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IAEA
International Atomic Energy Agency

**INTEGRATED
REGULATORY
REVIEW SERVICE
(IRRS)
- FULL SCOPE -**

TO

THE COMMONWEALTH GOVERNMENT OF AUSTRALIA

**Australian Radiation Protection and Nuclear Safety Agency
(ARPANSA)**

Sydney, Australia

25 June to 6 July 2007

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

INTEGRATED REGULATORY REVIEW SERVICE

IRRS

Under the terms of Article III of its statute, the International Atomic Energy Agency (IAEA) has the mandate to establish or adopt, in consultation and, where appropriate, in collaboration with competent organizations, standards of safety for protection of health and minimization of danger to life and property (including such standards for labour conditions), and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under bilateral or multilateral arrangements or, at the request of a State, to any of that State's activities concerning peaceful nuclear and radiation activities. This includes the publication of a set of Safety Standards, whose effective implementation is essential for ensuring a high level of safety. As part of its providing for the application of safety standards, the IAEA provides Safety Review and Appraisal Services, at the request of Member States, which are directly based on its Safety Standards.

In the regulatory framework and activities of the regulatory bodies, the IAEA has been offering, for many years, several peer review and appraisal services. These include: (a) the International Regulatory Review Team (IRRT) programme that provides advice and assistance to Member States to strengthen and enhance the effectiveness of their legal and governmental infrastructure for nuclear safety; (b) the Radiation Safety and Security Infrastructure Appraisal (RaSSIA) that assesses the effectiveness of the national regulatory infrastructure for radiation safety including the safety and security of radioactive sources; (c) the Transport Safety Appraisal Service (TranSAS) that appraises the implementation of the IAEA's Transport Regulations; and (d) the Emergency Preparedness Review (EPREV) that is conducted to review both preparedness in the case of nuclear accidents and radiological emergencies and the appropriate legislation.

The IAEA recognized that these services and appraisals had many areas in common, particularly concerning the requirements on a State to establish a comprehensive regulatory framework within its legal and governmental infrastructure and on a State's regulatory activities. Consequently, the IAEA's Department of Nuclear Safety and Security has developed an integrated approach to the conduct of missions on legal and governmental infrastructure to improve their efficiency, effectiveness and consistency and to provide greater flexibility in defining the scope of the review, taking into account the regulatory technical and policy issues.

The new IAEA peer review and appraisal service is called the Integrated Regulatory Review Service (IRRS). The IRRS is intended to strengthen and enhance the effectiveness of the State's regulatory infrastructure in nuclear, radiation, radioactive waste and transport safety, whilst recognizing the ultimate responsibility of each State to ensure the safety of nuclear facilities, the protection against ionizing radiation, the safety and security of radioactive sources, the safe management of radioactive waste, and the safe transport of radioactive material. The IRRS is carried out by comparisons against IAEA regulatory safety standards with consideration of regulatory technical and policy issues.

The new regulatory service is structured in modules that cover general requirements for the establishment of an effective regulatory framework, regulatory activities and management systems for the regulation and control in nuclear safety, radiation safety, waste safety, transport safety, emergency preparedness and response and security. The aim is to make the IAEA services more consistent, to enable flexibility in defining the scope of the missions, to promote self-assessment and continuous self-improvement, and to improve the feedback on the use and application of the IAEA Safety Standards. The modular structure also enables tailoring the service to meet the needs and priorities of the Member State. The IRRS is neither an inspection nor an audit but is a mutual learning mechanism that accepts different approaches to the organization and practices of a national

regulatory body, considering the regulatory technical and policy issues, and that contributes to ensuring a strong nuclear safety regime. In this context, considering the international regulatory issues, trends and challenges, and to support effective regulation, the IRRS missions provide:

- a balance between technical and policy discussions among senior regulators;
- sharing of regulatory experiences;
- harmonization of the regulatory approaches among Member States; and
- mutual learning opportunities among regulators.

Regulatory technical and policy discussions that are conducted during IRRS missions take into account the newly identified issues coming from the self-assessment made by the host organization, visits to installations to observe inspections and interviews with the counterparts.

Other legally non-binding instruments can also be included upon request of the Member States, such as the Code of Conduct (CoC) on the Safety and Security of Radioactive Sources, which was adopted by the IAEA Board of Governors in 2004 and for which more than 85 Member States have written to the Director General of the IAEA committing themselves to implementing its guidance, and the Code of Conduct on the Safety of Research Reactors, which was adopted by the IAEA Board of Governors in 2005.

The IRRS concept was developed at the IAEA Department of Nuclear Safety and Security and then discussed at the 3rd review meeting of the Contracting Parties of the Convention on Nuclear Safety in 2005. The meeting acknowledged the importance of the IAEA regulatory peer reviews now recognized as a good opportunity to exchange professional experience and to share lessons learned and good practices. The self-assessment performed prior to the IAEA peer review mission is an opportunity for Member States to assess their regulatory practices against the IAEA safety standards. These IAEA peer review benefits were further discussed at the International Conference on 'Effective Nuclear Regulatory Systems' in Moscow in 2006, at which note was taken of the value of IRRS support for the development of the global nuclear safety regime, by providing for the sharing of good regulatory practices and policies for the development and harmonization of safety standards, and by supporting the application of the continuous improvement process. All findings coming from the Convention on Nuclear Safety review meetings and from the Moscow conference are inputs for the IRRS to consider when reviewing the regulatory technical and policy issues.

In addition, the results of the IRRS missions will also be used as effective feedback for the improvement of existing safety standards and guidance and the development of new ones, and to establish a knowledge base in the context of an integrated safety approach. Through the IRRS, the IAEA assists its Member States in strengthening an effective and sustainable national regulatory infrastructure thus contributing towards achieving a strong and effective global nuclear safety and security regime.

The Global Nuclear Safety Regime has emerged over the last ten years, with international legal instruments such as safety Conventions and Codes of Conduct and significant work towards a suite of harmonized and internationally accepted IAEA safety standards. The IAEA will continue to support the promotion of the safety Conventions and Codes of Conduct, as well as the application of the IAEA safety standards in order to prevent serious accidents and continuously improve global levels of safety.

**INTEGRATED REGULATORY REVIEW SERVICE (IRRS)
-FULL SCOPE-**

REPORT TO

**THE COMMONWEALTH GOVERNMENT OF AUSTRALIA
Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)**

Sydney, Australia
25 June to 06 July 2007



REPORT

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) -FULL SCOPE-

REPORT TO

THE COMMONWEALTH GOVERNMENT OF AUSTRALIA AUSTRALIAN RADIATION PROTECTION AND NUCLEAR SAFETY AGENCY

Sydney, Australia
25 June to 6 July 2007

Mission date: 25 June to 6 July 2007

Regulatory body: ARPANSA (Australian Radiation Protection and Nuclear Safety Agency)

Location: ARPANSA Headquarters, Miranda, Sydney, Australia

Regulated facilities and activities: Research reactors, industrial and research applications, waste facilities, decommissioning and remediation, transport, emergency preparedness.

Organized by: IAEA

IAEA Review Team:	ULBAK Kaare	(Team Leader, Denmark)
	PANGBURN George	(Deputy Team Leader, USA)
	AGUILAR Jacques	(Reviewer, France)
	IRWIN Robert	(Reviewer, Canada)
	LEOTWANE Wilbert	(Reviewer, South Africa)
	REVILLA Jose Luis	(Reviewer, Spain)
	VARJORANTA Tero	(Reviewer, Finland)
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IAEA-2007

Issue date: August 2007

FOREWORD

by Mohamed ElBaradei
Director General

The General Conference Resolution of September 2006 related to the measures to strengthen international cooperation in nuclear, radiation and transport safety and waste management: “Recognizes the importance of an effective regulatory body as an essential element of national nuclear infrastructure, urges Member States to continue their efforts to increase regulatory effectiveness in the field of nuclear, radiation and transport safety and waste management, and consider availing themselves of the Secretariat’s new Integrated Regulatory Review Service (IRRS) and notes with satisfaction the increased interest of the Member States in the IRRS.”

At my opening speech of the fiftieth regular session of the General Conference in 2006, I stated that: “The Agency’s safety review services use the IAEA Safety Standards as a reference point, and play an important part in evaluating their effectiveness. This year we began offering, for the first time, an Integrated Regulatory Review Service (IRRS). This new service combines a number of previous services, on topics ranging from nuclear safety and radiation safety to emergency preparedness and nuclear security. The IRRS approach considers international regulatory issues and trends, and provides a balance between technical and policy discussions among senior regulators, to harmonize regulatory approaches and create mutual learning opportunities among regulators.”

5 March 2007 | Vienna, Austria
IAEA Board of Governors

A.1. Introductory Statement to the Board of Governors **A.1.1. by IAEA Director General Dr. Mohamed ElBaradei** *Integrated Regulatory Review Service*

“The newly established Integrated Regulatory Review Service (IRRS) is intended to help Member States enhance their legislative and regulatory infrastructures, and to harmonize regulatory approaches in all areas of safety. It will also be one of the most effective feedback tools on the application of Agency standards. The first full scope IRRS was conducted last year in France.”

The number of recommendations, suggestions and good practices is in no way a measure of the status of the regulatory body. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

At the request of the Commonwealth of Australia, an international team of eleven experts in radiation and nuclear safety visited the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), from 25 June to 6 July, 2007 to conduct a full scope Integrated Regulatory Review Service (IRRS) mission to review ARPANSA's regulatory framework and its effectiveness. ARPANSA is the regulatory body responsible for radiation protection and nuclear safety in relation to activities involving radiation sources and radiation and nuclear facilities undertaken by the Australian Government (Commonwealth) entities and their contractors.

The purpose of this IRRS mission was to conduct a review of ARPANSA's regulatory framework and the regulatory activities in all regulated sources, facilities and activities, to review its regulatory effectiveness and to exchange information and experience in the areas considered by IRRS. The review was carried out by comparison against IAEA regulatory safety standards and associated guidance as an international benchmark for safety, Codes of Conducts on the Safety of Research Reactors and the Safety and Security of Radioactive Sources, and relevant safety Conventions. It is expected that the IRRS mission will facilitate regulatory improvements in Australia and throughout the world from the knowledge gained and experiences shared by ARPANSA and the IRRS reviewers through the evaluation of the effectiveness of the Commonwealth's regulatory framework and its good practices.

The scope of the mission included sources, facilities and activities regulated by ARPANSA: research reactors, industrial and research activities, safety and security of radioactive sources, radioactive waste management, decommissioning, and remediation. Both regulatory technical and policy issues were addressed. Among the policy issues to be discussed, particular attention was paid to given on the issue of progress in achieving national uniformity of radiation protection in the Commonwealth and the six States and two Territories within Australia.

The significance of the IRRS mission for the Commonwealth and for ARPANSA was increased by an announcement by the Prime Minister of Australia on April 28, 2007 of a new government strategy for the future development of uranium mining and nuclear power in Australia. That strategy directed the Australian government to commence work immediately on work plans to address: 1) an appropriate nuclear energy regulatory regime; 2) skills and technical training gaps; 3) enhanced research and development; and 4) communications strategies for the public and other stakeholders. The work plans are to be completed in September 2007 and are proposed to be implemented in 2008.

The IRRS Review Team consisted of senior regulatory experts from seven Member States, four staff members from the IAEA and an IAEA administrative assistant. The IRRS team carried out the review of ARPANSA in all relevant areas: legislative and governmental responsibilities; responsibilities and functions of the regulatory body; organization of the regulatory body; activities of the regulatory body, including the authorization process, review and assessment, inspection and enforcement and the development of regulations and guides; safety and security of radioactive sources; emergency preparedness; radioactive waste management; decommissioning; remediation; transport; the management system and public information and communication.

As part of its visit, the team toured the OPAL research reactor with the Parliamentary Secretary to the Minister on Health and Ageing and held discussions with the Parliamentary Secretary on policy issues. Additionally, the team met with the heads of key advisory groups to the CEO of ARPANSA on the issue of national uniformity. From a series of intensive interviews and discussions with key personnel at ARPANSA and other organizations, and the observation of a number of inspections

across the whole spectrum of sources, facilities and activities, together with the documentation and self-assessment supplied by ARPANSA in advance of the mission, the team presented its findings based on the IAEA safety standards. Additionally, the IRRS team, together with ARPANSA management, discussed policy issues relating to the regulation of radiation and nuclear safety. The results of the discussions will serve as a useful basis for the evolution of future IRRS missions and will assist with continuous improvement in the regulation of radiation and nuclear safety.

The IRRS Review Team noted the significant effort made by ARPANSA in the preparation of the mission and the conduct of its self-assessment. Throughout the review the administrative and logistical support was outstanding and the team was extended full cooperation in technical regulatory and policy discussions with ARPANSA management and staff. The IRRS Review Team identified a number of good practices and made recommendations and suggestions that indicate where improvements are necessary or desirable to further continue improving effectiveness of regulatory controls. These recommendations and suggestions are made to an organization that is seeking to improve its performance and many of them are related to areas in which ARPANSA has already implemented a programme for change.

Particular strengths of ARPANSA, its policy, its regulatory framework and its regulatory activities identified by the IRRS team were:

- The use of advisory groups on radiation protection and nuclear safety themes;
- The use of international best practices in relation to radiation protection and nuclear safety when making a licence decision.
- The development and implementation of a National Directory for Radiation Protection as a means to progress the goal of national uniformity in radiation protection and nuclear safety;
- An active international involvement, particularly at the IAEA;
- A systematic approach to strategic planning for the management of regulation;
- Timely adoption of a Code of Practice for the security and safety of radioactive sources.

The report includes recommendations or suggestions where improvements are necessary or desirable to further enhance the legal and governmental infrastructure for radiation and nuclear safety. The IRRS Review Team believes that consideration of the following items should be given high priority either because they were identified in several areas of review or because the experts considered that they will contribute significantly to the enhancement of the overall performance of the regulatory system:

- Consideration in any proposed future amendment of the ARPANS legislation of an explicit reference to the requirement that an operator has the primary responsibility for safety, to reflect Principle 1 of IAEA Fundamental Safety Principles;
- Promotion of a national system for the classification of radioactive waste;
- Formalization of existing and established procedures, approaches and guides and preparation of such in some areas (e.g. enforcement strategy, development of guidance);
- Feedback from inspection experience into regulatory programmes;
- Establishment of a formal training programme for regulatory staff; and
- Incorporation of provisions for unannounced inspections in the inspection programme

The IRRS Review Team findings are summarized in Appendix V. There was a strong consensus among the IRRS Review Team that ARPANSA and IAEA Member States have been improving the regulation of nuclear and radiation safety worldwide through IAEA regulatory review missions and services.

I. INTRODUCTION

At the request of the Chief Executive Officer (CEO) of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), an IAEA team of eleven experts consisting of experts from seven Member and four staff members from the IAEA and an IAEA administrative assistant visited ARPANSA in June/July 2007 to conduct a full¹ scope Integrated Regulatory Review Service (IRRS). In February 2007, a preparatory mission was carried out at ARPANSA headquarters, Sydney to discuss the objective and purpose of the review as well as its scope in connection with all aspects of the work of ARPANSA.

The purpose of the mission was to conduct a review of the ARPANSA regulatory framework and the regulatory activities to review the regulatory effectiveness of ARPANSA and to exchange information and experience in the areas considered by IRRS. The areas reviewed were: legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; review and assessment; inspection and enforcement; the development of regulations and guides; safety and security of radioactive sources emergency preparedness; radioactive waste management, decommissioning, remediation; transport; emergency preparedness, management system and public information and communication.

In addition, the regulatory technical and policy issues considered in this review provide a greater understanding of the regulatory issues that may have international implications and assist in addressing specific technical issues relevant to the regulation of nuclear, radiation, radioactive waste and transport safety. Regulatory technical and policy issues were identified after reviewing a broad spectrum of information including insights resulting from the conclusions of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management and Convention on Nuclear Safety review meetings, international conferences and forums and previous IAEA safety review services.

The mission was conducted from June 25 to July 6 2007. Before the mission, ARPANSA made available a collection of advance reference material for the team to review. This material consisted of a large number of legal, regulatory and internal documents, in particular the report on self-assessment including the IAEA questionnaire. During the mission the team performed a systematic review of all topics using the report on self-assessment, the advance reference material, interviews with ARPANSA staff and direct observation of their working practices during inspections carried out by ARPANSA.

In 2005 the Australian National Audit Office (ANAO) had conducted a performance audit of ARPANSA's management of the regulation of Commonwealth radiation and nuclear activities. ANAO made 19 recommendations as a result of the audit. ARPANSA agreed with the recommendations and has undertaken actions to address them. The IRRS Team reviewed the report of the audit and ARPANSA's response in advance of its mission, but did not undertake a systematic assessment of ARPANSA's progress in addressing those findings. Such an assessment was determined to be outside the scope of the mission.

¹ All activities, practices and facilities regulated by ARPANSA

IRRS activities took place mainly at the ARPANSA headquarters, Miranda, and the ARPANSA laboratories in Yallambie, Melbourne. Site visits took place at the research reactor OPAL and at industrial sources facilities (see Appendix III).

II. OBJECTIVE AND SCOPE

The purpose of the mission was to conduct a full-scope IRRS mission to review the Australian federal legal and governmental infrastructure for nuclear, radiation, radioactive waste and transport safety and the effectiveness of the Australian Commonwealth regulatory body (ARPANSA) and to exchange information and experience among ARPANSA and the IRRS team with a view to contributing to harmonizing regulatory approaches and creating mutual learning opportunities among regulators.

The key objectives of this mission were to enhance nuclear and radiation safety by:

- ✓ Providing Australia (ARPANSA and governmental authorities) with a review of their nuclear and radiation safety regulatory technical and policy issues;
- ✓ Providing Australia (ARPANSA and governmental authorities) with an objective evaluation of their nuclear and radiation safety regulatory activities with respect to international safety standards;
- ✓ Contributing to the harmonization of regulatory approaches among Member States;
- ✓ Promoting sharing of experience and exchange of lessons learnt;
- ✓ Providing key staff in Australia (ARPANSA and governmental authorities) with an opportunity to discuss their practices with reviewers who have experience of other practices in the same field;
- ✓ Providing Australia (ARPANSA and governmental authorities) with recommendations and suggestions for improvement;
- ✓ Providing other States with information regarding good practices identified in the course of the review;
- ✓ Providing reviewers from States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field; and
- ✓ Providing Australia through completion of the IRRS questionnaire with an opportunity for self-assessment of its activities against international safety standards.

The scope requested by Australia for this IRRS mission was:

- Safety of research reactors;
- Radiation safety in industrial and research activities;
- Safety and Security of radioactive sources;
- Safety in the transport of radioactive material;
- Radioactive waste management;
- Decommissioning of nuclear facilities;
- Remediation of contaminated sites;
- Emergency preparedness;
- Management system; and
- Communication and public information.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

The preparatory work for the mission was carried out by the IRRS Team Coordinator Khammar Mrabit, NSRW/IAEA, and by the IRRS Deputy Team Coordinator David Graves, NSNI/IAEA. It is important to mention that, according to the IRRS guidelines, both the IRRS Team Leader, Mr. Kaare Ulbak, and the IRRS Deputy Team Leader, Mr. George Pangburn, belong to IAEA Member States rather than being IAEA staff. In accordance with the request from ARPANSA, and taking into account the scope as indicated above, it was agreed that the IAEA review team would be comprised of 7 external experts and three staff members² (see Appendix I). The working areas and the ARPANSA counterparts were distributed according to Appendix IV

During the preparatory period all documents of the advance reference material (ARM) were sent electronically by ARPANSA to the IAEA and distributed to the experts. All details and organizational aspects were defined with the nominated ARPANSA Counterparts – Liaison Officer Ms Rosemary Marcon.

A significant amount of work was carried out by the reviewers and by the IAEA staff before the review in order to prepare the initial impressions about the ARM, to review the answers to the questionnaire sent to ARPANSA, to prepare for the interviews and direct observations at the sites and to identify additional relevant material necessary to review during the mission.

An entrance team meeting was conducted on 24 June by the IRRS Team Leader, the IRRS IAEA Coordinator and the IRRS Deputy Coordinator to discuss the specifics of the mission, to clarify the basis for the review, background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers. The reviewers also reported their first impression on the advance reference material.

B) REFERENCES FOR THE REVIEW

The main reference documents provided by ARPANSA for the review mission are indicated in Appendix VI. The most relevant IAEA Safety Standards and other reference documents used for the review are indicated in Appendix VII.

C) CONDUCT OF THE REVIEW

During the mission, a systematic review was conducted for all the review areas with the objective of providing ARPANSA with recommendations and suggestions as well as of identifying good practices. The review was conducted through meetings, interviews and discussions with ARPANSA personnel, visits to relevant organizations, assessment of the ARM, and direct observations regarding the national practices and activities, particularly in the context of inspections.

The team performed its activities based on the Mission Programme given in Appendix II.

The entrance meeting was held on Monday 25 June with the participation of ARPANSA senior management. Opening remarks were made by the CEO of ARPANSA, Dr John Loy, the Team Leader and Team Coordinator.

The exit meeting was held on Friday 06 July with the ARPANSA authorities. The main conclusions were presented by the IRRS Team Leader, and closing remarks were made by Ms. Eliana Amaral, IAEA Director of the Division of Radiation, Transport and Waste Safety and Dr. John Loy, CEO of ARPANSA. The draft mission report was handed over to ARPANSA at the end of the meeting.

² Another staff member as observer/reviewer was added later.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

1.1 GENERAL

Legislative and statutory framework

GS-R-1 § 2.2 (1)

In December 1998, the Australian Parliament passed the *Australian Radiation Protection and Nuclear Safety Act 1998* (hereinafter, the “ARPANS Act”). This legislation created the Office of the CEO of ARPANSA and the Australian Radiation Protection and Nuclear Safety Agency, or ARPANSA. The functions of the CEO of ARPANSA include responsibility for the regulation of radiation protection and nuclear safety matters for government agencies of the Commonwealth of Australia and their contractors. In addition to the ARPANS Act, Parliament approved the *Australian Radiation Protection and Nuclear Safety (Licence Charges) Act 1998* which allowed for the imposition of annual licence charges and the ARPANS (Consequential Amendments) Act 1998 which required entities which would qualify as controlled persons prior to the commencement of the ARPANS Act in 1998 to file applications for licence by August 1999. The ARPANS Act itself has only been amended twice since its passage and these amendments were largely administrative in nature.

The ARPANS Act effectively prohibits controlled persons as defined in the ARPANS Act to undertake activities involving controlled facilities, controlled material and controlled apparatus in the absence of a licence or an exemption from the requirement to hold a licence. Regulation of radiation protection for non-Commonwealth entities in the 6 States and 2 Territories that make up Australia is the responsibility of the States and Territories. In addition, regulation of the mining and processing of radioactive ore (uranium mining and milling) is undertaken by the State or Territory in which that activity takes place and not by ARPANSA.

The CEO of ARPANSA also has other responsibilities, including providing advice to the government and the community on health effects of radiation, undertaking research in these areas, and providing services relating to radiation protection, nuclear safety and medical exposures to radiation.

The ARPANS Act expressly prohibits the CEO from authorizing by licence the construction or operation of: a nuclear fuel fabrication plant; a nuclear power plant; an enrichment plant or a reprocessing facility.

As mentioned previously, the ARPANS Act identifies that the CEO of ARPANSA has certain specific functions and duties. First among the CEO’s specified functions in Part 3 of the ARPANS Act is “...to promote uniformity of radiation protection and nuclear safety policy and practices across jurisdictions of the Commonwealth, the States and the Territories.” This provision recognises that there are distinct advantages in achieving a uniform national framework for radiation protection and control. The subject of national uniformity will figure prominently in this report, particularly as it may relate to the future direction of regulation of nuclear matters in Australia, including expanded uranium mining and processing, enrichment of uranium, fuel fabrication and licensing of nuclear power plants.

Establishment of an effectively independent regulatory body

GS-R-1 § 2.2 (2)

The ARPANS Act created ARPANSA and placed it within the portfolio of the Ministry for Health and Ageing. The CEO of ARPANSA reports to Parliament through the Parliamentary Secretary for the Minister for Health and Ageing. In addition, on matters of significance, the CEO reports to the Parliament either through the Minister or where matters are of significant concern, directly to Parliament. The CEO is the regulatory decision-maker for the activities within ARPANSA's jurisdiction and does not have to defer to any other body with respect to decisions made under the ARPANS Act. He is subject to direction by the Minister for Health and Ageing only in circumstances where the Minister is satisfied that it is in the public interest to give directions to the CEO of ARPANSA as to the performance of his or her functions or the exercise of his or her powers. As a result of this organizational relationship and the fact that the majority of licence holders regulated by the CEO of ARPANSA report to other Ministers, the effective independence of the regulator is assured.

Regulatory body - assigned responsibilities, authority, and resources

GS-R-1 § 2.2 (3)

The ARPANS Act assigns, inter alia, responsibility to ARPANSA for:

- authorization;
- regulatory review and assessment;
- inspection and enforcement; and
- establishing safety principles, criteria, regulations and guides.

Authorization

As stated above, the ARPANS Act applies only to controlled persons.

Controlled persons are defined in the Act as:

- (a) a Commonwealth entity,
- (b) a Commonwealth contractor,
- (c) a person in the capacity of an employee of a Commonwealth contractor,
- (d) a person in a prescribed Commonwealth place.

Controlled persons are prohibited from:

- (a) preparing a site for a controlled facility,
- (b) constructing a controlled facility,
- (c) having possession or control of a controlled facility,
- (d) operating a controlled facility; or
- (e) decommissioning, disposing of or abandoning a controlled facility;

unless authorized to do so by a facility licence; or the person is exempted in relation to the conduct concerned by the ARPANS Regulations (s30 of the ARPANS Act).

Controlled persons are also prohibited from dealing with controlled material or controlled apparatus unless authorized to do so by a source licence or unless exempted as prescribed in the ARPANSA Regulations.

Authorization takes the form of a facility licence or a source licence which once issued remains in force until cancelled or suspended. When making a licence decision (s 32 and s 33 of the ARPANS Act) requires the CEO in deciding whether to issue a licence to take into account the matters (if any) specified in the regulations, and to take into account international best practice in relation to radiation protection and nuclear safety. The Team considers this incorporation of international best practice in licensing decisions to be a good practice.

Assessment

A licence is issued by the CEO only after he has made a decision that the application for a licence satisfies the requirements of the ARPANS Act and the ARPANS Regulations. When determining whether or not to issue a licence (whether a source licence or a facility licence) the CEO must take into account not only matters set out in the regulations, but also international best practice in relation to radiation protection and nuclear safety. The CEO may also consider other relevant matters including any advice provided by the Nuclear Safety Committee. In the case of an application for a facility licence that relates to a nuclear installation, the CEO of ARPANSA must also take into account public submissions received in relation to that application.

Regulatory Review

Once a licence is issued, the licence holder has ongoing obligations which are addressed through the imposition of licence conditions that are set out in Section 35 of the ARPANS Act, Part 4, Division 4 of the ARPANS Regulations and those imposed by the CEO at the time of issuing a licence and subsequent to issuing a licence.

Licence conditions include the requirement that a licence holder investigate suspected breaches of licence condition, prevent accidents, comply with standards and the plans and arrangements submitted in the licence application, submit quarterly reports and obtain approval from ARPANSA for relevant changes having significant implications for safety, approval for disposal, among other things. The Licence Holder must comply with these licence conditions (ss 30(1) and 31(1) of the Act and failure to do so could result in prosecution and significant penalties being imposed.

Inspection

Part 7 of the Act, Powers of Inspection, empowers the CEO to appoint inspectors to determine if the ARPANS Act or the Regulations are being complied with by a licence holder. Compliance is monitored by a system of self reporting by the licence holder on a quarterly basis and through inspections conducted by the ARPANSA staff. All licences issued are subject to licence conditions imposed by Subsection 35(3) and 35(4) of the ARPANS Act which require that licence holders must allow the CEO of ARPANSA or a person authorized by the CEO (Inspectors) to enter and inspect the site or facility at reasonable times or authorize that person to inspect that source or apparatus as relevant.

An inspector has a number of formal inspection powers, including, searching premises for a hazardous thing, seizing that thing and requiring the controlled person to take such steps that the inspector considers necessary where it is in the interests of public health to exercise those powers in order to avoid an imminent risk of death, serious injury or serious damage to the environment. Inspectors have powers to seize hazardous material or any other thing that may be relevant to their investigation.

Enforcement

Breach of Licence Conditions

Sections 30(2) and 31(2) of the APRANS Act require that Licence holders must comply with the licence conditions attached to their source or facility licence. Failure to comply with those licence conditions could have a number of consequences including, referral to the Commonwealth Director of Public Prosecutions for prosecution, amending the licence conditions in various ways, including reducing the authorization, imposing or varying licence conditions or suspending or cancelling the licence.

The CEO can also suspend or cancel a licence if he believes that the Licence Holder or a person covered by the licence has committed an offence against the ARPANS Act, has failed to pay the annual licence charges or makes a finding that the licence was obtained improperly.

The CEO may give formal directions to a controlled person where he believes on reasonable grounds that the person is not complying with the ARPANS Act or regulations and if he believes that it is necessary to exercise his powers under this section in order to protect the health and safety of people or to avoid damage to the environment. The directions must be in writing and failure to comply with those directions could result in the matter being referred to the Commonwealth Director of Public Prosecutions and penalties being imposed up to a maximum of 30 penalty points.

If the CEO of ARPANSA gives a direction he must as soon as possible provide a copy of the direction to the Minister. The Minister must table the direction in the Australian Parliament within 15 sitting days. The ARPANS Act and the Regulations also contain provisions for an eligible person to request review of a licence decision, as defined in the Act. An eligible person can request a review of the licence decision within 60 days of the decision of the CEO. The review is undertaken by the Minister for Health and Aging. If the eligible person is dissatisfied with that review decision, the eligible person can request a review by the Administrative Appeals Tribunal (AAT). The AAT is a quasi-judicial body which reviews both the facts and the application of the law. Appeals are then available to the eligible person if the eligible person believes that an error of law, as defined in the *Administrative Decisions Judicial Review Act 1977* has occurred. Judicial review of that decision is undertaken by the Federal Court of Australia.

Australia's legal system also allows a person who has a genuine interest in an Australian Government administrative decision (an aggrieved person) if that person believes there has been an error of law, to also lodge an application under the *Administrative Decisions (Judicial Review) Act 1977* to review an error of law. An application for judicial review of a decision of the CEO of ARPANSA has only occurred on one occasion. An application for judicial review was lodged by Pacific Greenpeace Ltd against the CEO of ARPANSA's decision to issue a facility licence to the Australian Nuclear Science and Technology Agency (ANSTO) authorizing it to construct the Opal Research Reactor.

Establishing safety principles, criteria and guides

Section 15 of the ARPANS Act requires the CEO of ARPANSA to promote uniformity of radiation protection and nuclear safety policy and practices across jurisdictions of the Commonwealth, States and Territories; to provide advice on radiation protection, nuclear safety and related issues and to undertake research in relation to radiation protection, nuclear safety and medical exposures to radiation.

The CEO is assisted in this function through three advisory boards established under the ARPANS Act to facilitate the establishment of safety principles, criteria, and guides: the Radiation Health and Safety Advisory Council, the Radiation Health Committee and the Nuclear Safety Committee.

Establishing regulations

Section 85 of the ARPANS Act authorizes the Governor-General to make regulations prescribing matters required or permitted by the Act or necessary or convenient to be prescribed for carrying out or giving effect to this Act. The Australian Radiation Protection and Nuclear Safety Regulations 1999 came into effect on 18 March 1999. The regulations provide further detail on the manner in which dealings and activities are authorized under the Act.

GS-R-1 § 2.2 (4)

Under the ARPANS Act, the CEO of ARPANSA engages staff (Australian Public Service Staff under the *Public Service Act 1999*) to assist him carry out his functions. The CEO of ARPANSA and his staff constitute a statutory agency. The CEO on behalf of the Commonwealth of Australia may also engage consultants to assist him carry out his functions under the ARPANS Act.

In relation to the regulatory function of ARPANSA, at the time of the passing of the ARPANS Act, the Australian Government expressed its intention that those persons covered by the ARPANS Act would pay for regulation by way of fees and charges prescribed by regulation.

GS-R-1 § 2.2 (5)

ARPANSA has other functions beyond regulation of Commonwealth entities and their contractors. Those functions do not include promotion of nuclear technologies. They do, however, involve provision of services such as dosimetry, environmental monitoring, and education about the effects of radiation. These services may involve persons who are subject to licensing by ARPANSA. In addition the ARPANSA Science Branches provide advice to third parties which could include a controlled person. This apparent conflict is noted in the legislation which requires that the CEO must take all reasonable steps to avoid any conflict of interest between the CEO's regulatory functions and the CEO's other functions. The steps that the CEO has taken in both these circumstances are discussed in further detail in Chapter 2 and 3.

GS-R-1 § 2.2 (6), (7)

The ARPANS Act requires that activities such as possession or control of a controlled facility, decommissioning, disposal of or abandonment of a controlled facility are prohibited unless a facility licence has been issued by the CEO of ARPANSA to undertake those activities. Similarly each of the three steps involved in the preparation of a site, construction and operation of a waste store are prohibited without a facility licence for each of the three stages. Licences are only issued after the CEO determines that the application has satisfactorily addressed the requirements of the ARPANS Act and Regulations.

In addition, Regulation 48(3) of the ARPANSA Regulations requires that the holder of a source licence or a facility licence must ensure that dealings with the disposal of controlled material and controlled apparatus are in accordance with the following Codes of Practice:

- (a) the *Code of Practice for the Disposal of Radioactive Waste by the User*;
- (b) the *Code of Practice for the Near-Surface Disposal of Radioactive Waste in Australia*;

(c) the *Code of Practice for the Safe Transport of Radioactive Material*.

The ARPANS Act is silent on ARPANSA's function in regulating transport of radioactive material. However, Australia has adopted the IAEA TS-R-1, *Regulations for the Safe Transport of Radioactive Material, 2005 Edition Safety Requirements*, which it has reproduced in the *Code of Practice for the Safe Transport of Radioactive Substances*. In addition regulation 48(2) of the ARPANSA Regulations requires that:

“the holder of a source licence or a facility licence must ensure that all conduct and dealings with controlled materials, controlled apparatus and controlled facilities are in accordance with:

Code of Practice for the Safe Transport of Radioactive Material”

The Team notes that GS-R-1 § 2.2 (6) addresses “...adequate infrastructural arrangements shall be made for the safe transport of radioactive material...” ARPANSA appears to have made such arrangements through its development of the *Code of Practice for the Safe Transport of Radioactive Material* and its linkage in the regulations. The team suggests that, in the interests of clarity, any future revisions of the ARPANS Act provide a clearer legal basis for ARPANSA in regulating transport of radioactive material.

GS-R-1 § 2.2 (8)

The lead agency for emergency preparedness in Australia is Emergency Management Australia (EMA). Regulators in the States and Territories have the lead for responding to radiation incidents in their respective jurisdictions and ARPANSA provides technical assistance and support upon request to augment State or Territory capabilities. Additional discussion of the team's review of ARPANSA emergency preparedness activities is contained in Chapter 7, Emergency Preparedness.

GS-R-1 § 2.2 (9)

The legislative framework for physical protection and security of nuclear facilities in Australia is provided by the *Nuclear Non-Proliferation (Safeguards) Act 1987*. With respect to nuclear facilities, ARPANSA coordinates its regulatory functions with the Australian Safeguards and Non-Proliferation Office (ASNO) under a Memorandum of Understanding. In addition, the Commonwealth of Australia committed to implement the IAEA Code of Conduct on Safety and Security of Radioactive Sources in a letter of May 3, 2004 to the IAEA. ARPANSA led the effort with States and Territories to develop a Code of Practice for Security of Sources based on the IAEA Code of Conduct. Additional information on the Team's review of ARPANSA implementation of the Code of Practice is further described under Chapter 5.

GS-R-1 § 2.2 (10)

Australia does not currently have financial indemnification arrangements in place for third parties in the event of a radiation incident. However, the Australian Government has given an indemnity to ANSTO to meet any damages awarded against ANSTO or its contractors. The indemnity does not protect them from legal action and consequent legal costs.

GS-R-1 § 2.2 (11)

The ARPANS Act and Regulations require demonstrations that the licence holders possess the infrastructure to ensure that activities in relation to facilities and sources are safe.

The team reviewed ARPANSA's response to the IRRS questionnaire and held detailed discussions with ARPANSA management and staff regarding the requirements of *GS-R-1 § 2.2*. Based on those interactions, the Team concludes that the ARPANS Act's provisions are consistent with the requirements of *GS-R-1 § 2.2*.

GS-R-1 § 2.3

Operator responsibility

The ARPANS Act is silent with respect to the primary role of the operator in assuring the safety of licensed operations. However, this understanding is implicit in regulations which are imposed as licence conditions in both source and facility licences. These include Regulations 44-50, 52 and 53. The Team discussed these conditions with ARPANSA management and is confident that the regulations reflect ARPANSA's philosophy and approach to the primacy of operator responsibility in assuring safety. Given that this responsibility is Principle 1 of IAEA Fundamental Safety Principles, a fundamental of IAEA Safety Standards GSR-1, that it is clearly stated in Section 2.2 of Edition 1 of the National Directory of Radiation Protection and the Australian government's ongoing work in developing work plans for a new strategy for development of uranium mining and nuclear power in Australia, the Team suggests that any future amendments to the Act clearly address operator responsibility for safety.

Legislative requirements

GS-R-1 § 2.4

The ARPANS Act provides for effective control of nuclear, radiation and radioactive waste safety. As noted earlier the Act does not specifically address transport safety, but regulations and Code of Practice effectively provide those controls.

GS-R-1 § 2.4 (1)

The stated object of the ARPANS Act is to protect the health and safety of people and to protect the environment, from the harmful effects of radiation and it sets out effective objectives for protecting individuals, society and the environment from radiation hazards. This is accomplished in the specification of the functions of the CEO, the criteria for issuance of licences and the licence conditions to be included within those licences (Articles 15, 32, 33 and 35 of the ARPANS Act).

