



Australian Government

Australian Radiation Protection and Nuclear Safety Agency

**Closure of Recommendations and Suggestions from 2011
IAEA Integrated Regulatory Service Review of ARPANSA**

Regulatory Services Branch

May 2015

APPENDIX 1

1. Introduction

Between June and July 2007, an IAEA Integrated Regulatory Review Service (IRRS) team undertook a full scope mission of the Regulatory Branch at ARPANSA. A follow-up mission was then conducted in November 2011. The follow-up mission also included a module on medical exposure and patient protection.

As a result of the original mission in 2007 and the follow-up mission in 2011, a set of recommendations and suggestions for improvement were made by the IRRS team.

The object of this document is to provide an update on the status of the recommendations and suggestions. This document provides documented evidence of the closure of the recommendations and suggestions which were accepted by ARPANSA.

2. Description of Outstanding Recommendations and Suggestions at 2011 Follow-Up Mission

IAEA Reference (S = suggestion, R = recommendation)	Description
R3	ARPANSA should prepare regulatory guidance in relation to its expectation for the Periodic Safety Review imposed by condition on the facility authorising the operation of the OPAL reactor.
R9	ARPANSA should establish, implement, test, maintain and continuously improve in-house procedures and policies related to: <ul style="list-style-type: none">• The management of its role in nuclear or radiation events and emergencies arising with holders• The provision of appropriate information to all key stakeholders during and after events and accidents.
R11	ARPANSA should expand its regulatory management system to include measures to promote and support strong safety culture.
R12	ARPANSA should ensure that all necessary aspects of the compliance assurance programme are in place and are fully effective (eg guidance for package approval, plan for emergency preparedness, and 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).
S7	ARPANSA should establish clearly defined procedures addressing the regulatory requirements for amendment, suspension or cancellation of a licence.

APPENDIX 1

S13	ARPANSA should consider a systematic periodic assessment of the inspection programme to evaluate its continued effectiveness, using feedback and lessons learned from previous inspections.
S24	ARPANSA should consider developing guidance for clearance of materials from decommissioning.
S28	ARPANSA should consider the most effective way to determine the cost structure of the regulatory function, including a strategy for collecting the necessary data (ie 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 plan 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.
RF1	<p>In the revision of the ARPANS Act to be undertaken in 2012, the Australian Government should aim at ensuring full compliance of the Legal Framework with the IAEA Safety Standards. In particular, the revised Act should include explicit provisions and requirements for:</p> <ul style="list-style-type: none"> • The prime responsibility for safety to be placed on the operator • The legal basis for ARPANSA to regulate land transport of 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
RF2	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 its facilities and activities regulated by ARPANSA.
RF3	ARPANSA should establish or amend requirements to ensure protection of public health and safety by setting limits for liquid discharges from licensed activities.

APPENDIX 1

RF4	ARPANSA should establish a function to oversee the coordination of its emergency preparedness and response activities, to ensure harmonisation of its emergency preparedness and response functions and to promote an effective and timely emergency response.
RF5	The Australian Government should ensure the national framework clearly identifies and assigns responsibilities to ARPANSA and other appropriate organisations for nuclear and radiation emergency preparedness.
SF1	ARPANSA should initiate discussions with the State and Territory regulators on the possibility of organising joint training and development for inspectors and licence assessors with the aim of sharing resources and achieving national uniformity.
SF2	ARPANSA should revise the risk matrix used to assign inspection priorities to allow consideration of patient protection as an input to risk evaluation.
SF3	ARPANSA should better utilise 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.

3. Closure of Recommendations and Suggestions

Appendix 1 of this report provides a separate closure statement for each of the recommendations and suggestions above, including where possible, documentary evidence of the closure.

4. Conclusions

The implementation of the recommendations and suggestions is now complete, with one exception as noted below:

R3	The OPAL Periodic Safety Review guideline has now been modified to include OPAL Periodic Security Review. This has required wider consultation eg ASNO, an advanced draft is to be discussed at the Nuclear Safety Committee meeting, and ANSTO has requested that issuance of the guide be delayed until October. Based on progress and confidence, however, this recommendation may be closed.
-----------	--

Closure of 2011 IRRS Recommendation R3

Introduction

This recommendation was made in the 2007 report, under section 4.2.1 *Review and Assessment – Research Reactors*. It was repeated in the same section in the 2011 follow-up report.

2011 IRRS Recommendation R3

ARPANSA should prepare regulatory guidance in relation to this expectation for the Periodic Safety review imposed by condition on the facility authorising the operation of the OPAL reactor.

Initial ARPANSA Response

ARPANSA accepted the recommendation.

