



## ARPANSA's IRRS MISSION ACTION PLAN

### RECOMMENDATIONS & SUGGESTIONS FROM 2007 IRRS MISSION (To be completed by June 30 2012)

#### **IRRS R1 - Closed on basis of progress and confidence**

*ARPANSA should establish and implement a more comprehensive training programme for regulatory staff.*

PLAN: The ARPANSA inspector training program is reviewed biennially as part of the cycle of continuous improvement within the QMS; individual training needs are assessed annually and implemented via the ARPANSA Performance Development System (APDS).

PROGRESS: Investigations training programs run. Ongoing training programs planned.

#### **IRRS R2 - Closed & replaced by RF1 in 2011**

*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 should apply to all facilities and activities regulated by ARPANSA.*

PLAN: A regulatory guide will be produced by June 2012.

PROGRESS: Discussion paper and draft produced.

#### **IRRS R3 - Open**

*ARPANSA should prepare regulatory guidance in relation to its expectation for the Periodic Safety Review (PSR) imposed by condition on the facility authorizing the operation of the OPAL reactor.*

PLAN: A generic Research Reactor PSR Guide will be produced when the current PSR of OPAL is completed. This will allow lessons learned from the OPAL experience to be incorporated.

PROGRESS: Draft (based on IAEA Power Reactor) PSR being trialled during OPAL PSR process.

#### **IRRS R4 - Closed**

#### **IRRS R5 - Closed on basis of progress and confidence**

*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.*

PLAN: The Possess or Control Licence template will be revised to reflect the extent of dismantling operations which can be undertaken and a regulatory guide will be produced.

PROGRESS: To be completed by June 30 2012.

#### **IRRS R6 - Closed on basis of progress and confidence**

*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.*

PLAN: ARPANSA will produce a regulatory guide on decommissioning. It is not possible to put an expiry date on the HIFAR licence until a waste storage facility becomes available.

PROGRESS: Draft guide produced.

#### **IRRS R7 - Closed**

#### **IRRS R8 - Closed**

#### **IRRS R9 - (i) Open (ii) Closed on basis of progress and confidence**

*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.*

PLAN: An emergency preparedness plan EPP will be produced.

PROGRESS: Draft of tier 1 and tier 2 documentation completed.

### **IRRS R11 - Open**

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

PLAN: Produce a regulatory guide; integrate safety culture into assessment and inspection procedures.

PROGRESS: First draft of Holistic Safety Guide produced and currently undergoing stakeholder review.

### **IRRS R12 – Open**

*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).*

PLAN: Safety Guide under development by RHC will assist persons in meeting their responsibilities under the [Code of Practice for the Safe Transport of Radioactive Material](#) (the Transport Code) in relation to seeking approval from the competent authority for low dispersible radioactive material, special form radioactive material, the design of packages, and the validation of packages. The Safety Guide will complement the Transport Code, and the Guide provides advice and guidance on how to go about obtaining relevant approvals prescribed in the Transport Code. Operations Services maintains a Radioactive Materials Transport Register. A regulatory guide on transport of radioactive material and approval of transport packages is under preparation.

PROGRESS: Public comment period for Safety Guide ended in March. Transport approval checklists and Validation Certificate template have been produced.

### **IRRS S1 - Closed**

### **IRRS S2 - Closed**

### **IRRS S3 – Closed**

FURTHER ACTION: Senior officers from Queensland Health have been appointed as inspectors under s62(1)(b) of the Act; they are scheduled to conduct an inspection of ARPANSA Medical Radiation Services in May.

## **IRRS S4 – Closed**

### **IRRS S5 - Closed on basis of progress and confidence**

*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.*

PLAN: Officers from Medical Radiation Services and Radiation Health Services participate in Radiation Health Committee working groups on the development of codes of practice and safety guides. Standard operating procedures will be strengthened to foster stronger working relationships by requiring collaboration on relevant licence assessments and inspections with appropriate sections/branches.

