Australian Government

Australian Radiation Protection and Nuclear Safety Agency

Statement of Reasons

Decision by the CEO of ARPANSA on the Periodic Safety Review of the OPAL Reactor

and

consequential amendments to the OPAL Reactor Operating Licence (Facility Licence F0157)

22 October 2014

This Statement of Reasons does not form part of Facility Licence F0157 and in the event of any inconsistency between the Licence and this Statement, Facility Licence F0157 will prevail.

Contents

1 The Decision

I am satisfied that the Periodic Safety Review (PSR) of the Open Pool Australian Lightwater (OPAL) Reactor performed by the Australian Nuclear Science and Technology Organisation (ANSTO), and the documentation provided to ARPANSA in this regard, fulfil Licence Condition 13 of Facility Licence F0157. I am also satisfied that the information submitted by ANSTO in relation to Licence Condition 13 provides adequate assurance of the safety of the OPAL Reactor to allow its continued operation.

On these grounds, and based on further considerations recorded in this Statement of Reasons, on 22 October, pursuant to section 36(2) of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act), I decided to amend Facility Licence F0157 as follows:

1. remove Licence Condition 13;
2. remove Licence Condition 7; and,
3. issue new licence conditions:
   a) *The Licence Holder must, by 30 June 2015, submit to the CEO of ARPANSA a plan to implement the actions resulting from the first Periodic Safety Review in a form acceptable to the CEO of ARPANSA and report on progress in implementing the plan on a six-monthly basis. The plan must include provisions for analysis of interdependencies between safety factors and a program to support continuous improvement in the safety culture, including regular surveys by an independent organisation of the safety culture within the operating organisation.*
   b) The Licence Holder must carry out a Periodic Safety Review that re-examines the safety of the OPAL Reactor taking into account operating experience and international best practice in radiation protection and nuclear safety. A detailed plan for the Periodic Safety Review must be submitted to the CEO of ARPANSA no later than 30 November 2019. The plan and the subsequent carrying out of the Periodic Safety Review must follow the relevant regulatory guidance and must include an international peer review of safety of the OPAL Reactor. A comprehensive report and supporting documentation on the findings of the Periodic Safety Review and resulting Action Plan must be submitted to the CEO of ARPANSA no later than 30 November, 2021. The Licence Holder must subsequently perform Periodic Safety Reviews at times decided by the CEO of ARPANSA.

This Statement of Reasons outlines the reasoning behind my conclusions and decisions.

2 Background

2.1 What is a Periodic Safety Review (PSR)?

Operators of nuclear facilities are expected to continually review safety of their operations, and take necessary and appropriate actions to improve and promote safety on the basis of operational experience. International experience and practice also suggest that from time to time, it is in the interest of safety to perform comprehensive reviews of the safety of a facility, agree on recommended actions, develop an action plan and implement the plan in the lead up to the next comprehensive review. Such comprehensive reviews are referred to as *Periodic Safety Reviews*, or *PSRs*.

The objective[1] of a PSR is to determine by means of a comprehensive assessment:

- the adequacy and effectiveness of the management plans and arrangements and the structures, systems and components (equipment) that are in place to ensure plant safety until the next PSR or, where appropriate, until the end of planned operation (that is, if the facility will cease operation before the next PSR is due);
- the extent to which the plant conforms to current national and/or international safety standards and operating practices;
- safety improvements and timescales for their implementation; and
- the extent to which the safety documentation, including the licensing basis[2], remains valid.

The PSR can be regarded as one component in the gradual refinement of the understanding of the safety of a facility, for both the operator and the regulator, whilst also recognising that the ultimate responsibility for safety rests with the operator. The evolution of the safety understanding, as captured in a staged licensing and review process, encompasses analysis of site characteristics, consideration of safety features during construction, consideration of safety during operations (during commissioning, and continually during operations as well as through PSRs), considerations of safety of decommissioning, and considerations of the need for post-operational institutional control as well as requisites for site release. At each stage, enough analysis of subsequent stages of the life-cycle of a facility has to be demonstrated to understand broadly overall safety over the life cycle; specifically for a PSR, enough understanding of the safety of operations has to be demonstrated to allow the continued operation of the facility, i.e. to provide the regulator with sufficient assurance that the facility is 'safe'[3].

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1 Adapted from the IAEA Safety Standards; *Periodic Safety Review for Nuclear Power Plants*. Specific Safety Guide No. SSG-25, IAEA (2013) http://www-pub.iaea.org/books/IAEABooks/8911/Periodic-Safety-Review-for-Nuclear-Power-Plants

2 Defined as: "A set of regulatory requirements applicable to a nuclear installation. The licensing basis, in a addition to a set of regulatory requirements, may also include agreements and commitments made between the regulatory body and the licensee (e.g. in the form of letters exchanged or of statements made in technical meetings)." *Cf.* IAEA Safety Glossary. Terminology used in Nuclear Safety and Radiation Protection. 2007 Edition.

3 See correspondence from the Nuclear Safety Committee – *cf*. footnote 13.

2.2 The licence condition mandating a PSR for the OPAL Reactor

The relevant licence condition issued with the decision on 14 July 2006 to grant ANSTO a licence to operate the OPAL Reactor[4] was formulated as follows:

1. *Periodic Safety Review*
   - 1.1 *ANSTO must submit to the CEO of ARPANSA a periodic safety review that is a detailed re-examination of the safety of the OPAL Reactor taking into account operating experience and international best practice in radiation protection and nuclear safety.*
   - 1.2 *The first such review must be completed no later than two years after the completion of commissioning of the OPAL Reactor and must include revision of the Safety Analysis Report to the satisfaction of the CEO of ARPANSA.*
   - 1.3 *Reviews thereafter are to be conducted at intervals of no more than ten years.*
   - 1.4 *ANSTO must arrange for the periodic safety reviews to be the subject to international peer review.*

Licence conditions are, as per ARPANSA's Quality Management System, reviewed periodically and revised as necessary and appropriate, to keep them current and/or to simplify and clarify them. The above licence condition (now Licence Condition 13 or LC 13), was last revised on 7 January 2013 to read as follows:

> *LC 13: Licence holder must submit to the CEO of ARPANSA a detailed review that re-examines the safety of the OPAL Reactor taking into account operating experience and international best practice in radiation protection and nuclear safety, and that has been subject to international peer review. The first such review must be completed no later than two years after the date of the completion of the commissioning of the OPAL Reactor and thereafter at intervals agreed by the CEO of ARPANSA.*

The designated period of gaining operational experience (two years) is short compared to the usual ten-year cycle used in relation to power reactors. The OPAL Reactor is of a novel design with regard to several of its features and it was considered that valuable experience would be gained during 'hot commissioning' and early operation of the reactor that would expand and deepen the understanding of the safety of its features and operations; hence, two years was considered an appropriate time frame for the first PSR.

2.3 International best practice in relation to PSR for (research) reactors

The Act (section 32) mandates that the CEO takes into account International Best Practice, IBP, in licensing decisions for facilities. IBP can be sourced from documentation published by international organisations or under the terms of international agreements, although other sources for 'good practice' can be used as well.