Implementation

The PSR guide for facility development was initiated in November 2010. A draft that was completed in April 2011 was submitted to Nuclear Safety Committee (NSC) for comments. The NSC did not recommend the draft of that format and content at that time. Further work on the draft continued in 2014, after the review of the PSR of OPAL reactor was completed. The second draft, completed in December 2014 was internally reviewed by selected ARPANSA managers and discussed at the NSC meeting in March 2015.

A decision has been made to integrate security into the PSR guide and produce guidance that will incorporate safety, security and safeguard aspects in one document. This undertaking requires contributions and review of a broader group of stakeholders than previously contemplated (e.g. SCS section, ASNO and licence holders).

A third draft that includes security factors was produced in April 2015. At the moment, the document is being provided to ASNO for their contribution and comments related to safeguard expectations and good practice.

Considering the current status of the document and number of stakeholders involved, it is expected that the guide will be finalised by the end of June 2015.

Actions Identified and/or Completed (as of April 2015)

- An advanced draft that included security factors was produced in April 2015
- ASNO to complete incorporation the safeguard aspects into the document (end of April)
- Incorporation of comments arising from ARPANSA internal review + ASNO comments (mid-May)
- Providing the draft to selected licence holders (mid-May)
- Providing the draft to NSC members for comments (end of May)
- Incorporation of all comments and publishing the guide (end of June)
- ARPANSA Quality Committee (end of June)

Conclusion

As of April 2015, implementation of this recommendation is **ONGOING**.

Evidence of Progress - TRIM Reference

[R10/11584 REGULATORY GUIDE: Periodic Safety & Security Review \(Draft\)](#)

Closure of 2011 IRRS Recommendation R9

Introduction

This new recommendation was made in the 2011 follow-up report, under Chapter 7, *Emergency Preparedness*, in light of the post-Fukushima environment. The recommendation is about the role of ARPANSA as the National Competent Authority for the Emergency Notification and Assistance Conventions and as the Federal Government Regulator for Emergency Preparedness and Response.

2011 IRRS Recommendation 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.*

Initial ARPANSA Response

ARPANSA accepted the recommendation.

Implementation

In 2015 the Regulatory Services Branch has re-defined its regulatory approach to assessing and verifying licence holder compliance with international and national requirements for EPR through the development and implementation of the new Performance Objectives and Criteria (PO&C) for Emergency Preparedness and Response, which is one of eight (8) base-line modules to be inspected with licence holders. The EPR PO&C are available within ARPANSA's records management system, branch quality management system and intranet. The PO&C have been distributed to licence holders for feedback and clearly define ARPANSA's role in managing radiation events and emergencies.

These initiatives address and close the basis of the first element of the recommendation.

In 2014 the ARPANSA Incident Management Plan (IMP) (published on the ARPANSA intranet) was jointly developed by the Monitoring and Emergency Response Section, the Security and Community Safety Section and the Office of the CEO. This plan has been developed in accordance with International Best Practice, principally with IAEA GSR-2, and also takes into consideration the Australian Government Crisis Management Framework (AGCMF) and other existing national plans and arrangements for emergencies. All roles and responsibilities have been defined for both the operating organisations, the regulator, responding organisations and measures to ensure that international cooperation can be requested in accordance with the Conventions on Emergency Notification and Assistance.

The IMP has now been tested through a number of Table Top Exercises in a whole of government setting, including multijurisdictional environments. Moreover, the IMP has been activated twice for minor incidents and the performance of ARPANSA during these activations and exercises has been positive, with minor lessons learned captured for future improvements.

APPENDIX 1

An overarching EPR Strategy (also on the ARPANSA intranet) has been developed by ARPANSA's executive in 2014 in order to ensure that sustained preparedness arrangements are in place supporting the IMP (response plan).

These initiatives address and close the basis for the second element of the recommendation.

Actions Identified and/or Completed (as of April 2015)

- The EPR PO&C have been developed and implemented as part of ARPANSA's inspection regime
- The PO&C have been socialised with licence holders which has defined ARPANSA's role in assessing and validating preparedness and response arrangements with licence holders
- The IMP has been developed, implemented and tested during exercises and real events
- The IMP has been supported by the development of an EPR Strategy to ensure that sustainable EPR arrangements support the response plan (IMP)

Conclusion

As of April 2015, implementation of this recommendation is **COMPLETE**.

