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INTEGRATED REGULATORY REVIEW SERVICE (IRRS) FOLLOW–UP MISSION

TO

THE COMMONWEALTH GOVERNMENT OF AUSTRALIA

Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)

Sydney, Australia

7 to 15 November 2011

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

REPORT

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

FOLLOW-UP REPORT TO

THE COMMONWEALTH GOVERNMENT OF AUSTRALIA

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Mission date: 7 to 15 November 2011

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

Location: ARPANSA Headquarters, Sydney (Miranda), Australia

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

Organized by: International Atomic Energy Agency (IAEA)

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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 Government 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. The purpose of the mission was to undertake a peer review of ARPANSA's regulatory framework and its effectiveness against IAEA Safety Standards and to exchange information and experience on safety regulation. ARPANSA is the regulatory body responsible for radiation protection and nuclear safety in relation to activities with radiation sources and radiation and nuclear facilities undertaken by the Australian Government (Commonwealth) entities and their contractors.

In June 2010, the Commonwealth Government of Australia requested a Follow-up IRRS mission to review the progress in implementing improvements resulting from recommendations and suggestions made in the IRRS 2007 mission and reviewing the areas of significant regulatory changes since then. The scope of the IRRS follow-up mission covered the review of implementation of the 2007 recommendations and suggestions, as well as the review of the IRRS module on patient protection. The follow–up mission also included policy issue discussions on emergency preparedness and response, radioactive waste management and patient protection in the context of national uniformity.

The review was conducted from 8 to 15 November 2011 and the review team comprised of five senior regulators from five Member States, three staff members from the IAEA and an IAEA administrative assistant. ARPANSA had submitted to the IAEA, in advance of the mission, an information package including a status report on actions to implement the 2007 recommendations and suggestions. The IRRS activities took place at the ARPANSA Headquarters in Sydney as well as in the Yallambie premises.

The team concluded that the recommendations and suggestions from the 2007 IRRS mission have been taken into account by ARPANSA. Significant progress has been made in several areas and many improvements were carried out especially in the last 12 months. However, there was no comprehensive and coordinated action plan to address the 2007 recommendations and suggestions that was made available to the IRRS follow-up review team, but it was recognised there were a number of planning processes in place which collectively addressed many of the recommendations and suggestions. These included the Regulatory and Policy Branch business plans and the quality management system plans.

During this follow-up mission the IRRS team determined that 7 of the recommendations and 26 of the suggestions made by the 2007 IRRS mission had been effectively addressed and therefore could be considered closed. ARPANSA should be commended for this accomplishment. For the remaining recommendations and suggestions made, ARPANSA has made progress but has not completed all the necessary actions and consequently these findings have been left open. The IRRS team also concluded that ARPANSA should continue its efforts to reach full implementation.

During the 2011 follow-up mission, the IRRS team made note of the following strengths:

- The response to the TEPCO Fukushima Dai-ichi accident;
- The high level of in-house technical expertise in radiation safety;
- A recognition of the need and willingness to reorganize ARPANSA;
- The timely development of the national sealed source register in good coordination with other relevant organizations;
- The creation of the Australian clinical dosimetry service and the national diagnostic reference level database.

The IRRS team also identifies additional areas to further strengthen ARPANSA's regulatory infrastructure and to support the observed improvement activities.

- Making full use of the opportunity to revise the ARPANS Act in 2012;
- Completing implementation of the reorganization of ARPANSA;

- Influencing enhancement of the national framework for nuclear and radiation emergency preparedness;
- Establishing a coordinating function for ARPANSA's EPR arrangements;
- Better utilizing the expertise within ARPANSA with respect to the regulation of patient protection;
- Initiating the revision of RPS-14 to be aligned with GSR Part 3 to enhance its use nationally as the cornerstone of patient protection;
- Increasing its leadership role in the implementation of Codes of Practice in patient protection.

The IRRS team identifies areas where the Government should take actions specifically to enhance the national regulatory infrastructure for nuclear safety and security.

- Revise the ARPANS Act to take full account of international principles, recommendations and IAEA safety standards and guides;
- Enhance the national framework for nuclear and radiation emergency preparedness by clearly identifying and assigning responsibilities to ARPANSA and other appropriate organizations.

ARPANSA staff put significant effort in to the preparation for the mission. During the review the administrative and logistical support was excellent and the review team was extended full cooperation in technical discussions with ARPANSA staff. ARPANSA counterparts were enthusiastic and interested in obtaining further advice relating to the way they conduct their work, and their plans for further development.

I. INTRODUCTION

BACKGROUND

In 2007 at the request of the Commonwealth Government of Australia, an IAEA team of seven experts from Member States and four staff members from the IAEA and an IAEA administrative assistant visited ARPANSA from 25 June to 6 July 2007 to conduct a full[1] scope Integrated Regulatory Review Service (IRRS) to review ARPANSA's regulatory framework, and its effectiveness. The purpose of the mission was to undertake a peer review of ARPANSA's regulatory framework and the regulatory activities to review the regulatory effectiveness of ARPANSA and to exchange information and experience in the areas considered by the IRRS.

The selected areas reviewed were: legislative and governmental responsibilities; responsibilities and functions of the regulatory body; organization of the regulatory body; activities of the regulatory body including authorization; review and assessment; inspection and enforcement; the development of regulations and guides; safety and security of radioactive sources; radioactive waste management, decommissioning, remediation; transport; emergency preparedness, management system and public information and communication.

In 2007, the IRRS activities took place mainly at the ARPANSA Headquarters in Sydney (Miranda), and the ARPANSA Laboratories in Melbourne (Yallambie). The mission included a series of interviews and discussions with key personnel at ARPANSA and direct observation of their working practices during inspections carried out by ARPANSA. Site visits took place at the research reactor OPAL and at some industrial sources facilities.

The report was published in 2007 and was made publicly available at ARPANSA and IAEA web-sites.

FOLLOW-UP MISSION

In June 2010, the Commonwealth Government of Australia requested a Follow-Up IRRS mission, to review the measures undertaken following the recommendations and suggestions presented in the report of the 2007 IRRS mission.

The review was conducted from 7 to 15 November 2011. The team consisted of 5 senior regulatory experts from 5 Member States, 3 staff members from the IAEA, and an IAEA administrative assistant (Appendix I). IRRS activities took place at the ARPANSA offices in Sydney (Miranda) and Melbourne (Yallambie).

II. OBJECTIVE AND SCOPE

The purpose of the IRRS follow-up mission was to continue the work of improving regulatory effectiveness by reviewing ARPANSA's progress in response to IRRS mission recommendations and suggestions, identification of new good practices and to exchange information and experience among ARPANSA counterparts and the IRRS team with a view to contributing in harmonizing regulatory approaches and creating mutual learning opportunities among regulators.

The IRRS follow up mission was structured in order to take into account the progress in implementing improvements resulting from recommendations and suggestions made in the IRRS 2007 mission and reviewing the areas of significant regulatory changes since the last mission.

Those areas where no suggestions or recommendations were made on the 2007 IRRS mission were not included in the scope of the follow-up mission.

The general key objectives of the IRRS mission are to enhance the regulatory effectiveness by:

- Providing the host country (regulatory body and governmental authorities) with a review of

[1] All activities, practices and facilities regulated by ARPANSA.

their regulatory issues, in particular those highlighted in the 2007 mission;

- Providing the host country with an objective evaluation of their regulatory practices with respect to international safety standards;
- Contributing to the harmonization of regulatory approaches among Member States;
- Promoting the sharing of experiences and exchange of lessons learned;
- Providing key staff in the host country with an opportunity to discuss their practices and action plans considering the 2007 findings with reviewers who have experience of other practices in the same field;
- Providing the host country with recommendations and suggestions for improvement;
- Providing other States with information regarding new 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, in particular on how the host country is implementing the improvements.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

The preparatory work for the mission was carried out by the IRRS IAEA Coordinator Mr Hilaire Mansoux, the Deputy Coordinator Mr David Graves and Mr Ian Graham from ARPANSA.

An IRRS preparatory meeting was held on 5-6 July 2011 to discuss the technical and administrative details of the follow up mission to Australia. It took place in the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) offices in Sydney, Australia with the participation of the appointed IRRS Team Leader Mr Kaare Ulbak of the National Institute for Radiation Protection, Denmark; IRRS Deputy Team Leader Mr George Pangburn of the United States Nuclear Regulatory Commission (USNRC); IAEA Coordinator Mr Hilaire Mansoux and IAEA Deputy Coordinator Mr David Graves.

The preparatory meeting was opened by the CEO of ARPANSA, Mr Carl-Magnus Larsson, who provided an organizational overview and the main changes to the ARPANSA regulatory framework since 2007.

During the preparatory meeting discussions, it was agreed that the advance reference material (ARM), including the output from the self-assessment, would be provided to the IAEA in September 2011. In addition, the scope of the follow-up IRRS mission was agreed to include: progress made to address the 2007 IRRS mission findings and considering the changes since the 2007 mission in those areas where recommendations or suggestion were issued, together with a new area of review, namely patient protection. The topics for the policy issue discussions were also agreed to be on emergency preparedness and response, waste management and national uniformity with regards to patient protection. The ARM and the main agenda items of the follow up mission were discussed and agreed.

In accordance with the request from ARPANSA, and taking into account the scope of the follow up mission as indicated above, it was agreed that the IAEA review team would comprise of 5 senior regulators from 5 Member States (Denmark Spain, Sweden, Canada, and the United States) some of whom have already participated in the 2007 mission, under the IAEA coordination and an IAEA administrative assistant (see Appendix I). The working areas and the ARPANSA counterparts were nominated as outlined in Appendix III.

During the preparatory phase all documents comprising the ARM were made available to the IAEA review team. In particular, the main document about the status of actions related to recommendations and suggestions from 2007 IRRS mission was provided

The reviewers and the IAEA staff prepared before the mission, the initial impressions on the ARM, reviewed ARPANSA's action plan and prepared for the interviews during the mission with the counterparts.

An initial IAEA team meeting took place on Monday 7 November 2011 and was attended by the IRRS Review Team and the ARPANSA Liaison Officer, Mr David Tredinnick. The IRRS Team Leader and the IRRS IAEA Coordinator discussed specific aspects of the mission, the background and main issues from the 2007 IRRS mission, the basis for the review, context and objectives of the IRRS; and IRRS methodology for the review and the evaluation. The Liaison Officer presented the logistical and other aspects of the follow-up mission.

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

The entrance meeting was held on Tuesday, 8 November 2011 with the participation of the IRRS Review Team, the ARPANSA senior management and other ARPANSA staff contributing to the follow up mission.

Opening remarks were made by Mr Carl-Magnus Larsson. Several presentations were carried out and discussed during the entrance meeting, in relation to the objectives of the follow-up mission and the current ARPANSA organization. The status of the implementation of recommendations and suggestions from 2007 was discussed in order to understand the current situation and delineate the initial main areas to be discussed during the interviews with the counterparts.

During the mission, a systematic review was conducted of all recommendations and suggestions from the IRRS in 2007 with the objective of establishing progress made by ARPANSA in response to the 2007 mission, as well as identifying new good practices for the review as stated in the scope of the mission. The review was conducted in topical areas taking into account the previous experience of the experts in the 2007 mission, through meetings, interviews and discussions with ARPANSA personnel and assessment of the action plan. The team performed its activities in accordance with the Mission Programme, outlined in Appendix II.

The exit meeting was held on Tuesday, 15 November 2011 with the participation of the CEO of ARPANSA, the advisor to the Parliamentary Secretary, the team members and ARPANSA counterparts.

The main conclusions of the follow-up IRRS mission were presented by the IRRS Team Leader Mr Kaare Ulbak and closing remarks were made by Mr Carl-Magnus Larsson; and Mr Hilaire Mansoux on behalf of Mr Pil-Soo Hahn, Director of the Division of Radiation, Transport and Waste Safety of the IAEA.

The draft mission report was handed over to ARPANSA at the end of the meeting.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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.
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.

Findings from the 2011 Follow-Up Mission

Suggestion 1: The Australian Radiation Protection and Nuclear Safety Act 1998 (ARPANS Act) has not been reviewed since the IRRS full scope review in 2007. However, ARPANSA informed the IRRS team that the Department of Health and Ageing in July 2011 have announced that a review of the Act will be undertaken in the first half of 2012 to ensure that ARPANSA is properly supported to carry out its regulatory functions. Terms of Reference for the review will be provided later, and inputs to the review process and the Term of Reference can be given to the Department of Health and Ageing. ARPANSA also provided the team with a preliminary draft of the ARPANSA Board paper for the appropriate changes to the Act, which includes a specific reference to prime responsibility for safety resting with the entity responsible for the source or activity. The team notes that ARPANSA has met the intent of S1.

Beyond the legislative arena, the team reviewed applicable regulatory documents produced by ARPANSA that include the expectation that an operator bears primary responsibility for safety. These are the Regulatory Guide on Plans and Arrangements and the Regulatory Assessment Principles for Controlled Facilities. In addition, a project is currently underway to ensure that the operator's primary responsibility for safety is appropriately reflected in ARPANSA's Radiation Protection Series (RPS) No. 1, which is the top level document in the Radiation Protection Series of documents. The review and republishing of RPS 1 is expected to be completed in 2013.

Suggestion 1 (S1): is CLOSED.

Suggestion 2: The Australian Radiation Protection and Nuclear Safety Act 1998 (ARPANS Act) has not been reviewed since the IRRS full scope review in 2007. However, ARPANSA informed the IRRS team that the Department of Health and Ageing in July 2011 have announced that a review of the Act will be undertaken in the first half of 2012 to ensure that ARPANSA is properly supported to carry out its regulatory functions. Terms of Reference for the review will be provided later, and inputs to the review process and the Term of Reference can be given to the Department of Health and Ageing. The team notes that ARPANSA has met the intent of S2.

Meanwhile, ARPANSA has re-published the IAEA requirements, Regulations for the Safe Transport of Radioactive Material 2005 Edition, as the 2008 Edition of the ARPANSA Code of Practice for the Safe Transport of Radioactive Material (Radiation Protection Series No. 2). This Code sets out nationally uniform requirements for the transport of radioactive material and is prescribed in Regulation 48 of the Australian Radiation Protection and Nuclear Safety Regulations 1999 (ARPANS Regulations) as a general condition of Licence. An accompanying Safety Guide to assist users to comply with the Code was published in 2008.

Suggestion 2 (S2): is CLOSED.

New findings from the 2011 Mission

The announced review of the Australian Radiation Protection and Nuclear Safety Act 1998 (ARPANS Act) in 2012 will offer a unique opportunity to update the Act in line with the latest international

principles and recommendations for nuclear and radiation safety including security of radioactive sources and emergency preparedness and response. In particular the following IAEA Safety Standards and guidance should be used as primary references in the review process:

- IAEA Safety Standard Series No. SF-1, Fundamentals Safety Principles, 2006.
- IAEA Safety Standard Series No. GSR Part 3 (Interim), Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards Interim Edition, 2011.
- IAEA Safety Standard Series No. GSR Part 1, Governmental, Legal and Regulatory Framework for Safety, 2010.
- IAEA Safety Standard Series No. GS-R-2, Preparedness and Response for a Nuclear or Radiological Emergency, 2002.
- Code of Conduct on the Safety and Security of Radioactive Sources, 2004.

