

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

## **Regulatory Review Methods: Review of ANSTO Application for a Facility Licence to Operate the OPAL Research Reactor in Australia**

### *Case Study: Review of Operational Readiness*

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**Abstract.** This paper discusses the review methods used by assessors of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) in advising the CEO of ARPANSA on the application to by the Australian Nuclear Science and Technology Organisation (ANSTO) for a facility licence authorising it to operate the OPAL reactor. It focuses on an aspect of that review that considered the operational readiness demonstrated by ANSTO in relation to the OPAL reactor.

The review involved the systematic audit and assessment of the OPAL Business Management System against a comprehensive set of guidelines which were previously available to ANSTO. Assessment was also undertaken against international standards, principally the IAEA Safety Series.

The paper concludes that there is benefit to the assessment of nuclear and radiation safety of a regulator gaining a comprehensive knowledge of the business management system implemented by the operating organisation. This benefit extends beyond the licensing decision into operation using targeted inspection and informed application of regulatory check and balances.

### **1. Introduction**

On July 14 2006 the Chief Executive Officer of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) granted a [facility licence](#) [1] to the Australian Science and Technology Organisation (ANSTO) authorising the operation of the Open Pool Australian Light water (OPAL) reactor in Sydney.

Using Low Enriched Uranium fuel (LEU) and with a thermal capacity of 20MW the OPAL reactor is designed to operate up to 340 days per year. The main applications include the production of radioisotopes, irradiation of silicon for semiconductors and neutron beam research.

The OPAL reactor is the first new research reactor to be licensed by ARPANSA through every stage: preparation of the site for the reactor, construction (including cold commissioning) and this current licence stage that covers hot commissioning and routine operation.

In the period prior to the grant of the facility licence authorising ANSTO to operate the OPAL reactor, the principle regulatory task was the oversight of the construction of the reactor under the facility licence authorising ANSTO to construct the OPAL reactor. This stage covered the detailed engineering, manufacture and installation of the physical plant and engineered systems for the reactor. To ensure appropriate regulatory oversight the facility licence that authorised construction was subject

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to two key licence conditions. The ARPANS Regulations imposed a licence condition which required that;

The holder of a licence must not construct an item that is important for safety and that is identified in a safety analysis report, as part of the construction of a controlled facility, unless the CEO has given the holder, or the person approval to construct the item.

To amplify the requirements of this regulatory licence condition, the CEO of ARPANSA imposed an additional licence condition on the construction licence to ensure that the licence holder, ANSTO, understood the requirements of this approval process. In brief this licence condition required ANSTO to demonstrate that the design of each safety category 1 and safety category 2 structure system or component was subject to a detailed design and the construction of that item would be in conformity with that detailed design and the design had been reviewed and accepted by ANSTO (as the detailed design was undertaken by ANSTO's contractor INVAP SE). In addition ARPANSA required demonstration that the construction would be undertaken under a certified quality system.

These approvals processes became known as Request for Approvals (for construction) or RFA's. Sometimes the construction of a structure, system or component would have two approvals, one for manufacture and a second later approval for installation.

In total 131 separate requests for approval to construct were considered and approved by the CEO of ARPANSA.

A key element of any application for a facility licence is the submission of plans and arrangements for the management of safety. These are required to cover a range of areas including the arrangements for maintaining effective control of the facility; the safety management plan for the facility; the radiation protection plan for the facility; the radioactive waste management plan for the facility; the security plan and; the emergency plan. Whilst these provide a very broad framework for understanding the operational environment of the OPAL reactor, these plans and arrangements alone would not provide sufficient detail to judge the operational capability of ANSTO as the operating organisation in terms of nuclear and radiation safety.