Evidence of Implementation

[R15/03780 POC Emergency Preparedness and Response](#)

[ARPANSA Incident Management Plan](#) (link to IMP on ISAAC)

Closure of 2007 IRRS Recommendation R11

Introduction

This recommendation was made in the 2007 report under Chapter 8, *Management System for the Regulatory Body*, and is based on GS-R-3 §2.5.5 which states:

“The management system shall be used to promote and support a strong safety culture by:

- Ensuring a common understanding of the key aspects of safety culture within the organization;
- Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;
- Reinforcing a learning and questioning attitude at all levels of the organization.”

2011 IRRS Recommendation R11

ARPANSA should expand its regulatory management system to include measures to promote and support strong safety culture.

Initial ARPANSA Response

ARPANSA accepted the recommendation.

Implementation

In 2011 a Safety Analysis Section was formed with Regulatory Services Branch. A primary role of this section was to develop ARPANSA’s capabilities for holistic safety (known commonly within the IAEA as Systemic Safety). The holistic safety approach developed promotes a better understanding on the interactions between technical, human and organisational factors within a socio-technical system. The approach is consistent with IAEA Safety Fundamentals (SF-1 Paragraph 3.14) and has been well received by the IAEA where it was presented as a keynote presentation of IEM5 of the Fukushima Action Plan.

One of seven key characteristics used in the holistic approach is Safety Culture. The attributes of this are closely aligned with IAEA guidelines. Safety Analysis has developed guidelines for holistic safety that are published on the ARPANSA website. These incorporate Safety Culture. Tools have also been developed to assist regulatory staff and licence holders to assess safety culture. These are also available on the ARPANSA website.

Training has been provided to regulatory staff on safety culture.

ARPANSA has presented its holistic approach to national and international conferences (including those of the IAEA), at licence holder forums and to licence holders directly during information sessions and meetings. More recently Safety Analysis has developed Performance Objectives and Criteria covering safety culture that will be used by all inspectors.

APPENDIX 1

Actions Identified and/or Completed (as of April 2015)

- Guidance developed and published – REG-LA-SUP-240U – November 2012
- Assessment tools developed and published
- Training provided to regulatory staff
- Holistic safety and safety culture promoted through various national and international conferences
- Holistic safety and safety culture promoted to licence holders through various interactions, information sessions, meetings, etc.

Conclusion

As of April 2015, implementation of this recommendation is **COMPLETE**.

Evidence of Implementation – TRIM References and ARPANSA website links

[R12/08276 Holistic Safety Guidelines, November 2012, REG-LA-SUP-240U](#)

<http://www.arpansa.gov.au/Regulation/Holistic/index.cfm> ARPANSA website “Holistic Safety”
[webpages](#)

Closure of 2011 IRRS Recommendation R12

Introduction

This recommendation was made in the 2007 report under Section 9.2, *Compliance Assurance for Radioactive Material*.

At the time of the 2007 Mission, the IRRS team were of the opinion there was no formal compliance assurance programme, although ARPANSA has initiated work on draft regulatory guidance.

2007 IRRS Recommendation 12

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).

2011 IRRS Follow-up finding

The 2011 follow-up report states:

“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.*

Implementation

ARPANSA developed a Safety Guide on Approval Processes for the Safe Transport of Radioactive Material, Radiation Protection Series No. 2 and published it in November 2012. This Guide was prepared incorporating inputs from other competent authorities and stakeholders. This Guide is in use by stakeholders across Australia. ARPANSA also developed a Guide on Transport of Radioactive Material, REG-TR-SUP-360, that provides guidance for licence holders to comply with the requirements of the Transport Code.

Actions Identified and/or Completed (as of April 2015)

The Safety Guide on Approval Processes for the Safe Transport of Radioactive Material, Radiation Protection Series No. 2 is used by stakeholders across Australia and is available on ARPANSA website. ARPANSA’s Regulatory Guide (REG-TR-SUP-360) is in the Regulatory Branch Quality System and is used by Commonwealth licence holders.

Conclusion

As of April 2015, implementation of this recommendation is **COMPLETE**.

Evidence of Implementation - TRIM Reference

[REGULATORY GUIDE: Transport of Radioactive Material](#)

Closure of 2007 IRRS Suggestion S7

Introduction

This suggestion was made in the 2007 report under Chapter 4 *Activities of the Regulatory Body*, specifically section 4.1.2 *Guidance for Applicants*.

2007 IRRS Suggestion S7

ARPANSA should establish clearly defined procedures addressing the regulatory requirements for amendment, suspension or cancellation of a licence.

2011 IRRS Follow-up finding

ARPANSA has not yet established standard procedures for determining amendments, suspensions and cancellations. ARPANSA staff has acknowledged a need for these. Although progress is observed, some work remains before this suggestion may be considered closed.

Suggestion 7 (S7) is OPEN.

