Australian Government

Australian Radiation Protection and Nuclear Safety Agency

Statement of Reasons

Decision by the delegate of the CEO of ARPANSA on

Facility Licence Application A0266 from the

Australian Nuclear Science and Technology Organisation (ANSTO)
to Prepare a Site for, and Construct the

ANSTO SyMo Facility

13 May 2014

This Statement of Reasons does not form part of Facility Licence F0266 and in the event of any inconsistency between the Licence and the Statement, the requirements and licence conditions in Facility Licence F0266 will prevail.

Contents

1 The Licence Decision

On 13 May 2014, I decided to issue a licence under section 32 of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act), to the Australian Nuclear Science and Technology Organisation (ANSTO), to prepare a site for, and construct a *controlled facility* at the ANSTO Lucas Heights Science and Technology Centre (LHSTC), namely, the ANSTO *SyMo Facility* (referred to as the *SyMo Facility* in this Statement of Reasons). The licence application, signed by the Chief Executive Officer (CEO) of ANSTO, Dr Adrian Paterson, is dated 6 August 2012. Under regulation 6 of the *Australian Radiation Protection and Nuclear Safety Regulations 1999* (the Regulations), the proposed facility is a *prescribed radiation facility*.

Under section 35 of the Act I may impose licence conditions when I issue the licence. I have included the standard condition of licence relating to quarterly reporting.

The ARPANSA assessor identified that the HAZOP analysis and the risk assessment study for the *SyMo Facility* predates the final design of various elements of the facility. Final detailed design for the in-hot-cell and materials processing machinery will come at a later stage in the project and therefore I have recommended that this matter should be resolved once the final design is fixed and prior to authorisation for *Operation* of the facility. Therefore, the HAZOP analysis and risk assessment for the *SyMo Facility* should be revised and submitted to ARPANSA with applications to construct items that come into direct contact with the radioactive waste material. As a consequence, I have made the following licence condition:

> *The licence holder must not construct items of plant that will come into direct contact with the radioactive waste material during the Synroc process without the prior written approval of the CEO of ARPANSA. Applications for approval must demonstrate that the design is informed by comprehensive risk identification and hazards assessment and that construction will be undertaken under an appropriate quality management system.*

Considering that the proposed facility is a first of its kind facility for conditioning of intermediate level liquid waste applying Synroc technology, it is important that safety aspects of routine operation are clearly understood. In order to address this matter ANSTO has undertaken to perform a full scale trial using non-radioactive material as part of testing and commissioning of the plant and equipment of the facility. ARPANSA proposes to authorise full scale non-radioactive testing as part of commissioning under the first phase of an operating licence authorisation. ARPANSA will conduct inspection of testing and commissioning and will consider the results of this trial closely prior to authorising routine operation of the facility. The results of full scale trial will provide better understanding of the operation of the facility and will be important to develop procedures for operation and also for providing training to operators. I consider a full scale trial to be good practice when implementing new technology. I will advise ANSTO to provide the results of the full-scale trial as part of the full operating licence application for the facility.

The ARPANSA assessor notes that details of the commissioning procedures are not available and are expected to be developed based on the acceptance testing and the results of the full-scale trial. Therefore, the commissioning of the facility using non-radiological material will form part of the licence application for operation of the facility. As a consequence, I have made the following licence condition:

The licence holder must not undertake any testing using radioactive material or full plant testing of the facility using non-radioactive material as part of the construction.

The licence remains in force until it is cancelled or suspended under section 38 of the Act or until such time as it is surrendered under section 39 of the Act.

2 Reaching the Decision

2.1 The documentary evidence

The documentation submitted by ANSTO in support of the application including supplementary documentation requested by ARPANSA regulatory officers is listed in Appendix 1 of the Regulatory Assessment Report (RAR) R13/10192[1].

