANSTO's by 19 per cent; and
- triple all other source licence annual charges.

5.41 As noted above, ARPANSA wrote to all licence holders in March 2013 indicating that 'larger licence holders' were cross-subsidising the regulatory costs of the smaller licence holders, paying approximately 128 per cent of their regulatory costs, while smaller licence holders—small in terms of regulated inventory, not necessarily overall agency size—were only paying 26 per cent of their costs. The letters advised licence holders of ARPANSA's intentions and calculations, the cost changes for the particular agency, and invited comment. ARPANSA informed the ANAO that, in response to—the largely negative—stakeholder feedback on the proposal, the full cost increases would be gradually rolled out over three years rather than the intended two years, with the first increase to occur in 2014–15. Transitioning large increases in fees and charges over time allows Commonwealth licence holders to better plan and budget for their costs into the future, especially in a constrained resource environment.

5.42 As discussed, in December 2013, in the course of this audit, ARPANSA also advised the ANAO that it had begun a more detailed review of its cost recovery model and costing inputs.

Conclusion

5.43 When establishing ARPANSA in 1998, the Australian Government's intention was that 'Commonwealth entities regulated under the ARPANS Bill should bear the costs of such regulation, ensuring that there will be no additional burden on the Commonwealth or the public purse'.[161] The ARPANS Act authorises ARPANSA to recover costs associated with assessing licence

161 House of Representatives Hansard, 11 November 1998, p. 90.

applications and the annual management of each licence, with the fee or charge dependent upon the type and number of items covered in the licence. Annual management charges constitute ARPANSA's main source of revenue from regulatory activities, which totalled $4.43 million in 2012–13, the majority of which is collected from ANSTO and Defence as the predominant holders of sources and facilities.

5.44 While intra-government charging is excluded from the *Australian Government Cost Recovery Guidelines*[162], ARPANSA has informed stakeholders that it has adopted these Guidelines as a basis for implementing a good practice approach. There are, however, several areas where ARPANSA could adopt improvements to better align its cost recovery arrangements with the Guidelines.

5.45 The ANAO's analysis of ARPANSA's cost recovery datasets indicates that since 2008–09 ARPANSA has under-recovered its regulatory expenses by almost $4 million.[163] Additionally, revenues from its scientific and advisory services functions have been used to cross-subsidise its regulatory function, and ARPANSA's own calculations indicate that there is also cross-subsidisation occurring within the population of licence holders.[164]

5.46 Accurate cost recovery relies on regularly capturing and monitoring both direct and indirect staff effort and other costs for regulatory activities. The Guidelines set out key principles including that agencies undertake cost recovery on an activity basis where possible[165], so as to avoid cross-subsidisation between activities within an agency. However, ARPANSA does not have a method or system for regularly tracking the cost of its regulatory activities, including at an activity level.

5.47 The ANAO conducted a small sample test of annual charge payments, which identified an inconsistent approach by ARPANSA to pro-rating[166] and a

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162 Department of Finance and Administration, *Australian Cost Recovery Guidelines*, Financial Management Guidance No. 4, July 2005.

163 ARPANSA has not updated its methodology for calculating its regulatory cost inputs since 2009.

164 In effect, the higher fees and charges of some licence holders are being used to reduce the fees and charges of other licence holders.

165 The Guidelines advise that: 'any charges should reflect the costs of providing the product or service', p2, and 'as far as possible, the agency should identify costs against particular activities to minimise the need to distribute costs arbitrarily among activities', p. 40.

166 Under the Regulations, there are provisions for the pro-rating of the annual licence charge if the licence has not been held for a full financial year.

pattern of late payment of annual charge fees by agencies. These practices are inconsistent with the requirements of the Regulations, which require all annual charges to be paid before 31 July of that financial year, or, in the case of a new licence, 30 days after the licence is issued.

5.48 ARPANSA has made efforts in recent years to progressively recover more of its identified regulatory costs and minimise the estimated level of cross-subsidisation across regulated entities. In the course of the audit, ARPANSA advised the ANAO that it had initiated a further review of its cost recovery model.

6. Performance Measurement and Stakeholder Relationships

This chapter examines ARPANSA's key performance indicators, and also how regulated agencies provide feedback. The chapter concludes by reviewing ARPANSA's implementation of the recommendations from the previous ANAO audit.

Introduction

6.1 Well-defined performance indicators enable a regulator to measure, monitor and report regulatory performance, as well as providing measures to assess the extent to which they are meeting expectations. One input that affects regulatory performance and stakeholder expectations is the quality of the relationship between a regulator and its stakeholders; an open and responsive relationship can increase the level of voluntary compliance as there is transparency and confidence in the regulatory regime.

Performance measurement and indicators

6.2 Within the Australian Government's Outcomes and Programs framework, entities are expected to measure the performance of programs at two levels:

- through the goods and services produced and delivered under a program (deliverables); and
- the effectiveness of the programs in achieving objectives in support of respective outcomes (KPIs).[167]

6.3 Program deliverables are the goods or services delivered under a program, and key performance indicators should provide information (either qualitative or quantitative) on the effectiveness of programs in achieving objectives in support of outcomes.

6.4 In its Portfolio Budget Statement (PBS) and Annual Report, ARPANSA has one outcome listed—*Protection of people and the environment through radiation protection and nuclear safety research, policy, advice, codes, standards, services and*

167 ANAO Report No.28 2012–13 *The Australian Government Performance Measurement and Reporting Framework*, p. 49.

regulation—and one associated program—*Radiation protection and nuclear safety*. The program is broken down into three objectives, with one objective relevant to ARPANSA's regulatory role: e*nsure effective regulation and enforcement activities*. ARPANSA's regulatory program objective, deliverable and indicator for 2013–14 are outlined in Table 6.1.

Table 6.1: ARPANSA's 2013–14 regulatory performance framework

Program objective	PBS deliverable	PBS KPIs
Ensure effective regulation and enforcement activities	Number of inspections of facilities holding a Commonwealth licence (60)	Number of security incidents involving high activity radioactive sources requiring immediate reporting (<2)
		Number of safety incidents involving Commonwealth users of radiation (<10)

Source: ARPANSA 2013–14 Portfolio Budget Statements.

6.5 The ANAO examined ARPANSA's deliverables and key performance indicators, as presented in its Portfolio Budget Statements and reported in its annual reports, since 2009–10. Table 6.2 outlines the regulatory deliverables and KPIs that have been reported on in the ARPANSA annual reports.[168] ARPANSA has also developed internal indicators which have been published in its annual report since 2011–12. These are efficiency indicators and relate to the average time to assess facility and source licences and Regulation 51 requests.