GS-R-1 § 2.4 (2)

The legislation specifies facilities, activities and materials that are included in its scope, and provides for exemptions under certain criteria (see Article 13, Definitions, of the ARPANS Act).

GS-R-1 § 2.4 (3)

The ARPANS Act's licensing regime includes prohibition of certain activities. In addition, the regulations provide for exemption from licensing, based on findings that may be made by the CEO. In addition, the licensing process is reflective of the potential magnitude and nature of the hazard associated with the facility or activity.

GS-R-1 § 2.4 (4)

ARPANSA is the identified regulatory body to carry out the purposes of the ARPANS Act.

GS-R-1 § 2.4 (5)

The response above under GS-R-1 § 2.2 (4) addresses funding of the regulatory body.

GS-R-1 § 2.4 (6)

As described earlier, Section 30 of the ARPANS Act prohibits a controlled person from decommissioning, disposing of or abandoning a controlled facility unless authorized to do so by a facility licence. The licensing provisions of the Act and the Regulations provide the process for licensing.

GS-R-1 § 2.4 (7)

The legislation and regulations contain provisions for appeals of regulatory decisions and those provisions are described under GS-R-1 § 2.2 (3) above.

GS-R-1 § 2.4 (8)

Legal requirements governing continuity of responsibility when activities are carried out by several successive operators are defined in relation to activities of Commonwealth controlled persons and in addition where a Commonwealth controlled person proposes to transfer or dispose of sources or facilities to non-Commonwealth entities. Regulation 53 of the ARPANS Act requires that:

- A licence holder must only dispose of controlled apparatus or controlled materials with the approval of the CEO. 'Dispose of' within the context of Regulation 53 means the removal of controlled materials or controlled apparatus outside the jurisdiction of the ARPANS Act.
- If a licence holder transfers controlled apparatus or controlled materials to the possession of a controlled person, that person must, within 7 days of the transfer, tell the CEO:
 - (a) that the transfer has happened; and
 - (b) the name of the other person or body; and
 - (c) the number of the licence held by the other person or body; and
 - (d) the location of the controlled apparatus or controlled materials after the transfer.

The Licence holder must not dispose of, or transfer to the possession of another person or body, a controlled facility without the CEO's approval. Therefore the CEO has the power to reject a disposal (transfer outside his jurisdiction) of a controlled material, apparatus or a facility unless he is satisfied that the transfer is to a party that is subject to an effective regulatory regime.

It is important to note that the majority of disposals are within Australia to State and Territory jurisdiction and that the CEO is familiar with the regulatory regimes in each of those jurisdictions.

GS-R-1 § 2.4 (9)

The ARPANS Act allows for the creation of three advisory bodies under Part 4. These are the Radiation Health and Safety Advisory Council, the Radiation Health Committee, and the Nuclear Safety Committee. As noted earlier, these bodies advise the CEO in his execution of functions under the ARPANS Act.

GS-R-1 § 2.4 (10)

Section 15 of the ARPANS Act lists the CEO's functions. These functions include:

1. providing advice on radiation protection, nuclear safety and related issues;
2. undertaking research in relation to radiation protection, nuclear safety and medical exposures to radiation;
3. providing services relating to radiation protection, nuclear safety and medical exposures to radiation;
4. accrediting persons with technical expertise for the purposes of this Act;

Section 58 provides for the engagement of staff and consultants to assist the CEO to perform the specified functions in Section 15.

In addition, the regulatory staff who are primarily responsible for undertaking advice to the CEO on his regulatory function also participate in the development of papers and other material relating to the regulatory impact on radiation and nuclear safety. Additional details on the research and development activities undertaken by ARPANSA are included under Chapter 3.

GS-R-1 § 2.4 (11)

Australia's position regarding defining liability in respect of nuclear damage was documented in a December 2004 response to an IAEA questionnaire on the Status of Adherence by Member States to Nuclear Liability Instruments adopted under IAEA Auspices. In this response, ARPANSA took the position that it did not need to be a party to such instruments because of the small size of its program---limited to one facility, a 20 MW research reactor---with no potential for Tran boundary damage from that facility. As noted above, the Australian Government has given an indemnity to the operator of that reactor---ANSTO---to meet any damages awarded against ANSTO or its contractors in the event of a nuclear incident. The indemnity does not protect them from legal action and consequent legal costs. The Team concludes that this position is a reasonable one for the current regulatory program for nuclear installations in Australia.

GS-R-1 § 2.4 (12), (13)

The ARPANS Act does not explicitly require an applicant to provide financial assurance for decommissioning of facilities. However, Section 30 of the ARPANS Act prohibits a controlled person from decommissioning, disposing of or abandoning a controlled facility unless authorized to do so by a facility licence. The licensing provisions of the ARPANS Act and the Regulations provided the process for licensing. Because licences are issued to Commonwealth entities by a

Commonwealth entity (ARPANSA), it may be assumed that the resources to provide for adequate cleanup will be assured by the Australian government.

GS-R-1 § 2.4 (14)

The ARPANS Act defines the circumstances under which the CEO may find a licence holder to be in breach of licence and provides for formal enforcement action that may be taken associated with such a breach, including prosecution and the imposition of financial penalties by the Court. The ARPANS Act also requires breaches to be reported to the Parliament on a quarterly basis.

GS-R-1 § 2.4 (15)

Section 84 of the ARPANS Act provides that where the Act confers a power, discretion, duty or function on a person, the exercise of the power or discretion or the performance of the duty or function it is only authorized in so far as the exercise or performance is not inconsistent with Australia's obligations under relevant international agreements.

For the purposes of this section, an agreement is a ***relevant international agreement*** if immediately before the commencement of this Act, it was a relevant international agreement for the purposes of section 70 of the *Nuclear Non-Proliferation (Safeguards) Act 1987*; or it is an international agreement prescribed by the regulations.

Section 85 also allows for additional international agreements to be included in the list of relevant agreements. Currently these are:

- Agreement between the Government of Australia and the Government of New Zealand concerning the Transfer of Uranium;
- Agreement for Cooperation between Australia and the United States of America concerning Technology for the Separation of Isotopes of Uranium by Laser Excitation, Agreed Minute, and Exchange of Notes.

The Radiation Health and Safety Advisory Council, the Radiation Health Committee and the Nuclear Safety Committee informs the CEO on the adoption of recommendations, policies, codes and standards in relation to radiation protection and nuclear safety and also provides a mechanism by which the Australian government can implement any obligations under international treaties, conventions or agreements. Most recently the Radiation Health and Safety Advisory Council recommended that the CEO publish the Code of Practice for the Security of Radioactive Sources 2007.

GS-R-1 § 2.4 (16)

Part 4 of the ARPANS Act requires that each of the advisory bodies to the CEO include a person to represent the interests of the general public. Each of the bodies also allow for the inclusion of members from each State and Territory. The ARPANS Act also requires that:

- in the development and review of policies, codes and standards by the Radiation Health Committee, public consultation be undertaken;
- where the CEO receives an application for a licence to operate a facility, the ARPANS Regulations require that, as soon as practicable after receiving the application, the CEO must publish a notice in a daily newspaper circulating nationally, and in the *Gazette*, stating that the CEO intends to make a decision on the application;

if the application relates to a nuclear installation, the CEO must also include in the notice:

- (a) an invitation to people and bodies to make submissions about the application; and
- (b) a period for making submissions; and
- (c) procedures for making submissions.

In addition, Regulation 41 requires that in deciding whether to issue a licence for a controlled facility, the CEO must take into account the content of any submissions made by members of the public about the application.

GS-R-1 § 2.4 (17)

As stated above, the CEO can impose licence conditions at any time on the licence holder. Those licence conditions can be used to impose additional requirements on the licence holder. They can also be used to ensure that new codes of practice or obligations under international treaties are applied to any licences.

The team reviewed ARPANSA’s response to the IRRS questionnaire and held detailed discussions with ARPANSA management and staff regarding the requirements of *GS-R-1 §2.4*. Based on those interactions, the Team concludes that the ARPANS Act’s provisions are consistent with the requirements of *GS-R-1 § 2.4*.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: <i>SF-1 Principle 1: Responsibility for safety</i> states: “ <i>The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks.</i> ”
(2)	BASIS: <i>GS-R-1 §2.3</i> states “ <i>The prime responsibility for safety shall be assigned to the operator.</i> ”
(3)	BASIS: Preamble to the BSS under governmental regulations states “ <i>...legal persons have the primary responsibility for applying the standards...</i> ”
(4)	BASIS: <i>BSS §1.6</i> states “ <i>The principal parties having the main responsibilities for the applications of the Standards shall be:</i> <div style="margin-left: 40px;"> <i>(a) Registrants or licensees; and</i> <i>(b) Employers.</i>”</div>
S1	Suggestion: The Australian Government should consider in any proposed future amendment to the ARPANS legislation, an explicit reference to the requirement that an operator has primary responsibility for safety to reflect Principle 1 of IAEA Fundamental Safety Principles.
(1)	BASIS: <i>GS-R-1 §2.2 (6)</i> states “ <i>...adequate infrastructural arrangements shall be made for the safe transport of radioactive material....</i> ”

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	BASIS: BSS §2.9 states “ <i>The transport of radioactive sources shall be subject to the requirements of the IAEA Regulations for the Safe Transport of Radioactive Material and any applicable international convention.</i> ”
S2	Suggestion: The Australian Government should consider in any proposed future amendment to the ARPANS legislation that the legislation incorporate an explicit legislative basis for ARPANSA’s regulation of the land transport of radioactive material.
G1	Good Practice: The statutory requirement to take into account international best practice in radiation protection and nuclear safety in licensing decisions as required by s32(2) and s33(3) of the ARPANS Act is good practice.

AUTHORITY OF THE REGULATORY BODY

GS-R-1 § 2.6 (1)-(14)

The ARPANS Act is the primary statute for nuclear and radiation safety regulation of Commonwealth activities in this area and takes precedence in all cases except where the operation of specific part of the Act or regulations would prejudice Australia’s defence or National Security (s7 and s8 of the ARPANS Act).

Under the Act, ARPANSA has the authority to develop safety principles and criteria, issue guidance and to give policy advice to the Australian government on the types of regulations that may be made by the Governor-General for carrying out the purposes of the Act.

The legislation also gives ARPANSA the authority:

- to require an operator to provide any necessary information, including information from its suppliers, even if this information is proprietary,
- to issue, amend, suspend or revoke authorizations and to set conditions,
- to enter a site or facility at reasonable times to carry out an inspection,
- to enforce regulatory requirements,
- to communicate directly with governmental authorities at higher levels when it is considered necessary for exercising effectively the functions of the Regulatory Body,
- to liaise and co-ordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and transport of dangerous goods. While no specific legislative provision exists liaison occurs widely in practice. Formalized arrangements are being pursued.

The requirements of GS-R-1, paragraph 2.6 appear to be met, and hence the team has no specific recommendations or suggestions with respect to the authority of ARPANSA.

2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

Regulatory body - fulfilling statutory obligations

GS-R-1 § 3.1

The legislation assigns responsibilities to the CEO of ARPANSA as the Regulator to define policies, safety principles and associated criteria as a basis for the regulatory actions that are set out in its regulations and guides. In doing so the CEO must take into account international best practice in relation to radiation protection and nuclear safety, e.g. by incorporating IAEA Safety Standards.

GS-R-1 § 3.2 (1)

Section 85 of the ARPANS Act provides that the Governor General may make regulations (delegated legislation) under the ARPANS Act. A regulation made by the Governor General may be disallowed by the Parliament within 15 sitting days of the regulation being made and laid before both house of Parliament. The CEO of ARPANSA can promulgate Codes, Standards, guidelines and assessment criteria and principles to assess licence applications and issue guidance that is not legislative in character. In addition ARPANSA is continuing to prepare and adopt regulatory guidance on other matters such as how it interprets international best practice in radiation protection and nuclear safety and how it applies to regulatory licence decisions.

The CEO is assisted in this function by three advisory bodies that are established under the Act to facilitate the establishment of safety principles, criteria, and guides: the Radiation Health and Safety Advisory Council, the Radiation Health Committee and the Nuclear Safety Committee.

The Radiation Health and Safety Advisory Council (RHSAC) is tasked with functions regarding radiation protection and nuclear safety which include:

- identifying emerging issues and advising the CEO on them;
- examining matters of major concern to the community and to advise the CEO on those matters;
- advising the CEO on the adoption of recommendations, policies, codes and standards.

The Advisory Council membership includes the CEO, two radiation control officers, a representative of the general public and up to 8 other members. Each member, other than the CEO, is to be appointed by the Minister by written instrument. Before appointing a member, the Minister must consult the CEO in relation to the appointment such consumer groups and such environmental groups as the Minister considers appropriate. The Minister must not appoint a person as a member unless the Minister is satisfied that the person has expertise relevant to, or knowledge of, radiation protection or nuclear safety. The Minister must appoint a member to be the Chair of the Council.

The Radiation Health Committee (RHC) is tasked with various functions which include:

- the development of policies and to preparation of draft publications for the promotion of uniform national standards of radiation protection;
- the formulation of draft national policies, codes and standards in relation to radiation protection for consideration by the Australian Government and the states and territories; and
- the revision of national policies, codes and standards in relation to radiation protection to ensure that they continue to substantially reflect world best practice.

The Radiation Health Committee includes members from each of the States and Territories, the CEO, a representative of the Nuclear Safety Committee, a member representing the interests of the public and up to two other members. As noted above, the RHC is the lead organization in developing the National Directory for Radiation Protection, which is the key instrument in advancing the objective of national uniformity. Each member, other than the CEO, is to be appointed by the CEO by written instrument.

Before appointing a member, the CEO must consult the Council and such consumer groups and such environmental groups as the CEO considers appropriate. The CEO must not appoint a person as a member unless the CEO is satisfied that the person has expertise relevant to, or knowledge of, radiation protection or radiation health. The CEO must appoint a member to be the Chair of the Committee.

The Nuclear Safety Committee (NSC) has the following functions:

- to advise the CEO and the Council on matters relating to nuclear safety and the safety of controlled facilities;
- to review and assess the effectiveness of standards, codes, practices and procedures in relation to the safety of controlled facilities;
- to develop detailed policies and to prepare draft publications for the promotion of uniform national standards in relation to the safety of controlled facilities;
- to report to the CEO on matters relating to nuclear safety and the safety of controlled facilities.

Membership of the Committee includes the CEO, a person to represent the interests of the general public, a representative from the Radiation Safety Committee, a representative from the local government or local area affected by a controlled facility and up to eight other members. This committee operates at the request of the CEO of ARPANSA. Each member, other than the CEO, is to be appointed by the CEO by written instrument. Before appointing a member, the CEO must consult the Council and such consumer groups and such environmental groups as the CEO considers appropriate. The CEO must not appoint a person as a member unless the CEO is satisfied that the person has expertise in, or knowledge of: nuclear safety, other industrial or safety related regulation or a related area. The CEO must appoint a member to be the Chair of the Committee.

In addition to the Council and the two Committees, the Radiation Regulators Forum (RRF) has been established with members of regulators from all States and Territories. The terms of reference for RRF are:

- to provide a forum for radiations regulators to exchange information relating to radiation protection;
- to raise issues relating to radiation protection that would benefit from or which require national coordination;
- to refer relevant radiation protection issues to the Radiation Health Committee;
- to take relevant radiation protection issues from the Radiation Health Committee for consideration.

GS-R-1 § 3.2 (2)

ARPANSA reviews and assesses submissions on safety from the operators both prior to authorization (through the review of applications for licence) and periodically during operation (through the monitoring of compliance with the Act, Regulations and Licence). Plans and arrangements for

managing safety (which comprise information that must be submitted with a licence application) are binding on a licence holder (regulation 49) and must be reviewed and updated in accordance with regulation 50. Both regulation 49 and regulation 50 are licence conditions. In addition any relevant change (a change to the details relied upon in the application or a modification to a source or a facility) that has significant implications for safety must be approved by the CEO of ARPANSA prior to its implementation (regulation 51).

GS-R-1 § 3.2 (3) (i)-(x)

When issuing, amending, suspending or cancelling a facility or source licence (authorizations), subject to any necessary licence conditions, ARPANSA specifies in the licence document by reference to legal documents (the Act, the Regulation, Codes of Practice) and/or by specific licensing conditions, the following:

- the facilities (facilities licence) or activities (source licence) covered by the authorization,
- the requirements for obtaining ARPANSA approval for any relevant changes (modifications) to safety related aspects,
- the obligations of the operator in respect of its facility, equipment, radiation source(s) and personnel,
- any limits on operation and use (such as dose or discharge limits, action levels or limits on the duration of the authorization,
- requirements that arrangements be developed, maintained and implemented for the safe treatment, storage and disposal of radioactive wastes within or from the controlled facility,
- the requirements for incident reporting,
- the records that the operator is required to retain,
- the emergency preparedness arrangements.

GS-R-1 § 3.2 (4)-(6)

ARPANSA carries out regulatory inspections. ARPANSA's plans for inspections and the related follow-up, reporting and enforcement practices are addressed in detail in chapter 4.

Regulatory body – discharging its main responsibilities

GS-R-1 § 3.3 (1)-(5)

ARPANSA

- has established processes for dealing with applications, such as applications for the issuing of an authorization (facility licence, source licence). The processes are established by regulations and apply also to changing conditions such as a significant change to a licence holder's inventory that may require a separate authorization. In addition, internal guidance is used by ARPANSA. Some of the processes include consultation with the public, administrative departments and operators. Advice from advisory committees is also taken into account.
- specifies guidance and set out safety principles that may be used and requires operators/applicant to identify all relevant best international practice in relation to safety assessment.
- ensures that sensitive information such as proprietary information is protected.

- provides an explanation of the reasons for the rejection of a submission through decision letters in accordance with the common law principle of sound decision making.

GS-R-1 § 3.3 (6)

ARPANSA communicates with, and provides information to other competent governmental bodies, international organizations, and the public. It provides information on its criteria and decisions on its website.

GS-R-1 § 3.3 (7)

A licence holder must submit a variety of reports to ARPANSA each quarter. These reports include significant information related to the operating experience of the licence holder. The information is to be assessed by ARPANSA regulatory assessors and summarised in quarterly reports from the CEO to the Minister of Health and Ageing, who lays the reports before the Parliament. The reports summarise any items of safety significance and lessons learnt from incidents, events, breaches etc.

Regulation 63 specifies that the CEO must make guidelines about how licence holders will report their compliance with the Act, the Regulations and the licence conditions and how inspection of controlled facilities, controlled apparatus and controlled materials will be conducted. These questions are addressed in detail in chapter 5.

ARPANSA also is the Australian representative for reporting to the IAEA/NEA International Nuclear Event Scale (INES) and the Incident Reporting System for Research Reactors (IRSRR).

GS-R-1 § 3.3 (8)

ARPANSA ensures that compliance reports are complete and have been prepared by the appropriate representative of the operator. ARPANSA also ensures that reports are received within the required timeframe and ensures that any new or amended information is within the scope of the existing authorization held by the operator.

GS-R-1 § 3.3 (9)

ARPANSA regularly revise the regulatory principles and criteria to ensure that international best practice in radiation protection and nuclear safety has been taken into account in their development and they reflect feedback received from external stakeholders on a formal and informal basis. An example of this practice is the Regulatory Assessment Principles for controlled facilities (RAPS). In addition, some selected national nuclear regulatory guidance from the USA, UK and Canada has been used. For the OPAL Operating Licence, review information from West European Nuclear Regulatory Authorities (WENRA) has been used to augment ARPANSA regulatory guidance. In addition, guidance material related to radiation protection and nuclear safety draws heavily on IAEA Safety Standards and on ICRP documents.

GS-R-1 § 3.3 (10)

Regulation 50 requires the holder of a licence to review and update any plans and arrangements at least once every 12 months to ensure the health and safety of people and protection of the environment. Establishment of ARPANSA guidance and criteria for such review and update is further addressed in chapter 4.

GS-R-1 § 3.3 (11)

ARPANSA provides advice to the Government as required and through quarterly and annual reports on the operations of the CEO, ARPANSA, the Council, the Radiation Health Committee and the Nuclear Safety Committee. The reports must include details of directions given by the

Minister during the financial year under section 16 of the Act and details of any breach of licence conditions by a licensee of which the CEO is aware. The Minister must cause a copy of the reports to be laid before each House of the Parliament within 15 sitting days of the day on which the report was given to the Minister. The CEO may at any time cause a report about matters relating to the CEO's functions to be tabled in either House of the Parliament. If a serious accident or malfunction occurs at a nuclear installation, the CEO must cause a report about the incident to be tabled in each House of the Parliament no later than 3 sitting days after the incident occurs. The CEO must give a copy of the report to the Minister. In addition briefings on safety matters are provided to the Minister on a regular basis.

GS-R-1 § 3.3 (12)

As part of his consideration of whether or not to issue a licence, the CEO of ARPANSA must take into account international best practice in radiation protection and nuclear safety and also the matters set out in the Regulations. Regulation 41 includes the requirement that ARPANSA take into account whether the applicant has shown a capacity for complying with the regulations and the licence conditions that would be imposed under section 35 of the ARPANS Act. Conditions for licence specify, where required, the necessary qualifications or training for safe operation of a controlled facility or activity; compliance with these conditions is reviewed by regulatory officers.

In the case of the research reactors ARPANSA requires the operator to demonstrate that it had complied with accreditation and re-accreditation requirements. The practice has been for ARPANSA inspectors to observe these accreditation and re-accreditation activities. Licence conditions imposed by ARPANSA on the facility licence authorizing the operation of the HIFAR required formal authorization of personnel, apart from operators, directly involved with nuclear installations including fitness for duty.

GS-R-1 § 3.3 (13)

Once a licence is issued the ARPANSA inspection program includes an assessment of the state of compliance with the licence conditions including adherence to safety plans.

Regulatory body – cooperation with other relevant authorities

GS-R-1 § 3.4

ARPANSA cooperates with other relevant national, state and territorial authorities, advises them and provides information, as necessary in the following areas:

- Environmental protection;
ARPANSA provides advice to the Department of Environment and Water Resources in relation to its role in advising the Minister for Environment and Water Resources in relation to approvals relating to nuclear actions under the Environment Protection and Biodiversity Conservation Act 1999.
- Public and occupational health;
ARPANSA advises State and Territory radiation regulators on radiation safety matters.
- Emergency planning and preparedness;
ARPANSA provides advice to the Australian Government on planning for and responding to a radiological incident. ARPANSA is the designated competent authority for radiation

emergencies. In a radiation emergency, the States and Territories are responsible for emergency response and the protection of the public. However the States and Territories can request the support from the Australian Government in the form of expert advice, radiation measurement teams and environment and radiation dose assessment through ARPANSA. The emergency planning and preparedness activities of ARPANSA are further addressed in Chapter 7.

- Radioactive waste management (including determination of national policy); ARPANSA is working with the States and Territories of Australia to develop a national approach to management of radioactive waste and is developing new discharge limits, codes of practice and safety guides for radioactive waste management. In consultation with regulators in the States and Territories, the Agency implements the requirements of the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management. The Agency also represents Australia on the IAEA Waste Safety Standards Committee and coordinates Australian comments on draft standards.
- Safety in the transport of dangerous goods; ARPANSA provides advice to the Maritime Safety Authority and the Civil Aviation Safety Authority on the transport of radioactive material by sea and air.

Regulatory body – additional functions

GS-R-1 § 3.5

ARPANSA undertakes radiation measurement programs and surveys in the areas of medical exposures and environmental radiation. Services offered by ARPANSA consist of Personal Radiation Monitoring Service, Radiopharmaceutical Quality Assurance, and Ionizing Radiation Calibration Service and Radio analytical services. The work of ARPANSA's two technical and scientific branches and their support to the Regulation and Policy branch as well as to the RHSAC and RHC is further addressed in chapter 3.

Subsection 15 (2) of the ARPANS Act requires the CEO of ARPANSA to take all reasonable steps to avoid any conflict of interest between his regulatory functions and other functions. ARPANSA has Chief Executive Instructions (CEIs) advising staff on how to manage conflict of interest and requiring that any given written advice/service must be maintained in a register. Advice by an ARPANSA officer to a party seeking advice is provided under the following conditions:

- the ARPANSA advice will not be binding on the CEO in the exercise of his regulatory functions;
- the ARPANSA advice will be provided to ARPANSA Regulation and Policy Branch;
- if during the course of the preparation of the advice, the ARPANSA officer becomes aware that the Controlled Person is not complying with their obligations under the ARPANS Act and Regulations, the ARPANSA Regulation and Policy Branch will be advised of the suspected non-compliance and be provided with any evidence in the possession of the ARPANSA officer which indicates such non-compliance;
- should any conflict of interest be identified during the course of preparing the advice that would make it inappropriate for ARPANSA to continue to provide the advice, ARPANSA may cease doing so.

Any final written advice is to include the following notice prominently:

This Advice has been provided by ARPANSA on the basis that it does not bind the CEO of ARPANSA in any manner in the exercise of the CEO's regulatory functions.

In preparing a report to the CEO with respect to a licensing issue, the Director, Regulatory and Policy Branch must take into account relevant ARPANSA advice, if any, and bring it to the CEO's attention.

Whilst the policy requires the maintenance of a register, no potential conflicts have been reported to the Director Regulatory and Policy Branch since the new policy was promulgated.

The IRRS team observed that whilst a few cases of potential conflicts of interest did happen in the past, but necessary measures were implemented to rectify this situation to ensure that if any potential conflict of interest is identified it was appropriately managed.

As there is no other Australian Government body able to regulate the ARPANSA Science Branches use of radiation, ARPANSA must also comply with the ARPANS Act. In other words, the CEO of ARPANSA must make regulatory decisions in respect of ARPANSA's controlled material and controlled facilities. To eliminate any potential conflict of interest and the perception of a conflict of interest, the Department of Human Services, Victoria (DHS) has agreed to participate in inspections of the ARPANSA sources and facilities to advise the CEO on compliance issues. The arrangement is intended to be formalised in an MOU between the two agencies. The Team believes that this recognition of a potential conflict of interest is commendable and suggests that the arrangements with the State of Victoria be completed.

National uniformity

According to the ARPANS Act the CEO has the function to promote uniformity of radiation protection and nuclear safety policy and practices across jurisdictions of the Commonwealth, the States and the Territories (section 15 (a)). This provision stems from recognition that there would be distinct advantages in achieving a national uniform framework for radiation protection and nuclear safety control. This recognition led to the Australian Health Ministers' Conference (AHMC) in 1997 charging an expert group led by Dr. J McNulty to develop recommendations on how this outcome might be achieved. The McNulty Report, which recommended a legislative approach by the States and Territories to achieve national uniformity, was adopted by the AHMC in July 1998. A working group of ARPANSA's Radiation Health Committee was subsequently tasked with making recommendations for moving forward on national uniformity and concluded that, although a legislative approach could achieve the goal, it was unlikely to be accepted in some jurisdictions at that time, and that a non-legislative option, specifically development of a National Directory for Radiation Protection (NDRP) was therefore the better approach.

The Radiation Health Committee established under the ARPANS Act (s22-24) includes representatives of all jurisdictions and develops Codes and Standards for national adoption. During 2004, Edition 1 of NDRP was published. A cost-benefit analysis and final Regulatory Impact Statement were issued in 2005. The aim of NDRP is to provide nationally uniform requirements for the protection of people and the environment against exposure or potential exposure to ionizing (and non-ionizing) radiation and for the safety of radiation sources, including provisions for the national adoption of codes and standards in all fields (medical, industrial, nuclear, research). NDRP has been developed to address the needs of radiation protection regulators, but it will also benefit other sectors involved in implementing radiation controls, such as mine operators and occupational health and safety regulators. Major progress has already been achieved as nearly all jurisdictions are revising or reviewing their legislative and regulatory systems to adopt the provisions of the NDRP. Development of Edition 2 has commenced to cover additional material, including application of the NDRP to, among others:

- portable density/moisture gauges containing radioactive sources,
- exposure of Humans to ionizing radiation for research purposes,
- radiation protection and radioactive waste management in mining and mineral processing,
- radiation protection in dentistry,
- security of radioactive sources,
- safe use of fixed radiation gauges.

The Team had the opportunity to meet with the chairpersons of the advisory bodies to the CEO (RHSAC, RHC, NSC and RRF) and discuss their role of advising the CEO and in achieving national uniformity. The meeting showed the engagement from all parties in promoting and achieving uniformity across all jurisdictions through the NDRP. Generally all were satisfied with the concept of promoting uniformity through the NDRP. Although progress could have been faster all acknowledged the sometimes difficult and time-consuming process in adopting and implementing new legislation in all jurisdictions. Education and training of the staff are important and often troublesome for all the regulatory bodies and the possibility of common approaches and support among the regulators were discussed. Finally the possibility and suitability of a review mechanism on the progress in implementing the NDRP among the regulators, e.g. in the RRF was discussed.

With the large numbers of different jurisdictions in Australia (Commonwealth, States, Territories) the Team finds the instrument for achieving uniformity of radiation protection and nuclear safety policies and practices across Australia well chosen. The progress made so far on promoting uniformity is remarkable in a complex political, legal and administrative environment. A background paper for the RHSAC meeting in April 2007 on review of progress towards national uniformity is annexed (Appendix VIII) to this report.

The Team reviewed ARPANSA’s response to the IRRS questionnaire and held detailed discussions with the CEO, management and corporate counsel to inform the Team’s understanding on the responsibilities and functions of ARPANSA. The Team concludes that the Act’s provisions for the responsibilities of ARPANSA are consistent with the applicable responsibilities and functions of the regulatory body provisions of GS-R-1.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1 §2.2(5) states “ <i>no other responsibility shall be assigned to the regulatory body which may jeopardize, or conflict with, its responsibility for regulating safety.</i> ”
(2)	BASIS: GS-R-1 § 3.5 states “ <i>The regulatory body may also have additional functions. When such functions are undertaken, care shall be taken by the regulatory body to ensure that any conflict with its main regulatory functions is avoided and that the prime responsibility of the operator for safety is not diminished</i> ”
S3	Suggestion: The CEO of ARPANSA should consider an expedited implementation of the arrangement that has been put in place to utilise inspectors from the State of Victoria to inspect ARPANSA’s own compliance with the ARPANS Act in relation to its regulated sources and facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	BASIS: GS-R-1 §3.4 states: <i>“The regulatory body shall co-operate with other relevant authorities, advise them and provide them with information on safety matters.”</i>
(2)	BASIS: GS-R-1 §3.5 states: <i>“The regulatory body may also have additional functions.”</i>
G2	<u>Good Practice:</u> One of the functions of the CEO of ARPANSA is to promote uniformity of radiation protection and nuclear safety policy and practices across jurisdiction of the Commonwealth, the States and the Territories (Section 15 (1) (a) of the Act). The instrument for achieving uniformity is the National Directory of Radiation Protection (NDRP). The progress made by ARPANSA so far in promoting uniformity among the States and Territories has been remarkable.

3. ORGANIZATION OF THE REGULATORY BODY

3.1 GENERAL

Organizational structure, size and activities

GS-R-1 § 4.1

ARPANSA is included within the portfolio of Health and Ageing. The CEO of ARPANSA reports to the Parliament through the Parliamentary Secretary to the Minister for Health and Ageing. ARPANSA is effectively independent from any other Department that deals with the promotion of nuclear technologies. ARPANSA does however undertake activities that do require licences under the Australian Radiation Protection and Nuclear Safety Act 1998, including radiation facilities.

ARPANSA is located at Miranda in Sydney and at Yallambie in Melbourne. It is composed of the Office of the CEO; the Regulatory and Policy Branch; the Corporate Services Branch; the Medical Radiation Branch; the Environmental and Radiation Health Branch; and the Non Ionizing Radiation Branch. The total staff of ARPANSA is 132. Its current organizational structure is shown in Appendix XI.

There are three technical and scientific Branches, located in Yallambie, Melbourne, with a total staff of 76. These are the Non Ionizing Radiation Branch, the Environmental and Radiation Health Branch, and the Medical Radiation Branch. The latter two Branches conduct research in environmental and medical issues; maintain and develop measurement capacities; provide technical support to both Nuclear Safety Committee and the Radiation Health Committee that establish Safety Standards, Codes of Practice, Recommendations, Safety Guides and the National Directory for Radiation Protection. These technical and scientific Branches also provide advice and services in patient protection, evaluation of patient doses, dose reduction, personal radiation monitoring, calibration, health impact assessment, internal and environmental pathways modelling, NORM...etc. The research activities of the Branches are generally directed to areas which have a significant impact for Australia but not exclusively for ARPANSA's regulatory role. Areas such as medical exposures, uranium mining and NORM residues are cases in point. Other areas such as assessing environmental impact, effects on non-human biota and assessment methodologies for waste disposal are however relevant to ARPANSA' regulatory activities.

The Corporate Services Branch staffed with 25 members provides financial, human resource, administrative services and information and communication technology support for ARPANSA.

The Regulatory and Policy Branch is responsible for discharging the main regulatory functions of ARPANSA dealing with review and assessment, authorization, inspection and enforcement. The Branch has been playing the key role, assisted by ARPANSA Corporate Counsel, in managing the above main regulatory functions and providing advice to the CEO on the exercise of his main regulatory responsibilities and powers. In doing so, the Branch gets some technical support from Yallambie consisting of advice on particular issues relating to review and assessment. The IRRS Team believes that better co-ordination and co-operation between the scientific and technical Branches at Yallambie and Regulatory and Policy Branch would bring, in addition to efficiency and effectiveness gains, integration, more synergies and organizational harmonization.

The Regulatory and Policy Branch has a total staff of 25 officers regulating the entire Commonwealth nuclear and radiation facilities and activities. It has currently 32 licence holders,

some with a very varied use of radiations (e.g. ANSTO with 3 reactors -1 operating, 1 shutdown and 1 de-fuelled) and radioisotope production facilities as well as regulating the Commonwealth Scientific and Industrial Research Organization (CSIRO) with over 19 divisions spread across every state and territory.

The Policy and Source Security Section, within the Regulatory and Policy Branch, has inter alia the function of managing the relationship between ARPANSA and the Office of the Parliamentary Secretary. It oversees ARPANSA's national role in the security of sources.

ARPANSA has established and is implementing the Corporate Plan 2005- 2008 that has "three output groups" – Knowledge, information and services; national leadership; and regulation. ARPANSA has also established a "Business Plan (July 2007 – July 2008)" linked to the Corporate Plan for the function of regulation (Regulatory and Policy Branch Business 2007-2008). The Regulatory and Policy Branch Business Plan includes the following "Key Initiatives" for this financial year: Governance and organizational development; Stakeholder communication; Recovery of regulatory cost; Compliance; Government Policy; and Security.

The Australian Government announced last April a new strategy on "Uranium Mining, Processing and Nuclear Energy: A way Forward for Australia". As part of the implementation of the above strategy, the Government of Australia is preparing, for consideration in September 2007, the following major work plans:

- An appropriate nuclear energy regulatory regime – including those to govern any future potential nuclear energy facilities in Australia;
- Skills and technical training to address any identified gaps and needs to support a possible expanded nuclear energy industry;
- Enhanced research and development; and
- Communication strategies so that all Australians and other stakeholders can clearly understand what needs to be done and why.

The IRRS team appreciates ARPANSA's strategic forward looking approach and encourages it to prioritize and implement the approved Business Plan. However, the IRRS team believes that ARPANSA's strategic views should regularly be updated, to the extent possible, taking into account the national and international regulatory environment and challenges, including the newly established Australian Government strategy on "Uranium Mining, Processing and Nuclear Energy: A way Forward for Australia". These regulatory challenges are to be taken into account in order, inter alia, to complete and/or improve its regulatory processes and competences.

Budget

ARPANSA's budget is a part of the overall budget for the Health and Ageing portfolio, as confirmed by review of the 2007-08 Portfolio Budget Statement. ARPANSA's budget for FY 2007-2008 is approximately 26 million dollars Australian and funds the activities of ARPANSA and its 132 staff located in offices in Sydney and Melbourne. The Budget is composed of three distinct sources of revenue. These are from appropriations made by the Parliament, regulatory fees and charges, and revenue from other sources, including sale of goods and services.

The recovery of the cost of regulation by ARPANSA is achieved by the imposition of application fees and annual licence charges that are prescribed in the ARPANS Regulations 1999 and the

ARPANS (Licence Charges) Regulation 2000. The application fees and annual licence charges constitute the regulatory revenue.

Coordination with organization having related responsibilities

GS-R-1 § 4.2

Activities of ARPANSA's are affected by the operation of other Federal (Commonwealth) Acts, including the Environmental Protection and Biodiversity Conservation Act 1999, the Commonwealth Radioactive Waste Management Act 2005, the Occupational Health and Safety Act 1991 and the Nuclear Non-Proliferation (Safeguards) Act 1987.

Officers of ARPANSA are also authorized officers for the purpose of issuing permissions under the Customs Act 1901, in particular under the Customs (Prohibited Import) Regulations 1956 and the Customs (Prohibited Export) Regulations 1958. The Customs (Prohibited Import) Regulations of 1956 prohibited the import of radioactive material without permission and the Customs (Prohibited Exports) Regulations of 1958 prohibited the export of high activity radioactive materials without permission. The permission system is administered having regard to the regulatory requirements of the States and Territories and the licensing status of the permission applicant who may wish to receive the material in a particular State or Territory.

Activities that may be the subject of licensing by the CEO of ARPANSA may also require the approval of the Minister of the Environment and Water Resources under the Environmental Protection and Biodiversity Conservation (EPBC) Act 1999. These include actions that are designated as "nuclear actions" under the EPBC Act. In such instances, ARPANSA ensures that it co-ordinates with the Department of Environment and Water Resources as that Department undertakes its functions of advising the Minister under the EPBC Act. In terms of process this means that for specific licensing action, for example the preparation of a site for a proposed control facility, preparation of an Environmental Impact Statement and a decision from the Minister of Environment and Water Resources are necessary pre-conditions for ARPANSA to determine an application for a facility licence.