The primary evidence before me was the application, the supplementary documentation and the following:

a. the RAR referred to above;
b. international guidance relevant to international best practice (IBP);
c. regulatory guidance material, developed for applicants and for ARPANSA assessors, as referred to in the RAR and in this Statement of Reasons;
d. correspondence in relation to the decision of the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) on the proposed facility not being a controlled action under the *Environment Protection and Biodiversity Conservation Act 1999* (the EBPC Act) on 19 February 2013 (see Appendix 3 of the RAR);
e. the Radiation Protection Series suite of documents developed to support and promote national uniformity in radiation protection and nuclear safety across Australian jurisdictions;
f. discussions on the subject held with the Nuclear Safety Committee (NSC); the NSC is established under section 25 of the Act to, among other things, advise the CEO on matters relating to nuclear safety and the safety of controlled facilities; summary of meetings are available on the ARPANSA website[2]; and
g. submissions received during the public consultation period including issues raised during the community information session organised by ARPANSA at the Engadine Community Centre, Sutherland, on 16 May 2013. Transcripts are available on ARPANSA's website[3].

The proposed *SyMo Facility* will be at the back end of ANSTO's newly proposed Mo-99 manufacturing *ANM Facility* for which the CEO of ARPANSA granted a Licence to prepare a site on 4th October 2013. The intermediate level liquid waste (ILLW) arising from the *ANM Facility* is planned to be treated and solidified in an inert matrix using what is referred to as the synthetic rock, or SynRoc, technology. Additionally, the *SyMo Facility* will be used to similarly treat current alkaline ILLW from the building 54 Mo-99 production plant and legacy acidic ILLW. The *SyMo Facility* is a *prescribed*

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1 Lead reviewer was Dr Samir Sarkar, Regulatory Services Branch. Mr Martin Dwyer, Branch Head, Regulatory Services Branch, Mr Jim Scott and Mr John Ward, Regulatory Services Branch, Mr Selva Kumar, Legal Advisor, and Dr John Baldas, Medical Radiation Services Branch, were involved in the review of the application and of the RAR. Other ARPANSA regulatory officers were consulted as necessary.

2 http://www.arpansa.gov.au/AboutUs/Committees/nscmt.cfm

3 http://www.arpansa.gov.au/Regulation/Branch/consultation.cfm

radiation facility under regulation 6. Although it is not mandated in the Regulations to invite submissions from the public when making a decision whether or not to license such a facility, the application was included in the consultation process established for the *ANM Facility* considering its interface with the *ANM Facility.* The details of the proposed facility were presented at the community information session held at the Engadine Community Centre on 16 May 2013.

2.2 Matters the CEO must take into account when issuing a facility licence

The Act stipulates that the CEO, in issuing a facility licence, must take into account international best practice (IBP) in radiation protection and nuclear safety as it relates to the application and any matter specified in the Regulations. In addition, the Regulations specify information that *may* be requested by the CEO.

2.2.1 International best practice

Section 32 (3) of the Act mandates consideration of IBP but the Act does not provide a definition of IBP. The question of what constitutes IBP was discussed by Dr Loy (previous CEO of ARPANSA) in his Statement of Reasons[4] underpinning the decision to licence ANSTO to operate the Open Pool Australian Lightwater (OPAL) reactor. Dr Loy concluded:

> *"….taking into account IBP relating to radiation protection and nuclear safety with regard to the application before me involves the following being considered:*
>
> *a. the radiation protection and nuclear safety objectives included as a part of the design, compared with those laid out in the international safety framework that I find international best practice in radiation protection and nuclear safety;*
> *b. the specific safety features of the design compared to those recommended in the international safety framework and most successfully applied in recent reactor designs;*
> *c. the management of the design and construction project, the codes and standards applied to the design and construction of systems important to safety, compared with management approaches to the codes and standards used for similar systems in reactors designed in other countries with best practice safety systems; and*
> *d. the design outcomes for occupational radiation doses, discharges to the environment and consequent radiation doses to the public, and the likelihood of core damage, compared with those achieved in recent research reactors in advanced countries."*

Although Dr Loy's statement quoted above refers specifically to the construction of the OPAL reactor, I consider the principles embedded in the statement to be relevant to controlled facilities in general.