168 The program objective in 2009–10 and 2010–11 that captured ARPANSA's Commonwealth regulatory role was 'apply best practice regulation, through the revision of regulatory processes and the promotion of national uniformity in radiation protection'.

Table 6.2: ARPANSA's regulatory performance framework over time

Deliverables & KPIs in PBS	Reported results in Annual Report				
	2009–10	2010–11	2011–12	2012–13	2013–14
Deliverables (target)					
Number of inspections of facilities holding a Commonwealth licence (60)	40	49	62	59[(A)]	—
Efficient regulatory processes measured by the sum of the number of: licence application reports, licence amendment assessment reports, licence inspection reports per staff member (>7)	Not used	4	6	Not used	Not used
KPIs (target)					
Relevant and timely advice for Australian Government decision-making measured by Ministerial satisfaction	'Fully achieved'	Not used	Not used	Not used	Not used
ARPANSA will use surveys of Australian Government regulated entities to measure satisfaction with its services. ARPANSA aims to have more than 80 per cent of those surveyed respond favourably to its activities	'Fully achieved'	Not used	Not used	Not used	Not used
Acceptable safety culture observed amongst regulated entities Acceptable safety culture achieved in all observed entities, as assessed by a compliance program, including holistic safety assessments of a representative sample of entities[(B)]	Not used	Not used	'There were no major deficiencies observed'	Not used	Not used
Number of breaches of licence conditions by Commonwealth users (<20)	31	23	2	Not used[(C)]	Not used
Number of serious accidents by Commonwealth users (<5)	0	0	Not reported	Not used	Not used
Number of incidents involving Commonwealth users (up to 2011–12) (<40) Number of safety incidents involving Commonwealth users (since 2012–13) (<10)[(D)]	25	5	4[(E)]	6	—

Source: ARPANSA PBSs and Annual Reports between 2009–10 and 2013–14.

Note A: ARPANSA informed ANAO that for 2012–13, site visits were included in the total number of inspections.

Note B: This indicator was reported under the objective of 'develop and implement regulatory systems', but is directly relevant to ARPANSA's regulatory role.

Note C: ARPANSA reported the number of breaches with safety implications in its 2012–13 annual report (5) despite removing it as a KPI. As discussed in Chapter 4, ARPANSA amended the manner in which they report breaches from 2012–13, with the total number and identity of entities considered to have breaches with minor/no safety implications not reported.

Note D: ARPANSA's 2012–13 PBS stated that 'the target has been reduced from <40 to <10 due to recent trends in the number of incidents'.

Note E: The 2011–12 Annual Report stated that the annual target was <20. This appears to be incorrect.

6.6 Table 6.2 shows that the number of regulatory KPIs reported in ARPANSA's PBS and annual reports declined from five indicators in 2009–10 to one indicator for 2013–14. However, ARPANSA informed the ANAO that it intends to increase the range of KPIs as part of its PBS review process. As noted in Table 6.2, in 2011–12 ARPANSA included in its PBS a qualitative indicator relating to the safety culture of regulated entities, which was not included in later years. ARPANSA's reported result[169] for 2011–12 made no mention of holistic safety assessments of a representative sample of entities. Since the removal of the indicator, ARPANSA has further developed its safety analysis capacity within the Regulatory Services Branch and plans to conduct its first two safety assessments by June 2014.[170]

6.7 Prior to 2011–12, ARPANSA also reported accidents and incidents separately.[171] ARPANSA informed the ANAO in January 2014 that, as there had consistently been zero accidents, from the 2011–12 annual report onwards, only incidents (as defined by the *National Directory for Radiation Protection*) were reported. Schedule 13 of the *National Directory for Radiation Protection*—the Directory provides an agreed framework for radiation safety to be adopted by the Commonwealth, states and territories. Schedule 13 of the Directory lists 11 specific types of radiation incidents, the first one of which is 'Incidents that cause or may lead to radiation injuries or radiation doses *exceeding* the annual dose limits to workers or members of the public'.[172] This change in reporting means that only significant safety incidents are now publicly reported.

6.8 Additionally, the National Directory for Radiation Protection notes that the annual report of a regulatory authority should include 'a summary of all radiation incidents investigated'.[173] ARPANSA's annual reports are limited to

169 The reported result listed in Table 6.2 is truncated. In full, the reported result was: 'There were no major deficiencies observed and substantial progress by two key licence holders was determined by active regulatory oversight and liaison between the licence holder and regulator'.

170 The work of the Safety Analysis section is discussed from paragraph 4.36.

171 Prior to 2011–12, ARPANSA defined an incident as 'an event which involves a radiation exposure less than the regulatory limits', while an accident was defined as 'an event which involves a radiation exposure above regulatory limits'.

172 ARPANSA, *National Directory for Radiation Protection*, Radiation Protection Series No.6, July 2011, p. 37 (emphasis added). For further information also see http://www.arpansa.gov.au/RadiationProtection/arir/index.cfm [accessed 15 November 2013].

173 The Directory defines a radiation incident as:

Footnote continued on the next page…

reporting the number of such incidents. ARPANSA should consider whether, in the interests of transparency, some summary information on such incidents should be presented in a similar manner to the way ARPANSA currently discusses breaches.

Stakeholder feedback

6.9 Licence holders are among ARPANSA's primary stakeholders, and can provide feedback through various channels. These include:

- the ARPANSA website;
- post-inspection surveys;
- feedback on ARPANSA publications such as regulatory guides;
- formal communication (emails and letters to ARPANSA management);
- informal communication (conversations) with regulatory officers and management; and
- licence holder forums and specific agency forums.

6.10 Other stakeholders, such as members of the public and community groups, can also access some of these channels, and can participate in public consultation forums relating to nuclear facility licence applications.

Licence holders are generally satisfied with ARPANSA's regulatory performance

6.11 In the 2009–10 PBS, licence holder satisfaction with regulatory services was reported as a KPI with a target of at least 80 per cent satisfaction. This KPI is no longer reported in the PBS, although the ARPANSA Corporate Plan 2013–16 has a 'customer satisfaction' indicator, and ARPANSA reported that this target of 80 per cent for licence holders was met, as no licence holder rated ARPANSA's performance below satisfactory. ARPANSA informed the ANAO that this result is based on the feedback survey from the 2012 licence holder forum although the ANAO notes that only 12 different regulated agencies

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Any unintended or ill-advised event when using ionizing radiation apparatus, specified types of non-ionizing radiation apparatus or radioactive substances, which results in, or has the potential to result in, an exposure to radiation to any person or the environment, outside the range of that normally expected for a particular practice, including events resulting from operator error, equipment failure, or the failure of management systems that warranted investigation.

were represented (less than half of the total number of regulated agencies) and of the 52 attendees from these 12 agencies, only 18 completed the feedback survey, equating to a 35 per cent response rate.