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[4] Decision *by the CEO of ARPANSA on Application by ANSTO for a Licence to Operate the OPAL Reactor, Statement of Reasons*, ARPANSA (2006) http://www.arpansa.gov.au/pubs/regulatory/opal/op/oplic_reasons.pdf

For the purposes of the PSR, IBP needs to be considered in how to carry out a PSR and how to implement the findings. Relevant international guidance on PSRs for nuclear facilities has been published by the International Atomic Energy Agency (IAEA) in the Safety Guide: *Periodic Safety Review of Nuclear Power Plants*[5], which has recently been superseded by a Specific Safety Guide with the same title[6], both documents sit within the IAEA Safety Standard Series. The main reference for the ARPANSA reviewers was the 2003 document, noting that the 2013 document had not been finalised at the time, but also noting that the new Specific Safety Guide does not differ fundamentally from the one published in 2003.

The Safety Guides observe that PSRs are often incorporated in national regulatory frameworks for power reactors; the interval between such PSRs is commonly 10 years. The fundamentals of the methodology may be extended to other types of nuclear installations, such as waste management facilities.

The *Code of Conduct on the Safety of Research Reactors*[7] in section 19(d) places an obligation on regulators to:

"*review and assess submissions on safety…..periodically during the life of the research reactor*";

and in section 22(a) on the operator to

"*……carry out safety reviews at appropriate intervals throughout its life, including in relation to modifications, changes in utilization and significant experimental activities and the management of ageing. The safety assessments and periodic safety reviews should include all technical, operational, personnel and administrative aspects of safety related operations. The assessments and reviews should be well documented, subsequently updated in light of operating experience and significant new safety information and reviewed under the authority of the regulatory body.*"

I consider the carrying out of PSRs for research reactors – and addressing the objectives outlined in section 2.1 - to be IBP. However, specific guidance is not available for *research* reactors. In line with recommendations of international peer reviews[8], ARPANSA has developed draft regulatory guidance pertaining to PSRs for nuclear installations, based on the existing IAEA Safety Standards. I consider the aforementioned Safety Standards in conjunction with the IAEA Specific Safety Guide: *Use of a Graded Approach in the Application of the Safety Requirements for Research Reactors*[9] to be suitable to the review of the OPAL PSR and reflecting IBP. Finalisation of ARPANSA's regulatory guidance will take place based on the IAEA Safety Standards and experience from ARPANSA's review of the first PSR for the OPAL Reactor.

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5 NS-G-2.10; IAEA (2003) http://www-pub.iaea.org/books/IAEABooks/6725/Periodic-Safety-Review-of-Nuclear-Power-Plants-Safety-Guide

6 SSG-25, IAEA (2013; see footnote 1).

7 IAEA (2006); http://www-pub.iaea.org/MTCD/Publications/PDF/CODEOC-RR_web.pdf

8 *Integrated Regulatory Review Service (IRRS) Full Scope* http://www.arpansa.gov.au/pubs/regulatory/IRRS/2007IRRSreport.pdf and *Integrated Regulatory Review Service (IRRS) Follow-up Mission* http://www.arpansa.gov.au/pubs/regulatory/IRRS/IRRS-AULReportMarch2012.pdf

9 SSG-22, IAEA (2012) http://www-pub.iaea.org/MTCD/publications/PDF/Pub1547_web.pdf

The Safety Guide considers 14 safety factors, broadly covered under five umbrella categories of safety factors, being:

1. safety factors relating to the plant;
2. safety factors relating to safety analysis;
3. safety factors relating to performance and feedback from experience;
4. safety factors relating to management; and,
5. safety factors relating to the environment.

These are considered in sections 4.2 to 4.6 of this Statement of Reasons.

3 Reaching the Decision

3.1 The documentary evidence

The documentary evidence that I had regard to in reaching my decision includes the following:

a. the PSR documentation submitted by ANSTO, including supplementary documentation requested by ARPANSA regulatory officers as listed in the Regulatory Assessment Report (RAR) R13/11485[10];
b. the considerations and recommendations of ARPANSA staff based on the review of ANSTO's submissions, as documented in the RAR referred to above[11];
c. international guidance as briefly reviewed in section 2.3;
d. the former CEO Dr Loy's decision to issue a licence to operate the OPAL Reactor in 2006 (see footnote 4);
e. deliberations and correspondence on the subject by the Nuclear Safety Committee[12, 13] (NSC); summaries of NSC meetings are available on the ARPANSA website; and
f. other information relevant to the operations of the OPAL Reactor - while not being part of the information provided in support of the PSR and on which my decision covered in this Statement of Reasons is based, any such information that I am aware of may improve my understanding of matters of general importance to, and my confidence in, the safety of the OPAL Reactor.

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[10] http://www.arpansa.gov.au/pubs/regulatory/opal/rar-opal2014.pdf

[11] Lead reviewer was Mr Vaz Mottl, Safety Analysis Section, Regulatory Services Branch. Staff from ARPANSA participated in the review and preparation of advice underpinning the decision, *viz*. Mr Martin Dwyer, former Branch Head, Regulatory Services Branch; Mr Jim Scott, Head, Licensing and Compliance Section; Mr John Ward, Head, Safety Analysis Section; Dr Samir Sarkar, Licencing and Compliance Section; Mr Selva Kumar, National Uniformity and Regulatory Systems Section; Mr Martin Reynolds, General Counsel.

[12] The Nuclear Safety Committee is established under the Act and provides the CEO of ARPANSA with advice on nuclear safety and safety of controlled facilities. The Chair of the Committee is Dr Tamie Weaver. A mature draft of the RAR was reviewed by the NSC members Mr Don Macnab, Mr Peter Wilkinson and Mr Robert Lyon. More about function and membership can be found at http://www.arpansa.gov.au/AboutUs/Committees/nsc.cfm

[13] My delegate, Prof Peter Johnston, wrote to the NSC requesting specific advice on the PSR on 17 July 2014 http://www.arpansa.gov.au/pubs/regulatory/opal/NSCrequest-OPALPSR.pdf. I received the response from the NSC on 18 August 2014 http://www.arpansa.gov.au/pubs/regulatory/opal/NSCreply-OPALPSR.pdf.

The NSC noted in its correspondence (see footnote 13) that ARPANSA, when assessing the documentation relevant to the PSR, in some areas sampled the information provided by ANSTO for in-depth review using a risk-based approach. The NSC commented that specifically stating this helps in clarifying the delineation between the responsibilities and accountabilities of the operator on one hand, and of the regulator on the other hand. I agree with the NSC and note that ARPANSA's confidence in continued safe operation of the OPAL Reactor would be based on positive assurance, i.e. that enough information has been analysed to a sufficient depth to provide such assurance – whilst recognising that the ultimate responsibility for safe operation rests with ANSTO.

4 Reasons for the Decision

4.1 Scope of the PSR and submission of documentation

Based on the completion of the commissioning of the OPAL Reactor in November 2009, the submission of the PSR documentation was expected two years later, in accordance with the licence condition. The PSR documentation was approved by the ANSTO Reactor Assessment Committee (RAC) and Safety Assurance Committee (SAC) on 1 November 2011. The PSR was received by ARPANSA on 23 December 2011. While this represents a small delay, it is of no significance to safety and ARPANSA's regulatory staff was continuously kept informed of the progression of the work. Between 2011 and 2013, ANSTO also submitted the updated chapters of the Safety Analysis Report (SAR).

During the course of the review, supplementary information was received that addressed the shortfalls identified by the ARPANSA reviewers such as lack of information, unsubstantiated claims, and information on cumulative effects of implemented changes. The submission contained internal recommendations and 'lessons learned', as is good practice.

As required in LC 13, ANSTO had requested an international peer review in support of the PSR. The review findings, in total 41 recommendations and suggestions and ANSTO's responses to them, were reflected in the submission.