A key set of documents that did provide more detail in relation to the operational arrangements to be put in place by ANSTO was its integrated Business Management System (BMS). The BMS was a key component of the ANSTO application for a facility licence to operate the OPAL reactor. Whilst the application for the facility licence authorising operation of the OPAL reactor was formally submitted in a form accepted by the CEO on 8 October 2004, the first documents that outlined the BMS were provided to ARPANSA in late 2005. The vast majority of BMS documents were made available to the ARPANSA in 2006, many in May. The scale of the task of the review of this key management system was significant considering that at the same time ARPANSA was still reviewing requests for approval to construct structures, systems and components important for safety. Output from this review was one of several inputs to a decision by the ARPANSA Chief Executive Officer to grant a licence to operate the OPAL reactor to ANSTO (See Figure 1).

The process adopted by ARPANSA to assess the suitability of ANSTO's BMS to deliver the level of safety management necessary to satisfy the CEO that he should make a positive decision to grant the licence authorising operation of the OPAL reactor is detailed in the following pages.

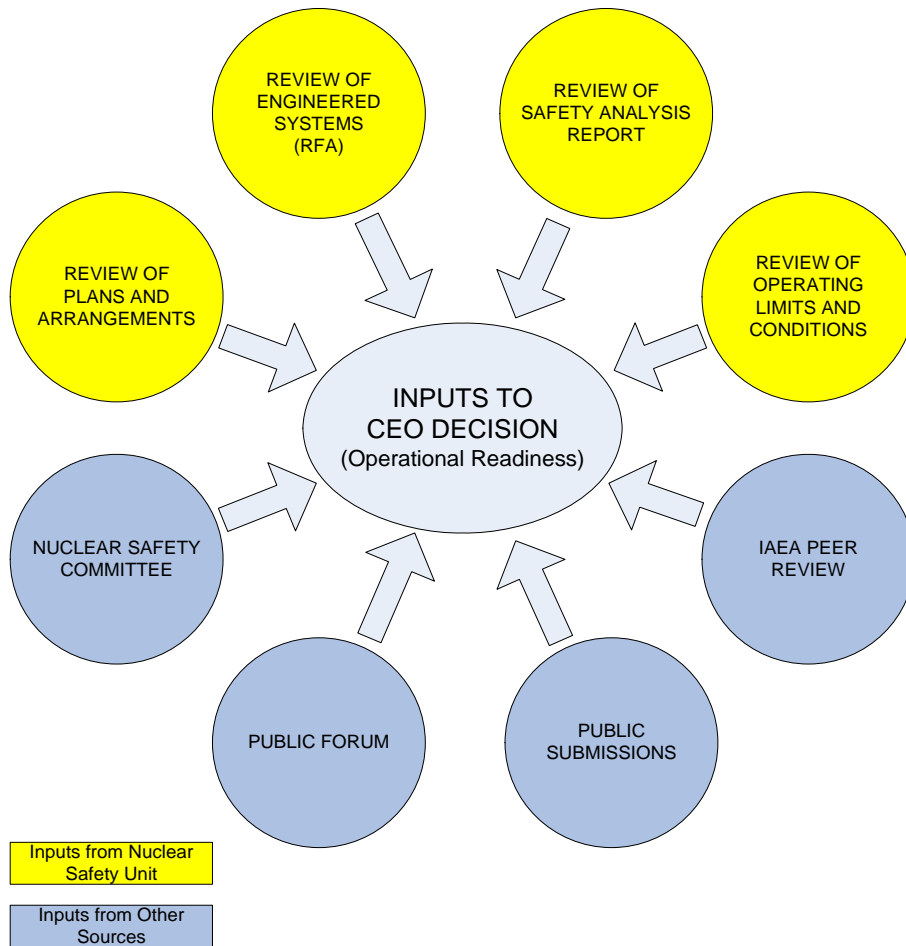


Figure 1: Major Inputs to CEO Decision to grant an Operating Licence

## 2. Regulatory Requirements

The regulatory requirements for Australian Commonwealth (Federal) Government departments, agencies and contractors to undertake actions in relation to nuclear facilities are specified in the following;

- [Australian Radiation Protection and Nuclear Safety Act 1998](#) [2]
- [Australian Radiation Protection and Nuclear Safety Regulations 1999](#) [3]

