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Audit Report No.30 2004–05
Performance Audit

Regulation of Commonwealth Radiation and Nuclear Activities

**Australian Radiation Protection and
Nuclear Safety Agency**

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of Australia 2005

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Canberra ACT
2 March 2005

Dear Mr President
Dear Mr Speaker

The Australian National Audit Office has undertaken a performance audit in the Australian Radiation Protection and Nuclear Safety Agency 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 and the accompanying brochure. The report is titled *Regulation of Commonwealth Radiation and Nuclear Activities*.

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

Yours sincerely



P. J. Barrett
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. The ANAO assists the Auditor-General to carry out his duties under the *Auditor-General Act 1997* to undertake performance audits and financial statement audits of Commonwealth public sector bodies and to provide independent reports and advice for the Parliament, the Government and the community. The aim is to improve Commonwealth public sector administration and accountability.

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Contents

Abbreviations	7
Glossary	8
Summary and Recommendations	11
Summary	13
Background	13
This audit	13
Key findings	14
Overall audit conclusion	18
Recommendations and ARPANSA response	19
Recommendations.....	20
Audit Findings and Conclusions	27
1. Introduction.....	29
Role of ARPANSA.....	29
Regulated activities	30
Funding and administration.....	32
Audit objective and approach.....	33
2. Managing the Regulatory Function	35
Introduction.....	35
Implementation of the regulatory function	35
Corporate and branch planning.....	36
Performance management and reporting	38
Managing risks	39
Conflict of interest.....	41
Stakeholder and client relationships	42
3. Management of Cost Recovery for Regulatory Activities.....	45
Introduction.....	45
ARPANSA's cost-recovery framework.....	45
Identifying and recording regulatory costs to be recovered	47
Setting fees and charges to recover costs	47
4. Licensing	51
Introduction.....	51
Guidance to applicants.....	52
Standard operating procedures.....	53
Accepting applications.....	54
Preparation of advice to the CEO	55
Licence conditions.....	57
Management of information	59
Timeliness of assessments	60

5. Monitoring Compliance.....	63
Strategic management of compliance.....	63
Targeting and resourcing of compliance activities	64
Facilitating awareness.....	66
Licence Handbook.....	66
Reporting by licensees	67
Inspections	73
6. Dealing with Breaches and Prohibited Activity.....	79
ARPANSA’s enforcement framework.....	79
Dealing with non-compliance	80
Appendices	83
Appendix 1: Functions of the CEO of ARPANSA.....	85
Appendix 2: Conflict of interest processes	87
Appendix 3: Regulatory assessment guidelines	88
Appendix 4: Reporting obligations under the ARPANS Regulations	89
Appendix 5: Examples of non-compliance with licence conditions	90
Appendix 6: Agency response.....	91
Index	95
Series Titles.....	96
Better Practice Guides.....	99

Abbreviations

ALARA	As low as reasonably achievable
ANAO	Australian National Audit Office
ANSTO	Australian Nuclear Science and Technology Organisation
ARL	Australian Radiation Laboratory
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
CEIs	Chief Executive Instructions
CEO	Chief executive officer
CSIRO	Commonwealth Scientific and Industrial Research Organisation
HIFAR	Hi-Flux Australian Reactor
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
KPIs	Key performance indicators
LAS	Licensing Administration System
NSB	Nuclear Safety Bureau
RRR	Replacement Research Reactor
SOP	Standard operating procedure
UV	Ultraviolet

Glossary

Abnormal occurrence	An unanticipated operational occurrence or an accident.
As low as reasonably achievable	The guiding principle behind radiation protection is that radiation exposures are kept as low as reasonably achievable (ALARA), economic and social factors being taken into account. This approach means that radiation doses both for workers and for the public are typically kept lower than their regulatory limits.
Conducts	Refer to the following activities: <ul style="list-style-type: none">• prepare a site for a controlled facility;• construct a controlled facility;• possess or control a controlled facility;• operate a controlled facility;• decommission a controlled facility; or• dispose of or abandon a controlled facility.
Controlled apparatus	Any of the following: (a) an apparatus that produces ionising radiation when energised or that would, if assembled or repaired, be capable of producing ionising radiation when energised; (b) an apparatus that produces ionising radiation because it produces radioactive material; (c) an apparatus prescribed by the regulations that produces harmful non-ionising radiation when energised.
Controlled facility	A nuclear installation; or a prescribed radiation facility.
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; a person in the capacity of an employee of a Commonwealth contractor; or a person in a prescribed Commonwealth place.

Dealing	The activities of controlled persons in relation to controlled material and controlled apparatus. 'To deal with' means any of the following: <ul style="list-style-type: none"> (a) possess, or have control of, the apparatus or material; (b) use or operate the apparatus, or use the material; and (c) dispose of the apparatus or material.
Ionising radiation	Electromagnetic or particulate radiation capable of producing ions directly or indirectly, but not including electromagnetic radiation of a wavelength greater than 100 nanometres.
Non-ionising radiation	Electromagnetic radiation of a wavelength greater than 100 nanometres.
Nuclear installation	Any of the following: (a) a nuclear reactor for research or production of nuclear materials for industrial or medical use (including critical and sub-critical assemblies); (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 an activity level prescribed in the regulations; (d) a facility for production of radioisotopes with an activity that is greater than the activity level prescribed in the regulations.
Prescribed radiation facility	A facility or installation that is prescribed by the regulations.
Reactive inspection	An inspection of a nuclear installation in response to a matter that arises from compliance monitoring activities, such as licence holder quarterly reports, incident reports or from whistleblower information. Such inspections are often carried out at short notice to the licence holder. They are not part of the pre-planned inspection program.
Source	Radioactive material or a radiation apparatus.

Summary and Recommendations

Summary

Background

1. The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is charged with protecting the health and safety of people and the environment from the harmful effects of radiation. The chief executive officer (CEO) of ARPANSA has powers to regulate Commonwealth activities involving radiation sources and nuclear facilities, including nuclear installations.

2. Entities must be authorised under licence if undertaking activities involving radiation sources or facilities.¹ A licence is only issued after an application for the proposed activity is determined to be compliant with the *Australian Radiation Protection and Nuclear Safety Act 1998* (the ARPANS Act) and the *Australian Radiation Protection and Nuclear Safety Regulations 1999* (the ARPANS Regulations).²

3. Compliance with legislative requirements is monitored by ARPANSA. Where an entity is not compliant with the ARPANS Act and Regulations, ARPANSA has a range of enforcement options available to it to enable the protection of the health and safety of people and the environment from the harmful effects of radiation.

This audit

4. The objective of this audit was to assess ARPANSA's management of the regulation of Commonwealth radiation and nuclear activities to ensure the safety of their radiation facilities and sources.

5. The audit was undertaken in response to an Order of the Senate requesting that the Australian National Audit Office (ANAO) investigate aspects of ARPANSA's licensing processes.³ The audit examined ARPANSA's:

- key governance arrangements supporting the regulatory function;
- recovery of regulatory costs;
- licensing processes;
- monitoring of compliance; and
- management of non-compliance and unlicensed activity.

¹ The ARPANS Act covers *controlled persons*, that is: a Commonwealth entity; a Commonwealth contractor; a person in the capacity of an employee of a Commonwealth contractor; or a person in a prescribed Commonwealth place. This report refers to controlled persons as entities.

² Unless exempt under Schedule 2 or Part 4, Division 1 of the ARPANS Regulations.

³ Senate Hansard, No.8, Thursday, 29 August 2002, p. 3997.

Key findings

Managing the regulatory function (Chapter 2)

6. The establishment of ARPANSA was complicated by late changes to its role and structure through amendments that occurred during the passage of legislation. Further, the size and scope of the regulatory function were underestimated during its planning and implementation. The number of sources was four times more than planned, and the number of facilities nearly three times more.

7. As a result, full implementation of the regulatory function was delayed.

8. The Regulatory Branch's operational objectives and activities are numerous, vary considerably in scope, are not prioritised, and are insufficiently specific to be clear or assessable. This risks diffusing both strategic direction and operational implementation.

9. ARPANSA has quality and quantity measures for the regulatory function. However, the measures do not enable assessment of key regulatory activities, such as licensing timeliness or the extent of compliance by licence holders.

10. Many regulatory objectives did not have related performance measures. Some measures and targets were no longer relevant, or varied from year to year, inhibiting performance comparisons.

11. ARPANSA has a risk management framework. Its risk profile focuses on risks to ARPANSA as an entity. It does not identify risks to key regulatory processes, such as unlicensed activity, or non-compliance by licence holders.

12. ARPANSA's Chief Executive Instructions (CEIs) address management of the potential for conflict of interest between the regulatory function and other functions.

13. However, overall management of conflict of interest is not sufficient to meet the requirements of the ARPANS Act and Regulations. Key aspects of the instructions, such as maintenance of a register of advices, have not been implemented. As well, the instructions do not require matters of conflict of interest to be documented. Potential areas of conflict of interest are not explicitly addressed or transparently managed. This includes ARPANSA's obligation under the ARPANS Act and Regulations to license itself to operate two facilities, and many sources, to conduct its non-regulatory functions.

14. ARPANSA has a customer service charter. However, it does not monitor or evaluate performance against the standards of the charter.

15. ARPANSA has a documented process for recording and actioning complaints. However, the Regulatory Branch does not maintain a complaints register, as required. As well, information on complaints is not managed and assessed for the purpose of monitoring and performance management (including reporting in annual reports).

Management of cost recovery for regulatory activities (Chapter 3)

16. ARPANSA is required to operate on a user-pays basis, to meet the government's requirements that entities regulated should bear the costs of such regulation. These costs include licensing and monitoring of compliance with the Act and Regulations.

17. However, ARPANSA does not have a documented cost-recovery policy/methodology, or other guidance addressing cost recovery.

18. Initially, ARPANSA used appropriated funds, transferred from the former Nuclear Safety Bureau (NSB), to subsidise licence fees. However, it has not defined whether appropriation funding is still used to subsidise fees.

19. Since ARPANSA's establishment, licence fees have increased considerably.

20. There is substantial under-recovery of costs. This is due, in part, to under-recording of regulatory costs. In addition, ARPANSA under-recovers those costs it has identified.

21. Fees are not supported by a robust activity-based costing system, despite assurances to licensees in 1999 that such a system would underpin fees. There is not a clear relationship between the costs of regulation for groups of clients and types of regulatory activity, and fees charged.

22. In particular, the costs of regulation of the Replacement Research Reactor (RRR) have been under-recovered.

23. A number of licensees have expressed concern at the lack of a direct relationship between ARPANSA's costs and its fees.

Licensing (Chapter 4)

24. Licensing is a key regulatory activity. Since its establishment, ARPANSA has received 158 applications and issued 134 licences.⁴

25. ARPANSA provides guidance to applicants. However, the guidance does not explicitly ask applicants to address the statutory matters against which they will be assessed.

⁴ To September 2004.

26. Consequently, applications are often inadequate. ARPANSA has often had to seek clarification from applicants during the assessment process.
27. The bulk of license assessments—some 75 per cent—were made without the support of robust, documented procedures. Assessments of applications were supported by draft procedures only, which staff were not required to follow.
28. Some 60 per cent of applications accepted for assessment have been processed without a fee. Accepting applications without a fee is a breach of ARPANS legislation.
29. ARPANSA's primary assessment guideline for reviewing applications does not explicitly align to ARPANSA's legislative requirements. It does not specifically address the statutory matters that the CEO must take into account when deciding whether to issue a licence.
30. Reflecting the lack of guidance, many reports to the CEO on assessment of an application did not provide a clear analysis of the extent to which the application satisfied the statutory matters.
31. ARPANSA has not rejected any applications for a licence. However, it has imposed special conditions on all licences issued. An example is requiring a licensee to develop an inventory of all controlled material and controlled apparatus.
32. Some of these conditions appear to be significant aspects of recognised international best practice, which is a necessary requirement for a licence.
33. ARPANSA advised that it does not consider that these applicants were deficient in demonstrating *radiation protection and nuclear safety*. However, ARPANSA does not have systematic arrangements in place to provide assurance that special conditions are not being used to overcome deficiencies within applications.
34. Nor does ARPANSA provide guidance to its staff on the circumstances under which a licence condition is appropriate, and the scope and application of licence conditions.
35. ARPANSA does not maintain a single database containing applicant and licence-holder information. Instead, it maintains three separate spreadsheets of information. Consequently, ARPANSA does not have a centralised database for monitoring or reporting its processing performance.
36. The ANAO estimated that the median time to process applications to June 2004 was 22 months. Some took four years to assess. The median for those lodged in 2003 was three months. That is, half exceeded ARPANSA's standard of three months for processing an application.

Monitoring compliance (Chapter 5)

37. ARPANSA advised that the effort spent on compliance monitoring is roughly proportional to the level of hazard. However, it does not have an overarching framework to articulate the role, or emphasis, for the various approaches to managing compliance. Nor does it have a strategy for identifying prohibited activity by non-licensed entities.

38. One aspect of ARPANSA's compliance approach is to raise awareness. To this end, ARPANSA has delivered presentations to licensees. The ANAO found that presentations were well focused on regulatory information.

39. ARPANSA does not systematically analyse, document or rank the likelihood and consequences of risk associated with a licence. These limitations reduce assurance that compliance efforts are directed to areas of greatest need in a cost-effective manner.

40. ARPANSA provides licensees with a handbook, which aims to set out all compliance requirements and conditions. However, the handbook does not include all licence conditions prescribed in the ARPANS Act and Regulations; and some reporting requirements are inconsistently specified. These and other limitations weaken, and sometimes detract from, licensees' understanding of regulatory requirements.

41. ARPANSA does not monitor or assess the extent to which licensees meet reporting requirements. The ANAO found that there had been under-reporting by licence holders.

42. For example, incidents or changes to inventories had sometimes not been reported within the time required, or not reported at all. As well, ARPANSA had not regularly received all annual reports required of licence holders.

43. ARPANSA has developed guidelines for entities to facilitate their reporting. However, the guidelines are out of date, do not reflect changed reporting requirements and do not specify a timeframe or format for reports. These inadequacies may have contributed to the observed deficiencies in licensee reporting.

44. ARPANSA does not have standard operating procedures (SOPs) to support its review of licensees' reports.

45. ARPANSA undertakes inspections to assess licensee compliance with licence requirements. However, staff determine inspection plans separately. ARPANSA does not have a risk-based program for inspections.

46. Implementation of individual inspection schedules is not monitored by ARPANSA, as relevant data is not readily available.

47. There has been marked variation in the extent of notice given to entities prior to inspections, which is not in accordance with stated procedures.

48. Inspection outcomes are documented in reports to the CEO. However, the extent and nature of reporting varied markedly. For example, terminology and compliance rating scales varied. Some reports did not clearly state whether a licensee was, overall, in compliance with conditions of the licence.

Dealing with breaches and prohibited activity (Chapter 6)

49. Enforcement actions have focused on non-compliance by licence holders, reflecting ARPANSA's approach to compliance. There have been few actions against unlicensed entities undertaking prohibited activities.

50. ARPANSA does not have a policy or other guidance addressing use of enforcement powers, notwithstanding that it has been responsible for enforcement since 1999. Actions in response to identified non-compliance are not undertaken in a structured and consistent manner.

51. ARPANSA does not grade, or otherwise categorise, the extent to which licensees are complying with the requirements of the ARPANS Act and Regulations. In turn, it does not have systematic structures in place to manage enforcement, including a process for escalating enforcement response.

52. ARPANSA has reported only one designated breach to Parliament. This is notwithstanding that there have been a number of instances where ARPANSA has detected non-compliance by licensees.

53. For example, ARPANSA issued a direction⁵ to a licence holder to cease use of radiation equipment following a serious injury. The direction was later revoked. The incident was not classified as a breach, notwithstanding that it was acknowledged that safety management had been inadequate.

Overall audit conclusion

54. The ANAO concluded that improvements are required in the management of ARPANSA's regulatory function. While initial under-resourcing impacted adversely on regulatory performance, ARPANSA's systems and procedures are still not sufficiently mature to adequately support the cost-effective delivery of regulatory responsibilities.

55. In particular, deficiencies in planning, risk management and performance management limit ARPANSA's ability to align its regulatory operations with risks, and to assess its regulatory effectiveness.