6.12 Since October 2012, ARPANSA has established an on-line survey instrument, to be completed anonymously by regulated entities after an inspection (prior to this on-line arrangement, ARPANSA would email survey requests to the nominated entity officer for a licence post-inspection). The on-line survey asks respondents to rate: the manner in which the inspection was conducted; the value of the inspection to the agency; the inspection; and the inspection report. Respondents are able to provide open-ended comments on these questions, and are invited to comment on how ARPANSA could improve its inspection process.

6.13 The ANAO examined the results from these surveys from March to May 2013, when 10 responses were received. Individual stakeholder views were variable, but overall they were satisfied with inspections by ARPANSA. Some suggestions for improvement included: increasing the depth of the inspection to reduce the number of overall inspections, and improving the timeliness of inspection reports. ARPANSA informed the ANAO that survey response are discussed at section meetings, and that the regulatory guide *What to expect during an Inspection* has recently been revised to take into account comments from the surveys.

6.14 Another avenue for licence holders to provide feedback is the annual licence holder forum.[174] Post forum surveys mainly focus on the conduct of the forum, although the survey includes two questions on ARPANSA's regulatory performance. Results from the most recent forum, in 2013—where 13 different regulated agencies were represented and the survey received an almost 40 per cent response rate—indicated that 73 per cent of respondents considered ARPANSA's regulatory performance over the past 12 months to be good or excellent, with 20 per cent finding ARPANSA's performance to be satisfactory. Respondents noted that they found particularly useful the opportunity to network with ARPANSA regulatory officers and other agency Radiation Safety

174 The forum provides ARPANSA with an opportunity to give regulatory updates and presentations on topical issues to its licence holders. Licence holders also give presentations at the forums. At the most recent forum held in October 2013, 44 participants representing 13 licence holders attended. A number of stakeholders noted that they found these forums informative, relevant and a good avenue for providing and receiving feedback.

Officers (RSOs) and receive information on ARPANSA's role and upcoming regulatory changes.

6.15 Stakeholders interviewed by the ANAO felt comfortable providing feedback to ARPANSA, particularly through informal means with the relevant branch head or section head. Only one stakeholder indicated a reluctance to provide formal negative feedback, and would choose to provide this informally face to face or via telephone. Overall, stakeholder feedback and survey results indicate a generally good working relationship between ARPANSA and licence holders.

ARPANSA has updated its Service Charter but does not report against its standards

6.16 A service charter is a public document which sets out the standards of service that customers (stakeholders) can expect from an organisation.[175] ARPANSA revised its service charter in September 2013. The current charter covers all of ARPANSA's functions, contains information on ARPANSA itself, what customers can expect from ARPANSA, and customer rights and responsibilities.

6.17 The ANAO's 2005 audit recommended that ARPANSA 'review and assess performance against customer service standards in its customer service charter; and systematically action and report on all complaints received'.[176]

6.18 The revised (September 2013) charter and its previous iteration noted that ARPANSA's performance against the charter will be incorporated in its Annual Report. While ARPANSA's annual reports note that it has committed to its service charter, these reports have tended only to describe the charter, and have not included any reporting against it. To illustrate, the 2012–13 Annual Report, when reporting on 'performance against service charter' describes the nature of ARPANSA's customers, the services it provides, that the charter provides for a complaints resolution mechanism and the statement that 'all corrective actions arising from client complaints are recorded'. The annual report does not report on the following, which are found in the service charter:

175 Australian Public Service Commission, *Foundations of Governance in the Australian Public Service*, September 2010, p. 38.

176 ANAO Audit Report No. 30 2004–05, *Regulation of Commonwealth Radiation and Nuclear Activities*, pp. 43-44.

- a number of high level service standards (primarily qualitative, for example ARPANSA's commitment to inform customers of fee and time estimates for work prior to commencement); and
- timeliness indicators (such as timeframes for responding to inquiries, timeframes for responding to freedom of information requests, and time frames for responding to complaints, compliments and suggestions which require a response).

Verbal complaints are not recorded

6.19 Complaints and compliments are an important indicator of client/stakeholder satisfaction with the service that is being provided to them. The service charter advises that complaints may be lodged where stakeholders believe ARPANSA has not met its service commitments. Stakeholders are advised to first try and resolve the matter with the relevant area. If the matter is not resolved, stakeholders can lodge a complaint with ARPANSA's centralised complaints handling area. The service charter also outlines the steps ARPANSA will take in addressing the feedback it receives.

6.20 The Regulatory Services Branch has a September 2012 Standard Operating Procedure (SOP) for managing regulatory complaints and compliments. The SOP provides that:

> This procedure applies to compliments and complaints received in writing. It does not apply to verbal compliments or complaints; these should be requested in writing. (original emphasis)

6.21 Previous versions of this SOP, in contrast, defined a complaint as 'any feedback from a stakeholder, written or verbal, of a negative nature' (emphasis added); recognising verbal complaints as a potentially valuable source of feedback. ARPANSA informed ANAO that:

> When the [*Standard Operating Procedure*] for managing complaints was revised in Sept 2012, a policy decision was taken to specifically exclude verbal complaints. If a verbal complaint is made, [regulatory] officers are instructed to request it in writing so that time is not wasted on spurious and unsubstantiated comments. No formal record of verbal complaints for the past three years has been made.

6.22 The SOP also states that complaints received should be reviewed and investigated if necessary, with section managers to monitor trends in complaints. Relevant information on complaints is also to be forwarded to the CEO's office for inclusion in the annual report. ARPANSA's 2008–09 and

2009–10 annual reports included information on the number of complaints received, the relevant service or activity, and the nature of the complaint. This information has not been included in subsequent annual reports.

6.23 The Regulatory Services Branch has, over time, adopted a variety of approaches to centrally recording feedback:

- The branch had a complaints register that covered 2005–06, but no register until June 2011. Three entries in this earlier register related to Commonwealth regulatory work, and included one verbal complaint.
- A positive feedback register covered the period February 2009 to July 2012, and included six relevant pieces of positive feedback.
- A combined 'complaints and compliments' register has been used since July 2011. The register indicates that from 1 June 2011 to October 2013, ARPANSA received 10 compliments and one complaint.[177]

6.24 Discussion of compliments and complaints received is a standing agenda item for Licensing and Compliance section meetings; a practical approach to considering feedback.

