

**Australian Government****Australian Radiation Protection and Nuclear Safety Agency**

Our ref: S2005/00376

24 October 2005

Ms K Ellis
Research Officer
Joint Committee of Public Accounts and Audit
Department of the House of Representatives
Parliament House
CANBERRA ACT 2600

Dear Ms Ellis

Australian National Audit Office Report No 30 of 2004/05

I refer to your letter dated 6 October 2005 providing further questions from the Committee. Responses to the Committee's further questions are provided below in the order in which the questions were asked.

- 1) As requested by the Chair during the hearing, please provide an update on the compliance with the ANAO recommendations and, where you have not finished complying with those recommendations, the anticipated date of compliance.**

I have attached an implementation schedule to this letter setting out the proposed timeframe in relation to the ANAO recommendations. My intention is that all recommendations will be addressed by March 2006.

- 2) Can you explain why the agency's risk profile did not include the regulatory risks of the consequence of ARPANSA not adequately addressing unlicensed activity or non-compliance by licence holders? Are not these the key risks that ARPANSA as an agency seeks to limit and control?**

Whilst I generally accept the critique made by the ANAO of ARPANSA's risk profile, I do point out that the risk of 'Licensed Bodies Performance' was identified in the ARPANSA risk profile dated December 2003. The key controls and management strategies to address this risk were seen as:

- Fully documented and robust licensing processes
- Inspection program and processes
- Compliance audit and enforcement powers.

The risks associated with unlicensed activity were considered in the ARPANSA critical success factors during the risk identification process. These risks were assessed to be low by regulatory officers.

Prior to the enactment of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act) and the *Australian Radiation Protection and Nuclear Safety Regulations 1999*, all Commonwealth agencies were canvassed as to whether they undertook activities that needed to be licensed under the Act. In 1999, all agencies were sent information about the legislative requirements and the agencies' responsibilities under the legislation so as to determine which agencies had controlled apparatus, material or facilities. All agencies which responded advising that they controlled items which were required to be licensed under the Act have been licensed, with various conditions attached to those licences depending on individual circumstances.

Nevertheless, ARPANSA is presently developing a strategy to further address the possibility of unlicensed activities by Commonwealth entities. A letter will be forwarded to all Commonwealth agencies providing information in relation to the requirement that Commonwealth entities must have certain radiation sources licensed under the Act, and seeking information on whether such sources are under the control of those agencies. ARPANSA will also undertake audits in relation to Commonwealth entities to verify that the returns from those agencies are accurate.

3) Can you explain why the Regulatory Branch does not keep a register of client complaints, as required by its Chief Executive Instructions? Were you aware of this requirement prior to the ANAO audit?

The Regulatory Branch took the view that keeping information about complaints and their resolution on licence holder and subject files met the intent of the Chief Executive Instructions (CEI). The Regulatory Branch now maintains a complaints register. Summary information from this register, and information in relation to the resolution of the complaints, will be reported in future Annual Reports.

4) Can you explain how you see the potential for conflict of interest created by the ARPANS Act, and whether you feel it is adequately accounted for under existing requirements?

As I state in my Chief Executive Instructions, in addition to any conflict of interest that may arise as in any other organisation because of personal interests, conflict of interest may arise in ARPANSA:

Where performance by the CEO of his advisory, research or services function may conflict or appear to conflict with the function of determining licences for Commonwealth entities under the Act. If not properly handled, this may result in the advice, research or other services being perceived by the recipient as being binding on the CEO in making a licensing decision. It is obviously also important that in performing the regulatory functions, ARPANSA staff involved in the regulatory process not also provide advice on how an entity should meet regulatory requirements.

Subsection 15(2) of the Act requires the CEO to take all reasonable steps to manage conflict of interest between the regulatory function and the CEO's other functions. For this purpose I issued a Chief Executive Instruction to address and minimize any conflict of interest. The Instruction provides guidance to staff on how to manage conflict of interest and on what constitutes a conflict of interest.

In fact, the issue of conflict of interest has not proved as problematic as first thought that it might. The existence of established guidance through the Radiation Protection Series and other national publications and a number of private sector bodies able to supply radiation protection advice and services has meant that ARPANSA advice has not needed to be sought on matters affecting regulated entities to the extent initially expected.

Having said that, the issue remains. I am generally satisfied that the approach set out in the CEI is adequate. However, the CEI is being reviewed and will be up dated to take into account the ANAO comments. Once the Instruction has been up dated, ARPANSA staff members will be notified of the requirement for all staff to comply fully with this Instruction. An in-house training session may well be appropriate to reinforce the importance of complying with the Instruction.