At the same time it would be possible to take account for the recommendations and suggestions in the 2007 IRRS Mission report which addressed:

- Principle of primary responsibility (S1);
- Explicit legislative basis for ARPANSA's regulation of the land transport of radioactive material (S2);
- Environmental chronic exposure situation control (S8);
- Decommissioning plans and associated financial resources (R6 and S12);
- Clarifying the role of ARPANSA for regulating safety and security of radioactive sources (S21);
- Clarifying the role of ARPANSA in the national framework for emergency preparedness and response (R9).

The IRRS team finds this review and revision very timely and offers the following recommendation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE FROM THE 2011 FOLLOW-UP MISSION	
(1)	**BASIS:** Code of Conduct § 18 states: *"Every state should have in place legislation and regulations that:* *(a) prescribe and assign governmental responsibilities to assure the safety and security of radioactive sources;* *(b) provide for the effective control of radioactive sources."*
(2)	**BASIS:** GSR Part 1 Requirement 2 states: *"The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are allocated."*
(3)	**BASIS:** GSR Part 1 Requirement 2 §2.5 states: *"…This framework for safety shall set out the following:* *(12) Provision for preparedness for, and response to, a nuclear or radiological emergency;* *(16) Responsibilities and obligations in respect of financial provision for the...decommissioning of facilities and termination of activities;* *(19) Provision for controls on the import and export of…radioactive material.*
(4)	**BASIS:** SF-1 Principle 1: Responsibility for safety states: *"The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks.*
RF1	**Recommendation:** In the revision of the Australian Radiation Protection and Nuclear Safety Act (ARPANS Act) to be undertaken in 2012, the Australian Government should aim at ensuring full compliance of the Legal framework with IAEA Safety Standards. In particular, the revised Act should include explicit provisions and requirements for: • the prime responsibility for safety to be placed on the operator; • the legal basis for ARPANSA to regulate land transport or radioactive

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE FROM THE 2011 FOLLOW-UP MISSION	
	material; • the legal basis for regulating existing exposure situations, remediation and clearance; • decommissioning plan and related financial provisions , • assigning ARPANSA a clear role in regulating the security of controlled material, controlled apparatus and controlled facilities and promoting national uniformity; • clarifying ARPANSA's role in the establishment and operation of the national framework for nuclear and radiological emergency preparedness and response; • introducing the concept of clearance into the Australian regulatory framework.

2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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.

Findings from the 2011 Follow-Up Mission

Suggestion 3: The IRRS team reviewed the agreement that ARPANSA has signed with Queensland Health (the State of Victoria could not provide the resources to support this initiative). The agreement provides for Queensland Health to participate in inspections with ARPANSA and includes details about process, treatment of information, remuneration, liability and occupational health & safety. The IRRS team discussed the implementation of the agreement with ARPANSA management and determined that from an operational perspective, the Queensland inspectors will accompany ARPANSA inspectors in their inspection of ARPANSA facilities and will jointly approve the inspection reports of those facilities. The IRRS team concludes that this arrangement meets the intent of S3.

Suggestion 3 (S3): is CLOSED.

New findings from the 2011 Mission

There were no new findings in the 2011 IRRS Follow-up Mission.

3. ORGANIZATION OF THE REGULATORY BODY

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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.
S5	**Suggestion**: 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.
S6	**Suggestion**: ARPANSA should consider its strategy for effective implementation of the "Workforce Planning and Development" document derived from its Corporate Plan 2005-2008.
R1	**Recommendation**: ARPANSA should establish and implement a more comprehensive training programme for regulatory staff.

Findings from the 2011 Follow-Up Mission

Suggestion 4: Since the 2007 IRRS mission, ARPANSA has undertaken a wide range of initiatives to prioritize its resources and activities to address challenges in its regulatory and corporate environments. These initiatives have included, but are not limited to the following:

- a significant reorganization of ARPANSA, reflective of both internal and external factors;
- a review of the Strategic Directions as part of the reorganization of the agency during 2010–2011 and identification of 10 key areas with associated outcomes and strategies;
- integration of the key areas thus defined in the 2011-2012 Portfolio Budget Statement;
- preparation of a revised Strategic Directions document for 2012 – 2016, that, after internal and external consultation, will be issued during the first half of 2012;
- review of Annual Business Plans prepared by the Branches and Offices in the Performance and Accountability Report by the Board on a quarterly basis.

The IRRS team reviewed documents and discussed the reorganization, strategic directions, key areas, budget planning and on-going operational monitoring with ARPANSA management. In the team's view, these initiatives have been well conceived and coordinated, particularly with the staff, and provide a strong planning basis for the future.

Suggestion 4 (S4): is CLOSED.

Suggestion 5: The IRRS team discussed with ARPANSA management its planned actions to strengthen the interaction between the regulatory and scientific staff located in Sydney and Melbourne, respectively. Strengthening the interactions between these two locations is an essential part of the recent reorganization of ARPANSA. In addition, the agency has taken other steps, which include:

- use of scientific staff to assist with inspection activities where appropriate;
- increased cross-branch and cross-campus activity as a result of the reorganization; and
- communication, coordination and integration processes to be developed and facilitated by the CEO Office progressively as a matter of priority.

The IRRS team notes that these planned activities demonstrate ARPANSA's commitment to strengthening the organization. Certain of these activities are underway, such as development of a

4–year inspection schedule with participation from both locations, while others will take additional time to complete.

Suggestion 5 (S5): is CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE.

Suggestion 6: The IRRS team discussed with ARPANSA its plans and activities to address workforce planning and development. The team reviewed a proposal for workforce and succession planning that was discussed and agreed in principle by the Board in October 2009. ARPANSA expects that significant progress in the implementation of the proposal will be achieved by June 2012 and will be managed by the new Corporate Office. The key actions to be undertaken include conducting resource analysis in all Branches/Offices to outwork the reform restructure (by end September 2011), finalizing the reform (by end December 2011) and developing the workforce management strategy by building on the October 2009 proposal (by June 2012). In its discussions with ARPANSA management, the team noted that there was a good understanding of workforce characteristics within the agency and in relation to the broader Australian Public Service and the challenges that those characteristics pose for the agency. The team believes that ARPANSA has made progress in this area, the graduate intern recruitment effort being one example, but acknowledges as noted above that more remains to be done.

Suggestion 6 (S6): is CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE.

Recommendation 1: The IRRS team discussed and reviewed progress made by ARPANSA in addressing this recommendation. Competencies for inspectors have been developed and are documented in OS-INS-SUP-280E Requirements & Competencies for Inspectors v3, May 2011. The team reviewed records of training provided since 2007 which documented that a wide range of training courses have been arranged for inspectors (and other staff), many of which have been given in-house. These include: Defence in Depth, Nuclear Reactor Severe Accident Analysis, Protective Security of Radioactive Sources and Technical Writing Skills, to name a few.

Further training is taking place in the second half of 2011, focusing on evidence gathering and interpretation. In 2011, the CEO requested the Audit and Fraud Control Branch of the Department of Health to look into two previous ARPANSA investigations. The lessons learned from this review will be communicated to all inspectors during the second half of 2011.

ARPANSA has a project underway to review training needs and document a training plan and schedule. This project is expected to be completed by December 2011. On-going review via refresher training would be on a 3 to 5 year cycle. Development of training plans for individual inspectors and monitoring of progress against the training and qualification schedule is an important step forward for the inspection staff.

Recommendation 1 (R1): is CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE.

New findings from the 2011 Mission

Partnering with the States and Territories on common training needs and potential joint training and development opportunities could save resources and have the practical effect of furthering the goal of National Uniformity including patient protection.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE FROM THE 2011 FOLLOW-UP MISSION	
(1)	**BASIS**: GSR Part 1 requirement 18 para. 4.13 states: *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills…."*
SF1	**Suggestion:** ARPANSA should initiate discussions with States and Territories regulators on the possibility of organizing joint training and development for inspectors and licence assessors with the aim of sharing resources and achieving national uniformity.

4. ACTIVITIES OF THE REGULATORY BODY

4.1 AUTHORIZATION

No recommendation or suggestion was made in this part of the IRRS 2007 report.

4.1.1 AUTHORIZATION – RESEARCH REACTORS

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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.

Findings from the 2011 Follow-Up Mission

Recommendation 2: This recommendation was initially raised in the context of the review of authorizations for research reactors, but for practical purposes is applicable to sources and industrial practices. The advance reference material for the IRRS mission and interviews confirm that ARPANSA is in agreement with this interpretation.

For the OPAL facility, ANSTO's safety management system provides internal guidance and requirements to determine the safety consequence of proposed changes under Regulations 51 and 52. ARPANSA has approved this guidance and requirements and reviews its implementation as part of its regulatory oversight. This approach has been demonstrated effective when implemented appropriately by the operator. Regulatory Guide RB-STD-43-00 "Regulatory Assessment Criteria for the Design of New Controlled Facilities and Modifications to Existing Facilities" addresses the assessment criteria for proposed modifications of the facility.

ARPANSA staff agreed that regulatory guidance documentation was still not complete, and did not cover all types of licences. One stated challenge related to the definition of safety significance for source holders, ARPANSA staff plans on adapting and expanding the above concepts and integrate in a generic guidance document that would address these matters.

Production of the generic guidance documentation is currently in the work plans and is due by the end of June 2012.

The IRRS review team acknowledges the progress made on this matter by ARPANSA. However, the original recommendation still is not fully addressed. Given the proposed expanded scope of ARPANSA's strategy, the IRRS review team concludes that R2 is closed and replaced by the recommendation below expanding its applicability to all facilities and activities regulated by ARPANSA.

Recommendation (R2): is CLOSED.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE FROM THE 2011 FOLLOW-UP MISSION	
RF2	**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. The guidance information should apply to all facilities and activities regulated by ARPANSA.

4.1.2 AUTHORIZATION – SOURCES AND INDUSTRIAL PRACTICES

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
S7	**Suggestion:** ARPANSA should establish clearly defined procedures addressing the regulatory requirements for amendment, suspension or cancellation of a licence.

Findings from the 2011 Follow-Up Mission

Suggestion 7: Licences are issued with no expiry date. Licensing actions include amendment, suspension, and surrender which is considered by ARPANSA staff to be equivalent to cancellation.

Amendments:

Amendments to a licence usually takes place as a result of a change in dealings by licence holders, or as a result of periodic review of licences which is conducted every three years to ensure consistency of the licences with reality in the field.

ARPANSA staff stated that requests for licence amendments by operators are considered equivalent to an application for a new licence and would require similar levels of information. However, this approach is not documented.

Some aspects of guidance for licence amendments are available in "Regulatory Guide: Plans and Arrangements for Managing Safety". It is also expected that resolution to R2 would provide essential guidance on the matter. However, a documented procedure addressing regulatory requirements covering all aspects of licence amendments is still not available.

Provision for licence amendments by ARPANSA's own suggestion would be addressed as part of S16.

Suspensions:

Suspensions are essentially seen as part of an enforcement policy and would be addressed as part of resolution to S16.

Surrender:

Regulatory Guide "Surrender of Facility Licence and Release from Regulatory Control" provides generic guidance and criteria for submissions related to surrender of a licence.

Although progress is observed, some work remains before this suggestion may be considered closed.

Suggestion 7 (S7): is OPEN.

New findings from the 2011 Mission

There were no new findings in the 2011 IRRS Follow-up Mission.

4.1.3 AUTHORIZATION – DECOMMISSIONING

No recommendation or suggestion was made in this part of the IRRS 2007 report.

4.1.4 AUTHORIZATION - REMEDIATION

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
S8	**Suggestion:** 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**.**

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
S9	**Suggestion**: 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.

Findings from the 2011 Follow-Up Mission

Suggestion 8: This suggestion concerns the authorization process for remedial actions in situations with potential environmental chronic exposures under the regulation of ARPANSA.

The 2007 Mission identified that there were no legal provisions and a lack of specific regulatory framework for remedial activities to be implemented for radiological contaminated sites not associated with operational facilities. The licences that have been issued do not correspond directly with activities to be authorized.

The Australian Radiation Protection and Nuclear Safety Act 1998 (ARPANS Act) has not been reviewed since the IRRS full scope review in 2007. However, ARPANSA informed the IRRS team that the Department of Health and Ageing in July 2011 have announced that a review of the Act will be undertaken in the second half of 2012 to ensure that ARPANSA is properly supported to carry out its regulatory functions. Terms of Reference for the review will be provided later, and inputs to the review process and the Term of Reference can be given to the Department of Health and Ageing. The team notes that ARPANSA has met the intent of S8.

Suggestion 8 (S8) is CLOSED.

Suggestion S9: This suggestion is also concerned with the authorization process for remedial actions in situations with potential environmental chronic exposures. There were, at the time of the 2007 Mission, two such situations under the regulation of ARPANSA: The South Alligator Valley former mining sites and the Maralinga former Atomic Weapon Test site.

The 2007 Mission identified that a surveillance programme should be implemented in rehabilitated sites to verify the long term effectiveness of the remedial actions and to manage the residual risk of the site.

ARPANSA has implemented the suggestion in relation to the South Alligator Valley site by requiring long term environmental monitoring at the site as a condition of building the radiological containment. A long term environmental monitoring programme was proposed by the licensee (Parks Australia) which was approved by ARPANSA. As for the Maralinga site, ARPANSA returned the site to the Government of South Australia in 2009. The CEO of ARPANSA approved the transfer of the Maralinga site from the Australian Government to the South Australian Government, only after the South Australian Government demonstrated to the CEO of ARPANSA that regulatory controls over the Maralinga site under South Australia's Radiation Protection and Control Act would require the registered occupier of the land to comply with the Maralinga Land and Environment Management Plan, and with any additional requirements deemed necessary by the South Australian Government and allow reasonable access to the site by authorized officers of the South Australia Government. The 2011 follow-up Mission team concludes that ARPANSA has met the intent of S9.

Suggestion 9 (S9): is CLOSED.

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

4.1.5 AUTHORIZATION – RADIOACTIVE WASTE MANAGEMENT

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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.

Findings from the 2011 Follow-Up Mission

Suggestion 10: This suggestion refers specifically to the regulation of liquid discharges of radioactive wastes generated in ANSTO facilities, a licensee regulated by ARPANSA.

In the case of ANSTO's operations, the establishment of authorized discharge limits for aqueous discharges was achieved, at the time of 2007 Mission, through agreement with Sydney Water. The team understood that ARPANSA was asked to comment on the methods used to derive the aqueous discharge limits and the limits established. Sydney Water had a memorandum of understanding with ANSTO whereby ANSTO reports aqueous discharges to Sydney Water with a copy to ARPANSA. However, there were no formal arrangements in place between ARPANSA and the organization(s) that regulates Sydney Water.

The team understood that the discharge limits in the agreement with Sydney Water were in accordance with international guidance, so this was not an immediate concern for safety. However, the 2007 Mission team understood this agreement with Sydney Water was a quite complicated administrative arrangement for regulatory oversight of aqueous discharges from the ANSTO site. Also, this arrangement didn't provide for strong regulatory oversight over the combined discharges from the ANSTO site.

The liquid discharges from ANSTO site to the sewer system is governed by the trade waste agreement between ANSTO and Sydney Water. Currently ANSTO reports monthly on the liquid discharges from the site to Sydney Water and ARPANSA. ARPANSA assesses the radioactive discharges to a that the limits set on the basis of WHO drinking water guidelines have not been breached. So far there has been no breach. Should there be a breach ARPANSA will deal with the situation using the compliance and enforcement powers available under the ARPANS Act.