The legislative framework for physical protection and security of nuclear material and facilities in Australia is provided by the Nuclear Non-Proliferation (Safeguards) Act 1987. With respect to nuclear facilities, ARPANSA coordinates its regulatory functions with the Australian Safeguards and Non-Proliferation Office (ASNO) under a Memorandum of Understanding.

ARPANSA has developed, as explained in GS-R-1 § 3.5, the Australian National Directory of Radiation Protection. The National Directory includes the overall framework for radiation protection in Australia agreed by the Commonwealth, States and Territories. The Directory also contains uniform regulatory elements which are adopted by each jurisdiction within its particular regulatory framework. Through the establishment and implementation of the National Directory, ARPANSA has good interfaces and liaison with regulatory Bodies in all States and Territories.

Use of consultants and contractors

GS-R-1 § 4.3

ARPANSA does not have sufficient technical and regulatory staff to cover all possible areas of technical expertise required for performing regulatory reviews and assessments or evaluating reviews and assessments. Therefore consultants and contractors are used by ARPANSA, inter alia, in areas such as geology, seismology, civil engineering, fire engineering, welding science, specialist

reactor physics and specialist materials. Independent peer reviews of licence applications have also been undertaken through the IAEA. Other regulators have also been engaged for public forum panels associated with the licensing stages of the OPAL research reactor. The branch also used the Australian Dams Safety Committee, Geoscience Australia and CSIRO to assist in civil engineering, seismic dating, fire engineering respectively. The IRRS Team appreciates the above transparent approach through independent peer reviews and involvement of other experts in licensing stages of the OPAL research reactor.

3.2 STAFFING AND TRAINING OF THE REGULATORY BODY

(GS-R-1 §4.6-4.8)

ARPANSA has established a “Workforce Planning and Development” document derived from its workforce planning policy spelt out in the Corporate Plan 2005-2008. This Workforce Planning and Development plan aims at:

- supporting and developing ARPANSA staff by continuing to improve its employment services with fair, open and consistent recruitment practices,
- implementing strategies to attract and retain outstanding performers, and
- creating opportunities for all staff to participate in staff development.

It also intends to provide strategies and training in the following areas:

- succession management,
- graduate recruitment,
- knowledge retention,
- staff retention,
- individual annual development plans,
- leadership development,
- external studies,
- performance management.

The IRRS team strongly encourages this strategic approach to staff planning and development and notes with satisfaction the approval of the graduate recruitment portion by the Executive Board to commence in 2008. As a result, actions for recruiting four junior professionals have been initiated. These four professionals will be allocated to a “home” branch. During the training period, each participant will spend four months in the home branch and three months in each of two other branches, including rotation in Sydney and Melbourne branches. The CEO of ARPANSA confirmed that graduate recruitment is to continue into the future, whilst funding is available, to meet ARPANSA’s needs and priorities. However, efforts should be made to ensure that current staff is in a position to provide effective on-the-Job-Training to these new recruits.

ARPANSA has a mechanism for identifying training needs, called the ARPANSA Performance Development System (APDS). APDS is a planning tool that lists staff training activities for the year ahead. However, there has been, so far, no formal well-defined comprehensive training programme on technical regulatory issues covering all main regulatory functions. Currently training is on-the-job and extensive mentoring is required from existing staff who may find it difficult to devote extra time to this mentoring. Therefore the issue is ensuring that current and future staffing levels are adequate to cope with ongoing activities and then with on-the-job training. In addition, refresher training and training on new regulated technologies and methodologies may be difficult to implement due to limited availability of sufficient staff. For example staffing in regulatory activities for waste management is thin. The same expert is responsible for inspection and assessments for not

only waste management facilities, but also other tasks in diverse areas such as radiopharmaceutical production. This may force staff to prioritize work in a reactive manner; with little allowance for proactive work (e.g. there is a generic inspection procedure for the operating waste facilities but little time to develop facility-specific procedures that would be useful for new staff). Furthermore, regulatory activities can be too much influenced by the experience of a single expert. This situation also leaves ARPANSA exposed to disruption should there be staff turnover.

It should be noted that about 70 years of nuclear safety experience has been lost in the past 3 years, and another 35 is likely to be lost due to retirement in the next 2 to 3 years. The Team had extensive discussions with ARPANSA management on staffing and training issues, in particular the difficulties faced by ARPANSA as a technical and regulatory body in recruiting highly qualified staff to current and future vacancies. To better address those issues of staff training, knowledge retention and succession management, the Team recommends that a formal well-defined comprehensive training programme on technical regulatory be established and that the Workforce Planning and Development document be further implemented by ARPANSA management.

3.3 ADVISORY BODIES TO THE REGULATORY BODY

Advisory Bodies

GS-R-1 §4.9

There are three statutory advisory bodies to the CEO: The Radiation Health and Safety Advisory Council, the Radiation Health Committee and the Nuclear Safety Committee. The structure and function of the advisory bodies are set out in the legislation (see chapter 2). Members of the advisory bodies are all required by the legislation to give written notice to the person appointing them of all interests, pecuniary or otherwise, that they have or acquire and that could conflict with the proper performance of their function as a member. The functions of the advisory bodies to advise the CEO are clearly set out in the legislation. It should be noted that the CEO is a member of these advisory bodies.

3.4 RELATIONS BETWEEN THE REGULATORY BODY AND THE OPERATOR

Relations with the operators

(GS-R-1 §4.10)

Formal communication is managed through formal correspondence and meetings including licence holder liaison meetings. ARPANSA aims at an open and professional relationship with the licensees. In addition to professional regulatory contacts (e.g. inspections, stakeholder liaison meetings), ARPANSA frequently holds discussions with licence holders (called the Licence holders forum) to discuss emerging issues. There are no formal agreements in place for the relationships or the meetings, but the practical arrangements have been working adequately.

The relationship with licence holders, as observed during inspections, is frank and transparent; however a suitable level of formality and distance is maintained so as to not give any appearance of inappropriate closeness or regulatory capture.

3.5 INTERNATIONAL CO-OPERATION

GS-R-1 §4.11

ARPANSA has entered into Memoranda of Understanding with:

- the US Nuclear Regulatory Commission;

- the Canadian Nuclear Safety Commission;
- the US Department of Energy concerning security of radioactive sources and emergency management;
- the National Nuclear Regulator of the Republic of South Africa (NNR);
- the National Regulatory Body of Vietnam, VARANSAC;

An arrangement is also in place with the United Kingdom’s Health and Safety Executive.

ARPANSA has been a key and proactive player in the development and implementation of international safety standards. It is represented by its CEO at the Commission on Safety Standards (CSS). Australia is also represented at the Radiation Safety Standards Committee (RASC), the Transport Safety Standards Committee (TRANSC), the Waste Safety Standards Committee (WASC) and the Nuclear Safety Standards Committee (NUSC). ARPANSA is an active member of the OECD’s Nuclear Energy Agency (NEA), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) currently chaired by Peter Burns of ARPANSA, who is also a member of ICRP Committee 4.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1 §4.1 states: <i>“The regulatory body shall have an organizational structure and size commensurate with the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities.”</i>
(2)	BASIS: Preamble to the BSS under “the regulatory authority” states: <i>“Such a regulatory authority must be provided with sufficient powers and resources for effective regulation...”</i>
(3)	BASIS: Preamble to the BSS under the regulatory authority states: <i>“The type of regulatory system adopted in a country will depend on the size, complexity and safety implications of the regulated practices and sources...”</i>
S4	Suggestion: ARPANSA should consider reviewing its current Corporate Plan and prioritize and implement the activities contained in the Regulatory and Policy “Business Plan”, to ensure that it has an effective and sustainable regulatory infrastructure that will respond appropriately to any national challenges, including the Australian Government’s Expanded Nuclear Industry Strategy.
(1)	BASIS: GS-R-1 §4.2 states: <i>“The main functions of review and assessment and inspection and enforcement shall be organized in such a way as to achieve consistency and to enable the necessary feedback and exchange of information. In addition, the authorities responsible for the different disciplines concerned in the regulatory process, such as those responsible for nuclear, radiation, radioactive waste and transport safety, shall be effectively co-ordinated.”</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S5	<p><u>Suggestion:</u> ARPANSA should consider a strategy for strengthening the working relationship between the Regulatory and Policy Branch and the scientific and technical branches in order to optimize its technical, research and regulatory functions. This strategy should include the provision of necessary budget and human resource to ensure the successful implementation of the Regulatory and Policy “Business Plan” and in particular to assure ongoing technical support for the carriage of the regulatory function.</p>
(1)	<p>BASIS: GS-R-1 §4.3 states: “...Whoever may provide such advice or assistance, arrangements shall be made to ensure that the consultants are effectively independent of the operator. If this not possible, then advice or assistance may be sought from other States or from international organizations whose expertise in the field concerned is well established and recognized.”</p>
G3	<p><u>Good Practice:</u> ARPANSA’s use of international peer review team and services from the IAEA is good practice.</p>
(1)	<p>BASIS: GS-R-1 §4.6 states: “The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, expertise and experience to undertake its functions and responsibilities.”</p>
(2)	<p>BASIS: Preamble to the BSS under “the regulatory authority” states: “Such a regulatory authority must be provided with sufficient powers and resources for effective regulation...”</p>
S6	<p><u>Suggestion:</u> ARPANSA should consider its strategy for effective implementation of the “Workforce Planning and Development” document derived from its Corporate Plan 2005-2008.</p>
G4	<p><u>Good Practice:</u> The Graduate Recruitment portion of the Workforce Planning and Development will, if effectively implemented, ensure the ongoing availability of appropriately trained and qualified staff and is good practice.</p>
(1)	<p>BASIS: GS-R-1 §4.7 states: “in order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff are aware of technological development and new safety principles and concepts.”</p>
R1	<p><u>Recommendation:</u> ARPANSA should establish and implement a more comprehensive training programme for regulatory staff.</p>
G5	<p><u>Good Practice:</u> ARPANSA is very engaged in the framework of international cooperation and in the establishment and implementation of international standards and undertakings. Bilateral agreements are well developed. These activities support the statutory requirement to incorporate international best practices into regulatory decisions. This is good practice.</p>

4. ACTIVITIES OF THE REGULATORY BODY

4.1 AUTHORIZATION

GS-R-1 §5.1 – 5.2

The Australian Radiation Protection and Nuclear Safety Act of 1998, Part 5, establishes the requirement that Commonwealth entities and their contractors must obtain a licence to undertake the activities spelled out in the Act. The prohibition of activities pertaining to sources and to facilities is addressed in sections 31 and 32 of the ARPANS Act.

At the time of this review, ARPANSA had 67 source licences and 37 facility licences for 33 licence holders.

GS-R-1 §5.3

The requirements for issuing a licence authorizing activities in relation to source and facility licences is set out in sections 32 to 34 of the ARPANS Act. The basis for an exemption for the requirement to obtain an authorization under a licence is set out in Regulation 37 and exempt dealings are described in Regulation 38 and in Schedule 2 of the Regulations. The information required by the CEO for an application for a licence is set out in the regulations, in particular regulation 39 and Part 1 and Part 2 of Schedule 3.

The statutory criteria to be considered by the CEO in deciding whether to issue a licence are addressed in section 32 and 33 of the Act and in Regulations 41 and 42.

When applications are reviewed, Regulatory Assessment Reports (RAR) are prepared by ARPANSA staff to inform the CEO's decision about the issuance of a licence. The format of the RAR is different for source licences and for facility licences. The depth of review is greater for facility licence applications. The RAR includes the opinion of staff about such matters as undue risk, net benefit, ALARA and an assessment of the licensee's ability to comply with the regulations and licence conditions. The IRRS team members compared the RAR prepared for category 2 sources in a calibration facility and for category 5 sources used for geological measurements. The depth of review is commensurate with the potential magnitude and nature of the hazard presented.

However, there is no predetermined approach to the assessment of applications for a licence that is based on the categorization of sources (effectively the risk level) for the requested activity. Sources are grouped in the regulations primarily for fee purposes. The groupings reflect the categorization of kinds of controlled material and controlled apparatus into similar hazard levels and therefore costing more or less to regulate.

The IRRS Team noted that the requirements for different kinds of licences are graded and that the assessment of licence applications is graded, but the ARPSANS Act does not provide the statutory basis for any other authorization process like registration or notification.

ARPANSA has developed clear procedures for receiving and assessing licence applications (see below)

4.1.1 AUTHORIZATION - RESEARCH REACTORS

There are 3 research reactors located within Australia with one facility operating and two facilities shutdown.

The OPAL reactor is a 20 MW multi-purpose pool type reactor. The OPAL facility construction licence was issued in April 2002. The licence authorizing operation of the reactor, including hot commissioning, was issued in July 2006. The OPAL Reactor achieved full power in November 2006 and is currently completing the hot commissioning phase.

The HIFAR reactor is a tank type reactor rated at 10 MW. HIFAR operated for 49 years and was shutdown permanently on 30 January 2007. The reactor has been de-fuelled.

The Moata reactor, an Argonaut type reactor, was shutdown in 1995 and partially decommissioned.

GS-R-1 §5.3

Prior to an authorization being issued for a facility licence authorizing activities for nuclear installations (including research reactor licences), a comprehensive set of information is required to be submitted to ARPANSA as part of the application for a facility licence for review. Section 34 of the Act requires the applicant to submit information in a form approved by the CEO. Regulation 39 of the Australian Radiation Protection and Nuclear Safety Regulations 1999 specifies the information that an application for a facility licence may be required to contain and includes the applicant's plans and arrangements for managing safety, detailed description of the facility including the Safety Analysis Report and operational limits and conditions.

GS-R-1 §5.4

RB-LA-SOP-2000, the Standard Operating Procedure for Licence Application Assessment, provides process guidance for the review and assessment of applications. The application is at first reviewed to determine whether it contains all of the necessary information. Approval of an acceptable application is a required step prior to beginning the review and assessment process of the submittal. RB-STD-42-00, Regulatory Assessment Principles for Controlled Facilities, describes the principles to be used when assessing an application for a facility licence as well as for approvals for changes to facilities already under a licence. In conjunction with RB-STD-42, Regulatory Guide RB-STD-43-00, Regulatory Assessment Criteria for the Design of New Controlled Facilities and Modifications to Existing Facilities, is used to provide guidance to the regulatory body when assessing an application for a new facility or modification to an existing facility. Procedure RB-STD-15-03, Regulatory Guideline on Review of Plans and Arrangements, provides the requirements that should be satisfactorily demonstrated in a licensee's or applicant's Plans and Arrangements prior to the regulatory body authorizing an operating licence. The documents make it clear that it is not a requirement, and that other means of demonstrating adequate compliance will be considered by ARPANSA. These documents are available on the ARPANSA website and provide significant information to an interested party as to what criteria are to be used to assess the submittal. While in general, the expectation from ARPANSA is that the submittal will address the criteria to be used in the assessment of the adequacy of the submittal (from the various documents on the website), there is not a single document that comprehensively addresses what information is required to be submitted for review in an application, nor is there a specific guidance document to address the desired, if any, format.

With regard to the timeliness of information submitted, ARPANSA does not have standardized policies or procedures related to timeliness of submittals nor the timeliness of review. Most deadlines are established informally, both internally and with the licensee, and are communicated to the licensee either by letter or less formal means (email). Typically the more significant the action

requested, the more formal the communication means. The Regulatory and Policy Branch has a Business Plan that established timeliness target and goals (performance indicators) for a number of regulatory actions and products related to the regulatory body. This Business Plan will operate for the financial year 2007-2008.

Where activities contain discrete stages of completion, such as the construction and commissioning of the OPAL reactor, the authorizations may be separate licences or include the discrete steps within a licence. Separate licences were required to be issued for the preparation of the site, construction, and operation of the OPAL facility. Within the construction and operating licences, conditions were imposed that constituted hold points for various activities. For example, the construction licence, FO0118-Construction, was issued for the OPAL facility in April 2002 and contained a statutory licence condition (Regulation 54) and a CEO imposed licence condition that set out the requirement to obtain the approval of the CEO of ARPANSA before commencing construction (including the manufacture, installation and cold commissioning) of each Safety Category 1 and 2 item specified in the Preliminary Safety Analysis Report that formed part of the application. Each request for approval by the applicant was reviewed and assessed by ARPANSA, and when satisfied that the appropriate conditions and arrangements were in place for the requested item, the CEO authorized the commencement of construction (whether manufacture, installation or cold commissioning) for the requested item. In the licence authorizing operation of the OPAL facility (F0157 dated 14 July 2006), the various stages of the hot commissioning program were specified. Included in the commissioning program was the requirement to submit a report to ARPANSA describing the results of each completed stage, and that approval would be needed from the ARPANSA CEO prior to continuing to the next stage. The submitted report was reviewed and assessed by ARPANSA to determine that the activities conducted during the stage had been satisfactorily completed. This approval from the CEO to continue to the next commissioning stage was formally transmitted to the licensee in a letter.

As noted above, the CEO of ARPANSA has the authority to attach licence conditions to licences. Section 35 of the Australia Radiation Protection and Nuclear Safety Act of 1998 identifies, in general, the types of conditions that may be imposed on any licensee. Section 36 of the Act provides the authority for ARPANSA, through the CEO, to impose new licence conditions, remove or vary licence conditions previously imposed, or to extend or reduce the authority previously granted by the licence. The Australian Radiation Protection and Nuclear Safety Regulations of 1999, Part 4, Division 4, describes the conditions imposed on all licences (items 44-55). Included in the list of conditions, under item 48, is "Compliance with Recommendations and Codes of Practice," and a list of Codes of Practice and Recommendations. The Licence Conditions Handbook, RB-STD-23-01, provides detailed information on how to read source and facility licences as well as more detailed information related to licence conditions. The Licence Conditions Handbook has no regulatory authority as a stand-alone document. However, it can be, and has been, referenced in Licences, and thus became a requirement for the licensee as a Condition of Licence.

GS-R-1 §5.5

Following an ARPANSA decision regarding the issue of a facility licence authorizing activities to be undertaken in relation to a nuclear installation, the CEO publishes a Statement of Reasons regarding the decision.

Section 32 of the Act and Regulation 41 of the Regulations specifies the matters to be taken into account by the CEO prior to issue of a facility licence. The Statement of Reasons describes the basis and rationale for the conclusion reached. Under the existing legislation, the CEO is required to consider international best practices in his decision on the licence. For example, during the review and assessment of the request for an operating licence for the OPAL reactor, the CEO's reasons for decision document listed the practices and documents utilized for satisfying this requirement. The

documents utilized in the review were the Code of Conduct on the Safety of Research Reactors, the Joint Convention on the Safety of Spent Fuel and the Safety of Radioactive Waste Management, the IAEA Safety Fundamentals, the Recommendations of the International Commission on Radiological Protection, and the IAEA Safety Requirements of NS-R-4, Safety of Research Reactors. For lower order approvals under the facility licence (for example, commissioning hold points), ARPANSA formally documents the decision and the basis for the decision. Examples were reviewed demonstrating both acceptance of the requested approval (OPAL commissioning stage progression) and refusal of a requested approval (OPAL reactor hall crane hoist). In both cases, the conclusion was supported by a detailed analysis of the associated information and was clearly communicated to the licensee via letter from the CEO of ARPANSA.

GS-R-1 §5.6

For subsequent amendments, cancellations, or suspensions of authorizations, Section 36 of the Act grants the CEO the authority to amend a licence. Section 38 grants the CEO the authority to suspend or cancel a licence if certain conditions exist. Since licences are issued with no expiration date and remain in force until cancelled or surrendered, there is no renewal process necessary. However, with regard to suspensions or cancellations, there are no formal internal procedures or processes established at this stage to address these items.

Regulation 51 is a statutory licence condition that requires that a licence holder seek the approval of the ARPANSA CEO prior to making a relevant change that will have “significant implications for safety” (quotation marks added). Regulation 52 requires that the licence holder report, on a quarterly basis, any relevant changes made to the facility that were unlikely to have significant implications for safety (Regulation 52).

Regulatory Guide RB-STD-43-00, Regulatory Assessment Criteria for the Design of New Controlled Facilities and Modifications to Existing Facilities, addresses the regulatory assessment criteria for modifications to existing facilities and is available on the ARPANSA website. However, ARPANSA does not have a clearly defined procedure or guide that describes what is meant by “significant implication for safety.” The staff indicated that they did not specifically reference the Regulatory Guide during their reviews and relied on experience, knowledge and engineering judgement to make a determination of whether a modification had significant implications for safety. Additionally, discussions with the ARPANSA staff indicated that there is no regulatory guidance that describes the information required to be submitted by a licensee in their request for approval for a modification requiring ARPANSA approval prior to implementation (Regulation 51) to support the review and assessment of the modification. This contrasts with the fairly specific guidance regarding the information that is required to be submitted to support a licence application.

The time frames associated with submittals and responses were determined informally and typically communicated via letter for more formal requests, and via telephone or email for less formal deadlines. Where a specific request for deadline is determined to be necessary, it is formally communicated to the licensee via letter.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1 §5.4 states <i>“The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization.”</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R2

Recommendation:

ARPANSA should prepare a regulatory guidance document that relates to regulation 51 conditions (relevant change with significant implications for safety) and covers guidance on the scope of the condition and the type of information that is required to be submitted by the licensee to support its application for an approval under regulation 51.

4.1.2 AUTHORIZATION - SOURCES AND INDUSTRIAL PRACTICES

GS-R-1 §5.4 Guidance for Applicants

ARPANSA provides applicants for a licence with a copy of the “Guide to the Australian Radiation Protection and Nuclear Safety Licensing Framework” (Edition 1, March 1999) and with a copy of a Source (or Prescribed Radiation Facility) Application Pack. The guide document describes how the ARPANS Act applies. Attachment A to the application pack states that applicants are required to provide detailed plans to ARPANSA describing arrangements in place to manage materials and apparatus including a Safety Management Plan, a Radiation Protection Plan, a Radioactive Waste Management Plan, a Security Plan, an Emergency Plan and an Environmental Management Plan.

Additional guidance for applicants is described in “Regulatory Guideline on Review of Plans and Arrangements” (RB-STD-15-03). This is a comprehensive document that addresses in detail how ARPANSA staff is required to review applications and, by extension, the scope and depth of the information that a licensee should provide in order to make a safety case for an application for a licence. The primary users of the guide are the CEO of ARPANSA and regulatory staff, but the introduction states that it “may also assist applicants in the preparation of licence applications.” RB-STD-15-03 is used for both facility and for source licences.

There is a requirement to submit a detailed demonstration of safety, and ARPANSA has appropriate guidance in the form of licence application packs for facilities and sources.

GS-R-1 §5.5 Regulatory Decisions

ARPANSA formally records the basis for each decision to issue a licence in the form of the regulatory assessment report (RAR) mentioned above and a memorandum to the CEO recommending the issue of a licence.

GS-R-1 §5.6 Procedures for amendment

The power to amend a licence is granted to the CEO of ARPANSA by section 36 of the Act.

Amendments are assessed in the light of the “Regulatory Guideline on Review of Plans and Arrangements”, but the procedure for amendment is not documented.

Regulation 51 requires a licence holder to obtain the prior approval of the CEO to make a relevant change with “significant implications for safety”. Such changes may (but not always) require an amendment. An amendment may be triggered, for example, if the licence holder requests that the licence be amended to remove time related licence conditions which have been satisfied, if the licence holder submits an application for a different type of source dealing or if an inspector recommends to the CEO that the licence be amended as a result of an inspection or an investigation.

There are, however, no guidelines for staff or licensees about what is meant by “significant implications for safety”.

Procedures for suspension or cancellation

The CEO is granted the power to cancel or suspend a licence by section 38 of the Act.

Suspension is an enforcement action. None have occurred so far.

For surrender of a licence, ARPANSA staff makes a written recommendation to the CEO that the licence be surrendered and a letter is sent to the licensee requesting that the original signed copy of the licence be returned.

ARPANSA has not yet established standard procedures for determining amendments, suspensions and cancellations. ARPANSA staff has acknowledged a need for these. This matter is also addressed in the recommendations of one other IRRS subject team.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1 §5.6 states <i>“any subsequent amendment, renewal, suspension or cancellation of the authorization shall be undertaken in accordance with a clearly defined and established procedure. The procedure shall include requirements for the timely submission of applications for renewal or amendment of authorizations. For amendment and renewal, the associated regulatory review and assessment shall be consistent with the requirements of para. 5.3.”</i>
S7	Suggestion: ARPANSA should establish clearly defined procedures addressing the regulatory requirements for amendment, suspension or cancellation of a licence.

4.1.3 AUTHORIZATION – DECOMMISSIONING

GS-R-1 §5.3. §5.4-5.6; WS-R-2, §2.1-4.2, §6.1-6.13; WS-R-5

Paragraph 30(1)(e) of the Act prohibits a controlled person from decommissioning, disposing of or abandoning a controlled facility unless the person is authorized to do so by a facility licence or the person is exempted in relation to the conduct concerned by regulations made for the purposes of this section. The appropriate facility licence in this case is a decommissioning licence which is issued under section 32 of the Act.

The ARPANS Act set out matters that must be addressed in an application for a decommissioning licence for controlled facilities.

Any proposed dismantling of a controlled facility would require a decommissioning licence. ‘Dismantling’ as used in the decommissioning guidance means the planned disassembly and/or removal of any structure, system or component that was covered by the operating licence, without which the controlled facility cannot operate or re-operate over any part of its domain of operation (including shutdown) to the same degree of safety. Dismantling activities thus defined are ‘disposing of’ safety-relevant parts of a controlled facility.

For example, dismantling, thus defined, of a controlled facility's electrical power supply system, cooling system or control system would require a decommissioning licence.

In making an application for a facility licence authorizing the decommissioning of a controlled facility, the Australian Radiation Protection and Nuclear Safety Regulations 1999 (Regulations) require the applicant to provide to the CEO of ARPANSA, as part of its application, the decommissioning plan and the schedule for decommissioning the controlled facility and information about other plans and arrangements describing how the applicant proposes to manage the controlled facility to ensure the health and safety of people, and the protection of the environment including, among other, the following information:

- applicant's arrangements for maintaining effective control of the facility,
- safety management plan for the controlled facility,
- radiation protection plan for the controlled facility,
- radioactive waste management plan for the controlled facility,
- security plan for the controlled facility,
- emergency plan for the controlled facility,
- decommissioning plan for the controlled facility,
- schedule for decommissioning the controlled facility.

After decommissioning, when asking for a licence to abandon a controlled facility, the regulations require the applicant to provide:

- results of decommissioning activities at the controlled facility,
- details of any environmental monitoring program proposed for the site.

The applications for a facility licence authorizing decommissioning are reviewed and assessed by ARPANSA in accordance with Regulatory Assessment Principles for controlled facilities RB-STD-42-00 Rev 1 (RAP's) and other written documentation like the (draft) "Regulatory Guidance for the Decommissioning of Controlled Facilities RB-STD-10-06" (Decommissioning Guide). The standard operating procedures for assessment of applications includes a standard letter that requires the additional information if further significant information is required.

Generic licence conditions for controlled facilities are contained in the Act (Section 35) and the Regulations (Division 4). Further licence conditions are issued for specific controlled facilities like the "ANSTO Licence Conditions Handbook". Licence conditions however are not relevant at the assessment stage.

It is a requirement of the Environment Protection and Biodiversity Conservation Act 1999 that a person who proposes to undertake a nuclear action as defined in the Act, including decommissioning of a nuclear installation, must seek the approval of the Minister for Environment and Water Resources to undertake that nuclear action. Approval for significant actions usually requires an Environmental Impact Assessment.

The Regulations require that when the CEO of ARPANSA receives an application for a facility licence relating to a nuclear installation, which includes a research reactor, he must advertise and seek submissions from members of the public about the application. The CEO of ARPANSA must take into account the content of those submissions in his Statement of Reasons when issuing a licence for a facility licence authorizing decommissioning.

4.1.4 AUTHORIZATION – REMEDIATION

SS115 App. VI; WS-R-3 § 2.2-4.7

There are currently two environmental chronic exposure situations that have required, or will require in the future, some remedial actions under ARPANSA regulatory control:

- The South Alligator Valley in the Northern Territory of Australia, now within the Kakadu National Park, is an area that was subject to uranium prospecting and mining from 1955 to 1964. The site was subsequently abandoned without any significant restoration, until 1990 when a limited “hazard reduction” program was performed.
- The Maralinga former Atomic Weapon Test site is located in a remote desert area in the State of South Australia. The remediation project was almost completed when the ARPANS Act commenced in 1999. ARPANSA licensed the end stages of the remediation of the site under a facility licence. The site is now at a stage that all operations have ceased and the licence holder is operating the facility in a caretaker mode.

Legal and Regulatory Framework

WS-R-3 §4.1-4.8

There is no facility or source licence under the ARPANS Act that expressly authorises remediation. ARPANSA adapted the established regulatory framework for licensing of controlled facilities in relation to both of the situations referred to above.

ARPANSA issued a facility licence authorizing Parks Australia North to decommission the controlled facility, located in South Alligator River.

In relation to the Maralinga site, ARPANSA issued a facility licence authorizing the Australian Government Department of Education, Science and Training (DEST) to operate the prescribed radiation facility, operation being the conduct of a project as set out in the licence authorization instrument.

Because of the lack of a specific regulatory framework for remediation activities, the form of the licence authorization stated within the licences that were issued does not correspond directly with activities to be authorized in each case.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: WS-R-3 §4.1 states “A national strategy shall be formulated to specify, prioritize and manage remediation situations, and to ensure that an adequate, legal and regulatory framework, supported where necessary by appropriate guidance material, is in place so that workers, the public and the environment are protected when remediation programs are undertaken ...”

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S8	<p><u>Suggestion:</u> The Australian Government should consider in any proposed future amendment to the ARPANSA legislation, an amendment to the regulatory framework to deal more explicitly with environmental chronic exposure situations and interventions not linked with accidental situations of controlled facilities.</p>

Objectives and Radiation Protection in Remediation Activities
WS-R-3 §2.1-2.3; §3.1-3.5

Both licences granted are facility licences under ARPANSA Act, however, the form of each authorization recognizes that the activities to be performed within the bounds of the given authorizations are to be considered interventions (as per ICRP 60 definition) and not activities within a regulated practice.

As a consequence of this, the clean up criteria for both the Maralinga project and the South Alligator Rivers rehabilitation project are established on a site specific basis in accordance with principles that apply to intervention situations, justification and optimization of the avertable annual dose to members of public.

Post-Remedial Activities
WS-R-3 §7.1-7.9

The remediated lands of the Maralinga project will be returned to the South Australian Government and in turn to the control of the traditional indigenous owners of the land, the Maralinga Tjarutja people, for their continued use and occupation. This restitution must contemplate the management of some residual risk on the site and some possible restrictions on the future use of parts of the site. Although decisions on the South Alligator Valley remediation project are not yet finalized, the same considerations will have to be taken into account.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<p>BASIS: WS-R-3 § 7.5 states: <i>“An appropriate program, including any necessary provision for monitoring and surveillance, shall be established to verify the long term effectiveness of the completed remedial measured for areas in which controls are required after remediation, and shall be continued until it is no longer necessary”</i></p>
(2)	<p>BASIS: WS-R-3 4.5 states: <i>“The legal framework shall provide the bases for establishing any restriction that may be placed upon the use of or access to the area before, during and, if necessary after remediation.”</i></p>
S9	<p><u>Suggestion:</u> ARPANSA should consider including a requirement for a formal long-term management plan for rehabilitated sites to be included in its licensing arrangements in the context of rehabilitated sites that may not to be released without restriction in the near future.</p>

4.1.5 AUTHORIZATION – RADIOACTIVE WASTE MANAGEMENT

ANSTO Waste Operations and Technology Development (WOTD)

As part of its regulatory activities, ARPANSA licenses and routinely inspects the facilities and activities of ANSTO's division for Waste Operations and Technology Development (WOTD). Radioactive wastes are produced from research reactor operations that include waste from MOATA, HIFAR, and OPAL. Also under ARPANSA's regulatory control are wastes generated by ANSTO Radiopharmaceuticals and Industrials (ARI). WOTD collects, treats and stores radioactive wastes generated by the activities of ANSTO facilities.

WOTD waste facilities consist of:

- Solid Waste facilities including storage of miscellaneous intermediate level solid waste, storage of drummed predominantly low level solid waste, storage of safeguarded and other nuclear material, storage of sealed sources, and gamma scanning facility to characterize the wastes;
- Liquid waste facilities including the effluent collection treatment systems, effluent treatment plant and storage of low and intermediate level liquid waste (excluding intermediate level waste from Mo-99 production) and storage of low level non-aqueous liquid waste;
- Waste Services operations including laundry and decontamination facility, analytical laboratory, processing of low level solid waste for radioactive waste repository (not yet decided), low level solid waste processing and interim storage, glass crushing and storage facility;
- Intermediate level liquid waste storage facility for receipt, storage and retrieval for processing of intermediate level liquid waste from Mo-99 production and solidification of intermediate level liquid waste from Mo-99 production.

Waste minimisation practices currently in place at ANSTO include segregation of wastes at the source (radioactive from non-radioactive) to reduce the potential for cross-contamination and to separate short-lived from long-lived waste, waste exemption process to allow for free-release of exempt level waste and the separation of short-lived from long-lived wastes to allow for decay and delay.

Authorized Limits for Aqueous and Airborne Discharges

WS-R-2 § 3.8, §5.8

The object of the ARPANS Act is "to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation." According to Standard Licence Condition 22 of the ANSTO Licence Conditions Handbook, the Licence Holder must provide a quarterly report to the CEO of ARPANSA that presents information on the activity of any radioactivity released to the environment during the quarter, reported against the authorized airborne and liquid effluent discharges for the controlled facility.

According to Schedule 3 Licence Conditions, Discharge Authorization means an authorization approved by the CEO which specifies the conditions and requirements which permit the planned and controlled release of radioactive material (gaseous) to the environment by a Licence Holder.

In the case of ANSTO’s operations, the establishment of authorized discharge limits for aqueous discharges is achieved through agreement with Sydney Water. The team understands that ARPANSA is asked to comment on the methods used to derive the aqueous discharge limits and the limits established. This arrangement may not be entirely satisfactory because it was understood that Sydney Water is no longer a regulatory body but now operates as a utility. Sydney Water has a memorandum of understanding with ANSTO whereby ANSTO reports aqueous discharges to Sydney Water with a copy to ARPANSA. However, there are no formal arrangements in place between ARPANSA and the organization(s) that regulates Sydney Water.

The team understands that the discharge limits in the agreement with Sydney Water are in accordance with international guidance, so this is not an immediate concern for safety. However, this is a complicated administrative arrangement for regulatory oversight of aqueous discharges from the ANSTO site. Also, this arrangement does not provide for strong regulatory oversight over the combined discharges from the ANSTO site.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: BSS Appendix III, § III.13(g) states: <i>”Registrants and licensees shall, if appropriate, verify the adequacy of the assumptions made for the prior assessment of radiological consequences of the discharges.”</i>
S10	Suggestion: ARPANSA should consider the establishment of a formal agreement with the State regulator of Sydney Water in order to facilitate more effective assurance of radiological safety of the public from all discharge pathways. ARPANSA should consider a more direct reporting mechanism for operators in relation to liquid discharges to the environment.

4.2 REVIEW AND ASSESSMENT

This section considers ARPANSA’s review and assessment processes using the requirements of GS-R-1 as the basis. The text references GS-R-1 as applicable.

GS-R-1 §5.7 – 5.8

The program of review and assessment conducted by ARPANSA was, in general, conducted in accordance with IAEA Safety Requirements.

ARPANSA has developed and utilized a number of documents during the review and assessment process. Many of these documents are closely related to the authorization/licensing process for new facilities as well as subsequent modifications to those facilities. As previously mentioned in Section 4.1 regarding Authorizations, Standard Operating Procedure RB-LA-SOP-2000, Licence Application Assessment, provides the process guidance for review and assessment of licence applications. Other pertinent documents utilized during the review include the ARPANSA Act, the Regulations, the Regulatory Assessment Principles (RB-STD-42-00) and the Guidelines for Review of Plans and Arrangements (RB-STD-15-03). These documents are all available to the licensee/applicant via the ARPANSA website. Depending on the nature of the submittal, other documents may be determined to be relevant and those would be utilized in the detailed review of the submitted information.

4.2.1 REVIEW AND ASSESSMENT - RESEARCH REACTORS

GS-R-1 §5.9 - 5.10

For research reactors, ARPANSA staff conducts detailed reviews of the submitted information utilizing the documents referenced above. If necessary, additional information is obtained from the applicant by a written request using the guidance contained in RB-LA-SOP-2000, Licence Application Request, or for less significant clarifications, the information may be obtained via e-mail or telephone. Expert advice not available within ARPANSA is utilized when necessary.

The major components of the programme for review and assessment are driven by receipt of requests from the licensee or applicant. Although the timing of receipt of these requests were outside the control of ARPANSA, major licensing submissions and requests for review of modifications under Regulation 51 were given a higher priority than routine reviews due to the potential impact of delay.

The Operating Licence for ANSTO regarding the OPAL facility contains a licence condition that the licensee must submit to the CEO of ARPANSA a periodic safety review that is a detailed re-examination of the safety of the OPAL reactor, and that the first such review must be completed no more than 2 years after completion of commissioning. The review team noted that the OPAL reactor was still undergoing hot commissioning at the time of this review, and that no programme has yet been established to identify the format, content, or methodology to conduct this required periodic safety review.

GS-R-1 §5.11

Regulation 51 is a licence condition that requires that the holder of a licence must seek the CEO's prior approval to make a relevant change that will have significant implications for safety. The licensee notifies ARPANSA of changes that they consider to have significant implications for safety and provides the safety case for ARPANSA to review. Guidance for review of submissions is contained in Procedure RB-STD-43-00, Regulatory Assessment Criteria for the Design of New Controlled Facilities and Modifications to Existing Facilities.