I have considered IBP, as relevant to different elements of my decision, in this Statement of Reasons.

2.2.2 The Regulations

Sub-regulation 41(3) stipulates matters the CEO must take into account in deciding whether to issue a facility licence. These are:

a. whether the application includes the information asked for by the CEO;

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[4] http://www.arpansa.gov.au/pubs/regulatory/opal/op/oplic_reasons.pdf - 764 kb - [pdf] - 19 Jul 2006

b. whether the information establishes that the proposed conduct can be carried out without undue risk to health and safety of people, and to the environment;
c. whether the applicant has shown that there is a net benefit from carrying out the conduct relating to the controlled facility;
d. 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;
e. 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;
f. whether the application has been signed by an office holder of the applicant, or a person authorised by the office holder of the applicant; and
g. if the application is for a facility licence for a nuclear installation – the content of any submissions made by members of the public about the application. (not mandatory in this case)

I have taken the above matters into account in making my decision and my reasons for issuing the licence are set out in this Statement of Reasons.

2.2.3 Other matters

Schedule 3, Part 1 of the Regulations specifies information that may be requested by the CEO – and that, if submitted, will be considered by the CEO when making a decision. ARPANSA has issued guidance on specific matters to consider when submitting such information, as referred to in the RAR and in this Statement of Reasons.

I have considered matters referred to in Schedule 3, Part 1 of the Regulations in this Statement of Reasons.

My decision is further informed by ARPANSA's ongoing licensing activities and compliance monitoring of activities at the ANSTO LHSTC. This information is not part of the information provided in support of the application and on which my decision is based. Any such information that I am aware of may, however, improve my understanding of matters of general importance to, and my confidence in, the safety of operations at ANSTO. Mention of such factors, where relevant, has been made in this Statement of Reasons.

For the purpose of my Statement of Reasons, *health* and *safety* refers to all factors that contribute to *protection of people and the environment from the harmful effects of ionising radiation*, which includes radiation protection and safety, nuclear safety, waste safety, transport safety, physical protection and security and emergency preparedness and response unless any such factor is referred to specifically. Consideration of safety as it relates to other matters, *e.g.* as covered in the work health and safety legislation, is outside of my mandate.

3 Reasons for my decision

In this section, I summarise my considerations in relation to the evidence before me against the provisions set out in the Act and the Regulations. I deal with the issues specified in sub-regulation 41 (3) in sections 3.1 to 3.6. Consideration is given to IBP and to other matters detailed in Schedule 3, Part 1 of the Regulations, as and when relevant.

3.1 Does the information include information asked for by the CEO?

In this section I consider in more detail four aspects that relate to the information submitted in support of the application; *viz*. the implications of a staged licensing process; the purpose and general design of the facility; the information submitted on site characteristics; and, finally, whether sufficient information has been submitted for the purpose of reaching a decision on authorisation to *prepare a site* and to *construct* the controlled facility.

3.1.1 Implications of a staged licensing process

It is implicit in the Act and the Regulations that the licensing of a facility will go through a number of stages, each covered by a licence. Schedule 3, Part 1 of the Regulations lists the general information that may be required to be submitted for all facility licence applications and the specific information that may be required to be submitted when applying for each of the licences listed below, namely to:

a. prepare a site for a controlled facility;
b. construct a controlled facility;
c. possess or control a controlled facility;
d. operate a controlled facility;
e. decommission a controlled facility; and
f. abandon a controlled facility.

An application may, depending on the nature of the facility, combine information related to more than one stage; however, separate licences will normally be issued. The application submitted by ANSTO is seeking authorisation to prepare a site and to construct a controlled facility.