6.25 Licence holders indicated that their preference was to provide feedback to ARPANSA through direct communication with a regulatory officer or, particularly in the case of negative feedback, to the Branch Head Regulatory Services. The risk of damaging the relationship with the regulator was noted as a reason for licence holders preferring to provide informal verbal communication.

6.26 As noted above, ARPANSA generally has good relationships with regulated entities and its records indicate that it receives few formal complaints. However, in light of licence holder comments to the ANAO that they have a preference for verbal communication, ARPANSA's decision in 2012 to not document such complaints means that it may not be accurately recording the extent of feedback that could legitimately be regarded as a

177 The one complaint did not relate to ARPANSA's regulatory work and was not even directed at ARPANSA, however because the complainant used the word 'complaint' in an email, ARPANSA actioned it as a formal complaint, even though the individuals 'complaint' was not directed at ARPANSA.

complaint. This approach may also limit opportunities for the future analysis of trends.[178]

The Parliamentary Secretary has provided positive feedback in the past

6.27 ARPANSA's CEO has written annually to the Parliamentary Secretary for Health and Ageing—now the Assistant Minister for Health—seeking comment on the relevance, quality and timeliness of ARPANSA's advice and reports provided to the Parliamentary Secretary, for reporting 'on the corresponding performance measure in our Annual Report'.

6.28 Between 2007–08 and 2009–10, the Parliamentary Secretary provided written feedback expressing satisfaction with the level of support provided by ARPANSA. No written feedback was provided for 2010–11 and 2011–12, and ARPANSA informed the ANAO that during this time the Parliamentary Secretary did not raise any issues of concern. No written request was provided to the Parliamentary Secretary in 2013.

6.29 In 2008–09 and 2009–10 reporting on the ministerial satisfaction KPI was included in the PBS and reported on in the Annual Report. In the other years, levels of ministerial satisfaction were not mentioned.

Implementation of previous ANAO recommendations

6.30 Audit recommendations from ANAO performance audits highlight actions that are expected to improve agency performance when effectively implemented. The appropriate and timely implementation of agreed recommendations is an important part of realising the full benefits of an audit.[179] Where agencies have agreed to a number of recommendations, it may be necessary to establish priorities for implementation based on the level of risk posed to the agency by the issue the recommendation addresses. Delays in implementation have consequences, similar to recommendations not being adequately implemented, as recommendations are expected to improve agency

178 Noting that, overall, the number of complaints may remain small, even accounting for verbal complaints.

179 The ANAO has recently conducted two audits that have examined agencies' implementation of audit recommendations: Audit Report No.25 2012–13 *Defence's Implementation of Audit Recommendations*; and Audit Report No.53 2012–13 *Agencies' Implementation of Performance Audit Recommendations*.

performance and address risks to an agency's successful delivery of its business.[180]

6.31 The ANAO's 2005 performance audit of ARPANSA's regulatory function[181] made 19 recommendations, many of which have been commented on, where relevant, throughout the current audit. The key themes of the recommendations from the 2005 audit are outlined below:

- Governance recommendations were made on topics such as performance reporting, cost recovery and internal planning documents.
- Risk assessment and risk management recommendations were made on topics such as the risk management framework and a risk-based approach to inspections.
- Licence management and compliance monitoring recommendations were made on topics such as reporting, education of licensees and monitoring of agency compliance.

ARPANSA instituted arrangements to implement the recommendations from the 2005 audit

6.32 ARPANSA created an internal review team in early 2005 to recommend strategies to implement the ANAO recommendations. At the time, ARPANSA intended that all recommendations would be implemented by the end of 2005, nine months after the audit tabled. ARPANSA's 2005–06 Annual Report stated that this team completed its work in March 2006, and that creation of a new organisational structure in April 2006 concluded the implementation of all recommendations. In the report the CEO stated that:

> The management of regulatory business processes is, of course, a matter for continuous improvement. I believe, however, that the steps that have been taken to date, through the regulatory review and now the Regulation and Policy Branch are an effective response to the recommendations contained within ANAO audit report.[182]

6.33 The ARPANSA Audit and Risk Committee was briefed on the internal review team's findings in June 2006, and in December 2006 the CEO published

180 ANAO Audit Report No.25 2012–13 *Defence's Implementation of Audit Recommendations*, pp. 30-31, 82.

181 ANAO Audit Report No.30 2004–05 *Regulation of Commonwealth Radiation and Nuclear Activities*.

182 ARPANSA, *Annual Report 2005–06*, p. 10.

a paper that detailed the work ARPANSA had done in implementing the recommendations. The focus of the paper was on improvements to the regulatory function across the broad areas of the ANAO recommendations, defined as: governance, cost recovery, licensing process, compliance monitoring and non-compliance. The CEO considered that 'the majority of ANAO recommendations have been fully implemented or substantially achieved'. However, the report did not make a conclusion against each recommendation directly, focusing instead on progress in improving ARPANSA's management of the broad areas noted above. A risk with this broad-banded approach is that not all issues identified in a recommendation are captured, particularly for recommendations that involve multiple parts.

6.34 The Audit and Risk Committee was further briefed in July 2007 that: 'In summary ARPANSA is of the view that it has implemented a comprehensive strategy to address all of the recommendations... The work still to be undertaken is part of our program of continuous improvement'. A November 2007 brief to the committee summarised actions taken and further actions planned based on the broad areas noted earlier.

6.35 A shortcoming in ARPANSA's 2006 and 2007 implementation briefings for their Audit and Risk Committee was that they were limited to proposing a solution or process, rather than the actual or intended action/s to be taken to address each recommendation. The ANAO has observed, in a recent audit on the implementation of audit recommendations, that a focus on process rather than substantive outcomes can provide false confidence in the rate of progress.[183]

Later assessments of progress contradicted earlier findings of full implementation

6.36 The next evidence of review and monitoring of the ANAO recommendations was in November 2009, approximately four and a half years after the ANAO's audit was tabled, when ARPANSA's senior management was provided with an updated version of the November 2007 brief noted in paragraph 6.34. Unlike previous reports on implementation progress, the November 2009 update included an assessment of progress against each

183 ANAO Audit Report No.25 2012–13 *Defence's Implementation of Audit Recommendations*, p.14.

recommendation.[184] Contrary to earlier statements that all recommendations had been implemented, this paper assessed that only one of the 19 ANAO recommendations were 100 per cent complete. The majority of recommendations were assessed as 80 per cent complete, while the lowest assessment was that one recommendation was 60 per cent complete. The basis for these ratings was not documented.