In considering whether or not to issue a facility licence the CEO of ARPANSA must take into account international best practice in radiation protection and nuclear safety and must also take into account a number of other matters set out in the Regulations made under the ARPANS Act. These include:

- Whether the information in the application establishes that the proposed conduct [operation] can be carried out without undue risk to the health and safety of people and to the environment;
- Whether the applicant has shown that there is a net benefit from carrying out the conduct relating to the controlled facility;

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- Whether the applicant has shown that the magnitude of individual doses, the number of people exposed, and the likelihood that exposure will happen are as low as reasonably achievable having regard to social and economic factors;
- Whether the applicant has shown a capacity for complying with these regulations and the licence conditions imposed under section 35 of the Act.

A key component of the application submitted by ANSTO was its plans and arrangements for managing safety, including its Business Management System (BMS).

Once that BMS had been reviewed, having regard to ARPANSA's regulatory guideline on the review of plans and arrangements, that review was provided to the CEO as part of his overall licence decision.

Once the CEO of ARPANSA was satisfied that he could issue a facility licence of the type applied for, the CEO was then able to attach conditions to that licence. Of particular relevance to this discussion is the licence condition specified in Regulation 49;

### ***Reg 49 Compliance with plans for managing safety***

*The holder of a licence must ensure that all dealings with controlled materials and apparatus and all activities related to controlled facilities, comply with plans and arrangements for managing safety of the source or facility, mentioned in the application.*

Regulation 49 provides the mechanism for ARPANSA to ensure that a licence holder follows their own plans and arrangements during operation. By linking these arrangements to a licence it provides measurable criteria that may be subject to assessment and inspection. As a consequence it was very important to review, assess and agree with the policies and controls that concerned nuclear or radiation safety specified in the OPAL BMS. ARPANSA also recognised that it was important to ensure that these controls were adequate at the time of licensing and that procedures relating to Change Control were adequate to ensure that the controls would be appropriately maintained (without degradation) into operation.

In August 2003, ARPANSA published a [Regulatory Guideline](#) [4] on the Review of Plans and Arrangements, the structure of which is shown in Figure 2. This document was developed to provide a comprehensive set of guidelines to licence holders and it is available on the ARPANSA internet site. Although adherence to the 338 individual guidelines is not mandatory, it would provide confidence that safety management policies and instructions are effectively specified and, if followed, will result in operation that complies with the licence holder's legal responsibilities under the Australian Radiation Protection and Nuclear Safety (ARPANS) legislation.

### **3. ARPANSA Approach to the Assessment**

At the time the licence was issued to ANSTO, the BMS was comprised of some 430 individual documents which were structured in a hierarchical framework on an electronic, intranet, platform. During the process of review it became clear that documents important for safety were to be found throughout the various levels of the BMS structure and it was therefore not possible to concentrate the regulatory review at a specific class of document. This made the process of review more challenging.

A further consideration was the timing of provision of BMS documents to the regulatory body. With over 50% of documents not available until May 2006 the review had to proceed in an efficient and structured manner. A key regulatory tool was the Regulatory Guideline on the Review of Plans and Arrangements. Each guideline was taken individually and the BMS assessed for compliance against the guideline. This entailed the location of the corresponding policy, procedure or instruction that

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addressed the requirement from within the BMS. An assessment of how comprehensively it satisfied the requirement was made. In addition, the BMS components were assessed having regard to international standards, especially IAEA Safety Standards. In some cases the review determined that there was an aspect of the BMS that did not meet the regulatory expectation set out in the Guideline.

An example of this regarded staffing. Many shift staff (reactor operators and shift managers) did not fully meet IAEA standards regarding previous reactor operating experience. After consideration, this shortfall was eventually balanced by acknowledgement of enhanced academic qualification of staff (compared with IAEA requirements), experience and knowledge of the reactor gained during the construction and cold commissioning of the reactor and a robust operator and shift manager training programme.