⁵ Under Section 41, the CEO may give written directions to a controlled person requiring the controlled person to take such steps in relation to the thing as the CEO considers appropriate.

56. As well, procedures for licensing and monitoring of compliance have not been sufficient, particularly as a licence continues in force until it is cancelled or surrendered. Current arrangements do not adequately support the setting of fees in a user-pays environment, nor ARPANSA's responsibilities for transparently managing the potential for conflict of interest.

57. ARPANSA has recognised the need to address these gaps, and advised that it intends to review and improve the business processes supporting its regulatory function to address this audit's recommendations.

Recommendations and ARPANSA response

58. The ANAO made 19 recommendations for improving ARPANSA's delivery of its regulatory function. ARPANSA agreed with all recommendations. ARPANSA's full response to the audit is provided in Appendix 6. The following was ARPANSA's summary response:

ARPANSA acknowledges the work of the ANAO and agrees that the business processes supporting its regulatory functions need improvement. It has established a review to bring forward detailed recommendations and to implement revised business processes. The review will take up the recommendations of the ANAO report.

ARPANSA has substantial regulatory achievements to its credit, not least in the safety assessment and licensing of the OPAL reactor where there were many positive steps taken to improve the transparency and accountability of the process and the decision on the construction licence withstood a challenge in the Federal Court.

The audit report points to areas where ARPANSA needs to explicitly identify and set out its approach to ensure greater transparency and consistency and ARPANSA will implement these recommendations.

ARPANSA acknowledges that it does need to develop further its compliance policy which is in its initial stages of development. Further development of ARPANSA's approach, in particular the issue of subsequent enforcement after a finding of actual breach, must grow out of application of the law in particular circumstances and be based upon the fundamental requirement that controlled persons whose interests are affected by such findings are afforded procedural fairness throughout the process.

ARPANSA accepts all the recommendations of the ANAO report.

Recommendations

**Recommendation
No.1
Paragraph 2.21**

The ANAO recommends that ARPANSA's Corporate and Branch plans address key priorities and strategies for delivering regulatory outcomes. This would include clearer articulation of objectives and prioritisation of those objectives.

ARPANSA response: Agreed.

**Recommendation
No.2
Paragraph 2.31**

The ANAO recommends that ARPANSA develop key performance indicators and targets for the regulatory function that inform stakeholders of the extent of compliance by controlled persons, and of ARPANSA's administrative performance.

ARPANSA response: Agreed.

**Recommendation
No.3
Paragraph 2.41**

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.

ARPANSA response: Agreed.

**Recommendation
No.4
Paragraph 2.50**

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.

ARPANSA response: Agreed.

**Recommendation
No.5
Paragraph 2.58**

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.

ARPANSA response: Agreed.

**Recommendation
No.6
Paragraph 3.31**

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.

ARPANSA response: Agreed.

**Recommendation
No.7
Paragraph 4.12**

The ANAO recommends that ARPANSA enhance guidance to applicants to better reflect the requirements of the ARPANS Act and Regulations and, in particular, to provide guidance on the statutory matters that the CEO must take into account.

ARPANSA response: Agreed.

**Recommendation
No.8
Paragraph 4.19**

The ANAO recommends that ARPANSA introduce appropriate systems to ensure its application processing complies with the requirements of the ARPANS Act and Regulations.

ARPANSA response: Agreed.

**Recommendation
No.9
Paragraph 4.32**

The ANAO recommends that ARPANSA enhance its licence application assessment processes by ensuring that:

- guidance to staff explicitly addresses specified statutory matters that the CEO must take into account; and
- regulatory assessment reports provided to the CEO on each application explicitly address the extent to which an application addresses these matters.

ARPANSA response: Agreed.

**Recommendation
No.10
Paragraph 4.40**

The ANAO recommends that ARPANSA develop a risk-based decision-making process for the use of additional licence conditions. This would require clear procedures and documentation addressing, inter alia, why and how conditions will be applied, monitoring of those conditions, and their costs and benefits.

ARPANSA response: Agreed.

**Recommendation
No.11
Paragraph 4.47**

The ANAO recommends that ARPANSA develop and implement a central database for the management of applicant and licence-holder information.

ARPANSA response: Agreed.

**Recommendation
No.12
Paragraph 4.54**

The ANAO recommends that ARPANSA monitor the timeliness of licence approvals against service standards, and report on this in its annual report.

ARPANSA response: Agreed.

**Recommendation
No.13
Paragraph 5.13**

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 licensees and the sources and facilities under their management; and
- targets compliance effort measures in accordance with assessed licensee risk.

ARPANSA response: Agreed.

**Recommendation
No.14
Paragraph 5.29**

The ANAO recommends that, to facilitate licensee understanding of and compliance with their obligations, ARPANSA revise or replace the Licence Handbook to address identified weaknesses.

ARPANSA response: Agreed.

**Recommendation
No.15
Paragraph 5.49**

The ANAO recommends that ARPANSA enhance its reporting guidelines by:

- implementing procedures to keep the guidelines up to date;
- specifying the level of supporting evidence required in reports;
- providing feedback to licensees on reports; and
- seeking client feedback on its guidelines.

ARPANSA response: Agreed.

**Recommendation
No.16
Paragraph 5.50**

The ANAO recommends that ARPANSA monitor compliance by licensees with reporting requirements.

ARPANSA response: Agreed.

**Recommendation
No.17
Paragraph 5.55**

The ANAO recommends that ARPANSA develop standard procedures, for the consideration and assessment of reports, that address:

- processes to provide assurance that licensee reports are appropriately assessed and acted upon; and
- the collation and monitoring of reported information for risk management purposes.

ARPANSA response: Agreed

**Recommendation
No.18
Paragraph 5.80**

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 licensee 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.

ARPANSA response: Agreed.

**Recommendation
No.19
Paragraph 6.19**

The ANAO recommends that, in order to provide greater assurance that failures to meet licence conditions are dealt with and reported appropriately, 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 graduated approach to enforcement action; and
- maintain a database of non-compliance and enforcement actions taken and their resolution.

ARPANSA response: Agreed.

Audit Findings and Conclusions

1. Introduction

Role of ARPANSA

1.1 In 1997, the Australian Government announced that it would establish a new agency to regulate Commonwealth radiation and nuclear safety activities. The agency would bring together activities previously undertaken by the Australian Radiation Laboratory (ARL) and the Nuclear Safety Bureau (NSB).⁶

1.2 The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) came into being on 5 February 1999, with the proclamation of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the ARPANS Act). The then minister advised the Parliament that the legislation:

... introduces, for the first time in Australia, a comprehensive regulatory framework for all Commonwealth radiation and nuclear activities. It closes a current gap in regulation where State and Territory Government activities, and private undertakings are regulated by State and Territory radiation laws, but Commonwealth agencies have operated without corresponding Commonwealth oversight and regulation.⁷

1.3 The object of the Act is to protect the health and safety of people and the environment from the harmful effects of radiation. ARPANSA has powers to regulate Commonwealth activities involving radiation sources and facilities, including nuclear installations (see Table 1.1 and Table 1.2). It administers a licensing regime and monitors compliance with the ARPANS Act and Regulations.

1.4 Other functions of ARPANSA include providing advice to government, conducting research, running a fee-for-service personal radiation monitoring service,⁸ and contributing to national uniformity in radiation protection. These other functions are outlined in Appendix 1. Undertaking these functions involves ARPANSA itself undertaking activities that are regulated by the ARPANS Act and Regulations.⁹

⁶ The ARL was responsible for providing advice to government and the community on the health effects of radiation, and for undertaking research and providing services in this area. The NSB was responsible for the regulation of ANSTO's reactors under the *Australian Nuclear Science and Technology Organisation Act 1987*.

⁷ House of Representatives, Hansard, Wednesday, 11 November 1998, p. 89.

⁸ This service involves the issue of radiation monitoring devices to employees in the public and private sectors. The devices record the level of exposure to ionising radiation and are returned to ARPANSA at regular intervals to assess the doses received. Dose reports are provided to employees and dose records are maintained by ARPANSA in a database.

⁹ For example, ARPANSA operates an electron linear accelerator and many controlled materials and apparatus (for example, sealed gamma-ray sources).

1.5 ARPANSA’s chief executive officer (CEO), as the statutory office holder, is the regulatory decision-maker and responsible for ARPANSA’s other functions.¹⁰

Regulated activities

1.6 At September 2004, 37 entities¹¹ were licensed by ARPANSA. These entities were responsible for nearly 6 000 sources of radiation and 48 facilities.

Sources

1.7 A source is either radioactive material or a radiation apparatus. The types of source regulated by ARPANSA are illustrated in Table 1.1.

Table 1.1

Source types regulated by ARPANSA

Type of Source	Definition	Examples
Radioactive material	Material which spontaneously emits ionising radiation in the form of alpha and beta particles, electrons, photons, neutrons or gamma rays.	Radioactive material used for teaching in universities Industrial radiography gauges
Radiation apparatus	Apparatus which produces non-ionising, electromagnetic radiation, such as in the form of microwave, infrared, visible light and ultraviolet radiation at a level that may cause health effects. or Apparatus that produces ionising radiation when energised or because it contains radioactive material.	Lasers in research laboratories Non-destructive testing X-ray devices in the aeronautical industry Dental X-ray unit

Source: ARPANSA

1.8 The majority of sources (85 per cent) are held by a small number of licence holders. In particular:

- the Department of Defence has 2 674 sources (these are used for research, testing and calibration);

¹⁰ The functions of the CEO are set out in Section 15 of the ARPANS Act.

¹¹ The ARPANS Act covers *controlled persons*, that is: a Commonwealth entity; a Commonwealth contractor; a person in the capacity of an employee of a Commonwealth contractor; or a person in a prescribed Commonwealth place. This report refers to a controlled person as an entity.

- the Commonwealth Scientific and Industrial Research Organisation (CSIRO) has 1 558 sources, used in a wide range of research activities; and
- the Australian Nuclear Science and Technology Organisation (ANSTO) has 961 sources (these are used for research and production of radioactive isotopes).

1.9 On the other hand, 20 licence holders have fewer than 10 sources each. For example, the National Gallery of Australia has one source, being a fixed X-ray unit.

Facilities

1.10 A facility is a particle accelerator; irradiator; arrangements for storage, production, processing or disposal of radioactive material; or nuclear installation. The types of facilities regulated by ARPANSA are illustrated in Table 1.2.

Table 1.2

Facility types regulated by ARPANSA

Type of facility		Definition	Example
Radiation facilities (Number at September 2004—32)	Particle accelerator	A machine using electric fields to accelerate charged particles.	Container examination facilities, incorporating an accelerator for scanning imported goods
	Irradiator	A structure that houses a large radioactive source and that can produce high radiation fields.	Gatri, which is an ANSTO facility designed to sterilise items
	Smaller facilities used for production, processing, use, storage, management or disposal of radioactive material.		Stores for radioactive sources
Nuclear installation (Number at September 2004—16)	Nuclear research reactor	A nuclear reactor used for research purposes.	ANSTO's HIFAR (Hi-Flux) and Replacement Research Reactors
	Larger facilities for the storage or disposal of radioactive material	Nuclear fuel storage facility or	ANSTO's fuel-handling and storage facilities
		Nuclear waste storage or disposal facility.	ANSTO's radioactive waste stores
Nuclear installation for the production of radioisotopes	A facility where radioisotopes are produced.	ANSTO's radioisotope production facilities	

Source: ARPANSA

1.11 The 48 facility licences are held by eight licence holders. Of these licences, 31 are held by ANSTO.

Funding and administration

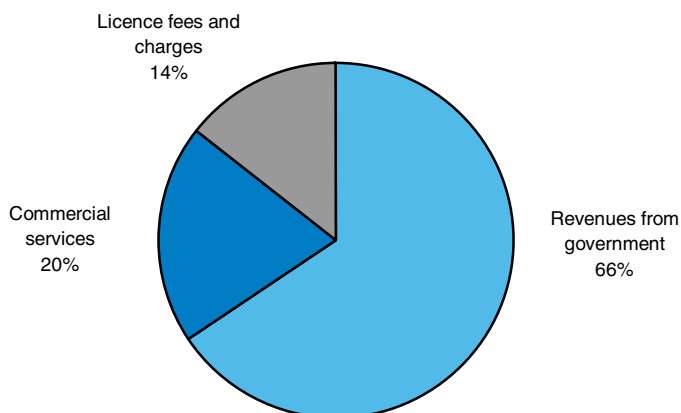
1.12 ARPANSA's total expenditure in 2003–04 was \$22.2 million, while its total revenue for the same period was \$24.06 million.¹² ARPANSA's funding comes from three sources:

- government appropriation for ongoing coordination and development of a national directory of codes of practice and standards, provision of technical and policy advice to government, and undertaking research;
- income from provision of commercial services, such as the personal radiation monitoring service; and
- licence application fees and annual licence charges.

1.13 The distribution of ARPANSA's income from these sources is shown in Figure 1.1.

Figure 1.1

Sources of ARPANSA's income, 2003–04



Source: ARPANSA financial statements for the year ended 30 June 2004

1.14 As previously noted, regulation is one of a number of functions undertaken by the CEO of ARPANSA (see Appendix 1). ARPANSA's Regulatory Branch largely administers its regulatory functions. The branch had 20 staff at the time of audit fieldwork, out of total ARPANSA staffing of 125.

¹² Includes an additional \$1.6 million in government appropriation to cover unfunded insurance payment in 2002–03 (ARPANSA 2003–04 Annual Report, p. 23).

1.15 The Regulatory Branch assists the CEO to regulate the Commonwealth's radiation and nuclear activities. It assesses applications for licences; makes recommendations to the CEO on applications, including on the imposition of licence conditions; monitors compliance reporting; undertakes inspections; investigates incidents; and makes recommendations to the CEO in relation to compliance and enforcement action.

Audit objective and approach

1.16 The objective of this audit was to assess ARPANSA's management of the regulation of Commonwealth radiation and nuclear activities to ensure the safety of their radiation facilities and sources.

1.17 The audit was undertaken in response to an Order of the Senate requesting that the ANAO investigate aspects of ARPANSA's licensing processes.¹³

1.18 The audit examined ARPANSA's:

- key governance arrangements supporting the regulatory function;
- recovery of regulatory costs;
- licensing processes;
- monitoring of compliance; and
- management of non-compliance and unlicensed activity.

1.19 The audit methodology included examination of files and documents, observations of ARPANSA's operations and interviews with ARPANSA staff, stakeholders and licensees.

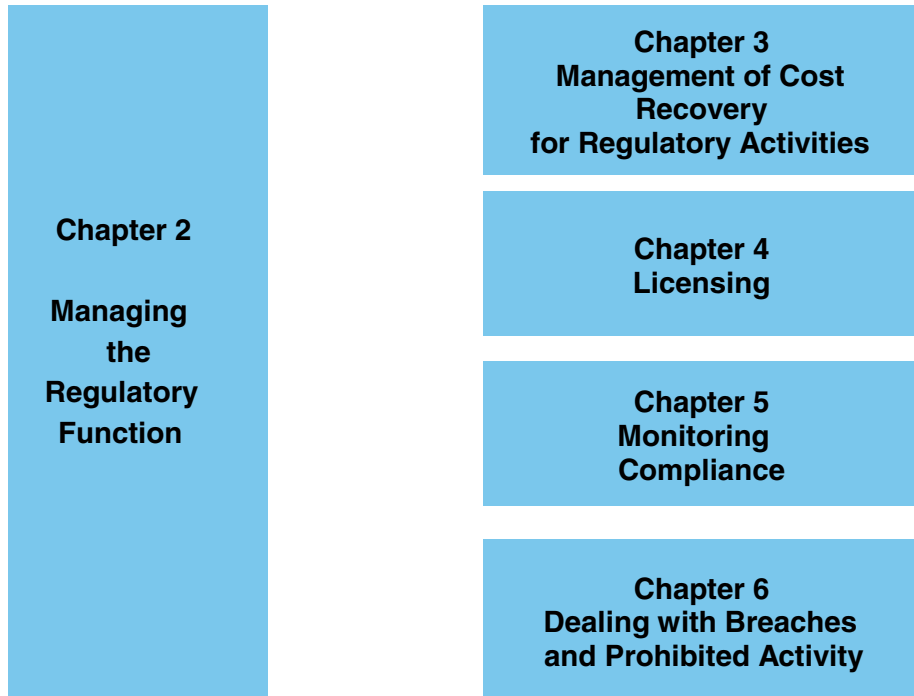
1.20 The audit was conducted in accordance with ANAO auditing standards at a cost of \$518 000. The ANAO engaged Origin Consulting to assist with the audit.