This document sets out the assessment criteria to be applied when assessing a request for approval for modification to a facility already authorized under a facility licence. Items 3.6 and 3.7 (Criteria 16-20) of this document provide guidance on how to categorize the hazards and determine the safety significance of a modification. In discussions with the ARPANSA staff, the determination of safety significance was based more on the experience and engineering judgement of the reviewer than on a systematic process for review of the specific criteria that might have been exceeded. The guidance does not define what constitutes "significant." While there is no evidence that a safety significance determination was not appropriate, the lack of clarity in what constitutes "significant implications for safety" may lead to regulatory inconsistency and inefficiency in dealings with the licensee, as well as negatively impact the licensee's resources. See Recommendation R2.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1 §5.10 states: " <i>The regulatory body shall prepare its own programme of review and assessment of the facilities and activities under scrutiny.</i> "
R3	<u>Recommendation:</u> ARPANSA should prepare regulatory guidance in relation to its expectation for the Periodic Safety Review imposed by condition on the facility authorizing the operation of the OPAL reactor.

4.2.2 REVIEW AND ASSESSMENT - SOURCES AND INDUSTRIAL PRACTICES

GS-R-1 §5.7

The process for assessing applications for a licence is described in the standard operating procedure “Licence Application Assessment” (RB-LA-SOP-2000). The standard operating procedure states, in section 6.3, that the “level of detail for the review should be commensurate with the hazards and risks associated with the controlled facility, controlled material or controlled apparatus and may take into account (such steps as a site visit, expert advice, legal advice and public submissions).

GS-R-1 §5.8

The principles for assessing a licence application for a controlled facility are described in “Regulatory Assessment Principles for Controlled Facilities” (RB-STD-42-00, Rev 1). The document addresses such fundamental principles as safety culture and defence in depth. The executive summary to RB-STD-42-00, Rev 1 states that the report “may assist operating organizations in the preparation of the safety analysis report that might accompany an application for a licence or other submission”. The introduction to the document adds that it “serves to inform the public about ARPANSA’s regulatory assessment process” (section 1.6).

GS-R-1 §5.9

There are clear procedures for receiving and reviewing a licence application. If, after receiving the application for a licence, additional information is needed from the applicant, the applicant has two weeks to provide the requested information. The two week time period is flexible depending upon the amount of additional information requested. From the time the application is judged acceptable (complete) by ARPANSA, the service standard for assessment is 60 days.

GS-R-1 §5.10

Licences are routinely reviewed, but the process is not documented. The process is oriented towards the revision of the format of the licence and the removal of time dependent conditions. A review of facility safety is also done at this point.

GS-R-1 §5.11

Any modification to a facility is controlled through the statutory licence condition regulation 51: “The holder of the licence must seek the CEO’s prior approval to make a relevant change that will have significant implications for safety.”

Review of Plans and Arrangements

The purpose of the document “Regulatory Guideline on Review of Plans and Arrangements” is to assist applicants to complete their licence application, to assist regulatory officers to assess licence applications and licence holders to review their plans and arrangements. The holder of a licence is required “at least once every twelve months, [to] review and update any plans and arrangements for managing the controlled facility, controlled material or controlled apparatus” to meet Regulation 50. Plans and arrangements are assessed at the time of the licence application (and any subsequent applications). Once the licence is issued, the licence holder must review plans and arrangements at least annually. Information about the review is reported to the CEO in the quarterly report.

4.2.3 REVIEW AND ASSESSMENT – DECOMMISSIONING

WS-R-2 §6.1-6.13, §7.2-7.5; WS-R-5

As a part of any application for a facility authorizing decommissioning, the CEO of ARPANSA requires a decommissioning plan and a specific safety case to be submitted for assessment. It is expected that the safety case and decommissioning plan should describe the process and arrangements for ensuring the safety of site personnel, the public and the environment.

ARPANSA regulatory assessors define their review and assessment of the documentation provided mostly in the “Regulatory Assessment Principles for Controlled Facilities RB-STD-42-00” (RAP’s) and in the “Regulatory Guidance for the Decommissioning of Controlled Facilities RB-STD-10-06” (draft Decommissioning Guide).

When reviewing the decommissioning safety analysis, a graded approach is accepted, in which the more serious the potential consequences are, according with a previous hazard categorization, the more onerous is the task of demonstrating that further protection is not reasonably practical. Any criteria that are relevant to the particular controlled facility and involve radiation dose limits are treated as mandatory.

Protection of Human Health and the Environment

WS-R-5 §2.1-2.5

Criteria concerning the protection of human health and the environment are taken into account during decommissioning activities, as this period is considered part of the original authorized practice and all radiation protection arrangements remain in force until the abandonment of the facility.

The operating organisation must develop, maintain and implement arrangements to ensure the radiation protection of employees and others, whether on site or elsewhere complying with the “National Standard for Limiting Occupational Exposure” required by Regulation 47. There are in force some others codes of practice prescribed in Regulation 48 or specifically by the licence, with Regulation 58 regarding prescribed practices, Regulation 59 regarding effective dose limits, and Regulation 62 regarding the annual equivalent dose limit.

It is required that the operating organisation’s radiation protection arrangements ensure that, for all decommissioning activities at the facility, effective radiation doses (including committed effective radiation doses) to persons do not exceed the established dose constraint. The ALARA principle should also be taken into consideration, so that (a) effective radiation doses, including committed effective radiation doses to persons; (b) the number of people who are exposed; and (c) the likelihood of incurring exposures to radiation, are kept as low as reasonably achievable, social and economic factors being taken into consideration.

Responsibilities associated with Decommissioning

WS-R-5 §3.1-3.8

The responsibilities associated with decommissioning are established through the requirement to obtain a separate facility licence authorizing the conduct of “decommissioning”. To obtain a licence the applicant must submit the information that may be requested for this licence authorization as set out in the regulations.

ARPANSA has not yet established radiological criteria for releasing sites after decommissioning controlled facilities, neither for a green field end point, releasing the site without any radiological use restriction, neither for the brown field end point, site restricted to a future industrial use. Although ANSTO has no intention to release any part of the site in the near future, the establishment of the end point radiological criteria would help in the design of the final decommissioning plan for HIFAR reactor.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: WS-R-5 §3.6 states “ <i>The responsibilities of the regulatory body include: Establishing safety and environmental criteria for the decommissioning of facilities, including criteria for clearance of materials during decommissioning and condition on the end state of decommissioning and on the removal of controls..</i> ”
R4	<u>Recommendation:</u> ARPANSA should publish guidelines that establish the stage at which a decommissioned facility may be released without any further radiological restriction and/or the continuing restrictions that may apply.

Decommissioning Strategy
WS-R-5 §4.1-4.8

As the ANSTO site consists of several facilities regulated by ARPANSA, some interdependences are taken into consideration in order to accept some common strategies for the facilities located in the site like a common radioactive waste management.

ARPANSA does not have a role in the formulation of the proponent’s licensing strategy for the decommissioning of the HIFAR reactor. ARPANSA’s role is to assess the proposal having regard to the statutory requirements of the ARPANS Act. Following the final shut down of the HIFAR reactor the operator of HIFAR, ANSTO, is applying for a facility licence authorizing it to “posses or control” the reactor during preparation for decommissioning, rather than proceeding to apply for a licence to decommission the reactor. The action of decommissioning is characterized as a nuclear action for the purposes of the EPBC Act and requires a separate approval under that Act.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: WS-R-5 §4.3 states: “ <i>The decommissioning strategy shall take into account that, until authorization has been given to implement the final decommissioning plan, the facility shall be considered an operating facility. All the applicable requirements for the facility shall then remain in place unless the regulatory body has agreed to their reduction on the basis of a reduction of the hazards (e.g. the removal of nuclear material from the facility).</i> ”
R5	<u>Recommendation:</u> ARPANSA should publish guidance that makes clear that once the reactor is shut down, the activities or operations that cannot be done using operational methods or within the bounds of the safety case for normal operation should be part of the planning for decommissioning of the reactor.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S11	<p><u>Suggestion:</u> ARPANSA should consider providing guidance to make clear what the licensing process is in the transition period between final shutdown and decommissioning for controlled facilities.</p>

Decommissioning Plan WS-R-5 §5.1-5.14

It is required that the operating organisation prepare and submit a decommissioning plan that ARPANSA uses to assess whether or not the decommissioning proposal provides reasonable assurance that decommissioning can be carried out safely.(D-1 checked; D-15 checked)

The decommissioning plan describes the proposed decommissioning strategy, the responsibility of the operating organisation during decommissioning, the proposed decommissioning activities, and arrangements for ensuring the safety of occupational personnel, the public and the environment.

The decommissioning plan is progressively updated by the operating organisation throughout the life of the facility and is included as a part of each licence application that is submitted to ARPANSA throughout the operating life of the facility. A graded approach decommissioning plan should be submitted prior to an application for a licence to operate. ARPANSA required ANSTO, in licence condition 4.12 for the OPAL reactor, to submit an initial decommissioning plan with the authorization to operate, in order to facilitate early planning for decommissioning and maintenance of important records for this objective (D-1 checked, D-15 checked).

**Funding
 WS-R-5 §6.1-6.5**

There is no explicit mechanism within either the legal or organisational framework of the regulatory body to ensure adequate financial resources are available to cover the costs of decommissioning and radioactive waste management including disposal. Financing the future decommissioning of governmental owned facilities regulated by ARPANSA is intended to be assured by the Australian Government.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<p>BASIS: WS-R-5 § 6.1 states: <i>“National legislation shall set out the responsibilities with respect to financial provisions for decommissioning. These provisions shall include establishing a mechanism to provide and ensure adequate financial resources for safe and timely decommissioning.”</i></p>
S12	<p><u>Suggestion:</u> The Australian Government should consider amending the ARPANS legislation to impose a requirement that decommissioning plans provide estimated budgets for decommissioning, including costs for the management of the resulting waste.</p>

Decommissioning Management
WS-R-5 §7.1-7.6

ARPANSA requires, in the draft regulatory guide for the decommissioning of controlled facilities, the operating organisation to ensure that conducts at the facility are for the approved purposes of decommissioning, and to develop, maintain and implement arrangements for the safe decommissioning of the facility in compliance with the relevant limits and conditions. The arrangements must provide a description of the organisation, including structures and lines of communication, delegations, responsibilities and authorities, functions, duties, and competencies required.

The decommissioning regulatory guide also requires the operating organisation to maintain design records, plant descriptions, design calculations, design reviews, specifications and drawings, as may be needed to maintain and safely decommission the facility.

Conduct of Decommissioning
WS-R-5 §8.1-8.8

After HIFAR reactor shutdown, ANSTO is applying for a facility licence authorizing it to “possess or control” authorization for the shutdown HIFAR reactor. ANSTO includes within this application the performance of some significant dismantling activities as part of preparation for decommissioning followed by period of 10 years of “safe enclosure” of the facility.

ANSTO licensing strategy for HIFAR is not consistent with criterion WS-R-5 8.2 that requires a final decommissioning plan to be submitted for approval within 2 years after the final shutdown (unless an alternative schedule for the submission of the final decommissioning plan is specifically authorized by the regulatory body). This is so that any deferred period after shutdown should be contemplated in the context of an authorized decommissioning plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: WS-R-5 §8.2 states: “... <i>If a facility is shut down and no longer use for its intended purpose, a final decommissioning plan shall be submitted for approval with two years of the cessation of the authorized activities, unless an alternative schedule for the submission of the final decommissioning plan is specifically authorized by the regulatory body.....</i> ”
R6	Recommendation: The Australian Government should introduce an amendment to the ARPANS legislation to require a timely submittal of a decommissioning plan by an operator. If a Possess or Control authorization is to be granted to ANSTO after the HIFAR reactor shutdown, ARPANSA should limit the period of such an authorization with an expiry date and require the submission of a final decommissioning plan for the reactor.

RAP 12 deals with conservative proven design and engineering practices. Technologies incorporated in the design are proven technologies, developed though; innovation, laboratory scale demonstration, operating prototypes, and use in other facilities.

The draft ARPANSA decommissioning guide establishes that operating organization must develop, maintain and implement arrangements for the safe treatment, storage and disposal of radioactive wastes within or from the facility. These arrangements must include consideration of the following:

- amount, category and nature of the waste that will be generated during decommissioning;
- possibilities for removal of the waste from regulatory control;
- possibilities for the reuse and recycling of materials, equipment and premises;
- generation of secondary waste in the decommissioning process and its minimisation to the extent practicable;
- presence of non-radiological hazards (e.g. asbestos);
- availability of waste recycling or treatment plants, storage facilities and disposal sites;
- any special requirements for the packaging and transportation of radioactive waste (e.g. activated materials);
- traceability of the origin and nature of the wastes arising from the decommissioning process; and
- the potential impact of the wastes on the workers, the public and the environment.

The decommissioning guide establishes that the operating organisation must develop, maintain and implement arrangements dealing with:

- the effects of incident and accidents or other emergencies arising from dismantling activities;
- a suitable training and periodic retraining of all personnel who have responsibility for any decommissioning activities that may affect safety;
- implementation of a quality system covering all activities associated with the decommissioning of the facility, which may have an influence on its safe decommissioning.

Completion of Decommissioning **WS-R-5 §9.1-9.6**

On completion of decommissioning ARPANSA is requiring the licence holder or applicant of an ultimate disposal or transfer of the facility to demonstrate compliance with “Regulatory Guidelines on Review of Plans and Arrangements RB-STD-15-03” and the draft Decommissioning Guide.

Post-decommissioning activities include a post-decommissioning radiological characterisation survey and a comparison of those results with the results of an earlier (pre-decommissioning), baseline radiological characterisation survey which should demonstrate that the decommissioned facility is in a safe state.

The post-decommissioning documentation should show, as far as possible, that all radioactive materials present at the beginning of decommissioning are accounted for and their ultimate destination is confirmed.

4.2.4 REVIEW AND ASSESSMENT - RADIOACTIVE WASTE MANAGEMENT **WS-R-1 §5.7-11**

The plans and arrangements for effective control, safety management, radiation protection, waste management, ultimate disposal, transfer, security and emergency arrangements are part of each licence application. ARPANSA is preparing a Code of Practice on Predisposal Management of Radioactive Waste (draft in preparation). Among other things, this document is intended for use during the licensing process for waste management facilities as contemplated in the national strategy for radioactive waste management.

Guidance on the review of the plans and arrangements for the management of radioactive waste include overall waste management, limiting radiation exposure to workers and members of the public, waste packaging, interim storage and discharges has also been issued to ARPANSA staff undertaking the reviews and assessments for approval of the application. This guideline document is issued as Regulatory Assessment Principles (RAPs RB-STD-42-00 Rev 1) for controlled facilities emphasis the ALARA principle and the requirement to meet radiation protection limits. This document will be used by ARPANSA staff involved in the licensing for waste disposal facilities. In December 2006, ARPANSA issued Regulatory Guidance For Radioactive Waste Management Facilities: Near Surface Disposal Facilities; And Storage Facilities. This Guidance is directed particularly at the assessment of the proposed Commonwealth Radioactive Waste Management Facility.

4.3 INSPECTION AND ENFORCEMENT GS-R-1-1 §5.12, 5.13

A function of the CEO of ARPANSA is to monitor compliance with Division 1 of Part 5 of the ARPANSA Act. To assist the CEO to carry out this function, inspectors are appointed by the CEO under Section 7 of the Act. The ARPANSA Inspection Policy is identified and described in RB-INS-MAN-1000, Regulatory Inspection Policy. Also included in the policy are the requirements and competencies for inspectors, expectations regarding personal conduct, and a training and skills development program (non-mandatory).

The Inspection Policy references Procedure RP-INS-SOP-1000 v3, Regulatory Inspection Procedure, for the development of the overall inspection plan/programme to be conducted regarding licence holders, as well as providing guidance to the inspectors on the preparation and conduct of individual inspections. The team determined that no unannounced inspections were conducted as part of the inspection programme.

Specific observations related to ARPANSA inspection activities associated with licence holders regulated by ARPANSA are described below.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1 §5.14 states: “ <i>regarding establishment of an inspection programme: “The regulatory body shall establish a planned and systematic inspection programme.”</i> ”
(2)	BASIS: GS-R-1 §5.15 states: “ <i>”regarding the different types of inspections: “Inspections by the regulatory body, both announced and unannounced, shall be a continuing activity.”</i> ”
R7	<u>Recommendation:</u> ARPANSA should incorporate into its internal guidance a requirement to include unannounced inspections in its compliance program for all licensees.

4.3.1 INSPECTION – RESEARCH REACTORS GS-R-1 §5.14

Nuclear installations subject to inspection include one operating research reactor (OPAL) and two shut down research reactors (both de-fuelled). The inspection and enforcement programme ensures that facilities, equipment, and work performance meet all necessary requirements; that relevant documents and instructions are being complied with; persons employed by the operator are

appropriately trained and qualified; non-compliances with operating authorizations are complied with within a reasonable time frame; and the operator is managing safety in a proper and responsible manner. The inspection programme currently includes only announced and reactive inspections. ARPANSA has no minimum inspection requirement formally established for the research reactors. However, by CEO direction, it is expected that each facility will receive at least one inspection per year. For the operating reactor, the current inspection programme is established on the basis of one announced inspection a month, and for the shut down reactors, the programme is a minimum of one inspection a year related to the respective risks associated with these facilities. Inspections are conducted to verify that the operator is in compliance with conditions established in the licence. The activities of suppliers and contractors are monitored by observations of ongoing activities and the operator is held responsible for the quality of the material, components, and services provided by the contractor. Enforcement actions were somewhat informal for lesser significant non-compliances, although the ARPANS Act provides clearer authority for sanctions if necessary.

The ARPANSA Regulatory Inspection Policy (RB-INS-MAN-1000 version 2 October 2004), does not appear to be consistently applied to develop a planned and systematic inspection programme. Each inspection team inside ARPANSA develops its own programme (without necessarily using the guidance in the written directives but taking into account the feedback of preceding inspections). For nuclear facilities, the amount of inspection (number of inspections) conducted is determined by the potential hazards associated with the type of facility as well as the operating and regulatory history of the facility. Although there is no programmatic minimum number of inspections required, a minimum of one inspection per year is expected by the CEO. However, the current inspection plan developed by the Reactor Safety Section is targeting one inspection per month at the operating reactor. Also, there does not appear to be a systematic periodic assessment of the inspection programme to determine if the programme needs to be modified utilizing lessons learned from previous inspections. Given the limited inspection staff, the majority of the staff's time has been occupied with the review, assessment, and inspection associated with the licensing and commissioning of the OPAL reactor. The scope of review and inspection associated with oversight of the licensing and commissioning of the OPAL reactor ensured that most areas important to safety have been inspected. A review of the list of inspections conducted concluded that a wide range of topics important to safety had been inspected. The head of the Reactor Safety Section indicated that following commissioning, his plan is to arrange an inspection programme utilizing the functional organization and plans and arrangements of the licensee as a guide to ensure that all regulated areas are continually inspected.

GS-R-1 §5.15

The ARPANS Act, section 35 (3) states that a facility licensee must allow the CEO, or person authorized by the CEO, access to the facility to verify compliance with regulatory requirements (paraphrased). Section 63 of the Act states that an inspector is not authorized to enter the premise of a facility unless the occupier of the premise has consented to the entry. This would appear to somewhat contradict the authority stated in Section 35. ARPANSA conducts only announced inspections on a routine basis, although the inspectors have the authority to enter a facility at any time (for reactors). A resident inspector programme is not utilized. For announced inspections, the operator is typically notified of the general inspection subject matter or topic every six months. A more detailed schedule for each specific inspection is sent to the licensee at least two weeks before the inspection and includes the purpose, scope and proposed timetable of the inspection. No unannounced inspection had been performed on nuclear installations in the recent past and no inspection was conducted during night shifts and on weekends. Current inspections are conducted on weekdays by two ARPANSA inspectors and typically last one day. Consultants are not used for inspection. Expert advice is obtained where the needed expertise does not reside within the

ARPANSA staff, but the responsibility for regulatory decisions based on this information clearly remains with ARPANSA.

GS-R-1 §5.16

In addition to announced inspections, ARPANSA inspectors also conduct reactive inspections when they determine that facility conditions warrant immediate investigation.

GS-R-1 §5.17

Inspection findings are communicated during an exit meeting before the inspectors leave the site following an inspection. This preliminary information is followed by a draft inspection report sent to the operator. Taking into account the comments of the operator and justifying those not included, the final inspection report is sent to the operator. Inspection findings that are potential non-compliances are not identified to the licensee as potential non-compliances until after they have responded in writing to the facts of the issue described in the exit meeting and the draft inspection report.

The inspection is not organised in such a way to provide a synthesis of the inspection findings and a categorization of issues regarding non-compliances and other issues requiring corrective actions, requests for additional information and observations. As noted in a good practice observed during the IRRS mission to France, it would be useful that ARPANSA reviews its inspection reports or associated letter format in order to provide a synthesis of the inspection and a categorization of issues regarding non-compliances and other issues requiring corrective actions, requests for additional information and observations.

The inspection procedure (RB-INS-SOP-1000 version 3, December 2006) directs that following an inspection the inspection team will hold a team meeting to discuss lessons learned and make a file note of any future actions for the benefit of other inspectors. The documentation associated with each inspection is maintained in a binder in the inspector area of the ARPANSA office.

OPAL inspection:

During the IRRS mission, two IRRS team members accompanied two ARPANSA inspectors during an inspection of the OPAL reactor. Based on the observations made during this visit, the inspection was well prepared, it was well structured and professionally conducted, and it covered the requisite items in GS-R-1 5.13 and 5.17.

Prior to the inspection, the lead inspector prepared a file note defining the main objectives (coverage of OPAL Plans and Arrangements with regard to maintenance and to ensure that the Licence Holder is complying with these), the potential subjects and the proposed plan of the inspection. The preparation for the inspection was quite thorough and detailed. The items to be inspected were well identified. The previous inspection items that were being reviewed were well referenced.

The format of the inspection observed was: an initial meeting with the reactor manager and 3 ANSTO employees, mainly responsible for maintenance, in order to precisely identify the subjects of the inspection. Afterwards, the inspectors met with licensee staff in the maintenance building to review documents and ask questions regarding the topics scheduled in the file note. At this meeting the regulatory requirements associated with the ARPANSA authorization of the facility were scrutinized and discussed. The meeting was followed by an inspection of the facility itself. After a

short meeting between the inspectors to finalize observations and determine strategy, an exit meeting was then conducted with the licensee and the inspectors' findings, deviations and deficiencies were presented together with requests for correction.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1 §5.17 states, regarding the feedback: <i>“Regulatory inspectors shall be required to prepare reports of their inspection activities and finding, which shall be fed back into the regulatory process.”</i>
S13	Suggestion: ARPANSA should consider a systematic periodic assessment of the inspection programme to evaluate its continued effectiveness, using feedback and lessons learned from previous inspections.
S14	Suggestion: ARPANSA should consider an appropriate mechanism be included in its inspection procedures to ensure that there is a synthesis of issues from all compliance activities (inspections and reviews) in its correspondence with holders in order to improve the understanding of holders of the key issues that arose out of inspection activities.

4.3.2 INSPECTION – SOURCES AND INDUSTRIAL PRACTICES

GS-R-1 §5.12

In principle, all areas are covered. In practice, some of the lower risk activities have not been inspected since they were licensed. The risk ranking of a licence can be modified after an inspection. It is clearly explained in inspection procedures that the purpose of the inspection is to check compliance with regulations and licence conditions.

GS-R-1 §5.13

The procedures for preparing, conducting and reporting on inspections are well established and followed as regulatory inspection procedure RB-COM-SOP-1000 v3 that was issued in February of 2007. IRRS team members observed that inspections conformed to the purposes described above.

Inspections did not appear to diminish the prime responsibility of operators, but encouraged them to improve their safety management.

GS-R-1 §5.14

The inspection program planning is described in “Guidance on Developing and Maintaining the Regulatory Branch Inspection Schedule (RB-INS-SUP-0500) and the annual inspection schedule is documented on a proforma titled “Planned Inspection Schedule for Licence Holders” (RB-INS-FORM-500B).

A document titled “Inspection Schedule” is attached to the Regulatory Inspection Procedure (RP-INS-SOP-1000 v3, Dec 2006). The document describes, among other things, the guidelines for the development and maintenance of the inspection schedule.

The IRRS Team members were shown a six-month rolling inspection plan, but it had not been maintained since 2005 when the risk-ranking matrix described below was brought into use.

GS-R-1 §5.15

There are no unannounced inspections, only planned and reactive inspections. Inspection is a continuous activity, with about 10 inspections per year per inspector. Consultants are not involved in inspections.

ARPANSA's self-assessment questionnaire indicates that a file on "lessons learned" is kept to record inspection outcomes. Regulatory Inspection Procedure (RP-INS-SOP-1000 v3, Dec 2006), states in section 5.15 that the inspector should "make a file note of any future actions for the benefit of inspectors.

Scope of inspection and enforcement and the inspection programme

The ARPANSA website presents the ARPANSA corporate plan, part 4 of which specifies the priorities for 2005 – 2008. One of these priorities is "to undertake a program of inspections to be determined each year on a basis of risk."

A risk-ranking matrix is used to stratify all licensees into risk levels in order to determine priorities for inspections for all facilities and source licensees. The matrix was developed several years ago and a member of ARPANSA staff has been tasked with refining the risk matrix to better reflect inspection priorities. The licensees posing the highest risk have all been inspected.

Frequencies for inspections have been set by the CEO at once per year per facility and at once per three years per source licence.

The conduct of inspections of industrial and research practices

GS-R-1 §5.13

IRRS team members observed two inspections: an inspection of an industrial pool-type irradiator facility (GATRI) at the ANSTO site in Sydney and an inspection of a calibration facility, the "Teletherapy Laboratory", in Melbourne. In each case, two ARPANSA inspectors performed the inspection and two IRRS team members accompanied them.

In neither inspection did the inspectors take their own survey meters. Inspectors conducted radiation dose rate measurements using licensee instrumentation.

Inspectors who visited GATRI described their inspection as a "desktop audit and walkthrough".

In both cases, the inspectors followed the ARPANSA Inspection Procedure. The inspections were thorough and comprehensive. Inspectors concluded with a summary of their findings.

Inspectors noted that the maintenance manual for the GATRI facility was under review at the last inspection (Dec 2005), but still has not been finalized. Licensee representatives stated that the review is largely to do with formatting, not content. There was no substantive reason given for the delay, other than it is a lengthy document. Inspectors thought that the delay had no implications for safety. The inspection report will recommend that the manual be completed as soon as possible with the CEO to be advised.

Inspectors opened and closed the inspection at GATRI using the ARPANSA script for inspections and promised to send an inspection report within 21 days.

The Teletherapy Laboratory inspection in Melbourne was also conducted according to ARPANSA's procedures. Inspectors did not bring portable gamma radiation survey meters. IRRS team members noted that a survey meter is one of the items on the Inspector's Preparation Checklist under "Day Before" items.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: BSS § 2.38 states in part <i>"Monitoring and measurements shall be conducted of the parameters necessary for verification of compliance with the requirements of the Standards."</i>
R8	<u>Recommendation:</u> ARPANSA inspectors should always carry an appropriate hand-held radiation monitor to enable them to perform an independent verification of licensee measurements while conducting inspections.
(1)	BASIS: GS-R-1§4.10 states: <i>"Mutual understanding and respect between the regulatory body and the operator and a frank, open and yet formal relationship, shall be fostered."</i>
G6	<u>Good Practice:</u> In the observed source, waste and decommissioning inspections, ARPANSA staff closed the inspection by asking the licensees for feedback about the conduct of the inspection. This is good practice.

Reports of inspections of industrial and research practices GS-R-1 §5.17

Inspection reports were prepared by ARPANSA inspectors to a 30-day reporting standard. Reports were prepared in accordance with ARPANSA standard procedures.

4.3.3 INSPECTION – DECOMMISSIONING GS-R-1 §5.14-5.15, §5.17-5.18; WS-R-2 §6.1-6.13

Only the MOATA reactor is currently being decommissioned. The reactor is in a stand by situation waiting for final dismantling.

The inspection programme for nuclear installations under decommissioning does not differ from the regime for other nuclear installations and consists of the minimum of one inspection per year. Further inspections are supposed to be undertaken in future during active decommissioning, associated with regulatory "hold points." The planned inspections are systematic and the licensee is informed before hand and given information as to the areas that the inspection will focus on.

4.3.4 INSPECTION – RADIOACTIVE WASTE MANAGEMENT GS-R-1 § 5.12-5.24; GS-G-1.3

IRRS team members accompanied ARPANSA inspectors as they carried out a planned inspection of ANSTO's waste management facilities. For carrying out its inspections, ARPANSA followed the standard operating procedure RP-INS-SOP-1000 v3 (2006). Current practice is to perform one planned inspection per year of ANSTO's waste management facilities.

There were two instances during the inspection when the IRRS team felt that ARPANSA inspectors could have been more assertive with the licensee:

- in pursuit of training records for external contractors employed by the licensee. The particular instance involved external contractors who performed tasks that were part of a work package to upgrade a facility active ventilation system.
- in identifying that the licensee specified minimum staffing levels in some work procedures.

Long discussions took place between ARPANSA and the licensee over these issues but the outcome, in particular for item 2, did not appear to be conclusive. In both instances, ARPANSA’s inspection approach in dialog with the licensees could have been more assertive (the inspectors tended to take a suggestive posture). The fact that both are agencies of the Government of Australia may influence the nature of the relationship between ARPANSA and the licensee.

ARPANSA does not have an organization wide feedback mechanism for sharing of experience from inspections—presently, feedback occurs by informal means.

ARPANSA’s inspections vary in scope and frequency according to the relative hazard of the authorized activities. For example, there does not appear to be a documented basis for frequency of inspection of ANSTO’s waste management facilities. There is a practice that nuclear installations of F1 hazard category are inspected once a year, and reactive inspections are carried out when the need arises.

ARPANSA should ensure that licence holders demonstrate that contractors are appropriately trained and properly supervised in the conduct of their work.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE	
(1)	BASIS: GS-R-1 § 5.17 states: <i>“Regulatory inspectors shall be required to prepare reports of their inspection activities and findings, which shall be fed back into the regulatory process.”</i>
S15	Suggestion: ARPANSA should consider implementing an appropriate mechanism to ensure the timely dissemination of internal feedback gained from inspections to the rest of the staff engaged in inspections.

4.4 ENFORCEMENT

GS-R-1 §5.18

The ARPANSA Regulatory Compliance Policy, requirements for compliance and the associated enforcement actions are applicable to all ARPANSA issued licence holders.

A function of the CEO of ARPANSA is to monitor compliance with Division 1 of Part 5 of the ARPANSA Act. Part 5, Division 3 of the ARPANSA Act dictates a range of enforcement actions that ARPANSA, through the CEO, can take with regard to controlled persons under various circumstances. ARPANSA’s Regulatory Compliance Policy, RB-COM-MAN-0500, was issued in December 2006. Under this policy, ARPANSA’s regulatory compliance program includes promotion, verification, and enforcement activities. The specific ARPANSA policies on promotion and enforcement are currently under development. The Compliance Policy states that the enforcement policy will propose a graduated approach to enforcement.

Licenses and inspectors identify non-compliance as part of their inspections and routine activities. The inspectors and licenses review non-compliances to determine the regulatory or safety significance of the non-compliance. Licenses are required to prevent, investigate and rectify potential breaches of licence conditions under Regulations 44 and 45. The licensee is also required to report non-compliances, including potential breaches, in their required quarterly reports to ARPANSA. However, there is no specific guidance or definition as to what level of non-compliance constitutes a breach. Once the inspectors become aware of non-compliances through inspection or notification, and the significance of the non-compliance is determined, a description of the non-compliance and its significance is submitted to the CEO who may make a determination that the licensee was in breach of the licence. If the licensee has taken appropriate corrective actions, or has proposed acceptable corrective actions, then the issue is considered resolved from an enforcement perspective. The corrective actions will be reviewed during a future inspection activity. If the corrective actions are not acceptable, then more correspondence may be necessary to achieve satisfactory corrective actions from the licensee. If the licensee continues to fail to implement adequate corrective actions, then the CEO may still determine that the licensee is in breach and take more significant enforcement actions. Any actions taken prior to determination of a breach are not considered enforcement actions. Inspectors have the authority to discuss non-compliances with the licenses and if they are satisfied that the licensee is taking adequate corrections and the issue is not safety significant, then no further action is taken.

ARPANSA considers only the actions taken in accordance with Part 5, Division 3 of the Act to be formal enforcement actions. Those actions include the giving directions to controlled persons; amending, suspending or cancelling the licence; applying for an injunction; or forfeiture.

GS-R-1 §5.18-19

Section 30 of the Act requires that the holder of a facility licence, and a person covered by a facility licence, must comply with the conditions of the licence. This obviously implies that if a licensee finds itself not in compliance with a licence condition that they must return to compliance with the licence conditions or be in breach. Regulations 44 and 45 require that licenses must prevent, investigate and rectify breaches of licence conditions. Regulations 44 and 45 do not specifically extend to non-compliances that do not reach the “breach” threshold (as determined by the CEO). However, Regulation 49, “Compliance with plans for managing safety,” requires that the licence holder must ensure that all activities related to controlled facilities comply with the plans and arrangements for managing safety of the facility mentioned in the licence application. Included in the plans and arrangements are the licensee’s plans for maintaining compliance. Inspection reports and informal practices such as discussions with the licensee provide other means of encouraging licenses to correct non-compliances. Corrective actions are reviewed as part of the inspection program (inspection preparations in Standard Operating Procedure RB-INS-SOP-1000, Inspection Procedure). For minor (which is not defined) non-compliances, the licensee is only subsequently notified if the corrective actions are not completed. This notification is typically completed via email. A written letter is not typically initiated to address non-compliances that are determined to be of minor safety significance.

GS-R-1 §5.20-21

For situations deemed to be serious and considered to pose an imminent radiological hazard, ARPANSA has the authority, under Sections 36 and 38 of the Act, to amend, suspend, or cancel a licence. Additionally, Section 41 gives the CEO the authority to exercise powers as necessary to protect the health and safety of people or to avoid damage to the environment. Inspectors have the authority under Part 7 of the act to take actions to the extent that it is necessary for the purpose of

avoiding an imminent risk of death, serious illness, serious injury or serious damage to the environment.

GS-R-1 §5.22

Enforcement decisions under Section 41 of the Act provide that the CEO may provide written directions to a controlled person. Lower level regulatory decisions regarding non-compliances may or may not be provided to the licensee in writing depending on the significance of the non-compliance. Written notification may be via inspection report, or if the determination is made that a breach of licence conditions occurred, then a letter may be initiated from the CEO.

GS-R-1 §5.23

ARPANSA has established the authority of the inspectors to take on-the-spot enforcement action as described in Part 7 (Powers of Inspection etc.) of the Act.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1 §5.18 states: <i>“Enforcement actions are designed to respond to non-compliance with specified conditions and requirements.”</i>
S16	Suggestion: ARPANSA should consider the most effective means of finalizing a comprehensive compliance strategy (incorporating its enforcement policy) that clearly identifies or defines the levels of non-compliance (for example, what constitutes a minor non-compliance or breach) and the appropriate response (whether enforcement or other actions) available to the regulatory body to address each.

4.5 REGULATIONS AND GUIDES

This section considers regulations and guides for research reactors, industrial and research practices and waste facilities using the requirements of GS-R-1 as the basis. The text references GS-R-1 as applicable.

GS-R-1-1 §5.25-28

The Australian Radiation Protection and Nuclear Safety Act 1998, Section 85, establishes that the Governor-General may make regulations required or permitted by the Act, or necessary or convenient to be prescribed for carrying out the Act. Included in Section 85 are a number of functions that the regulations may provide. In practice, proposed regulations are drafted by knowledgeable personnel and submitted through the Health and Ageing Minister to the Governor General. The Governor-General signs the applicable regulations which then lie before Parliament for 15 days. During the 15-day period either house of Parliament may disallow the regulation. If the regulation is not disallowed, then it becomes law.

The current body of Regulations is the Australian Radiation Protection and Nuclear Safety Regulations 1999.

Within the Act, Section 15 states that one of the functions of the CEO is to “promote uniformity of radiation protection and nuclear safety policy and practices across jurisdictions of the Commonwealth, the States and the Territories.” This functional requirement provides the basis for the development or endorsement and implementation of codes and standards under the Act. Regulation 48 requires that certain licence holders must ensure that all conduct and dealings with controlled materials, controlled apparatus and controlled facilities are in accordance with a specified list of Recommendations and Codes of Practice.

Industry Codes or Standards have not been specifically incorporated into the regulations and are implemented as conditions to a specific licence. Any specific Code or Standard must be approved in a specific authorization or as part of an overall licensing action where the Code or Standard was included within the Plans and Arrangements submitted for review as part of the licence application.

4.5.1 REGULATIONS AND GUIDES - RESEARCH REACTORS

A number of regulatory guidance documents related to research reactors have been generated to provide guidance both to the regulatory staff as well as to the licensees/applicants. Some of these documents predate ARPANSA and the staff recognizes that review and updating of the guidance documents would be helpful. The guidance document development is initiated when ARPANSA management determines that guidance would be appropriate. Not all regulations have associated guidance documents. The guidance documents reviewed apply to controlled facilities. According to the ARPANSA staff, the main purpose for the guidance documents is to address nuclear science and engineering matters relevant to the information the CEO is required to take into account when assessing licence applications, and are used primarily by ARPANSA assessors. An additional purpose is to inform and assist the operating organization in preparing applications and submissions, and to inform the public of ARPANSA's regulatory assessment process. ARPANSA's approach has been to minimize the number of regulatory guidance documents by issuing only one document for each principal stage in the life of a controlled facility (e.g. Regulatory Assessment Criteria for the Design of New Controlled Facilities and Modifications to Existing Facilities), unless there was a special need for a separate document.