6.37 Since November 2009, there has been continuing assessment of progress in implementing the ANAO recommendations as outlined in Table 6.3.

Table 6.3: Reviews of progress in implementing 2005 ANAO recommendations since November 2009

Date	Source of review	Finding
October 2010	Internal audit	• 15 recommendations complete • 4 remaining recommendations to be addressed by March 2011
October 2011	DoHA	• 2 recommendations complete • 11 recommendations partially complete • 6 recommendations incomplete
December 2011	Internal report to executive management	• 6 recommendations 'closed' • 10 recommendations 'closed on the basis of progress and confidence' • 3 recommendations 'open'
September 2012	Briefing for Audit & Risk Committee	• 12 recommendations complete • 7 remaining recommendations considered to be at least 80 per cent complete
January 2013	Regulatory branch assessment	• 16 recommendations complete • 3 remaining recommendations between 80% and 90% complete
April 2013	CEO Assessment	• 15 recommendations complete • 2 recommendations partially complete • 2 recommendations incomplete

184 Monitoring of progress in implementing recommendations from the 2005 audit was done in conjunction with monitoring recommendations and suggestions from the 2007 and later the 2011 IRRS missions. The 2007 IRRS mission made 12 recommendations and 30 suggestions. After the 2011 IRRS mission, 34 of these 42 items were closed, and another 15 were added (six recommendations and nine suggestions).

Date	Source of review	Finding
June 2012 to September 2013	Briefings for Audit and Risk Committee[(A)]	• 17 recommendations complete • 2 outstanding (1 requiring 'active management', the other requiring 'regular monitoring')

Source: ANAO analysis of ARPANSA information.

Note A: Briefings were provided to the Audit and Risk Committee on a quarterly basis from June 2012 to September 2013.

6.38 From 2012 onward, the Audit and Risk Committee has been actively monitoring ARPANSA's progress in addressing outstanding recommendations. The March 2012 minutes recorded that:

> a project plan to finalise all recommendations from the IRRS and ANAO is in the final stages and significant progress has been reported in implementing the recommendations; however evidence will need to be provided to confirm this progress.

6.39 The plan referred to in the committee minutes identified actions to be undertaken by specific ARPANSA staff; an appropriate means of assigning responsibility. In June 2013, two further recommendations assessed as incomplete were added to the committee's internal audit recommendations tracker.

Some recommendations have not been implemented to the extent considered by ARPANSA

6.40 This current ANAO audit is not a direct follow up from the 2005 audit, as it does not focus primarily on the issues and recommendations made in the previous audit. However in the course of audit fieldwork and analysis the ANAO has been able to assess the extent to which ARPANSA has implemented the 2005 recommendations. A summary of recommendations the ANAO does not consider to be fully implemented is at Appendix 6. Overall, the ANAO's analysis indicates that:

- 11 recommendations have been adequately implemented[185];

185 This includes Recommendation 11 (The ANAO recommends that ARPANSA develop and implement a central database for the management of applicant and licence-holder information). This recommendation has been assessed as incomplete by ARPANSA, however in October 2013 ARPANSA implemented the long awaited regulatory management system LAD (Licence Administration Database). Chapter 2 has also noted the improved records management with the introduction of TRIM, which was not in use at the time of the previous audit.

- 6 recommendations have been partially implemented; and
- 2 recommendations have been insufficiently implemented.

Monitoring and reporting on progress has not led to timely implementation

6.41 Since the November 2009 assessment of implementation status, there has been periodic monitoring and assessment of the progress in implementing the recommendations. The ANAO's assessment of the implementation status of individual recommendations, detailed in Appendix 6, over eight years after the recommendations were originally made, shows that six of the 19 recommendations have been partially implemented and two insufficiently implemented. ARPANSA's experience highlights that of other agencies—that monitoring and reporting on implementation is a necessary but not a sufficient condition for achieving the timely and adequate implementation of audit recommendations.[186]

Conclusion

6.42 Well-defined performance indicators enable a regulator to measure, monitor and report on regulatory performance, as well as providing measures to assess the extent to which the regulator is meeting expectations. Over time, ARPANSA's public reporting has reduced to only one Key Performance Indicator (KPI)—the number of safety incidents involving Commonwealth users—as a basis for measuring the effectiveness of the regulatory function. While this measure is appropriate, it does not reflect the breadth of ARPANSA's regulatory work, and ARPANSA could consider developing additional indicators, particularly to reflect its recent focus on promoting holistic safety and a safety culture amongst licencees.[187]

6.43 The quality of the relationship between a regulator and its stakeholders can affect regulatory outcomes, and establishing open and responsive relationships can increase the level of voluntary compliance by reinforcing confidence and transparency in the regulatory framework. ARPANSA has established a range of channels to enable stakeholder feedback and

186 ANAO Audit Report No.25 2012–13 *Defence's Implementation of Audit Recommendations*, pp.13-14.

187 In 2011 ARPANSA established a team to assess and improve the safety culture of licence holders, including developing an assessment tool to conduct safety culture reviews.

communication. ARPANSA's own surveys and stakeholder feedback provided to the ANAO during the course of this audit, indicate that stakeholders reported a general level of satisfaction with ARPANSA's regulatory performance; with differing opinions on scope for improvement, particularly in terms of timeliness and consistency. Overall, stakeholders reported that ARPANSA was approachable and professional, and commented on the generally positive working relationship between ARPANSA and its regulated entities.

6.44 The ANAO's 2005 performance audit of ARPANSA's regulatory function[188] made 19 recommendations. Between 2005 and 2007, work on implementing the recommendations was limited, leading to significant delays in ARPANSA progressing to an adequate stage of implementation. Notwithstanding regular monitoring by ARPANSA management and its Audit and Risk Committee, as well as several assessments of progress in implementing the recommendations, the ANAO assessed that only 11 of the 19 recommendations from this earlier audit had been adequately implemented, with six assessed as partially implemented.

Ian McPhee
Auditor-General

Canberra ACT
7 May 2014

188 See paragraph 6.

Appendices

Appendix 1: Agency Responses

Australian Government
Australian Radiation Protection and Nuclear Safety Agency

Ref: R14/03937

23 April 2014

Dr Tom Ioannou
Group Executive Director
Performance Audit Services Group
Australian National Audit Office
19 National Circuit
BARTON ACT
PO Box 707
Canberra ACT 2601

Dear Dr Ioannou

Proposed audit report on the Regulation of Commonwealth Radiation and Nuclear Activities

I refer to correspondence from the Australian National Audit Office (ANAO) of 18 March 2014 regarding the proposed audit report on the Regulation of Commonwealth Radiation and Nuclear Activities. The proposed audit report has been provided to the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) pursuant to sub-section 19(1) of the *Auditor-General Act 1997*.