ARPANSA is required by law to be licensed to deal with controlled material and controlled apparatus, just as any other controlled person is required to be licensed under the Act; there is no exemption for ARPANSA from the requirement for a licence. The recommendation to issue a licence to the Yallambie campus science branches was made to me by the Regulatory Branch in the same manner as the Regulatory Branch assessed other applications for a licence. The licences are administered by Yallambie campus Branch Directors who are my 'nominees' in the Branches which hold the controlled material and apparatus. Compliance with the licence is monitored by the Regulatory Branch in the same way as for other licence holders.

In order to increase the transparency of ARPANSA's self licensing processes, ARPANSA is currently negotiating with a State radiation regulator to be involved in undertaking compliance inspections of ARPANSA facilities and contributing to inspection reports which would form part of the submissions to me in relation to those sources and facilities. Although the Act requires that I decide whether to grant a licence for radiation activities undertaken by ARPANSA, and it requires me to consider whether to specify licence conditions, or to consider whether the licence conditions have been breached, the participation of an independent radiation regulator in the recommendations to me will reduce any perception of conflict of interest.

5) As CEO responsible for licensing decisions, do you feel the information contained in applications and staff advice has been sufficient to assess the application against the statutory matters?

Yes. The statutory matters are matters 'to be taken into account' in my licensing decisions. I have written at length about my interpretation of taking into account the various matters in my statement of reasons for my decision to issue a construction licence to the Replacement Research Reactor. The taking into account of the statutory matters flows from assessment of the information identified in Schedule 3, Parts 1 and 2 of the Regulations in the light of the internationally accepted framework of radiation protection and nuclear safety.

6) Do application guides and packs now ask applicants to explicitly address the statutory matters against which they are to be assessed, and are staff reviewing applications required to pose their advice in terms of these statutory matters?

No. The application packs and guides focus on the plans and arrangements that are called for in Schedule 3 of the Regulations. These are the plans and arrangements that the licence holder will be required to comply with through the licence condition imposed by Regulation 49. The information sought in the application pack, however, is sufficient for ARPANSA assessors to fully consider the statutory requirements. Nevertheless, the application packs are currently being reviewed and enhanced in response to Recommendation 7 of the ANAO.

7) According to the ANAO, ARPANSA does not have a strategy for identifying prohibited activity by non-licensed entities. Has the risk of unlicensed activity been addressed by ARPANSA at any stage since 1999? In your opinion, has public health and safety been compromised at any time by lack of attention to unlicensed activity?

See the answer to question 2 above.

Taking into account the outcomes from the activities in 1998 and 1999, and knowing the range of responsibilities undertaken by Commonwealth entities that may involve application of radiation, I judge that public health and safety is unlikely to have been compromised.

Radioactive sources, prescribed radiation facilities and nuclear facilities are used almost exclusively by Commonwealth scientific and technical organisations which are already licensed. Any unlicensed activities are likely to be for use of low hazard apparatus such as mail or baggage X-ray machines for security purposes, or non-ionizing apparatus such as ultraviolet lamps. Such apparatus are generally of negligible risk to the public.

That is not to say that there may be Commonwealth entities with unlicensed sources. ARPANSA is currently preparing a letter to all Commonwealth agency Secretaries or Chief Executive Officers, providing information on the types of sources and facilities which are required to be licensed under the Act, and seeking advice on whether their respective agency possesses or operates such sources or facilities.

8) How has the under-reporting by licensed entities occurred without drawing attention? How has this been addressed?

A small amount of under-reporting previously occurred in relation to annual reviews of plans and arrangements by licence holders with small, low hazard inventories. Reporting by licence holders of more hazardous facilities has, in general, been good.

To address under-reporting and encourage uniform reporting standards, ARPANSA has developed a comprehensive electronic reporting *proforma* and accompanying guidance document for prescribed facilities and source licence holders. This includes 'nil' returns which are still reported quarterly. Reminders about compliance reporting obligations are sent to licence holders quarterly.

The Regulatory Management Information System, currently being developed by ARPANSA will include a facility to generate a report of licence holders who have not provided a quarterly or annual report. This report will be run quarterly, and all licence holders who have not provided a

report, as a condition of their licence, will be followed up.

- 9) An internal review found in 2003 that ARPANSA's licensee handbook needed improvement and did not sufficiently relate to the licensee's responsibilities under the ARPANS Act. Why had this not been acted on when the ANAO were undertaking their audit fieldwork? What is the status of the handbook now and have revisions been made?**

The aim of the Licence Conditions Handbooks were to assist licence holders by bringing together in one place the licence conditions imposed by the Act, the Regulations and the CEO at the time of issuing the licence; providing a single reference point in relation to licence holder obligations, rights and responsibilities; and ensuring consistency in licence conditions between licence holders.