ARPANSA does not have a formalized internal program or process for the development of regulatory guidance. Determination of the need to initiate a regulatory guide is made by ARPANSA management. Once the determination is made that a regulatory guidance document should be initiated, the task is assigned to members of ARPANSA staff. The staff interviewed indicated that in addition to previous ARPANSA regulatory practices, they would review international guidance to ensure that the latest information was utilized. Once the document is drafted, it is up to the CEO, under Section 26 of the Act, to determine whether the guidance document is to be reviewed by the Nuclear Safety Committee (some were reviewed by the Nuclear Safety Committee and some were not). The CEO also makes the determination as to whether the guidance document will be made available for public review and comment.

ARPANSA does not maintain a comprehensive, readily available list of regulatory guidance documents. When asked for a list of regulatory guidance documents available, the staff replied that there was no central location or repository for regulatory guidance and that they would have to generate a list or locate which guides had been created. On the ARPANSA public website, the section that was labelled as Regulatory Guidance did not list the major guidance documents utilized in the OPAL reactor review. ARPANSA does not appear to have a policy regarding which regulatory guides are public documents and which may not be accessible to the public. There is no formal program in place for periodic review and updating of regulatory guidance to ensure that international best practices are taken into account.

4.5.2 REGULATIONS AND GUIDES – SOURCES AND INDUSTRIAL PRACTICES

GS-R-1 §5.25 – 5.28

The ARPANSA regulations were promulgated in 1999. The regulations have been amended since 1999 to address such matters as the revision of the amount of application fees and the clarification of provisions related to prescribed activity levels for nuclear waste storage and disposal facilities.

ARPANSA maintains a file of proposed recommendations for changes to the regulations. The IRRS team members reviewed a list of these proposed regulatory changes dated October, 2005 from file # S2004/00796.

The National Directory for Radiation Protection - Edition 1.0 was published in August 2004 for the purpose of the harmonization of radiation protection across Australia's states and territories. ARPANSA has followed the publication of Edition 1.0 by such additional actions as the provision of regulatory guidance about reporting accidents. ARPANSA will revoke the current user disposal code following the publication of edition 2.0 of the National Directory for Radiation Protection.

GS-R-1 §5.26

As described in GS-R-1, the ARPANSA regulations establish the broad requirements. The licences specify the more detailed conditions and requirements.

GS-R-1 §5.27

Numerous guides pertaining to the regulation of sources and industrial practices have been published and others are being developed. The regulations and guides generally cover the nature and extent of the facilities and activities regulated.

Most of the regulatory guidance is contained in codes of practice and safety guides in the Radiation Protection Series. Examples of documents relevant to the regulation of sources, facilities and activities are:

- “Safe Use of Fixed Radiation Gauges”, Radiation Protection Series No. 13, (Code of Practice and Safety Guide), January, 2007
- “Security of Radioactive Sources”, Radiation Protection Series No. 11, (Code of Practice), January, 2007
- “Recommendations for Limiting Exposure to Ionizing Radiation” (1995) and National Standard for Limiting Occupational Exposure to Ionizing Radiation (2002)
- “Portable Density/Moisture Gauges Containing Radioactive Sources”, Radiation Protection Series No. 5, (Code of Practice and Safety Guide), May, 2004.
- “Code of Practice for safe use of sealed radioactive sources in borehole logging (1989), Radiation Health Series # 28
- “Code of Practice for the safe use of industrial radiography equipment” (1989)
- “Code of Practice for the design and operation of non-medical irradiation facilities” (1988)

The codes of practice specify that they are prescriptive and may be referenced by regulations or conditions of a licence and that they contain practice specific requirements that must be satisfied to ensure an acceptable level of safety and security.

The safety guides provide practice specific guidance about how to achieve the requirements set out in Radiation Protection Standards and Codes of Practice.

Numerous additional Codes of Practice, standards and guides are in development. A list of fourteen of these is described in “Status and projected publication dates for Radiation Protection Series, June 2007” which is agenda item for the Radiation Health Committee meeting of July 18-19, 2007.

The Code of Practice on the Security of Radioactive Sources (January, 2007) has not yet been implemented.

Ad hoc regulatory guidance is also issued, for example, the April 2005 “Interim statement on the use of sealed sources beyond their recommended working life”.

4.5.3 REGULATIONS AND GUIDES – DECOMMISSIONING

GS-R-1 5.25, 5.27; WS-R-1; WSR-2; WS-R-3; WS-R-5

There are a number of recommendations, safety guides and other forms of non-mandatory guidance developed by ARPANSA to assist licence holders comply with the authorization issued to them. A number of others are currently under development.

An example of an important regulatory guidance document is the Regulatory Guidance for the Decommissioning of Controlled Facilities under the Australian Radiation Protection and Nuclear Safety Act 1998, RB-STD-10-06 Rev 0, March 2007. This guide, which currently is in draft form, is a comprehensive collection of valid legal requirements and recommendations for the full process of decommissioning controlled facilities. It will assist the applicant in preparing application and will serve to inform the public of ARPANSA’s assessment process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1 §5.27 states: <i>“Guides, of a non-mandatory nature, on how to comply with the regulations shall be prepared, as necessary. These guides may also provide information on data and methods to be used in assessing the adequacy of the design and on analyses and documentation to be submitted to the regulatory body by the operator.”</i>
S17	Suggestion: ARPANSA should consider the most effective means of finalising RB-STD-10-06, Regulatory Guidance for the Decommissioning of Controlled Facilities under the Australian Radiation Protection and Nuclear Safety Act 1998, and publish it as soon as possible.
(1)	BASIS: GS-G-1.4 §3.12 states in part <i>“...At a later stage detail regulation and guides should be developed to cover aspects such as the conduct of operations, training of staff, reporting requirements and emergency preparedness...”</i>
G7	Good Practice: RB-STD-10-06, Regulatory Guidance for the Decommissioning of Controlled Facilities under the Australian Radiation Protection and Nuclear Safety Act 1998, although not yet finalized and endorsed by the CEO of ARPANSA, represents a good practice because it provides a comprehensive collection of requirements and recommendations for the full process of decommissioning of nuclear facilities.

4.5.4 REGULATIONS AND GUIDES – RADIOACTIVE WASTE MANAGEMENT

In the area of radioactive waste management, ARPANSA has prepared a number of regulatory documents for licensees. In these documents, which have been drafted in support of ARPANSA’s licensing activities, there is some intermingling of requirements, guidance and material of a policy nature. For example, Regulatory Guidance for Radioactive Waste Management Facilities: Near Surface Disposal Facilities; and Storage Facilities (December 2006) covers material from national regulations, an international convention, and detailed guidance material from IAEA publications (e.g., on waste package acceptance requirements). However, it appears to be largely a policy document for regulatory decision making. In the area of radioactive waste management, licensees would probably benefit from a better structuring of regulatory documents. The regulatory document series directed towards national uniformity appears to be well structured.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	 BASIS: GS-R-1, §5.27 states: <i>“Guides, of a non-mandatory nature, on how to comply with the regulations shall be prepared, as necessary.”</i>
S18	 Suggestion: ARPANSA should consider the most effective means of developing its regulatory guidance to ensure that it includes an appropriate review and approval process including consideration of involvement by advisory committees and the public; a method for determining accessibility of the guidance document to stakeholders, including the public; and a method for periodic review of the guidance document to ensure that it provides current regulatory information and current best international practices.

5. SAFETY AND SECURITY OF RADIOACTIVE SOURCES

Australia is in the process of implementing the guidance of the IAEA Code of Conduct on the Safety and Security of Radioactive Sources (the Code). Australia committed to implement the Code in a letter to the IAEA dated May 2004.

ARPANSA plays a major role in the implementation of the Code, in its own jurisdiction and at the national level. This section of the IRRS report reviews the highlights of the implementation work that ARPANSA has already commenced, in cooperation with other Australian agencies. The discussion also identifies some key programs and points to matters that ARPANSA will need to address to move toward full implementation of the Code.

The IRRS Team notes that ARPANSA (and Australia) face complexities in implementing some of the provisions of the Code by having to do so within nine jurisdictions. The use of the National Directory of Radiation Protection to establish uniformity of regulatory requirements may be helpful in dealing with many of these challenges.

This section discusses the safety and security of radioactive sources, using as a basis, the guidance of the Code with appropriate references where required. The import and export of radioactive sources is discussed, but in no more depth than these topics are addressed in the Code itself. The IAEA Guidance on the Import and Export of Radioactive Material, which elaborates on the import and export provisions of the Code, is not addressed.

Source safety and security matters are intertwined throughout the Code because the measures taken to ensure the safety of sources also serve to provide a significant measure of source security. Much of the safety guidance of the Code is similar to the requirements of GS-R-1 and has been addressed in other parts of the report with suggestions and recommendations from the IRRS Team as noted.

This section does not review the current situation against each single provision of the code, but focuses on some key elements of the Code, namely the national register, the regulatory framework and the import and export.

General

In 2002, the Radiation Health Committee of ARPANSA identified the need to develop a code of practice related to the safety and security of radioactive sources. The committee approved development of a code of practice as well as a national register of sources and export control on high activity radioactive sources.

In parallel (9 December, 2002), the Council of Australian Governments (COAG) initiated a broad national review of the regulations, reporting and security around the storage, sale and handling of a wide variety of hazardous materials. The review included relevant Commonwealth, State and Territory agencies in consultation with the National Counter Terrorism Committee. One of the four sub-reviews focused on the regulation and control of radiological material and was undertaken by ARPANSA in cooperation with the Australian Safeguards and Non Proliferation Office (ASNO), other Australian government agencies and the regulatory authority in the State of Queensland. The COAG report addresses both radioactive sources and nuclear materials, however only radioactive sources are discussed here. The COAG report contains some overviews of international practices.

ARPANSA, being involved in both the COAG Report and the Radiation Health Committee's Code of Practice on the Security of Radioactive Sources, managed to drive them in a consistent manner and used the IAEA Code of Conduct on the Safety and Security of Radioactive Sources, published in 2004, as a key reference.

ARPANSA's Radiation Health Committee published, in January of 2007, the Code of Practice on the Security of Radioactive Sources. This document deals mainly with the domestic components of the security of radioactive sources in use, storage and transport. It is intended that the code of practice be given the force of law by each State and Territory and the Commonwealth, and that it be administered by the regulatory authority in each jurisdiction as part of the regulatory framework governing the use of radioactive sources. The enforcement of the code of practice relies on the adoption of the second edition of the National Directory for Radiation Protection (see other sections of the report). The code of practice sets a security outcome to be achieved using a risk informed, performance based approach. These security measures are set in a scalable manner based on the threat level and have to be formulated into a radioactive source security plan or source transport security plan to be approved by the regulatory body. The IAEA Code of Conduct document is not referenced in the Code of Practice on Security of Radioactive Sources.

The COAG Report received restricted publication as "Report on the Regulation and Control of Radiological Material" on 7 November 2006. The COAG report, approved in April 2007, assesses the situation in Australia and makes recommendations for improving the control of radioactive sources in the light of guidance from the Code of Conduct. This COAG Report refers to ARPANSA's Code of Practice on the Security of Radioactive Sources and includes it as part of the overall Australian strategy.

The IRRS Team notes the efforts of Australian governments and of ARPANSA in particular, in recent years, to address the issue of the safety and security of radioactive sources. The IAEA Code of Conduct has been and will continue to be used as a key reference to direct Australian radioactive source programs. The IRRS team also notes how the strong interaction between safety and security promoted by the IAEA Code of Conduct is being managed by Australia. In particular, the IRRS team considers with satisfaction that the ongoing co-operative measures between the nine jurisdictions should facilitate the harmonization of regulatory instruments. It is intended that, going forward, the respective jurisdictions will amend the existing regulatory framework to include additional requirements for the safety and security of radioactive sources as they are identified.

The IRRS Team has reviewed the twelve recommendations related to the safety and security of radioactive sources of the COAG report. All the recommendations are in line with the provisions of the IAEA Code of Conduct and their implementation will satisfy the commitment of the Australian government to implement the Code.

The COAG Report recommendations are appended as Appendix IX – COAG Recommendations.

The implementation of the COAG recommendations will begin in July 2007. The work to be done is significant, the time frame is tight and ARPANSA has to play a major role. The federal structure of Australia is not a facilitating factor for the implementation of this national program. However, the difficulties may be overcome with the permanent and strong support of all Governments.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: Preamble to the BSS under national infrastructures states: <i>“Essential parts of a national infrastructure are: legislation and regulations; a Regulatory Authority empowered to authorize and inspect regulated activities and to enforce the legislation and regulations;...”</i>
(2)	BASIS: Code of Conduct section 5(a) states: <i>“The objectives of this Code are, through the development, harmonization and implementation of national policies, laws and regulations, and through the fostering of international cooperation, to: (i) achieve and maintain a high level of safety and security of radioactive sources...”</i>
S19	Suggestion: ARPANSA should determine the most effective means for coordinating with States and Territories to develop implementation plans for each of the recommendations in the COAG Report. For example, requests through formal channels should be sent, as needed, to State and Territory governments in order to maintain momentum and to help to overcome such potential difficulties as lack of resources.

The collection of data to create the interim national register of sources (see below) has not been an easy process, and some difficulties still exist. More difficulties may yet appear. The first phase to develop the interim register has been conducted in an efficient and effective manner with encouraging results. The following phases are critical to ensure the success of the program, and ultimately the improvement of the safety and security of sources in Australia.

National Register of radioactive sources (Provision 11 of the Code)

The COAG Report identified ARPANSA as the agency tasked to establish a national register of radioactive sources of category 1 and category 2, with the cooperation of the States and Territories. There is currently an interim national register based on the information made available to ARPANSA by the other regulators. This register is being kept in ARPANSA premises. The interim register contains data identifying all category 1 and 2 sources in Australia, along with details of radionuclide, form, activity, and postal code location. Since its creation, the register has usually been updated on a quarterly basis. ARPANSA has sought additional data relating to the device or container for each source. ARPANSA has reported some difficulties with the collection of the appropriate information. The design and development of an appropriate electronic tool to manage this register is in progress but issues related to the collection of data need to be resolved. The confidentiality of the information is handled by ARPANSA in accordance with the protective security manual of the Commonwealth.

The IAEA has established and is promoting, in nearly one hundred member states the use of the Regulatory Authority Information System (RAIS). This is not only a register of radioactive sources but aims at helping regulatory bodies better manage all their regulated sources and facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: BSS §2.34 (c) states: <i>“Sources shall be kept secure so as to prevent theft or damage and to prevent any unauthorized legal person from carrying out any of the actions specified in the General Obligations for practices of the Standards ...”</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	BASIS: Code of Conduct section 11 states: <i>“every state should establish a national register of radioactive sources.”</i>
S20	Suggestion: ARPANSA should consider the most effective means of expediting its establishment of an on-line secure national sealed source registry.

Source Search and Recovery

Australia has enhanced facilities and services to search for missing sources, secure found sources and to intervene in the event of an accident or a malicious act involving a radioactive source. Car mounted gamma radiation survey equipment has been set up to search for missing sources. This equipment was tested in December of 2006 to search for a source in Western Australia.

Legislation, Regulations and Regulatory Body (Provisions 18-22 of the Code)

In the broad program flowing from implementation of the COAG decisions, there are clear provisions and plans having a direct impact on the regulatory framework of the Commonwealth and the States and Territories. These impacts include the need for the Code of Practice for the Security of Radioactive Sources to be enforced in all jurisdictions, the need to clearly identify the regulatory authorities and the scope and depth of their mandate in each jurisdiction governing the use of radiation and the State and Territorial jurisdictions must have the required legal basis to adequately regulate the security of radioactive sources.

These provisions are satisfactory to the IRRS Team. The coordination role of ARPANSA, in particular in this regulatory task is vital. The amount of work to be done is significant.

ARPANSA, being the radiation safety regulator of commonwealth entities, is undertaking and planning many actions to satisfy national programs and thus follow the guidance of the Code.

ARPANSA’s regulations and perhaps the ARPANS Act, will need to be revised to clarify the legal function of ARPANSA in regulating safety and security of radioactive sources. This revision will also provide the opportunity to revise the licensing, inspection and enforcement processes to better include security requirements.

The subject of security is not excluded in the current ARPANSA regulatory framework, since the regulations set requirements for a “security plan for the controlled facility” and “security plans for the controlled material or controlled apparatus”. These plans are assessed and reviewed by ARPANSA as documented in the Regulatory Assessment Reports and inspection reports.

The leadership of ARPANSA, in the national program to enhance the safety and security of radioactive sources, is crucial. ARPANSA clearly has to perform as a model for the other regulators.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<p>BASIS: Code of Conduct section 18 states: <i>“Every state should have in place legislation and regulations that:</i></p> <p><i>(a) prescribe and assign governmental responsibilities to ensure the safety and security of radioactive sources;</i></p> <p><i>(b) provide for the effective control of radioactive sources.”</i></p>
S21	<p>Suggestion:</p> <p>ARPANSA should consider the most effective means to clarify the project plan for this activity, including the delineation of milestones and regulatory reporting, to enhance its regulatory framework and serve as an example for other Australian regulators.</p>

Import and export of radioactive sources (Provisions 23-26 of the Code)

The export control of radioactive sources has been introduced to satisfy Australia’s commitments to the International Atomic Energy Agency’s Code of Conduct on the Safety and Security of Radioactive Sources (<http://www.arpansa.gov.au>). Export of radioactive sources is regulated by the Customs (Prohibited Exports) regulations that were drafted by ARPANSA and came in force on December 31, 2005. These regulations include the following provisions:

- Designation of ARPANSA officers as authorized for these regulations,
- Requirement for permission to export high activity radioactive sources (categories 1 and 2). A permit is needed for each single export. Permission request and review process, with a standard application form.

ARPANSA issues an export permission based on the information provided in the application (including contact details and a copy of licence for the recipient of the source in the other foreign State). The export is verified in consultation with the Department of Defence. Since January 2006, ARPANSA has issued 21 permissions for the export of 25 high activity sources. To date, ARPANSA has not authorized any exports under the “exceptional circumstances” provision of section 26 of the IAEA Code.

Australia is currently developing bilateral arrangements for import and export control with Canada.

Import control of radioactive material has been covered by the Customs (Prohibited Imports) Regulations for many years. All radioactive materials are subject to these regulations, without any exemption or a graded approach. ARPANSA plans to work with the Australian Customs Service to amend these regulations to more specifically address the issue of high activity sources and consider guidance from the Code.

In practice, when ARPANSA receives an import permission application (28 applications received in the last 18 months), it also consults with the importer State regulator and with ASIO.

RECOMMENDATIONS, SUGGESTIONS, AND GOOD PRACTICES	
(1)	BASIS: Code of Conduct section 24 states: <i>“Every State intending to authorize the import of radioactive sources in Categories 1 and 2 of Annex 1 to this Code should consent to their import only if the recipient is authorized to receive and posses the source under its national law and the State has the appropriate technical and administrative capability, resources and regulatory structure needed to ensure that the source will be managed in a manner consistent with the provisions of this Code.”</i>
S22	<u>Suggestion:</u> ARPANSA should consider the most appropriate steps it must take to advise the responsible portfolio to amend the Customs (Prohibited I) Regulations to clarify the application of the IAEA Code.

Dissemination of the code

By means of the Radiation Health Committee, the Radiation Regulators’ Forum, the Licence Holders Forum and the Annual Meetings of the Australian Radiation Protection Society, ARPANSA is increasing the awareness of interested parties about the IAEA Code of Conduct on the Safety and Security of Radioactive Sources and the implications of its implementation in Australia. As the federal program takes its first steps, the awareness of interested parties will also increase.

6. NATIONAL INFRASTRUCTURE FOR RADIOACTIVE WASTE, DECOMMISSIONING AND REMEDIATION

The IRRS mission covered some of the areas of concern for control of public exposure to radiation. ARPANSA's regulatory activities in the area of public exposure control are largely restricted to regulation of facilities related to radioactive waste management, decommissioning and the activity of remediation—hence these areas are the focus of this section. ARPANSA completed the self-assessment questionnaire titled “Questionnaire for the IAEA Review Service on the Control of Public Exposure, including Waste Management and Decommissioning”. ARPANSA regulates only Commonwealth entities and contractors; hence the sections of the questionnaire completed were those that concern Commonwealth-regulated activities.

ARPANSA has little direct involvement with the regulatory control of foodstuffs, commodities, radon, NORM residues and materials for recycling—these are the responsibility of state regulators. Some of these areas are covered in ARPANSA's national codes of practice and safety guides directed toward national uniformity, namely:

- Radiation protection and radioactive waste management in mining and mineral processing (RPS 9),
- Recommendations for Limiting Exposure to Ionizing Radiation (1995) and National Standard for Limiting Occupational Exposure to Ionizing Radiation (RPS 1),
- National Directory for Radiation Protection (RPS 6).

At present, ARPANSA is developing guidance material for management of NORM. These are being developed to promote national uniformity.

Australia signed the Joint Convention on 13 November 1998. The convention requires, inter alia, that appropriate steps be taken to review the safety of any radioactive waste facility existing at the time the convention enters into force and ensure that, if necessary, all reasonably practicable improvements are made to upgrade the safety of such a facility. Australia ratified the Joint Convention on the 5th August 2003.

National Waste Management Policy and Strategy

GS-R-1 § 3.4 § 6.7; WS-R-1 § 4.4; WS-R-2 § 5.3, 5.5; WS-R-3 § 4.6; JC Art 32

The radioactive waste management policy and strategy of the Government of Australia is elaborated in detail in the Australian national report for the “Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (October 2005)”. Responsibility for Australia's radioactive waste management policy and strategy rests with the Australian Department of Education, Science and Training (DEST).

The Australian government radioactive waste management policy requires that all radioactive waste originating within Australia be stored, or disposed of, in Australia at suitably-sited facilities after being categorised in accordance with agreed international best practice.

Australia does not generate any high level waste. All spent fuel is transported back overseas and Australia will receive back some intermediate level waste. Successive Australian governments have

made it very clear that they reject any proposal to import high level radioactive waste from overseas for storage in Australia.

At present low and intermediate level radioactive waste is stored by Australian Government and State and Territory agencies at over one hundred locations around Australia in both rural areas and urban centres. Many individual waste producers currently have the responsibility of looking after their own radioactive waste. Each state and territory is responsible for the management of radioactive waste generated by government agencies, individuals and organisations within their jurisdiction.

From the late 1980's to 2004, the Government of Australia through DEST led an initiative to site a national facility for the disposal of low level radioactive waste. On 14 July 2004, the Government of Australia decided to abandon the establishment of a national disposal facility following legal action by the Government of South Australia.

Commonwealth Radioactive Waste Management Facility

In July 2004, the Government announced that it would construct co-located facilities on Australian Government land for the management of low and intermediate level radioactive waste produced by Australian government agencies (i.e., waste generated by Commonwealth agencies). The Australian Government aims to ensure that its radioactive waste is properly managed through establishment of the Commonwealth Radioactive Waste Management Facility (CRWMF).

On July 15 2005 the Australian Government announced three potential locations to be investigated for the CRWMF. The three locations are Department of Defence properties located near Katherine and Alice Springs in the Northern Territory (these sites are named in the Commonwealth Radioactive Waste Management Act 2005). Since May 15, 2007, a fourth site, a volunteer site, in the Northern Territory has been added to this list of candidate sites.

Once a preferred site is selected, the proposal to construct the CRWMF at that site will be referred to the Minister for the Environment and Water Resources for assessment under the Environment Protection and Biodiversity Conservation Act 1999. The assessment process, including the development of an environmental impact statement, is expected to take about two years. The proponent will also need to obtain approvals under the Australian Radiation Protection and Nuclear Safety Act 1998 from ARPANSA.

When making a decision to issue a licence the CEO of ARPANSA must take into account "international best practice" in radiation protection and nuclear safety. This requires both the applicant and the regulator to identify the relevant international best practice in radiation protection and nuclear safety and apply it to either the application (applicant) or the review of the application (CEO of ARPANSA). In this way both the applicant and ARPANSA's CEO have a duty to maintain an understanding and awareness of international best practice in this area. Best international practice for the long term management of spent fuel and radioactive waste, in the context of Australian law, is discussed in Section 4.4 of the document Decision by the CEO of ARPANSA on Application by ANSTO for a Licence to Operate the OPAL Reactor Statement of Reasons, 14 July 2006. It is also discussed in the ARPANSA Regulatory Guidance for Radioactive Waste Management Facilities: Near Surface Disposal Facilities; and Storage Facilities (December 2006),

Waste Acceptance Criteria

WS-R-1 § 5.1-5.12; WS-R-2 §5.31-5.32

ARPANSA has provided detailed regulatory guidance for development of waste acceptance criteria (WAC) for near surface disposal of radioactive waste in the following documents:

- Section 3.4 of Regulatory Guidance for Radioactive Waste Management Facilities: Near Surface Disposal Facilities; and Storage Facilities (December 2006), and
- Section 4.6 and Appendix G of Safety Guide for Predisposal Management of Radioactive Waste (Draft Guide, October 2006).

Classification System for Radioactive Waste

GS-R-1 § 6.7; WS-R-2 § 3.5; SS-111-G-1.1

Australia does not have a national system for the classification of radioactive waste (RHS-35 suggests a system). The Radiation Health Committee considered the issue but did not take a final decision on a national classification system. Operators often have their own waste categorization schemes; categorization schemes are usually linked to waste processing steps not disposal. A national classification system provides a common waste segregation scheme for waste producers based upon the disposal endpoint. Additionally it provides a classification system useful for national planning for long term management of wastes and a system for reporting national inventories of radioactive waste (e.g., reporting for the Joint Convention).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: WS-R-2 § 3.5 states “... <i>the regulatory body shall ensure that an appropriate waste classification scheme is established in accordance with national programmes and requirements and international recommendations.</i> ”
S23	Suggestion: ARPANSA should consider the most effective means to promote a national system for classification of radioactive waste. This would serve national uniformity and would assist state governments with regulatory oversight of radioactive waste, particularly if the proposed Commonwealth Radioactive Waste Management Facility (CRWMF) were to become a national facility.

National Inventory for Radioactive Waste

JC Article 32

Appendices D and E of Australia’s national report for the “Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management” provide information on Australia’s inventories of radioactive waste and spent fuel.

Clearance of Radioactive Waste

WS-R-2 §3.8, §5.21; RS-G-1.7

ARPANSA is currently applying the 1985 Code of Practice for the disposal of Radioactive Waste by the User to clear small quantities of radioactive waste to controlled municipal landfills and sewers (in essence, conditional clearance). ANSTO practices unconditional clearance of radioactive waste using the exemption levels found in Schedule 2, Part 2 of the ARPANS Regulations 1999 and RS-G-1.7. Generic activity limits for disposal by the user of solid, liquid and gaseous radioactive

wastes are being proposed for the second edition of the National Directory; these are intended for use by small institutional waste generators.

ARPANSA does not yet have guidance or criteria for clearance of the larger volumes of materials typically associated with decommissioning, nor for release of scrap metal for recycling. None of ARPANSA’s licensees have started decommissioning activities, so this is an issue for future consideration.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: WS-R-2 §3.8 states: “... <i>the regulatory body shall also consider establishing criteria for the clearance of materials.</i> ”
S24	<u>Suggestion:</u> ARPANSA should consider developing guidance for clearance of materials from decommissioning.

7. EMERGENCY PREPAREDNESS

The overall infrastructure requirements for emergency preparedness are given in GS-R-1, §6.2 to §6.6, with further detailed requirements expounded in the specific Safety Standard, GS-R-2, Preparedness and Response for a Nuclear or Radiological Emergency.

This section of the IRRS-report assesses the role, resources and capabilities of ARPANSA against these safety standards.

GS-R-1 §6.2 - 6.6

7.1 The role of ARPANSA

The mission of ARPANSA is to protect the Australian people and environment from the harmful effects of radiation. In this function ARPANSA has two primary roles: direct regulatory role (as the Commonwealth nuclear installation regulator) and advisory role (for Government, States and Territories). Australia is a Federation of States and Territories and they have the responsibility for first response to a radiation emergency. Australian Government Agencies with radiation protection expertise and additional radiation emergency response capabilities, such as ARPANSA, ANSTO and Defence, can act in support of the States and Territories, when requested.

In broader context, ARPANSA's emergency preparedness arrangements are implemented under the Commonwealth Disaster Plan (COMDISPLAN), which is maintained and coordinated by Emergency Management Australia. COMDISPLAN has sub plans, which cover emergencies associated with radioactive space debris, visiting nuclear powered warships and terrorist use of radioactive material.

ARPANSA is the designated National Competent Authority for Radiation Emergencies, both domestic and abroad. ARPANSA is also a WHO Collaboration Centre for Radiation Protection, and together with the Peter MacCallum Cancer Centre, is a member of the WHO Radiation Emergency Medical Preparedness and Assistance Network.

The Team visited ARPANSA's Melbourne office, where its health physics function is located. Based on the visit and the interviews, it was clear to the Team how strong the health physics competence within ARPANSA was. Connected to health physics, ARPANSA has organized and developed an Emergency Operations Unit.

With respect to ARPANSA's regulatory functions and its oversight in particular of its relationship with ANSTO, the Team noted the following: Based on the material made available to the Team and the interviews, the Team considered that during the OPAL reactor licensing, ARPANSA reviewed the emergency preparedness arrangements in a systematic and thorough manner. The Team also noted that ANSTO's emergency preparedness arrangements are subject to ARPANSA's inspections.

However, with regard to operation of the OPAL reactor, the Team noted some lack of clarity between ARPANSA and ANSTO with regard to emergency management. There doesn't seem to be a clear distinction between roles, responsibilities and rights regarding ANSTO being the nuclear operator and ARPANSA its direct nuclear regulator. Therefore, the Team was of the view that ARPANSA would benefit from clarifying how it

- reviews and approves periodically emergency plans and arrangements (except what is written above about OPAL reactor); its not clear if ARPSANSA, its role and functions are documented in a comprehensive and clear manner in ANSTO's emergency preparedness plans,
- inspects and tests these arrangements (including equipment),
- participates in emergency drills (completeness of scenarios, analysis of emergency situations, communication, coordination and co-operation arrangements with different regulators for on-site and off-site).

Malicious actions and handling of orphan sources are covered by ARPANSA's planning system.

7.2 Resources and abilities

ARPANSA's Environmental Radiation and Health Branch (located in Melbourne) has the Health Physics Section, whose Section Head acts as the Radiation Emergency Preparedness Coordinator. Thru this Coordinator, the resources of the Section and other scientific capabilities of ARPANSA are used for the advisory functions and purposes entrusted to ARPANSA.

During the past years, the Branch has organized and developed an Emergency Operations Unit. The unit maintains

- the capability to maintain to meet short notice requests in the event of radiation emergencies or events,
- the infrastructure to deploy wider ARPANSA staff to aid in a large scale radiation incident,
- specialist equipment.

The Team visited and interviewed the unit. The unit is well equipped (gamma and alpha/beta spectroscopy, neutron detection, mobile and satellite based communications technologies), very mobile (transportable equipment, vehicles), well trained and motivated.

The number of ARPANSA staff involved full-time in work on emergency preparedness is limited, but the number that is available to engage in work in an emergency situation can be large.

The Team noted that ARPANSA's Regulatory and Policy Branch is considering draft written procedures for its staff about how to manage an emergency in an ARPANSA licensee's facility. It suggests that the procedures be finalized and put in force promptly and involve the Yallambie emergency management infrastructure.

ARPANSA has not developed a structured organizational chart for its emergency organization, which would involve also ARPANSA's Regulatory and Policy Branch. Such a chart would show key positions reserved for individuals occupying certain positions in the ARPANSA's Regulatory and Policy Branch, and would be based on these individuals' functions in the every-day work of ARPANSA. The chart would also identify persons responsible for all external communication matters. Also, the Team considered that ARPANSA might benefit from drawing up and updating a list of staff members on duty, who could respond shortly after having been alerted.

The Team noted that ARPANSA would benefit from a related training program.

ARPANSA does not have an emergency centre or established arrangements at the premises of its Sydney office. It does not have all the necessary, secured lines and facilities for independently

assessing abnormal situations, for communications with other organizations involved in the emergency network, for receiving vital information from operators as well as from its Melbourne office, and for external communications (including meeting the media, if needed).

The Team noted that ARPANSA was a party to the international ARGOS program involving nine countries. ARGOS is a Decision Support System for emergencies, and provides tools for getting an overview of the emergency situation, creating prognosis of how the situation will evolve, analysing and visualizing measurements, calculating consequences, deciding on appropriate countermeasures, and handling information to the public. ARPANSA will install and evaluate the applicability of ARGOS for Australian purposes.

The Team appreciated this participation and agreed that ARPANSA needs independent capabilities to

- assess the situation, its potential seriousness, how it may be developing and what kind of radioactive consequences (plume, contaminations, etc) might be expected with respect to ARPANSA's mission to being able to protect Australian people and the environment and being able to advise the Government on protective measures needed,
- provide the public and other administration with appropriate information. The Team believes that in emergency situations, media and members of the public would also turn to ARPANSA for reliable information.

The Team noted that this would also imply senior management engagement and resources, since the Team considered that ARPANSA would need dedicated staff for the emergency preparedness in ARPANSA's Sydney office.

The Team noted that ARPANSA had no automatic radiation monitoring stations installed close to its research reactor or elsewhere in Australia. However, the Team appreciates that ARGOS also addresses this.

Australia has a long history of receiving visiting nuclear powered warships in a number of Australian ports. The Team found the documented emergency preparedness arrangements for the visits, which were based on over 30 years of experience, to be thorough and well functioning.

Regarding ARPANSA's emergency preparedness arrangements, the Team observed some lack of awareness and differences in professional views during the interviews. The Team was of the opinion that this was at least partially due to the fact that ARPANSA does not have in-house training on current emergency preparedness arrangements, which would increase the awareness of all of ARPANSA's professional staff.

7.3 Decision-making in emergency situations

The Team recognized that ARPANSA operates in the multi-jurisdictional context for Australian radiation emergency preparedness. The emergency preparedness arrangements involve many players at the ministerial level, Commonwealth, State and Territory authorities, and operational levels. There is a written allocation of responsibility for notification and decision-making.

However, ARPANSA has both the regulator and advisor roles and in both cases the relatively large number of players and wide net of communications can pose a potential source of delays and loss of information, in particular in the early phases of the emergency situation. Streamlining the emergency organization and communication routes might bring benefits.

With respect to emergencies during transportations (in particular spent nuclear fuel), the Team felt that ARPANSA would benefit from revisiting its regulation and arrangement.

7.4 Exercises

ARPANSA observes ANSTO’s emergency drills. However, ARPANSA’s Regulatory and Policy Branch does not practise itself and does not participate in ANSTO’s drills in order to test and improve its own emergency preparedness arrangements (in particular, how communication, coordination and cooperation really works in the Australian multi-jurisdictional context, and between ARPANSA’s Sydney and Melbourne offices).

7.5 Quality Assurance programme

The Team noted with appreciation that ARPANSA’s Melbourne office has a well functioning QA-program in place for emergency equipment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<i>(1)</i>	BASIS: GS-R-2, §4.2 -4.6
<i>G8</i>	<p><u>Good Practice:</u> ARPANSA has a strong health physics capability and a well equipped, very mobile, well trained and motivated Emergency Operations Unit for meeting short notice requests and deploying wider ARPANSA staff to aid in a large scale radiation incident.</p>
<i>(1)</i>	BASIS: GS-R-2: §2.1 - 2.6, 5.2-5.24, §4.53 - 4.55
<i>R9</i>	<p><u>Recommendation:</u> ARPANSA should establish, implement, test, maintain and continuously improve in-house procedures and policies related to:</p> <ul style="list-style-type: none"> • the management of its role in nuclear or radiation events and emergencies arising with holders. • the provision of appropriate information to all key stakeholders during and after events and accidents.

8. MANAGEMENT SYSTEM FOR THE REGULATORY BODY

8.1 Introduction

ARPANSA has established and is further developing in a systematic manner an overarching management system (MS) for all of its operations. The Team noted that in 2004-2005 the Australian National Audit Office (ANAO) conducted an audit which covered the regulatory MS. The audit report³ was made available to the Team. Since the report contains recommendations to revise and improve the MS, the Team decided not to consider or repeat those areas and recommendations, where ARPANSA has development activities ongoing based on the recommendations of the audit report.

Although the Audit report was not subject to Team review, the Team noted as a good international practice the proactive stance of the ANAO in producing a series of “Better Practice Guides” to support and assist all regulators in their efforts. The Team also noted that in the development of its MS, ARPANSA was making use of such a “Better Practice Guide”⁴.

The main components of the ARPANSA MS are Corporate Governance, Quality Management, Management of Human resources, Property Management, and Financial Management. The Team’s review of ARPANSA MS was based on IAEA Safety Standard GS-R-3, and the main review results are presented in a structure following GS-R-3.