PROGRESS: Standard operating procedures have been revised. Staff from Medical Radiation Branch are participating in a recent inspection of medical sources. Radioactive Waste Safety staff are participating in inspections of waste facilities. Staff from Medical Radiation Branch are participating in RPS14 review.

### **IRRS S6 - Closed on basis of progress and confidence**

*ARPANSA should consider its strategy for effective implementation of the “Workforce Planning and Development” document derived from its Corporate Plan 2005-2008.*

PLAN: A position of Human Capital Manager will be established and duties of the role will include workforce planning and development and its associated strategy and processes.

PROGRESS: A Human Capital manager has recently been appointed and the work required is underway. Focus on Executive Level staff development through ARPANSA projects. Operations Services Section Manager Leadership and Team Development program commenced.

### **IRRS S7 - Open**

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

PLAN: Development regulatory guidance by June 2012

PROGRESS: A new Compliance and Enforcement Policy and regulatory guide on ARPANSA’s graded approach to non-compliance have been produced.

### **IRRS S8 - Closed**

### **IRRS S9 - Closed**

### **IRRS S10 – Closed & replaced by RF2 in 2011**

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

PLAN: Limits on liquid discharges (WHO drinking water guideline) as per current trade waste agreements will be incorporated into licence conditions. Licence templates will be revised accordingly. Relevant licences will be reissued with additional conditions.

PROGRESS: A review of ANSTO's nuclear installation licences is underway and will result in them being reissued in a revised format with a licence condition setting the limits for liquid discharges. In conjunction with this, the licence template for nuclear installations is being revised.

### **IRRS S11 - Closed**

### **IRRS S12 - Closed**

### **IRRS S13 – Open**

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

PLAN: Review of the inspection program is undertaken on a 2-yearly basis in conjunction with review of the Inspection Policy and Procedure as required by the branch quality management system. Process for reviewing lessons learned to be included in operating procedure.

PROGRESS: Feedback from inspections is now a regular item for Compliance & Enforcement section meetings. The inspection procedure is currently being revised.

## **IRRS S14 - Closed**

### **IRRS S15 - Closed on basis of progress and confidence**

*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.*

As for IRRS S13 above

### **IRRS S16 - Closed on basis of progress and confidence**

*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.*

PLAN: Compliance and Enforcement Policy and guidance will be produced.

PROGRESS: Compliance and Enforcement Policy and Regulatory Guide: Graded Approach to Non-Compliance drafted and pending final approval. Further guidance on severity of non-compliance has been drafted; currently waiting on legal advice.

### **IRRS S17 - Closed on basis of progress and confidence**

*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.*

PLAN: Revise the Decommissioning Guide.

PROGRESS: Draft of guide circulated internally for comment.

### **IRRS S18 - Closed on basis of progress and confidence**

*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.*

PLAN: ARPANSA produces regulatory guides which are posted on its website. These guides are developed where considered necessary, and also as a result of requests by licence holders. When new guidance becomes available, licence holders are informed by email via the ARPANSA licence administration distribution list, and also via the Regulatory Notice Board on the ARPANSA website. The vast majority of regulatory guidance documents are developed under the oversight of the Operations Services Quality Management Committee. When the guidance has a potential to have a major impact on licence holders, drafts are circulated to licence holders for comment and feedback. In addition, where new regulatory guidance is prepared for licensing of significant installations, international peer review may be undertaken. The regulatory guides which are produced by Operations Services are reviewed at least every two years as a requirement of the Quality Management System.

#### **IRRS S19 - Closed**

#### **IRRS S20 - Closed**

#### **IRRS S21 - Closed**

#### **IRRS S22 - Closed**

#### **IRRS S23 - Closed**

#### **IRRS S24 - Open**

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

PLAN: Clearance levels will be added to the Decommissioning Guide.

PROGRESS: Draft of clearance levels produced.