As highlighted in the report, under the *Australian Radiation Protection and Nuclear Safety Act 1998* ARPANSA is the Australian Government's primary authority on radiation protection and nuclear safety, and independently regulates the radiation sources, radiation facilities and nuclear installations of Australian Government entities and contractors. This includes over 40 entities and their contractors with existing licences covering approximately 65,000 individual sources and 36 facilities.

ARPANSA welcomes the opportunity to contribute to the audit which assesses the effectiveness of ARPANSA's management of the regulation of Commonwealth radiation facilities and sources, including ARPANSA's compliance with its legislative requirements, and acknowledges the commentary provided within the report.

ARPANSA agrees with the recommendations contained therein and will continue to:

- advance the internal framework for managing declaration of interests and the related procedures and processes
- advance the internal procedures for licence application assessment to support and promote a risk-informed approach
- strengthen the existing risk-informed compliance monitoring program and strategic targeting of inspections, and

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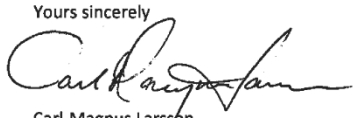
- improve the frequency of our rigorous self-inspection program and explore options for a broader base of suitable organisations for independent review of ARPANSA's own licences.

I note that during the audit the ANAO closely examined ARPANSA's regulatory cost recovery model. While no recommendations have been made, ARPANSA agrees with the ANAO's view that it should further improve the alignment with the Australian Government Cost Recovery Guidelines. ARPANSA will continue to advance the cost recovery model in a staged approach in consultation with licence holders. This will be supported by ARPANSA's current review of the regulatory delivery model to reduce regulatory burden.

Yours sincerely



Carl-Magnus Larsson
CEO of ARPANSA

Australian Government

UNCLASSIFIED

ansto
Nuclear-based science benefiting all Australians

16 April 2014

Dr Tom Ioannou
Group Executive Director
Performance Audit Services Group
Australian National Audit Office

Dear Dr Ioannou

Re: ANSTO comments on extract of proposed audit report on Regulation of Commonwealth Radiation and Nuclear Activities

I refer to your letter dated 18 March 2014 (ref PAR 11708).

Thank you for the opportunity to provide comment on the Australian National Audit Office's Extract of Proposed Audit of *Regulation of Commonwealth Radiation and Nuclear Activities.*

ANSTO's response is contained in Attachment 1 and Attachment 2 to this letter.

About ANSTO

ANSTO is Australia's national nuclear agency focused on bringing the benefits of nuclear science and technology to Australia. ANSTO's nuclear expertise is deployed locally and internationally in radiopharmaceutical production, supporting Australia's non-proliferation agenda, provision of landmark infrastructure for academic and industrial users, and contributing to national priority areas, such as health, materials engineering and water resource management.

Thank you for involving ANSTO in this process.

If you need any further information or support in relation to the matters addressed in the report, please do not hesitate to contact me.

Yours sincerely

Dr Adi Paterson
Chief Executive Officer

Enc:

Attachment 1 – ANSTO comments on Extract of proposed audit report on Regulation of Commonwealth Radiation and Nuclear Activities.

Attachment 2 – Letter from ARPANSA CEO to ANSTO CEO dated 7 February 2013

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Australian Government
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AFCD/CAE/OUT/2014/ 79

Mr Ian McPhee PSM
Auditor-General for Australia
Australian National Audit Office
GPO Box 707
CANBERRA ACT 2600

Dear Mr McPhee,

EXTRACT OF PROPOSED AUDIT REPORT ON REGULATION OF COMMONWEALTH RADIATION AND NUCLEAR ACTIVITIES

Thank you for the opportunity to review and provide comments on the subject report, provided to Defence on 18 March 2014. The Defence response is contained at Annexes A and B.

As noted in the report and our response, Defence holds a large number of low level sources, the majority of which are used as safety devices for the illumination of sights, gauges etc.

Defence would also like to note ARPANSA's flexibility and understanding when dealing with Defence. This has resulted the urgent supply of a medical CT scanner to the Middle East. ARPANSA adopted some flexibility in its procedures which directly contributed to the defence of Australia.

Yours sincerely

Geoffrey Brown OAM
Chief Audit Executive
Audit & Fraud Control Division

3 April 2014

Annex A: Defence Response
Annex B: Proposed Amendments, Editorials and Information Request Responses

Appendix 2: The IAEA Fundamental Safety Objective and Safety Principles

1. The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation.

2. The ten safety principles are written in non-specialist language and should form the basis for achieving the fundamental safety objective.

Safety principle	Description
1: Responsibility for safety	The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks.
2: Role of government	An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained.
3: Leadership and management for safety	Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks.
4: Justification of facilities and activities	Facilities and activities that give rise to radiation risks must yield an overall benefit.
5: Optimization of protection	Protection must be optimized to provide the highest level of safety that can reasonably be achieved.
6: Limitation of risks to individuals	Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.
7: Protection of present and future generations	People and the environment, present and future, must be protected against radiation risks.
8: Prevention of accidents	All practical efforts must be made to prevent and mitigate nuclear or radiation accidents.
9: Emergency preparedness and response	Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents.
10: Protective actions to reduce existing or unregulated radiation risks	Protective actions to reduce existing or unregulated radiation risks must be justified and optimized.

Source: IAEA, *Fundamental Safety Principles,* Safety Fundamentals No. SF-1, Vienna, 2006.

Appendix 3: Licence Applications Examined

Application #	Agency	Equipment (type of application)	Date submitted (time taken)
A0265	CSIRO	Variation in use of existing laser (amendment to existing source licence)	July 2012 (8 days)
A0223	ANU	Laser (new source licence	January 2010 (50 days)
A0196	DFAT	Hand held x-ray units and explosive detection equipment (amendment to existing source licence	February 2008 (459 days)
A0221	Customs	Veterinary X-ray machine for Customs dogs (amendment to existing source licence	February 2010 (340 days)
A0222	ANSTO—Bragg Institute	Neutron beam instruments (amendment to existing source licence	January 2010 (474 days)
A0233	Defence	Possession of CT Scanners (new source licence	November 2010 (11 days)
A0232	CSIRO	Operation of mobile deuterium-tritium neutron generator (new facility licence)	October 2010 (49 days)
A0269	ANSTO	Combined prepare site & construction of Interim Waste Storage (new facility licence)	August 2012 (withdrawn)
A0277	ANSTO	Prepare site for Interim Waste Storage (new facility licence)	March 2013 (268 days)(A)
A0279	ANSTO	Construction of Interim Waste Storage (new facility licence)	April 2013 (227 days)(A)

Source: ANAO analysis of ARPANSA information.