8.2 ARPANSA’s Management System, structure and generic features (GS-R-3, § 2.1 – 2.10)

8.2.1 Corporate Governance and General Aspects of the MS

The main components of the ARPANSA Corporate Governance are

a) Strategic Planning framework (see figure 1):

- Portfolio Budget Statements, which sets and reports ARPANSA’s outcome, outputs and funding basis for each budget year,
- Corporate Plan, which outlines vision, values and key business objectives, strategies and outputs for the next three years,
- Risk management plan, which identifies and analyses business risks and how they are managed on corporate, controlled persons and regulatory process levels,
- Fraud control plan, which identifies and analyses fraud risks and how they are managed,
- Business plans (for each of the ARPANSA’s branches), which describe specific actions to achieve strategies under output group; specific products, services and resources needed; and indicators to measure performance, and
- Individual performance agreements, which contain elements that relate to ARPANSA’s output groups as set out in the above mentioned Corporate Plan and branch specific business plans,

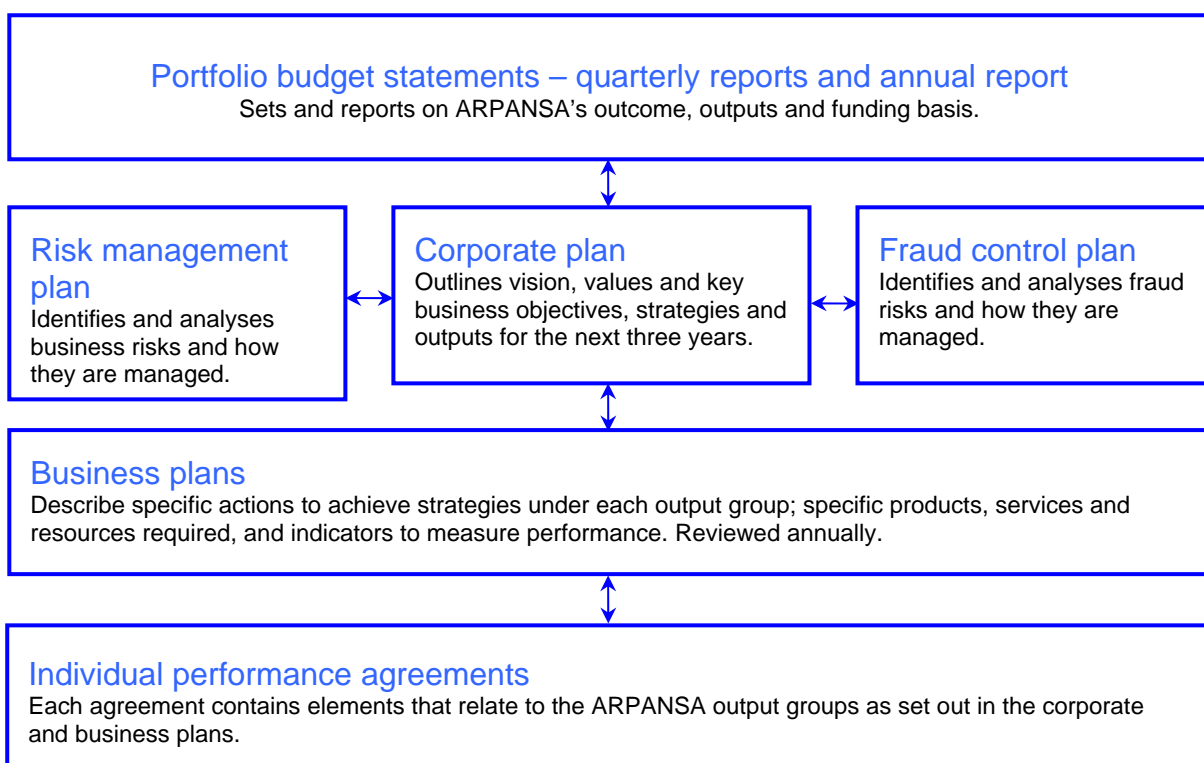
³ The Auditor-General Audit Report No.30 2004-05, Performance Audit

⁴ Administering Regulation, Better Practice Guide, 2007, Australian National Audit Office

b) Particular organizational structures:

- Executive Board of Management (EBOM), which is an in-house Board with one external member, assisting the CEO to meet his statutory functions and responsibilities,
- ARPANSA management committees, such as the Audit committee, which provides independent assurance and assistance to the CEO and the Executive Board of Management on ARPANSA’s risks, control and compliance framework, and its external accountability responsibilities.

Figure 1: ARPANSA Corporate Governance – Strategic Planning Framework



The team appreciates ARPANSA’s Corporate Governance framework, which the Team considers to be well established and systematic.

However, after reviewing the framework, the Team has the following significant observations to offer.

The operating environment of radiation and nuclear regulators all over the world is undergoing major transitions due to issues like Kyoto process and global warming, changes in global energy mixes, security of energy supplies, major potential increase in the use of nuclear energy and related nuclear fuel cycle services etc. In changing times, regulators have to anticipate future directions and sensitivities, keep their governments aware of the national as well as international regulatory challenges and times spans involved. Also radiation and nuclear safety regulators have to be prepared to meet the new regulatory challenges in a high quality manner.

In light of recent political discussion in Australia (“Uranium Mining, Processing and Nuclear Energy - opportunities for Australia” study published by Australian Government, Department of Prime Minister and Cabinet, and the Prime Minister’s statement of 28 April 2007); the long time spans related to nuclear new builds; and ARPANSA’s current regulatory framework, competences and resources, the Team has the view that ARPANSA would benefit from:

- expanding its “Corporate governance - strategic planning framework” to include the element of analysing changing operational environment, both ARPANSA’s external and internal operational environment. The Team further considered beneficial that ensuring effective and time saving introduction of this new element and its implementation, an executive level event be organized for the EBOM.
- urgently preparing a strategic road-map for ARPANSA to identify, analyse and suggest ways forward with respect to related regulatory challenges and how they could be met (inter alia, to include needed new safety regulations, regulatory processes, structures, competences and resources).

The Team reviewed minutes of the EBOM and interviewed members of the Board. In light of ARPANSA’s strategic corporate and priority issues, the Team felt that ARPANSA’s good corporate governance would benefit from revisiting the EBOM’s composition, working methods and issues it takes on its agenda.

The Team appreciated the Branch level business planning⁵, which includes targets and measure, the a step by step way to engage whole staff in the planning process, and plan to develop the business plan further to include resource planning.

In light of these future regulatory challenges and ARPANSA’s organizational unity and integration, the Team also considered that ARPANSA would benefit from reconsidering the role, composition and agenda of the EBOM to enable this important Corporate Governance body to more effectively and efficiently support ARPANSA in strategic and priority issues.

ARPANSA applies a graded approach based on its risk ranking methodology for reviews and inspections. The approach is based on hazard - control matrix, where hazard categories 1...3 are assigned based on potential for detriment to people and the environment, and the control categories 1...3 per the demonstrated ability to maintain safety of the licensed source or facility. This matrix provides nine risk ranking classes based on which the regulatory efforts are implemented. The approach is implemented for inspection purposes, but not used for licensing purposes. The procedure to implement risk ranking is not formalized and documented.

ARPANSA’s Risk Management Framework comprises a Risk Management Policy, a Risk Management Plan, and risk management methodology and control process. ARPANSA has created a strategic risk register. The Team considered that ARPANSA has an appropriate risk management framework. The process itself needs to be developed to be more comprehensive with respect to

⁵ Regulatory and Policy Branch, Business Plan, July 2007 - June 2008

corporate risks, controlled persons risks and risks related to the regulatory process. Further, in ARPANSA's risk management methodology, risk identifications process needs to be developed.

In the MS framework, the Team recognize two issues related to the system of managing of conflicts of interest:

- In addition to its regulatory activities, ARPANSA provides a range of commercial services. The Team noted that ARPANSA has instructions in place on what constitutes a conflict of interest and how to manage it.
- ARPANSA licenses itself in cases where it carries out activities with sources or facilities. The Team notes, that a Memorandum of Understanding is being put in place with the Victorian Regulator to review and inspect those sources and facilities. In addition, inside ARPANSA there is managerial and organizational separation and independence regarding the branches, which regulate and utilize sources and facilities.

In light of the size of nuclear and radiation practices program in Australia, the Team considered that the issues of conflict of interest are properly managed by ARPANSA.

The Team was informed in detail of a number of targeted improvement and development tasks ongoing in the area of corporate governance. The Team appreciates and supports the ongoing work in all areas.

8.2.2 Quality System

ARPANSA's quality system complies with ISO/IEC 17025 and AS/NZS ISO 9001 standards. Seven of ARPANSA's significant service activities have been accredited by the National Association of Testing Authorities (NATA) to be compliant with the ISO/IEC 17025:1999.

However, the completeness of the set of QA-procedures and the consistency regarding how the staff implement these procedures in every day regulatory work, needs to be reviewed and developed further by ARPANSA.

8.2.3 Safety Culture

Safety arises from every working level of the organization and from every individual. Therefore safety is strongly and directly influenced by

- How any organization is managed,
- what kind of atmosphere and culture there is in the everyday working place and
- what kind of attitudes the management has and reflects to the staff, both verbally and non-verbally.

The Team noted that ARPANSA does not currently have safety culture documented in its MS (or QS) to promote and support strong safety culture in ARPANSA's activities, relationships and interactions with its licence holders.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<p>BASIS: GS-R-3, §2.1 - §2.4 states: “A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:</p> <p>—Bringing together in a coherent manner all the requirements for managing the organization;</p> <p>—Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;</p> <p>—Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety.”</p>
G9	<p>Good Practice: ARPANSA’s regulatory strategic planning framework is systematic. This is good practice.</p>
(1)	<p>BASIS: GS-R-3 §2.1, 6.1. 6.4. 6.5 states:</p> <ul style="list-style-type: none"> • See text above; • “Independent assessments shall be conducted regularly on behalf of senior management: <ul style="list-style-type: none"> —To evaluate the effectiveness of processes in meeting and fulfilling goals, strategies, plans and objectives; —To determine the adequacy of work performance and leadership; —To evaluate the organization’s safety culture; —To monitor product quality; —To identify opportunities for improvement.”
G10	<p>Good Practice: The ARPANSA Audit Committee provides an effective oversight of the effectiveness of the implementation of internal controls and assists in a value added manner the CEO in risk management and compliance with financial management and accountability. Also, ARPANSA has a thorough internal audit plan, which is developed using a risk-based approach.</p>
(1)	<p>BASIS: GS-R-3 §2.1, 2.8, §5 states: A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:</p> <p>—Bringing together in a coherent manner all the requirements for managing the organization;</p> <p>—Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;</p> <p>—Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety”</p>
R10	<p>Recommendation: ARPANSA should review the completeness of its existing set of QA-procedures related to regulatory work and ensure consistency in the manner of their implementation in everyday regulatory work.</p>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<p>BASIS: GS-R-3 §2.5 5 states : <i>The management system shall be used to promote and support a strong safety culture by:</i></p> <p>—<i>Ensuring a common understanding of the key aspects of safety culture within the organization;</i></p> <p>—<i>Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;</i></p> <p>—<i>Reinforcing a learning and questioning attitude at all levels of the organization.”</i></p>
R11	<p><u>Recommendation:</u> ARPANSA should expand its regulatory management system to include measures to promote and support strong safety culture.</p>
(1)	<p><u>BASIS:</u> GS-R-3 §2.1, 3.8-3.11 ; see text above.</p>
S25	<p><u>Suggestion:</u> ARPANSA should consider expanding its “Corporate governance - strategic planning framework” to include an analysis of the contemporary operational environment and developing a process for interaction with appropriate federal government departments to support the development and implementation of the framework. ARPANSA should consider the preparation of a strategic road-map to identify, analyse and suggest ways forward with respect to related regulatory challenges and how they could be met (inter alia to include needed new safety regulations, regulatory processes, structures, competences and resources).ARPANSA should consider an executive level training event be organized for the EBOM to facilitate the implementation of this measure ARPANSA should consider revisiting the activities of the EBOM in light of any reconsideration of corporate strategies and emergent priorities.</p>
(1)	<p>BASIS: GS-R-3 §2.1, 3.8-3.11; see text above</p>
S26	<p><u>Suggestion:</u> ARPANSA should consider the enhancement of its risk management process to include further development of the risk identification process.</p>

8.3 Management responsibility (GS-R-3, §3.1 - 3.14)

In the Team’s view, ARPANSA management has demonstrated its commitment to the establishment, implementation, assessment and continual improvement of the MS. In particular, the recent development of the MS has been very professional and systematic. The stepwise approach taken to introduce and develop the MS, which in Team opinion is vital in ensuring the staff engagement, a good one.

However, the Team was of the opinion that it was not evident that all the adequate resources are allocated to carry out the above mentioned activities. In this regard, the Team emphasized that accurate, well functioning cost recovery scheme would bring inherently more financial independence.

Values have been developed and communicated to staff.

ARPANSA has fully recognized the importance of stakeholder relationships in its work. In order to address the stakeholder relationships in a systematic and comprehensive manner, a strategy is under preparation. Also, methods to measure customer satisfaction are being developed at the branch level. The Team noted that ARPANSA benefits from these development tasks and might wish to consider adding elements of modern customer care programs to its development work.

Management has developed several policies for the organization. With respect to the Cost Recovery Policy, the Team’s views concerning its implementation are presented later in 8.4 below.

The management has established strategic planning framework under the Corporate Governance activities described above (§2. ARPANSA’s Management System).

ARPANSA hasn’t assigned an individual reporting directly to senior management who has specific responsibility and authority for:

- coordinating the development and implementation of the Management System, and for its assessment and continual improvement;
- reporting on the performance of the Management System, including its influence on safety and safety culture, and any need for improvement;
- resolving any potential conflicts between requirements and with the processes of the Management System.

This responsibility is within each Branch management structure.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-3 §3.1 states: <i>Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system and shall allocate adequate resources to carry out these activities.</i>
S27	Suggestion: ARPANSA management has demonstrated its commitment to the establishment, implementation, assessment and continual improvement of the MS. However, ARPANSA management should consider the resource allocation for the above mentioned activities in order to ensure that adequate resources are allocated in accordance with the above mentioned commitment.

8.4 Resource management (GS-R-3, §4.1 - 4.5)

Based on multiple interviews that the Team members carried out, it is evident that there is a shortage of professional human resources both in radiation and nuclear safety fields. Partially this is due to the budget constraints and partially due to difficulties in filling open vacancies with qualified persons.

In the core of ARPANSA’s mission is protecting the health and safety of people, and the environment, from the harmful effects of radiation (ionizing and non-ionizing). High quality, independent and objective regulatory decisions are based on results from scientific and technical research work.

ARPANSA’s organizational resources include a strong research arm located in Melbourne which is able to support the regulatory framework. The Team was left with the impression, that the regulatory framework could use and benefit more from this research resource. For example,

introducing a closer customer - supplier relationship between the regulatory and research arms of ARPANSA would bring, in addition to effectiveness and efficiency gains, also organizational unity and integrations.

Senior management has determined competence requirements and set up a training program for all staff. However, this program is mainly based on commercially available training programs and the regulatory in-house training program needs to be developed further.

All staff have regular performance appraisal under their individual ARPANSA Performance Development Scheme, which is an individual workplan and training agreement that is reviewed each quarter.

ARPANSA has a Working Environment Group and an Occupational Health and Safety committee to monitor and manage the infrastructure and working environment necessary for safe work.

In March 2006, ARPANSA issued the policy of cost recovery. ARPANSA is committed to recovering the full costs of its regulatory activities from its licence holders. Implementation of this policy is in its early phases.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-3 §4.1 states: <i>“Senior management shall determine the amount of resources necessary and shall provide the resources to carry out the activities of the organization and to establish, implement, assess and continually improve the management system.”</i>
S28	Suggestion: ARPANSA should consider the most effective way to determine the cost structure of the regulatory function, including a strategy for collecting the necessary data (i.e. exact spent person hours per activity), tailoring appropriate software for tracking personnel time and other costs, and preparing a communication plan in order to communicate the cost recovery program to the staff and main stakeholders. ARPANSA should consider the desirability of early co-operation between the financial administration and operation branches in developing and implementing the cost recovery system .

8.5 Process implementation (GS-R-3, §5.1 - 5.29)

Most of ARPANSA’s processes, as well as their sequence and interactions, are documented in their quality system. The processes are not particularly grouped into core and supporting processes, but the process development work is ongoing. The Team appreciated ARPANSA’s ongoing efforts in reviewing the completeness of the Quality system and the set of procedures currently included in Quality system manual.

Each process has a process owner with appropriate authority and responsibility for the process. A regulatory management and action tracking system is available to formally track each regulatory issue and its pathway within ARPANSA.

High quality management of information is fundamental to a regulator’s obligation to be accountable and transparent. ARPANSA has a formal records management system that operates within defined Business Classification Rules; is administered by records management professionals and is under the auspices of an Information Management professional (equivalent to a Chief Information Officer (CIO)).

There has been a significant number of external audits of the regulatory processes in recent years, in particular the recent review by the ANAO. These audits have served for developing, planning, implementing assessing and continuously improving the processes.

ARPANSA is taking into use Regulatory Management Information System TRIM, which includes the following elements:

- record management system,
- workflow monitoring and control,
- performance measurement,
- collaborative working.

TRIM was demonstrated to the Team. The system appeared comprehensive, worked well, was effective and its visualization tools were both informative and helpful.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-3 §5.11 - 5.21 states: <i>“The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved.”</i>
G11	Good Practice: The introduction (in a short period of time) of a well functioning, easy to use Regulatory Management Information System TRIM, which includes record management system, workflow monitoring and control, performance measurement, and collaborative working, is good practice.

8.6 Measurement, assessment and improvement (GS-R-3, §6.1 - 6.18)

ARPANSA monitors and measures the effectiveness of the Management System to confirm the ability of the processes to achieve the intended results and to identify opportunities for improvement. This is kept under review by the senior staff of the organisation within the context of its regulatory senior staff meetings, executive board of management meetings and through the performance and accountability reporting. In addition an internal audit committee and internal audit contractor regularly assess the performance of the organisation.

Management at all other levels carry out self-assessment to evaluate the performance of work. However, safety culture in ARPANSA is under consideration and development.

For the purpose of regular independent assessments in ARPANSA, there is an internal audit committee and an internal audit contractor who provides audit services to ARPANSA. The focus of both the committee and the contractor is on overall organisational compliance issues including financial management, compliance with other statutory requirements and the implementation of risk management. An audit program specifically related to the matters set out above has not been undertaken. However in 2004-2005 the Australian National Audit Office conducted an audit of the efficacy of the implementation of the ARPANSA regulatory management system. Much of the work on the improvement of the management of the regulatory function stems from the 19 recommendations made in this report.

There is no organizational unit established with the responsibility for conducting independent assessments. It is not clear that individuals conducting independent assessments do not assess their own work.

Senior management evaluate the results of the independent assessments. A full management response to the ANAO audit of 2004-2005 has been prepared⁶.

Non-conformances are determined and remedial actions taken to prevent their recurrence. Whilst this does not occur within a fully integrated quality management system it does occur within ARPANSA's current management system within the regulatory area.

Opportunities for improvement of the Management System are identified and actions to improve the processes are selected, planned and recorded. This is done formally at the Board level as well as informally through identification of opportunities for improvement through individual management meetings. All major improvements are tracked through project plans including the undertaking of a risk assessment of the project as well as a budget attributed to the achievement of the project and on-going implications for resources once the improvement is made. The process of tracking and closing out improvements needs to be formalized within the ARPANSA management system.

ARPANSA does not, and does not require its licence holders to evaluate in a systematic manner operational experience or events from other licence holders in Australia or abroad.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-3 §6.1 - 6.10 states: <i>“The effectiveness of the management system shall be monitored and measured to confirm the ability of the processes to achieve the intended results and to identify opportunities for improvement.”</i>
G12	Good Practice: ARPANSA's systematic and professional manner to improve and develop its Management System is good practice.

⁶ The most recent response was by the CEO in his final report on the implementation of the recommendations of this audit report that he published and placed on the ARPANSA website in December 2006.

9. TRANSPORT OF RADIOACTIVE MATERIALS

9.1 Legislative and Governmental Responsibilities

The ARPANS Act does not explicitly give to the CEO the responsibility for regulation of the transport of radioactive material, even for Commonwealth entities. The responsibility for transport of radioactive material is given in the annex A of the code of practice entitled "Safe Transport of Radioactive Material". The code of practice is made mandatory by the ARPANS regulations 1999. The responsibility is shared by 11 different authorities (ARPANSA for Commonwealth entities, the six states, the two territories and the sea and air safety authorities). There is no memorandum of understanding between ARPANSA and either the Civil Aviation Safety Authority or the Australian Maritime Safety Authority. However, the Agencies informally discuss regulatory matters on a periodic basis.

Since ARPANSA only regulates land transport for Commonwealth entities, the IRRS Team could not check which regulations are in place for international transport (sea and air).

The regulations in force for land transport are IAEA regulations 1996 as revised in 2000. The current regulations of IAEA TS-R-1 2005 edition are not applied. The 2005 edition must be mandatory for international transport through the international modal regulations for sea and air transport.

For other countries having federal organizations (e.g. Canada, Germany and the United States of America) only one authority issues certificates of approval for packages. The IRRS team considers that the regulatory regime is not structured and resourced in a manner commensurate with the potential magnitude and nature of the hazard to be controlled (GS-R-1 2.1 in part) in particular if nuclear and uranium activities are expanded. Eleven authorities cannot reach the minimum staff to be efficient and competent in the field of transport of radioactive material.

The CEO of ARPANSA can issue only certificates of approval for land transport and for package applied by Commonwealth entities. Sea and Air safety authorities validate the certificate issued by ARPANSA in case of transport by sea or air.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: SS112 states: <i>"Where there are several responsible authorities, close co-operation between them is essential, and there should be legal or formal agreements between them covering the responsibilities of each authority..."</i>
S29	Suggestion: ARPANSA should review the current system of approvals for transport to consider the possibility of having one competent authority for the transport of radioactive material, with memoranda of understanding or protocols with other competent authorities for transport of dangerous goods.

9.2 Compliance assurance

There is no formal compliance assurance programme, although ARPANSA has initiated work on draft regulatory guidance.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: TS-R-1 §307 states: <i>“The competent authority is responsible for assuring compliance with these Regulations.”</i>
R12	<u>Recommendation:</u> ARPANSA should ensure that all necessary aspects of the compliance assurance programme are in place and are fully effective (e.g. guidance for package approval, plan for emergency preparedness, inspections of all entities involved in transport of radioactive material, refresher training course for both industry and inspectors, distribution of information to industry and more complete inter-ministerial and interstate liaisons).

References to Chapter 9

- [1] IAEA Safety Standards Series Safety Requirements TS-R-1 “Regulations for the safe transport of radioactive material”, 2005 Edition.
- [2] IAEA Safety Standards Series Safety Guide “Compliance Assurance for the Safe Transport of Radioactive Material”, SS-112

10. PUBLIC INFORMATION

GS-R-1 §3.3(6)

The IAEA has not yet developed specific guidance on information and communications to the public for use as part of IRRS missions. However the IRRS team has reviewed this area in response to the Australian Government's request to include information and communications in the scope of the mission.

The legislation gives only indirectly to ARPANSA the right and possibility to inform the public on radiation protection and nuclear safety matter. While ARPANSA has undertaken many such activities described below, it does not have documented objectives and goals for public information and communication activities, nor a strategy how to achieve them. The Team noted that currently ARPANSA does not have a full time professional Communications Officer. However, the Team appreciates that ARPANSA uses various actions in an effort to provide the public with information relevant to ARPANSA's safety mission. These include the following:

Information regarding Facility Licence Applications: When the CEO receives an application for a facility licence, as soon as practicable after receiving the application the CEO publishes a notice in a daily newspaper circulating nationally, and in the Government Gazette, stating that the CEO intends to make a decision on the application. In the case of a nuclear installation, which includes a research reactor, nuclear fuel store, substantial waste storage or disposal facility, or a substantial radioisotope production facility, the CEO includes in the notice an invitation to people and bodies to make submissions about the application. As a part of the continuing process for the future, public submissions received will be placed upon the website, unless they are specifically requested to be confidential.

Reports to Parliament: Information on ARPANSA's activities is reported to the Parliament on a quarterly and annual basis. These reports include details of breaches, facilities licensed, reports received and operations of the CEO, ARPANSA and the Council and Committees. This information is also made available to the public and posted on the ARPANSA website.

Radiation Health and Safety Advisory Council and Committees: One of the functions of the Radiation Health Committee as set out in the Act (Para 23(1)(e)) is "to consult publicly in the development and review of policies, codes and standards in relation to radiation protection."

Licensing of the OPAL Reactor: In cases of the application for a construction licence and operating licence for the OPAL Reactor, ARPANSA placed a newspaper advertisement and a notice in the Government Gazette. It also advertised in relevant local newspapers, advised and provided copies of the full application to stakeholder organisations known to have an interest, made a detailed summary available via the ARPANSA web site, made printed and electronic copies available in major libraries, relevant local libraries, and ARPANSA Sydney and Melbourne offices.

As part of the public submission process for the reactor, at the discretion of the CEO, a public forum was held. The Team was informed that public comments received had significant impact on ARPANSA's assessment.

ARPANSA's website (www.ARPANSA.gov.au): During the IRRS Mission, ARPANSA opened its redesigned website. The new website was designed with the public in mind. The Team familiarized

itself with the new site and found it easy to use, informative and appealing to web-users. The Team noted that ARPANSA posts on the website a variety of information regarding its regulatory activities. For example, all the comments received for construction licence for the Replacement Research Reactor were also placed online, as part of the debate on a major topical and social issue.

Fact sheets: Information in the form of fact sheets on a range of topics such as cosmic radiation exposure; ionizing radiation and health; radon in homes; radioactivity in domestic smoke alarms; radioactive waste management in Australia; power lines - electromagnetic fields and possible adverse health effects; mobile telephones and health effects; radiation emissions from microwave ovens; ultraviolet radiation; etc. are posted on the ARPANSA website. In addition, school groups are provided tours of the Yallambie laboratories on request.

Technical reports arising from the activities of the scientific branches of ARPANSA are made available on the website as well as reports relating to Australia's compliance with international convention on spent fuel and radioactive waste management and the conventions on nuclear safety.

The Team supports these efforts and development tasks which ARPANSA has undertaken in the areas of Stakeholder communication/Surveys and Forums, and Stakeholder Guidance.

In light of supporting ARPANSA's development efforts, the Team noted that ARPANSA might benefit from procedures or basic guidance to be formalized and documented on such public information and communication elements like:

- criteria what, when and how to inform the public on events; positive or negative, big or small, national or international, except as described above about the formal public participation process, there are not
- how to balance between transparent and confidential information,
- how to balance between correct and best available information, and the degree of reliability before news is released,
- language and editing: how to balance formulations for public consumption between correct and understandable information
- topics that ARPANSA would not discuss with/in public (e.g. energy politics)
- use of spokesmen vs. every expert consulting with the media and public, and how to deal with direct press contacts to experts and requests for interviews with individual experts,
- during abnormal and emergency situations, in particular involving security issues, guidance and rules who has the responsibility to inform the public, and what are the restrictions.
- process of preparation of press releases, texts etc.
- use of public surveys to clarify, how well ARPANSA is known by the public, what are the public's needs and expectations, how satisfied it is; all this to form the basis for an information and communication strategy,
- participation in exhibitions, press or public outreach activities,
- training of ARPANSA staff for talking with and writing to media.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1 §3.3(6) states: <i>“The regulatory body shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public.”</i>
S30	Suggestion: ARPANSA should consider the further development and documentation of its public information and communication processes, procedures, public information and communication strategies to support its effective implementation.

11. POLICY ISSUES

11.1 Enhancing regulatory effectiveness and competence

Background:

Governments should ensure that the regulatory body is competent and has the necessary resources to fulfil its mission in relation to independent oversight and assurance to ensure public and environmental protection. The industry generally recognizes that nuclear and radiation safety is a prerequisite for sustainable development and that effective nuclear and radiation safety regulatory control is needed.

Challenges in maintaining and enhancing regulatory effectiveness and competence remain in many Member States. There is still no consensus on how to measure regulatory effectiveness. Regulatory bodies should consider what the IAEA services can do to strengthen their effectiveness.

There are a number of factors to take into account regarding effectiveness and competence:

- Harmonization with international practices,
- Commitment to resource planning,
- Commitment to knowledge management,
- Assessment of workforce competencies,
- Commitment to staff training and development,
- Commitment to continuous improvement and safety management systems,
- Promotion of the sharing of experience and lessons learned,
- Use of regulatory performance indicators.

A major challenge facing many Member States continues to be establishing, maintaining and improving technical competence in the regulatory body and technical support organizations as experienced staff retire, facilities age and the use of nuclear applications expands. Regulatory effectiveness and efficiency can be enhanced through:

- Merging regulatory responsibilities, previously separated amongst different agencies, into one regulatory body,
- More risk-informed approaches to enhance proportionality of regulatory activities,
- Regulatory body application of modern management systems,

Integrated safety oversight programmes including the use of regulatory indicators.

Discussion:

As mentioned earlier in the report the effectiveness and competence of the regulatory body is enhanced by the requirement to take into consideration international best practices in radiation protection and nuclear safety, in particular during regulatory decision making. This is practically demonstrated by ARPANSA's strong participation in international safety activities and the direct imperative in the legislation that the CEO of ARPANSA must take into account international best practices in radiation protection and nuclear safety when making licence decisions.

Benchmarking against international standards and best practice (through this IRRS mission) is part of ARPANSA's commitment to continuous improvement.

The 2005 external audit of the regulatory function conducted by the Australian National Audit Office and the development of its internal Corporate Plan and Regulatory Business Plan, including regulatory performance indicators, also provide opportunities for ARPANSA to improve its regulatory effectiveness.

ARPANSA's management recognizes the need for a sufficient number of well trained staff, formal training programmes and a staff retention strategy. ARPANSA has initiated a recruitment plan, some training activities and a programme for developing regulatory experience. However, the efforts should continue to meet current and future regulatory needs.

Enhancing the regulatory effectiveness can also be achieved through the practical arrangements to manage some regulatory requirements such as regular reporting. However, the high frequency of reporting (quarterly reports from all licensees to ARPANSA and ARPANSA reporting to the Minister) may not be the most effective use of limited regulatory resources. It is the conclusion of this discussion that a review of such mechanisms may contribute to optimizing scarce resources and allow for time to conduct more in-depth analysis of operational data. In Finland, for example, the regulatory body STUK managed to convince the Government, while complying with current legislation, to submit detailed reports on some regulatory issues only every three years.

Safety culture was also briefly discussed and ARPANSA Management is fully aware of its importance and is committed to continue promoting safety culture within ARPANSA and with the licensees.

11.2 Risk-informed and performance-based approach to regulation

Background:

In some Member States, there is a trend towards more scientific, risk-informed and performance-based approach to regulation, rather than a wholly compliance-based approach. Similarly, new licensing procedures are being developed to improve predictability of the process and help to reduce financial risks of nuclear power plant construction. It would therefore be essential that there be a framework to guide the regulatory transition.

Key elements

- Guidance exist for risk informed regulatory decision making
- Process for determining the safety significance of regulatory actions
- Defined outcomes based on promoting safety
- Prioritise regulatory activities based on safety significance
- Expectations for balancing risk-informed and deterministic decision-making

Discussion:

The discussions included how the USNRC has adopted a risk-informed approach to its regulatory programs. NRC's approach uses risk insights, rather than specific risk criteria, to inform its regulatory decisions in a variety of areas. This approach is a graded one, which at one end of the spectrum employs Probabilistic Risk Assessments in evaluating the significance of events at nuclear power plants and making determinations under its Reactor Oversight Program. At the other end of the spectrum, risk insights from operational experience and professional judgment are applied to inspection, licensing and program development in the areas of nuclear materials and decommissioning. These have included the frequency and scope of materials inspections, cleanup criteria for release of sites for unrestricted use and licensing guidance for various materials users.

This approach helps minimize unnecessary regulatory burden on licensees and helps assure that NRC's resources are efficiently and effectively applied.

ARPANSA currently applies a deterministic approach approximately based on hazard categorization for the source or facility. This approach could better combine the inherent risk of a source or facility with the management performance of the operator and give an enhanced awareness of the residual risk. ARPANSA is moving toward an approach that recognises the desirability of compliance monitoring based around residual rather than inherent risk.

The Probabilistic Safety Assessment of the OPAL Reactor was not utilized directly during regulatory safety assessments. Once the Probabilistic Safety Assessment is built upon through experience of operation, ARPANSA may rely on it more heavily when conducting safety assessments.

11.3 Openness and transparency

Background:

Openness and transparency in regulation is essential to encourage continuous improvement of performance and building public confidence. The international community promotes openness through several services. However, finding a proper balance between public availability of information and protection of confidential data remains a challenge.

Key elements

- Strategies for engagement of stakeholders
- Stakeholder involvement in regulatory decision making
- The basis for regulatory decisions made available to stakeholders
- Use of electronic communication, including the internet, for communication to stakeholders
- Low threshold for informing stakeholders of nuclear and radiation safety related information

Stakeholder engagement is important for effective regulation. Hence it is important for regulatory bodies to develop and implement strategies for engagement with their stakeholders so that trust in the regulatory body's competence, integrity and impartiality can be established. This was regarded as being important because, even though some stakeholders may not always agree with a decision, if there is trust and respect they will accept the integrity of the decision making process.

Discussion:

ARPANSA has not developed a formal strategy for sharing information with the public (see chapter 10 for more details). However, many different actions are being taken by ARPANSA to improve openness and transparency. The web site of ARPANSA contains substantial information on general issues related to ionizing radiation (Radiation and Health Fact Sheets). There is little information about the general daily regulatory activities conducted. However, the licensing process of the OPAL reactor is well documented, including all three statement of reasons that accompanied the CEO's licensing decisions.

The regulations make provisions for formal public information and consultation when an application for a nuclear facility is submitted to ARPANSA. Some of the Safety assessment reports for radiation prescribed facility licence shown to the reviewers during the mission also indicate that public is informed about the application through the press. The development of new codes of practices by committees includes a public consultation phase, as required by the Regulations. The

ARPANS Act clearly states that both radiation health and nuclear safety committees have to consult publicly in the development and review of policies, codes and standards.

The Web site has been completely redesigned very recently (actually the new web site was made available to the public during the IRRS mission on Monday July 2). One of the objectives was to make information more accessible. ARPANSA recognizes that there will probably be a heightened public interest in its work with the current examination of the role of uranium mining and nuclear power in Australia's economy and energy mix. Various international experiences of building relationships with the public and the media were discussed. In Finland and Denmark, the regulatory bodies have organized training sessions for journalists for them to better understand the nuclear technologies. The positive impact in both countries is that Regulatory Body's view point is more often considered and reported in the press. In the US, the public meetings organized by the NRC for local populations surrounding a particular site have always been welcomed and attended by an interested audience. NRC also employs other techniques, such as webcasting many of its Commission meetings and making a substantial volume of its regulatory documents available to any member of the public via the Internet. ARPANSA emphasized that it is currently not a general practice for federal agencies in Australia to hold open meetings or to have them on-line via internet. However, agendas and summaries of the committees and council meetings, committees' publications of programme statements and reports are available on the web.

One of the difficulties that ARPANSA believes it must deal with when communicating with the public is to avoid, to the extent possible, the perception that the provision of information on the regulated industry is being undertaken as an advocate for the industry.

11.4 Human Resources and Knowledge Management

Background:

In many regions, the human resource of the nuclear community is aging. With the nuclear renaissance in some Member States there is a need for increased human resources. The need for knowledge management of the existing human resources and for knowledge sharing is recognized. The new move towards network building for global knowledge sharing and management is showing promising results. Efforts in this direction need to continue to ensure availability of resources. Also, facilities critical to the conduct of important safety research need to be preserved.

Key elements are:

- Plans to attract and retain staff;
- Existing strategies to identify, capture, and transfer knowledge internally and externally;
- National or regional training centres;
- Identified specialized skills and identified strategies to maintain and build competence;
- Appropriate emphasis on regulatory research and technical support organizations.

Discussion:

Human resource issues are of particular concern for ARPANSA management. The issue is not simply the availability of funds to recruit people, but rather to find qualified and experienced people in radiation protection, nuclear safety and regulatory matters. As with many regulatory agencies, the potential for substantial numbers of retirements from the work force along with a looming increase in work load, make this issue a primary focus of management in ARPANSA. There are currently a

number of positions open, and an international recruitment campaign has been initiated in relation to some of those roles. In particular for regulating nuclear safety, it is difficult to identify competent people and to motivate them to join ARPANSA since there is only one nuclear facility to regulate and not so many opportunities to make a career. Recruiting from outside Australia is also a challenge due to its geographic location relative to many of the centres of expertise in nuclear technology. In radiation safety, the situation is less critical because there are reasonable numbers of people with the right technical skills available on a national scale.

The option to set up cooperative agreements with other regulatory bodies abroad was discussed, in order to have staff trained over long period of time and to give an international dimension to their career. This type of cooperation would benefit the already experienced staff. In this connection, the experience of Finland has been very positive over the last twenty years. Generally, this approach is most effective when an exchange of trained and experienced personnel can be arranged.

For junior professionals, ARPANSA is setting up a formal graduate recruitment programme. It will be implemented next year with the recruitment of four new junior staff (BSc or MSc level). Persons selected for this programme will spend time in each of the technical branches of ARPANSA over their first year, thus exposing them to the full range of agency activities.

The availability of IAEA training material, including the Post Graduate Education and specialized Courses were presented as a starting point for developing a formal training programme for the Australian Regulators.

With the potential future increase of the nuclear industry in Australia, there will be a need for a larger regulatory staff with a broader scope of competences. This could be anticipated in the recruitment plans of ARPANSA, which will certainly play an important role in the future regulatory framework. It is, to a certain extent, a measure that anticipates an expanded industry into the future.

11.5 The promotion of national uniformity in radiation protection

Background:

Of the functions of the CEO of ARPANSA is “to promote uniformity of radiation protection and nuclear safety policy and practices across jurisdictions of the Commonwealth, the States and the Territories.” The federal regulatory framework makes several provisions that contribute to this national uniformity, among them the council and committees. In addition, a specific instrument for the development of the national uniformity in radiation protection has been created in 1999: the national directory for radiation protection (NDRP). In the preparation of this IRRS mission (letter of CEO dated May 08), the CEO of ARPANSA has invited the reviewers to address this specific policy issue in the following terms:

“ARPANSA has developed a National Directory for Radiation Protection. This represents an agreed approach to radiation protection throughout the nine jurisdictions of Australia (the Commonwealth of Australia, six States and two Territories). In 1999, the Australian Health Ministers Conference (made up of Health Ministers of each jurisdiction) agreed that a national directory would be the best way to achieve uniformity in radiation protection. Since that time the first edition of the National Directory has been produced by ARPANSA, under the auspices of the Radiation Health Committee. The directory has now been adopted by each jurisdiction. ARPANSA is currently preparing a second edition of the Directory for public consultation. I welcome this opportunity to have experts involved in this mission to focus on the efficacy of the Directory and its promotion within the jurisdictions to achieve national uniformity in radiation protection.”