With the agreement of ARPANSA, the PSR systematically evaluated the 14 safety factors identified in the international guidance on PSR (see section 2.3).

Nuclear security is not covered in the PSR, nor evaluated in this Statement of Reasons. This is in accordance with international practice; however, ARPANSA is currently finalising its analysis of the Periodic Security Review covered under LC 14[14], which includes an analysis of security response. Emergency response (consequence management), independent of whether the initiating event was related to safety or security, is the focus of separate analysis by ARPANSA.

[14] *LC 14: The licence holder must submit to the CEO of ARPANSA a detailed review of the physical protection and security systems, taking into account operating experience and developments in the security environment and international best practice in protective security for nuclear installations. The first such review must be completed no later than two years after the date of completion of the commissioning of the OPAL Reactor and thereafter at intervals agreed with the CEO of ARPANSA, taking into account developments in the security environment.*

The ARPANSA reviewers considered the totality of information received over time to be satisfactory. I agree with their conclusion. I note, however, that significant requests for supplementary information had to be made despite the sign-off by both RAC and SAC on 1 November 2011. I also share the view of the ARPANSA reviewers that the general structure and clarity of the documentation should be improved in the next PSR, although it has to be borne in mind that this was the first PSR for the OPAL Reactor; international experience suggests that cumulative experience over the life-time of a facility results in subsequent PSRs being less cumbersome with increased clarity. The experience gained by ARPANSA will also lead to improved guidance on structure and content, thus contributing to a more efficient process.

Conclusion
I conclude that timing and scope, completeness, and the inclusion of an international peer review in the process of developing the PSR, satisfy the requirements of LC 13 as regards those aspects.

4.2 Safety factors relating to the plant

The safety factors considered under this umbrella relate to: plant design; actual condition of structures, systems and components (SSCs)[15]; equipment qualification; and, ageing. These are considered in more detail in sections 2.5 to 2.8 of the RAR and are therefore only briefly summarised here.

The ARPANSA reviewers consider that ANSTO has demonstrated that the design basis is aligned with current standards and requirements related to SSCs, and that ANSTO had reviewed and updated the documentation relevant to SSCs and provided satisfactory information as to implementation of actions in the After-action Programme. The ARPANSA reviewers pointed out that the link between a recommendation and the underpinning observation or issue was not always clearly evident. The actual condition of SSCs was assessed for those with major safety significance, as deemed from the OPAL SAR. The ARPANSA reviewers considered this approach being reasonable, bearing in mind the short duration of operations of the OPAL Reactor. The ARPANSA reviewers also agreed with the analysis of the actual conditions of the identified SSCs. Information regarding qualification of certain SSCs of primary safety relevance was found by ANSTO to be satisfactory from the safety perspective but sometimes scattered and incomplete; such issues have been captured in the After-action Programme.

The design, status and qualification of SSCs are important elements of ageing management of the plant. Ageing essentially starts the moment the plant is commissioned; this is recognised by ANSTO. The ARPANSA reviewers found ANSTO's plans for ageing management to be well advanced, but they also identified that the link between ageing management and occurrences in the past of potential relevance to ageing could be improved.

I agree with the ARPANSA reviewers' assessment of safety factors relating to the plant.

[15] The updated Safety Guide, SSG-25 (see footnote 1) uses the additional qualifier "important to safety" in relation to the SSCs.

Conclusion
I consider the design basis and actual condition of SSCs are compliant with current requirements; and that qualification and ageing management is adequate. I conclude, based on the evidence before me, that the review of *safety factors relating to the plant* provides sufficient assurance of safety of the OPAL Reactor.

4.3 Safety factors relating to safety analysis

The safety factors under this umbrella include: deterministic safety analysis; probabilistic safety assessment; and hazard analysis. These are considered in more detail in sections 2.9 – 2.11 of the RAR and are therefore only briefly summarised here.

The PSR considered *inter alia* the analysis of initiating events from the perspective of currency and completeness, and the reviewers noted the identification of new initiating events that have already been, or will be, incorporated in the SAR. The probabilistic safety assessment has been reviewed by ANSTO but remains unchanged; the short duration of operational experience provides only limited information feedback and although some upgrades have taken place over time, they have little impact on the probabilistic assessment. The ARPANSA reviewers were satisfied with the currency of the probabilistic safety assessment. The probabilities and consequences associated with internal and external hazards were analysed and the ARPANSA reviewers concluded that currently installed and applied measures to mitigate the identified hazards are adequate for the projected OPAL operation in the next PSR period.

I agree with the reviewers' assessment. I also note that specific consideration has been made separately of experiences gained from the nuclear accident following the Great East-Japan Earthquake and Tsunami in 2011. This is further discussed in section 4.8.2 of this Statement of Reasons.

Conclusion
I consider the current status and forward plans for deterministic and probabilistic safety assessments, and hazard analysis, to be satisfactory. I conclude, based on the evidence before me, that the review of *safety factors relating to safety analysis* provides sufficient assurance of safety of the OPAL Reactor.

4.4 Safety factors relating to performance and feedback of experience

The safety factors under this umbrella include: safety performance; and, use of experience from other plants and research findings. These are considered in more detail in sections 2.12 – 2.13 of the RAR and are therefore only briefly summarised here.

The safety performance has been assessed against relevant indicators. The analysis of performance has been generally satisfactory and associated actions adequately logged. There are some examples of negative trends but these may well be related to the increased availability of the reactor with time. The exposures to radiation on-site and off-site are well within limits. The After-action Programme has adequately captured issues where improvements are desirable. The ARPANSA

reviewers were satisfied that the overall safety performance of the OPAL Reactor, as presented in the PSR, showed no indication of substandard performance against safety-related indicators.

In addition to taking stock of operational safety-related experience from the OPAL Reactor – and equally important – is the need to take account of operating experience from other reactors (overseas) as well as current research. Direct comparison with other reactors is not straightforward as designs vary considerably. Nevertheless, the ARPANSA reviewers found that ANSTO has healthy collaborative arrangements with other operators and is taking advancing research into account.

The ARPANSA reviewers were generally satisfied with the safety factors relating to performance and feedback of experience, but recommended that efforts should be made to maximise the benefits of lessons learned. I agree with the assessment of the ARPANSA reviewers.

Conclusion
I consider that ANSTO's systems for identifying and taking stock of operational experience, from the OPAL Reactor as well as from overseas, and from research, are satisfactory. I conclude, based on the evidence before me, that the review of *safety factors relating to performance and feedback of experience* provides sufficient assurance of safety of the OPAL Reactor.

4.5 Safety factors relating to management

The safety factors under this umbrella include: organisation and administration[16]; procedures; human factors; and, emergency planning. These are considered in more detail in sections 2.14 – 2.17 of the RAR and are therefore only briefly summarised here.

Of particular relevance here is safety culture which is addressed indirectly under the specific safety factors Safety Performance (Safety Factor 8); Organisation and Administration (Safety Factor 10); the Human Factors (Safety Factor 12); and also in introductory remarks: *"Quality assurance (QA) and safety culture are not considered to be separate safety factors because they should be an integral part of every activity affecting safety"* (see footnote 5). Whilst ARPANSA reviewers accept that quality assurance and safety culture are mutually supportive they do not regard them as being combined. The PSR of the OPAL Reactor does not discuss the ANSTO safety culture, and specifically the OPAL Reactor safety culture in detail. Therefore, the assessment under the PSR should for the future be strengthened by more explicitly examining the effect and influence of leadership and culture on safety of the operation of the reactor. Although not used for this PSR, the updated IAEA PSR Safety Guide (see footnote 1) highlights safety culture as a key safety factor.