1.21 The audit findings are discussed in the following chapters, as illustrated in Figure 1.2.

¹³ Senate Hansard, No.8, Thursday, 29 August 2002, p. 3997.

Figure 1.2

Report structure



2. Managing the Regulatory Function

This chapter examines ARPANSA's processes for managing the regulatory function.

Introduction

2.1 ARPANSA is required to manage a complex regulatory regime, with considerable interest from stakeholders. This regime includes accepting and reviewing applications for a licence to manage a source or facility, monitoring compliance of entities with their obligations under the ARPANS Act and Regulations, and exercising powers to address non-compliance and unlicensed activities.

Implementation of the regulatory function

2.2 Planning for the implementation of ARPANSA began in 1996. It was undertaken by a committee drawn from the then Department of Health (including the ARL) and the former NSB.

2.3 Planning focused on the new regulatory function, including the establishment of the regulatory framework. Issues considered by the committee included:

- internal management arrangements;
- the role of advisory committees;
- the range of tasks to be taken over from the NSB and ARL;
- the extent of radiation uses by the Commonwealth;
- identification of the regulatory tasks to be performed for the licensing function;
- resourcing;
- cost recovery; and
- legal aspects, such as appeals.

2.4 The committee estimated that, at the time, there were 1 447 sources and 17 facilities in existence. It based the estimates on data drawn from a personal radiation monitoring service database, maintained by the ARL, and from the NSB's knowledge of ANSTO's activities. Based on these estimates, ARPANSA commenced with nine regulatory staff in February 1999.

2.5 However, this data was not sufficiently comprehensive, and actual circumstances varied markedly from the estimates. The number of sources was

four times more than expected, at nearly 6 000. There were 48 facilities, nearly three times more than originally estimated.

2.6 In addition, amendments made by the Parliament to the proposed ARPANS legislation changed the scope of the regulatory function. These included the requirement to assess applications against international best practice and to consider any public submissions on licence applications in relation to nuclear installations.¹⁴

2.7 Implementation of the new regulatory regime was more complex and took longer than expected. For example, ARPANSA's 1999–2000 annual report noted that:

- there had been less progress than expected in establishing important policies and practices; and
- the process of licensing Commonwealth entities using radiation sources or facilities was more difficult than envisaged.

2.8 As it became evident that progress with key tasks was taking longer than expected, ARPANSA responded by more than doubling staff numbers from nine to 22.

2.9 As discussed later in this report, full implementation of ARPANSA's regulatory function was delayed. ARPANSA took four years to issue some licences (see Paragraph 4.48), and it has only recently commenced a compliance inspection program (see Paragraph 5.67).

2.10 Overall, the establishment of ARPANSA was complicated by late changes to its role and structure. However, more detailed planning, including in regard to the likely scale of the regulatory task, would have facilitated smoother and more effective implementation.

Corporate and branch planning

2.11 ARPANSA has an overarching Corporate Plan, supported by branch and section plans.

2.12 The Corporate Plan articulates ARPANSA's role: its principal aim, strategic planning framework, and focus on outputs for the next three years. The current plan, for the period 2002–05, identifies *Regulation of Commonwealth Activities* as one of five output groups. The objective for the regulatory output is:

¹⁴ In addition, the CEO was given the powers and responsibilities of a departmental secretary, and ARPANSA was created as a statutory agency in the terms of the *Public Service Act 1999*.

... to continue to implement an effective, quality assured, Commonwealth regulatory system with the following elements: the setting of standards for safety and licensing of nuclear installations, radiation facilities and radiation sources; review and assessment of applications, licensing and regulation; verification of compliance, audit and inspection; and enforcement of the ARPANS Act.¹⁵

2.13 The Corporate Plan states that the strategy for achieving this objective is *using their licensing powers and working with Commonwealth agencies to ensure the safety of the radiation facilities and sources operated by them*. The plan notes that the focus of the regulatory function will change from that of assessing licence applications *to one of verifying compliance with licences and with radiation protection and nuclear safety standards*.

2.14 Notwithstanding the stated strategies, ARPANSA advised the ANAO that it did not see its role as ensuring the safety of facilities and sources, as ultimately this was the responsibility of licensees.

2.15 However, as discussed at Paragraph 1.3, ARPANSA is charged with protecting the health and safety of people and the environment. The ANAO considers that ARPANSA should amend its Corporate Plan so that it accurately reflects ARPANSA's responsibilities.

Regulatory Branch plan

2.16 The Regulatory Branch is responsible for delivering the regulatory outputs of application assessment, licence compliance monitoring, and enforcement. It has an extensive Branch Plan, which contains tasks, timelines and responsibilities.

2.17 However, the nature and purpose of the plan has not been well articulated. The title varies within the document between a *Work Plan* and *Strategic Plan*.¹⁶

2.18 There are 41 objectives in total. Some of these are not clearly specified or vary substantially in scope. For example, some were specified as broad issues, such as *nuclear installations* or *licence holders' information management*. The specification of subsidiary activities was also insufficient to be clear or assessable. For example, one activity was described as *policy/procedures to be developed*. Such general statements provide limited guidance to management and staff on what is intended to be achieved.

¹⁵ ARPANSA Corporate Plan 2002-05, p. 13.

¹⁶ Regulatory Branch Work Plan and Implementation Activities January 2002 – June 2004, Revision 4, February 2004.

2.19 In addition, objectives were not prioritised or allocated resources. Management of a large number of objectives, without prioritisation, risks diffusing both strategic direction and operational implementation. In particular, it does not provide a clear distinction between those objectives necessary to meet ARPANSA's legislative obligations, and those that contribute in other ways (eg. to ARPANSA being more efficient or effective).

2.20 ARPANSA advised that it recognises that its planning processes can be improved for greater management of effectiveness.

Recommendation No.1

2.21 The ANAO recommends that ARPANSA's Corporate and Branch plans address key priorities and strategies for delivering regulatory outcomes. This would include clearer articulation of objectives and prioritisation of those objectives.

ARPANSA response: Agreed.

Performance management and reporting

2.22 ARPANSA does not have a systematic and documented performance management framework.

2.23 There are a number of quality and quantity measures for its regulatory function.¹⁷ However, reflecting the weaknesses in the planning documents, these measures provide limited information for management to assess ARPANSA's performance against key performance indicators (KPIs).

2.24 For example, the measures used do not enable the assessment of key regulatory activities. They do not measure licensing timeliness, or the extent to which licence holders are complying with conditions of their licences.

2.25 As well, many Regulatory Branch objectives did not have related performance measures, and some measures were no longer relevant.

2.26 Measures used also varied markedly from year to year, with no clear reasons for the changes. This variation makes it difficult to compare performance over time. For example, in its last three annual reports ARPANSA has not reported against the performance measure of *100 per cent compliance*. Compliance monitoring is discussed further in Chapter 5.

2.27 Assessment and reporting of compliance by entities in managing radiation sources and facilities would provide a more insightful indicator of the extent to which they comply with their regulatory obligations.

¹⁷ The Corporate Plan does not set down regulatory measures. Measures are set down in ARPANSA's Branch Plan.

Targets and benchmarks

2.28 Reflecting the above limitations, there is variable use of, and quality in, performance benchmarks and targets.

2.29 For example, the 2002–03 annual report had a quality measure, *inspections meet ARPANSA's inspection and reporting criteria*. However, the ANAO found that ARPANSA had not established inspection and reporting criteria to enable this to be assessed. Despite the absence of the relevant criteria, ARPANSA's annual report stated *All inspections meet ARPANSA's inspection and reporting policy and procedures*.

2.30 The ANAO considers that performance management and reporting would be strengthened by:

- aligning measures and targets with planned regulatory activities and outcomes; and
- regularly reporting achievement against these measures and targets.

Recommendation No.2

2.31 The ANAO recommends that ARPANSA develop key performance indicators and targets for the regulatory function that inform stakeholders of the extent of compliance by controlled persons, and of ARPANSA's administrative performance.

ARPANSA response: Agreed.

Managing risks

2.32 ARPANSA established a risk management framework in 2000–01. The framework sets down the methodology by which risk identification is undertaken, monitored and reviewed within ARPANSA.

2.33 The framework is one of two key overarching documents establishing ARPANSA's risk management approach (see Figure 2.1). The other is an operational policy document. The latter sets out the broad roles of staff, branch directors and the Audit Committee in regard to risk management.

Figure 2.1

ARPANSA's risk management documentation



Source: ANAO

2.34 Supporting the risk management framework and policy is ARPANSA's Strategic Risk Management and Audit Plan.

2.35 The plan contains an organisational risk profile. It also describes the processes used to develop the strategic audit program.¹⁸ Collectively, these are consistent with recognised standards¹⁹ and form the basis of the Strategic Risk Management and Audit Plan.

2.36 The risk profile focuses on risks to ARPANSA as an entity. For example, the profile includes the risk that the performance issues for bodies regulated by ARPANSA impact on ARPANSA. The documented effect of the realisation of this risk is loss of reputation.

2.37 However, the ANAO found that the risk profile did not clearly address key regulatory responsibilities. For example, one risk issue identified is *licence*

¹⁸ The risk profile identifies risks according to: issue; effect; risk factors; and key controls and management strategies.

¹⁹ AS/NZS 4360:1999, Risk Management.

holder expectations. However, it is not clear what particular planned regulatory responsibilities this addresses.

2.38 As well, the profile does not identify the key regulatory risks of the consequence of ARPANSA not adequately addressing unlicensed activity or non-compliance by licence holders. Given the nature of the activities being regulated, the consequences of entity non-compliance could be substantial both for ARPANSA and affected stakeholders.

2.39 ARPANSA's regulatory operations would be strengthened by enhancing its risk management framework to address, in an explicit and structured way, key operational risks to achieving regulatory outcomes and strategies to address those risks, including necessary resource allocations.

2.40 Identification of these risks should also clearly distinguish risk to effective regulation from risks to the bodies regulated.

Recommendation No.3

2.41 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.

ARPANSA response: Agreed.

Conflict of interest

2.42 In addition to its regulatory function, ARPANSA provides a range of commercial services to Commonwealth, State, Territory and private sector organisations. To address parliamentary concern that the regulatory function be managed independently of these services, Section 15(2) of the ARPANS Act requires the CEO to take all reasonable steps to manage conflict of interest between the regulatory function and the CEO's other functions.

2.43 ARPANSA has Chief Executive Instructions (CEIs) that advise staff on how to manage conflicts of interest.²⁰ The instructions provide guidance to staff on what constitutes a conflict of interest and how it should be handled. For example, the CEIs require that where the CEO has given written advice to an entity on any issue of radiation protection or services this advice must be maintained in a register.

2.44 However, the ANAO found that ARPANSA has not established such a register. Further, the CEIs do not require the response to a potential or perceived conflict to be documented.

²⁰ The required processes are set down in Appendix 2.

2.45 For example, ARPANSA assessed an application for a low-level waste repository. The ARPANSA working group assessing the application comprised members from both the Regulatory Branch and an ARPANSA service branch.²¹

2.46 As well, ARPANSA is required to hold a licence for any activities that it carries out with either sources or facilities. It has therefore had to license itself to operate two facilities (a linear accelerator and a teletherapy laboratory) and over 200 sources, in order to conduct its non-regulatory functions (see Paragraph 1.4). The CEIs do not explicitly address how ARPANSA's licensing of itself is to be managed in a transparent manner, or how it is to monitor and address the risk of non-compliance for itself.

2.47 In the above examples, the potential for conflict of interest and the means of managing it have not been documented.

2.48 These weaknesses reduce assurance for stakeholders that ARPANSA has a robust and transparent process for handling potential conflicts of interest, consistent with its legislative responsibilities.

2.49 The licensing of ARPANSA's own activities, in particular, warrants more robust governance arrangements. Possible considerations include contractual arrangements for these activities.

Recommendation No.4

2.50 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.

ARPANSA response: Agreed.

Stakeholder and client relationships

2.51 ARPANSA's customer service charter, launched in 2001, sets down who it considers to be its key stakeholders (called *customers*).

²¹ The Environment Radiation Health Branch had previously undertaken water sampling at the proposed site for the repository.

2.52 The charter meets many of the guidelines set out in the *Client Service Charter Principles*²² issued by the Department of Finance and Administration. For example, it lists ARPANSA's service delivery standards. However, ARPANSA has failed to comply with the requirement in the Principles that it publish information, in each annual report, on how it performed against charter commitments. Moreover, ARPANSA has yet to measure or evaluate its performance against its service delivery standards, despite stating in the charter that it would do so.

Complaints

2.53 The charter advises how complaints can be lodged if customers or members of the public believe that ARPANSA has failed to meet its service commitments.

2.54 The charter advises customers, in the first instance, to try to resolve the matter with the staff member with whom they have been dealing, or the staff member's supervisor. If the matter cannot be resolved in this way, customers are advised to write to the Director of Corporate Services in Sydney.

2.55 Internally, processes for recording and actioning complaints are set down in ARPANSA's *Quality Assurance Manual*. Each of ARPANSA's five branches is required to maintain a register of all complaints received. However, the ANAO found that the Regulatory Branch, which was examined in this audit, does not maintain a complaints register.

2.56 The absence of a register undermines ARPANSA's ability to meet the intentions reflected in its service charter and *Quality Assurance Manual*. It hampers management's ability to monitor the adequacy of responses to complaints. It also limits ARPANSA's ability to analyse the nature and cause of complaints.

2.57 The ANAO also found that ARPANSA's annual report does not provide an accurate record of complaints received. It has reported only three complaints lodged since 1998–99, all for 2002–03. However, the ANAO found several instances where written complaints were not reported. For example, written complaints sent directly to the Regulatory Branch were not forwarded to the Director of Corporate Services. They were not reported in ARPANSA's annual report.

²² The *Principles* outline the matters that agencies should consider when developing or reviewing their client service charters.

Recommendation No.5

2.58 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.

ARPANSA response: Agreed.

3. Management of Cost Recovery for Regulatory Activities

This chapter examines ARPANSA's recovery of its regulatory costs from applicants and licensees.

Introduction

3.1 When establishing ARPANSA, the government decided that:

... entities regulated ... should bear the costs of such regulation, ensuring that there will be no additional burden on the Commonwealth or the public purse.²³

3.2 ARPANSA was required to establish user-pays initiatives in regard to its regulatory costs as soon as possible.²⁴ These costs of regulation include the licensing process and ongoing management of licensee compliance with licence conditions. ARPANSA was empowered to charge licence application fees under the ARPANS Act and Regulations and annual licence charges under the *Australian Radiation Protection and Nuclear Safety (Licence Charges) Act 1998*.²⁵

ARPANSA's cost recovery framework

3.3 The principles of good cost recovery practice are indicated in several publications, such as Department of Finance guidelines.²⁶ Broadly, these guidelines require agencies to set charges according to the cost of the service or product provided, and to review charges and the arrangements for them on a periodic basis.

3.4 Effective management of cost recovery requires a robust policy/methodology framework. Relevant matters for such a framework include the definition of cost recovery, the legal basis for charges, and the calculation of costs and fees.

3.5 However, ARPANSA does not have a documented cost recovery policy or other guidance addressing cost recovery.

²³ Senate Hansard, Monday 23 November 1998, p. 412.

²⁴ As noted in Chapter 1, ARPANSA also raises substantial revenue from clients for commercial services, such as personal radiation monitors. This audit addressed the recovery of regulatory costs only.

²⁵ Annual licence charges are characterised as a tax, as distinct from a fee for service. Application fees, however, are not characterised as a tax. ARPANSA charges for other services, such as personal radiation monitors, are made under other legislation and are fees for service rather than taxes.

²⁶ *Commonwealth Cost Recovery Guidelines for Regulatory Agencies*, Department of Finance and Administration (2002). This updates earlier guidance on cost recovery from the department. Several ANAO audit reports, such as Audit Report No.17 2003–04 *AQIS Cost Recovery Systems Follow-Up Audit*, have also addressed implementation of cost-recovery principles.