Discussion:

The issue of national uniformity in radiation protection was discussed in several occasions during the mission and is referred to in several chapters of the report. A specific session took place on Friday, 29 June during which ARPANSA staff provided the IRRS Team with some detailed information on the history, evolution and implementation of the directory. A subsequent discussion session was also organized on Monday 2 July with the CEO of ARPANSA, the chairpersons of the Radiation Health and Safety Advisory Council, the Radiation Health Committee, Nuclear Safety Committee and the Radiation Regulators Forum.

The history of the discussions between all the Australian radiation safety regulators back to the years 90s was reported, as well as the agreement to establish a sort of regulatory model, based on IAEA standards and established best practices, to be implemented by each State, Territory and Commonwealth regulators. The decision to progress uniformity through the development of the National Directory was made in August 1999. Edition 1 of the National Directory, published in August 2004, was a very positive sign of good will from all parties. The drafting of Edition 2 started right after the publication of Edition 1, and it is now ready for the public consultation.

From the discussions, it appears that this unanimous enthusiasm and commitment for further improving the national uniformity in regulating radiation and nuclear safety is still intact and the future looks quite promising. Despite some difficulties, the process of bringing everybody together is going on. In addition to the national directory, there are other recent achievements towards the harmonization of radiation protection: the code of practice for the security of radioactive sources and the development of codes of practice for medical applications and uranium mining and processing. There is still a long way to go but eventually one day the nine regulators of radiation and nuclear safety of Australia will come up with unique set of harmonized regulations for all nine jurisdictions.

One of the big achievements of the National Directory, mentioned by the participants at different occasions, is the harmonization of the exemption levels throughout the different jurisdictions of Australia. The Council and the Committee periodically review the implementation of the National Directory. The CEO of ARPANSA also sent a formal letter on March 2006 to all regulators requesting information about the progress on its implementation.

However, there is no formal process to monitor the effective implementation of the National Directory into the various regulatory frameworks and it was noted that the function of the CEO of ARPANSA is to promote uniformity but not to control its implementation. The IRRS Team suggested the possibility of establishing an internal self assessment and peer reviews between the nine regulators. Since the National Directory was published in 2004, and considering the lengthy process of revising legislation and regulations, it was concluded that a lot has been achieved.

Some similarities and difficulties of other countries with harmonization of radiation protection were discussed. These include:

- The relationships between the US NRC and the 34 Agreement States within the US;
- The European Union with its 27 countries trying to elaborate and implement directives and recommendations; and
- The IAEA and its Member States receiving its assistance under the “*Model Project on upgrading radiation protection infrastructure*” that lasted for more than ten years.

The importance of keeping a permanent communication between interested parties was addressed and stressed. The stronger legal framework of the European Union, with the issuance of directives,

to be implemented into national regulatory and penalties for States not doing so was found interesting by Australians. The time consuming process and the voluntary optimism were recognized as universal parameters.

The uniformity of radiation safety regulations is being very much appreciated by licensees, in particular those who are operating in different jurisdictions.

The team of reviewers acknowledged that promotion of uniformity is a reality in Australia, and that extensive progress has been made within a relative short period of time. It has been suggested that Australia host the next international conference on regulatory infrastructures, to better expose to the international community its on-going efforts and its achievements in this area.

11.6 Emergency response

Background:

The mission of ARPANSA is to protect the Australian public and environment from the harmful effects of radiation. In this function ARPANSA has two primary roles: direct regulatory role (as the Commonwealth nuclear installation regulator) and advisory role (for Government, States and Territories).

ARPANSA has strong the health physics competence located in its Melbourne office. Connected to health physics, ARPANSA has awell organized, developed and equipped Emergency Operations Unit.

With respect to ARPANSA's regulatory functions in emergency preparedness, licensing reviews and inspections for nuclear facilities are done in a systematic and thorough manner.

However, the issues of communication, coordination and cooperation between authorities during emergencies, emergency preparedness arrangements and procedures inside ARPANSA's regulatory arm and relationship between ANSTO as nuclear operator and ARPANSA as its regulator were discussed.

Discussion:

It was recognized that ARPANSA operates in the multi-jurisdictional context for Australian radiation emergency preparedness. The emergency preparedness arrangements involve many players at different levels including the ministerial level, Commonwealth, State and Territory authorities, and operational levels.

There is a written allocation of responsibility for notification and decision-making. However, ARPANSA has both the regulator and advisor roles and in both cases the relatively large number of players and wide net of communications can pose a potential source of delays and loss of information, in particular in the early phases of the emergency situation. Streamlining the emergency organization and practical communication routes might bring benefits.

It was recognized that ARPANSA's regulatory arm would benefit if it would establish, implement, test, maintain and continuously improve in-house procedures and policies:

- managing for its role in nuclear or radiation events and emergencies arising with licence holders.

- describing how it provides the public and other administration with appropriate information during and after events and accidents.

With regard to operation of the OPAL reactor in any emergency circumstances, the Team noted some lack of clarity between ANSTO as a nuclear operator and ARPANSA as its regulator. It would be beneficial to clarify further and document these roles, responsibilities and rights.

11.7 Implementations of measures to improve security of sources

Background:

Australia was very active in the development of the IAEA Code of Conduct on the safety and security of radioactive sources. Australia committed itself very rapidly for the implementation of the Code (May 2004) as well as for the implementation of the associated guidance on import and export of radioactive sources (November 2004). Some national actions have already been initiated (see chapter 5 of this report) and a lot remain to be done. However, the CEO of ARPANSA, when requesting the IRRS Mission, express the will to brief the IRRS Team on the current status.

Discussion:

The safety and security of radioactive sources was only briefly mentioned during the formal policy issue sessions of the Mission. The CEO mentioned the development of the Code of Practice for the security of radioactive source. He considers that the whole process was managed in a very collegial way with other regulators and governmental agencies involved. Now comes the time for all Regulators to implement the code.

The current non-binding status of the Code of Conduct was discussed. ARPANSA welcome any discussion on that at the international level, and would see no major difficulty to strengthen the commitment of States (through a convention for example).

Expert members of the IRRS Team had a meeting in Canberra with the Assistant Secretary of the Chemical, Biological, Radiological and Nuclear (CBRN) security division of the Department of the Prime Minister and Cabinet. This division was established in 2003 to provide independent advice to the prime minister and to coordinate between the different federal agencies, states and territories governments. Liaison at the international level on security issues is also part of this division's activities. The Assistant Secretary will go and visit States in North America and Europe in the coming weeks. A presentation of the national framework related to the security of hazardous materials was given, in order to clarify the specific role of ARPANSA. The work done by IAEA in the recent years to provide guidance on safety and security of radioactive sources was found very useful by the Australian government.

11.8 Stakeholders consultation

Background:

In the specific context of Australia and the federal organization of the regulatory control of ionizing radiation the consultation with the different stakeholders is an important matter.

In addition to the specific actions towards public information (see above), the different fora where ARPANSA is being active are the federal government, the radiation safety regulators community and the licence holders, which are mainly federal public organizations.

Discussion:

With the States and Territories Regulatory Bodies, some formal mechanisms for consultation and exchange of experience established by the ARPANS Act are working quite well: the Radiation Health and Safety Advisory Council, the Radiation Health Committee and the Nuclear Safety Committee. However, all Regulatory Bodies are not involved in these groups

A less formal arena has been established recently to gather all Regulatory Bodies: the Radiation Regulators Forum. Regulators meet periodically to exchange on the national directory, its implementation. Significant problems are reported and advice from other regulators on specific licence issues may be requested. The Radiation Regulators Forum may, if appropriate, call the attention of the Radiation Health Committee.

There is a similar and recent initiative of European radiation safety regulators to gather and address new issues in radiation protection to be addressed to the European Commission.

In the context of this regulatory forum, a specific working group has been established to address the practicalities of updating the regulatory regime in accordance with the increase of the uranium mining industry. This working group involves regulators and operators. One of the main items being discussed is the methodology and requirements for the environmental impact assessment. US NRC is expecting to receive about 15 new applications for mining activities in a near future. A standard environmental impact assessment has been developed to provide guidance to the applicants and improve the efficiency of the review by the regulator.

With its licensees, ARPANSA has also set up a forum of licence holders, in which exchange of views between the regulator and the licensee can take place in an informal way and outside of any regulatory process. Two meetings have been organized so far.

In addition, a survey was conducted in 2005 to collect from the licensees their expectations on their relationship with ARPANSA. ARPANSA is still in the process of analysing the information collected and of identifying priorities for implementation. One of the clear priorities is to develop appropriate regulatory guidance.

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APPENDIX II – MISSION PROGRAMME

Mission Programme		
Sunday 24 June		
2.00pm – 6.00pm	IRRS Review Team briefing in Trades Hall meeting room at Radisson Hotel	
Monday 25 June		
8.15am	Depart to ARPANSA Headquarters in Miranda	
9.00am – 1.00pm	Entrance meeting at Miranda offices of ARPANSA <ul style="list-style-type: none"> • Welcome and introduction • Opening remarks • Introduction of IAEA experts • Briefing for IRRS team on regulatory body and review areas 	John Loy Kaare Ulbak and Khammar Mrabit Rhonda Evans
1.00pm – 2.00pm	BBQ lunch with counterparts and other ARPANSA staff	
2.00pm – 3.00pm	<ul style="list-style-type: none"> • Introduction of counterparts and working arrangements • Orientation and housekeeping • Closing remarks 	Rhonda Evans Kaare Ulbak
Tuesday 26 June		
8.15 am	Depart to ARPANSA Headquarters in Miranda	
9.30 – 11.15am	Presentation on authorization, review & assessment, inspection & enforcement	Rhonda Evans All reviewers except Tero Varojoranta
11.15am – 4.00pm	Interviews with ARPANSA staff	IRRS Review Team
4.00pm - 6.00pm	IRRS Review Team Daily Meeting	IRRS Review Team
Wednesday 27 June		
7.45 am	Depart Hotel by taxis to ANSTO for inspection of OPAL until 4.00 pm	Jacques Aguilar David Graves
8.15 am	Depart to ARPANSA Headquarters in Miranda	
9.15am – 11.30am	Depart ARPANSA for ANSTO Lucas Heights for tour of OPAL and meeting with Parliamentary Secretary and staff	John Loy Rhonda Evans Khammar Mrabit Kaare Ulbak George Pangburn
9.30am	Depart Miranda for visit to HIFAR at ANSTO	Jose-Luis Revilla John Rowat Phil Mabbott Vince Diamond

Mission Programme		
11.00am	Depart Miranda for inspection of GATRI at ANSTO	Bob Irwin Hilaire Mansoux Diane Harrison John Fredriksen
9.30am – 4.00pm	Interviews with ARPANSA staff	Tero Varojoranta
9.30am – 1.00pm	Continue work on thematic area	Wilbert Leotwane
11.00am – 4.00 pm	Interviews with ARPANSA staff	Kaare Ulbak Khammar Mrabit George Pangburn
1.00pm – 4.00pm	Desktop exercise in assessment of licence application for HIFAR	Jose-Luis Revilla John Rowat Rhonda Evans Phil Mabbott
4.00pm – 6.00pm	IRRS Review Team Daily Meeting	
Thursday 28 June		
6.30am	Depart Hotel for 8.15am flight to Melbourne for inspection of teletherapy laboratory at Yallambie offices if ARPANSA	Bob Irwin Hilaire Mansoux Jim Scott
8.15 am	Depart Hotel to ARPANSA Headquarters	
9.30 am	Depart Miranda for inspection of ANSTO waste operations	Wilbert Leotwane John Rowat
9.30am – 4.00pm	Interviews with ARPANSA staff	Kaare Ulbak Khammar Mrabit George Pangburn Tero Varojoranta Jose-Luis Revilla
9.30am – 4.00pm	Continue work on thematic area	Jacques Aguilar David Graves
3.30pm – 6.00pm	IRRS Review Team Daily Meeting	
Friday 29 June		
8.15am	Depart Hotel to ARPANSA Headquarters	
9.30am – 12.00noon	Interviews with ARPANSA staff	Kaare Ulbak Khammar Mrabit George Pangburn
9.30am – 12.00noon	Continue work on thematic area	Tero Varojoranta Bob Irwin Hilaire Mansoux Jacques Aguilar David Graves Jose-Luis Revilla Wilbert Leotwane John Rowat

Mission Programme		
1.00pm – 4.00pm	Policy issues	Kaare Ulbak Khammar Mrabit George Pangburn David Graves Hilaire Mansoux
4.00pm – 6.00pm	IRRS Review Team Daily Meeting	
Saturday 30 June		
8.30am – 6pm	Team meeting/drafting report	
Sunday 1 July		
8.30am – 12 noon	Team meeting/drafting report	
12.30pm	Social event - Lunch at Peter Doyle Restaurant – Sydney circular Quay	
Monday 2 July		
8.15am	Depart Hotel to ARPANSA Headquarters	
9.30am – 10.30am	Joint Session - Processes of development and implementation of regulations and guides	Rhonda Evans Peter Burns Vince Diamond
10.30am – 12noon	Interviews with ARPANSA staff	IRRS team
1.00pm – 4.00pm	Interviews with ARPANSA staff	IRRS team
2.00pm – 4.00pm	Meeting with representatives of advisory bodies	Kaare Ulbak Khammar Mrabit George Pangburn
4.00pm – 6.00pm	IRRS Review Team Meeting	
Tuesday 3 July		
6.00am	Depart hotel for 7.40am flight to Canberra for meetings with ministerial adviser and source security policy makers	Bob Irwin Hilaire Mansoux David Tredinnick
6.30am	Depart hotel for 8.15am flight to Melbourne for meeting with REOU- pick-up at airport by REOU vehicle	Tero Varojoranta
8.15am	Depart Hotel to ARPANSA Headquarters	
9.00am – 3.30pm	Interviews with ARPANSA staff Discussions between IRRS Reviewers and Counterparts on draft report section	Kaare Ulbak Khammar Mrabit George Pangburn David Graves Jacques Arguilar John Rowat Jose Luis Revilla Wilbert Leotwane

Mission Programme		
3.30 pm – 5.30pm	IRRS Review Team Meeting	
Wednesday 4 July		
8.15am	Depart Hotel to ARPANSA Headquarters	
9.00am – 4.00pm	Interviews with ARPANSA staff Drafting Report	IRRS Team
4.00pm – 6.00pm	IRRS Review Team Daily Meeting First draft full report given to counterpart	
Thursday 5 July		
8.15am	Depart Hotel to ARPANSA Headquarters	
9.00am - 3.00pm	Drafting and finalization of mission report	
4.00pm	Plenary discussions on counterparts comments, final drafting and issuance of draft report	
Friday 6 July		
9.00 am	Depart Hotel to ARPANSA Headquarters	
10.00am	Policy Issues	
10.30am	Morning tea with counterparts and other ARPANSA staff	
11.30am	Exit meeting	
Saturday 7 July Departure from Sydney		

APPENDIX III – SITE VISITS

1.	Inspection of OPAL – Sydney
2.	Visit to Yallambie MRB- Melbourne
3.	Inspection of GATRI at ANSTO Sydney
4.	Inspection of ANSTO waste operation
5.	Desktop exercise in the assessment of licence application for HIFAR
6.	Inspection of Teletherapy Laboratory, ARPANSA Yallambie

APPENDIX IV – MISSION COUNTERPARTS

Item	Subject Area	IRRS Experts	Lead Counterparts
	Legislative and governmental responsibilities	<ul style="list-style-type: none"> • K. Ulbak • G. Pangburn • K. Mrabit 	<ul style="list-style-type: none"> • John Loy • Rhonda Evans • Olga Liavas • Ian Graham
	Responsibilities and Functions of the Regulatory Body	<ul style="list-style-type: none"> • K.Ulbak • G. Pangburn • K. Mrabit 	<ul style="list-style-type: none"> • Rhonda Evans
	Organization of the regulatory body	<ul style="list-style-type: none"> • K.Ulbak • G. Pangburn • K. Mrabit 	<ul style="list-style-type: none"> • Rhonda Evana
	Activities of the Regulatory Body	<ul style="list-style-type: none"> • J. Aguilar • D. Graves • R. Irwin • H. Mansoux • T. Varjoranta • J. Revilla 	<ul style="list-style-type: none"> • Rhonda Evana • Jim Scott • Guenael Le Cann • V Diamond • John Ward • J. Loy • Rhonda Evans • Peter Burns • D. Lawrence • LeonRailey
	Management System for the Regulatory Body	<ul style="list-style-type: none"> • T. Varjoranta 	<ul style="list-style-type: none"> • Ian Graham

	Emergency Planning and Preparedness	<ul style="list-style-type: none"> • T. Varjoranta 	<ul style="list-style-type: none"> • S. Solomon • M. McGavin • V. Diamond • J. Ward
	Policy Issues	<ul style="list-style-type: none"> • K. Ulbak • G. Pangburn • K. Mrabit • D. Graves • T. Varjoranta 	<ul style="list-style-type: none"> • John Loy • Rhonda Evans • Olga Liavas • Ian Graham
	Decommissioning and remediation	<ul style="list-style-type: none"> • J. Revilla • J. Rowat • W. Leotwane 	<ul style="list-style-type: none"> • P. Mabboot • Vince Diamond • R. Evans • S. Sarkar
	Radioactive Waste	<ul style="list-style-type: none"> • J. Rowat • W. Leotwane 	<ul style="list-style-type: none"> • P. Burns • S. Sarkar
	Public Information	<ul style="list-style-type: none"> • T. Varjoranta 	<ul style="list-style-type: none"> • D. Tredinnick • R. Evans
	Safety and Security of Radioactive Sources	<ul style="list-style-type: none"> • R. Irwin • H. Mansoux 	<ul style="list-style-type: none"> • D. Tredinnick

REVIEWERS AND CONTRIBUTORS



APPENDIX V – RECOMMENDATIONS, SUGGESTIONS, GOOD PRACTICES

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
A	Legislative and governmental responsibilities	S1	<i>The Australian Government should consider in any proposed future amendment to the ARPANS legislation, an explicit reference to the requirement that an operator has primary responsibility for safety to reflect Principle 1 of IAEA Fundamental Safety Principles.</i>
S2		<i>The Australian Government should consider in any proposed future amendment to the ARPANS legislation that the legislation incorporate an explicit legislative basis for ARPANSA’s regulation of the land transport of radioactive material.</i>	
G1		<i>The statutory requirement to take into account international best practice in radiation protection and nuclear safety in licensing decisions as required by s32(2) and s33(3) of the ARPANS Act is good practice.</i>	
B	Responsibilities and functions of the regulatory body	S3	<i>The CEO of ARPANSA should consider an expedited implementation of the arrangement that has been put in place to utilise inspectors from the State of Victoria to inspect ARPANSA’s own compliance with the ARPANS Act in relation to its regulated sources and facilities.</i>

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		G2	<i>One of the functions of the CEO of ARPANSA is to promote uniformity of radiation protection and nuclear safety policy and practices across jurisdiction of the Commonwealth, the States and the Territories (Section 15 (1) (a) of the Act). The instrument for achieving uniformity is the National Directory of Radiation Protection (NDRP). The progress made by ARPANSA so far in promoting uniformity among the States and Territories has been remarkable.</i>
C	Organization of the regulatory body	R1	<i>ARPANSA should establish and implement a more comprehensive training programme for regulatory staff.</i>
		S4	<i>ARPANSA should consider reviewing its current Corporate Plan and prioritize and implement the activities contained in the Regulatory and Policy “Business Plan”, to ensure that it has an effective and sustainable regulatory infrastructure that will respond appropriately to any national challenges, including the Australian Government’s Expanded Nuclear Industry Strategy.</i>

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	<i>Recommendations, Suggestions or Good Practices</i>
		S5	<i>ARPANSA should consider a strategy for strengthening the working relationship between the Regulatory and Policy Branch and the scientific and technical branches in order to optimize its technical, research and regulatory functions. This strategy should include the provision of necessary budget and human resource to ensure the successful implementation of the Regulatory and Policy “Business Plan” and in particular to assure ongoing technical support for the carriage of the regulatory function.</i>
		S6	<i>ARPANSA should consider its strategy for effective implementation of the “Workforce Planning and Development” document derived from its Corporate Plan 2005-2008.</i>
		G3	<i>ARPANSA’s use of international peer review team and services from the IAEA is good practice</i>
		G4	<i>The Graduate Recruitment portion of the Workforce Planning and Development will, if effectively implemented, ensure the ongoing availability of appropriately trained and qualified staff and is good practice.</i>

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	<i>Recommendations, Suggestions or Good Practices</i>
		G5	<i>ARPANSA is very engaged in the framework of international cooperation and in the establishment and implementation of international standards and undertakings. Bilateral agreements are well developed. These activities support the statutory requirement to incorporate international best practices into regulatory decisions. This is good practice.</i>
D	Activities of the regulatory body Authorization Research Reactors	R2	<i>ARPANSA should prepare a regulatory guidance document that relates to regulation 51 conditions (relevant change with significant implications for safety) and covers guidance on the scope of the condition and the type of information that is required to be submitted by the licensee to support its application for an approval under regulation 51.</i>
	Authorization - Sources and Industrial Practices	S7	<i>ARPANSA should establish clearly defined procedures addressing the regulatory requirements for amendment, suspension or cancellation of a licence.</i>

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	<i>Recommendations, Suggestions or Good Practices</i>
	Authorization – Decommissioning	S8	<i>The Australian Government should consider in any proposed future amendment to the ARPANS legislation, an amendment to the regulatory framework to deal more explicitly with environmental chronic exposure situations and interventions not linked with accidental situations of controlled facilities.</i>
		S9	<i>ARPANSA should consider including a requirement for formal long-term management plan for rehabilitated sites to be included in its licensing arrangements in the context of rehabilitated sites that may not to be released without restriction in the near future.</i>
	Authorization Radioactive Waste Management	S10	<i>ARPANSA should consider the establishment of a formal agreement with the State regulator of Sydney Water in order to facilitate more effective assurance of radiological safety of the public from all discharge pathways. ARPANSA should consider a more direct reporting mechanism for operators in relation to liquid discharges to the environment.</i>
	Review and assessment – Research Reactors	R3	<i>ARPANSA should prepare regulatory guidance in relation to its expectation for the Periodic Safety Review imposed by condition on the facility authorizing the operation of the OPAL reactor.</i>

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
	Review and assessment - Decommissioning	R4	<i>ARPANSA should publish guidelines that establish the stage at which a decommissioned facility may be released without any further radiological restriction and/or the continuing restrictions that may apply.</i>
		R5	<i>ARPANSA should publish guidance that makes clear that once the reactor is shut down, the activities or operations that cannot be done using operational methods or within the bounds of the safety case for normal operation should be part of the planning for decommissioning of the reactor.</i>
		R6	<i>The Australian Government should introduce an amendment to the ARPANS legislation to require a timely submittal of a decommissioning plan by an operator If a Possess or Control authorization is to be granted to ANSTO after the HIFAR reactor shutdown, ARPANSA should limit the period of such an authorization with an expiry date and require the submission of a final decommissioning plan for the reactor.</i>
		S11	<i>ARPANSA should consider providing guidance to make clear what the licensing process is in the transition period between final shutdown and decommissioning for controlled facilities</i>

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		S12	<i>The Australian Government should consider amending the ARPANS legislation to impose a requirement that decommissioning plans provide estimated budgets for decommissioning, including costs for the management of the resulting waste.</i>
	Inspection and Enforcement	R7	<i>ARPANSA should incorporate into its internal guidance a requirement to include unannounced inspections in its compliance program for all licensees.</i>
	Inspection – Research Reactors	S13	<i>ARPANSA should consider a systematic periodic assessment of the inspection programme to evaluate its continued effectiveness, using feedback and lessons learned from previous inspections.</i>
		S14	<i>ARPANSA should consider an appropriate mechanism be included in its inspection procedures to ensure that there is a synthesis of issues from all compliance activities (inspections and reviews) in its correspondence with holders in order to improve the understanding of holders of the key issues that arose out of inspection activities.</i>

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	<i>Recommendations, Suggestions or Good Practices</i>
	Inspection – Sources and Industrial Practices	R8	<i>ARPANSA inspectors should always carry an appropriate hand-held radiation monitor to enable them to perform an independent verification of licensee measurements while conducting inspections.</i>
		G6	<i>In the observed source, waste and decommissioning inspections, ARPANSA staff closed the inspection by asking the licensees for feedback about the conduct of the inspection. This is good practice.</i>
	Inspection – Radioactive Waste Management	S15	<i>ARPANSA should consider implementing an appropriate mechanism to ensure the timely dissemination of internal feedback gained from inspections to the rest of the staff engaged in inspections.</i>
	Enforcement	S16	<i>ARPANSA should consider the most effective means of finalizing a comprehensive compliance strategy (incorporating its enforcement policy) that clearly identifies or defines the levels of non-compliance (for example, what constitutes a minor non-compliance or breach) and the appropriate response (whether enforcement or other actions) available to the regulatory body to address each.</i>

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	<i>Recommendations, Suggestions or Good Practices</i>
	Regulations and Guides - Decommissioning	S17	<i>ARPANSA should consider the most effective means of finalising RB-STD-10-06, Regulatory Guidance for the Decommissioning of Controlled Facilities under the Australian Radiation Protection and Nuclear Safety Act 1998, and publish it as soon as possible.</i>
		G7	<i>RB-STD-10-06, Regulatory Guidance for the Decommissioning of Controlled Facilities under the Australian Radiation Protection and Nuclear Safety Act 1998, although not yet finalized and endorsed by the CEO of ARPANSA, represents a good practice because it provides a comprehensive collection of requirements and recommendations for the full process of decommissioning of nuclear facilities.</i>
	Regulation and Guides – Radioactive Waste Management	S18	<i>ARPANSA should consider the most effective means of developing its regulatory guidance to ensure that it includes an appropriate review and approval process including consideration of involvement by advisory committees and the public; a method for determining accessibility of the guidance document to stakeholders, including the public; and a method for periodic review of the guidance document to ensure that it provides current regulatory information and current best international practices.</i>

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
E	Safety and Security of radioactive sources	S19	<i>ARPANSA should determine the most effective means for coordinating with States and Territories to develop implementation plans for each of the recommendations in the COAG Report. For example, requests through formal channels should be sent, as needed, to State and Territory governments in order to maintain momentum and to help to overcome such potential difficulties as lack of resources.</i>
		S20	<i>ARPANSA should consider the most effective means of expediting its establishment of an on-line secure national sealed source registry.</i>
		S21	<i>ARPANSA should consider the most effective means to clarify the project plan for this activity, including the delineation of milestones and regulatory reporting, to enhance its regulatory framework and serve as an example for other Australian regulators.</i>
		S22	<i>ARPANSA should consider the most appropriate steps it must take to advise the responsible portfolio to amend the Customs (Prohibited I) Regulations to clarify the application of the IAEA Code.</i>

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
F	National infrastructure for Radioactive waste, Decommissioning and Remediation	S23	<i>ARPANSA should consider the most effective means to promote a national system for classification of radioactive waste. This would serve national uniformity and would assist state governments with regulatory oversight of radioactive waste, particularly if the proposed Commonwealth Radioactive Waste Management Facility (CRWMF) were to become a national facility.</i>
		S24	<i>ARPANSA should consider developing guidance for clearance of materials from decommissioning.</i>
G	Emergency Preparedness	R9	<p><i>ARPANSA should establish, implement, test, maintain and continuously improve in-house procedures and policies related to:</i></p> <ul style="list-style-type: none"> • <i>ARPANSA should establish, implement, test, maintain and continuously improve in-house procedures and policies related to the management of its role in nuclear or radiation events and emergencies arising with holders.</i> • <i>The provision of appropriate information to all key stakeholders during and after events and accidents.</i>
		G8	<i>ARPANSA has a strong health physics capability and a well equipped, very mobile, well trained and motivated Emergency Operations Unit for meeting short notice requests and deploying wider ARPANSA staff to aid in a large scale radiation incident.</i>

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	<i>Recommendations, Suggestions or Good Practices</i>
H	Management System for the regulatory body	R10	<i>ARPANSA should review the completeness of its existing set of QA-procedures related to regulatory work and ensure consistency in the manner of their implementation in everyday regulatory work.</i>
R11		<i>ARPANSA should expand its regulatory management system to include measures to promote and support strong safety culture.</i>	
S25		<i>ARPANSA should consider expanding its “Corporate governance - strategic planning framework” to include an analysis of the contemporary operational environment and developing a process for interaction with appropriate federal government departments to support the development and implementation of the framework. ARPANSA should consider the preparation of a strategic road-map to identify, analyse and suggest ways forward with respect to related regulatory challenges and how they could be met (inter alia to include needed new safety regulations, regulatory processes, structures, competences and resources). ARPANSA should consider an executive level training event be organized for the EBOM to facilitate the implementation of this measure ARPANSA should consider revisiting the activities of the EBOM. in light of any reconsideration of corporate strategies and emergent priorities.</i>	

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		S26	<i>ARPANSA should consider the enhancement of its risk management process to include further development of the risk identification process.</i>
		S27	<i>ARPANSA management has demonstrated its commitment to the establishment, implementation, assessment and continual improvement of the MS. However, ARPANSA management should consider the resource allocation for the above mentioned activities in order to ensure that adequate resources are allocated in accordance with the above mentioned commitment</i>
		S28	<i>ARPANSA should consider the most effective way to determine the cost structure of the regulatory function, including a strategy for collecting the necessary data (i.e. exact spent person hours per activity), tailoring appropriate software for tracking personnel time and other costs, and preparing a communication plan in order to communicate the cost recovery program to the staff and main stakeholders. ARPANSA should consider the desirability of early co-operation between the financial administration and operation branches in developing and implementing the cost recovery system</i>
		G9	<i>ARPANSA's regulatory strategic planning framework is systematic. This is good practice</i>

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		G10	<i>The ARPANSA Audit Committee provides an effective oversight of the effectiveness of the implementation of internal controls and assists in a value added manner the CEO in risk management and compliance with financial management and accountability. Also, ARPANSA has a thorough internal audit plan, which is developed using a risk-based approach.</i>
		G11	<i>The introduction (in a short period of time) of a well functioning, easy to use Regulatory Management Information System TRIM, which includes record management system, workflow monitoring and control, performance measurement, and collaborative working, is good practice.</i>
		G12	<i>ARPANSA's systematic and professional manner to improve and develop its Management System is good practice.</i>
I	Transport of Radioactive Material	R12	<i>ARPANSA should ensure that all necessary aspects of the compliance assurance programme are in place and are fully effective (e.g. guidance for package approval, plan for emergency preparedness, inspections of all entities involved in transport of radioactive material, refresher training course for both industry and inspectors, distribution of information to industry and more complete inter-ministerial and interstate liaisons).</i>

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	<i>Recommendations, Suggestions or Good Practices</i>
		S29	<i>ARPANSA should review the current system of approvals for transport to consider the possibility of having one competent authority for the transport of radioactive material, with memoranda of understanding or protocols with other competent authorities for transport of dangerous goods.</i>
J	Public Information	S30	<i>ARPANSA should consider the further development and documentation of its public information and communication processes, procedures, public information and communication strategies to support its effective implementation.</i>

APPENDIX VI – REFERENCE MATERIAL PROVIDED BY ARPANSA

<i>Law(s) governing the siting, design, construction, commissioning, operation or decommissioning of nuclear installations, other facilities, activities and practices</i>
<i>Synopsis of the constitutional legislative system of the country and the responsibilities of the various government departments that deal with nuclear installations</i>
<i>An outline of the administrative structure of government departments and other bodies dealing with nuclear installations and how they all interrelate and</i>
<i>Regulations on nuclear, radiation, waste management, transport safety and security of radioactive sources</i>
<i>Legal status and responsibilities assigned by law to the regulatory body;</i>
<i>Objectives of the regulatory body and how it maintains its effective independence</i>
<i>Regulatory body safety policy and quality management system</i>
<i>Procedures for assessment and review of technical submissions</i>
<i>Inspection practices;</i>
<i>Enforcement practices;</i>
<i>Role and responsibilities in relation to nuclear emergencies</i>
<i>A typical licence; and list of applicable codes and standards.</i>
<i>Written response to IRRS questionnaire</i> <i>Modules I-VIII including effectiveness questions</i>
<i>Pre-appraisal questions (if applicable)</i>
<i>Specific questions (as applicable)</i>
<i>Thematic questions (as applicable)</i>
<p><i>Self-assessment analysis and results</i></p> <p><i>The Australian Radiation Protection and Nuclear Safety (ARPANS) Bill 1998 was passed by the House of Representatives in May 1998, however Parliament was prorogued for the Federal Election before the Bill could be considered by the Senate. The Bill's were reintroduced into Parliament and were passed by both Houses of Parliament on Thursday 10th December 1998.</i></p> <p><i>Copies of material relating to the introduction of the Bills to Parliament, their debate and the accompanying explanatory memorandum can be found at http://www.arpansa.gov.au/legframe.htm#bills</i></p> <p><i>ARPANS Act 1998 and</i> <i>ARPANS Regulations 1999</i> <i>ARPANS (Licence Charges) Act 1998</i> <i>ARPANS (Consequential Amendments) Act 1998</i> <i>Available at http://www.arpansa.gov.au/legframe.htm</i></p>
<p><i>Environment Protection and Biodiversity Conservation Act 1999</i> <i>Australian Nuclear Science and Technology Organisation Act 1987</i> <i>Commonwealth Radioactive Waste Management Act 2005</i> <i>Occupational Health and Safety Act 1991</i> <i>Nuclear Non-Proliferation (Safeguards) Act 1987</i> <i>All other legislation referred to here is available at www.austlii.edu.au</i></p>

<p><i>Customs Regulations - Under Regulation 9AD of the Customs (Prohibited Exports) Regulations 1958, an export permission from authorised officers of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is required for the export of high activity radioactive sources. Under Regulation 4R of The Customs (Prohibited Imports) Regulations 1956, an import permission from authorised officers of Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is required for the import of radioactive substances.</i></p>
<p><i>Final versions and upcoming drafts of Codes of Practice, Standards, Recommendations and Safety Guides are available at</i> http://www.arpansa.gov.au/Publications/codes/rps.cfm, http://www.arpansa.gov.au/rhs_pubs.htm and http://www.arpansa.gov.au/Publications/codes/rhs.cfmhttp://www.arpansa.gov.au/Publications/Drafts/index.cfm .</p>
<p><i>Guidance for radioactive waste management facilities</i> http://www.arpansa.gov.au/pubs/radwaste/rwmfacilities_reg_guid.pdf</p>
<p><i>Additional guidance for current and prospective ARPANSA licence holders is available at</i> http://www.arpansa.gov.au/Regulation/applicants/index.cfm</p>
<p><i>Final versions and upcoming drafts of Codes of Practice, Standards, Recommendations and Safety Guides are available at</i> http://www.arpansa.gov.au/Publications/codes/rps.cfm, http://www.arpansa.gov.au/rhs_pubs.htm and http://www.arpansa.gov.au/Publications/codes/rhs.cfmhttp://www.arpansa.gov.au/Publications/Drafts/index.cfm .</p>
<p><i>Draft Code of Practice for the Predisposal management of radioactive waste</i></p>
<p><i>National Directory for Radiation Protection, CEO Statement of reasons for licensing (siting, construction, operation) of OPAL</i> http://www.arpansa.gov.au/pubs/regulatory/opal/ceo_reasons.pdf, http://www.arpansa.gov.au/pubs/rrrp/comm_on_issue.pdf and , http://www.arpansa.gov.au/pubs/rrrp/op/oplic_reasons.pdf .</p>
<p><i>CEO of ARPANSA Response to the ANAO Report December 2006</i></p>
<p><i>Regulatory Review Consultative Committee (established to advice CEO on ANAO report) (RRCC) 6 month report</i></p>
<p><i>RRCC 12 month report</i></p>
<p><i>RRCC final report</i></p>
<p><i>Australian National Audit Office Performance Audit of Regulation of Commonwealth radiation and nuclear activities 2004-2005</i></p>
<p><i>National Directory of Radiation Protection draft of 2nd edition Feb 2007</i></p>
<p><i>McNulty Report on national uniformity</i></p>
<p><i>Background to the establishment of national uniformity in radiation protection</i></p>
<p><i>Other regulators of nuclear activities and other Government agencies involved in nuclear activities</i></p>
<p><i>Updated organisational chart – April 2007</i></p>
<p><i>Workforce Development Framework</i></p>
<p><i>Learning and Development Strategy</i></p>