I also note that the NSC in its correspondence (see footnote 13) has identified the issue of safety culture. The NSC:

"recommends ARPANSA to encourage ANSTO to devote a more significant portion of the PSR to discussing the influence and impact of safety culture of the operations, maintenance and management of OPAL; this is important given that the updated IAEA guidance acknowledges the influence of safety culture, and its importance is recognised across all high hazard industries."

[16] In SSG-25 rephrased to read "Organization, the management system and safety culture"

Safety culture was considered in Dr Loy's decision from 2006. It is captured in the current LC 7, under the heading "Safety Culture", as follows:

> *LC 7: The licence holder must implement a program to support continuous improvement in the safety culture of the operating organisation, including regular surveys by an independent organisation of the safety climates within the operating organisation. Such surveys must be at intervals agreed to by the CEO of ARPANSA and the results provided to the CEO of ARPANSA.*

I consider the requirement on reporting on safety culture requires strengthening. I have therefore reformulated the requirements and integrated them within the programme for implementation of actions based on the PSR, to be periodically reported to ARPANSA. Sections 6.2 and 6.3 outline the rationale for this move.

The ANSTO arrangements for selecting and adequately training personnel, and for managing the human-machine interface, were considered acceptable to the ARPANSA reviewers, noting that further analysis related to what is termed 'holistic safety' is warranted[17].

ANSTO has developed a comprehensive system for development and revision of procedures. The information has provided a reasonable overview of the relevant administrative systems in place. This system is regularly monitored by ARPANSA through its inspection programme and is considered by the ARPANSA reviewers to be satisfactory.

The ARPANSA reviewers found the description of emergency planning generally satisfactory. ANSTO regularly performs emergency exercises which are monitored by ARPANSA inspectors. Feedback from such exercises has been used to improve the emergency planning. As indicated in section 4.1, the arrangements for consequence management are subject to separate analysis by ARPANSA.

The ARPANSA reviewers concluded that the PSR provided generally satisfactory information regarding safety factors related to management, but also that there was scope for improvement, including the following: "Human factors should be addressed in all aspects of OPAL operations, and should include reviews of the processes and the design of the operating environment. Relevant utilisation and maintenance tasks should also form part of the assessment". I agree with the reviewers' conclusions as well as with their recommendation.

Conclusion

I consider the information provided in the PSR with regard to organisation and administration; procedures; human factors; and, emergency planning, to be satisfactory although a number of areas for improvement have been identified, among them monitoring and reporting of safety culture. Notwithstanding the need for attention to such issues, I conclude, based on the evidence before me, that the review of *safety factors relating to management* provides sufficient assurance of the safety of the OPAL Reactor.

[17] *Holistic Safety Guidelines*, ARPANSA (2012) http://www.arpansa.gov.au/Regulation/Holistic/index.cfm

4.6 Safety factors relating to the environment

There is only one safety factor under this umbrella: radiological impact on the environment. This is considered in more detail in section 2.18 of the RAR and is therefore only briefly summarised here

ANSTO's review addressed adequately the radiological impact assessment of all effluents, including on-site and off-site monitoring systems. The presented information appropriately demonstrated that the radiological impact of the OPAL Reactor's operation has been insignificant over the period covered by the PSR. ARPANSA's reviewers were generally satisfied with the documentation but recommended consideration of future OPAL operations in the surveillance programme. I agree with the reviewers conclusions.

Conclusion
I consider the information provided in the PSR to be satisfactory with regard to discharges and their control. I conclude, based on the evidence before me, that the review of *safety factors relating to the environment* provides sufficient assurance of safety of the OPAL Reactor.

4.7 Global assessment of safety factors

The objective of the *global assessment* is to present an assessment of plant safety that takes into account all unresolved shortcomings, corrective actions and/or safety improvements and the plant strengths identified in the review of all PSR safety factors. The RAR considers the global assessment in more detail in section 2.19 and the global assessment is therefore only briefly reviewed here.

The NSC noted the importance of examining the interdependence of the 14 safety factors and that a system approach improves understanding of the strengths and vulnerabilities of the reactor's operations (see footnote 14), and recommended that in line with the holistic or system safety approach:

"ANSTO's PSR and ARPANSA's assessment of it places greater emphasis on examining interrelationships and interdependence between the 14 individual safety factors assessed. This will ensure the analysis is comprehensive and addresses all key aspects of safety."

The main findings of the ARPANSA reviewers were that strengths and weaknesses had been identified and discussed in the PSR; however, the assessment of the safety factors, as well as individual shortcomings and corrective actions in combination has not been presented in a systematic manner.

I agree with the assessors and with the NSC advice. I therefore consider that, whilst individual safety factors have been assessed and found satisfactory, there is a need for ANSTO to further consider their interdependence in the implementation of actions following the PSR. I have therefore included this in the new licence condition related to implementation of the findings from the PSR. Section 6.3 elaborates on this condition.

Conclusion
I consider the global assessment should, in future PSRs, demonstrate improved considerations of the interdependence of the 14 safety factors as part of the examination of holistic, or systemic, safety. Notwithstanding this consideration, I conclude, based on the evidence before me, that the *global assessment* provides sufficient assurance of safety of the OPAL Reactor as currently operated.

4.8 Other considerations

The ARPANSA reviewers further considered the update of the *Safety Analysis Report (SAR)* resulting from the PSR. They also considered ANSTO's preliminary assessment that had been requested by ARPANSA, of safety factors relevant to the accident at the Fukushima Daiichi Nuclear Power Plant following the Great East-Japan Earthquake and Tsunami in March 2011; and events of safety relevance at the OPAL Reactor.

4.8.1 The Safety Analysis Report (SAR)

During the course of ARPANSA's review of the PSR, ANSTO submitted updated chapters of the SAR. ARPANSA's reviewers sampled selected chapters from the SAR for an in-depth review. This process is outlined in more detail in section 2.20 of the RAR.

Over-all, the ARPANSA reviewers were satisfied the update of the SAR adequately considers the relevant modifications implemented between years 2006 and 2011, international operating experience, and that relevant standards have been appropriately considered during the SAR review. Some outstanding issues remain and the ARPANSA reviewers recommend these to be logged in the After-action Programme.

4.8.2 Preliminary assessment of the lessons learned from the accident at the Fukushima Daiichi Nuclear Power Plant following the Great East-Japan Earthquake and Tsunami in March 2011

The Great-East Japan Earthquake and Tsunami triggered the worst nuclear power plant accident since the Chernobyl accident in 1986. This occurred at the Fukushima Daiichi nuclear power plant on the coast of the Fukushima Prefecture on the main island of Japan, Honshu. While the external triggering event was the very large earthquake and resulting tsunami, the accident could have been avoided if adequate attention had been paid to analyses that demonstrated that a tsunami of a height of about 15 m at the site was not improbable. The sea defence was insufficient for a tsunami this high and all diesel generators were, with one exception, rendered inoperable and thus unable to compensate for the loss (caused by the earthquake) of off-site AC power. With only limited and temporary DC power from accumulators on site, the situation developed into a station black-out and discharges from three overheated and melting cores led to significant contamination of land and coastal waters.