The 2011 Follow-up Mission noted that no major progress has been made since 2007 in formalizing the arrangement followed "de facto" by ANSTO, Sydney Water and ARPANSA. ARPANSA demonstrated that they received periodic information from ANSTO on the liquid discharges to the environment, as per the licensing conditions. The 2011 Follow-up Mission noted that these discharge constraints are not included in the licence conditions of ANSTO facilities. In addition, the role of ARPANSA in regulating liquid discharge of any facility is not clear for the IRRS review team. Therefore, the IRRS team concludes that suggestion 10 is closed and replaced with a new recommendation

Suggestion 10 (S10) is CLOSED.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE FROM THE 2011 FOLLOW-UP MISSION	
(1)	**BASIS:** GSR Part 3 requirement 12 §3.27 *"The government or the regulatory body shall determine what additional restrictions, if any, are required to be complied with by registrants and licensees to ensure that the dose limits specified in Schedule III are not exceeded owing to possible combinations of doses from exposures due to different authorized practices."*
RF3	**Recommendation:** ARPANSA should establish or amend requirements to ensure protection of public health and safety by setting limits for liquid discharge from licensed activities.

4.2 REVIEW AND ASSESSMENT

No recommendation or suggestion was made in this part of the IRRS 2007 report.

4.2.1 REVIEW AND ASSESSMENT – RESEARCH REACTORS

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
R3	**Recommendation:** 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.

Findings from the 2011 Follow-Up Mission

Recommendation 3: According to ARPANSA staff, ANSTO committed to submit such a Periodic Safety Review (PSR) by November 2011, which corresponds to two years after completion of the commissioning programme for the OPAL reactor. The conduct of this PSR is required by Condition 2 of the OPAL Operating Licence.

ARPANSA informed ANSTO of their expectation that IAEA Safety Guide (NS-G-2.10) should be utilized in the conduct of its first Periodic Safety Review.

At the time of the follow-up mission, ARPANSA was developing a draft Regulatory Guide on Periodic Safety Reviews. ARPANSA staff will use the experience gained in the conduct and the review of this first Periodic Safety Review in completion of its formal regulatory guidance on the matter.

The IRRS review team concludes that R3 will remain relevant for future Periodic Safety Reviews in Australia and considers it should remain open.

Recommendation 3 (R3) is OPEN.

New findings from the 2011 Mission

There were no new findings in the 2011 IRRS Follow up Mission.

4.2.2 REVIEW AND ASSESSMENT – SOURCES AND INDUSTRIAL PRACTICES

No recommendation or suggestion was made in this part of the IRRS 2007 report.

4.2.3 REVIEW AND ASSESSMENT – DECOMMISSIONING

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
R4	**Recommendation:** 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.
R5	**Recommendation:** 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.
S11	**Suggestion:** 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.
S12	**Suggestion:** 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.

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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**.**

Findings from the 2011 Follow-Up Mission

Recommendation 4: At the time of the 2007 Mission, ARPANSA had 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, nor for a brown field end point, restricting the site to a future industrial use. The 2007 Mission thought that, 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 the HIFAR reactor.

ARPANSA has issued Version 2 of the *Standard Operating Procedure for Managing Surrender of Licence* (RPB-LA-SOP-246) (SOP for Licence Surrender). The SOP for License Surrender provides general guidance on the criteria which permit a license to be surrendered and establishes the stage at which a decommissioned facility may be released without any further radiological restriction.

ARPANSA is also on the verge of finalizing the draft *Regulatory Guidance for the Decommissioning of Controlled Facilities* (RPB-LA-SUP-240K) (by June 2012). Section 8 of this document describes post-decommissioning activities including the need for baseline radiological characterization surveys to demonstrate that the decommissioned facility is in a safe state.

As for guidelines that establish the stage at which a decommissioned facility may be released with continuing restrictions that may apply, such guidelines will be developed by ARPANSA on a case by case basis. The team concludes that R4 is closed.

Recommendation 4 (R4) is CLOSED.

Recommendation 5: Following the final shut down of the HIFAR reactor, the operator of HIFAR, ANSTO, applied for a facility licence authorizing it to "possess or control" the reactor rather than proceeding to apply for a licence to decommission the reactor. ANSTO included within its application the performance of some significant dismantling activities as part of this preparation for decommissioning without having implemented the final Decommissioning Plan.

The 2007 Mission understood that, if a decommissioning plan is not in force, all the applicable requirements for the facility shall 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**).**

Currently ARPANSA's requirements are reflected in Licence F0184 (HIFAR Possess or Control). Essentially, specified refurbishment projects can be approved but the removal of items of plant containing radionuclide levels above those specified in the ARPANSA Regulations are prohibited. ARPANSA has also provided guidance in the form of a series of letters to the licence holder (ANSTO) in regards to what activities can be undertaken under a "possess or control" licence.

These letters are now being formalized into a set of guidelines for "radiological decommissioning with the caveat that the license holder should be aware of other statutory requirements outside the requirements of the ARPANS Act. The action to formalize the letters into a guideline is expected to be completed by December 2011. The team concludes that R5 is closed on the basis of progress and confidence.

Recommendation 5 (R5) is CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE.

Suggestion 11: Following the final shutdown of the HIFAR reactor, the operator (ANSTO) was applying for a facility licence authorizing it to "Posses or Control" the reactor during the preparation for decommissioning, rather than proceeding to apply for a licence to decommission the reactor. ANSTO included within its application the performance of some significant dismantling activities as part of this preparation for decommissioning, which was to be followed by a period of 10 years of "safe enclosure" of the facility without having a proper decommissioning licence.

The 2007 Mission understood that this preparatory period for decommissioning (pre-decommissioning activities) and the 10 years of "safe enclosure" should be within the scope of a well-established and approved Decommissioning Plan, unless some other reasons exist and the regulatory body accepts.

There is still no national waste repository in place in Australia. However, the National Radioactive Waste Management Bill 2010 is currently before the Australian Parliament. The lack of a repository could be a severe constraint for decommissioning activities.

ANSTO has not been required by ARPANSA to obtain a licence for decommissioning because of the lack of a repository to dispose of the decommissioning wastes. It is ARPANSA's intention to limit the duration of any Possess and Control licence issued to a nuclear facility to prepare for decommissioning once a national waste repository is in place. The team concludes that S11 is closed.

Suggestion 11 (S11) is CLOSED.

Suggestion 12: The 2007 Mission noticed that there was no explicit mechanism within either the legal or organizational framework of the regulatory body to ensure adequate financial resources are available to cover the costs of decommissioning including radioactive waste management and disposal. The team thought the financial aspects is a key issue in order to assure adequate funding is in place for safe decommissioning.

The ARPANS legislation is silent on the question of budget for decommissioning. However, Regulation 41 of ARPANS Regulations requires the CEO to consider certain matters to issue a facility licence and that includes "whether the applicant has shown a capacity for complying with these regulations". It is felt that under this provision, the CEO can consider if the applicant has the necessary budget for decommissioning and radioactive waste management.

The Australian Radiation Protection and Nuclear Safety Act 1998 (ARPANS Act) has not been reviewed since the IRRS full scope review in 2007. However, ARPANSA informed the IRRS team that the Department of Health and Ageing in July 2011 has announced that a review of the Act will be undertaken in the first half of 2012 to ensure that ARPANSA is properly supported to carry out its regulatory functions. Terms of Reference for the review will be provided later, and inputs to the review process and the Term of Reference can be given to the Department of Health and Ageing. The team notes that ARPANSA has met the intent of S12.

Suggestion 12 (S12) is CLOSED.

Recommendation 6: The 2007 Mission noted that ANSTO's 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 observation led to R6 of the report.

The first part of the recommendation relating to amendments to the regulatory framework to address considerations of production and submission of decommissioning plans is now addressed in section 1 of the present report and in SF1.

Regarding the second part of the recommendation, the IRRS review team noted the following:

- The HIFAR Possess and Control authorization was issued in 2008; this licence has no time limit.

- ARPANSA did not formally request ANSTO to produce a decommissioning plan. However, there are ongoing discussions between ARPANSA and ANSTO on this matter. There is an agreement that ANSTO will provide a first decommissioning plan by mid-2012.

The IRRS review team understands that the lack of a national repository imposes limitations on short term options for decommissioning; however, it is of the opinion that submission of a detailed decommissioning plan is essential to provide for a clear basis for the management of the HIFAR facility. It was agreed during the review that ARPANSA will formalize the ongoing discussion and request the submission of a decommissioning plan. On this basis the team concludes that R6 can be closed on the basis of progress and confidence.

Recommendation 6 (R6) is CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE.

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

4.2.4 REVIEW AND ASSESSMENT – RADIOACTIVE WASTE MANAGEMENT

No recommendation or suggestion was made in this part of the IRRS 2007 report.

4.3 INSPECTION AND ENFORCEMENT

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
R7	**Recommendation:** ARPANSA should incorporate into its internal guidance a requirement to include unannounced inspections in its compliance program for all licensees.

Findings from the 2011 Follow-Up Mission

Recommendation 7: ARPANSA has included in its revised Compliance Policy (OS-MAN-280 Version 4) a recommendation on a frequency for unannounced inspections of 10%. Guidance is provided (OS-INS-SOP-280 Version 5) on limits to possible notification prior to unannounced inspections to avoid undue disruption in operation and ensure key personnel are available.

A review of recent inspections and of 2010-2015 planned inspection schedule confirms that the conduct of unannounced inspections is now included in ARPANSA's compliance programme.

Recommendation 7 (R7) is CLOSED.

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

4.3.1 INSPECTION – RESEARCH REACTORS

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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.

Findings from the 2011 Follow-Up Mission

Suggestion 13: Since the 2007 mission, ARPANSA has established a four year inspection schedule for its licensed facilities. This schedule is dynamic and is reviewed periodically through planning meetings of inspection staff and is based on a risk informed evaluation of the licence holders. Currently, this process is not formalized. ARPANSA staff is now working towards formalizing the process, to provide for better integration of the facility licences. A feedback loop will be integrated into the inspection procedures (RPB-INS-SOP-280). Also, a detailed set of principles and procedures for inspection planning and assessment of inspection programmes (including the feedback loop) will be integrated into RPB-INS-SOP-280.

Although improvement was observed on this matter since the 2007 IRRS mission, the IRRS team notes that no provision appears to be in place or planned to ensure periodic systematic assessments of the inspection programme.

Such an assessment should include consideration of operational data, events data, risk insights, and views of inspectors and licence holders on the efficiency and effectiveness of the inspection programme. The frequency of the assessment should be based on the size and complexity of the ARPANSA programme and should allow enough data to make meaningful conclusion.

Suggestion 13 (S13) is OPEN.

Suggestion 14: During the 2007 IRRS mission, the review team noted that the inspections reports were not organized in such a way to provide a synthesis of the inspection findings and a categorization of issues regarding non-compliances, issues requiring corrective actions, requests for additional information and observations.

ARPANSA staff was requested to provide a sample of past and more recent inspection reports. From a comparison of this sample, the review team concludes there is a significant improvement in the structure of the reports, in their simplification and providing clearer identification of findings and conclusions.

Additional guidance on the content of inspection reports is provided in Inspection Procedure OS-INS-SOP-280 version 5 (Draft).

The policy of ARPANSA is now to publish inspection reports on its website.

Suggestion 14 (S14) is CLOSED.

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

4.3.2 INSPECTION – SOURCES AND INDUSTRIAL PRACTICES

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
R8	**Recommendation:** 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.

Findings from the 2011 Follow-Up Mission

Recommendation 8: Procedure OS-INS-SUP-280C "Guidance for inspectors" Version 3 was provided; this procedure states that the inspector should pack radiation monitoring equipment one day before the inspection if this equipment is required. The same element of guidance to inspectors was observed during the 2007 mission; in this no evidence of change in practice related to this recommendation was observed during the follow-up mission. ARPANSA staff stated that it maintains a complete set of radiation monitoring instruments for alpha, beta, gamma, neutron, electronic personal dosimeters and gamma spectrometry; inspectors are trained on how and when to use these instruments.

Inspection reports were shown providing evidence that radiation field measurements are taken, when part of the normal scope of the inspection. ARPANSA staff stated that it was practice to carry monitors when in the field, despite the scope of inspection, but we could not confirm that this practice was formalized as an expectation for inspectors.

The IRRS review team is of the view that the Guidance for inspector could better expand on conditions under which hand-held monitors should be required during inspections, more specifically during which radiation field or contamination measurements are to be independently taken for regulatory purposes, or where radiation detectors are deemed essential to assist in personnel protection.

Recommendation 8 (R8) is CLOSED.

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

4.3.3 INSPECTION - DECOMMISSIONING

No recommendation or suggestion was made in this part of the IRRS 2007 report.

4.3.4 INSPECTION – RADIOACTIVE WASTE MANAGEMENT

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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.

Findings from the 2011 Follow-Up Mission

Suggestion 15: The suggestion refers to inspection and enforcement. The suggestion arose in the course of an inspection on radioactive waste management matters, but it can be extended to the general inspection procedure. The 2007 Mission team identified that ARPANSA didn't have an organization-wide feedback mechanism for sharing of experience from inspections.

Currently, inspectors discuss the outcomes of inspections and lessons learnt but till now there is no formal process in place to capture this feedback. The use of regular meetings of the inspection staff to review and to share lessons learned in inspection is incorporated in the latest draft (version 5) of the Quality Management System document of the Inspection Procedure (OS-INS-SOP-280). The version of the document is expected to be completed by December 2011. In addition, ARPANSA will develop an inspection register to keep track of inspection findings and lessons learned. The follow-up Mission team concludes that S15 is closed on the basis of progress and confidence.

Suggestion 15 (S15) is CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE.

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

4.4 ENFORCEMENT

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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.

Findings from the 2011 Follow-Up Mission

Suggestion 16: ARPANSA staff provided a draft Enforcement Guideline document providing:

- categorization levels of non-compliance against specified clauses of the regulations; and
- a graded enforcement strategy.

According to ARPANSA staff, the Enforcement Guideline had completed internal reviews and was close to a stage for which it could be issued for comments to external stakeholders.

ARPANSA staff expects that the document will be finalized by the end of June 2012.

Suggestion 16 (S16) is CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE.

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

4.5 REGULATIONS AND GUIDES

No recommendation or suggestion was made in this part of the IRRS 2007 report.

4.5.1 REGULATIONS AND GUIDES – RESEARCH REACTORS

No recommendation or suggestion was made in this part of the IRRS 2007 report.

4.5.2 REGULATIONS AND GUIDES - SOURCES AND INDUSTRIAL PRACTICES GS-R-1 §5.25-5.28

No recommendation or suggestion was made in this part of the IRRS 2007 report.

4.5.3 REGULATIONS AND GUIDES – DECOMMISSIONING

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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 ARPANS Act 1998, and publish it as soon as possible.

Findings from the 2011 Follow-Up Mission

Suggestion 17: The 2007 IRRS Mission team found particularly important with regard to decommissioning activities, that the ARPANSA Regulatory Guidance for the Decommissioning of Controlled Facilities RB-STD-10-06 which was being drafted at the time of the Mission. Having such a guide was considered as a Good Practice. The Mission suggested putting the guidelines in force as soon as possible to anticipate regulatory requirements in order to help future decommissioning strategy.

The *Regulatory Guidance for the Decommissioning of Controlled Facilities* has now been re-numbered as "RPB-LA-SUP-240K". Although the document is in use, it is still a draft and has not been finalized and published. It is expected to be completed by June 2012. The team concludes that S17 is closed on the basis of progress and confidence.

Suggestion 17 (S17) is CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

4.5.4 REGULATIONS AND GUIDES – RADIOACTIVE WASTE MANAGEMENT

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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.