Implementation

Amendment of licence

Under section 36 of the Act, the CEO may impose additional licence conditions, remove or vary licence conditions that were imposed by the CEO or extend or reduce the authority granted by the licence.

Amending a licence is one of the enforcement options available to the CEO in response to non-compliance. Depending on the nature of the non-compliance, it may be considered appropriate to amend the licence to facilitate compliance or address any new risks that have been identified.

Alternatively, amendment of a licence may be requested by the licence holder. Requests for licence amendments to extend the authority granted by the licence are considered equivalent to requests for new licences and require similar levels of information and assessment. Licence holders are required to complete a licence application form to apply for such amendments.

Licence amendments may also result from ARPANSA's quarterly or annual reviews of licence holder compliance reports, or as a result of a more systematic review conducted every three years to ensure the licence reflects the current operational situation.

Suspension or Cancellation of Licence (s38)

Under section 38 of the Act, the CEO may decide to suspend or cancel a licence in circumstances where a condition of the licence has been breached by the licence holder or by a person covered by the licence; where there are reasonable grounds to believe that an offence has been committed by the licence holder or by a person covered by the licence; or where the licence was obtained improperly.

Suspension or cancellation of a licence could have serious implications for the licence holder's continued business or operations. When making decisions about such action, this will be taken into account however the overriding consideration is protecting the health and safety of people and the environment.

APPENDIX 1

When making a decision whether or not to reissue a licence that had been suspended or cancelled ARPANSA will take into account the licence holder's compliance history. Where the licence has been cancelled, the licence holder will be required to make a new application.

Actions Identified and/or Completed (as of April 2015)

ARPANSA's enforcement strategy and graded approach to non-compliance is documented in Compliance and Enforcement Strategy v2 and REGULATORY GUIDE: Graded Approach to Non-Compliance v2 - both approved and issued in January 2015 (first issued June 2012).

The periodic licence review process is documented in the Periodic Licence Review Procedure v1.1 and includes Periodic Licence Review Checklist v2 (issued in April 2013).

Licence application forms require the applicant to indicate whether it is a new application or licence amendment.

Conclusion

As of April 2015, implementation of this recommendation is **COMPLETE**.

Evidence of Implementation - TRIM Reference

[R12/05072 Compliance and Enforcement Strategy REG-MAN-270](#)

[R12/05069 REGULATORY GUIDE: Graded Response to Non-Compliance REG-COM-SUP-270J](#)

[R10/03618 Periodic Licence Review Procedure REG-LA-SOP-248](#)

[R10/03617 Periodic Licence Review Checklist REG-LA-FORM-248A](#)

[R11/04633 Source Licence Application Form & RAR \(Low Hazard Sources\) REG-LA-FORM-240N](#)

[R14/13737 Source Licence Application Form \(Medium – High Hazard Sources\) REG-LA-FORM-240A](#)

Closure of 2007 IRRS Suggestion S13

Introduction

This suggestion was made in the 2007 report under Chapter 4.3 *Inspection and Enforcement*. The IRRS team were of the opinion that inspections were not organised in such a way to provide a synthesis of the inspection findings and a categorisation of issues regarding non-compliances and other issues requiring corrective actions, requests for additional information and observations.

2007 IRRS Suggestion S13

ARPANSA should consider a systematic periodic assessment of the inspection programme to evaluate its continued effectiveness, using feedback and lessons learned from previous inspections.

2011 IRRS Follow-up finding

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.

Implementation

The Inspection Strategy (Chapter 1, ARPANSA Inspection Manual) requires periodic assessment of the effectiveness and efficiency of the inspection program. This will be achieved by an annual (EOFY) analysis of inspection outcomes to inform compliance activity, future inspection planning, procedures and guidance as described in Chapter 3, ARPANSA Inspection Manual.

The latest version of the Licence Administration Database (LAD) provides for inspection findings to be recorded thus allowing non-compliances, performance deficiencies and good practices to be searchable across all licence holders. Feedback from post-inspection surveys, conducted and independently evaluated by the Office of the CEO, will also be taken into account.

A report on the annual review will be produced and published on the ARPANSA website.

Actions Identified and/or Completed (as of April 2015)

The ARPANSA Inspection Manual (a compilation of several QMS inspection documents) is in the final stages of preparation. LAD version 1.5.40 is currently undergoing testing and is due for release by the end of April.

Conclusion

As of April 2015, implementation of this recommendation is **COMPLETE**.

Evidence of Implementation - TRIM Reference

[R15/02143 ARPANSA Inspection Manual](#)

Closure of 2011 IRRS Suggestion S24

Introduction

This suggestion was made in the 2007 report under Chapter 6 *National Infrastructure for Radioactive Waste, Decommissioning and Remediation*.