3.6 ARPANSA issued several letters to licensees in 1999, which set out some aspects of its proposed approach to cost recovery. However, these were indicative outlines, which did not provide a clear and comprehensive policy framework for cost recovery. They were not developed further into a policy.

3.7 The absence of an articulated cost recovery framework increases the risks of:

- money appropriated for other purposes being inadvertently used to support regulatory activity;
- unplanned and inequitable cross-subsidisation between clients or activities;
- lack of clarity between moneys raised under taxation charges or cost recovery arrangements;
- avoidable concerns by stakeholders about the setting of charges; and
- decisions on the level and scope of regulation being less cost-effective than may otherwise be the case.

3.8 In this context, the ANAO notes that ARPANSA's funding base, on establishment, included appropriation funding transferred from the former NSB. This funding was initially used to subsidise fees to major licensees, which were incorporated into the overall ARPANSA appropriation.

3.9 However, ARPANSA has not clearly defined whether an equivalent, or other amount, of appropriation funding is still used to subsidise fees in general for the costs of particular licence applications, or used for other purposes. A clear policy framework would delineate the management of these funds, among other issues. At the least, this would enable ARPANSA to identify whether it is meeting its obligations under legislation and government policy.

3.10 The ANAO also found that, in response to fee increases, a number of clients have requested that ARPANSA justify the basis of its fees and charges. Comments by entities have included:

We fail to understand the reasoning behind the costing method used by ARPANSA.

There is no doubt that the time for a detailed review of charges is past and there is an urgent need to conduct a review.

3.11 A more explicit framework for cost recovery is required to support systematic decision-making for cost recovery. It is required for internal management purposes, to inform stakeholders, and to provide assurance that ARPANSA fulfils its legislative and policy obligations. It would also provide a more robust structure for the recording of costs and the setting of charges. These issues are discussed below.

Identifying and recording regulatory costs to be recovered

3.12 The bulk of regulatory effort occurs within the Regulatory Branch. ARPANSA records the direct and indirect costs associated with this branch.

3.13 ARPANSA also allocates overhead costs, such as a proportion of the costs of the CEO and work by advisory committees, to the regulatory function. These allocations are based on the relative number of staff working within Regulatory Branch in each year.

3.14 Other areas of ARPANSA also engage in regulatory work. For example, ARPANSA established project teams for major licence applications, such as the Replacement Research Reactor (RRR) and the waste repository. These project teams include contributions from staff outside the Regulatory Branch.

3.15 However, the cost of these other staff engaged in regulatory functions is not recorded or attributed to the regulatory function. This has resulted in an under-recording of costs to be recovered. Due to limitations in ARPANSA's data systems, the ANAO was not able to estimate the quantum of these costs.

3.16 As a result, ARPANSA's cost-recording practices are not activity-based and do not support the recovery of all regulatory costs.

Setting fees and charges to recover costs

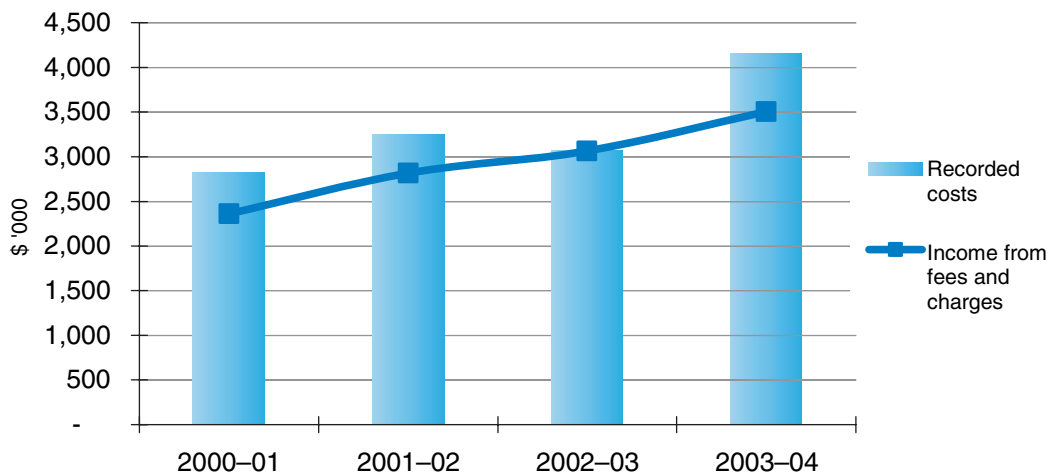
Extent to which ARPANSA recovers recorded costs

3.17 ARPANSA advised the ANAO that it aims to fully recover the recorded cost of its regulatory activities from licensees through fees and charges.

3.18 However, the ANAO found that, except in 2002–03, ARPANSA has under-recovered its recorded regulatory costs (see Figure 3.1).

Figure 3.1

ARPANSA's identified regulatory costs and income from fees and charges, 2000–01 to 2003–04



Source: ARPANSA

3.19 Since 2000–01, ARPANSA has under-recovered recorded regulatory costs by some \$1.55 million, or 12 per cent of identified costs. The actual under-recovery is greater because these costs do not include all regulatory effort, as noted above.

3.20 ARPANSA advised that the level of under-recovery was offset by the NSB appropriation. In effect, ARPANSA used this funding to subsidise some regulatory costs. For example, in at least one instance ARPANSA did not pass on the costs of some unplanned inspections, peer review, and public forums to a licensee. Instead, it absorbed these costs from appropriation funding.

3.21 There is no framework or clear process for these decisions. Accordingly, ARPANSA is unable to provide assurance that it is meeting the government's cost recovery requirements (see Paragraph 3.1).

3.22 In addition, the costs of regulating the RRR were substantially greater than ARPANSA expected. In recognition of this, ARPANSA received additional one-off funding of \$800 000 in the 2003–04 Budget.

Linking fees and charges to activities

3.23 It is better practice, as far as feasible, for regulators to identify costs against particular activities, to minimise the need to distribute overhead costs

arbitrarily among activities.²⁷ In considering this principle, regulators need to balance accuracy and precision against the costs of particular methods.

3.24 However, in practice, ARPANSA has set fees on the basis of comparability to fees imposed by State regulators and using international regulator experience. They are not based on a robust analysis of the costs of regulating the clients or providing services.

3.25 Indeed, system limitations mean that ARPANSA is not able to readily identify and monitor the cost of regulatory effort associated with particular client groups or types of licence.

3.26 ARPANSA commissioned reviews of its licence charges and fees in 1999 and 2003. Both reviews recommended that ARPANSA relate charges more closely to the costs attributable to particular licences.

3.27 For example, the 1999 review recommended that ARPANSA implement an activity-based costing system. ARPANSA advised licensees that it would implement the recommendation.

3.28 The 2003 review focused on ARPANSA's costs of monitoring the RRR. It found that regulatory costs for the reactor were \$1.104 million, compared with \$87 500 recovered through the licence charge.²⁸ The review noted that *In terms of fairness and equity, it is not acceptable for particular licences or clients to be disadvantaged vis a vis others in the regulatory charging regime.* It also found that *there was most likely significant cross-subsidisation ... from across the whole ARPANSA regulatory function.*

3.29 ARPANSA advised that it did not agree with some of the review's assertions or assumptions. However, during the course of this audit, ARPANSA further advised that it now intends to implement the review's recommendations.

3.30 Overall, ARPANSA's current approach to cost recovery does not align well with recognised better practice or the requirement that regulated entities bear the costs of regulation. A more robust and systematic framework is required to guide cost recovery, including recording of relevant costs and alignment of fees and charges with costs.

²⁷ This was most recently articulated in Department of Finance and Administration (2002), *Commonwealth Cost Recovery Guidelines for Regulatory Agencies*, p. 31.

²⁸ The ANAO notes that the annual licence charge for the period 2002-03 was actually \$43 750.

Recommendation No.6

3.31 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.

ARPANSA response: Agreed.

4. Licensing

This chapter examines ARPANSA's licensing processes.

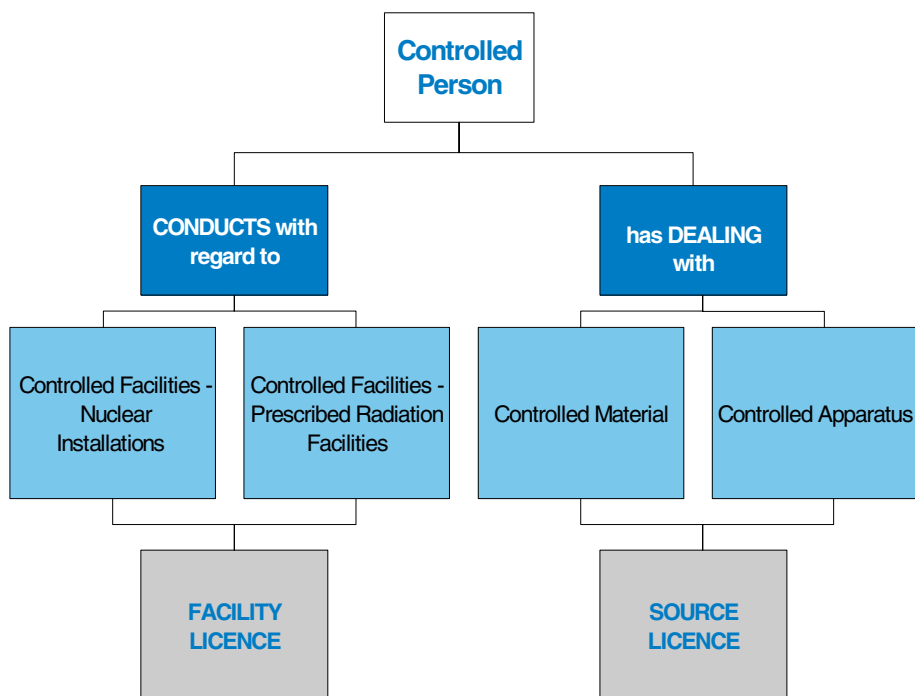
Introduction

4.1 Licensing is a key regulatory activity of ARPANSA. A licence is a legal document that authorises a controlled person²⁹ to undertake activities that would otherwise be prohibited under the ARPANS Act and Regulations.

4.2 ARPANSA issues two types of licence: for a source (see Paragraph 1.7) or for a facility (see Paragraph 1.10). Depending on their circumstances, entities may require a source licence, a facility licence, or both, as illustrated in Figure 4.1 (the Glossary provides further definitions).

Figure 4.1

Overview of when a licence is required



Source: ARPANSA

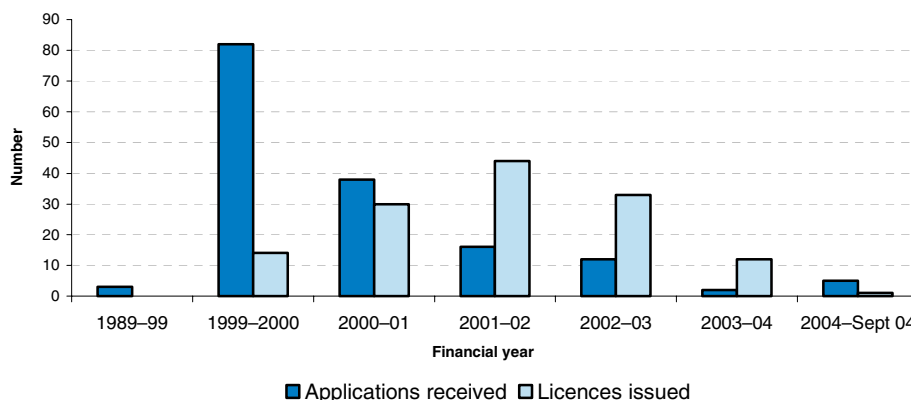
²⁹ A controlled person is: a Commonwealth entity; a Commonwealth contractor; a person in the capacity of an employee of a Commonwealth contractor; or a person in a prescribed Commonwealth place.

4.3 Under Division 2 of the ARPANS Act, the CEO or the CEO’s delegate makes the decision on whether a licence is issued. The CEO has not delegated this power.

4.4 Since ARPANSA’s establishment, it has received 158 applications and 134 licences have been issued, as illustrated in Figure 4.2.³⁰

Figure 4.2

Licence applications received and licences issued



Source: ARPANSA

4.5 The initial peak in applications reflects the influx of licence applications for those activities being undertaken when the ARPANS Act and Regulations were enacted.

4.6 A licence continues in force until it is cancelled or surrendered.³¹ This reinforces the need for robust and systematic processes for licensing and monitoring of compliance, as discussed in the remaining parts of this report.

Guidance to applicants

4.7 ARPANSA’s guidance to applicants comprises an applicant guide³² and application packs. The applicant guide includes a description of ARPANSA’s licensing framework. Its purpose is:

... to provide information to Commonwealth entities who may require a licence under the *Australian Radiation Protection and Nuclear Safety (ARPANS)*

³⁰ Figure 4.2 illustrates the time lag in issuing licences, discussed at Paragraph 4.48.

³¹ Section 37 of the ARPANS Act.

³² *Guide to the Australian Radiation Protection and Nuclear Safety Licensing Framework*, Edition 1, March 1999.

Act 1998 [the ARPANS Act] to enable them to deal with (ie possess, have control of, use, operate or dispose of) radiation sources. The guide describes to whom and what the Act applies. It also addresses a number of general administrative and legal matters such as appeal procedures, ongoing licensing requirements and monitoring and compliance.

4.8 The application packs contain an application template and directions on some of the information applicants need to provide in support of their application. For example, applicants are advised to provide a description of the proposed conduct (for a facility) or dealing (for a source). They must also lodge a series of plans and arrangements, which detail how the applicant will manage safety if licensed.

4.9 However, the ANAO found that application packs do not explicitly ask applicants to address the statutory matters against which they will be assessed. These are matters that the CEO must take into account when deciding to issue a licence (discussed further at Paragraph 4.20). For example, the guide does not inform applicants that the CEO must take into account international best practice in radiation protection and nuclear safety when considering an application for a licence.

4.10 As a result, ARPANSA has often found applicant documentation to correlate poorly with the ARPANSA legislation. It has often had to seek clarification from applicants during the assessment process.

4.11 Expanding guidance to address these omissions would assist applicants to identify and provide information required for assessment, and to prepare applications that address the areas on which they will be assessed. It would also improve the transparency of the application assessment process.

Recommendation No.7

4.12 The ANAO recommends that ARPANSA enhance guidance to applicants to better reflect the requirements of the ARPANS Act and Regulations and, in particular, to provide guidance on the statutory matters that the CEO must take into account.

ARPANSA response: Agreed.

Standard operating procedures

4.13 In July 2003, ARPANSA finalised standard operating procedures (SOPs) addressing receipt; assessment and recommendation; and issuing of a licence. Previously, ARPANSA had draft procedures only. The draft procedures did not provide guidance on a number of matters, such as:

- form of letters to applicants (for example, acknowledgement of applications);

- entering applicant information on information systems;
- the correct form for a regulatory assessment report to the CEO; and
- how to undertake, record and document site visits and inspections.

4.14 In addition, there was no formal requirement for the draft procedures to be followed. Accordingly, the bulk of licence assessments—some 75 per cent—were made without the support of robust, documented procedures. This has reduced assurance that assessments of applications were made consistently and appropriately.

Accepting applications

4.15 Under Section 34 of the ARPANS Act, ARPANSA can accept applications only if they are:

- in the correct form;
- appropriately signed; and
- accompanied by a fee.

4.16 ANAO analysis of a sample of applications identified that all applicants had used the required form.³³ All applications reviewed had been appropriately signed, receipted and acknowledged by letter.

4.17 However, some 60 per cent of applications had been accepted for assessment without being accompanied by a fee. These applications were nevertheless processed by ARPANSA. If a fee was not later submitted by the applicant, it was sought before a licence was issued.

4.18 The ANAO noted that acceptance of applications, without a fee, is a breach of ARPANSA legislation.

Recommendation No.8

4.19 The ANAO recommends that ARPANSA introduce appropriate systems to ensure its application processing complies with the requirements of the ARPANS Act and Regulations.

ARPANSA response: Agreed.

³³ ARPANSA considers applications that use the application pack to be in the correct form.