Findings from the 2011 Follow-Up Mission

Suggestion 18: At the time of the 2007 Mission, ARPANSA had prepared a number of guidance documents for licensees in support of licensing activities in the area of radioactive waste management. The team members found that licensees would probably benefit from a better structuring of regulatory documents to incorporate all the actors implied in the issue of waste management.

A draft regulatory document for radioactive waste management titled *Regulatory Advice for Radioactive Waste Management Facilities: Storage and Near Surface Disposal Facilities* has been developed (dated August 2011) for consultation. The team concludes that the content of the draft document meets the intent of S18 and can be closed on the basis of progress and confidence.

Suggestion 18 (S18) is CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

5. SAFETY AND SECURITY OF RADIOACTIVE SOURCES

General

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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.

Findings from the 2011 Follow-Up Mission

Suggestion 19: The IRRS team discussed with ARPANSA the progress made since 2007 in addressing the Council of Australian Governments (COAG) Report on the Regulation and Control of Radiological Material. A (Security-in-Confidence) plan to implement the COAG Report was produced in 2008. ARPANSA, has coordinated the uniform implementation of the COAG report findings. The report contained 10 recommendations with 13 activities needed to address those recommendations. As of July, 2011, 6 of those activities were fully completed and the remainder were either nearly completed or were on-going. The IRRS team finds that this approach has been effective in moving forward to assure greater safety and security of radiological sources within Australia as discussed in Suggestions 20-22 below.

Suggestion 19 (S19) is CLOSED.

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

National Register of Radioactive Sources (Provision 11 of the Code)

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
S20	**Suggestion:** ARPANSA should consider the most effective means of expediting its establishment of an on-line secure national sealed source registry**.**

Findings from the 2011 Follow-Up Mission

Suggestion 20: The IRRS team discussed with ARPANSA its progress since the 2007 review, in cooperation with the States and Territories, in development of an online national register of high activity radioactive sources. The system has been operational since December 2009 and currently includes Category 1, 2 and 3 sources within Australia. It will ultimately include sources from import to final disposition since there are no manufacturers of sources within Australia. In addition, the team had a demonstration of the features and capabilities of the system, which draws data on a daily basis from the registers operated by each of the States and Territories.

Suggestion 20 (S20) is CLOSED.

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

Source Search and Recovery

No recommendation or suggestion was made in this part of the IRRS 2007 report.

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

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
S21	**Suggestion:** 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.

Findings from the 2011 Follow-Up Mission

Suggestion 21: The IRRS team reviewed the self-assessment and discussed with ARPANSA its activities and leadership in finding a way to implement and enforce the Code of Practice for the Security of Radioactive Sources across Australia. ARPANSA has used the vehicle of the National Directory for Radiation Protection and thereby made the Code a mandatory requirement in all jurisdictions. In addition, ARPANSA has provided training and guidance in the application of the Code and has assisted jurisdictions in the inspection for compliance and has conducted its own inspections for compliance within its Commonwealth jurisdiction. ARPANSA is active through the Radiation Health Committee in promoting and nationally coordinating the approach to regulating the safety and security of radioactive sources within all Australian Jurisdictions. ARPANSA has received legal advice that the regulation of security is within the scope of its powers under the ARPANS Act. As noted above, these activities have been successful in moving forward the security of high activity radioactive sources within Australia.

Suggestion 21 (S21) is CLOSED.

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

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

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
S22	**Suggestion:** 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.

Findings from the 2011 Follow-Up Mission

Suggestion 22: As explained in the 2007 IRRS report, import control of radioactive sources is covered by the Customs (Prohibited Imports) Regulations. During the follow-up mission, ARPANSA explained the process by which it enforces this regulation, in cooperation with the Customs Administration, and in compliance with the Code of Conduct and its associated import and export Guidance. This process is documented and fully operational. ARPANSA has not taken any action to amend the Custom Regulations and therefore considered the S22 to remain open. However, the IRRS review team considered that amending the Regulations is not justified and would not bring any added value. It was therefore agreed that S22 is not relevant any longer and can be closed.

Suggestion 22 (S22) is CLOSED.

New findings from the 2011 Mission

During the course of the follow up mission, and while reviewing the implementation of Suggestions 19 to 22, the achievements of the last four years and the on-going programme in the establishment of a register of high activity sealed sources of the Commonwealth, the States and Territories, it appears to the IRRS Team that ARPANSA should be commended for its efforts to liaise with the Customs Administration, ASNO and the importing state regulators when it comes to regulation of the import and export of radioactive sources.

ARPANSA has conducted regional outreach with other nations in Southeast Asia in advancing their programme in import and export control of radioactive sources.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE FROM THE 2011 FOLLOW-UP MISSION	
(1)	Code of Conduct on Safety of Radioactive Sources, § 20 (m) states: *"Every State should ensure that the regulatory body established by its legislation has the authority to liaise and coordinate with other governmental bodies and with relevant non-governmental bodies in all areas relating to the safety and security of radioactive sources"*
GPF1	**Good Practice:** ARPANSA has been very proactive in working with multiple national organizations that are competent authorities in areas interrelated with safety and security of radioactive sources, in particular their import and export control. This has resulted in excellent collaboration and cooperation, resulting in considerable progress being made on some key provisions of the Code of Conduct on Safety and Security of Radioactive Sources.

Dissemination of the code

No recommendation or suggestion was made in this part of the IRRS 2007 report.

6. NATIONAL INFRASTRUCTURE FOR RADIOACTIVE WASTE, DECOMMISSIONING AND REMEDIATION

National Waste Management Policy and Strategy

No recommendation or suggestion was made in this part of the IRRS 2007 report.

Commonwealth Radioactive Waste Management Facility

No recommendation or suggestion was made in this part of the IRRS 2007 report.

Waste Acceptance Criteria

No recommendation or suggestion was made in this part of the IRRS 2007 report.

Classification System for Radioactive Waste

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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.

Findings from the 2011 Follow-Up Mission

Suggestion 23: At the time of the 2007 Mission, Australia didn't have a national system for the classification of radioactive waste. The Mission found particularly important to have a national system for the classification of radioactive waste. 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.

ARPANSA has published a Safety Guide for Classification of Radioactive Waste (Radiation Protection Series No. 20) (2010), which sets out non-prescriptive, best-practice guidance for classifying radioactive waste and is based on IAEA General Safety Guide, Classification of Radioactive Waste GSG-1 (2009). The team concludes that ARPANSA has met the intent of S23.

Suggestion 23 (S23) is CLOSED.

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

National Inventory for Radioactive Waste

No recommendation or suggestion was made in this part of the IRRS 2007 report.

Clearance of Radioactive Waste

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
S24	**Suggestion:** ARPANSA should consider developing guidance for clearance of materials from decommissioning**.**

Findings from the 2011 Follow-Up Mission

Suggestion 24: At the time of the 2007 Mission, ARPANSA did not have any guidance or criteria for clearance of the larger volumes of materials typically associated with future decommissioning activities, nor for release of scrap metal for recycling. The Mission found important, for the

decommissioning projects, to be able to make use of some guidance about clearance criteria for the residual material to be produced in decommissioning projects.

ARPANSA is currently engaging with ANSTO on a prospective decommissioning licence application which is being proposed in the next year or two. As radiological clearance will be an issue on which ANSTO will need guidance, a project is underway to prepare regulatory guidance material. This will be done with existing international criteria material. The project is expected to be completed in 2012. The IRRS review team acknowledges ARPANSA's intention to develop the guidance material but concludes that S24 remains open.

In addition, the team noted that the concept of clearance is not used in the radiation safety regulatory framework of Australia. ARPANSA is ready to introduce it beyond the regulation of decommissioning and to develop appropriate regulatory guidance. It has been agreed in the course of the mission to list it in the items to be covered by the review and revision of ARPANS Act. (See section 1 and RF1).

Suggestion 24 (S24) is OPEN.

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

Policy Issue Discussion

The Commonwealth, States and Territories are all responsible for the management of radioactive wastes generated within their areas of responsibility. Currently, the Commonwealth activities are governed by the Commonwealth Radioactive Waste Management Act of 2005. New legislation has been introduced, the National Radioactive Waste Management Bill 2010. The intent of this new legislation is to introduce procedural fairness rights for stakeholders during establishment of a radioactive waste management facility, and also introduces the possibility of accepting wastes from other States. The Bill is currently before the Senate. The Bill maintains one volunteer site, the Muckaty Station in the Northern Territory, while removing from consideration of three potential sites on Defence land that had previously been proposed.

Currently, radioactive waste is generated from medical, industrial, agricultural and research uses of radioisotopes and nuclear material, and is stored at over 100 locations throughout the Commonwealth. The most comprehensive information regarding the inventory and oversight of radioactive waste in the Commonwealth as well as the States and Territories is contained in the Joint Convention national report, available on the ARPANSA website.

The topic of the use of probabilistic safety analysis (PSA) for a waste management facility was discussed among the ARPANSA staff and the IRRS team members. ARPANSA's intent is to use a mix of deterministic and probabilistic methodologies. While it was recognized that it was difficult to be precise with probabilistic predictions related to long term waste storage facilities, PSA may be useful in examining a range of potential consequences or outcomes, and for gaining understanding of system performance.

The use of synroc as a storage medium was discussed. Although not a new technology, it has not been used in Australia, other than in a laboratory setting. This is probably a medium that will be utilized in the to-be-proposed waste facility. Waste acceptance criteria still need to be determined by the proponent/operator in consultation with ARPANSA based on the concept for the waste management facility and fully consistent with ARPANSA's safety goals. The criteria should be developed using international best practices including IAEA guidance. It was recognized that there exists two main waste streams; that generated by ANSTO facilities (including the OPAL research reactor) and that generated by everyone else.

ARPANSA has a guidance document (2006) for radioactive waste storage and near surface disposal, and it was recognized that the guidance needs to be updated to take into account international best practices and to revise the structure to make the guidance more practically usable.

If the remaining potential waste facility site is not utilized, the option may exist to request for volunteer sites. How this process is implemented was discussed for Australia as well as in other Member States via the IRRS team members.

The El Sherana near-surface radiological disposal facility located in the Kakadu National Park was discussed from a technical and regulatory standpoint. Relicensing of the facility will reflect the current phase of the facility's lifetime (active institutional control). The need for resolving issues with legacy sites (i.e. uranium mine tailings) is a significant challenge, not only for Australia, but also for many other Member States. Team members suggested that ARPANSA consider involvement in a new IAEA forum regarding legacy sites in East Asia.

7. EMERGERGENCY PREPAREDNESS

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
R9	**Recommendation:** 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. • the provision of appropriate information to all key stakeholders during and after events and accidents.

Findings from the 2011 Follow-Up Mission

Recommendation 9: The IRRS team found that a number of the findings presented in the report of the 2007 mission have been addressed by ARPANSA.

The IRRS team reviewed the current status regarding ARPANSA's role as regulator of emergency preparedness and response (EPR) arrangements at the ANSTO facilities. The ARPANSA reorganization in May of 2011 moved the responsibility for emergency prevention to ARPANSA's Sydney office. One consequence of this is increased awareness of the need to include EPR in the inspection activities of the ARPANSA staff that work directly with regulating ANSTO. However, the team observed that the lack of clarity regarding the roles of ARPANSA and ANSTO in preparing and responding to a nuclear emergency that was identified during the 2007 IRRS mission remains. Regarding ARPANSA's role as a regulator, the IRRS team proposes that ARPANSA assumes a more active role as regulator with regards to the EPR planning at ANSTO facilities and in deciding the suitability of the ANSTO emergency plans. Specifically, active supervision through inspecting emergency plans, site exercises and quality assurance programmes are appropriate.

ARPANSA's other role as a regulatory body is to provide radiation protection and nuclear safety advice to the Australian Government and to the public during a domestic or an overseas nuclear emergency. The nuclear accident in Japan in 2011 demonstrated and clarified ARPANSA's role during a nuclear emergency overseas. During a domestic emergency, ARPANSA should ensure that accident reporting, relevant plant information and monitoring data are reported to ARPANSA in a timely manner if an accident occurs. These are necessary conditions for ensuring that ARPANSA could perform its role as the Australian government's expert advisor and information source if an accident or incident occurs.

The IRRS team concludes that the 1st item of R9 remains open.

At the time of the 2007 IRRS review the EPR efforts at ARPANSA were concentrated in the Emergency Section in Melbourne. One observation of the 2007 review was that EPR needed to be more effectively represented at the Sydney office. One result of the reorganization of ARPANSA in May 2011 is the widening of the responsibilities for EPR across the organization to also incorporate the Sydney Office (Security and Community Safety Section and the CEO Office). The Melbourne office retains EPR responsibilities primarily in the Monitoring and Emergency Response section and the Environmental and Public Health section in the Radiation Health Services Branch. The

responsibilities within the EPR area are delineated by the different responsibilities of the organizational units. Regarding responsibilities for EPR, the Security and Community Safety section has the responsibility for strategic planning and integration with the Australian Government. They are also responsible for physical security and security of radiation sources as well as interfacing with the security authorities.

The Melbourne office train and sustain response teams and coordinate at the operational level with first responders maintaining a first class field capability. The field response capabilities and health physics competence have developed and continued to maintain an appropriate capability for emergency response, continuing the good practice identified in the 2007 IRRS Mission. In addition, a modern functional emergency centre has been built and completed during 2011 at the Melbourne office. ARPANSA has established emergency arrangements and facilities at the Sydney office and secure communications between the Melbourne and Sydney offices. Also, the radiological assessment capabilities that are focused on emergency response have been enhanced. The Environmental and Public Health section has developed various modeling, monitoring and assessment capabilities focused on EPR, including a now fully deployed ARGOS capability for prognoses and decision support, which was successfully applied during the Fukushima accident. ARPANSA demonstrated an effective response to the Fukushima accident in Japan in March 2011. The response process led to the development of highly effective and informative assessment protocols which enhanced their ability to provide frequent updates of event prognoses, and a clear task structure that facilitated effective and regular reporting to key stakeholders. These have developed into procedures for ARPANSA's EPP and have already been identified as useful practices by other countries.

As a result of the demonstration of ARPANSA's role in providing health and radiation protection advice to the public and to the Australian Government during the Fukushima accident in Japan 2011, ARPANSA has started the development of an Emergency Preparedness Plan (EPP) documenting the operational, technical and communications elements with the flexibility to respond to different types of radiological or nuclear emergencies. The IRRS team finds that the ongoing development of the ARPANSA EPP plans would benefit from assessing the consequences from dimensioning scenarios, especially at the ANSTO facilities, as guidance in dimensioning the preparedness activities at ARPANSA.

Although considerable work is left to achieve a complete and documented EPP, the framework and structure of a multi-tiered strategic and operational plan is in place and some of the key strategic and operational documents exist. In addition, many key findings regarding ARPANSA's EPR planning noted in the IRRS 2007 report have been addressed. This important progress plus the other improvements mentioned here are significant steps towards establishing and implementing an emergency programme for providing appropriate information to key stakeholders during and after events and accidents. The IRRS team concludes that these arrangements meet the intent of the 2nd item of R9, and therefore recommends that the 2nd item of Recommendation 9 be changed from open to closed on the basis of progress and confidence.

Recommendation 9 (R9) is: 1st item: OPEN

2nd item: CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE

New findings from the 2011 Mission

The IRRS team participated in an EPR policy discussion with ARPANSA staff from both the Sydney and Melbourne offices. The discussions focused on the Australian legislation regarding EPR, where there are local, state and national plans covering specific nuclear and radiological emergencies, including radiological terrorism incidents, but there is no overarching nuclear emergency plan. ARPANSA's role in the current legislation is not clear. The discussions also focused on ARPANSA's role as the regulator of ANSTO. The results of the latter discussion contribute to the conclusion of the team that the 1st item of tR9 remains open.