The accident prompted national and international reviews of the regulatory infrastructure and of safety factors at nuclear sites. ARPANSA requested ANSTO to assess the implications and lessons learned from the accident at the Fukushima Daiichi NPP, with regard to the safety of the OPAL Reactor. The initial PSR submission dated 23 December 2011 included The *Preliminary Assessment of Implications for the OPAL Safety Case and Lessons Learnt from the Fukushima Dai-ichi NPP Event*.

Although the document considered the information available at the time it was developed, which was the end of March 2011 (shortly after the accident); it resulted in a number of recommendations for the OPAL Reactor safety case. ANSTO subsequently issued revision B of the document (April 2012). The assessment is outlined in more detail in section 2.21 of the RAR.

The scope of ANSTO's review included the revision of the set of initiating events previously considered for the OPAL Reactor safety analysis. It included reconsideration of the design basis of the OPAL Reactor as well as beyond design basis events. The following events were specifically reviewed in the aftermath of the accident at the Fukushima Daiichi nuclear power plant:

- station black-outs (black-out up to 30min, 30min to 10 days and more than 10 days);
- internal events (coolant leaks, heavy water leaks, missiles generated from rotating components, heavy load drops);
- external events (aircraft impact, bushfires, industrial and transportation accidents, military activities, on-site activities, extreme wind, earthquake);
- combination of external events (external hazards in conjunction, consequential external hazards and coincidental external hazards);
- hydrogen gas explosion;
- spent fuel pool cooling; and,
- venting of reactor containment.

ANSTO has recommended changes to the OPAL Reactor safety case with regard to station black-out. The loss of power (black-out) safety analysis should be updated so a 15 day black-out is included. The existing analysis covers the plant black-out lasting up to 10 days. The recommendation for blackout extension is based on ANSTO having determined the OPAL Reactor fuel 'ever-safe time' which is 15 days. A number of other changes have been recommended, including a further assessment of the emergency planning. The recommendations have been logged in the After-action Programme.

I consider continued vigilance regarding external and internal hazards that cause multiple failures from a triggering event to be of utmost importance. While the responsibility clearly rests with the operator, complacency among regulators and other bodies that have direct or indirect roles in overseeing the operations may be equally detrimental to the safety of operations. Being vigilant of hazards that may cause multiple severe accident scenarios remains essential and is an important element of the safety culture – equally important for operators and regulators.

I note that at the time this Statement of Reason was written, ANSTO submitted to ARPANSA the final version of their re-assessment of the OPAL Reactor considering lessons learnt from the Fukushima accident. The document titled *Safety Re-assessment of OPAL in the light of the Fukushima Daiichi Accident* followed the IAEA Safety Report Series No.80[18] issued in 2014. ANSTO has indicated that recommendations from this assessment will be included in the After-action Programme. ARPANSA's regulatory review of the final report will be conducted independently of the review of the PSR.

[18] IAEA (2014) http://www-pub.iaea.org/books/IAEABooks/10522/Safety-Reassessment-for-Research-Reactors-in-the-Light-of-the-Accident-at-the-Fukushima-Daiichi-Nuclear-Power-Plant

4.8.3 OPAL events

Between 2006 and 2011, OPAL reported 796 events in total. The vast majority of the events were occurrences with no or negligible safety significance. Twenty six events were categorised by ANSTO to be nuclear safety-related. In addition to those events, ARPANSA requested details and assessed the information regarding numerous other events within the period.

Four events were rated *Level 1: Anomaly* on the IAEA International Nuclear and Radiological Event Scale (INES). The INES assessment determines a level of safety significance on the scale from 1 to 7, where level 1 is denotes an 'anomaly' and level 7 denotes a 'major accident' corresponding to the scale of the accidents at the Chernobyl and Fukushima Daiichi nuclear power plants. Level 0 or below scale rating, denotes that the event had no safety significance. Two of the events rated level 1 were related to the nuclear fuel (fuel plate displacement and fuel assembly drop); one event constituted a non-compliance with Operational Limits and Conditions; and, one event concerned incorrect reactor trip set points. None of these events resulted in release of any radioactive material.

Another issue was encountered during the 'hot commissioning' phase of the OPAL Reactor, where a gradually increased level of radioactivity was detected in the Primary Cooling Circuit. The test that followed indicated that the source of contamination was a fuel assembly. The fuel had either been contaminated with uranium on the surface during production, or there was a minor leak of radioactive substances through the cladding. The fuel was removed from the reactor, isolated and contained.

The investigations into the more significant events pointed to design deficiencies, procedural deficiencies or maintenance-related causes. Human factors were considered to be a contributor to many of the events.

The reports to ARPANSA also included 39 events related to health physics. The majority of these events were minor personnel contaminations. None of the health physics events resulted in significant doses to the personnel.

4.8.3.1 Fuel plates displacement event: the 'fuel fault'

The most significant event occurring at the OPAL Reactor between 2006 and 2011 involved fuel plate displacement, referred to as the 'fuel fault' event. It caused the shut-down of the reactor for an extended period of time. The event was assessed to be INES Level 1: Anomaly. No release of radioactive material into the reactor cooling circuit and atmosphere was detected.

ANSTO conducted extensive investigations that resulted in fuel assembly design modification. The modification was approved by Dr Loy in May 2008[19] with two additional licence conditions imposed on ANSTO under section 35(1)(d) of the Act. In his decision, Dr Loy took into consideration the conclusions from reviews carried out by NSC members and external consultants.

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[19] *Decision and Statement of Reasons by the CEO of ARPANSA on the Submission from ANSTO Seeking Approval under Regulation 51 of the ARPANS Regulations to Modify the Design of the OPAL Reactor Fuel Assemblies to Incorporate a Stopper and to Recommence Operation of the Reactor with the Modified Fuel Assemblies*, ARPANSA (2008) http://www.arpansa.gov.au/pubs/regulatory/opal/modifiedfuelstatement160608.pdf

The licence conditions articulated requirements for further investigation of the OPAL Reactor environmental conditions, and conduct of an additional review of the fuel design. To demonstrate compliance with these licence conditions, ANSTO submitted documentation that was reviewed by ARPANSA as well as an external consultant. Although the reviews pointed to some inadequacies, the reviews generally demonstrated that the matter had been appropriately addressed by ANSTO. The remaining outstanding relevant matters overlap with the issues identified in the OPAL PSR and have been logged into the After-action Programme.

In addition to matters referred to above and for the purpose of the decision in relation to the Periodic Safety Review, I have also considered the satisfactory operational record of the modified fuel from when it was introduced in 2008 to present-day operations. ANSTO has developed an adequately comprehensive OPAL fuel performance monitoring programme. The results from the monitoring have not indicated any release of radioactive substances to the coolant circuit; no fuel cladding damage has been observed; and, no signs of mechanical damage (e.g. resulting from excessive vibration in the core) have been observed. While some issues are still outstanding from ARPANSA's review of documentation specific from the investigations into the fuel fault, the totality of information provides me with confidence that the current fuel design is fit for purpose.

Conclusions
I consider the update of the SAR to be an adequate reflection of modifications and experience and I conclude, based on the evidence before me, that the *safety analysis report* provides sufficient assurance that the OPAL Reactor meets safety and licensing requirements and the safety design criteria.

I consider continued monitoring of 'lessons learned' from the 2011 nuclear accident in Japan – and other experience – to be an essential element of safety culture. I conclude, based on the evidence before me, that ANSTO has taken adequate steps to *take stock of relevant experience from the accident at the Fukushima Daiichi Nuclear Power Plant* in its management of safety of the OPAL Reactor.