Preparation of advice to the CEO

4.20 In deciding whether to issue a licence, the CEO must take into account a number of matters prescribed in the ARPANS Act and Regulations (see Table 4.1).³⁴

Table 4.1

Statutory matters to be taken into account by the CEO

1. International best practice in relation to radiation protection and nuclear safety
2. Whether the information establishes that the proposed conduct (or controlled apparatus of material) can be carried out without undue risk to the health and safety of people, and to the environment
3. Whether the applicant has shown that there is a net benefit from carrying out the conduct relating to the controlled facility
4. Whether the applicant has shown that the magnitude of individual doses, the number of people exposed, and the likelihood that exposure will happen, are as low as reasonably achievable (ALARA), having regard to economic and social factors
5. Whether the applicant has shown a capacity for complying with these Regulations and the licence conditions that would be imposed under Section 35 of the ARPANS Act³⁵

Source: ARPANS Act and Regulations

Review of applications

4.21 To support the decision-making of the CEO, Regulatory Branch staff review each application to assess whether the application is in accordance with the ARPANS Act and Regulations.

4.22 In reviewing applications, staff are guided by the *Regulatory Guideline on Review of Plans and Arrangements*.³⁶ This guideline specifies a number of requirements which applications are reviewed against. These include:

- arrangements for maintaining effective control;
- safety management;
- radiation protection;
- radioactive waste management;
- security plan; and
- emergency plan.³⁷

³⁴ The CEO must also take into account whether the application includes the information asked for by the CEO and whether the application has been signed by an office holder of the applicant, or a person authorised by an office holder of the applicant.

³⁵ If the application is for a facility licence for a nuclear installation, the CEO must also take into account the content of any submissions made by members of the public about the application.

³⁶ Facility applications are also reviewed against other guidelines, depending on the type of conduct being licensed (see Appendix 3).

³⁷ Regulation 39 of the ARPANS Regulations enables ARPANSA to request an applicant's plans and arrangements, as set down in Appendix 3.

4.23 For each requirement, the guideline specifies detailed performance expectations. For example, in assessing an applicant's emergency plan, one expectation is that it demonstrates identification of accident situations in terms of the hazard, the personnel at risk, and the consequences of potential accidents.

4.24 In reviewing applications, ARPANSA may also have regard to relevant codes or standards of practice, international best practice and public submissions.

4.25 However, while the guideline, codes, practice and submissions address many key aspects of radiation and nuclear safety, these documents are not explicitly aligned to the legislative matters that the CEO must take into account in making a decision. In particular, the guideline on plans and arrangements—the primary assessment guideline—does not specifically address the statutory matters specified in the legislation.³⁸

4.26 These limitations increase the risk that staff may not consistently, or adequately, address the matters specified in the ARPANS Act and Regulations in preparing reports and recommendations to the CEO.

Advice to the CEO

4.27 Once a review of an application is complete, staff prepare a regulatory assessment report for the CEO's consideration. The ANAO found that assessment reports addressed the adequacy of applicants' plans and arrangements to manage safety.

4.28 However, reflecting the lack of guidance to staff in the application review process, many regulatory assessment reports did not provide a clear analysis of the extent to which the application satisfied each of the statutory matters. For example, one report did not explicitly state whether the application was consistent with international best practice. It simply stated:

The application refers to a number of Australian standards, IAEA standards, and ICRP Recommendations, for the conduct of the facility demonstrating the applicant's commitment to comply with international best practice.

4.29 A further report did not draw a conclusion on whether the applicant was meeting international best practice. Instead it stated:

... comparisons have been drawn between [the agency] and similar organisations, both here and overseas, through either documentation or the direct knowledge and experience of Regulatory Branch officers.

³⁸ Similarly, facility-specific regulatory assessment guidelines do not reflect the statutory matters (Appendix 3).

4.30 In regard to whether there was a net benefit, one report asserted that the authorised use of radiation results would have societal benefits, rather than assessing whether this would be the case for the particular application.

4.31 A more thorough analysis and articulation of the adequacy of applicant information relevant to the statutory matters would contribute to greater consistency and transparency in advice to the CEO, for the benefit of all stakeholders.

Recommendation No.9

4.32 The ANAO recommends that ARPANSA enhance its licence application assessment processes by ensuring that:

- guidance to staff explicitly addresses specified statutory matters that the CEO must take into account; and
- regulatory assessment reports provided to the CEO on each application explicitly address the extent to which an application addresses these matters.

ARPANSA response: Agreed.

Licence conditions

4.33 Under Section 35 of the ARPANS Act, the CEO may impose special licence conditions when issuing a licence. The CEO's decision is informed by recommendations made by staff in regulatory assessment reports. Formulation of these recommendations includes review by Regulatory Branch management and ARPANSA's legal adviser.

4.34 ARPANSA advised that the purpose of special conditions is to require licence holders to achieve, within an agreed timeframe, improvements in their safety documentation, framework or processes. Conditions have also been used to overcome gaps within licence applications. Applicant guidance states:

It is recognised that in the case of existing (activities) at the time of enactment of the ARPANS Act, 5 February 1999, not all the information (required in an application) may be available at the time of application for licence to operate the facility. Following review of submitted information, a schedule for improvement or development of the outstanding plans and arrangements will be agreed between ARPANSA and the applicant, and the licence may be issued subject to the additional information being provided within the agreed timeframe.³⁹

4.35 The CEO of ARPANSA has not rejected any application for a licence. However, special conditions have been imposed on all licences issued. Most

³⁹ Facility licence application pack, Edition 1, March 1999, p. 4.

conditions have focused on directing licence holders to provide information which relates to statutory requirements. Examples of conditions have included requirements that the licence holder must:

- provide ARPANSA with the Final Safety Analysis Report within a timeframe agreed by the CEO once the facility becomes operational;
- include in the radiation protection plan for the facility, dose constraints and ALARA⁴⁰ objectives for workers and for members of the public, acceptable to the CEO;
- develop an inventory of all controlled material and controlled apparatus; and
- finish a waste management plan.

4.36 Some of these conditions appear to be significant aspects of recognised international best practice, and are being used several years after the 1999 enactment of the legislation—for example, the requirement to develop an inventory of all controlled material and controlled apparatus.

4.37 ARPANSA advised that it does not consider that these applicants were deficient in demonstrating *radiation protection and nuclear safety consistent with the CEO being able to exercise his statutory discretion to issue a licence*. ARPANSA further advised that *such conditions are used to promote continuous improvement of old conducts and dealings with contemporary practices*. However, the ANAO found that ARPANSA does not have systematic arrangements in place to provide assurance to stakeholders that imposed conditions are not being used to overcome deficiencies within applications.

4.38 More broadly, the ANAO found that ARPANSA does not have a policy or guidance to staff to support the use of special conditions to address such matters as:

- in what circumstances to recommend a licence condition; or
- the scope and application of licence conditions.

4.39 The ANAO considers that such guidance to staff would facilitate transparency and provide assurance to stakeholders and applicants that conditions are not used to overcome deficiencies in applications and, conversely, that they do not impose unnecessary cost burdens on licensees.

⁴⁰ The guiding principle behind radiation protection is that radiation exposures be kept as *low as reasonably achievable (ALARA)*, economic and social factors being taken into account. This commonsense approach means that radiation doses both for workers and for the public are typically kept lower than their regulatory limits.

Recommendation No.10

4.40 The ANAO recommends that ARPANSA develop a risk-based decision-making process for the use of additional licence conditions. This would require clear procedures and documentation addressing, inter alia, why and how conditions will be applied, monitoring of those conditions, and their costs and benefits.

ARPANSA response: Agreed.

Management of information

4.41 Information management is an important contributor to effective regulatory management. It enables monitoring and assessment of the licensing function, so that both management and stakeholders are provided with the necessary insight into any performance issues, such as licensing assessment delays.

4.42 ARPANSA does not maintain a single database containing all applicant and licence-holder information. Instead it maintains three separate spreadsheets, which separately record:

- the date of receipt of an application⁴¹;
- the date of payment of an application fee; and
- the status of review of applications and when a licence was issued.

4.43 This approach to information management has made tracking and monitoring of licence applications difficult. For example, data are not readily available to calculate the time taken to process an application, from receipt to the issuing of a licence.

4.44 Similarly, ARPANSA does not maintain a single database containing licence-holder compliance information. These data are not readily available to inform management of compliance by licensees, or to support reporting of the extent of licence-holder compliance.

4.45 ARPANSA has recognised the need for improved applicant information and has been developing a Licensing Administration System (LAS) database for several years. However, ARPANSA advised that it is now reviewing the appropriateness of the proposed LAS, and examining other systems to manage applicant and licence-holder information. For example, it is considering use of a database that has been developed by the International Atomic Energy Agency (IAEA).

⁴¹ This spreadsheet also contains a brief description of the application, the regulatory officer assigned and the agency contact.

4.46 The ANAO considers that better collection and maintenance of applicant and licence-holder information centrally would facilitate the management of the regulatory function. It would also support accountability and provide transparency for ARPANSA's performance, and facilitate assessment of licence holders' compliance with the ARPANS Act and Regulations. ARPANSA's current arrangements do not provide such information.

Recommendation No.11

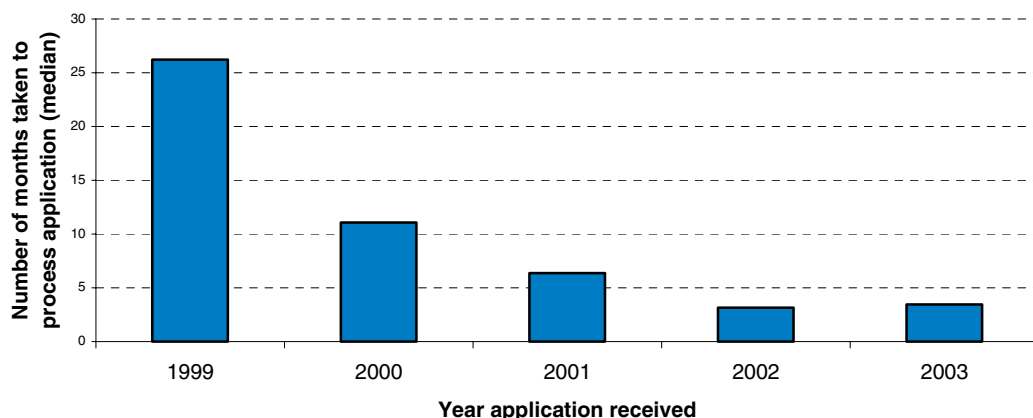
4.47 The ANAO recommends that ARPANSA develop and implement a central database for the management of applicant and licence-holder information.

ARPANSA response: Agreed.

Timeliness of assessments

4.48 Neither the ARPANS Act or the Regulations specify a time period in which a decision must be made on an application. ARPANSA's Regulatory Branch has developed an internal processing standard of three months. However, it does not monitor the extent to which this standard is met. ARPANSA does not report in its annual report on the time taken to process applications.

4.49 The ANAO estimated processing times from ARPANSA documents and spreadsheets. This indicated that the median time for processing all applications at June 2004 was 22 months. For those applications lodged in 1999, the median time was 26 months, with processing times decreasing for later applications (see Figure 4.3).

Figure 4.3**Months taken to process an application, by year of application**

Source: ANAO

4.50 The median processing time for applications received in 2003 was three months. That is, half of the 2003 applications still exceeded the internal target of three months.

4.51 ARPANSA advised that delays in early years had resulted from the backlog of applications, the need for more information in applications and ARPANSA delaying the processing of applications received in the transitional period in favour of later applications. This was because applications in the transitional period were in compliance with the ARPANS legislation until a licence was granted or refused;⁴² whereas those applicants who applied after the expiry of the transition period could not deal with sources or undertake unlicensed activities in relation to a facility until licensed.

4.52 The ANAO found that the extent of licensing delays, and their causes, were not presented to the Parliament through ARPANSA's annual reports.

4.53 The absence of performance information relating to the timeliness of one of ARPANSA's key regulatory roles has reduced assurance to stakeholders that the licence application process is being managed effectively.

⁴² Section 8 of the *ARPANS (Consequential Amendments) Act 1998*, provided for existing Commonwealth activities to be in compliance with the ARPANS Act if applications for these were lodged by August 1999.

Recommendation No.12

4.54 The ANAO recommends that ARPANSA monitor the timeliness of licence approvals against service standards, and report on this in its annual report.

ARPANSA response: Agreed.

5. Monitoring Compliance

This chapter examines ARPANSA's processes for monitoring compliance by entities with licence conditions and the legislation.

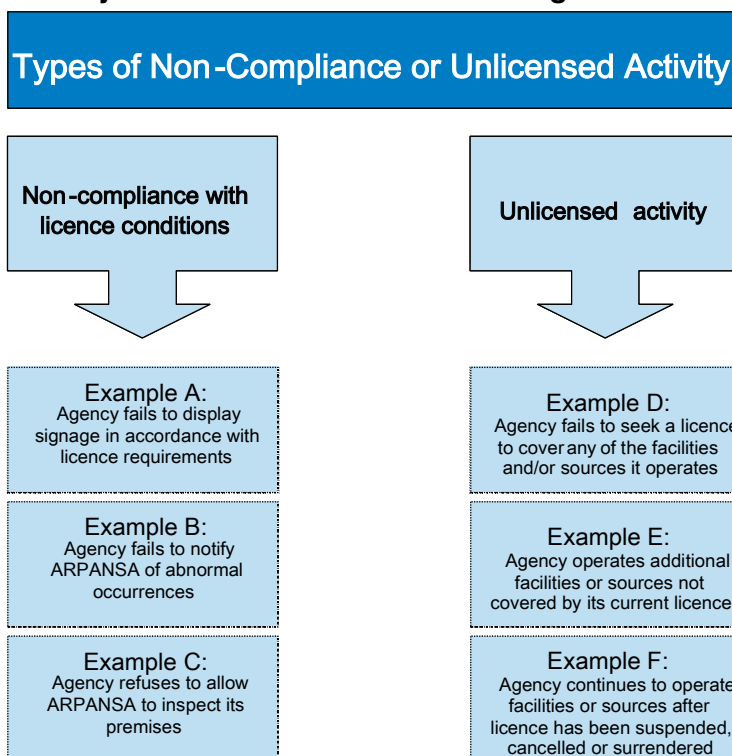
Strategic management of compliance

5.1 Section 15(1)(h) of the ARPANS Act specifies that the CEO of ARPANSA has the function to monitor compliance of controlled persons with the ARPANS Act, whether or not they hold a licence. Reflecting this requirement, ARPANSA's Corporate Plan includes the strategy of *working with Commonwealth entities to ensure the safety of the radiation facilities and sources operated by them.*

5.2 As illustrated in Figure 5.1, prohibited activity includes non-compliance with licence conditions and unlicensed activity.⁴³

Figure 5.1

Prohibited activity under the ARPANS Act and Regulations



Source: ANAO analysis of ARPANSA information

⁴³ Prohibited activity is defined under Part 5, Division 1 of the ARPANS Act.

5.3 ARPANSA has a number of approaches to promote and monitor compliance. These approaches are discussed from Paragraph 5.14 onwards. They include:

- facilitating entities' awareness of ARPANSA's role and of their responsibilities under the ARPANS Act and Regulations;
- issuing a *Licence Handbook* to all licensees;
- reporting by licensees; and
- undertaking inspections.

5.4 ARPANSA does not specify the role or emphasis to be given to the various compliance approaches. As well, its approaches have largely focused on self-regulation, and on identifying non-compliance by licence holders. That is, ARPANSA does not have an explicit framework or a strategy for it to identify prohibited activity by non-licensed entities.

5.5 In practice, ARPANSA relies on notifications by others, such as the Australian Customs Service, to identify unlicensed activity. A more systematic approach to the risk of prohibited activity by non-licensed entities is warranted in order to identify mitigation measures. For example, possible measures include writing to entities without a licence, to obtain confirmation that they do not possess any radiation sources or facilities.

5.6 More generally, the ANAO considers that the absence of an overarching compliance policy reduces assurance that non-compliant and prohibited activity is being identified in a structured manner, in accordance with the ARPANS Act and Regulations.

5.7 During the course of this audit, ARPANSA established a Regulatory Compliance Working Group. ARPANSA advised that the group aims to address the management of its compliance approach.

Targeting and resourcing of compliance activities

5.8 ARPANSA advised that the effort spent on compliance monitoring is roughly proportional to the level of hazard associated with the facilities and sources under licence. It further advised that staff consider issues such as:

- the hazard of the conduct of dealings by the licensee;
- matters arising in the licence assessment;
- the licensee's history of compliance; and
- feedback from earlier inspections.