Because of the unique make-up of the Australian political entities, it is important that the emergency preparedness and response is coordinated between the States, Territories and the Commonwealth. The EPR is handled differently within these jurisdictions, coming from different agencies within each jurisdiction regarding radiation safety, radiation protection and emergency response. The lack of uniformity in the governing structure for emergency preparedness coupled with the fact that ARPANSA does not have a clear role in the national EPR system results in a significant need for proper national coordination of the emergency preparedness roles and capabilities amongst the 9 jurisdictions in Australia. A more coordinated national preparedness would facilitate the effective use of available resources in an emergency situation and ensure a timely response. The Fukushima accident in Japan 2011 clarified ARPANSA's national role in providing radiation protection and nuclear safety advice to the Australian Government and to the public for an overseas nuclear emergency. However, this role is not captured in the ARPANSA legislation or the Australian legal framework. To improve the clarity of ARPANSA's role in emergency preparedness and response, suggestions that should be considered in the coming review and revision of the ARPANS Act with regard to EPR are presented in section 1 of this report.

As progress proceeds on the development of the EPR organization, ARPANSA could benefit from a more detailed review of their EPR plans. Detailed recommendations on all aspects of the programme are out of the scope of this follow-up IRRS Mission but can be obtained at a future date through an IAEA Emergency Preparedness REView (EPREV).

The IRRS team observes that there is a need for coordinating the emergency preparedness and emergency response within Australia between the 9 jurisdictions. In addition, there is also a need for coordinating the emergency preparedness and response within ARPANSA. Both of these are needed to ensure an effective and timely response.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE FROM THE 2011 FOLLOW-UP MISSION	
(1)	**BASIS:** GS-R-2 § 5.4 states *"The emergency arrangements shall include the clear allocation of responsibilities, authorities and arrangements for co-ordination in all phases of the response."*
RF4	**Recommendation:** ARPANSA should establish a function to oversee the coordination of its emergency preparedness and response activities, to ensure harmonization of its emergency preparedness and response functions and to promote an effective and timely emergency response.
(1)	**BASIS:** GRS Part 1 Requirement 8 states: *"The government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency."*
(2)	**BASIS:** GS-R-2 § 3.4 states *"…Legislation shall be adopted to allocate clearly the responsibilities for preparedness and response for a nuclear or radiological emergency and for meeting the requirements established in this Safety Requirements publication. This shall include establishing or identifying an existing governmental body or organization to act as a national co-ordinating authority…to co-ordinate the resolution of differences and incompatible arrangements between the various response organizations.…"*
RF5	**Recommendation:** The Australian Government should ensure the national framework clearly identifies and assigns responsibilities to ARPANSA and other appropriate organizations for nuclear and radiation emergency preparedness.
(1)	**BASIS:** GSR Part 1 § 2.21 states *" …the government shall establish a nationwide system, including emergency response arrangements, to protect the public in a nuclear or radiological emergency declared as a consequence of an incident … outside the territories and jurisdiction of the State."*
GPF2	**Good Practice:** Arrangements made by ARPANSA during response to the Tepco Fukushima Dai-ichi accident in Japan in March 2011 were excellent. The response process led to the development of informative assessment protocols and a clear task

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE FROM THE 2011 FOLLOW-UP MISSION	
	structure that facilitated effective and regular reporting to key stakeholders.

8. MANAGEMENT SYSTEM FOR THE REGULATORY BODY

8.1 Introduction

No recommendation or suggestion was made in this part of the IRRS 2007 report.

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

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
R10	**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.
R11	**Recommendation:** ARPANSA should expand its regulatory management system to include measures to promote and support strong safety culture.
S25	**Suggestion:** 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.
S26	**Suggestion:** ARPANSA should consider the enhancement of its risk management process to include further development of the risk identification process.

Findings from the 2011 Follow-Up Mission

Recommendation 10: The IRRS team reviewed documents related to Quality Assurance within the agency and discussed operational changes in QA procedures and processes since 2007 with ARPANSA management. The team understands that virtually all QA procedures have been completed and they are subject to a 2 year review cycle. Adherence to QA procedures in daily regulatory work is the responsibility of individual staff members and their supervisors. Oversight of QA implementation is provided on an ongoing basis by the Quality Committee which was established in December 2007 and meets monthly. External stakeholders (licensees) of ARPANSA also provide input on the quality of regulatory services through an annual License Holders Forum, which includes both open comment and discussion sessions as well as surveys of ARPANSA's performance. Finally, ARPANSA is planning to apply for certification according to ISO 9001 in 2012. The IRRS team believes that these various practices and procedures adequately address the intent of R10.

Recommendation 10 (R10) is CLOSED

Recommendation 11: The IRRS team reviewed the self-assessment and discussed with ARPANSA its plans and activities to promote and support strong safety culture, beyond its existing programmatic activities in this area. The team learned that a new section has been established in ARPANSA to undertake holistic safety assessment with an emphasis on organizational management and control, human factors and safety culture. This section is still being staffed, but already has several projects underway to accomplish this outcome. The section is also well engaged with the international

community on best practices in safety culture and is using the vehicle of license holder forums to engage on guidance development and expectations. It is also working to enhance safety culture within the ARPANSA organization through quality assurance as well as discussions at an upcoming management retreat. The new Safety Analysis Section plans to analyse licence holder performance with an emphasis on organizational control, safety culture and human factors. The team believes that these activities reflect further enhancements to safety culture but notes that additional work remains in achieving the objective of R11 and therefore this recommendation remains open.

Recommendation 11 (R11) is OPEN

Suggestion 25: The IRRS team reviewed the self-assessment and discussed with ARPANSA its progress and activities to address this suggestion. These activities include:

- Establishment of the Office of the CEO and its attendant role in leading the planning, integration, liaison and coordination activities with other Departments of the Federal Government.
- Development of the 2011–2012 Portfolio Budget Statement and the ongoing revision of Strategic Directions document.
- Conduct of Executive Board retreats to address strategic and operational issues.

More comprehensive processes for government liaison and advice have been proposed and will be developed and led by the new CEO Office and stronger networks have been established with senior government officials by the CEO. A number of executive retreats have been conducted to lead the strategic planning associated with the reform and will continue for similar purposes into the future. The CEO is also developing a plan for the future structure and operation of the Board to be implemented later in 2011. The IRRS team believes that these activities address S25, but notes that certain of them remain to be completed

Suggestion 25 (S25) is CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE

Suggestion 26: ARPANSA has made considerable progress in enhancing its risk management process since the 2007 IRRS review. The IRRS team reviewed an enterprise-wide risk assessment conducted in 2008 by a consultant as well as a report to the Audit and Risk Committee in March 2011. The latter report acknowledged that risk identification processes have been imbedded into the business planning processes but noted that additional work needed to be done to more fully integrate risk considerations into everyday operations. The team discussed with ARPANSA management the work that has been done in this regard, which includes linkage of risk to key activities and strategies; consideration of high priority project risks, corporate risks and safety risks; as well as risk reviews reported to and reviewed by the Board on a quarterly basis as part of its Performance and Accountability report.

Suggestion 26 (S26) is CLOSED

New findings from the 2011 Mission

There were no new findings in the 2011 IRRS Follow up Mission.

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

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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.

Findings from the 2011 Follow-Up Mission

Suggestion 27: The team discussed with ARPANSA management its plans and activities related to improvement of the Management System, with particular emphasis on resources to support that system. It is clear that the lead for the activity resides in the new Office of the CEO, which as mentioned earlier has the lead for facilitating strategic planning, performance setting and monitoring and reporting and quality and risk management and good corporate governance in general. The process of fully standing up the new Office is on-going, including staffing of several vacant positions, and should be completed over the next year.

Suggestion 27 (S27) is CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE

New findings from the 2011 Mission

There were no new findings in the 2011 IRRS Follow-up Mission.

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

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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.

Findings from the 2011 Follow-Up Mission

Suggestion 28: The IRRS team discussed with ARPANSA management the ongoing work in determining the cost structure of the regulatory function. From these discussions it was clear that while a number of activities have been undertaken, additional work remains to be done. Completed activities include establishment of cost centres for regulatory functions and emplacement of software which will allow capture of time by regulatory function and cost centre. The team notes that regulatory officers do not routinely enter time spent on their assigned functions and that this poses a challenge to the success of capturing this information. Once entered, the information should allow ARPANSA to better review and analyse the data annually in support of full cost recovery. The Operations Services Branch and the Corporate Office are working cooperatively in the achievement of this task. An Action Plan has been prepared for the completion of the cost recovery review by June 2012.

Suggestion 28 (S28) is OPEN

New findings from the 2011 Mission

There were no new findings in the 2011 IRRS Follow up Mission.

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

No recommendation or suggestion was made in this part of the IRRS 2007 report.

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

No recommendation or suggestion was made in this part of the IRRS 2007 report.

9. TRANSPORT OF RADIOACTIVE MATERIALS

9.1 Legislative and Governmental Responsibilities

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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.

Findings from the 2011 Follow-Up Mission

Suggestion 29: ARPANSA informed the Team that Australia's constitutional arrangements at present preclude the possibility of ARPANSA being the single competent authority and that it would be very difficult to have one competent authority for the transport of radioactive material. The team also discussed the issue with 2 state regulators who had the same view. In light of this, ARPANSA has been working on a Memorandum of Understanding to reach an understanding among all Australian jurisdictions to enable ARPANSA to provide expert technical services to other competent authorities relating to approvals under the Code of Practice for the Safe Transport of Radioactive Material (RPS No. 2). This draft will be discussed with the other jurisdictions.

Suggestion 29 (S29) is CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE.

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

9.2 Compliance assurance

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
R12	**Recommendation:** 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).

Findings from the 2011 Follow-Up Mission

Recommendation 12: The Radiation Health Committee (RHC) has agreed that a guidance document on approvals for transport be prepared and an ARPANSA Safety Guide (*Approval of Special Form Radioactive Material, Low Dispersible Radioactive Material, Design of Packages, and Shipments*) is well advanced. ARPANSA's inspections of ANSTO's facility covers transport related inspections including ANSTO's delivery of radiopharmaceuticals as well as transport related parts of ANSTO's quality management system. However, an effective compliance programme has not been fully developed and formalized.

Recommendation 12 (R12) is OPEN

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

10. PUBLIC INFORMATION

RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 MISSION	
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.

Findings from the 2011 Follow-Up Mission

Suggestion 30: The IRRS team reviewed a 2011 consultant's report on communication strategy and discussed communications with ARPANSA management. The report identified an overall communications framework for the agency --

"...be an organisation that is highly effective at informing and influencing key stakeholders and the broader community on matters relating to radiation protection and nuclear safety."

and supporting recommendations to improve the agency's communications with its stakeholders. In addition, ARPANSA has identified communications and education as one of its 10 key areas. Finally, the Office of the CEO has recently hired a communications specialist to assist in implementation of this strategy.

Suggestion 30 (S30) is CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE

New findings from the 2011 Mission

There were no new findings in the 2011 Follow-up Mission.

11. MEDICAL EXPOSURE AND PATIENT PROTECTION

Medical exposure and patient protection were not part of the main IRRS mission in 2007. At the preparatory meeting prior to the follow-up IRRS mission it was agreed that the thematic module covering this area should be performed in conjunction with the follow-up mission. Note, occupational radiation protection and public protection in the medical radiation facilities are not part of the scope of the module.

ARPANSA is the regulatory body for Commonwealth Entities only, but it also has an additional role – that of promoting national uniformity. A primary means for this is the development of Codes of Practice and accompanying Safety Guides, overseen by the RHC, and approved by the Australian **Health Ministers' Conference (**AHMC). Once approved and placed in the National Directory for Radiation Protection (NDRP), there is the obligation that the CoP will be implemented in each of the State and Territory jurisdictions through, typically, either appropriate legislative processes or some alternative means, such as licence conditions. In the case of medical exposure, there are 4 Codes of Practice that are relevant - RPS 8, RPS 10; RPS 14; and RPS 19.

The IRRS reviewers looked at the activities of ARPANSA in each of these roles with respect to medical exposure in Australia. In addition to interviews and discussions with relevant ARPANSA personnel, the reviewers attended the RHC meeting on 9 November, and the next day interviewed two members of RHC, each being senior regulatory officers in charge of radiation protection in their states. Further, the mission included a policy discussion session on National Uniformity and Patient Protection, attended by the IRRS team and interested parties from ARPANSA. The following is based in all these, together with the submitted SAT questionnaire and other submitted material.

11.1. Review of the Activities of the Regulatory Body

Background

As described fully in the 2007 report, ARPANSA is the regulatory body for Commonwealth Entities only. In the case of facilities performing medical exposures, this means that the vast majority of medical radiation facilities are regulated by one or other of the 8 State or Territory regulatory bodies. The number of medical radiation facilities that are Commonwealth Entities is few – primarily Department of Defence facilities, but also includes facilities associated with the Commonwealth Scientific and Industrial Research Organisation (CSIRO) (Antarctica and ship-based), Indian Ocean Territories, Customs and Immigration, and Health Services Australia, for example. None of these facilities has CT or interventional radiology facilities, being almost exclusively either dental and/or fixed and mobile plain film radiography, with a few fluoroscopy units. There are no nuclear medicine facilities or radiation therapy facilities.

11.1.1 Authorization of Medical Radiation Facilities and Activities

GSR Part 1 – Requirements 23, 24, 4.29-4.39

Background

Details of authorization processes (application forms, guidance on applications, etc.) were described fully in the 2007 Report and will not be replicated here.

Comments

It is noted that the document *Regulatory Guide: Applying for a Source Licence* and the *Regulatory Guideline on Review of Plans and Arrangements* contain no information on what is required with respect to medical exposure and patient protection.

When a licence is issued, the controlled apparatus and controlled material (e.g. mammographic x-ray unit, conventional dental x-ray unit, mobile or portable medical x-ray unit, fixed medical x-ray unit, OPG dental x-ray unit) are listed in Schedule 1, and specific licence conditions are placed in Schedule 2 for the specified items from Schedule 1. This provides the means for mandating compliance with the 4 Codes of Practice (RPS 8, 10, 14 and 19), as appropriate.

RPS 14 was placed on the NDRP in 2008. Compliance with it was then added to relevant existing licences issued by ARPANSA. With the introduction of compliance with RPS 14 as a licence condition, there were some educative seminars given at some medical radiation facilities to explain what this meant, but this did not appear to be part of an established system for assisting the implementation of a new CoP.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE FROM THE 2011 FOLLOW-UP MISSION	
(1)	**BASIS:** GSR Part 1 §4.34 states: *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process."*
RF6	**Recommendation:** It is recommended that specific guidance is developed and made available to licence applicants to address the areas on medical exposure and patient protection in RPS 8, 10, 14 and 19.

11.1.2 Review and Assessment of applications for Medical Radiation Facilities

GSR Part 1 – Requirements 25, 26, 4.40-4.48

Background

Full details were given in the 2007 Report. A Standard Operating Procedure, *Licence Application Assessment, OS-LA-SOP-242*, prepared by the Operations Services, sets out procedures to be followed for licence applications, including those involving facilities or sources to be used to perform medical exposures.

OS-LA-SOP-242 includes details on technical assessment, including review against relevant codes of practice; site visits; and expert advice, including that from other offices or services of ARPANSA.

OS-LA-SOP-242 also notes that the level of detail for this review should be commensurate with the hazards and risks associated with the proposed conduct or dealing.