The licence condition handbook, however, was never intended to be a substitute for the licence holder's obligation to understand the legislative framework and the licence holder's obligations under the legislation.

ARPANSA reviewed the effectiveness of the Handbook and concluded that it is generally effective but identified several disadvantages where improved outcomes could be achieved. No serious deficiencies were identified in the Handbook other than annual reporting of licence holder reviews of plans and arrangements required by regulation. This is included in ARPANSA guidance for licence holder reporting.

ARPANSA now issues new and revised licences by explicitly including Standard Licence Conditions in a schedule which forms part of the licence rather than by reference to the Handbook. The Licence Handbook is currently being revised with the intention of the Handbook being a general reference to legislative requirements and ARPANSA licensing processes. Licence conditions will be specified in a schedule annexed to each licence issued or revised.

- 10) The ANAO audit found that inspection schedules were determined separately by staff and were not subject to a risk-based program. Please advise the Committee how decisions are made about inspection schedules; at what level they are made; and, whether you are satisfied that inspection efforts represent the best use of resources in terms of ensuring general compliance and public health and safety.**

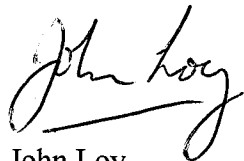
Schedules for inspection of licence holders are based on the ranking, by ARPANSA officers, of the risk to people and the environment associated with the radioactive material, apparatus or facility covered by the licence. The risk "consequence" is determined from the hazard level of the source or facility and is assessed during the review of a licence application by ARPANSA staff. The risk "likelihood" is determined by ARPANSA from the level of control exercised by the licence holder over the licensed activity, commensurate with the hazard level. The assessment of likelihood is based on the licence holder's plans and arrangements for achieving safety, and modified by the licence holder's compliance record assessed from compliance reporting, ARPANSA inspections and incidents and accident records.

The inspection schedules are developed by the regulatory officers, reviewed by Section Managers and approved by the Director of the Regulatory Branch.

In the context of the regulatory review process flowing from the ANAO report, ARPANSA is seeking a more systematic and overall process of regulatory risk management. This risk assessment activity will rely heavily on the Regulatory Management Information System, currently being developed. The risk assessments will also be reviewed and adjusted if necessary, following the receipt of quarterly and annual reports, and will also take into consideration information provided through inspections and the investigation of any accidents or other identified licence condition breaches.

I am happy to provide any further information if required by the Committee.

Yours sincerely

A handwritten signature in cursive script that reads "John Loy". The signature is written in black ink and is positioned above the printed name and title.

John Loy
CEO of ARPANSA

**Action taken/to be taken by ARPANSA
in response to the ANAO recommendations as at 24.10.2005**

Recommendation No.1	<p>The ANAO recommends that ARPANSA's Corporate and Branch plans address key priorities and strategies for delivering regulatory outcomes. This would include clearer articulation of objectives and prioritisation of those objectives.</p>	<p>ARPANSA has prepared a strategic regulatory framework that sets out the fundamental ways that ARPANSA seeks to achieve regulatory outcomes for inclusion in the newly prepared corporate plan. The paper has been considered by the RRCC and has been circulated to all licence holders for comment. This policy paper has been incorporated into the ARPANSA 2005/08 Corporate Plan.</p> <p>A more strategic Regulatory Branch Business Plan has been prepared; it will be completed by mid November after holding a one day externally facilitated workshop involving all Regulatory Branch staff.</p>
Recommendation No.2	<p>The ANAO recommends that ARPANSA develop key performance indicators and targets for the regulatory function that inform stakeholders of the extent of compliance by controlled persons, and of ARPANSA's administrative performance.</p>	<p>The revised Regulatory Branch Business Plan has had KPIs added which will be monitored and reported in future Annual Reports so as to provide information about licence holder and ARPANSA performance.</p> <p>KPIs attributed to licence holder performance will be consulted with all licence holders before being finalised.</p>
Recommendation No.3	<p>The ANAO recommends that ARPANSA enhance its risk management framework to identify risks to achievement of regulatory outcomes, mitigation strategies to manage those risks, residual risks, and a process of systematic monitoring of residual risks and their treatment.</p>	<p>ARPANSA is revising its risk management framework and has identified the risks to achievement of regulatory outcomes. The revised framework will be completed by December 2005. It will include a Risk Management Communication Strategy by which info on risk management policy; risk application, techniques and evaluation; review mechanisms; and current risk issues are communicated to external and internal stakeholders.</p>
Recommendation No.4	<p>The ANAO recommends that ARPANSA strengthen management of the potential for, or perceptions of, conflict of interest, in accordance with legislative responsibilities, by:</p> <ul style="list-style-type: none">• ensuring adequate documentation of all perceived or potential conflicts of interest;• taking action to better manage the conflict of interest arising	<p>ARPANSA is reviewing and preparing to 'relaunch' its policy and procedures for managing conflict of interest.</p> <p>With regard to regulation of its own use of sources and facilities, to increase transparency, ARPANSA will be seeking the assistance of the Victorian State regulator to take part in inspections and assessments of ARPANSA's own radiation activities.</p>