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 IRRS review team considered that some guidance about clearance criteria for the residual material would be useful for the upcoming decommissioning projects. In 2011, the IRRS review team acknowledged ARPANSA's intention to develop the guidance material.

2007 IRRS Suggestion S24

ARPANSA should consider developing guidance for clearance of materials from decommissioning.

2011 IRRS Follow-up finding

ARPANSA is ready to introduce it beyond the regulation of decommissioning and to develop appropriate regulatory guidance.

Suggestion 24 (S24) is OPEN.

Implementation

ARPANSA has drafted the Regulatory Guide for Decommissioning of Controlled Facilities to provide guidance to licence holders, assessors and interested parties on planning, conduction and completing the decommissioning of controlled facilities. It aims to assist in ensuring that the decommissioning is conducted in a safe and environmentally acceptable manner in accordance with international best practice. This document includes guidance for clearance of materials from decommissioning. The document is in the process of finalisation.

Actions Identified and/or Completed (as of April 2015)

The Regulatory Guide: Decommissioning of Controlled Facilities is in the final stage. It will be sent to stakeholders for comment and is expected to be published at the end of June 2015.

Conclusion

As of April 2015, implementation of this suggestion is **COMPLETE**.

Evidence of Implementation - TRIM Reference

[R10/04213 REGULATORY GUIDE: Decommissioning of controlled facilities \(Draft\)](#)

Closure of 2011 IRRS Suggestion S28 (also from 2007 IRRS)

Introduction

This suggestion was made in the 2007 report under Chapter 8, *Management Systems for the Regulatory Body*.

2007 IRRS Suggestion S28

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.

ARPANSA Response

ARPANSA is committed to recovering the full costs of its regulatory activities from its licence holders, and an implementation plan is in its early stages.

2011 IRRS Follow-Up Mission

In revisiting suggestion 28, the 2011 IRRS Follow-Up Mission made the following finding:

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

Implementation

Actions Identified and/or Completed (as of March 2015)

ARPANSA implemented activity-based time tracking within the Regulatory Services Branch in 2014, and has developed a long-term plan for implementing an appropriate cost recovery framework. The plan involves several phases and ongoing activities including the collection and analysis of reliable data. ARPANSA will continue to advance its cost recovery model in a staged approach in consultation with licence holders, supported by the new regulatory delivery model to reduce regulatory burden.

The plan reflects the principles described in the Australian Government Cost Recovery Guidelines.

APPENDIX 1

Although changes to regulations associated with fees and charges are planned in the coming year or two, the long-term plan culminates in an improved framework by the time the legislation sunsets in 2019.

A management system for the development and implementation of full cost recovery of ARPANSA's regulatory functions exists and is in use. This is evidenced by:

- The existence of a Cost Recovery Framework which outlines the policy and procedures implemented, the data that needs collection and the analysis to be undertaken by the time the ARPANSA Licence Charges Regulations 'Sunset' in 2019.
- The existence of a Regulatory Services Cost Recovery Tracker system (in the form an electronic spreadsheet) for the input of activity based costing data.
- A Project Management Plan that sets out the steps to be taken within specified timelines, and which is adequately resourced.

Conclusion

As of April 2015, implementation of this recommendation is **COMPLETE**.

Evidence of Implementation - TRIM Reference

[R15/02246 Cost Recovery Framework Feb 2015](#)

[R15/02247 Cost Recovery Progress Chart Feb 2015](#)

[P:\ACTIVITY TRACKER\Cost Recovery Tracker \(March 2015 Onwards\)](#)

Closure of 2011 IRRS Recommendation RF1

Introduction

This recommendation was made in the 2011 report under Chapter 1, *Legislation and Governmental Responsibilities*. The recommendation is about the (then impending) review of the *Australian Radiation Protection and Nuclear Safety Act 1999* (ARPANS Act).

2011 IRRS Recommendation RF1

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 the 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.*

Initial ARPANSA Response

ARPANSA accepted the recommendation.

Implementation

Consultants were engaged by the Department of Health in 2012 to review the Act. ARPANSA made submissions to the review. ARPANSA’s submissions included proposals that the Act include provisions to give effect to the IRRS recommendation. Not all were accepted by the Department of Health. The table below shows that only one of the six dot points above was accepted by the Department of Health.