Comments

Evidence presented about appropriate technical assessment in the inspection of radiology facilities only referred to compliance testing of equipment and occupational exposure of staff, no mention was made of patient protection being considered or that use was being made of the technical expertise present in the Melbourne-based Medical Radiation Services Branch.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE FROM THE 2011 FOLLOW-UP MISSION	
(1)	**BASIS:** GSR Part 1 § 4.41 states: *"Technical and other documents submitted by the applicant shall be reviewed and assessed by the regulatory body to determine whether the facility or activity complies with the relevant objectives, principles and associated criteria for safety.*
RF7	**Recommendation:** ARPANSA should ensure that the technical expertise available in the Medical Radiation Service Branch is more formally involved in the assessment and review of licence applications involving medical exposure.

11.1.3 Inspection and Enforcement of Medical Radiation Facilities

GSR Part 1 – Requirements 27-30, 4.49-4.60

Background

Full details on inspections and the inspection programme were given in the 2007 Report.

Comments

There are several internal ARPANSA documents giving guidance on inspections, how to perform them, competencies required, etc., but there did not appear to be any specific guidance with respect to medical exposure and patient protection.

Inspection priorities were established using a risk matrix including likelihood and consequence of harm in the relevant practice. Medical radiation facilities have been assigned a low or medium priority on the basis of this risk matrix approach. Evidence presented included only consideration of equipment compliance and occupational exposure, patient protection was not explicitly considered as a component of this risk evaluation. The result is that, at the time of the mission, few inspections to medical radiation facilities had occurred or were planned in the future.

It is acknowledged that resources available for inspection duties are limited. It is also questioned whether the requisite expertise for effectively inspecting the implementation of RPS 10, 14, and 19 is available in the current personnel performing inspections.

All licence holders are required to report to the CEO quarterly, using a pro forma, which covers many aspects of radiation protection. No recent inspections of medical radiation facilities had been conducted, however reports tendered were lists of "no changes" or "no actions" to standard questions. Further, the pro forma does not highlight the need to report anything with respect to patient protection.

The combination of the lack of inspections, with the necessary expertise, and the nominal quarterly reporting would seem to suggest that ARPANSA's regulatory oversight of its licensed medical radiation facilities is administrative only.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE FROM THE 2011 FOLLOW-UP MISSION	
(1)	**BASIS:** GSR Part 1, Requirement 29 states: *"Graded approach to inspections of facilities and activities Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.*
SF2	**Suggestion:** ARPANSA should revise the risk matrix used to assign inspection priorities to allow consideration of patient protection as an input into the risk evaluation.
SF3	**Suggestion:** ARPANSA should better utilize the expertise available in the Medical Radiation Services Branch to make inspections of medical radiation facilities more effective with respect to medical exposure and patient protection.

11.1.4 Development of regulations and guides for medical exposure in medical radiation facilities

GSR Part 1 – Requirements 32-34 § 4.61-4.62

Background

At the time of the mission, there are 4 Codes of Practice applicable to medical exposure and patient protection – RPS 8, 10, 14 and 19. In the case of RPS 14, there are also 3 companion Safety Guides (RPS 14.1, 14.2, 14.3). RPS 10 includes a Safety Guide.

Comment

These CoPs have a very significant role, both for ARPANSA and its regulated Commonwealth Entities, and for the State and Territory regulatory bodies through the NDRP – in other words, the CoPs state what needs to be done by whom to ensure radiation protection in medical exposure. It is therefore crucial that each CoP represents international best practice and, as a minimum, that they are consistent with the IAEA Basic Safety Standards (BSS). The codes of practice were developed during the currency of IAEA BSS (IAEA Safety Series 115) which is currently being replaced by (General Safety Requirements Part 3 (GSR Part 3).

In fact, IAEA Safety Series 115 was not a key document in the development of the 4 Codes of Practice mentioned above which derive from a wide range of international guidance. There are numerous differences between Australian guidance and the BSS, although most are minor. However, it is useful to suggest areas where revision of the key guidance in patient protection, RPS14, could be aligned with the new BSS (GSR Part 3). In particular the new BSS:

- does not include the exposure of individuals as part of medico-legal procedures;
- explicitly de-couples the patient and the exposure to allow, for example, the unintended or accidental exposure of the wrong body part to remain within the radiation protection framework;
- provides an improved definition of qualified expert including medical physicists. Australia has a very established system, under the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM), for the training and accreditation of medical physicists in 3 specialties. The use of such accredited medical physicists needs to be invoked to be consistent with the BSS;
- requires justification of radiological procedures to be carried out through consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate;
- requires the use of relevant national or international referral guidelines in performing an individual justification;
- addresses the issue of justification of a radiological procedure on an asymptomatic individual that is intended to be performed for the early detection of disease, where this procedure is not part of an approved health screening programme;
- requires calibration for non-radiotherapy equipment;
- includes improved requirements for optimisation, dosimetry and quality assurance.

As part of the implementation process of RPS14, a review after 2 years was included. This review has received only a small amount of feedback, but the adoption of the new BSS provides sufficient reason for improvement and alignment that a revision should be undertaken.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE FROM THE 2011 FOLLOW-UP MISSION	
(1)	**BASIS:** GSR Part 1, Requirement 33 states: *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained."*
RF8	**Recommendation:** ARPANSA should initiate the review and revision of RPS 14 to ensure that it is aligned with and consistent with the requirements of the new BSS, GSR Part 3.

11.2 Policy Discussion: National Uniformity and Patient Protection

Notwithstanding the current review and possible revision of RPS 14 noted above, it is the implementation of RPS 14 that is crucial to achieving radiation protection for medical exposure across Australia. ARPANSA can achieve this directly for its jurisdiction through its licensing system, but it appears to be more challenging for the State and Territory regulators, due to several reasons.

Impediments to full implementation, with respect to medical exposure, include:

- some jurisdictions have radiation protection legislation that makes it very difficult to invoke a CoP in its entirety or even parts of a CoP;

- some jurisdictions' regulatory bodies are a unit in the Ministry of Health, while others are a part of an Environmental Protection Authority - the latter having an environmental focus rather than a health focus, and in two jurisdictions regulation is split between Health and Mining;
- some jurisdictions view the use of sources in medicine as being the responsibility of the professions, and hence effectively place a low priority on radiation protection regulatory responsibility for medical exposure and patient protection;
- many of the jurisdictions' regulatory bodies are small, with limited resources including a paucity of staff with the specialist expertise necessary to effectively regulate the implementation of the CoPs;
- one approach noted was to focus on "testing the equipment" and occupational exposure. Better protection of the patient is likely to be achieved by considering "how the equipment is being used".

Consequently, radiation protection of the patient has been very unevenly implemented in the various States and Territories. RHC is proving to be a good forum for the development of CoPs and SGs, as part of moving towards national uniformity, but implementation is a challenge. There could be the need for an additional role for the RHC – that of assessing the success in the implementation of a given CoP at some point after its entry into the NDRP. Further, the RHC could possibly even discuss or plan how each State or Territory can or would introduce an upcoming CoP, before its adoption. These additional roles for RHC may improve the implementation of a given CoP. They would also provide feedback on what proves to be easy to implement and what was more difficult. This experience could then be useful in the development of new or revised CoPs and SGs. ARPANSA could take the lead in introducing these actions into the RHC.

Discussions during the mission raised the concept of using "parallel strategies" to bring about more effective implementation of the CoPs, in particular RPS14. The basis for such strategies was to capture the need to comply with RPS 14 in order to gain some other benefit. For example, in order to receive the reimbursement from Medicare, a facility needs to be appropriately accredited, such as by Diagnostic Imaging Accreditation Scheme **(**DIAS). If the accrediting body is made aware that part of the accreditation should include confirmation that the facility is in "compliance with RPS14", then this provides a strong and additional incentive for actually achieving compliance with the radiation protection requirements of RPS14. Other avenues to explore might include hospital or facility accreditation under the ISO 9000 series scheme.

The need for core competencies of inspectors was raised in the discussions. Again the context was to improve the implementation of RPS14, with meaningful and value-adding inspection in all jurisdictions being a crucial component of this. ARPANSA and RHC should consider national strategies for how inspection across all States and Territories could be enhanced through the specification of core competencies and means for how this might be achieved.

Effective CoPs require the involvement of all the affected players, in particular the relevant professional bodies. This is true not only in the development of the CoP, which was the case in the development of RPS 14, but also in the application of the CoP. ARPANSA has an important role to play as a national facilitator and advocator to increase awareness of RPS 14 (and other CoPs) and its role in setting the standards for medical exposure and patient protection. Again, this is in parallel to the pure regulatory approach. There should be regular contact with the professional societies for example Royal Australian and New Zealand College of Radiologists (RANZCR), Australian Institute of Radiography (AIR), Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM), Australian and New Zealand Society of Nuclear Medicine (ANZSNM), Australian Dental Association (ADA) to name just a few. A particular need is the development of referral guidelines or appropriateness criteria to assist medical practitioners in requesting only appropriate imaging procedures.

A further means to promote awareness about the need for patient protection is to reach the general public. ARPANSA could have an educative role in providing patient protection information, in

particular on how it is (or should be) achieved in Australia. Such information might be made available on the ARPANSA website.

As noted above, there is a requirement for the use of DRLs in RPS 14. However there is a prior need for the establishment of DRLs for Australia. At the time of the mission, a project to establish national DRLs for CT is underway, utilizing a database at ARPANSA. Completion of this exercise and the extension to other areas of diagnostic imaging and image guided interventional procedures should be seen as a priority. Discussions indicated that there had been about a 10% participation in the CT survey to date, but more was needed to have an adequate sample to establish national DRLs. It was felt that RHC members could play a bigger role in the process by actively promoting participation in the survey for facilities in their jurisdictions.

ARPANSA is a primary standards dosimetry laboratory (PSDL), and provides a calibration service to Australia, underpinning all radiation therapy treatments in Australia.

The recent formation of the Australian Clinical Dosimetry Service (ACDS) is an exemplary step to tackle the ever increasingly difficult challenge of ensuring that a planned radiation therapy treatment is in fact delivered in terms of dose and volume. Few countries around the world have such a service. The usefulness of such a service is indicated by the approximate 90% subscription of radiation therapy centres.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE FROM THE 2011 FOLLOW-UP MISSION	
(1)	**BASIS:** GSR Part 3 § 3.166 states: *"In accordance with para. 3.153(d) and (e), the medical physicist shall ensure that:* *(a) All sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols;* *(b) Calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals approved by the regulatory body;* *(c) Calibrations of radiotherapy units are subject to independent verification prior to clinical use;* *(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory."*
GPF3	**Good Practice:** The formation of ACDS is seen as a novel initiative in providing the continuing safe delivery of radiation treatments.
SF4	**Suggestion:** The Government should ensure that ACDS continues and develops in order to provide a high level of dosimetric assurance to meet current and future advances in radiation therapy.
(1)	**BASIS:** GSR Part 3 § 3.147 state: *"The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality, to enable the requirements of para. 3.168 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances."*
(2)	**BASIS:** GSR Part 3 § 3.168 states: *"Registrants and licensees shall ensure that:* *(a) Local assessments, on the basis of the measurements required in para. 3.167, are made at* *approved intervals for those radiological procedures for which diagnostic reference levels have been established (para. 3.147);* *(b) A review is conducted to determine whether the optimization of protection and safety for* *patients is adequate, or whether corrective action is required if, for a given*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE FROM THE 2011 FOLLOW-UP MISSION	
	radiological procedure: *(i) typical doses or activities exceed the relevant diagnostic reference level; or* *(ii) typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient."*
GPF4	**Good_Practice:** The formation of the NDRL Database is an excellent vehicle for establishing initial values of DRLs, and then for continuing to collect data to enable timely updates of the DRL values.
(1)	**BASIS:** GSR Part 1, Requirement 34 states: *"The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available."*
SF5	**Suggestion:** ARPANSA should take the lead in RHC to introduce a means for both monitoring the success of the implementation of CoPs within the context of medical exposure and patient protection, and for planning in advance how implementation might be achieved in each jurisdiction.
SF6	**Suggestion:** ARPANSA should engage more generally with government initiatives to improve quality in health care, with a view to parallel strategies, in addition to regulatory requirements, to increase the effectiveness of the implementation of RPS 14.
SF7	**Suggestion:** ARPANSA should continue to develop its relationships with a wide a set of professional bodies and other organizations as possible to promote awareness about the need to comply with the CoPs to ensure internationally accepted patient protection.
(1)	**BASIS:** GSR Part 1 § 4.61 states: *"The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides. These processes shall involve consultation with interested parties in the development of the regulations and guides, with account taken of internationally agreed standards and the feedback of relevant experience. Moreover, technological advances, research and development work, relevant operational lessons learned and institutional knowledge can be valuable and shall be used as appropriate in revising the regulations and guides.*
(2)	**BASIS:** GSR Part 3 § 3.157 states: *"Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure."*
SF8	**Suggestion:** ARPANSA should seek to assist RANZCR regarding the development of radiation protection aspects of referral guidelines or appropriateness criteria to assist medical practitioners in referring only appropriate medical imaging procedures.
(1)	**BASIS:** GSR Part 3 § 3.147 sates: *"The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality, to enable the requirements of para. 3.168 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances."*
SF9	**Suggestion:** ARPANSA should continue to assign high priority to the completion of the survey to establish CT DRLs for Australia, and together with the relevant professional. bodies establish DRLs in other areas of diagnostic imaging and image guided interventional procedures.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:		
1. Kaare ULBAK	National Institute of Radiation Protection, Denmark	ku@sis.dk
2. George PANGBURN	United States Nuclear Regulatory Commission (USNRC)	george.pangburn@nrc.gov
3. Christian CARRIER	Canadian Nuclear Safety Commission (CNSC)	christian_carrier@cnsc-ccsn.gc.ca
4. Lynn HUBBARD	Swedish Radiation Safety Authority	lynn.hubbard@ssm.se
5. Jose Luis REVILLA	Consejo de Seguridad Nuclear (CSN)	jlrg@csn.es
IAEA STAFF MEMBERS		
1. Hilaire MANSOUX	Division of Radiation, Transport and Waste Safety	H.Mansoux@iaea.org
2. David GRAVES	Division of Nuclear Installation Safety	D.Graves@iaea.org
3. John LE HERON	Division of Radiation, Transport and Waste Safety	J.Le.heron@iaea.org
4. Irene BOLLOZOS-SEMAÑA	Division of Radiation, Transport and Waste Safety	I.I.Bollozos@iaea.org
OFFICIAL ARPANSA LIAISON OFFICER:		
1. David TREDINNICK	Australian Radiation Protection and Nuclear Safety (ARPANSA)	David.Tredinnick@arpansa.gov.au