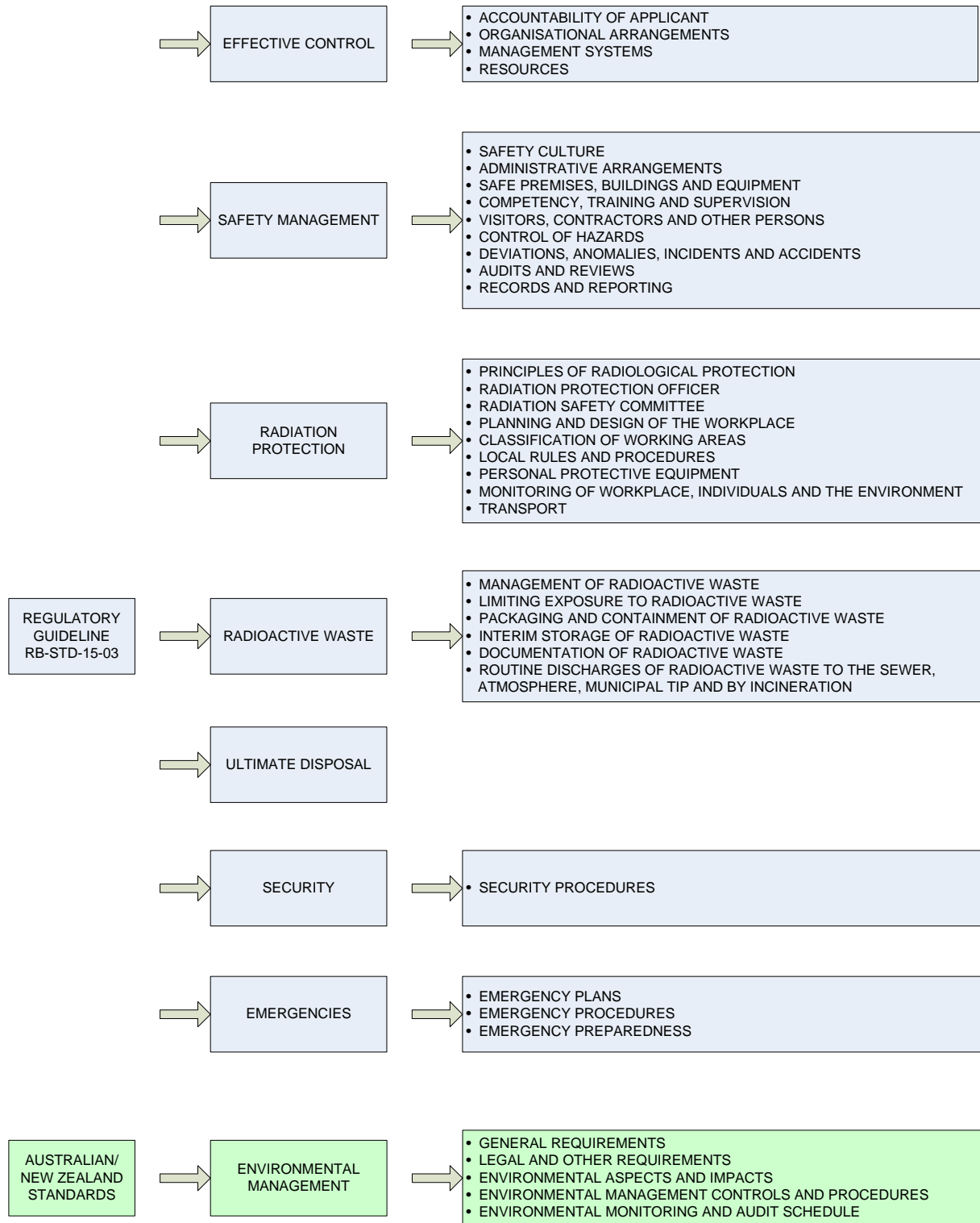
Another issue identified in the review regarded safety culture and in particular the absence of safety performance indicators (SPIs). The use of SPIs was considered to be international best practice in indicating the level of safety performance and to determine whether the prevailing attitude to safety throughout the operating organisation was positive. ARPANSA staff reviewers were concerned that, prior to operation, there was a prevailing attitude amongst operations staff and management that the reactor had been demonstrated to be virtually invulnerable. This may have, in part, been due to pride in the facility and the need to maintain a positive public image. However from a regulatory viewpoint, the attitude was considered to weaken the safety culture. Recognising the importance of safety culture and SPIs, the CEO of ARPANSA attached an additional licence condition covering each on the operating licence

The outcome of the assessment of each guideline was discussed in an ARPANSA Regulatory Assessment Report. This report and the conclusion drawn from it were, along with various other input, used by the ARPANSA CEO in deciding whether to grant the licence (See Figure 1).