Dot point	The revised Act should include explicit provisions and requirements for:	Health response:
1.	<i>The prime responsibility for safety to be placed on the operator;;</i>	This is already stipulated in RPS documents and there is no need to re-state it in the Act. Not accepted.
2.	<i>The legal basis for ARPANSA to regulate land transport for radioactive material;</i>	Not accepted as power to regulate transport exists. CEO can authorise “dealing with” a source and “dealing” includes “possess or have control of”.
3.	<i>The legal basis for regulating existing exposure situations, remediation and clearance;</i>	Accepted. Draft ARPANSA Bill has provisions for licensing of remediation of legacy sites. (Note - Sub-regulation 38(6) provides CEO power to exempt dealing with ‘bulk material with a mass of more than 1,000 kg’)
4.	<i>Decommissioning plan and related financial provisions</i>	Not accepted. The legal basis for requiring decommissioning plans is already available (see Schedule 3, Part 1, Item 20 of ARPANS Regulations). Evidence of

APPENDIX 1

Dot point	The revised Act should include explicit provisions and requirements for:	Health response:
		financial capacity can be sought with the powers available in section 39 of the Act. Also ARPANSA's <i>REGULATORY GUIDE: Licensing of Radioactive Waste Storage and Disposal Facilities v2 (March 2013)</i> provides guidance on demonstration of financial capacity.
5.	<i>Assigning ARPANSA a clear role in regulating the security of controlled material, controlled apparatus and controlled facilities and promoting national uniformity;</i>	Not accepted. The Act as it is currently worded provides the CEO the power to regulate security even though the word "security" is not used in the Act. Legal advice from the AGS in 2008 had also stated that given the nature of the subject matter (nuclear and radiation facilities and sources) the power to regulate security is reasonably incidental to the power in the Act to regulate safety. Paragraph 15(1)(a) of the Act already makes it the CEO's duty to promote national uniformity.
6.	<i>Clarifying ARPANSA's role in the establishment and operation of the national framework for nuclear and radiological emergency preparedness and response.</i>	Not accepted. Section 15 already states the CEO has the duty "to provide advice on radiation protection, nuclear safety and related issues". This provides the statutory basis to coordinate the establishment and operation of a national framework for nuclear and radiological emergency preparedness and response.

Actions Identified and/or Completed (as of April 2015)

A comprehensive review of the six aspects was undertaken. One of the six was accepted and has been addressed. A draft bill to amend the ARPANS Act, incorporating dot point 3, has been prepared and submitted.

Note that ARPANSA agrees that prime responsibility resides with the licence holder. This is reflected in the 2015 regulatory delivery model.

The ARPANS Act was reviewed. Recommendation RF1 can be closed on the basis of this review, and confidence in the Government's legislative process. It is expected that the bill will be tabled in Parliament before the end of 2015.

Conclusion

As of April 2015, implementation of this recommendation is **COMPLETE**.

Closure of 2011 IRRS Recommendation RF2

Introduction

This recommendation was made in the 2011 report under Chapter 4, *Authorisation*.

2011 IRRS Recommendation RF2

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.

Initial ARPANSA Response

ARPANSA accepted the recommendation.

Implementation

In 2012 ARPANSA's Safety Analysis Section within Regulatory Services Branch developed guidance on how to determine when a change has significant implications for safety. This guide was reviewed by stakeholders before approval and publication in January 2013.

The guide establishes clear thresholds for when a change must be submitted under Regulation 51. Key principles of the guide are that the thresholds are based on; the potential consequences rather than overall risk; that the possibility of a change being improperly conceived or executed is considered, and; the consideration of cumulative minor changes are made. Thresholds are based on:

- Radiation doses to people above statutory dose limits or dose constraints
- Releases to the environment above discharge authorisation to that result in long term increased background radiation levels of above 20 µSv/year
- The impact on safety systems that form a primary means of ensuring nuclear safety and radiation protection
- •The impact on organisational controls and human performance
- The potential to introduce or affect the likelihood or consequence of a dangerous occurrence
- Impacts on Security

The guidance was developed and published – January 2013 – REG-RC-SUP-250A

Conclusion

As of April 2015, implementation of this recommendation is **COMPLETE**.

Evidence of Implementation – TRIM Reference and ARPANSA website link

[R12/07417 REGULATORY GUIDE: Regulation 51 – How to determine when a change has significant implications for safety](#)

Closure of 2011 IRRS Recommendation RF3

Introduction

This recommendation was made in the 2007 report under Section 4.1.5, *Authorisation - Radioactive waste Management*.

At the time of the 2007 Mission, the IRRS Team considered that there were no formal arrangements in place between ARPANSA and the organisation(s) that regulate Sydney Water in relation to regulation of radioactive liquid discharges as the discharges limits were established through Trade Waste agreements with Sydney Water. Therefore, the IRRS Team made a suggestion in this regard.