Note A: These applications were approved on 29 November 2013. At the time of the ANAO's analysis, these were ongoing.

1. The ANAO's approach to selecting applications for examination was targeted to examine applications of different agencies, types and assessment times. Three of the applications relate to ANSTO's current applications for the

interim waste storage facility at Lucas Heights—one was withdrawn and subsequently split into two separate applications; as at September 2013 both were ongoing.[189] Three of the remaining seven applications were selected because they took between 11 and 16 months to process. To provide balance, two quick applications (both between one and two weeks) and two mid-range applications (both taking seven weeks) were also examined.

189 ARPANSA initially advised ANSTO in June 2012 that they were prepared to consider a combined application for both site preparation and construction licences, and that only one fee would be required. In January 2013, ARPANSA determined that this approach was not in accordance with the fee requirements in the ARPANS Act, and informed ANSTO that they now required two separate applications. ARPANSA also considered that the initial application did not adequately address all possible sources of waste that could be stored in the interim waste storage. In January 2013, ANSTO withdrew this combined application after discussions with ARPANSA, and two separate applications were submitted in April 2013.

Appendix 4: Licensing of Legacy Sites

1. The IAEA fundamental safety principles state that regulatory authorities have to regulate sources of radiation for which no other organisation has responsibility, such as some natural sources, radioactive residues from some past facilities and activities (that were either not subject to regulatory control or to a less rigorous regime of control), and other 'orphan sources'.[190]

2. A legacy site is a radioactive site that existed prior to the introduction of the ARPANS Act in 1998. The two main legacy sites with which ARPANSA is involved are Maralinga and Little Forest.

Little Forest is a long standing unlicenced legacy site

Little Forest is located near Lucas Heights in Sydney, New South Wales. The site was used by the Australian Atomic Energy Commission—ANSTO's predecessor—as a disposal site for low level radioactive waste from 1960 to 1968. Radioactive material was placed in 79 trenches at the site. As well as containing radiological material such as uranium and plutonium, the site also contains hazardous non-radiological material such as beryllium oxide (which ARPANSA does not regulate). ANSTO applied for a licence for the site in 2000 as part of its waste operations facility licence, but due to the site itself not being an operational facility and difficulties with the ARPANS Act in licensing legacy sites it was excluded from the application assessment. The site currently remains unlicenced.[191]

Maralinga is a legacy site that was licenced

Between 1955 and 1963 a program of nuclear weapons development tests was conducted by the United Kingdom at Maralinga in South Australia. This testing led to widespread radioactive contamination of the local environment. A $108 million rehabilitation project was implemented between 1995 and 2000. In 2000 ARPANSA authorised the Department of Resources, Energy and Tourism (now the Department of Industry) to operate the Maralinga site as a controlled facility under the ARPANS Act and in 2001 formally advised the cleanup of the site had achieved the safety standards required. In 2009, ARPANSA transferred the Maralinga licence to the South Australian Environmental Protection Authority, who then officially handed the lands back to its traditional owners.

190 IAEA, *Fundamental Safety Principles*, Safety Standards Series No. SF-1, 2006, Vienna, pp. 7, 15.

191 ANSTO informed the ANAO in April 2014 that it is in the process of submitting a revised licence application which will be completed before June 2015.

3. ARPANSA has advised the ANAO that the regulation of legacy sites is currently problematic: they may contain mixed contamination and therefore are not the sole responsibility of ARPANSA[192]; and in particular the ARPANS Act does not contain explicit provisions for the granting of a licence for a legacy site as the options under the Regulations for statutory licensing are not designed to cover such cases.

4. The 2012 review of the Act by an external consultant recommended that the ARPANS Act be amended to provide greater flexibility for ARPANSA to issue licences for processes or sites where this is the most appropriate way to manage risk. For example, the Maralinga site was licenced for remediation activities despite the contamination not being caused by a prescribed facility.[193] The 2007 IAEA IRRS report also noted that the Maralinga licence did not correspond directly with the activities authorised under the licence.

5. The *Regulatory Services Branch Plan 2013–14* states ARPANSA will prepare and implement a strategy for how best to manage legacy sites by December 2013. ARPANSA informed the ANAO that a strategy for managing legacy sites has not been previously developed due to the lack of clarity within the Act on an approach to licensing this issue as well as an absence of international guidance on legacy sites, until recently.[194]

192 Mixed contamination means that a site does not only contain radioactive material but other contaminants, for example heavy chemicals, meaning it is not the sole responsibility of ARPANSA.

193 There are types of licences applicable under the ARPANS Regulations for the de-commissioning, disposal or abandonment of a prescribed radiation facility formerly used as a nuclear or atomic weapon test site. ARPANSA consider that the difficultly in applying these types of licences to the Maralinga site was that the contamination did not arise from a prescribed radiation facility.

194 This issue may be addressed with the Department of Health's proposed amendments to the ARPANS Act (see paragraphs 1.22 to 1.24).

Appendix 5: Investigation into ARPANSA's Handling of the Investigation of Two Incidents at ANSTO

1. During a routine inspection in June 2009, an ANSTO employee raised concerns with ARPANSA regarding two contamination events that occurred at ANSTO in September 2007 and August 2008. ARPANSA later investigated both incidents and concluded that there were no compliance issues with the licence conditions in either incident. The ANSTO employee later notified the ARPANSA CEO of a potential conflict of interest that in the individual's opinion called into question ARPANSA's independence and impartiality.[195]

2. In February 2011, the CEO of ARPANSA requested assistance from the Department of Health (then DoHA) in carrying out a review into ARPANSA's handling of these incidents, including the concerns raised by the ANSTO employee. The DoHA review considered that, while perceived doubts existed around an ARPANSA staff member's actions in one case, further investigation was not considered warranted as that staff member had resigned from ARPANSA.[196] The DoHA review also concluded that the investigation into the August 2008 incident was satisfactory, however concerns raised about the incident on 3 September 2007 had not been fully investigated. In response, ARPANSA initiated an independent review into the two contamination incidents, which concluded that:

> Neither the interim nor the final inspections reports sufficiently examined [*individual*] allegations that a contamination incident involving [*individual*] and [*individual*] occurred during the morning of 3 September 2007.[197]

3. The CEO of ARPANSA committed to a number of follow up actions to improve ARPANSA's regulatory management:

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195 For a more detailed account of the events surrounding this issue, see KPMG, *Australian Radiation Protection and Nuclear Safety Agency: Independent review of Yttrium-90 contamination on 3 September 2007*, redacted version, 19 June 2012, pp. 4-5, available at <http://www.arpansa.gov.au/pubs/disclosure/KPMGReport.pdf> [last accessed 30 January 2014].