APPENDIX II – MISSION PROGRAMME

IRRS MISSION PROGRAMME		
Monday, 7 November 2011		
IRRS Opening Review Team Meeting		
14:00-18:00	IRRS Opening Review Team meeting	IRRS Review Team ARPANSA Liaison
Tuesday, 8 November 2011		
IRRS Entrance Meeting		
09:00 – 12:00	Welcome, Introduction of ARPANSA Senior Staff, IRRS Review Team and ARPANSA Counterparts Presentation of IRRS Follow up process and objectives, specific aspects of the mission Overview of the current ARPANSA organization and major changes since July 2007	IRRS Review Team ARPANSA Counterparts
12:00 – 13:30	Lunch Break	
13:30 – 16:30	Module Review (All review areas, including patient protection and EPR)	IRRS Review Team ARPANSA Counterparts
16:30 – 17:00	Coffee Break	
17:00 -	IRRS Daily Review Team Meeting	IRRS Review Team ARPANSA Liaison Officers
End of the day	**Travel of Mr John Le Heron (Patient Protection Reviewer), Ms Lynn Hubbard (EPR Reviewer) and Mr Kaare Ulbak (Team Leader) to Melbourne**	
Wednesday 9 November 2011		
Daily Discussions / Interviews		
09:00 – 10:30	Module Review (All review areas, including patient protection and EPR)	IRRS Review Team ARPANSA Counterparts
09:00 – 10:30	RHC	Team Leader, Mr John Le Heron
10:30 – 11:00	Coffee Break	
11:00 – 13:00	Continuation Module Review (All review areas, including patient protection and EPR)	IRRS Review Team ARPANSA Counterparts
13:00 – 14:30	Lunch Break	
14:30 – 16:30	Continuation Module Review (All review areas, including patient protection and EPR)	IRRS Review Team ARPANSA Counterparts
16:30 – 17:00	Coffee Break	
17:00 -	IRRS Daily Review Team Meeting	IRRS Review Team ARPANSA Liaison Officers

IRRS MISSION PROGRAMME		
Thursday, 10 November 2011		
Daily Discussions / Interviews		
09:00 – 11:00	Interview Simon Critchley and Keith Baldry	John Le Heron, Kaare Ulbake
10:30 – 11:00	Coffee Break	
11:00 – 13:00	Module Review (All review areas, including patient protection and EPR)	IRRS Review Team ARPANSA Counterparts
13:00 – 14:30	Lunch Break	
14:30 – 16:30	Policy issue session on **EPR via video conference**	IRRS Review Team ARPANSA Counterparts
16:30 – 17:00	Coffee Break	
17:00 -	IRRS Daily Review Team Meeting	IRRS Review Team ARPANSA Liaison Officers
Evening	**Return of Team Leader and Ms Lynn Hubbard to Sydney**	
Friday, 11 November 2011		
Daily Discussions / Interviews		
09:00 – 10:30	Module Review (All review areas, including patient protection)	IRRS Review Team ARPANSA Counterparts
10:30 – 11:00	Coffee Break	
11:00 – 13:00	Module Review (All review areas, including patient protection) Policy issue session on **Waste via video conference**	IRRS Review Team ARPANSA Counterparts
13:00 – 14:30	Lunch Break	
14:30 – 16:30	Module Review (All review areas)\ Policy issue session on **National uniformity and Patient protection via video conference**	IRRS Review Team ARPANSA Counterparts
16:30 – 17:00	Coffee Break	
17:00 -	IRRS Daily Review Team Meeting	IRRS Review Team ARPANSA Liaison Officers
Evening	**Return of Mr John Le Heron**	
Saturday, 12 November 2011		
IRRS Review Team meeting and Mission report drafting		
09:30 -	IRRS Daily Review Team Meeting Report writing	IRRS Review Team
Sunday, 13 November 2011		
Submission of IRRS Draft Mission report to ARPANSA		
12:00 – 14:00	Lunch	IRRS Review Team ARPANSA

IRRS MISSION PROGRAMME		
		Counterparts
15:00	Draft IRRS mission report to be sent to ARPANSA	IRRS Review Team
Monday, 14 November 2011		
Plenary Meeting		
08:30 – 11:00	Internal ARPANSA draft report discussion	ARPANSA Counterparts
11:00 – 13:00	Plenary meeting – Review of draft report	IRRS Review Team ARPANSA Counterparts
13:00 – 14:30	Lunch Break	
14:30 – 16:00	Continuation if needed: Plenary meeting – Review of draft report	IRRS Review Team ARPANSA Counterparts
16:00 – 16:30	Coffee Break	
17:00 -	IRRS Daily Review Team Meeting	IRRS Review Team ARPANSA Liaison Officers
Tuesday, 15 November 2011		
Exit Meeting		
10:30 – 12:00	Exit Meeting	IRRS Review Team ARPANSA Counterparts

APPENDIX III – LIST OF MISSION COUNTERPARTS

Item	Subject Area	IRRS Experts	Lead Counterparts
1	LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	Mr Kaare Ulbak Mr George Pangburn	Ms Helen Topfer
2	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	Mr Kaare Ulbak Mr George Pangburn	Mr Jim Scott
3	ORGANIZATION OF THE REGULATORY BODY	Mr Kaare Ulbak Mr George Pangburn	Mr Ian Graham Mr Jim Scott
4	ACTIVITIES OF THE REGULATORY BODY		
4-1	AUTHORIZATION		
4.1.1.	Research Reactors	Mr Christian Carrier	Mr John Ward
4.1.2.	Sources and Industrial Practices	Mr Christian Carrier	Mr Jim Scott
4.1.3.	Decommissioning	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
4.1.4	Remediation	Mr Jose Luis Revilla	Mr Carl-Magnus Larsson Mr Ian Graham
4.1.5	Radioactive Waste Management	Mr Jose Luis Revilla	Mr Jim Scott
4.2.	REVIEW AND ASSESSMENT		
4.2.1	Research Reactors	Mr Christian Carrier	Mr John Ward

Item	Subject Area	IRRS Experts	Lead Counterparts
4.2.2.	Sources and Industrial Practices	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
4.2.3.	Decommissioning	Mr Jose Luis Revilla	Mr John Ward
4.2.4	Radioactive Waste Management	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
4.3	INSPECTION AND ENFORCEMENT	Mr Christian Carrier	Mr Jim Scott
4.3.1.	Research Reactors	Mr Christian Carrier	Mr Jim Scott Mr John Ward
4.3.2.	Sources and Industrial Practices	Mr Christian Carrier	Mr Jim Scott
4.3.3.	Decommissioning	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
4.3.4	Radioactive Waste Management	Mr Jose Luis Revilla	Mr Jim Scott Mr John Ward
4.4	ENFORECEMENT	Mr Christian Carrier	Mr Jim Scott
4.5	REGULATIONS AND GUIDES	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
4.5.1	Research Reactors	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
4.5.2	Sources and Industrial Practices	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
4.5.3	Decommissioning	Mr Jose Luis Revilla	Mr Jim Scott Mr John Ward
4.5.4	Radioactive Waste Management	Mr Jose Luis Revilla	Mr Carl-MagnusLarssson

Item	Subject Area	IRRS Experts	Lead Counterparts
5	SAFETY AND SECURITY OF RADIOACTIVE SOURCES		
	General	Mr George Pangburn	Mr Loch Castle
	National Register of Radioactive Sources (Provision 11 of the Code)	Mr George Pangburn	Mr Loch Castle
	Source Search and Recovery	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
	Legislation, Regulations and Regulatory Body (Provisions 18-22 of the Code)	Mr George Pangburn	Mr Loch Castle
	Import and export of radioactive sources (Provisions 23-26 of the Code)	Mr George Pangburn	Mr Loch Castle
	Dissemination of the Code	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
6	NATIONAL INFRASTRUCTURE FOR RADIOACTIVE WASTE, DECOMMISSIONING AND REMEDIATION		
	National Waste Management Policy and Strategy	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
	Commonwealth Radioactive Waste Management Policy	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
	Waste Acceptance Criteria	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
	Classification System for Radioactive Waste	Mr Jose Luis Revilla	Mr Carl-Magnus Larsson Mr Jim Scott MrGeoff Williams

Item	Subject Area	IRRS Experts	Lead Counterparts
	National Inventory of Radioactive Waste	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
	Clearance of Radioactive Waste	Mr Jose Luis Revilla	Mr Jim Scott Mr John Ward
7	**EMERGENCY PREPAREDNESS**	Ms Lynn Hubbard	Mr Loch Castle
8	**MANAGEMENT SYSTEM FOR THE REGULATORY BODY**		
8.1	**Introduction**	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
8.2	**ARPANSA's Management System, structure and generic features**	Mr Kaare Ulbak Mr George Pangburn	Mr Ian Graham Mr Martin Dwyer Mr John Ward
8.3	**Management Responsibility**	Mr Kaare Ulbak Mr George Pangburn	Mr Ian Graham
8.4	**Resource Management**	Mr Kaare Ulbak Mr George Pangburn	Mr Ian Graham Mr Martin Dwyer
8.5	**Process Implementation**	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
8.6	**Measurement, assessment and improvement**	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
9	**TRANSPORT OF RADIOACTIVE MATERIALS**		
9.1	**Legislative and Governmental Responsibilities**	Mr Kaare Ulbak	Ms Helen Topfer Mr Samir Sarkar
9.2	**Compliance assurance**	Mr Kaare Ulbak	Mr Samir Sarkar
10	**PUBLIC INFORMATION**	Mr Kaare Ulbak Mr George Pangburn	Mr Ian Graham

Item	Subject Area	IRRS Experts	Lead Counterparts
11	**POLICY ISSUES**		
11.1	**Enhancing regulatory effectiveness and competence**	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
11.2	**Risk-informed and performance based approach to regulation**	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
11.3	**Openess and transparency**	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
11.4	**Human Resource and Knowledge Management**	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
11.5	**The promotion of national uniformity in radiation protection**	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
11.6	**Emergency Preparedness**	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
11.7	**Implementation of measures to improve security of sources**	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	
11.8	**Stakeholders consultation**	*Area not reviewed as there were no recommendations or suggestions in the 2007 IRRS mission*	

REVIEWERS AND CONTRIBUTORS

APPENDIX IV – RECOMMENDATIONS AND SUGGESTIONS FROM THE 2007 IRRS MISSION

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status after the2011 Follow-up Mission
1	LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	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.	CLOSED
		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.	CLOSED
		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.	
2	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	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.	CLOSED

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status after the2011 Follow-up Mission
		G2	Good Practice: 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	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.	CLOSED
		S5	Suggestion: 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.	CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status after the2011 Follow-up Mission
		G3	Good Practice: ARPANSA's use of international peer review team and services from the IAEA is good practice.	
		S6	Suggestion: ARPANSA should consider its strategy for effective implementation of the "Workforce Planning and Development" document derived from its Corporate Plan 2005-2008.	CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE
		G4	Good Practice: 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.	
		R1	Recommendation: ARPANSA should establish and implement a more comprehensive training programme for regulatory staff.	CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE
		G5	Good Practice: 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.	
4	ACTIVITIES OF THE REGULATORY BODY			
4.1	AUTHORIZATION	*No recommendation, suggestion or good practice identified*		

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status after the2011 Follow-up Mission
	RESEARCH REACTORS	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.	CLOSED
	SOURCES AND INDUSTRIAL PRACTICES	S7	Suggestion: ARPANSA should establish clearly defined procedures addressing the regulatory requirements for amendment, suspension or cancellation of a licence.	OPEN
	DECOMMISSIONING	*No recommendation, suggestion or good practice identified*		
	REMEDIATION	S8	Suggestion: 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.	CLOSED
		S9	Suggestion: 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.	CLOSED

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status after the2011 Follow-up Mission
	RADIOACTIVE WASTE MANAGEMENT	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.	CLOSED
4.2	REVIEW AND ASSESSMENT	*No recommendation, suggestion or good practice identified*		
	RESEARCH REACTORS	R3	Recommendation: 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.	OPEN
	SOURCES AND INDUSTRIAL PRACTICES	*No recommendation, suggestion or good practice identified*		
	DECOMMISSIONING	R4	Recommendation: 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.	CLOSED
		R5	Recommendation: 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.	CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status after the2011 Follow-up Mission
		S11	Suggestion: 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.	CLOSED
		S12	Suggestion: 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.	CLOSED
		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.	CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE
	RADIOACTIVE WASTE MANAGEMENT	*No recommendation, suggestion or good practice identified*		
4.3	INSPECTION AND ENFORCEMENT	R7	Recommendation: ARPANSA should incorporate into its internal guidance a requirement to include unannounced inspections in its compliance program for all licensees.	CLOSED

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status after the2011 Follow-up Mission
	RESEARCH RECTORS	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.	OPEN
		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.	CLOSED
	SOURCES AND INDUSTRIAL PRACTICES	R8	Recommendation: 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.	CLOSED
		G6	Good Practice: 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.	
	DECOMMISSIONING	*No recommendation, suggestion or good practice identified*		
	RADIOACTIVE WASTE MANAGEMENT	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.	CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status after the2011 Follow-up Mission
4.4	ENFORCEMENT	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.	CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE
4.5	REGULATIONS AND GUIDES	*No recommendation, suggestion or good practice identified*		
	RESEARCH REACTORS	*No recommendation, suggestion or good practice identified*		
	SOURCES AND INDUSTRIAL PRACTICES	*No recommendation, suggestion or good practice identified*		
	DECOMMISSIONING	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.	CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE
		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.	

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status after the2011 Follow-up Mission
	RADIOACTIVE WASTE MANAGEMENT	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.	CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE
5	SAFETY AND SECURITY OF RADIOACTIVE SOURCES	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.	CLOSED
	National Register of Radioactive Sources (Provision 11 of the Code)	S20	Suggestion: ARPANSA should consider the most effective means of expediting its establishment of an on-line secure national sealed source registry.	CLOSED
	Source Search and Recovery	*No recommendation, suggestion or good practice identified*		
	Legislation, Regulations and Regulatory Body (Provisions 18-22 of the Code)	S21	Suggestion: 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.	CLOSED

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status after the2011 Follow-up Mission
	Import and export of radioactive sources (Provisions 23-26 of the Code)	S22	Suggestion: 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.	CLOSED
	Dissemination of the Code	*No recommendation, suggestion or good practice identified*		
6	NATIONAL INFRASTRUCTURE FOR RADIOACTIVE WASTE, DECOMMISSIOINING AND REMEDIATION			
	National Waste Management Policy and Strategy	*No recommendation, suggestion or good practice identified*		
	Commonwealth Radioactive Waste Management Facility	*No recommendation, suggestion or good practice identified*		
	Waste Acceptance Criteria	*No recommendation, suggestion or good practice identified*		
	Classification System for Radioactive Waste	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.	CLOSED
	National Inventory of Radioactive Waste	*No recommendation, suggestion or good practice identified*		
	Clearance of Radioactive Waste	S24	Suggestion: ARPANSA should consider developing guidance for clearance of materials from decommissioning.	OPEN

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status after the2011 Follow-up Mission
7	EMERGENCY PREPAREDNESS	G8	Good Practice: 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.	
		R9	Recommendation: 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.	OPEN
			• the provision of appropriate information to all key stakeholders during and after events and accidents.	CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE
8	MANAGEMENT SYSTEM FOR THE REGULATORY BODY			
	ARPANSA's Management System, structure and generic features	G9	Good Practice: ARPANSA's regulatory strategic planning framework is systematic. This is good practice.	
		G10	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.	