<p>Criteria for RHC membership is stated in Section 24 of the ARPANS Act, criteria for membership of the NSC is stated in Section 27 of the ARPANS Act, criteria for the membership of the RHSAC is stated in Section 21 of the ARPANS Act</p> <p>http://www.arpansa.gov.au/AboutUs/Committees/rhc.cfm , http://www.arpansa.gov.au/AboutUs/Committees/nsc.cfm , http://www.arpansa.gov.au/AboutUs/Committees/rhsac.cfm</p>
<p>All ARPANSA licence holders have licence condition requiring an inventory of radiation sources be kept and updated quarterly. The inventory can be audit by ARPANSA during inspections.</p> <p>A national register of high activity sealed radiation sources is complete and contains data in relation to the type, serial number, activity is generally included, additional data on topics such as container serial number are being added as available.</p> <p>a) http://www.arpansa.gov.au/pubs/annualreport/2005-06/2005-06ar.pdf b) Regulatory & Policy Branch Business Plan</p>
<p>ARPANSA administers four international conventions – the Convention on Nuclear Safety, the Joint Convention on the safety of Spent Fuel Management and the Safety of Radioactive Waste Management, the Convention on the Early Notification of a Nuclear Accident, the Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency. Reports on our compliance with CNS and the JC are available at http://www.arpansa.gov.au/pubs/cns_rpt2.pdf and http://www.arpansa.gov.au/RadiationProtection/Factsheets/jointconvention.cfm</p>
<p>An application pack for a source licence and another for a prescribed radiation facility are available at http://www.arpansa.gov.au/Regulation/applicants/index.cfm</p>
<p>Information regarding applications, authorizations, amendments and compliance is reported in Annex A of the Quarterly Report which can be found at http://www.arpansa.gov.au/AboutUs/Corporate/quarterlyreports.cfm and Appendix 4 of the Annual Report which can be found at http://www.arpansa.gov.au/AboutUs/Corporate/annualreports.cfm .</p>
<p>Information regarding inspections is reported in Annex A of the Quarterly Report which can be found at http://www.arpansa.gov.au/AboutUs/Corporate/quarterlyreports.cfm and Appendix 4 (Table 29) of the Annual Report which can be found at http://www.arpansa.gov.au/AboutUs/Corporate/annualreports.cfm .</p>
<p>Code of Practice for the Security of Radioactive Sources (Radiation Protection series publication 11) can be found at http://www.arpansa.gov.au/Publications/codes/rps11.cfm</p>
<p>All licensees are required to include any abnormal doses as part of their quarterly report and this is included in the ARPANSA quarterly report. ANSTO provide detailed information regarding occupational and this is reported in the ARPANSA Annual Report (Table 34).</p>
<p>A list of services is available at http://www.arps.org.au/Products_Services.php#SERVICES%20OFFERED</p>
<p>Regulatory Quality Manual</p>
<p>Technical report 145 Monitoring for post-accident recovery Recommendations for Intervention in Emergency Situations Involving Radiation Exposure (2004) rps7</p>
<p>ANSTO Handbook</p>

Regulatory Guides and Handbooks

RB-STD-42-00 Rev 1 Oct 2001—Regulatory Assessment Principles for Controlled Facilities.
RB-STD-15-03 Rev 0 Aug 2003—Regulatory Guidelines for the Review of Plans and Arrangements.
RB-STD-43-00 Dec 2000. Regulatory Assessment Criteria for the design of new controlled facilities and modifications to existing facilities (previously RG-5).
RB-STD-09-04—September 2004. Regulatory Principles for the Assessment of Commissioning of the Replacement Research Reactor.
RB-STD-10-06 Rev 0 –Nov. 2006. Regulatory guideline for the Decommissioning of Controlled Facilities.
RG-4 –April 1999—ARPANSA Criteria for the Siting of Controlled Facilities.
RG-12 –Aug. 1999. ARPANSA Criteria for the Safety Analysis of Controlled Facilities.
RG 8-Aug 1999-ARPANSA Criteria for the Licensing of new Controlled Facilities.
RB-STD 61-01 Rev 0 Glossary of terms used by ARPANSA—October 2001
RB-STD-53-01 Rev 0 Licence Conditions Handbook—General Handbook—Aug 2001
RB-STD-47-00 Rev 1-Licence Condition Handbook –ANSTO Handbook—May 2001
RB-COM-SUP-0500A Guidance for licence holder quarterly reporting Version 2 March 2005
RB-COM-SUP-0500D Regulatory Guide No 4: Seeking an Exemption from Source Licence (IR) Version 1 Draft
RB-COM-SUP-0500E Regulatory Guide No 5: Seeking an Exemption from Source Licence (NIR) Version 1 Draft
RB-COM-SUP-0500B Regulatory Guide No 1: Reporting an Accident Version 1 April 2007
RB-COM-SUP-0500C Regulatory Guide No 3: Managing changes to the source inventory Version 1 Draft

ARPANSA Standard Operating Procedures

RB-REG-SOP-2000 Version 2—Regulatory Incident Response Plan—Jan. 2006
RB-INS-Man-1000—Policy on Regulatory Inspections—Version 2 October 2004
RB-INS-FORM-0500 Inspection schedule Version 2 October 2004
RB-INS-SUP-0500 Guidance on inspection schedule Version 2 October 2004
RB-INS-SOP-1000-Inspection Procedure for Planned Inspections Version 3 February 2007
RB-INS-FORM-1000C Inspection Notification Proforma Version 2 October 2004
RB-INS-FORM-1000D Workplace Hazard Identification Check list Version 1 March 2003
RB-INS-FORM-1000E Record of Meeting Version 2 October 2004
RB-INS-FORM-1000I Inspection Report Version 2 October 2004
RB-INS-FORM-1000J Transmittal Letter Version 2 October 2004
RB-INS-FORM-1000L Inspectors Preparation Check list Version 1 March 2003
RB-INS-SUP-1000A What to expect when an ARPANSA inspector visits Version 1 October 2004
RB-INS-SUP-1000B Inspector's preparation checklist Version 1 March 2003
RB-INS-SUP-1000C Entrance script Version 1 March 2004
RB-INS-SUP-1000D Exit script Version 1 October 2004
RB-IP-SOP-0100 –The Processing of Permit Applications for Customs Prohibited Import Release for Non Medical Radioisotopes. Version 1 October 2003.
RB-IP-SUP 0100 Table of Dangerous Substances Version 1 October 2003.
RB-IP-FORM-001 Application for permission to import Version 1 October 2003
RB-IP-FORM-002 Application for permission to import ... (12 month permit) Version 1 October 2003
RB-LA-SOP-1000 Licence Applications Receipt and Checking. Version 2 July 2003
RB-LA-FORM-1000B Request for Debtor Invoice Version 1 July 2005
RB-LA-FORM-1000C Licence Application Checklist Version 2 July 2005
RB-LA-FORM-1000D Application Fee Advice Version 2 July 2005
RB-LA-FORM-1000E Valid Application Acknowledgement Version 2 July 2005
RB-LA-FORM-1000F Annual Licence Charge & Licence Application Fees Version 1 July 2005
RB-LA-SOP-2000 Licence Application Assessment-Version 2 July 2003.
RB-LA-FORM-2000B Request for Further Information Version 2 July 2005
RB-LA-FORM-2000C Site Visit Report Proforma Version 1 June 2003
RB-LA-FORM-2000D Proforma for RAR – Source Licence Version 2 July 2005
RB-LA-FORM-2000E Proforma for RAR – Facility Licence Version 2 July 2005
RB-LA-SOP-3000 Issuing a Licence Version 2 July 2005
RB-LA-FORM-3000A Memo to the CEO Version 2 July 2005
RB-LA-FORM-3000B Source Licence Proforma Version 2 May 2005
RB-LA-FORM-3000C Facility Licence Proforma Version 3 August 2005
RB-LA-FORM-3000D Letter to Licence Holder with Source Licence Version 2 May 2005
RB-LA-FORM-3000E Letter to Licence Holder with Facility Licence Version 2 May 2005

RB-LA-SUP-3000B How to read a source licence Version 2 August 2005
 RB-LA-SUP-3000C How to read a facility licence Version 3 August 2005
 RB-LA-SUP-3000D Licence Condition – Extracts from the Act & Regs Version 1 Aug 2006
 RB-RA-SOP-1000—Creating a File Version 2 July 2005
 RB-RA-SOP-1500 Managing Receipt of Regulatory Related Documents Version 1 September 2003
 RB-RA-SOP-500 Managing Receipt of Regulatory Related Documents Version 1 September 2003
 RB-RA-FORM-500 Summary of Incoming regulatory related documents Version 1 August 2003
 RB-RA-SOP-1500 Maintenance of Documents within Regulatory Files Version 1 August 2003
 RB-RA-SUP-1000-Guidance on Regulatory Branch Good Document Practices Version 1 August 2003
 RB-RA-SUP-2000A Guidance on Regulatory Branch good document practices Version 1 August 2003
 RB-IP-FORM-001 Application for Permission to Import Non Medical \Radioactive Substances Version 1 October 2003.
 RB-IP-FORM-002 Application for Permission to Import non Medical Radioactive Substances--12 Month Permit Version 1 October 2003.
 RB- RA- Form 1000 A-Creating a file (Version 1 August 2003)
 RB- RA- Form 1000 B-Related Binder (Version 1 August 2003)
 RB- RA- Form 1000 C-Folio Transfer (Version 1 August 2003)
 RB- RA- Form 1000 D-File closed (Version 1 August 2003)
 RB- RA- Form 1000 F-File Full (Version 1 August 2003)
 RB-RA-FORM-1500A Summary of Incoming Regulatory Related Documents Version 1 August 2003
 RB-RA-FORM -2000A File Note Version 1 August 2003
 RB-COM-MAN-0500 Regulatory Compliance Policy Version 1 November 2004
 RB-COM-SOP-0500 Managing licence holder compliance reports Version 2 July 2005
 RB-COM-FORM-0500A Reporting proforma for source licence holders Version 1 January 2005
 RB-COM-FORM-0500B Reporting proforma for PRF licence holders Version 1 March 2005
 RB-COM-FORM-0500C Quarterly reporting notice proforma Version 1 March 2005
 RB-COM-FORM-0500D Reg 53(2) Transfer notice Version 2 August 2005
 RB-COM-FORM-0500E Reg 53(1) Disposal request Version 2 August 2005
 RB-COM-FORM-0500F Interim statement on use of sealed sources beyond RWL Version 1 April 2005
 RB-COM-FORM-0500G Accident Notification Version 1 April 2007
 RB-IMGT-SOP-1000 Instrument Management Version 1 September 2004
 RB-IMGT-FORM-1000A Instrument register form Version 1 September 2004
 RB-IMGT-FORM-1000B Instrument management request form Version 1 September 2004
 RB-IMGT-FORM-1000C Instrument unavailability logging form Version 1 September 2004
 RB-IMGT-FORM-1000D Instrument late request form and late return logging Version 1 September 2004
 RB-IMGT-FORM-1000E Instrument defect report form Version 1 September 2004
 RB-IMGT-FORM-1000F Instrument loan service review form Version 1 September 2004
 RB-IMGT-SOP-2000 Instrument Maintenance Version 1 September 2004
 RB-IMGT-SOP-3000 Instrument Loan Version 1 September 2004
 RB-PR-SOP-1000 Stakeholder Feedback Version 1 September 2005

Australian Standards and Codes of Practice

The National Health and Medical Research Council (NHMRC) Radiation Health Series (RHS) (see <http://www.arpana.gov.au/Publications/codes/rhs.cfm>) eg RHS 21 Revised statement on cabinet X-ray equipment for examination of letters, packages, baggage, freight and other articles for security, quality control and other purposes (1987) and Radiation Protection Series (RPS) (see <http://www.arpana.gov.au/Publications/codes/rps.cfm>) series of guidance for specific dealings are the main documents used along with the following:

1. Safety in Laboratories Part 4: Ionizing Radiation, Standards Australia, Australia Standard AS 2243.4:1998, 1998
2. AS/NZS Safety in laboratories - Non-ionizing radiations – Electromagnetic, sound and ultrasound (2004) (AS/NZS 2243.5: 2004)
3. Australian/New Zealand Standard Laser Safety Part 1: Equipment classification, requirements and user's guide (2004) (AS/NZS 2211.1: 2004)
4. Australian/New Zealand Standard Laser safety - Safety of optical fibre communication systems (1997)(AS/NZS 2211.1: 1997)
5. Australian Standard AS/NZS 3200.2.201:1996 Approval and Test Specifications Medical Electrical Equipment Part 2.201 Particular Requirements for Safety – Dento-maxillofacial X-ray Equipment
6. Australian / New Zealand Standard Medical electrical equipment - General requirements for safety – Parent Standard (AS/NZS 3200.1.0: 1998)
7. International Labour Office document Safety in the use of radiofrequency dielectric heaters and sealers: A practical guide (1998).

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| | <ol style="list-style-type: none"><li data-bbox="229 152 1426 215">8. International Commission on Non-Ionizing Radiation Protection Guidelines on limits of exposure to static magnetic fields, Health Physics (1994) 66, 100-106<li data-bbox="229 215 1426 275">9. International Commission on Non Ionizing Radiation Protection Guidelines on Limits of Exposure to Broad Band Incoherent Optical Radiation (0.38 to 3 μm), Health Physics (1997) 73, 539-553 |
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APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

	Publication No.	Name of Publication
[1]		Code of conduct on the Safety of Research Reactors
[2]	111-G-1.1	Classification of Radioactive Waste
[3]	35 – G2	Safety in the Utilization and Modification of Research Reactors
[4]	DS113	The Management Systems for Regulatory Bodies
[5]	GS-G-1.1	Organization and Staffing of the Regulatory Body for Nuclear Facilities
[6]	GS-G1.2	Review and Assessment of Nuclear Facilities by the Regulatory Body
[7]	GS-G-1.3	Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body
[8]	GS-G-1.4	Documentation for use in Regulation of Nuclear Facilities
[9]	GS-G-1.5 (2004)	Regulatory Control of Radiation Sources
[10]	GS-R-1	Legal and Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety
[11]	GS-R-2 (2002)	Preparedness and Response for Nuclear and Radiological Emergencies requirement
[12]	GS-R-3 (DS338)	Management System for Facilities and Activities (Draft safety standard series)
[13]	IAEA TECDOC 1388	Strengthening control over radioactive sources in authorized use and regaining control over orphan source national strategies (2004)
[14]	INSAG 17	Independence in Regulatory Decision Making
[15]	INSAG 20	Stakeholder Involvement in Nuclear Issues
[16]	INSAG 21	Strengthening the Global Nuclear Safety Regime
[17]	Legal Series No.14	Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency Adopted on 26 September 1986 at the 18 th 1986 plenary meeting
[18]	NS-R-4	Safety of Research Reactors
[19]	NS-G-4.1	Commissioning of Research Reactors
[20]	NS-R-3	Site evaluation for Nuclear Installation
[21]	RS-G-1.7 (2004)	Application of the Concepts of Exclusion, Exemption and Clearance

	Publication No.	Name of Publication
[22]	RS-G-1.8 (2005)	Environmental and Source monitoring for Purpose of Radiation Protection
	Publication No.	Name of Publication
[23]	RS-G-1.9	Categorization of Radioactive Sources, Safety Standard Series
[24]	SS 115 (1996)	International Basic Safety standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources
[25]	TS-R-1	Regulations for the Safe Transport of Radioactive materials
[26]	TS-R-1 (2005)	Regulations for the Safe Transport of Radioactive Material
[27]	WS-G-2.1	Decommissioning of Nuclear Power Plants and Research Reactors
[28]	WS-G-2.1 (1999)	Decommissioning of Nuclear Power Plants and Research Reactors
[29]	WS-G-2.2 (1999)	Decommissioning of Medical, Industrial and Research Reactors
[30]	WS-G-2.3	Regulatory Control of Radioactive Discharges to the Environment
[31]	WS-G-2.4 (2001)	Decommission of Nuclear Fuel Cycle Facilities
[32]	WS-G-2.5 (2003)	Predisposal Management of Low and Intermediate Level Radioactive Waste
[33]	WS-G-2.6 (2003)	Predisposal Management of High Level Radioactive Waste
[34]	WS-G-2.7	Management of Waste from the use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education
[35]	WS-G-6.1	Storage of Radioactive Waste
[36]	WS-R-1 (1999)	Near Surface Disposal of Radioactive Waste
[37]	WS-R-2 (2000)	Predisposal Management of Radioactive Waste including Decommissioning
[38]	WS-R-3 (2003)	Remediation of areas contaminated by past activities and accidents
[39]	WS-R-5 (2006)	Decommissioning of facilities using Radioactive Material
[40]		Code of Conduct on the Safety and Security of Radioactive Sources
[41]		Guidance on the Import and Export of Radioactive Sources

APPENDIX VIII – REVIEW OF PROGRESS TOWARDS NATIONAL UNIFORMITY

RHSAC Item 5.2 27 April 2007

In **August 1999** AHMC agreed to progress uniformity through the development of the National Directory for Radiation Protection, to be managed by the Radiation Health Committee. The AHMC decision included:

- a process for issue resolution, designed to meet the COAG requirements for national standard setting by Ministerial Councils;
- required agreement by a majority of ten out of the thirteen members of the Radiation Health Committee;
- a process of full Consultation with relevant stakeholders, including Radiological Advisory Councils in Most States and Territories; and
- final changes to the directory to be approved by AHMC.
- after approval, the regulatory elements of the directory shall be adopted in each jurisdiction as soon as possible, using existing Commonwealth/State/Territory regulatory frameworks.
- Recognising that a variety of agencies have a legislated responsibility for aspects of radiation safety (eg .mines, occupational health and safety and transport agencies in many jurisdictions), these other agencies are to be actively involved in measures to progress national uniformity, including the development of the national directory.
- The adoption of uniform national regulatory controls (eg.via mirror legislation) will be considered further following the completion of the initial draft of the national directory, and in light of the recommendations of the planned national competition policy review of radiation protection.

Edition 1 of the National Directory was published in **August 2004**, following a conditional endorsement from AHMC in July 2004. The condition required additional cost-benefit analysis to be undertaken to meet the requirements of each jurisdiction.

During 2005 the additional cost-benefit analysis was undertaken, resulting in AHMC confirming out of session in **December 2005** that the final RIS met the requirements of all jurisdictions, and that the NDRP should be implemented in all jurisdictions in accordance with AHMC's July 2004 decision.

In **March 2006** the CEO wrote to all jurisdictions confirming that Ministers had endorsed the NDRP and requesting advice on progress with implementation of the NDRP. The responses to that letter are summarised in the following table:

Jurisdiction	Response
ACT	1 June 2006: Provisions of NDRP already being implemented. The Radiation Protection Bill 2006 was presented to the Legislative Assembly on 30 March 2006. Drafting instructions for Radiation Protection Regulation 2006 are being prepared. Expect to replace the old Act and Regulation in early 2007.
NSW	19 May 2006: Currently reviewing regulatory framework bearing in mind

NDRP1. In 2002, NSW amended the Radiation Control Act 1990 to provide direct adoption of documents forming part of the NDRP. Also amended licence, registration & accreditation provisions of the Act to provide that applicants must meet any relevant requirements in a document so adopted. Preparing an instrument to adopt documents in Sch 11 of NDRP1. Also written to Workcover Authority about adoption of RPS3.

20 Sep 2006: In July 2006 adopted Codes in Sch 11 of NDRP1.

NT	No reply received
QLD	No reply received
SA	No reply received
TAS	4 May 2006: Well advanced in implementation. Radiation Act 2005 was formulated to cover provisions of NDRP1. Draft regulations adopt provisions, particularly exemptions.
VIC	3 May 2006: Passed Radiation Act 2005. Currently scoping regulations.
WA	Radiological Council has formed a working group to review WA's principal legislation. Will report to Minister late 2006.

While Qld, NT and SA did not reply at that time, they have recently provided the following advice on their progress on uniformity.

QLD: Legislation has been changed to ensure all of the changes required have been made (there weren't many). Also, Regulations have steadily been changed so that there will be almost no changes required by the time NDRP v2 is released. The requirement for an annual report is still a difficulty regarding how this should fit into the reporting framework. Despite this, the production of a very comprehensive annual report which will be able to be updated each year is at an advanced stage. Apart from the annual reporting mechanism, Qld is running quite consistently with the NDRP v1.

NT: Has amended legislation and expects the new Act to come into operation this year when new regulations are gazetted.

SA: Currently updating Act and Regulations to give effect to provisions consistent with NDRP. Current regulations are not too different from NDRP, but revision is required. The Act is expected to be completed within 12 months and the Regulations will follow soon after. The Codes of Practice are currently adopted via conditions of licence.

The final RIS of NDRP1 included the following statement:

The Directory will be reviewed by the Radiation Health Committee within 3 years of its commencement to evaluate its effectiveness and efficiency.

In some jurisdictions different aspects of radiation protection have different regulators. For example, non-ionizing radiation in some jurisdictions is regulated by OH&S or Workcover Authorities rather than the radiation protection regulator, and in mining, the mining regulator sometimes regulates radiation protection matters. The NDRP is intended to provide the uniform regulatory elements that can be adopted regardless of the actual regulatory body.

To follow up on implementation of the RF Standard (RPS3), the CEO prepared a draft letter for all jurisdictions' radiation regulators to send to their relevant Workcover Authority, asking for advice on progress in implementing the Standard. ARPANSA has adopted RPS3 in Schedule 1 of the

ARPANS Regulations. The Australian Communications & Media Authority has used the limits in RPS 3 in regulations covering the telecommunications and broadcast industries. The following table summarises the responses provided to radiation regulators in States and Territories regarding implementation of RPS3 by Workcover Authorities:

Jurisdiction	Letter sent to Workcover Authority	Response from Workcover Authority
ACT	No	
NSW	Yes	Workcover did not support changes to workplace safety legislation to pick up the Standard. Workcover felt DEC was the appropriate regulator for both ionizing and non-ionizing radiation. Workcover did indicate that they continue to promote the relevant ARPANSA Standards as demonstrating best practice and providing standards for the purposes of complying with NSW OH&S legislation.
NT	Yes	No reply received as yet.
QLD	No, but took it to an IDC on the NDRP	Responsibility falls to Workplace Health & Safety Queensland. They use Standards in a manner whereby compliance with extant Standards is expected, or an equivalent approach demonstrated. RPS3 is being used in this way.
SA	Yes	No reply received as yet.
TAS	Yes	Reply received at the time the Government was in caretaker mode, indicating that no comment could be provided at that stage. No more detailed response has been received since that time.
VIC	No	
WA	To be advised	

Note that non-ionizing radiation was not included in NDRP edition 1, although RPS3 was included in Schedule 11 listing codes and standards for adoption in all jurisdictions.

Recent reviews of uranium mining and nuclear energy have considered the regulation of the mining industry, including uniformity. A single regulator for uranium mining and nuclear energy activities was proposed.

ARPANSA's submission to the UMPNER Review included the following:

Currently, three uranium mines operate in Australia—the Ranger mine in the Northern Territory and the Olympic Dam and Beverley mines in South Australia. The Honeymoon mine in South Australia is expected to commence operations in the next 12 months. Increasing uranium mining and exports will require expansion of regulatory activity and would be aided by simplification of the present arrangements.

The current regulatory arrangements applying to uranium mining in these states are stringent, complex, and vary between and within the Commonwealth, South Australian and Northern Territory governments. ARPANSA's view is that the Commonwealth and State/Territory governments should work cooperatively in order to harmonise the regulation of uranium mining,

taking account of the different circumstances between jurisdictions (including states where uranium mining might be permitted in the future).

In terms of radiation safety, the Commonwealth, State and Territory governments have made significant progress in the harmonisation of regulations through the development of the National Directory on Radiation Protection and the Code of Practice and Safety Guide for Radiation Protection and Radioactive Waste Management in Mining and Mineral Processing (the Mining Code).

The submission also commented that:

The regulation of nuclear power facilities would require inputs from a variety of disciplines. These include:

- nuclear safety;*
- environmental assessment;*
- operational radiation protection;*
- nuclear weapons proliferation;*
- development of policy and legislative frameworks; and*
- auditing and inspections of facility operations.*

At present these specialities are distributed across several Australian Government agencies and some of them are also reproduced by State and Territory Governments. Under present constitutional arrangements many nuclear fuel cycle facilities would require licensing by State or Territory regulators. The role of the Australian Government currently is to ensure satisfying the obligations set out in several international treaties to which Australia is a signatory. To set up agencies across all Australian jurisdictions and expect them to develop the required competencies in all areas would be inefficient and expensive. In addition from a compliance point of view, organisations operating in several jurisdictions would have to comply with different requirements adding significantly to compliance costs.

In ARPANSA's view, the potential impact of regulation on the economics of nuclear power in Australia is such that any investment will only be able to be made if there is a clear national regulatory structure established, based upon international best practice in radiation protection and nuclear safety. Given the complexity and scope of regulatory requirements these functions should be centralised in one (or a small number) of agencies under Australian Government control. Such an agency would then be able to maintain the required expertise, develop effective policies and regulatory frameworks and implement these in a uniform manner across Australia. This strategy would reduce the cost of regulation and the cost of compliance as organisations would not have to deal with multiple authorities for approvals.

Such a national nuclear regulator could be established through a Commonwealth-State co-operative mechanism or by the Commonwealth using a range of its Constitutional powers. The particular regulatory decision-making model could be the subject of further discussion – whether there be a sole statutory decision-maker as is the case for ARPANSA; decisions made by the Minister (or Ministers) as applies in France; or some form of 'board' or 'commission' along the lines of the United States and Canada.

The legislation establishing the national nuclear regulator would need to define its scope. Its coverage could simply be the health and safety of people. It could extend to cover the protection of the environment; and the administration of nuclear safeguards.

The Appendix to the submission also discussed uniformity issues as follows:

ARPANSA Submission to UMPNER

Extract from Appendix A- Uranium mining and milling

Radiation protection in the uranium mining industry

The basic concepts of radiation protection for application in the uranium industry are contained in the code of practice RPS 1 Recommendations for Limiting Exposure to Ionizing Radiation (Printed 1995 - Republished 2002) [2] and in RPS 6 National Directory for Radiation Protection Edition 1.0 (2004) [3].

These documents, especially the National Directory, will be updated as required. In this way, new information and developments in international standards will be transferred to and given effect in state and territory regulations.

Uniformity in Radiation Protection Regulation

The current situation in Australia is that mining in all forms including uranium mining is regulated by each state and territory, with the Commonwealth having a role in coordinating uniformity of regulatory outcomes.

The National Directory

While Australia consists of nine legally separate jurisdictions for the purposes of regulating the safety of radioactive practices and waste, the jurisdictions are working together to develop and implement a uniform national set of policies and practices in radiation protection and nuclear safety. The instrument to achieve national uniformity is the National Directory for Radiation Protection. Specifically, under Section 15 of the Australian Radiation Protection and Nuclear Safety Act 1998, the CEO of ARPANSA is responsible for promoting uniformity of radiation protection and nuclear safety policy and practices across the jurisdictions of the Australian government and the States and Territories. The Radiation Health Committee established under the Act includes representatives of all jurisdictions and develops Codes and Standards for national adoption. During 2004, Edition 1 of the National Directory for Radiation Protection was published.

The aim of the National Directory is to provide nationally uniform requirements for the protection of people and the environment against exposure or potential exposure to ionizing and non-ionizing radiation and for the safety of radiation sources, including provision for the national adoption of codes and standards. The National Directory has been developed to address the needs of radiation protection regulators but it will also benefit other sectors involved in implementing radiation controls, such as mine operators and occupational health and safety regulators.

Development of Edition 2 has commenced to cover additional material, including application of the National Directory to mining and mineral processing.

Specific examples

Summaries of the current situations in the two uranium-producing jurisdictions (South Australia and the Northern Territory) are presented below. In both SA and NT, the old Radiation Protection Acts are being revised to adopt the provisions of the National Directory for Radiation Protection (Edition 1) thereby ensuring uniformity of regulation. When Edition 2 of the National Directory is produced, with its expanded coverage including mining and mineral processing, it is envisaged that similar revision of State and Territory Acts will occur.

Northern Territory

The Radiation Protection Act 2004 will come into effect in 2006. This Act is based on the National Framework for Radiation Protection as contained in the National Directory for Radiation Protection, Edition 1. Until the start of the new Act, the legislative and regulatory system is covered by four Acts including the Mining Management Act 2001 which is administered by the Department

of Primary Industry, Fisheries and Mines. This Act provides for the authorization of mining activities, management of mining sites and the protection of the environment, safety and health of people on mining sites.

South Australia

The principal legislation in South Australia which provides the legislative and regulatory framework for uranium mining is the Radiation Protection and Control Act 1982 (RPC Act).

The South Australian RPC Act and Radiation Protection and Control (Ionizing Radiation) Regulations 2000 (IR Regulations) under the RPC Act provide for controls for the safety of radioactive waste management. The RPC Act and IR Regulations are currently being reviewed with the intention to adopt the provisions of the National Directory for Radiation Protection (Edition 1).

The mining and milling of radioactive ores in South Australia is subject to regulatory control via a licence issued under the RPC Act. Conditions attached to the licence require uranium mining operators to comply with the requirements of the Australian government Code of Practice and Safety Guide for Radiation Protection and Radioactive Waste Management in Mining and Mineral Processing (2005) (RPS 9) and the Recommendations for Limiting Exposure to Ionizing Radiation (RPS 1).

Companies that hold licences to mine or mill radioactive ores are required, under conditions on the licences, to report annually on radioactive waste production and management. The operation of mines and management of radioactive wastes on site also involve approvals of facilities such as tailings dams and evaporation ponds, waste management plans, and releases of radionuclides into the environment. The Radiation Protection Division of the EPA is responsible for granting approvals under the above Mining and Mineral Processing Code. In its assessment of applications for approval of waste management plans and waste disposal facilities, the EPA consults with the Department of Primary Industries and Resources South Australia (PIRSA) that issues a mining lease under Mining Act 1971. Mining operations are periodically inspected by the EPA and quarterly meetings are held to review safety of operations, including radioactive waste management.

In the case of radioactive wastes remaining from mining or processing of radioactive ores which ceased prior to the introduction of the RPC Act, legislative control is achieved via registration of the sites as premises under the RPC Act.

Radiation safety officers

The Mining Code requires mine operators to appoint radiation safety officers who have the appropriate qualifications and experience acceptable to the relevant regulatory authority. At present, there is a shortage of radiation safety officers in the industry and this could become a major problem if there is a significant expansion in uranium production.

While radiation courses related to medical and occupational hygiene are available in Australian tertiary institutions, there are currently no training courses specific to the regulation of the uranium industry. The development of accredited courses would assist in filling this gap. In addition a campaign for the recruitment of science graduates to work in the area of uranium mining radiation safety would be helpful.

Conclusion

Enhancing current regulatory arrangements through harmonisation of the existing regime will ensure that Australia's global reputation as a safe, reliable, socially and environmentally responsible supplier of uranium is optimised. In addition, an efficient regulatory regime will provide the general public with assurance that all potential risks associated with uranium mining are being effectively managed. Furthermore, continued regulatory certainty is an important factor for attracting the investment required for the expansion of the Australian uranium industry.

References:

- [1] Australian Radiation Protection and Nuclear Safety Agency, Code of Practice and Safety Guide for Radiation Protection and Radioactive Waste Management in Mining and Mineral Processing, Radiation Protection Series No. 9, 2005,
<http://www.arpana.gov.au/pubs/rps/rps9.pdf>
- [2] <http://www.arpana.gov.au/pubs/rps/rps1.pdf>
- [3] <http://www.arpana.gov.au/rps6.htm>

APPENDIX IX – COAG RECOMMENDATIONS

RECOMMENDATIONS OF THE REPORT ON THE REGULATION AND CONTROL OF RADIOLOGICAL MATERIAL

In December 2002, the Council of Australian Governments (COAG) agreed to a national review of the regulation, reporting and security around the storage, sale and handling of hazardous materials. The review has been conducted in four parts covering ammonium nitrate, radiological, biological and chemical materials.

On 13 April 2007, COAG agreed to the recommendations from the Report on the Regulation and Control of Radiological Material. These include regulating the secure storage, possession, use and transport of certain radiological materials to minimise the risk that such material can be misused by terrorists.

The recommendations agreed to by COAG are described below.

Nuclear material

Recommendation 1: Adopt CPPNM

Adopt the recent amendments to the International Atomic Energy Agency (IAEA) Convention on the Physical Protection of Nuclear Material (CPPNM) in domestic legislation and ratify the amendment. This will strengthen Australian Safeguards and Non-Proliferation Office's (ASNO) authority to ensure nuclear facilities are secured.

Recommendation 2: Scalability in security plans

Scalability in security plans should be introduced for permit-holders and the plans tested through exercises. This should be extended beyond Australian Nuclear Science and Technology Organisation (ANSTO) to uranium mines and small quantity permit-holders and, where it is, it should be done in consultation with other relevant jurisdictions as necessary. ASNO may accept invitations to participate in existing, relevant exercises or choose to conduct their own.

Recommendation 3: Increased inspections of permit-holders and uranium mines

Using a risk-based approach, increase the frequency and intensity of ASNO inspections of permit-holders and uranium mines in particular to meet the expanding commitment in this area.

Recommendation 4: Security at proposed radioactive waste store

In-principle agreement to providing nuclear safeguards and security measures consistent with both IAEA standards and domestic legislation at the proposed Commonwealth radioactive waste management facility.

Recommendation 5: Coordinated approach to outreach

ASNO to continue its outreach and inspection work to ensure the national nuclear material accounts are complete. Where appropriate, this work should be coordinated with Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) and state authority efforts in relation to controlling radioactive materials.

Recommendation 6: Memoranda of Understanding

Memoranda of understanding should be developed between state and territory regulators, ARPANSA and ASNO regarding security regulation at nuclear facilities. This initiative will assist in avoiding duplication across jurisdictions at the same facility.

Radioactive sources

Recommendation 1: Legal authority

Each jurisdiction should take the necessary steps to ensure that its radiation safety legislation gives the required legal basis to adequately regulate the security of radioactive sources, including making of standards, licence conditions, compliance monitoring and enforcement mechanisms.

Recommendation 2: Education and awareness outreach

An education and awareness-raising program targeting users of categories 1, 2 and 3 radioactive sources should be conducted by ARPANSA in conjunction with relevant state and territory radiation regulators and ASNO where appropriate. The outreach program should focus on the security of radioactive sources, including the recommendations of this report as well as the Code of Practice for the Security of Radioactive sources.

Recommendation 3: Monitoring equipment to prevent illegal movement of radioactive sources

The Commonwealth, through ARPANSA and the Australian Customs Service, in conjunction with the states and territories, should review the effectiveness of the existing radiation monitoring in Australia to detect the illegal or inadvertent movement of radioactive sources with regard to external borders and related infrastructure in which radioactive sources may be transported through or stored in during their import or export from Australia. The review should bring forward recommendations for any enhanced monitoring required.

Recommendation 4: Radioactive sources import and export controls

Procedures for authorizing the import or export of Category 1 and 2 radioactive sources should be harmonised with the IAEA's *Guidance on the Import and Export of Radioactive Sources*.

Recommendation 5: Establishment of minimum penalties for illegal possession of radioactive sources

All jurisdictions should standardise offences and implement consistent minimum penalties for illegal possession, use and transport of radioactive material. This should be managed through the Radiation Health Committee in consultation with the relevant departments in each jurisdiction.

Recommendation 6: Uniform national standards for security of radioactive material

All jurisdictions should implement the Code of Practice on the Security of Radioactive Sources, once agreed by all jurisdictions, on an expedited basis.

The Commonwealth, through ARPANSA, in consultation with the states and territories, should prepare or amend such other codes of practice as necessary to establish a regulatory framework to regulate the security of radioactive sources during all stages of the life cycle including manufacture, transportation, use, storage and disposal. Such codes of practice should form part of the National Directory for Radiation Protection.

Recommendation 7: Management of disused radioactive sources

All jurisdictions should ensure that adequate inventories of disused radioactive sources exist, that safe and secure waste stores are available to their jurisdiction for such sources, and comprehensive waste management plans are prepared and implemented to ensure the number of radioactive sources available for malicious use is minimised.

Recommendation 8: Securing orphaned radioactive sources

The Commonwealth, through ARPANSA, should establish and maintain a capability for searching for missing Category 1, 2 and 3 radioactive sources and, in consultation with relevant jurisdictions, securing such sources when found.

Recommendation 9: Audit of Category 1 and 2 radioactive sources

Each jurisdiction should undertake an audit of Category 1 and 2 radioactive sources (as identified in the draft Code of Practice on the Security of Radioactive Sources) to verify that sources within these categories are under regulatory control.

Recommendation 10: National radioactive source incident notification system

The Commonwealth, in consultation with states and territories, should establish a centralised notification system for regulators in jurisdictions to report stolen, lost or orphaned radioactive sources to ARPANSA. This system should be linked with relevant Commonwealth agencies.

Recommendation 11: National radioactive source register

The Commonwealth, through ARPANSA, with the cooperation of the states and territories, should establish, in the near term, an up-to-date secure intranet-based national register of Category 1 and 2 radioactive sources, including, as a minimum, the following information about each radioactive source: licence number, licence-holder, manufacturer, model, serial number, isotope, activity level and application. The register is to allow tracking of radioactive sources at intra and inter-jurisdictional levels. In consultation with the Radiation Health Committee, once the register is established, its extension should consider covering Category 3 sources.

Recommendation 12: Transfer of radioactive sources

Jurisdictions should develop a uniform national regulatory approach to authorizing the transfer of Category 1 and 2 radioactive sources in the near term and Category 3 radioactive sources in the medium term, in order to avoid the risk of such sources becoming uncontrolled and acquired by persons with malicious intent.

APPENDIX X – LIST OF ABBREVIATIONS

ALARA	As Low As Reasonably Achievable
ANSTO	Australian Nuclear Science and Technology Organisation
APDS	ARPANSA Performance Development System
ARPANSA	Australian Radiation Protection and Safety Agency
CEO	Chief Executive Officer
COAG	Council of Australian Governments
CRWMF	Commonwealth Radioactive Waste Management Facility
CSIRO	Commonwealth Scientific and Industrial Research (Australia) Organisation
CSS	Commission of Safety Standards
DEST	Department of Education, Science and Training (Australia)
EPREV	Emergency Preparedness Review
HIFAR	High Flux Australian Reactor
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IRRS	Integrated Regulatory Review Services
IRRT	International Regulatory Review Team
NDRP	National Directory for Radiation Protection
NEA	Nuclear Energy Agency (OECD)
NSC	Nuclear Safety Committee
NUSC	Nuclear Safety Committee
OECD	Organization for Economic Cooperation and Development
OPAL	Open Pool Australian Light Water Reactor
RAP	FAO Regional Office For Asia and the Pacific
RAR	Reasonably assured resources (This is a category of uranium resources)
RASC	Radiation Safety Committee
RaSSIA	Radiation Safety and Security of Radioactive Sources Infrastructure Appraisal
RHC	Radiation Health Committee
RHSAC	Radiation Health and Safety Advisory Council
RRF	Radiation Regulators Forum
TranSAS	Transport Safety Appraisal Service
TRANSC	Transport Safety Committee
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
WAC	Waste Acceptance Criteria
WASC	Waste Safety Committee
WOTD	Waste Operations and Technology Development

APPENDIX XI – ARPANSA ORGANIZATIONAL CHART