The staged licensing process is aligned with the framework typically used to manage major projects. A staged project development and licensing process, which involves sequential regulatory reviews, mitigates problems arising from potentially important issues overlooked at the onset of the project. I consider the staged approach to completion of major projects to be IBP.

The issue of a staged licensing process has been briefly discussed by ARPANSA elsewhere in relation to management of radioactive waste[5]. It was concluded that, notwithstanding the fact that breaking up the licensing process into stages can be considered IBP, it is still necessary for the applicant to provide, at the time of submission of a licence application for a particular stage in the life-cycle of a facility, enough information about the specific stage covered in the application *and* about subsequent stages, to allow the CEO to form a view of the feasibility of the overall concept and the safety implications for the lifetime of the facility. The questions to be answered in relation to the application before me are thus:

a. does the application provide necessary and sufficient information about the purpose of the facility and about the stages subsequent to siting, to allow an informed decision of whether the site and the design of the facility are suitable for the proposed conduct (section 3.1.2); and

[5] Regulatory Guide: *Licensing of Radioactive Waste Storage and Disposal Facilities v2* http://www.arpansa.gov.au/Regulation/wasteguide.cfm

b. with respect to the siting aspect *per se*, does the application provide necessary and sufficient information (section 3.1.3).
c. with respect to the construction aspect *per se*, does the application to construct the *Facility* provide necessary and sufficient information (section 3.1.4).

3.1.2 Purpose and general outline of the facility

The *SyMo Facility* is a proposed purpose built facility at ANSTO LHSTC to apply Synroc technology for immobilisation of waste from ANSTO's Mo-99 production processes. This plant will be built within a new building to be located near the proposed site for the planned ANSTO Nuclear Medicines *ANM Facility.* The *ANM Facility* is subject to separate assessment.

The plant is designed to handle current alkaline Intermediate Level Liquid Waste (ILLW) from the Building 54 Mo-99 production plant, future alkaline ILLW from ANM and acidic legacy waste stored in both the Building 57 ILLW tanks and as solid waste in TS1 containers from the previous Mo-99 production plant.

Once waste is processed by the Synroc plant, using specialist equipment inside hot cells, the waste is incorporated into a consolidated glass ceramic (alkaline waste) or ceramic (legacy waste) form inside a stainless steel container.

The application states that completed Synroc cans will be moved as a batch inside shielded flasks from the new facility to existing intermediate level solid waste (ILSW) storage pits in B27 for on-going management by ANSTO Waste Operations. The ILSW storage in B27 is operated under ARPANSA licence F0260. The purpose and characteristics make that facility a *nuclear installation* under regulation 11.

No other purpose has been stated by the applicant or is considered in ARPANSA's review of the licence application.

The application outlines in general terms the processes for treating the liquid waste material. The key systems include: the transfer system; storage tanks; transfer waste room; process system room; filling hot cells; evacuation bake-out and sealing hot cells; unloading hot cell; and auxiliary system covering off-gas, active ventilation and instrumentation. Consideration is given to the implications of the operations on site and outside the perimeter of the LHSTC.

The RAR developed by the ARPANSA assessors has considered the material submitted by ANSTO in support of the application. The material goes into some detail relating to both the general and specific aspects of safety at the site. This includes general information (RAR section 2.1), the plans and arrangements for managing safety (RAR section 2.2), the specific site aspects (RAR section 2.3).

ANSTO performed accident analyses for this facility and this was included in the Preliminary Safety Analysis Report (PSAR) as required by Part 1 of Schedule 3 of the Regulations and this is reviewed in section 2.4 of the RAR. ANSTO considered that the bounding case accident for off-site dose is a severe earthquake causing damage to the feed tank and bunker, and recommended this accident as reference accident for the *SyMo Facility*.