Analysis of events indicates that incident levels are stable and that the safety significance, if any, is generally low. Whilst a low rate and severity of events is a good goal to which to aspire, in itself does not equate to safety. Safety is rather the presence of defences within the system, environment and processes. While full closure of the investigations into fuel displacement is still outstanding, I consider that ANSTO has implemented appropriate measures to ascertain the integrity of the fuel and core. Operational experience since 2008 supports this view and I conclude that reviews of *matters related to events and to the integrity of the fuel and core* provide sufficient assurance of safety of the OPAL Reactor.

4.9 Matters identified in the Australian Radiation Protection and Nuclear Safety Regulations 1999

In order to evaluate whether the licensing basis remains valid, it is also helpful to assess the safety performance of the OPAL Reactor in relation to "matters the CEO must take into account when issuing a facility licence", outlined in sub-regulation 41(3) of the Australian Radiation Protection and

Nuclear Safety Regulations 1999 (the Regulations). Such matters were considered by former CEO Dr Loy in his Statement of Reasons supporting the decision to issue a licence to ANSTO to operate the OPAL Reactor in 2006 (see footnote 4). Matters identified in the sub-regulation of direct relevance here are:

a. whether the information establishes that the proposed conduct can be carried out without undue risk to the health and safety of people, and to the environment;
b. whether the applicant has shown that there is a net benefit from carrying out the conduct relating to the controlled facility;
c. whether the applicant has shown 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 economic and social factors; and
d. whether the applicant has shown a capacity for complying with these regulations and the licence conditions that would be imposed under section 35 of the Act.

I consider these matters below, focusing on whether the licensing basis remains valid and whether the conclusions drawn by Dr Loy have been confirmed through operational experience or subsequent assessments.

4.9.1 Does the information establish that the proposed conduct can be carried out without undue risk to the health and safety of people, and to the environment?

Dr Loy considered the Radiation Protection Objective and the Technical Safety Objective to be relevant and based in IBP. The technical and managerial – as relevant to plans and arrangements for safety - considerations would ensure that all occupational exposure, exposure of the public and the environment would be minor; and that the likelihood of accidents, and their consequences should they occur (or be caused by a security-related event), would be small.

The plans and arrangements for safety are in many instances applied ANSTO-wide. They have been the subject of scrutiny by ARPANSA recently in relation to decisions to prepare a site for, and to construct, three major facilities at the Lucas Heights Science and Technology Centre (LHSTC): the *ANSTO Nuclear Medicine Facility* (a nuclear facility); the *Interim Waste Store* (a nuclear facility); and, the *SyMo Facility* for treatment of liquid waste (a prescribed radiation facility). The Regulatory Assessment Reports and Statements of Reasons supporting those decisions are all available from the ARPANSA website[20,21,22]. The plans and arrangements for safety have been considered satisfactory. However, there remain unresolved issues regarding spent fuel and radioactive waste management; these are commented on in the next section.

The event management is a recognised valuable source of information for the operating organisation in its continuous effort to improve safety. ARPANSA maintains a close oversight of the OPAL event investigations as well as the investigation findings. The information presented in the PSR documents together with the ARPANSA assessment demonstrated that the system for OPAL event

[20] Decision of the CEO – ANSTO ANM facility http://www.arpansa.gov.au/News/whatsnew/news1_140627.cfm
[21] Licence Interim Waste Store application http://www.arpansa.gov.au/Regulation/ReturnofWaste/index.cfm
[22] Licence application http://www.arpansa.gov.au/Regulation/Branch/symo.cfm#decision

management appropriately addresses the need for in-depth event investigations. I am satisfied there is a mechanism in place to effectively utilise lessons learnt from the events to reduce risks associated with future operations.

4.9.2 Is there net benefit from carrying out the conduct relating to the controlled facility?

As reasoned by Dr Loy, this issue concerns the concept of justification as outlined in the relevant recommendations from the International Commission on Radiological Protection, ICRP. Since the operation licence was issued, the ICRP Recommendations have been updated[23]; however, justification remains a cornerstone in the international framework for radiation protection and nuclear safety that I consider IBP.

While radiation protection is an important element in judging whether a practice is justified, there are a variety of other factors unrelated to radiation protection that have to be considered when discussing justification, which includes *inter alia* societal considerations. Dr Loy expressed the view that such considerations rest properly with Government. In the case of the OPAL Reactor, Dr Loy considered there is benefit of being able to perform scientific research and to produce radiopharmaceuticals, by use of neutrons generated through nuclear fission in the OPAL Reactor, and that the very limited radiological impact associated with the operation of the reactor would not offset this benefit. The operational experience to date does not contradict this conclusion.

Notwithstanding the above, it is necessary to point out that there remains unresolved issues with regard to spent fuel and solid and liquid radioactive waste management (except for such waste that can be safely discharged to the atmosphere, or with sewage water under the arrangements with Sydney Water). Current arrangements with the US Department of Energy regarding return of spent fuel will not cover fuel that has been irradiated later than May 2016. While storage of spent fuel on site, as is current practice until it is shipped to the US, is an acceptable temporary measure from the safety perspective, ANSTO needs to demonstrate an appropriate spent fuel strategy beyond the current arrangements. I am aware that this issue is given high priority at ANSTO and that different options are being explored.

As referred to earlier, one of the major purposes of the OPAL Reactor is the irradiation of uranium targets for the production of molybdenum-99 (which generates technetium-99m, used in various medical applications). The production of radiopharmaceuticals is a cornerstone in the justification of the OPAL Reactor; however, it leads to the generation of liquid intermediate-level radioactive waste, which is planned to be converted to an inert form in the aforementioned *SyMo Facility*. At the present, there is no final destination for such waste in Australia, although the national policy calls for the establishment of a *National Radioactive Waste Management Facility* (NRWMF) for disposal of low-level waste, and for the storage of intermediate level waste pending its ultimate disposal. The

[23] The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103; Ann. ICRP 37 (2-4), 2007

most recent report under the terms of the *Joint Convention*[24] provides further details on the Australian policy and framework for spent fuel and radioactive waste management.

The current situation with regard to final management of radioactive waste in Australia has also led ANSTO to apply for a licence to prepare a site for, and to construct, the *Interim Waste Store*, mentioned in section 4.9.1, at the LHSTC, to temporarily store radioactive waste from reprocessing of HIFAR[25] fuel, when this waste is returned from France, which is expected to take place towards the end of 2015.

ANSTO's plans and arrangements for management of radioactive waste on site are considered satisfactory and may continue to provide adequate safety for many years to follow. However, sustained production of radioactive waste requires a long-term plan and an ultimate solution. This was recognised by Dr Loy in his Statement of Reasons supporting the decision to issue ANSO with a licence to operate the OPAL Reactor in 2006. Eight years later, and following the repeal of the *Commonwealth Radioactive Waste Management Act 2005,* now replaced with the *National Radioactive Waste Management Act 2012* – and despite developments as regards the conceptual design – we are still not near the first disposal campaign at the NRWMF. However, the Government's commitment to the establishment of the facility remains strong (see footnote 25). The potential safety implications caused by the delay – which are not going to be serious in the short term – need to be managed by ANSTO. It should also be noted that the *Australian Nuclear Science and Technology Act 1987* prohibits the LHSTC from becoming a disposal facility for radioactive waste.

4.9.3 Are the magnitude of individual doses, the number of people exposed, and the likelihood that exposure will happen, as low as reasonably achievable, having regard to economic and social factors

As pointed out by Dr Loy in his licensing decision regarding operation of the OPAL Reactor, this matter goes to whether radiation protection at the OPAL Reactor is optimised – the principle of optimisation of radiation protection being another cornerstone of the system for radiation protection that I consider IBP (see footnote 23).