5.9 However, these considerations are largely informal and were not systematically documented by staff or agreed by management. Risk judgements by staff were not systematically moderated, reducing assurance that compliance actions were based on a consistent approach.

5.10 ARPANSA does not have a systematic and documented analysis of the likelihood and consequences of various risks for a given licence, such as potential misuse of sources or poor management by licensees. In particular, there is no systematic risk ranking of licence holders that considers the likelihood and the consequences of non-compliance, which can be used to provide a consistent basis for deciding the compliance effort to be devoted to particular entities or sources.

5.11 ARPANSA advised that, although it did not have a formal risk-management framework, it was developing relevant experience through compliance monitoring and assessment.

5.12 The ANAO considers that the absence of an overall, risk-based, compliance framework has reduced assurance that compliance effort is directed to areas of greatest risk in a cost-effective manner. A more systematic approach is necessary to:

- identify the role and integration of its compliance approaches;
- systematically assess the relative risks of each licensee and hazard; and
- facilitate the allocation of available resources across the compliance approaches.

Recommendation No.13

5.13 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 licensees and the sources and facilities under their management; and
- targets compliance effort measures in accordance with assessed licensee risk.

ARPANSA response: Agreed.

Facilitating awareness

5.14 Licensees are responsible for complying with the conditions of their licences. Nevertheless, it is good regulatory practice to aid licensees' understanding of their obligations and responsibilities, and to make them aware of how to conform appropriately to licence conditions and other requirements.

5.15 ARPANSA's principal method for communicating these expectations has been through presentations to some licensees. Presentations have focused on the major licensees, who manage the bulk of facilities and sources.

5.16 The ANAO reviewed a number of presentations and found that they appropriately addressed issues such as the requirements of the legislation, the role of ARPANSA, important definitions, and additional requirements by ARPANSA.

5.17 However, presentations did not address some major compliance risks, such as the need to ensure that all conducts are authorised by licences.

5.18 In addition, decisions on when, and to whom, to give presentations were largely informal. There was no overall schedule of presentations. In particular, there was no explicit strategy for communicating requirements to smaller entities. Any radiation activities undertaken by these entities are also subject to the ARPANS legislation.

5.19 ARPANSA advised that it is developing a Regulatory Compliance Policy. It intends that the policy will address the role of promotion and education activities. The ANAO considers that the policy should include arrangements to obtain feedback on the effectiveness of these activities.

Licence Handbook

5.20 When a licence is granted, the licensee is issued a Licence Handbook. The handbook contains general information and guidance, licence conditions common to particular types of licences (for example, to source licences and facility licences), and conditions that are particular to each licence holder.

5.21 The handbook is intended to be the single reference point for licence holders, setting out compliance requirements and licence conditions. It is therefore a key tool in encouraging compliance, and in assisting licensees to self-assess and to report breaches or events.

5.22 The handbook provides a substantial amount of background information for licensees. It addresses matters such as the management of sources and facilities, reporting to ARPANSA, and how to interpret the licence.

5.23 However, the ANAO found that handbooks examined in this audit did not include all licence conditions prescribed in the ARPANS Act and Regulations. This reduces their effectiveness as a support for licensee compliance. For example, handbooks did not reflect the requirement for licensees' annual review of plans and arrangements to be forwarded to ARPANSA. Also, some reporting requirements described in the handbook were inconsistent with, or expressed in different terms from, the reporting guidelines (guidelines are discussed further from Paragraph 5.42). This increases the risk that requirements will not be complied with consistently.

5.24 The ANAO also found that the glossary to handbooks does not define several relevant terms, such as 'abnormal event', reducing assurance that licensees will consistently report incidents.

5.25 The ANAO considers that improvements are required to assist licensees to comply with the legislation. This could be in the form of a more clearly articulated handbook, addressing current omissions, or other appropriate alternative arrangements.

5.26 An internal review in 2003 also confirmed the need for such improvements. It found that the handbook *actually distracts licence holders from the Act and Regulations. The conditions in the Act and Regulations have not been given proper regard nor are they fully understood.* The review also identified difficulties in version control of the various handbooks, noting that, for the 167 licence holders, there were 743 variations in the controlled parts of the handbook.

5.27 The review recommended that, to address these limitations, the handbooks be withdrawn progressively, and that licences be re-issued in a clearer format.

5.28 ARPANSA has yet to address the review findings.

Recommendation No.14

5.29 The ANAO recommends that, to facilitate licensee understanding of and compliance with their obligations, ARPANSA revise or replace the Licence Handbook to address identified weaknesses.

ARPANSA response: Agreed.

Reporting by licensees

5.30 The ARPANS Act and Regulations impose a number of reporting requirements on licensees (see Appendix 4). To give effect to these requirements, ARPANSA requires licence holders to submit the following three types of reports:

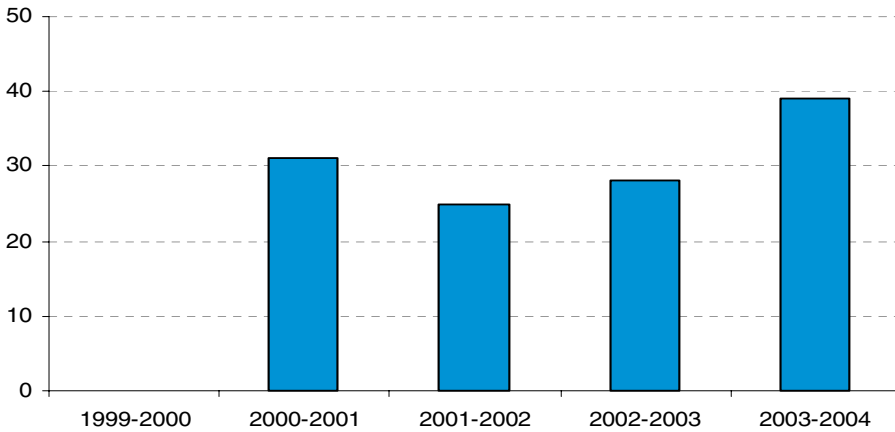
- *incident or ad hoc reports*. These are required according to the ARPANS Act and Regulations, particularly in regard to specified events, such as a change in practices or inventories, abnormal occurrences and breaches of licence conditions. These reports must be submitted within specified times;
- *quarterly reports*. These describe any abnormal occurrences during the quarter, changes to plant or procedures, any radioactivity released to the environment, or changes to controlled materials, apparatus or facility. These reports must be submitted within 28 days of the end of the quarter; and⁴⁴
- *annual reports*. These describe the licensees' operating experience; maintenance and testing; abnormal occurrences; modifications; results of review of management plans and arrangements; results of radiation monitoring and surveys; inventories of materials; releases of controlled materials; and other matters.

Licensee compliance with reporting requirements

Incident or ad hoc reports

5.31 The number of abnormal occurrences reported to ARPANSA is shown in Figure 5.2. An abnormal occurrence is an unanticipated operational occurrence, or an accident. Abnormal occurrences can occur for a number of reasons, and do not necessarily indicate a breach, or poor management by the licensee.

⁴⁴ Until early 2004, quarterly reports did not have to be lodged unless a relevant change or event had occurred. In March 2004, this requirement was changed, and agencies were required to make 'nil return' reports even if no relevant change or abnormal occurrence had taken place.

Figure 5.2**Abnormal occurrences reported to ARPANSA, 1999–2000 to 2003–04**

Source: ARPANSA

5.32 However, the ANAO found that there were also some incidents, or changes to inventories, which were either not reported within the time required by the reporting guidelines, or not reported at all. Examples included:

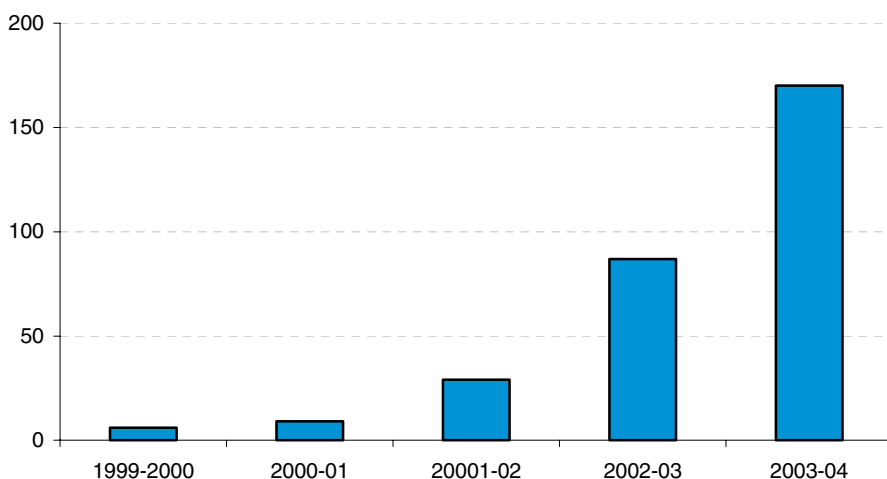
- entities adding to source inventories without notifying ARPANSA—in one case, this was identified after the event through informal contact with the licensee; in another, ARPANSA identified the change through an inspection; and
- an accident during use of a facility, which caused injury to staff—this should have been reported immediately. However, it was not notified to ARPANSA until the next quarterly report.

Quarterly reports

5.33 The number of quarterly reports submitted to ARPANSA are shown in Figure 5.3. This indicates that the number of quarterly reports received by ARPANSA has increased substantially in recent years. ARPANSA advised that it considered that the increase was, in part, due to requiring reports from all licensees from March 2004, not just those where there was a change in circumstances, as was previously the case.

Figure 5.3

Quarterly reports received by ARPANSA, 1999–2000 to 2003–04



Source: ARPANSA

5.34 Notwithstanding the increasing number of quarterly reports submitted, ARPANSA was unable to advise whether all licensees were meeting the requirements. ARPANSA did not have a systematic process for monitoring reports. For example, there is no benchmark or target number of expected reports. In addition, the number of reports is not routinely collected (the data for Figure 5.3 had to be compiled manually by ARPANSA for this audit).

5.35 Accordingly, ARPANSA does not have data to assess the extent to which licensees comply with quarterly reporting requirements. The ANAO considers that a more systematic approach, including recording and monitoring of the submission of reports, is required to ensure that quarterly reports contribute to compliance monitoring and management, as required.

Annual reports

5.36 The ARPANS Act and Regulations require that *all* licensees report to ARPANSA at least once each financial year.

5.37 As with quarterly reports, ARPANSA does not routinely identify how many annual reports should be received. Nor does it record and monitor the extent to which the required number of reports is submitted, or the timeliness with which they are submitted.

5.38 There has been under-reporting by licensees. For example, in 2000–01, ARPANSA received only five annual reports out of 44 licensees.

5.39 For the purposes of this audit, ARPANSA conducted a one-off exercise to assess reports due and received for 2003–04. Eighty-seven annual reports were due for 2003–04, of which 62 had been submitted as at 29 November 2004.

5.40 ARPANSA has not articulated and enforced the reporting requirements of licensees. For example, ARPANSA advised that it does not seek reports from some source licence holders. Further, the fourth quarterly report is often treated as sufficient to meet the requirement for an annual report, notwithstanding that these are separate requirements.

5.41 Overall, the ANAO found that some entities are not fully complying with reporting requirements. ARPANSA lacks supporting procedures for monitoring reporting and for addressing non-reporting or late reporting.

Guidance to licence holders on reporting

5.42 To facilitate licensee reporting, ARPANSA has developed guidelines on reporting. These guidelines are incorrectly described as *draft*, notwithstanding that the guidelines have been finalised.

5.43 The ANAO found that the guidelines were consistent with the ARPANS Act and Regulations. However, the guidelines did not clearly articulate some of the ARPANS Act and Regulations' reporting requirements. For example, the guidelines did not specify a time within which annual reports should be submitted, risking delays in the receipt of reports.

5.44 The guidelines were also out of date, as they did not reflect recent changes to reporting practices. In particular, the requirement for entities to submit *nil return* quarterly reports was not included.

5.45 Further, the guidelines did not specify a standard format for reports. As a result, reports submitted by entities varied markedly in the issues addressed and in the level of detail provided. This limits ARPANSA's ability to extract consistent, and sufficient, information to inform it about licensees' compliance.

5.46 Licensee advice to the ANAO confirmed that they considered the guidelines did not adequately specify the level of detail required in reports. Licensees also advised that they were not provided with feedback on the quality of reports submitted. Overall, ARPANSA does not monitor satisfaction with such guidance.

5.47 Some licensees include supporting evidence for assertions made in reports, for example by providing copies of new policies. However, ARPANSA guidelines do not require such evidence and it is not standard practice. Accordingly, some licensees do not provide evidence in support of assertions in reports.

5.48 As one of ARPANSA's key compliance approaches, licensee reporting requires a more systematic approach to the sufficiency of reporting. Relevant considerations include the level of assurance sought from reports, and procedures to provide this assurance.

Recommendation No.15

5.49 The ANAO recommends that ARPANSA enhance its reporting guidelines by:

- implementing procedures to keep the guidelines up to date;
- specifying the level of supporting evidence required in reports;
- providing feedback to licensees on reports; and
- seeking client feedback on its guidelines.

ARPANSA response: Agreed.

Recommendation No.16

5.50 The ANAO recommends that ARPANSA monitor compliance by licensees with reporting requirements.

ARPANSA response: Agreed.

ARPANSA's consideration of reports

5.51 ARPANSA advised that reports are reviewed against obligations contained in the licence and the Licence Handbook.⁴⁵ Regulatory Branch informs the CEO whether any issues arise from the licensee's report.

5.52 However, this assessment is not supported with guidance to staff on matters to be considered in reports, or the circumstances under which the report should be raised with the CEO. ARPANSA advised that it is now developing draft policies and standard operating procedures (SOPs) to address this.

5.53 Information from reports, such as the extent of compliance or abnormal occurrences, can provide valuable insight into licensee conduct. This information is held in files but is not systematically collated in a central database or repository. This limits ARPANSA's ability to monitor trends in compliance across licensees, and to inform and support a risk-based approach to its compliance activities and regulation.

⁴⁵ To support this process, the Regulatory Branch established a database of licence conditions. However, the database was out of date and not routinely used by staff.

5.54 Overall, the absence of a systematic and transparent approach to managing reports reduces assurance that reports are consistently and appropriately analysed and that the target level of licence compliance is occurring.

Recommendation No.17

5.55 The ANAO recommends that ARPANSA develop standard procedures, for the consideration and assessment of reports, that address:

- processes to provide assurance that licensee reports are appropriately assessed and acted upon; and
- the collation and monitoring of reported information for risk-management purposes.

ARPANSA response: Agreed.

Inspections

5.56 Inspections are a key regulatory tool. They provide the opportunity to verify that entities are complying with their licences. They also provide a mechanism to educate entities on their responsibilities.

5.57 All staff undertaking inspections are required to possess, or to be acquiring, a qualification in Statutory Investigation and Enforcement. Training activities have focused on legal awareness, external (scientific) auditing, report writing and negotiation skills.

ARPANSA's inspection framework

5.58 The CEO issued draft guidelines on inspections in 2000, and sought public comment on them. In the light of comments received, the guidelines were revised, and replaced with two documents in March 2003.

5.59 The first document is a Policy on Regulatory Inspections, which includes the objectives of the inspection program, and the planning and scheduling of inspections. ARPANSA's objectives for the inspection program are set out in Table 5.1.

Table 5.1

Inspection objectives

- monitor, assess and verify that a licence holder’s activities are in accordance with requirements;
- monitor prohibitions under the ARPANS Act and Regulations;
- respond to reports of non-compliance, abnormal events or accidents; and
- conduct investigations in response to reports or other actions.

Source: ARPANSA

5.60 The second document is a SOP for conducting planned inspections.⁴⁶ The major stages and elements of the SOP, which are supported by templates and checklists, are outlined in Table 5.2.

Table 5.2

Elements of the SOP for planned inspections

1. Preparation	2. Performance	3. Reporting
Purpose and scope	Timing	Preliminary report
Inspection team	Entrance meeting	Informing branch management
Document review	Documentation	Transmittal
Checklist	Interviews	Review by licence holder
Inspection timetable	Observations	Final report
Inspection strategy	Recording	Response
Approval	Final team meeting	Follow-up
Notification	Exit interview	Record keeping
Equipment		

Source: ANAO, based on ARPANSA documentation.