2007 IRRS Suggestion 10

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.

2011 IRRS Follow-up finding

The 2011 Follow-up Mission noted that no major progress has been made since 2007 in formalising the arrangement for liquid discharges. Therefore, the IRRS team concludes that Suggestion 10 is closed and replaced with a new recommendation, RF3.

2011 IRRS Recommendation 3 (RF 3)

ARPANSA should establish or amend requirements to ensure protection of public health and safety by setting limits for liquid discharge from licensed activities.

Implementation

ARPANSA revised the ANSTO Waste Operations Facility Licence and added the discharge limits for liquid discharges to the Licence F0260 as a licence condition.

Actions Identified and/or Completed (as of April 2015)

Licence condition 16 of Facility Licence F0260 stipulates ANSTO to comply with the discharge limits for liquid waste. A revised licence, F0260, was issued to ANSTO on 1 March 2013.

Conclusion

As of April 2015, implementation of this recommendation is **COMPLETE**.

Evidence of Implementation - TRIM Reference

[F0260 Waste Operations Facility Licence](#)

Closure of 2011 IRRS Recommendation RF4

Introduction

This new recommendation was made in the 2011 report under Chapter 7, *Emergency Preparedness* in light of the post-Fukushima environment. The recommendation is about improving ARPANSA's internal coordination and governance arrangements for emergency preparedness and response (EPR).

2011 IRRS Recommendation RF4

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.

Initial ARPANSA Response

ARPANSA accepted the recommendation.

Implementation

In 2014 ARPANSA created the EPR Strategy Committee in order to strengthen the internal coordination and governance arrangements for EPR. This committee focusses on harmonising preparedness and response functions and promotes effective and timely responses.

The committee meets on a monthly basis and is represented by the Security and Community Safety Section, the Emergency Preparedness and Response Section and the Office of the CEO. Reporting of key decisions and actions are then promulgated to the Executive Group for endorsement and commitment to action.

This committee has already made a number of significant changes to the way in which EPR is coordinated across ARPANSA and across the Australian Government more broadly.

Moreover, ARPANSA also now regularly attends the Australian Government Exercise Coordination Group (administered by the Australian Government Crisis Coordination Centre – the Australian National Coordinating Authority) in order to coordinate national exercises and plans relating to nuclear and radiation incidents and events.

These initiatives address and close the basis of the recommendation.

Actions Identified and/or Completed (as of April 2015)

- Creation of the EPR Strategy Committee
- Attendance on the Australian Government Exercise Coordination Group

Conclusion

As of April 2015, implementation of this recommendation is **COMPLETE**.

Closure of 2011 IRRS Recommendation RF5

Introduction

This new recommendation was made in the 2011 report under Chapter 7, *Emergency Preparedness*, in light of the post-Fukushima environment. The recommendation is about improving the clarity of ARPANSA’s role for nuclear and radiation emergency preparedness and response.

2011 IRRS Recommendation RF5

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.

Initial ARPANSA Response

ARPANSA accepted the recommendation.

Implementation

In 2014, through the participation within the Australian Government Exercise Coordination Group (chaired by the National Coordinating Authority), ARPANSA’s roles and responsibilities have been updated and clearly defined in a number of national plans and arrangements. These include, but are not limited to:

Plan	Initiating Events	Comments
Commonwealth Disaster Plan	Safety and Natural Disasters	The Commonwealth Disaster Plan assigns ARPANSA with supporting roles to any jurisdiction that requests assistance. Assistance is normally requested when a jurisdiction’s capacity or capability is deemed inadequate to deal with the event.
National Counter-Terrorism Plan	Security Incidents or Events	The National Counter Terrorism Plan assigns ARPANSA with supporting roles to any jurisdiction. Any activation of the NCTP automatically assigns Federal Government responsibility, and ARPANSA is defined as a leading technical support organization for nuclear and radiological events.

ARPANSA also believes that the CEO of ARPANSA has adequate legal authority to *‘protect the people and the environment from the harmful effects of radiation’* during nuclear and radiological incidents and events.

Actions Identified and/or Completed (as of April 2015)

- Updating of roles and responsibilities in the Commonwealth Disaster Plan
- Updating of roles and responsibilities in the National Counter Terrorism Plan

Conclusion

As of April 2015, implementation of this recommendation is **COMPLETE**.

Closure of 2011 IRRS Suggestion SF1

Introduction

This suggestion was made in the 2011 report under Chapter 1, *Legislation and Governmental Responsibilities*. This suggestion is about the uniform training of inspectors and assessors.