The objective of occupational dose reduction at the time of licensing was to achieve doses below 2 mSv per year – this remains unchanged. As Dr Loy pointed out, this 'ALARA objective' does not fully resonate with the principle of optimisation. In practice, however, doses to reactor staff are on average considerably lower. This observation can be extended to e.g. staff at ANSTO Health working on radiopharmaceuticals production following irradiation of uranium targets in the neutron field generated through nuclear fission.

Figure 1 shows how the exposure of the reactor operations staff (and other staff) has varied between 2004 and 2014. Radiation doses of reactor operations staff decreased between 2006-2007 which coincided with the shutdown of the HIFAR reactor and the startup of the OPAL Reactor.

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[24] Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. National Report of the Commonwealth of Australia. October 2014. http://www.arpansa.gov.au/News/whatsnew/news1_141010.cfm

[25] The High Flux Australian Reactor, or HIFAR, operated between 1958 and 2007. It is now permanently shut down and is covered by a 'possess and control' licence issued by ARPANSA.

Between 2007-2008 the doses fell to almost zero due to the shutdown of the OPAL Reactor following the 'fuel fault'. Then following the restart of the OPAL Reactor in 2008, radiation doses increased to a roughly constant value of 0.15 mSv effective dose per quarter which equates to around 0.6 mSv effective dose per annum, which is significantly less than the 20 mSv (averaged over 5 years: 50 mSv in a single year) annual effective dose limit for occupational exposure.

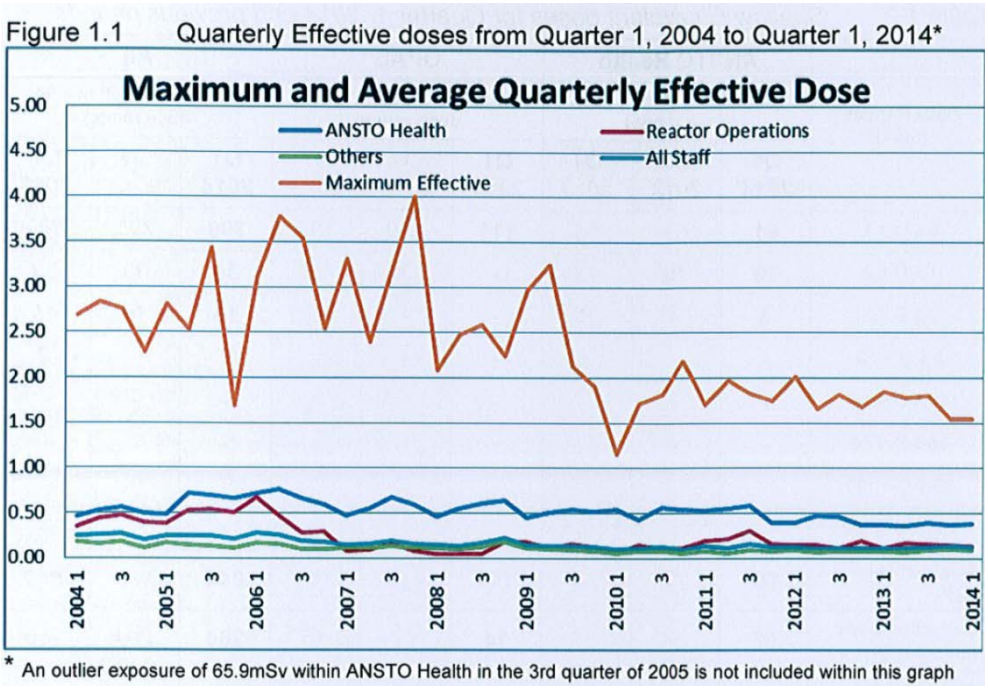

Figure 1. Quarterly effecive doses (in millisievert, mSv) for various occupationally exposed groups at ANSTO LHSTC. Data from the ANSTO Dosimetry Report for January to March 2014, submitted to ARPANSA.

With regard to liquid and airborne discharges, the doses from airborne discharges in the last 10 years have been less than 5 µSv effective dose per annum to a member of the public with the average airborne discharge dose to a member of the public at a 1.6 km radius estimated to be 2.52 µSv in 2013-14. The assumptions underlying the estimates are conservative, i.e. actual exposures are in all likelihood considerably lower. The liquid effluent doses to a member of the public are estimated to be at least an order of magnitude lower at around 0.1 µSv per annum. It should be noted that these discharges and doses are from the entire LHSTC site, and the contribution from OPAL would be less than this.

The events that were considered by ANSTO and ARPANSA to be of safety significance and justified INES classification did not result in release of radioactive substances. In addition to these events, ANSTO reported events such as skin or personal items contamination, resulting in small radiation doses. A number of events resulted in increased radiation levels in certain areas; however, no significant doses were received by the personnel.

4.9.4 Has the licence holder shown the capacity for complying with the regulations and licence conditions?

ANSTO, being the only operator of nuclear installations in Australia, and with experience from two earlier reactors (MOATA, licence surrendered 2010; and HIFAR, permanently shut down 2007), has considerable capacity to safely operate its facilities. As pointed out by Dr Loy in his licence decision, the commissioning of the OPAL Reactor meant that the support of expertise from the vendor, INVAP, would be wound down so that ANSTO became effectively the 'owner' (in safety-related sense) of the reactor and of all supporting technical and procedural arrangements for its safe operation. Dr Loy expressed confidence in the way ANSTO was assuming the 'ownership'. While he noted occurrences of non-compliance with his previously issued construction licence, he had not detected any pattern of systematic non-compliance.

Various aspects of safety are monitored by ARPANSA staff by reviewing the quarterly reports, by performing inspections, by reviewing licence applications (e.g. for making relevant changes with implications for safety under regulation 51), and by other means. The RAR lists 25 inspections over the period 2006 – 2011 (see section 3.1 of the RAR). While there have been observations that justify improvements on ANSTO's part, if anything there has been a generally positive trend. Experience since 2011 does not contradict these observations. Over the period covered by the PSR, breaches of licence conditions (one per year) were declared in 2007, 2008, 2009 and 2010 (section 4.1 of the RAR). In all instances, these breaches related to regulation 49 (compliance with plans and arrangements for managing safety), *viz.* the appointment of an OPAL Shift Manager that did not follow the appropriate accreditation process; a breach of the OPAL Operational Limits and Conditions; a change of the OPAL Reactor shift roster did not follow appropriate risk management control process; and, a non-compliance with requirements for the Main Control Room documentation. In recent years, three breaches were declared from 2012 up to September 2014, all relating to regulation 49. The breaches concerned: use of unauthorised tools during fuel assembly clamping; non-compliances with instructions for management of clear plastic at the pool top; and, deviation from requirements for the staff during a specific utilisation operation.

Continuous vigilance by the operator and regulator coupled with the implementation and maintenance of a good safety culture, should keep the number of breaches and other occurrences with implications for safety as low as reasonably achievable. The level of redundancy and reactor design defence-in-depth takes into account the possibility of occurrences with safety significance so that consequences are mitigated. Nevertheless, vigilance remains of prime importance in the effective management of safety; essential elements are further outlined in ARPANSA's guidelines[26] (see also footnote 17). Dr Loy also commented on the need for continuous vigilance of safety culture in his decision to issue ANSTO with an operating licence for the OPAL Reactor. This state of 'chronic unease' with the technical, procedural, behavioural, and organisational contributors to safety promotes continuous improvement of the same and a climate where production and delivery is not allowed to take priority over safety.