Selection and planning of inspections

5.61 A risk-based regulatory system seeks to target inspections based on the nature, significance and scope of the risks associated with licensees and non-licensees. Better practice is for all regulated entities to be covered, with higher risk entities or hazards visited more often and/or subjected to more intensive visits.

⁴⁶ Inspection Procedure for Planned Inspections.

5.62 ARPANSA's 2002–03 annual report advised that it had developed a rolling six-month schedule of inspections which:

... is informed by the licence holder's safety performance and licence compliance record and commensurate with the hazards and risks associated with the particular conducts and/or dealings of the licence holder.

5.63 In March 2004, ARPANSA promulgated guidance to staff on developing and maintaining the Regulatory Branch planned inspection schedule. This guidance stated that the schedule of inspections should be *Risk based: according to the source; use; sector; track record; and any lessons learned*.

5.64 However, the ANAO found that in practice ARPANSA does not have an overall program of inspections that takes account of the relative risk of each licensee. Instead, each Regulatory Branch staff member is responsible for developing and maintaining their own inspection schedules.

5.65 These individual schedules are not supported by explicit criteria and rankings, or by systematic consideration of data from licensee reports. Staff set their schedules according to their own judgement of hazard and knowledge of the licence holder's safety performance and licence compliance record.

5.66 The lack of an integrated, systematic, risk-based approach increases the risk that compliant organisations may be over-inspected, and non-compliant licensees under-inspected. This reduces assurance to stakeholders that ARPANSA is effectively detecting and deterring unlicensed conduct or non-compliance.

Conduct of inspections

5.67 In 2002, after the great bulk of activities had been licensed, ARPANSA began to focus its regulatory effort on undertaking inspections.⁴⁷

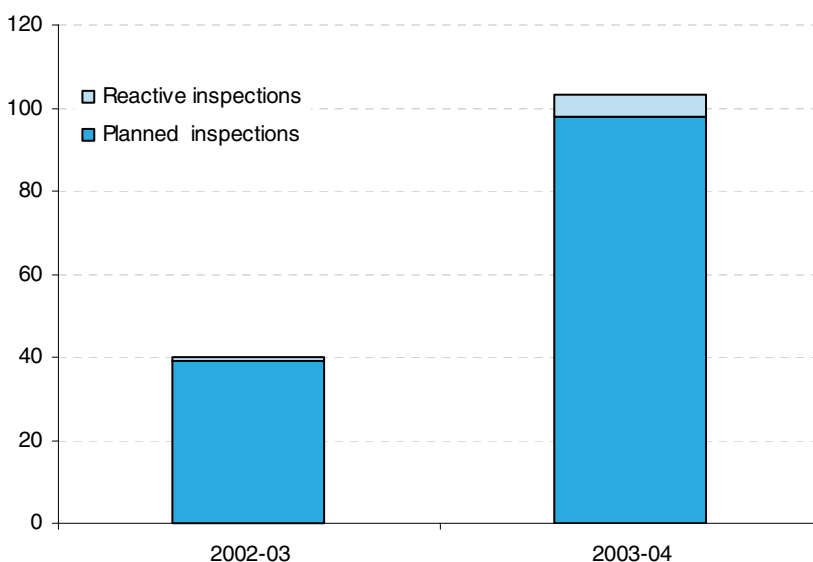
5.68 Prior to this, ARPANSA conducted a number of on-site activities of various types. These activities were undertaken to gain an understanding of, and information about, activities covered by the transitional arrangements under the *Australian Radiation Protection and Nuclear Safety (Consequential Amendments) Act 1998*, or for the purpose of monitoring compliance with issued licences, including Regulation 51.

⁴⁷ ARPANSA's Corporate Plan 2002–2005, p. 9.

5.69 The status of these activities has varied over time and they have been defined as *site visits*, *audits*, *inspections* and, since 2002–03, *reactive inspections* and *planned inspections*.⁴⁸ This reflects the evolving nature of ARPANSA’s approach to such activity.

5.70 The number of inspections conducted in the past two years is shown in Table 5.3. Most inspections have been part of a planned program. However, there are also some reactive inspections, which are carried out at short notice. These are triggered by an incident or accident or by one of ARPANSA’s compliance-monitoring activities, such as review of a quarterly report.

Table 5.3
Compliance inspections by ARPANSA, 2002–03 to 2003–04



Source: ARPANSA

5.71 Information on planned inspections or outcomes against the plan is not collated or readily available. As noted above, each inspector manages their own program. Staff are required to update their schedule as inspections are completed, but this is not consistently carried out. Accordingly, management is not able to effectively monitor implementation of inspections, or performance of these inspections, within a risk-based compliance program.

⁴⁸ For example, for the period 1999–2000, ARPANSA undertook nine audits. These were undertaken as part of the transition arrangements under the Consequential Amendments Act, whereby the CEO was vested with the power to monitor the HIFAR and Moata reactors until licensed.

5.72 The ANAO also found that there was marked variation in the extent of prior notice given to entities. The SOP indicates that staff should generally give two weeks notice to the licence holder of a planned inspection.

5.73 The ANAO found that, in response to representations from one agency, some staff agreed to give the agency six weeks notice. They also gave it the proposed inspection schedule.

5.74 However, the ANAO found that there was no documentation supporting the reasons for the additional notice, or its implications for risk management and equity between licensees. ARPANSA has acknowledged that such practices were not consistent with its policies. ARPANSA advised at the conclusion of this audit that it has now notified the agency that inspections of premises will review the standard notice period.

Reporting on inspections

5.75 Once an inspection has been completed, ARPANSA prepares a preliminary report, which is sent to the licensee. This usually occurs within one week of the inspection. An ANAO review of a sample of preliminary reports indicated that this requirement is usually met.

5.76 Once comments have been received on the preliminary report, the final report is prepared. This is sent to the CEO for consideration and, if necessary, action.

5.77 The purpose of the inspection report is to document the extent of compliance by the licensee, and to provide the basis for any action recommended to the CEO. Templates support the preparation of reports.

5.78 However, the ANAO found that the extent and manner of reporting varied markedly. For example, reports used different terminology and rating scales to indicate the extent to which licensees were complying. Some did not state clearly whether a licensee was, overall, in compliance with their licence conditions. This hinders a consistent provision of advice to the CEO in making decisions on any recommended action.

5.79 ARPANSA does not provide guidance to staff on the use of terminology and how to rate the extent of compliance by a licence holder. ARPANSA advised that reporting practices had been evolving and that it had established an *inspection documents working group* to address matters raised during the course of the audit.

Recommendation No.18

5.80 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 licensee 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.

ARPANSA response: Agreed.

6. Dealing with Breaches and Prohibited Activity

This chapter examines ARPANSA's response to non-compliance or unlicensed activity.

ARPANSA's enforcement framework

6.1 The ARPANS Act and Regulations carry powers to address non-compliance and unlicensed activities by controlled persons. They empower the CEO to amend, suspend or cancel a licence, give directions to the licensee, apply for an injunction or recommend prosecution.

6.2 Since ARPANSA's establishment, it has:

- amended licences;
- given a direction⁴⁹; and
- issued a breach and reported it to the Parliament.⁵⁰

6.3 The ANAO notes that ARPANSA's enforcement actions have focused on non-compliance by licence holders. This reflects its approach to compliance, which is predominantly focused on identifying licence holders who have not complied with conditions of licences (see Paragraph 5.4.) That is, there have been few actions against entities undertaking unlicensed activities.

6.4 However, the ANAO found that ARPANSA does not have a policy or other guidance addressing the use of these powers, notwithstanding that ARPANSA has been responsible for enforcement since 1999.

6.5 In practice, ARPANSA has managed non-compliance with entities through a variety of means: on-site meetings, correspondence and emails.

6.6 For those incidents of identified non-compliance the ANAO reviewed, ARPANSA generally took prompt action to raise concerns with licensees. Most licensees also responded promptly and took corrective action.

6.7 Nevertheless, the ANAO considers that the absence of such policy guidance increases the risk that enforcement action may not be consistent with the legislation, or undertaken on an equitable and risk-managed basis.

⁴⁹ The direction was subsequently revoked, see Table 6.1.

⁵⁰ ARPANSA has never suspended nor cancelled a licence, applied for an injunction or recommended prosecution.

Dealing with non-compliance

Assessing non-compliance and appropriate responses

6.8 The absence of policy guidance addressing enforcement action, and limited structure around monitoring licensee reports and assessing inspection reports, limit ARPANSA's ability to assess and appropriately respond to non-compliance.

6.9 ARPANSA does not grade or otherwise categorise the extent to which licensees are complying with the requirements of the ARPANS Act and Regulations. In turn, it does not have structures in place to manage its enforcement response, including a process for escalating its enforcement approach.

6.10 This also impacts on the extent to which ARPANSA reports to the Parliament on licence compliance. The ARPANS Act and Regulations require that any breach of licence conditions be reported to Parliament.

6.11 ARPANSA advised that the two terms 'breach' and 'non-compliance' are synonymous:

The use of the alternatives is rather a product of the fact that the Act talks of 'monitoring compliance' on the one hand and 'breach' on the other. The practice [by ARPANSA staff] has developed of referring to it as non-compliance rather than breach.

6.12 ARPANSA has reported only one designated breach.⁵¹ This is notwithstanding that there have been a number of instances where ARPANSA has detected non-compliance by licensees through its inspections or other means.

6.13 While ARPANSA may consider some of this non-compliance minor, others have had implications for safety, as is illustrated by the example in Table 6.1. Appendix 5 provides further examples of identified non-compliance.

⁵¹ This was a breach of licence condition by a controlled person under the construction licence issued to ANSTO to construct the RRR. A Commonwealth contractor constructed heavy water cut-outs for the reactor pool tank without the approval of the CEO of ARPANSA (as is required by Regulation 54 of the ARPANS Regulations).

Table 6.1**Example of accident by a licence holder**

One licence holder's inadequate safety management contributed to the exposure of two workers to UV radiation. It was the second such accident within a six-month period. The radiation exposure caused injury, requiring medical treatment. ARPANSA considered this incident sufficiently serious to issue a direction⁵², which required the licence holder to cease use of the relevant equipment until they could demonstrate they met the requirements of the ARPANS Act and Regulations. The letter accompanying the direction advised that there had been several identified breaches. These breaches were not reported to Parliament.

ARPANSA issued a 'notice of revocation of [the] direction' two days later. This was in response to a request by the licensee offering to develop and implement an action plan over a three-and-half month period to address concerns.

Obligations under Section 41(4) of the ARPANS Act and Regulations require ARPANSA to advise its minister of any direction as soon as possible, and provide a copy to the minister. It did not do so. ARPANSA advised that this was because the direction had been revoked.

Source: ARPANSA

6.14 The ANAO has obtained legal advice that non-compliance, such as in the example in Table 6.1, is a breach of licence conditions. It should therefore be classified as such and reported to the Parliament in accordance with the ARPANS Act and Regulations.

6.15 More broadly, a more structured approach is required to guide ARPANSA's assessment of and response to non-compliance and its reporting obligations. The necessary elements include policies and procedures for:

- rating and grading the extent of compliance by licence holders with the ARPANS Act and Regulations;
- appropriate graduated response to non-compliance, including use of enforcement action; and
- determining what constitutes a breach of a licence.

Performance reporting on compliance and enforcement

6.16 This more structured approach to categorising non-compliance is also necessary to support improved performance management and reporting of the extent of compliance (Recommendation No. 2, Paragraph 2.31).

⁵² Section 41 of the Act provides that, where the CEO believes that there is non-compliance and there is a need to protect health and safety, the CEO may issue a direction to the licensee.

6.17 The ANAO considers that more comprehensive reporting of non-compliance, whether or not deemed to be a breach, is warranted. This would provide greater assurance to Parliament and other stakeholders that ARPANSA is discharging its responsibilities effectively.

6.18 It could also encourage a more proactive approach by licensees to compliance by identifying those entities that have not complied with their obligations under the ARPANS Act and Regulations.

Recommendation No.19

6.19 The ANAO recommends that, in order to provide greater assurance that failures to meet licence conditions are dealt with and reported appropriately, 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 graduated approach to enforcement action; and
- maintain a database of non-compliance and enforcement actions taken and their resolution.

ARPANSA Response: Agreed.

Canberra ACT
2 March 2005



P. J. Barrett
Auditor-General

Appendices

Appendix 1: Functions of the CEO of ARPANSA

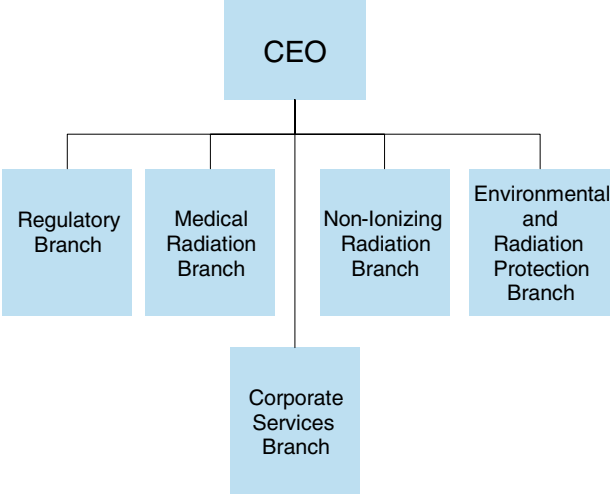
Section 15 of the ARPANS Act specifies that the CEO of ARPANSA has the following functions:

- to promote uniformity of radiation protection and nuclear safety policy and practices across jurisdictions of the Commonwealth, the States and the Territories;
- to provide advice on radiation protection, nuclear safety and related issues;
- to undertake research in relation to radiation protection, nuclear safety and medical exposures to radiation;
- to provide services relating to radiation protection, nuclear safety and medical exposures to radiation;
- to accredit persons with technical expertise for the purposes of the ARPANS Act and Regulations;
- to monitor and report on the operations of ARPANSA, the Radiation Health and Safety Advisory Council, the Radiation Health Committee and the Nuclear Safety Committee;
- to monitor compliance with the prohibitions set out in Division 1, Part 5 of the ARPANS Act and make recommendations to the Director of Public Prosecutions; and
- to undertake such other functions as conferred by the Act, the Regulations or any other law.

The CEO carries out these functions with assistance from the staff of five ARPANSA branches, located in Melbourne and Sydney (see the figure on the following page).⁵³

⁵³ The Regulatory Branch is located in Sydney and the Corporate Services branch is co-located in Sydney and Melbourne, while all other branches are located in Melbourne.

ARPANSA's organisational structure



Source: ARPANSA

Appendix 2: Conflict of interest processes

ARPANSA's Chief Executive Instructions outline the following processes for managing conflict of interest.

All ARPANSA employees must, in the case of any potential conflict of interest between the CEO's regulatory and other functions, refer the matter immediately to the relevant branch director. The branch director must immediately report the matter to the CEO for direction.

In providing direction on handling of any issue of conflict of interest between the CEO's regulatory functions and the CEO's other functions, the CEO may determine that:

- *The conflict of interest is sufficient to require that ARPANSA not perform the other functions that lead to a conflict with the regulatory functions; or*
- *ARPANSA may undertake the other functions against a set of terms and conditions as set out in an instruction to the relevant branch director and that may include:*
 - *Provision of information to persons or agencies with whom ARPANSA employees are dealing in respect of that matter, fully disclosing all of the relevant circumstances;*
 - *An acknowledgement by the outside agency of all the relevant facts and circumstances, including an acknowledgement that the provision of advice, services or research do not in any way affect the independent exercise of discretion involved in the performance of the CEO's regulatory functions;*
 - *All formal advice provided in relation to the issue being given only as a formal ARPANSA Advice.*

ARPANSA employees must not, without the approval of the CEO, assist in the performance of the CEO's regulatory functions and the CEO's other functions in connection with the same task or matter.

Where an ARPANSA employee provides advice or services, or undertakes research, in relation to a Commonwealth entity, the advice, services or research must not affect the independent exercise of CEO's discretions and the discretions of staff assisting the CEO in the performance of the CEO's regulatory functions. Nor must the employee indicate the outcome of any regulatory decision.