2011 IRRS Suggestion

ARPANSA should initiate discussions with States and Territories regulators on the possibility of organising joint training and development for inspectors and licence assessors with the aim of sharing resources and achieving national uniformity.

Initial ARPANSA Response

For possible consideration by the Radiation Health Committee (RHC) which has representatives from each jurisdiction

Implementation

In discussions with the States and Territories, it was agreed that it is not the role of regulators to provide training, and particularly training for the purposes of 'accreditation' of their own staff to undertake inspections. Rather the training is seen as the responsibility of qualified training academies and institutions, or a registered training organisation under the *National Vocational Education and Training Regulator Act 2011*, administered by the Australian Skills Quality Authority (ASQA).

To this end a 2015 survey of jurisdictions was undertaken, and showed that typically a State Radiation Inspector is required to obtain a Certificate IV relating to inspections (such as for Victoria wherein the 2014 Annual Report states: "*All full-time officers have now completed the Certificate IV in Government (Investigations) PSP41504. The part-time authorised officers will undertake this training next financial year, after which all authorised officers in the radiation team will have completed the course.*")

For ARPANSA all inspectors are required to successfully complete the Certificate IV in Government (Statutory Compliance) - PSP41404 before undertaking inspections of ARPANSA licensees.

Additionally all jurisdictions (except the Commonwealth) make use of 'Accredited Compliance Testers', who assess specified radiation emitting devices or premises housing radioactive material on behalf of that Jurisdiction, thereby allowing the issue a 'Compliance Certificate' that allows the source to be registered and used.

The total number of accredited/licenced/registered Compliance Testers Australia-wide is 691 as at Dec 2014, although some compliance testers have authorisations in multiple Jurisdictions, and the scope of the authorisations vary within each jurisdiction, and between jurisdictions.

APPENDIX 1

Actions Identified and/or Completed (as of April 2015)

As Jurisdictions progress the requirement for their inspectors to have a relevant Certificate IV qualification, and as they continue to implement the Mutual Recognition of Accredited 'Compliance Testers' from other Jurisdictions, national uniformity in these areas will continue to be strengthened.

Conclusion

As of April 2015, implementation of this suggestion is **COMPLETE**.

Evidence of Implementation - TRIM Reference

[R15/04832 Table of authorisations, accreditations and required inspector training, and in support of the statements made above.](#)

Closure of 2011 IRRS Suggestion SF2

Introduction

This recommendation was made in the 2011 report, section *11.1.3 Inspection and Enforcement of Medical Radiation Facilities*.

2011 IRRS Recommendation SF2

ARPANSA should revise the risk matrix used to assign inspection priorities to allow consideration of patient protection as an input into the risk evaluation.

Initial ARPANSA Response

ARPANSA accepted the recommendation.

Implementation

The guidance was initially developed in 2008. Based on the IRRS SF2 recommendation arising from the Follow-up Report ([R12/02944](#)), the [Risk Ranking Methodology REG-COM-SUP-270F](#) (R13/00020) was revised to include consideration for patient protection in January 2013. Since that time, the guidance has been revised again in June 2013.

This current revision includes a section that gives guidance on considering patient exposure in the hazard category determination process.

Actions Completed (as of April 2015)

Revised draft produced later in 2012 and approved by ARPANSA management in January 2013

Conclusion

As of April 2015, implementation of this recommendation is **COMPLETE**.

Evidence of implementation – TRIM reference

[R13/00020 Risk Ranking Methodology v3 June 2013](#)

Closure of 2011 IRRS Suggestion SF3

Introduction

This recommendation was made in the 2011 report under section 11.1.3, *Inspection an Enforcement of Medical Radiation Facilities*.

2011 IRRS Recommendation SF2

ARPANSA should better utilise 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.

Initial ARPANSA Response

ARPANSA accepted the recommendation.

Implementation

Section 1.2 of the ARPANSA inspection procedure was revised in June 2012 (version 6) to include members from the ARPANSA Medical Radiation Services Branch in medical inspections where possible. A member of Medical Radiation Services Branch participated in a medical inspection at Defence Enoggera Barracks in March 2012. ARPANSA has very few medical radiation licence holders and so medical inspections are infrequent.

Actions Completed (as of April 2015)

Revised inspection procedure produced in June 2012 (version 6) to include involvement of ARPANSA Medical Radiation Services.

Conclusion

As of April 2015, implementation of this recommendation is **COMPLETE**.

Evidence of implementation – TRIM reference

[R12/01673 Inspection notification letter for Defence Enoggera Barracks involving Anthony Wallace of Medical Radiation Services Branch](#)

[R11/01760 Inspection Procedure v8, Jan 2015 \(see change register\)](#)