[26] ARPANSA (2013) Regulatory Guide: Plans and Arrangements for Managing Safety, v4 http://www.arpansa.gov.au/pubs/regulatory/guides/REG-LA-SUP-240B.pdf

I do not doubt that ANSTO has the *capacity* to comply with the regulations and licence condition. The level of compliance *in practice* is demonstrated by examples of improvements through better practices as well as by instances of breaches of licence conditions. While the compliance thus can be improved, it does not give rise to general concern over the safety of OPAL operations.

Conclusion:
With regard to whether the conduct can be carried out without undue risk to the health and safety of people and the environment; justification; optimisation; and, capacity to comply with the regulations and licence conditions: I consider that the record of events demonstrates that the conclusions recorded in the 2006 decision to issue ANSTO with a licence to operate the OPAL Reactor have been borne out in practice; although the framework for safety has been reviewed and revised in the meantime, no fundamental new elements have been introduced to this framework that in a major way changes the basis for licensing of the OPAL Reactor; the licensing basis as far *as factors identified in section 41 of the Regulations* go, thus remains valid. However, the management of spent fuel and the final management of solid or solidified radioactive waste remain an unresolved issue, and the maintenance and continuous improvement and the safety culture should be given priority.

5 After-action Programme

The ARPANSA reviewers have considered the After-action Programme for implementation of the actions identified during the course of the PSR, as well as the time-line for implementation. ANSTO has also committed to implement the recommendations made by ARPANSA based on ARPANSA's review of the documentation, and recommendations by the international peer review team, and will report six-monthly on progress. I agree with the ARPANSA reviewers in their assessment of the After-action Programme; however, I consider it good practice to mandate its implementation, and I have therefore issued a specific licence condition to that effect. This issue is further considered in section 6.3.

6 Conclusions; removal of licence conditions; and, issuance of new licence conditions

6.1 Removal of Licence Condition 13

I am satisfied that the Periodic Safety Review, and the documentation provided to ARPANSA in this regard, fulfil Licence Condition 13 of Facility Licence F0157. I am also satisfied that the information submitted by ANSTO in relation to Licence Condition 13 provides adequate assurance of the safety of the OPAL Reactor to allow its continued operation. This conclusion should normally be considered valid for a period up to the next PSR, i.e. in this case for a period of about 10 years, and is valid for the reactor as currently designed, maintained and operated; changes may require specific approval and any safety-related events during future operations may necessitate reconsideration.

Licence Condition 13 can be removed.

6.2 Removal of Licence Condition 7

Licence Condition 7 relates to safety culture. While the conditions have been in place since 2006, they have not been optimally designed in terms of accountability for safety culture, including monitoring and reporting to ARPANSA. This does not in any way suggest that ANSTO ignores safety culture. However, issuing a licence condition on safety culture as a separate entity rather than integrated with *all* considerations of safety, has not promoted a natural and effective mechanism for exchange of information between ANSTO and ARPANSA on this issue.

On that basis I remove Licence Condition 7.

However, the substance of Licence Condition 7 is integrated into the plan to implement the findings from the PSR, and will be reported on during the implementation; this plan is subject to a new licence condition as outlined below.

6.3 Licence condition on implementation of actions resulting from the first PSR

The PSR has provided ANSTO (and ARPANSA) with valuable information and given rise to a significant number of recommendations, which when implemented will support the future safe operation of the OPAL Reactor. ANSTO has logged the identified actions in the After-action Programme. The significance of the Programme calls for some formality. I also note that this was considered of utmost importance by the NSC in its correspondence to me on the matter (see footnote 12). E.g. the NSC advised as follows:

"The PSR provides a program or plan of 'lessons-to-be-learned'. However, it is important that these become lessons actually learned (i.e. tangible changes made to procedures, practices and operations). ARPANSA should be satisfied that the after-action program is appropriate and also hold ANSTO to account for ensuring that the program is adequately followed through and monitored."

Based on considerations reviewed in this Statement of Reasons, the advice from the NSC, and the conclusions on accountability for safety culture in section 6.2 and elsewhere in this Statement of Reasons, I issue the following licence condition:

> *The Licence Holder must, by 30 June 2015, submit to the CEO of ARPANSA a plan to implement the actions resulting from the first Periodic Safety Review in a form acceptable to the CEO of ARPANSA and report on progress in implementing the plan on a six-monthly basis. The plan must include provisions for analysis of interdependencies between safety factors and a program to support continuous improvement in the safety culture, including regular surveys by an independent organisation of the safety culture within the operating organisation.*

6.4 Licence condition on future PSRs

In considering a relevant time for the next PSR, I take note of the usual 10-year interval for PSRs for power reactors. While research reactors are generally used for a variety of purposes, which may change with time, I consider ANSTO has now gained substantial experience as to the safety

performance of the OPAL Reactor; which justifies the move to a longer time interval. A plan for the next PSR should be submitted two years in advance of the time the PSR is submitted. I consider inclusion of an international peer review of the safety of the OPAL Reactor in connection with the PSR to be good practice, which provides an effective mechanism for operational and research-related feedback. Requesting the plan to be submitted by 2019 effectively gives ANSTO five years to implement the After-action Programme and gain further operational experience before submitting the plan. A 10-year cycle for subsequent PSRs seems reasonable at this point, but can be varied according to circumstances and experience.

On the basis of the above, I issue the following licence condition:

> *The Licence Holder must carry out a Periodic Safety Review that re-examines the safety of the OPAL Reactor taking into account operating experience and international best practice in radiation protection and nuclear safety. A detailed plan for the Periodic Safety Review must be submitted to the CEO of ARPANSA no later than 30 November 2019. The plan and the subsequent carrying out of the Periodic Safety Review must follow the relevant regulatory guidance and must include an international peer review of safety of the OPAL Reactor. A comprehensive report and supporting documentation on the findings of the Periodic Safety Review and resulting Action Plan must be submitted to the CEO of ARPANSA no later than 30 November, 2021. The Licence Holder must subsequently perform Periodic Safety Reviews at times decided by the CEO of ARPANSA.*

6.5 Further issues for ANSTO to consider

The RAR of the OPAL Reactor PSR suggested twelve recommendations to ANSTO. In addition to the expectations integrated into the new licence condition (e.g. safety culture, action progress reporting), ARPANSA's review identified some shortcomings ANSTO should consider. Details and reasoning for the recommendations are described in the RAR (see footnote 10).

A few RAR recommendations relate to the presentation of the information submitted, e.g. referencing of the support documentation, substantiation of some assertions made in the submission and justifications of actions resulting from the PSR.

The second group of the RAR recommendations address gaps found in some ANSTO's analyses. For example, the performance analysis did not include the event cause/contributor analysis in detail; human factor consideration did not fully address all OPAL areas of operation; and the OPAL Business Management System analysis lacked some assessments.

Other recommendations concerned the OPAL operation projection for the next PSR period. For instance, the effectiveness of the current surveillance programme for the radiological impact of the reactor on the environment was not assessed in the light of the projected future operation.

I am satisfied that a number of the shortfalls have been addressed within the regulatory review process and requests for additional information and the rest will be added to the After-action programme. The outlined recommendations highlight the areas for improvement. Where appropriate, ARPANSA will reflect these findings in the PSR guidance currently under development.