#### **IRRS S25 - Closed on basis of progress and confidence**

*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, competencies 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.*

PLAN: The Office of the CEO is developing and progressively implementing systems and processes for Agency Planning & Integration, Government & International Liaison, Project Coordination & Support, Communication & Education Support and Quality Management. Regular Executive Group retreats are conducted to address strategic and operational issues. The strategic planning framework will be revised by the end of June 2012 the other systems and processes will be progressively implemented over a period of time as required in each case.

PROGRESS: Strategic Directions and Corporate Plan documents completed. Branch planning and budget development underway.

### **IRRS S26 - Closed**

#### **IRRS S27 - Closed on basis of progress and confidence**

*ARPANSA management has demonstrated its commitment to the establishment, implementation, assessment and continual improvement of the Management System (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.*

PLAN: The outworking of the ARPANSA reform which addresses the necessary activities will continue with the provision of resourcing required. The Office of the CEO will also engage a consultant to conduct a scoping exercise and advise on review and updating the corporate quality manual, identifying other services for inclusion, with the long term objective of achieving ISO 9001 certification.

PROGRESS: The resource to improve the MS as described above has been put in place. Activities include conducting and implementing the reform, the resulting establishment and filling of new positions and recruitment of staff as required. Strategic Management Committee briefed on implementing ISO 9001 certification.

### **IRRS S28 - Open**

*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.*

PLAN: Review the real cost of regulatory activities by function and by licence holder and prepare proposals for fee structure that better aligns financial burden.

PROGRESS: Current fees adjusted so that cost recovery through licence fees now meets approximately 90% of costs. Full survey of regulatory staff completed. Full costs associated with regulatory activities documented. Preliminary discussion and comment sought from 2 major licence holders. Draft fee proposal(s) being prepared for licence holder comment.

### **IRRS S29 - Closed on basis of progress and confidence**

*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.*

PLAN: Current system of approvals will be reviewed. ARPANSA is developing a MOU with all relevant competent authorities. A national system to manage and authorise the transport of Security Enhanced Sources across Australia's borders is being developed. A Transfer Protocol is expected to be endorsed by the Radiation Regulators Forum by June.

PROGRESS: Review of current system underway. An MOU is currently being drafted by Legal Services. Transfer Protocol almost complete.

### **IRRS S30 - Closed on basis of progress and confidence**

*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.*

PLAN: The Communications Officer in the Office of the CEO will develop a communications strategy and policy for the agency by June 2012.

PROGRESS: A revision of ARPANSA's draft Communications Strategy and the communications component of the Emergency Preparedness Plan are underway and draft media and social media policies have been prepared.

## RECOMMENDATIONS & SUGGESTIONS FROM 2011 IRRS FOLLOW-UP MISSION

### IRRS RF1

*In the review 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 environmental chronic exposure situations and remediation; decommissioning plan and related financial provisions , assigning ARPANSA a clear role in regulating security of radioactive sources; giving ARPANSA a clear role and mandate in the establishment and operation of the national framework for nuclear and radiological emergency preparedness and response.*

PLAN: Where possible, amendments to the ARPANS Act to achieve IRRS RF1 will be made in line with the current review of the ARPANS Act that is being undertaken by DOHA.

PROGRESS: A submission was made by CEO of ARPANSA on 11 April 2012 to the consultant (Communio Group) with proposals for the amendment of the Act.

### IRRS RF2

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

Refer to IRRS S10 above

### IRRS RF3

*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.*

PLAN: ARPANSA has liaised with Emergency Management Australia (EMA) in the development of the ARPANSA Incident Management Plan (IMP). EMA has provided planning advice and guidance documents to assist in the preparation of nationally harmonised response plans and has agreed to review ARPANSA's IMP which will ensure that any response is timely and effective.

#### **IRRS RF4**

*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.*

PLAN: ARPANSA has provided submissions to the Review of the ARPANS Act to ensure that our emergency preparedness and response functions are captured through appropriate legislation.

#### **IRRS RF5**

*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.*

PLAN: Incorporate guidance into existing regulatory guides for licence applicants where proposed dealing involves patient exposure.