196 This issue has also been discussed in past Senate estimate hearings. See in particular: Senate Community Affairs Legislation Committee 15 February 2012 estimates, p. 150; Senate Community Affairs Legislation Committee 17 October 2012 estimates, p. 56.

197 KPMG, *Australian Radiation Protection and Nuclear Safety Agency: Independent review of Yttrium-90 contamination on 3 September 2007*, 19 June 2012, pp. 2, 21.

- a review of the conduct of ARPANSA in relation to compliance and licensing matters;
- improve the transparency of regulatory oversight;
- review ARPANSA's actions based on informants;
- review ARPANSA's inspection procedures including the development of inspection reports;
- review of the licensing structure and conditions for all ANSTO activities; and
- systematically evaluate the safety culture at ANSTO.

4. The ANAO examined the implementation of the initiatives listed above. While no formal follow-up reviews were conducted on their implementation, the issues have been largely addressed by ARPANSA, with the exception of the final point: ARPANSA advised that it is currently undertaking a holistic safety review of the OPAL reactor (due to be completed by the end of June 2014) which encompasses safety culture. Once completed, further review activity will be progressively undertaken in respect to other areas of ANSTO.

Appendix 6: The ANAO's Assessment of the Implementation of Recommendations from the 2005 Audit

1. The table below summarises the ANAO's assessment where the ANAO did not consider a recommendation to be adequately implemented. As noted in Table 6.3, as at September 2013 ARPANSA considered that only recommendations 6 and 11 had yet to be implemented.

Rec No.	Recommendation	ANAO assessment of implementation
3	The ANAO recommends that ARPANSA enhance its risk management framework to identify risks to achievement of regulatory outcomes, mitigation strategies to manage those risks, residual risks, and a process of systematic monitoring of residual risks and their treatment.	Partial Chapter 2 has noted deficiencies with ARPANSA's regulatory risk management, including clear identification of risks, clearly developed mitigation strategies, and residual risks.
4	The ANAO recommends that ARPANSA strengthen management of the potential for, or perceptions of, conflict of interest, in accordance with legislative responsibilities, by: • ensuring adequate documentation of all perceived or potential conflicts of interest; • taking action to better manage the conflict of interest arising from its regulatory role in respect of its own sources and facilities; and • implementing and ensuring compliance with instructions issued.	Partial Chapter 2 has noted inadequate documentation of conflicts of interest, limited action and insufficient implementation to address self-regulation, and an empty conflict of interest register.
5	The ANAO recommends that ARPANSA: • review and assess performance against customer service standards in its customer service charter; and • systematically action and report on all complaints received.	Partial Chapter 6 has noted no evidence that ARPANSA review and assess performance against charter standards.

Rec No.	Recommendation	ANAO assessment of implementation
6	The ANAO recommends that, in order to provide assurance that cost recovery is consistent with better practice and government policy, ARPANSA: • develop a policy framework to guide its cost recovery arrangements; and • have sufficiently reliable data, and analysis, on cost elements to support management decisions on cost recovery—such analysis should include the alignment of fees and charges with the costs of regulation for particular groups of clients or types of licences, to the extent that this is cost effective.	Insufficient Chapter 5 has noted ARPANSA's cost recovery arrangements does not consistently reflect better practice and government policy. Cross-subsidisation continues, and fees and annual charges are not clearly aligned with regulatory effort. The ANAO has noted that these arrangements are currently under review.
8	The ANAO recommends that ARPANSA introduce appropriate systems to ensure its application processing complies with the requirements of the ARPANS Act and Regulations.(A)	Insufficient Chapter 3 has noted that, in the current ANAO audit sample, six out of 10 applications were being processed, and even approved, before payment was received. This approach is not consistent with the relevant legislation and documented procedures for managing applications.
13	The ANAO recommends that ARPANSA develop and implement an explicit, systematic and documented overall strategic compliance framework that: • identifies and articulates the purpose, contribution, resourcing and interrelationships of the various compliance approaches; • is based on systematic analysis of the risk posed by licencees and the sources and facilities under their management; and • targets compliance effort measures in accordance with assessed licencee risk.	Partial Chapter 4 has noted that ARPANSA's compliance effort is not clearly linked to assessed licencee risk. ARPANSA's guidance also does not clearly articulate the interrelationships between the various compliance approaches.
17	The ANAO recommends that ARPANSA develop standard procedures, for the consideration and assessment of reports, that address; • processes to provide assurance that licencee reports are appropriately assessed and acted upon; and • the collation and monitoring of reported information for risk management purposes.	Partial Chapter 4 has noted a lack of monitoring of reported information to identify trends and support a risk-based approach.

Rec No.	Recommendation	ANAO assessment of implementation
18	The ANAO recommends that ARPANSA establish a systematic, risk-based framework for compliance inspections that includes: • an integrated inspection program based on systematic and transparent assessment of the relative risks of facilities and hazards; • inspection reporting procedures that clearly assess the extent of licencee compliance with licence conditions; • recording of report findings in management information systems, to facilitate future compliance activity, and analysis of licence compliance trends; • accountable and transparent procedures for discretionary judgements, where compliance inspections vary from standard procedures; and • reporting on ARPANSA's performance in conducting inspections	Partial Chapter 4 has noted ARPANSA's inspection program is not directly linked to assessed licencee risk ratings. Report findings are not subject to trend analysis to inform future compliance activity.

A description of the assessment terminology is outlined below:

Partial: This category encompasses two types of partial implementation:

- Action taken was less extensive than recommended by ANAO: action either fell short of the intent of the recommendation, or only addressed some of the intended issues.
- ARPANSA may have established a process or procedure to address an issue, however the specific action noted in the recommendation has not been done. This could also be categorised as 'pre-emptive closure'.

Insufficient: Either no action has been undertaken, or the action taken does not sufficiently address the recommendation.

Note A: This recommendation was based on a sample analysis of licence applications, which found that ARPANSA had accepted 60 per cent of applications for assessment without being accompanied by a fee, in breach of ARPANSA legislation.

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