The regulatory assessment of the Business Management System commenced in February 2006. A single member of the assessment team worked full time on this aspect of the review and was supported by a further two team members on some specialist areas.

The ongoing regulatory assessment of BMS documents was effectively undertaken in parallel with the ANSTO development of the BMS generally. This provided the opportunity for the regulatory body to issue early advice to the applicant, ANSTO, where the view had been formed that an aspect of the BMS did not compare favourably with international best practice in nuclear safety. The regulatory guideline was very important in this regard as it showed that the regulatory advice was based on pre-existing expectations rather than the whim of the assessor. As a result of this dynamic and timely review method the applicant was able to make improvements to the quality of the documentation submitted.

Although the advice of the reviewer to the CEO was that he could make positive findings in relation to the BMS system overall, in the context of the licence decision, a number of areas were highlighted as necessary to draw to the applicant's attention so that they could be addressed post licensing. The CEO identified these in a [statement of reasons](#) [5] for granting the operating licence.



**Figure 2: Structure of Regulatory Guideline for Review of Plans and Arrangements**

Note: Guidelined on Environmental Management are not included in the guide. Instead ARPANSA reviewers assessed against Australian/New Zealand Standards on Environmental Management

#### **4. Conclusions Drawn from Assessment Process**

The primary purpose of the assessment of the BMS was to provide advice to the CEO on the operational readiness of ANSTO in relation to the OPAL reactor.

The thorough nature of the assessment process ensured that ARPANSA gained a comprehensive understanding of the ANSTO's safety management system at the time of licensing. The review resulted in a total of 25 recommendations to the CEO for matters that should be kept under active consideration subsequent to the issue of the licence, in recognition that certain aspects of the safety management system would be tested during the actual implementation phase post licensing. These recommendations have formed the basis of planning and resource allocation in the period since licensing, principally through a programme of targeted planned inspections in areas with significance on nuclear and radiation safety.

The relationship between an independent regulator and licence holder necessarily has elements of tension, which must be maintained in the appropriate balance to assure nuclear safety. It is the role of the regulator to ensure that the requirements of nuclear safety remain paramount. There are many examples of industrial accidents arising from a gradual (and often sub-conscious) acceptance of increased risk on the basis that past operation has been successful. The comprehensive assessment of the BMS against a predefined set of criteria showed that ANSTO has systems in place to maintain and prioritise safety matters. The knowledge of these systems that was obtained by ARPANSA during licence assessment (and has been maintained since) has been essential to verifying that these systems are implemented in accordance with Regulation 49 and, to deliver appropriate regulatory checks and balances.

At their simplest, the BMS are an agreed set of procedures. However they have a more fundamental purpose to assure the delivering safe operation of the reactor. The ongoing regulatory challenge is to be assured that a product of implementation of the BMS will be assurance of nuclear and radiation safety and its continuous improvement.

**REFERENCES**

- [1] [Facility Licence F0157](#)  
www.arpansa.gov.au
- [2] Australian Radiation Protection and Nuclear Safety Act 1998  
[www.comlaw.gov.au](#)
- [3] Australian Radiation Protection and Nuclear Safety Regulations 1999  
[www.comlaw.gov.au](#)
- [4] Regulatory Guideline on Review of Plans and Arrangements  
Reference [RB-STD-15-03](#) - Version 0 - August 2003
- [5] Decision by the CEO of ARPANSA on Application by ANSTO for a Licence to Operate the  
OPAL Reactor - [Statement of Reasons](#) – 14 July 2006  
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