#### **IRRS RF6**

*ARPANSA should ensure that the technical expertise in the Medical Radiation Service Branch is more formally involved in the assessment and review of licence applications involving medical exposure.*

PLAN: Integrate this requirement into existing operating procedure.

PROGRESS: Licence assessment procedure revised to require collaboration with MRSB on assessment of applications for medical sources or facilities.

#### **IRRS SF1**

*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.*

PLAN: Implement through the Radiation Health Committee (RHC) which has representatives from each jurisdiction.

PROGRESS: RHC agreed that the topic for the next Best Practice Regulation workshop should be developing a framework for cross-training of inspectors and peer reviews.

#### **IRRS 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.*

PLAN: Revise risk ranking matrix to include consideration of patient exposure where the dealing involves the use of medical apparatus.

### **IRRS SF3**

*ARPANSA should better utilise the expertise available in the Medical Radiation Branch to make inspections of medical radiation facilities more effective with respect to medical exposure and patient protection.*

PLAN: Integrate this requirement into existing operating procedures.

PROGRESS: Inspection procedure revised to require collaboration with MRSB on inspections of medical sources or facilities.

### **IRRS SF4**

*ARPANSA should initiate the review and revision of RPS14 to ensure that it is aligned with, and consistent with, the requirements of the new BSS, GSR Part 3.*

PLAN: Implement through the RHC program of development and review of RPS publications. ARPANSA will undertake a gap analysis of RPS 14 vs the BSS and prepare a proposal to the RHC for revision of RPS 14.

### **IRRS SF5**

*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.*

PLAN: The ACDS is presently funded as a trial to ascertain whether it optimally fulfils the role as an independent external auditor for Australian radiation oncology providers. The trial will be reviewed in 2013 and decisions made to extend, modify or end the trial. The review will be preceded by a trial evaluation to assure the scope is correct and ARPANSA has begun a process of internal discussions to prepare for the pilot evaluation.

### **IRRS SF6**

*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 RPS14.*

PLAN: ARPANSA is represented on the Diagnostic Imaging Accreditation Scheme and seeking to incorporate the determination of local DRLs in this scheme as well as through regulatory conditions on licences as another driver to increase the effectiveness of the implementation of RPS14. Other measures to improve quality in health care are being pursued through other parts of the Medical Benefits Division of DOHA and the TGA.

### **IRRS SF7**

*ARPANSA should continue to develop its relationship with a wide set of professional bodies and other organisations as possible to promote awareness about the need to comply with the CoPs to ensure internationally accepted patient protection.*

PLAN: The ACDS has a strong on-going interaction with the three professional colleges within Australia, the Royal Australian and New Zealand College of Radiologists, the Australian College of Physical Scientists and Engineers in Medicine and the Australian Institute of Radiology. The ACDS has presented at all the annual college meetings for these bodies in addition to numerous less formal presentations at State branches, and while visiting therapy centres for audits. The Diagnostic Imaging and Nuclear Medicine section of ARPANSA also has had strong on-going interaction with the professional colleges on the implementation of DRLs and other aspects of RPS14. Additionally, ARPANSA is arranging a more formal arrangement for regular meetings with each of colleges as part of its agency-wide stakeholder engagement plan.

### **IRRS SF8**

*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.*

PLAN: ARPANSA is currently evaluating options for a comprehensive strategy for the implementation of the training of medical users of radiation in radiation protection using the ICRP113 document. Additional resources for educational aspects of radiation protection in medicine are identified as a priority in ARPANSA's new Strategic directions 2012-2016 document. Resourcing will be discussed in upcoming budget discussions. Canadian and UK referral guidelines have been developed and are in use which could be used as a model for the Australian context.

### **IRRS SF9**

*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.*

PLAN: ARPANSA submitted proposed CT DRLs to RANZCR in early 2012 and RANZCR has agreed to the national adoption of these DRLs which will be published in 2012. Work has begun on establishing working arrangements with Interventionalists and Breastscreen Australia to establish DRLs in those areas.