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status after the2011 Follow-up Mission
		R10	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.	CLOSED
		R11	Recommendation: ARPANSA should expand its regulatory management system to include measures to promote and support strong safety culture.	OPEN
		S25	Suggestion: 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.	CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status after the2011 Follow-up Mission
		S26	Suggestion: ARPANSA should consider the enhancement of its risk management process to include further development of the risk identification process.	CLOSED
	Management responsibility	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.	CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE
	Resource management	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.	OPEN

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status after the2011 Follow-up Mission
	Process implementation	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.	
	Measurement, assessment and improvement	G12	Good Practice: ARPANSA's systematic and professional manner to improve and develop its Management System is good practice.	
9	TRANSPORT OF RADIOACTIVE MATERIALS			
	Legislative and Governmental Responsibilities	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.	CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE
	Compliance Assurance	R12	Recommendation: 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).	OPEN

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices	Status after the2011 Follow-up Mission
10	PUBLIC INFORMATION	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.	CLOSED ON THE BASIS OF PROGRESS AND CONFIDENCE

APPENDIX V – RECOMMENDATIONS/SUGGESTIONS AND GOOD PRACTICES FROM THE 2011 IRRS FOLLOW UP MISSION

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
1	LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	RF1	**Recommendation:** In the revision of the Australian Radiation Protection and Nuclear Safety Act (ARPANS Act) to be undertaken in 2012, the Australian Government should aim at ensuring full compliance of the Legal framework with IAEA Safety Standards. In particular, the revised Act should include explicit provisions and requirements for: • the prime responsibility for safety to be placed on the operator; • the legal basis for ARPANSA to regulate land transport or radioactive material; • the legal basis for regulating existing exposure situations, remediation and clearance; • decommissioning plan and related financial provisions , • assigning ARPANSA a clear role in regulating the security of controlled material, controlled apparatus and controlled facilities and promoting national uniformity; • clarifying ARPANSA's role in the establishment and operation of the national framework for nuclear and radiological emergency preparedness and response; • introducing the concept of clearance into the Australian regulatory framework.
3	ORGANIZATION OF THE REGULATORY BODY	SF1	**Suggestion:** ARPANSA should initiate discussions with States and Territories regulators on the possibility of organizing joint training and development for inspectors and licence assessors with the aim of sharing resources and achieving national uniformity.
4	ACTIVITIES OF THE REGULATORY BODY		

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
4.1	AUTHORIZATION – RESEARCH REACTORS	RF2	**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. The guidance information should apply to all facilities and activities regulated by ARPANSA.
4.1.5	AUTHORIZATION – RADIOACTIVE WASTE MANAGEMENT	RF3	**Recommendation:** ARPANSA should establish or amend requirements to ensure protection of public health and safety by setting limits for liquid discharge from licensed activities.
5	SAFETY AND SECURITY OF RADIOACTIVE SOURCES		
	Import and export of radioactive sources (Provisions 23-26 of the Code)	GPF1	**Good Practice:** ARPANSA has been very proactive in working with multiple national organizations that are competent authorities in areas interrelated with safety and security of radioactive sources, in particular their import and export control. This has resulted in excellent collaboration and cooperation, resulting in considerable progress being made on some key provisions of the Code of Conduct on Safety and Security of Radioactive Sources.
7	EMERGENCY PREPAREDNESS	RF4	**Recommendation:** ARPANSA should establish a function to oversee the coordination of its emergency preparedness and response activities, to ensure harmonization of its emergency preparedness and response functions and to promote an effective and timely emergency response.
		RF5	**Recommendation:** The Australian Government should ensure the national framework clearly identifies and assigns responsibilities to ARPANSA and other appropriate organizations for nuclear and radiation emergency preparedness.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		GPF2	**Good Practice:** Arrangements made by ARPANSA during response to the Tepco Fukushima Dai-ichi accident in Japan in March 2011 were excellent. The response process led to the development of informative assessment protocols and a clear task structure that facilitated effective and regular reporting to key stakeholders.
11	MEDICAL EXPOSURE AND PATIENT PROTECTION		
11.1.1	Authorization of Medical Radiation Facilities and Activities	RF6	**Recommendation:** It is recommended that specific guidance is developed and made available to licence applicants to address the areas on medical exposure and patient protection in RPS 8, 10, 14 and 19.
11.1.2	Review and Assessment of Application for Medical Radiation Facilities	RF7	**Recommendation:** ARPANSA should ensure that the technical expertise available in the Medical Radiation Service Branch is more formally involved in the assessment and review of licence applications involving medical exposure.
11.1.3	Inspection and Enforcement of Medical Radiation Facilities	SF2	**Suggestion:** ARPANSA should revise the risk matrix used to assign inspection priorities to allow consideration of patient protection as an input into the risk evaluation.
		SF3	**Suggestion:** ARPANSA should better utilize the expertise available in the Medical Radiation Services Branch to make inspections of medical radiation facilities more effective with respect to medical exposure and patient protection.
11.1.4	Development of regulations and guides for medical exposure in medical radiation facilities	RF8	**Recommendation:** ARPANSA should initiate the review and revision of RPS 14 to ensure that it is aligned with and consistent with the requirements of the new BSS, GSR Part 3.
11.2	Policy Discussion: National Uniformity and Patient Protection	GPF3	**Good Practice:** The formation of ACDS is seen as a novel initiative in providing the continuing safe delivery of radiation treatments.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		SF4	**Suggestion:** The Government should ensure that ACDS continues and develops in order to provide a high level of dosimetric assurance to meet current and future advances in radiation therapy.
		GPF4	**Good_Practice:** The formation of the NDRL Database is an excellent vehicle for establishing initial values of DRLs, and then for continuing to collect data to enable timely updates of the DRL values.
		SF5	**Suggestion:** ARPANSA should take the lead in RHC to introduce a means for both monitoring the success of the implementation of CoPs within the context of medical exposure and patient protection, and for planning in advance how implementation might be achieved in each jurisdiction.
		SF6	**Suggestion:** ARPANSA should engage more generally with government initiatives to improve quality in health care, with a view to parallel strategies, in addition to regulatory requirements, to increase the effectiveness of the implementation of RPS 14.
		SF7	**Suggestion:** ARPANSA should continue to develop its relationships with a wide a set of professional bodies and other organizations as possible to promote awareness about the need to comply with the CoPs to ensure internationally accepted patient protection.
		SF8	**Suggestion:** ARPANSA should seek to assist RANZCR regarding the development of radiation protection aspects of referral guidelines or appropriateness criteria to assist medical practitioners in referring only appropriate medical imaging procedures.
		SF9	**Suggestion:** ARPANSA should continue to assign high priority to the completion of the survey to establish CT DRLs for Australia, and together with the relevant professional. bodies establish DRLs in other areas of diagnostic imaging and image guided interventional procedures.

APPENDIX VI – REFERENCE MATERIAL PROVIDED BY ARPANSA

1. EMERGENCY PREPAREDNESS PLAN
   1.1. ARPANSA Emergency Preparedness Plan Strategy (version 2) (EPP-MAN-010) September 2011
   1.2. ARPANSA Emergency Preparedness Plan Operations (version 3) (EPP-MAN-020) September 2011
   1.3. ARPANSA Emergency Preparedness Plan Monitoring (version 1) (EPP-MAN-030) September 2011
2. MEDICAL
   2.1. Code of Practice: Radiation Protection in the Medical Applications of Ionizing Radiation (Radiation Protection Series No. 14) May 2008
   2.2. Example Licence – Medical Exposure
   2.3. National Directory for Radiation Protection (Including Amendments 1-5, Republished July 2011) Radiation Protection Series No. 6
   2.4. Safety Guide: Radiation Protection in Diagnostic and Interventional Radiology (Radiation Protection Series No. 14.1) August 2008
   2.5. Code of Practice: Exposure of Humans to Ionizing Radiation for Research Purposes (Radiation Protection Series No. 8) May 2005
   2.6. Safety Guide: Radiation Protection in Nuclear Medicine (Radiation Protection Series No. 14.2) August 2008
   2.7. Regulatory Guide: Reporting an Accident
   2.8. Standard Operating Procedure for Licence Application Assessment (version 5) (OS-LA-SOP-242) June 2011
   2.9. Standard Operating Procedure for Periodic Licence Review Procedure (version 1) (RPB-LA-SOP-248) (April 2010)
   2.10. Information Brief on ARPANSA's Medical Radiation Services Branch (July 2011)
   2.11. Answers to SAT Questionnaire – Medical
3. POLICY ISSUES
   3.1. Regulatory Assessment Principles for Controlled Facilities (RB-STD-42-00) October 2001
   3.2. Regulatory Guidance for Radioactive Waste Management Facilities: Near Surface Disposal Facilities and Storage Facilities (December 2006)
   3.3. ARPANSA EPR Policy Considerations
   3.4. Discussion Paper on Radioactive Waste
4. STATUS REPORT (attachments)
   4.1. Requirements and Competencies for Inspectors (version 3) (OS-INS-SUP-280E) May 2011
   4.2. DRAFT Regulatory Guide: Periodic Safety Review
   4.3. DRAFT revised Standard Operating Procedure for Managing Surrender of Licence (version 2) (RPB-LA-SOP-246) June 2011
   4.4. DRAFT Regulatory Guidance for the Decommissioning of Controlled Facilities under the Australian Radiation Protection and Nuclear Safety Act 1998 (RPB-LA-SUP-240K) May 2010
   4.5. Facility Licence F0184 – ANSTO
   4.6. Official Correspondence from ARPANSA to ANSTO on the application of Facility Licence F0184 (4 April 2007)
   4.7. Official Correspondence from ARPANSA to ANSTO on the application of Facility Licence F0184 (20 September 2007)
   4.8. Official Correspondence from ARPANSA to ANSTO on the application of Facility Licence F0184 (15 September 2008)
   4.9. Official Correspondence from ARPANSA to ANSTO on the application of Facility Licence F0184 (26 March 2009)
   4.10. Official Correspondence from ARPANSA to ANSTO on the application of Facility Licence F0184 (26 August 2009)
   4.11. DRAFT Regulatory Inspection Policy (version 4) (OS-MAN-280)

4.12. DRAFT Inspection Procedure (version 5) (OS-INS-SOP-280)
4.13. Guidance for Inspectors (version 3) (OS-INS-SUP-280C) December 2008
4.14. Structure of the Draft Virtual Organisation Plan on EPP
4.15. ARPANSA Regulatory Quality Management System Register of Documents (RPB-MAN-000) September 2008
4.16. ARPANSA Operations Services Quality Committee Terms of Reference (version 3) July 2011
4.17. DRAFT Safety Guide: Approval of Special Form Radioactive Material, Low Dispersable Radioactive Material, Design of Packages an d Validation of Packages, and Shipments (Radiation Protection Series Publication No. 2.2) July 2011
4.18. Australian Radiation Protection and Nuclear Safety Act 1998 (July 2011)
4.19. Regulatory Guideline on Review of Plans and Arrangements (RB-STD-15-03) August 2003
4.20. Regulatory Assessment Principles for Controlled Facilities (RB-STD-42-00 Rev 1)
4.21. Recommendations for Limiting Exposure to Ionizing Radiation (1995) (Guidance Note[NOHSC:3022(1995)]) and National Standard for Limiting Occupational Exposure to Ionizing Radiation [NOHSC:1013(1995)] Republished March 2002 (Radiation Protection Series No. 1)
4.22. Safe Transport of Radioactive Material (2008 Edition) (Radiation Protection Series No. 2)
4.23. Australian Radiation Protection and Nuclear Safety Regulations 1999 (July 2011)
4.24. Memorandum of Understanding between ARPANSA and Queensland Health
4.25. ARPANSA Strategic Directions 2008-2012
4.26. (Sample) 2010/2011 Regulatory and Policy Branch Business Plan
4.27. Performance and Accountability Report 2010/2011
4.28. ARPANSA Portfolio Budget Statement 2011-2012
4.29. Four year rolling inspection schedule as at 30 August 2011
4.30. Proposal for workforce and succession planning (ARPANSA Executive Board of Management Meeting – October 2009)
4.31. Official Correspondence from ARPANSA to National Parks, Environment Australia on the Facility Licence FV0093 (June 2009)
4.32. ARPANSA Memorandum: Maralinga – Considerations (26 November 2009)
4.33. ANSTO reports to Sydney Water and ARPANSA on liquid effluent discharges (January to June 2011)
4.34. DRAFT ARPANSA Regulatory Advice for Radioactive Waste Management Facilities: Storage and Near Surface Disposal Facilities (August 2011)
4.35. Report to the Radiation Regulators Forum on Implementation of COAG Report – Regulation and Control of Radiological Material (July 2011)
4.36. National Sealed Source Register
4.37. Safety Guide: Classification of Radioactive Waste (Radiation Protection Series No. 20) April 2010
4.38. ARPANSA Organizational Chart
4.39. ARPANSA Enterprise Risk Assessment (June 2008)
4.40. ARPANSA Internal Audit – Final Report Risk Management Review March 2011
4.41. ARPANSA Communication Strategy (15 April 2011)
4.42. Status Report of Actions to Implement the Recommendations and Suggestions from the IRRS Mission to Australia in June/July 2007

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. **IAEA SAFETY STANDARDS SERIES GS-R-1 –** *Legislative and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*
2. **IAEA SAFETY STANDARDS SERIES GSR Part 1 –** *Governmental, Legal and Regulatory Framework for Safety*
3. **IAEA SAFETY STANDARDS SERIES GS-G-1.1** – *Organization and Staffing of the Regulatory Body for Nuclear Facilities*
4. **IAEA SAFETY STANDARDS SERIES GS-G-1.2** – *Review and Assessment of Nuclear Facilities by the Regulatory Body*
5. **IAEA SAFETY STANDARDS SERIES GS-G-1.3** – *Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body*
6. **IAEA SAFETY STANDARDS SERIES GS-G-1.4** – *Documentation for use in Regulation of Nuclear Facilities*
7. **IAEA SAFETY STANDARDS SERIES GS-G-1.5** – *Regulatory Control of Radiation Sources*
8. **IAEA SAFETY STANDARDS SERIES GS-R-2** –*Preparedness and Response for a Nuclear or Radiological Emergency Safety Requirements*
9. **IAEA SAFETY STANDARDS SERIES GS-R-3** – *Management System for Facilities and Activities*
10. **IAEA SAFETY STANDARDS SERIES NS-R-1** – *Safety of Nuclear Power Plants: Design Safety Requirements*
11. **IAEA SAFETY STANDARDS SERIES NS-R-2** – *Safety of Nuclear Power Plants: Operation Safety Requirements*
12. **IAEA SAFETY STANDARDS SERIES NS-R-4** – *Safety of Research Reactors*
13. **IAEA SAFETY STANDARDS SERIES NS-G-4.1** – *Commisioning of Research Reactors*
14. **IAEA SAFETY STANDARDS SERIES SS115** – *International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources*
15. **IAEA SAFETY STANDARDS SERIES GSR Part 3 (Interim)** – *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*
16. **IAEA SAFETY STANDARDS SERIES TS-R-1** – *Regulations for the Safe Transport of Radioactive Material*
17. **IAEA SAFETY STANDARDS SERIES WS-G-2.1** – *Decommissioning of Nuclear Power Plants and Research Reactors*
18. **IAEA SAFETY STANDARDS SERIES WS-G-2.2** – *Decommissioning of Medical, Industrial and Research Reactors*
19. **IAEA SAFETY STANDARDS SERIES WS-R-1** – *Near Surface Disposal of Radioactive Waste*
20. **IAEA SAFETY STANDARDS SERIES WS-R-2** – *Predisposal Management of Radioactive Waste including Decommissioning*
21. **IAEA SAFETY STANDARDS SERIES WS-G-2.3** – *Regulatory Control of Radioactive Discharges to the Environment*
22. **IAEA SAFETY STANDARDS SERIES WS-G-2.4** – *Decommissioning of Nuclear Fuel Cycle Facilities*
23. **IAEA SAFETY STANDARDS SERIES WS-G-2.5** – *Predisposal Management of Low and Intermediate Level Radioactive Waste*
24. **IAEA SAFETY STANDARDS SERIES WS-G-2.6** – *Predisposal Management of High Level Radioactive Waste*
25. **IAEA SAFETY STANDARDS SERIES WS-G-2.7** – *Management of Waste from the use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education*

APPENDIX VIII – ARPANSA ORGANIZATIONAL CHART