	<p>from its regulatory role in respect of its own sources and facilities; and</p> <ul style="list-style-type: none"> • implementing and ensuring compliance with instructions issued. 	
Recommendation No.5	<p>The ANAO recommends that ARPANSA:</p> <ul style="list-style-type: none"> • review and assess performance against customer service standards in its customer service charter; and • systematically action and report on all complaints received. 	<p>ARPANSA is working to ensure a consistent approach to the handling of complaints across the regulatory and service functions of ARPANSA within the ARPANSA Quality Management System.</p> <p>The Customer Service Charter will be reviewed and forwarded to all licence holders annually, together with a feedback form. The first feedback survey will be undertaken in March 2006, so as to allow the results to be included in the 2006 Annual Report.</p> <p>Complaints handling performance, as with other Customer Service Charter requirements, will be reported in future Annual Reports.</p>
Recommendation No.6	<p>The ANAO recommends that, in order to provide assurance that cost recovery is consistent with better practice and government policy, ARPANSA:</p> <ul style="list-style-type: none"> • develop a policy framework to guide its cost recovery arrangements; and • have sufficiently reliable data, and analysis, on cost elements to support management decisions on cost recovery—such analysis should include the alignment of fees and charges with the costs of regulation for particular groups of clients or types of licences, to the extent that this is cost-effective. 	<p>ARPANSA has prepared a draft policy framework on cost recovery as recommended by the ANAO. It sets out the basis for the current fees and charges and future models for cost recovery. That paper has been reviewed by the RRCC and has been circulated to all licence holders for comment. Comments closed on 21.10.05</p> <p>ARPANSA is installing software to record regulatory activity in relation to individual licence holders. This activity will be costed and will form the basis for a more transparent recording of regulatory costs by licence holder and by source and facility licence. This program will commence in November 2005 and activity based costing will form the basis for future reviews of fees and charges.</p> <p>ARPANSA will follow the Government Cost Recovery Guidelines as much as possible, bearing in mind that those Guidelines exempt cost recovery from other Government agencies.</p>
Recommendation No.7	<p>The ANAO recommends that ARPANSA enhance guidance to applicants to better reflect the requirements of the ARPANS Act and Regulations and, in particular, to provide guidance on the statutory matters that the CEO must take into account.</p>	<p>The current information pack to applicants will be reviewed and rewritten during October-November 2005. It will be submitted to the RRCC for comment. The RRCC includes two members who are from agencies which are current major ARPANSA licence holders.</p>

Recommendation No.8	The ANAO recommends that ARPANSA introduce appropriate systems to ensure its application processing complies with the requirements of the ARPANS Act and Regulations.	Once the applicant information pack is rewritten, and consulted with the RRCC, it will be used as a template to develop an information pack for ARPANSA officers assessing applications. To be prepared in conjunction with the applicant info pack in November 2005.
Recommendation No.9	The ANAO recommends that ARPANSA enhance its licence application assessment processes by ensuring that: <ul style="list-style-type: none"> • guidance to staff explicitly addresses specified statutory matters that the CEO must take into account; and • regulatory assessment reports provided to the CEO on each application explicitly address the extent to which an application addresses these matters... 	Implementing ANAO recommendations 7 and 8 as above (November 2005) will result in ANAO recommendation 9 also being completed.
Recommendation No.10	The ANAO recommends that ARPANSA develop a risk-based decision-making process for the use of additional licence conditions. This would require clear procedures and documentation addressing, inter alia, why and how conditions will be applied, monitoring of those conditions, and their costs and benefits.	The use of additional licence conditions is now relatively rare as the licensing or pre-existing activities have been completed. A paper on the role of additional licence conditions will be prepared by the end of November 2005.
Recommendation No.11	The ANAO recommends that ARPANSA develop and implement a central database for the management of applicant and licence-holder information.	The implementation of a central regulatory management information system is seen as very important to address several of the ANAO recommendations, particularly in relation to risk management and report monitoring. ARPANSA has completed the system scope and project plan for the information management system. ARPANSA currently developing the user requirements and will engage a programmer to build the system in several stages to be completed by mid 2006.
Recommendation No.12	The ANAO recommends that ARPANSA monitor the timeliness of licence approvals against service standards, and report on this in its annual report. .	‘Service standards’ for assessment of licence applications and applications for reg 51 modifications will be included in the Regulatory Branch plan. Performance will be monitored and reported in future Annual Reports.
Recommendation No.13	The ANAO recommends that ARPANSA develop and implement an explicit, systematic and documented overall strategic compliance framework that:	In order for ARPANSA to develop an explicit, systematic and documented overall strategic compliance framework, it must firstly address ANAO recommendations 7, 14, 15, 16 and 18. These recommendations will be addressed by 31.12.05, after which time the overall compliance framework will be documented, to be completed by March