Written advice on any issue of radiation protection or nuclear safety, or a related issue, must only be given by the CEO or by a person to whom the CEO has delegated the function of providing such advice.

- *The director, Standards Policy and Corporate Support Branch is to maintain a register containing details of the substance of any advice given as an ARPANSA Advice.*
- *In preparing a report to the CEO in regard to a licensing issue, the Director, Regulatory Branch, must take into account any relevant ARPANSA Advice and bring them to the CEO's attention.*

Appendix 3: Regulatory assessment guidelines

The table below summarises the guidelines used by ARPANSA when assessing applications for a source and/or facility licence.

Application type	Relevant guideline	Purpose of guideline
SOURCE and FACILITY	1. Regulatory Guideline on Review of Plans and Arrangements	This regulatory guideline sets out the information requirements that should be satisfactorily demonstrated in an applicant's or a licence holder's plans and arrangements. The primary users of this guideline are the CEO of ARPANSA and regulatory staff. The document may also assist applicants in the preparation of licence applications and licence holders in the review of their current plans and arrangements.
	2. Regulatory Assessment Principles (RAPs)	This document describes the assessment principles to be applied by ARPANSA when assessing an application for a facility licence, as well as approvals under licence for changes to facilities already the subject of a facility licence.
FACILITY	3. Draft Statutory Matters for the Siting of Controlled Facilities	<p>Siting refers to the selection of a suitable site for a controlled facility, which may include sites near urban areas. It is the first principal stage in the life of a facility, and is part of the policy of defence in depth against hazards from controlled facilities. Conservative siting also allows the designer more flexibility in designing for safety.</p> <p>This document sets out the process and statutory matters used by ARPANSA when it assesses an application for a licence to site a controlled facility. In preparing this document, the agency drew upon extensive international publications and experience, especially from the International Atomic Energy Agency (IAEA).</p>
	4. Regulatory Assessment Statutory Matters for the Design of New Controlled Facilities and Modifications to Existing Facilities	This regulatory guideline describes the statutory matters to be applied by ARPANSA when assessing an application for a facility construction licence, as well as approvals under licence for modifications to facilities already the subject of a facility licence. This document supplements ARPANSA's Regulatory Assessment Principles for Controlled Facilities.

Source: ARPANSA

Appendix 4: Reporting obligations under the ARPANS Regulations

Regulation	Reporting obligation
45(3)	If the holder of a licence identifies a breach, the holder of a licence must also tell the CEO as soon as reasonably practicable.
46(2)(c) 46(2)(d)	<p>If an accident involving controlled materials, apparatus or materials happens, the holder of a licence must:</p> <ul style="list-style-type: none"> • tell the CEO about the accident within 24 hours of it happening; and • give the CEO a written report about the accident within 14 days of it happening.
50(2)	The holder of a licence must, after conducting a review and update of plans and arrangements, give the CEO information about the review.
52(2)	The holder of a licence must, at least once every three months (referred to by ARPANSA as quarterly reporting) tell the CEO about any changes (that are unlikely to have significant implications for safety as per Regulation 52(1)).
53(2)	The holder of a licence must tell the CEO (within seven days) about movements of controlled apparatus, controlled materials and controlled facilities—transfer has happened, name of recipient, recipient licence number, new location.

Source: ARPANS legislation

Appendix 5: Examples of non-compliance with licence conditions

The ANAO identified several instances of non-compliance by licensees with licence conditions, from examination of a sample of files.

Examples of identified non-compliance
No standard safe operating procedures for working with UV sources.
Access to a laser by members of the public, risking safety.
An accident occurred in use of a facility, causing injury to staff, but was not notified to ARPANSA until the next quarterly report.
A licensee failing to list sources on inventory.
A licensee failing to provide evidence of corrective action to address an identified concern.
Failure to review a radiation safety manual as required by the licence. This was one of a number of examples of failure to comply with licence conditions for this licence.
Agency failed to add a laser to its inventory as required.
Agency possessed an apparatus before an application was submitted, in breach of the ARPANS Act and Regulations.
Agency is <i>yet to fully comply with all its special licence conditions</i> .

Source: ANAO analysis of ARPANSA records

Appendix 6: Agency response

ARPANSA's Response to the ANAO Performance Audit: Regulation of Commonwealth Radiation and Nuclear Activities—ARPANSA

ARPANSA'S REGULATORY ACHIEVEMENTS

During the six years of its existence, ARPANSA has achieved significant regulatory outcomes consistent with the object of the ARPANS Act and the government's intentions in establishing the agency. These achievements include that it has:

- brought under safety regulation all the radiation sources and facilities and the nuclear installations used by Australian Government agencies at the time the ARPANS legislation came into force. The assessment and licensing process confirmed that these activities were safely managed and resulted in licence holder plans and arrangements for radiation protection and nuclear safety being substantially upgraded to modern standards;
- developed a substantial framework of radiation protection and nuclear safety guidance for licence holders and the public;
- built ARPANSA's reputation as an effective regulator by promoting a thorough understanding of its role and regulatory requirements with major licence holders;
- brought hazardous non-ionising radiation sources and facilities under a clear regulatory regime for the first time in Australia;
- dealt effectively and efficiently with high priority new applications for licences authorising novel uses of radiation, for example for applications proposed by the Australian Customs Service; and
- undertaken the assessment and licensing relating to the siting and construction of the Replacement Research Reactor (now the OPAL). A research reactor had not been constructed in Australia for over 40 years and there are few new research reactors in the world. The assessment process included an international peer review, a public forum that supplemented the public submission process, and formal advice from the Nuclear Safety Committee. The decision by the CEO on the construction licence withstood challenge in the Federal Court of Australia.

REVIEW OF REGULATORY PROCESSES SUPPORTING REGULATORY EFFECTIVENESS

ARPANSA acknowledges the work of the ANAO in this audit and agrees that the business processes supporting its regulatory functions need improvement. A formal review has been established to recommend changes to business processes and to oversee their implementation. The review will act upon all the ANAO recommendations.

The review will be directed by an SES officer recruited from outside ARPANSA and reporting to the CEO. It will consult stakeholders and staff. There will be an external consultative group of people with relevant expertise and backgrounds to advise the review.

MANAGING THE REGULATORY FUNCTION

ARPANSA acknowledges the points made by the ANAO about the assumptions upon which planning for ARPANSA's regulatory work was based and the changes to the draft legislation prior to its enactment. The legislation did 'grandfather' existing conducts and dealings, provided an application for licence was received by August 1999. As the lawfulness of the operations or the dealing was guaranteed as a consequence of the 'grandfathering', ARPANSA staggered the commencement of review, giving priority to those regarded as higher hazard, including the reactors, spent nuclear fuel, radioactive wastes and radioisotope production. Monitoring of compliance later grew in relative significance as the licensing assessments of the grandfathered activities were completed.

ARPANSA agrees that quality and quantity measures for the regulatory function need to be improved. This is relatively straightforward in terms of measures of its own regulatory activities. It will, however, be important to avoid over-reliance on simple measures of 'the extent of compliance by licence holders' as assurances of regulatory effectiveness and the achievement of safety. This is a difficult issue for all safety regulators. As is made clear in international radiation and nuclear safety standards, the licence-holder has the primary responsibility for the safety of the operation undertaken using the source or facility. The regulatory body establishes standards and criteria for safety, assesses the operator's plans and arrangements against those standards and criteria, and monitors compliance. Lying behind what might be termed 'mechanical' compliance, which can be measured, is the safety culture in the operating organisation. This is not so readily quantified and therefore cannot be reported in the same manner as other regulatory activities.

ARPANSA acknowledges that it needs to demonstrate better that conflict of interest between its regulatory and other functions it is responsible for are appropriately managed. It has been the case, however, that conflict of interest has not loomed as large as was thought likely at the time the legislation was drafted. ARPANSA does not accept that simply performing a radiation measurement for a licence applicant that is not directly related to its subsequent application for licence necessarily represents a conflict of interest. In addition, unlike other radiation safety regulators, the Act requires that the CEO of ARPANSA license ARPANSA's own use of sources and facilities.

MANAGEMENT OF COST RECOVERY FOR REGULATORY ACTIVITIES

ARPANSA agrees with the recommendation for a clear and firmly based cost recovery policy that improves transparency and that it should improve its cost data collection and analysis. It does need to be borne in mind that the application fees and annual charges are set by Regulation, which necessarily limits their flexibility and the degree to which a particular fee or charge can continuously reflect the precise level of regulatory activity.

LICENSING

The ARPANSA Act and Regulations stipulate matters that the CEO is to 'take into account' in deciding whether to issue a licence. The CEO must make findings of fact about these matters. The intention of the applicant guidance provided by ARPANSA is to draw out how ARPANSA reviewers will assess information provided by the applicant (for example, plans and arrangements to be applied in management of sources and facilities) so as to inform the CEO of the findings that are open for him to make about that material. Once he has made his findings of fact, it is then the responsibility of the CEO to consider issues of relevance and weight in his overall decision making process.

It is to be expected that, at least for applications of any complexity, there will be a need for ARPANSA reviewers to seek clarification and additional information from applicants. This is not indicative of a flaw in the application process rather it is a common occurrence in review of applications in the wider context of administrative decision making.

While acknowledging the need for clear procedures for assessment of applications, it is worth pointing out that there is a single decision-maker (the CEO) and a limited number of decisions on licensing, thereby increasing the likelihood of consistency. For nuclear installations, the CEO has published the reasons for his licensing decision, addressing the statutory matters to be taken into account.

There is a distinction between the matters of fact relevant to a decision to award a licence and subsequent imposition of licence conditions on a licence. Apart from those licence conditions that are mandated by the Act and the

Regulations, the CEO has a power to impose additional licence conditions. ARPANSA does not accept the suggestion in the ANAO report that additional licence conditions were used to address fundamental deficiencies in applications. Rather the purpose of these additional licence conditions was to provide an impetus to the licence holders to upgrade the plans and arrangements to modern standards and to encourage a culture of continuous improvement in relation to particular licence holders.

ARPANSA notes the finding that the median time to process applications was 22 months. That estimate includes the time during which applications in regard to pre-existing conducts and dealings were 'grandfathered' by the legislation. ARPANSA has not set a standard time for assessing applications, as they vary in complexity and novelty, but will address overall service standards for licence assessment as a part of the regulatory review.

MONITORING COMPLIANCE

DEALING WITH BREACHES AND PROHIBITED ACTIVITY

Consistent with international practice, ARPANSA considers both monitoring compliance and dealing with breach and prohibited activity to be part of the compliance framework. ARPANSA acknowledges the need for there to be an overall compliance framework and policy, but this needs to be developed in the light of the experience gained from the careful application of the law to particular factual circumstances affecting an individual licence holder or other category of controlled person.

Reporting by licensees and the monitoring of compliance through inspections are, as noted in the ANAO report, key activities within the compliance framework. ARPANSA has been systematising its efforts in these areas and the regulatory review will continue with this process in the light of the ANAO recommendations. In particular, it will address how to take an appropriately risk-based approach to establishing a program of compliance inspections.

ARPANSA operates on the basis of providing procedural fairness to any controlled person whose interests are affected by a preliminary view that they are in breach of the Act or Regulations. Hence, initial views about 'non-compliance' are put to controlled persons, including the factual basis upon which that view of possible 'non compliance' has been formed. Very often, the controlled person will respond with acceptable actions and in those circumstances, whilst a breach may have occurred, the rectification of that breach usually means that subsequent enforcement action is not required.

In the case referred to in the report where a Direction was issued, this was revoked after the licence holder concerned agreed to address the issue in a satisfactory way and as a high priority. The matter is being referred to in ARPANSA quarterly reports to the Parliament.

Index

A

applicant guidance, 57, 93

B

breach, 16, 18-19, 54, 68, 79-82, 89-90, 94

C

compliance, 13-20, 23-24, 29, 33, 35-39, 42, 45, 52, 53, 59-61, 63-68, 70-73, 75-78, 80-82, 85, 92, 94
conflict of interest, 14, 19-20, 41-42, 87, 93
cost recovery, 15, 21, 35, 45-46, 49-50, 93

E

enforcement, 13, 18-19, 25, 33, 37, 79-82, 94

F

facilities, 13-14, 20, 23-24, 29-31, 33, 35-38, 42, 63-66, 78, 88-89, 91, 93

I

inspection, 17-18, 24, 33, 36-37, 39, 48, 54, 64, 69, 73-78, 80, 94
international best practice, 16, 36, 53, 56, 58

L

licence conditions, 16-17, 22, 24-25, 33, 45, 55, 57-59, 63, 66-68, 72, 77-78, 80-82, 90, 93
licence fees, 21, 46-50

Licence Handbook, 17, 23, 64, 66-67, 72

M

monitoring, 13, 15-17, 19-20, 22, 24, 29, 32-33, 35, 37-38, 41, 49, 52-53, 59, 63-65, 68, 70-71, 73, 75-76, 80, 94

N

non-compliance, 13-14, 18, 25, 33, 35, 41-42, 63-65, 74-75, 80-82, 90, 94
nuclear installation, 13, 29, 31, 36-37, 55, 91, 93

R

regulatory assessment reports, 22, 56-57
Replacement Research Reactor, (RRR) 15, 31, 47-49, 80, 91

S

service charter, 14, 21, 42-44
source, 13-14, 20, 23, 29-33, 35-38, 42, 51, 53, 61, 63-66, 69, 71, 75, 88, 90-93
standard operating procedures, (SOPs) 17, 53, 72, 74, 77
statutory matters, 15-16, 21-22, 53, 56-57, 88, 93

U

unlicensed activity, 13-14, 33, 41, 63-64, 79

Series Titles

Audit Report No.29 Performance Audit
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Department of Defence

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Department of Foreign Affairs and Trade
Australian Trade Commission

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Australian Broadcasting Corporation
Special Broadcasting Service Corporation

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Army Capability Assurance Processes
Department of Defence

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Integrity of Medicare Enrolment
Health Insurance Commission

Audit Report No.23 Performance Audit
Audit Activity Report: July to December 2004
Summary of Results

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Investment of Public Funds

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Audits of the Financial Statements of Australian Government Entities for the Period Ended 30 June 2004

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The Australian Taxation Office's Management of the Energy Grants (Credits) Scheme

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Taxpayers' Charter
Australian Taxation Office

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Regulation of Non-prescription Medicinal Products
Department of Health and Ageing
Therapeutic Goods Administration

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The Administration of the National Action Plan for Salinity and Water Quality
Department of Agriculture, Fisheries and Forestry
Department of the Environment and Heritage

ANAO Audit Report No.30 2004–05
Regulation of Commonwealth Radiations and Nuclear Activities

Audit Report No.16 Performance Audit
Container Examination Facilities
Australian Customs Service

Audit Report No.15 Performance Audit
Financial Management of Special Appropriations

Audit Report No.14 Performance Audit
Management and Promotion of Citizenship Services
Department of Immigration and Multicultural and Indigenous Affairs

Audit Report No.13 Business Support Process Audit
Superannuation Payments for Independent Contractors working for the Australian Government

Audit Report No.12 Performance Audit
Research Project Management Follow-up audit
Commonwealth Scientific and Industrial Research Organisation (CSIRO)

Audit Report No.11 Performance Audit
Commonwealth Entities' Foreign Exchange Risk Management
Department of Finance and Administration

Audit Report No.10 Business Support Process Audit
The Senate Order for Departmental and Agency Contracts (Calendar Year 2003 Compliance)

Audit Report No.9 Performance Audit
Assistance Provided to Personnel Leaving the ADF
Department of Defence
Department of Veterans' Affairs

Audit Report No.8 Performance Audit
Management of Bilateral Relations with Selected Countries
Department of Foreign Affairs and Trade

Audit Report No.7 Performance Audit
Administration of Taxation Rulings Follow-up Audit
Australian Taxation Office

Audit Report No.6 Performance Audit
Performance Management in the Australian Public Service

Audit Report No.5 Performance Audit
Management of the Standard Defence Supply System Upgrade
Department of Defence

Audit Report No.4 Performance Audit
Management of Customer Debt
Centrelink

Audit Report No.3 Business Support Process Audit
Management of Internal Audit in Commonwealth Organisations

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Department of Immigration and Multicultural and Indigenous Affairs

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Department of Defence

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