	<ul style="list-style-type: none"> identifies and articulates the purpose, contribution, resourcing and interrelationships of the various compliance approaches; is based on systematic analysis of the risk posed by licensees and the sources and facilities under their management; and targets compliance effort measures in accordance with assessed licensee risk... 	2006.
Recommendation No.14	The ANAO recommends that, to facilitate licensee understanding of and compliance with their obligations, ARPANSA revise or replace the Licence Handbook to address identified weaknesses.	Reliance on the Licence Handbook has been reduced for new and revised licences by including conditions explicitly on the licence. The Licence Handbook will be revised and retained as a general reference source for licence holders to be informed about the Act, Regulations and licence holder rights and obligations.
Recommendation No.15	The ANAO recommends that ARPANSA enhance its reporting guidelines by: <ul style="list-style-type: none"> implementing procedures to keep the guidelines up to date; specifying the level of supporting evidence required in reports; providing feedback to licensees on reports; and seeking client feedback on its guidelines. 	The reporting guidelines have been revised and enhanced. There will be further consultation with licence holders on the new guidelines in the next quarter. Arrangements for regular feedback are being addressed.
Recommendation No.16	The ANAO recommends that ARPANSA monitor compliance by licensees with reporting requirements.	Recent quarterly reports do clearly report on this compliance.
Recommendation No.17	The ANAO recommends that ARPANSA develop standard procedures, for the consideration and assessment of reports, that address: <ul style="list-style-type: none"> processes to provide assurance that licensee reports are appropriately assessed and acted upon; and the collation and monitoring of reported information for risk management purposes. 	This recommendation is closely linked with ANAO recommendations 15 and 16. Acting on this recommendation will be assisted by the enhancement of the management information system.
Recommendation No.18	The ANAO recommends that ARPANSA establish a systematic, risk-based framework for compliance	Pending completion of the management information system, ARPANSA will undertake a sound risk assessment of a sample of different types of licence holder, taking into

	<p>inspections that includes:</p> <ul style="list-style-type: none"> • an integrated inspection program based on systematic and transparent assessment of the relative risks of facilities and hazards; • inspection reporting procedures that clearly assess the extent of licensee compliance with licence conditions; • recording of report findings in management information systems, to facilitate future compliance activity, and analysis of licence compliance trends; • accountable and transparent procedures for discretionary judgements, where compliance inspections vary from standard procedures; and • reporting on ARPANSA's performance in conducting inspections. 	<p>account the nature, location and use of the source/facility, the safety processes in place, and the licence holder's past compliance history. Drawing on the outcomes of this sample, the reporting functions of the management information system will be developed in order to undertake risk assessment across the licence holder cohort.</p> <p>A rating scale will be introduced for assessing licence holder compliance and common report format and terminology will be introduced for consistent appraisal and recommendations to the CEO.</p> <p>Once these enhancements have been made, an overall inspection schedule, explicitly based on risk, will be prepared.</p> <p>Reporting of ARPANSA and licence holder performance will be undertaken. Any licence holder performance measures will be consulted with licence holders.</p>
<p>Recommendation No.19</p>	<p>The ANAO recommends that, in order to provide greater assurance that failures to meet licence conditions are dealt with and reported appropriately, ARPANSA:</p> <ul style="list-style-type: none"> • develop internal systems, policies and procedures to support a consistent approach to defining non-compliance and breaches; • have a robust framework to support a graduated approach to enforcement action; and • maintain a database of non-compliance and enforcement actions taken and their resolution. 	<p>A matrix of responses to potential situations will be drawn up and consulted with licence holders, before 31.12.05. The purpose of the matrix will be to provide a consistent and appropriate graduated regulatory response, which is known to all licence holders.</p> <p>The regulatory action taken will be recorded on the central database, and monitored for effect.</p>