For all the aspects mentioned above, the ARPANSA assessors concluded that sufficient information is provided. I agree for the purpose of the siting and construction licence, but note that detailed information about radiation exposure risks to staff during operation, particularly during more

invasive maintenance tasks for the facility is scarce. ARPANSA expects to receive more detailed information as final detailed design of the equipment and the plant in the facility is completed. I expect ANSTO to give detailed radiation exposure mitigation information based on detailed risk identification analysis on final equipment design and procedures for the facility ahead of applying for an operating licence, or as part of the application for an operating licence.

I note that ANSTO has indicated the secondary waste to be generated (e.g. maintenance waste) during operation of the facility and the quantity of such waste will be estimated during the trial of the proposed full-scale plant. I have also considered the features considered in the design to facilitate decommissioning and details of design features for decommissioning are presented in the RAR (section 2.3.2.7). I am satisfied with the features considered in the design to facilitate decommissioning with an aim to minimise exposure during decommissioning.

3.1.3 The site

For the purpose of an authorisation to *prepare a site* for a controlled facility, I may request (as specified in Schedule 3, Part 1 of the Regulations) *a detailed site evaluation establishing the suitability of the site*; and information on *the characteristics of site, including the extent to which the site may be affected by natural and man-made events*.

Section 2.3 of the RAR concerns the characteristics of the site. The ARPANSA assessors have reviewed the information submitted and noted that a detailed analysis of the characteristics of the site was performed during the process of licensing the OPAL reactor. International best practice related to the site evaluation for a nuclear facility can be found in the International Atomic Energy Agency (IAEA) Safety Requirements: *Site Evaluation for Nuclear Installations*, NS-R-3, published in 2003. A draft IAEA Safety Guide DS433: *Safety Aspects in Siting for Nuclear Installations* (2013) which provides guidance for meeting the international safety objectives in the siting of a nuclear facility has also been available to the assessors[6]. Factors to be considered during the siting stage have also been listed in the previously mentioned guide on waste facilities (see footnote 5). The *SyMo Facility* is not a Nuclear Installation (NI), it is a Prescribed Radiation Facility (PRF). The previous evaluations during the licensing of the OPAL Reactor and more recent assessment for the *ANM Facility* confirm the suitability of the site for the *SyMo Facility*.

The site evaluation considers:

a. the effects of external events occurring in the region of the particular site;
b. the implication on relevant safety elements when multiple facilities are collocated on the same site (specifically, the collocation of a new facility at an existing site);
c. the characteristics of the site and its environment that could influence the transfer to persons and the environment of radioactive material that has been released; and

6 *Safety Aspects in Siting for Nuclear Installations* (IAEA draft DS433, 2013)

d. the population density and population distribution and other characteristics of the external zone in so far as they may affect the possibility of implementing emergency measures and the need to evaluate the risks to individuals and the population.

The RAR considers a number of aspects related to the site:

a. the radiological baseline, based on the ANSTO radiological survey results, will establish a point of reference for assessing the changes to the radiological situation on site caused by the operation of the facility);
b. geography, hydrology and land use;
c. external events considered within the boundaries of the design basis: bushfires, seismology and meteorology;
d. human events; and
e. demographic considerations.

The ARPANSA assessor noted in the RAR that the preliminary risk assessment for the SyMo Facility showed that there were no credible scenarios with the potential to cause significant dose (i.e. occupational effective dose of greater than 15 mSv on-site or 1 mSv for a member of the public off-site) beyond the facility itself.

I consider the totality of site information available for the LHSTC, and for the specific location of the proposed facility, provided by ANSTO to be sufficient to proceed with reaching a decision on authorisation to *prepare a site* and to *construct* the *SyMo Facility*.

As part of the *ANM Facility* licence evaluation, information suggested that severe external events which might lead to accidents 'beyond design basis' are highly unlikely. However, the LHSTC is located in an area within Sydney's south-west that is growing in terms of population size. This is relevant to the size of the population that may be exposed to radiation in the event of an accident and to the effectiveness of the operations of the rescue service in the event of a severe accident. Population and demographic projections for 2046 have been considered in this analysis.

The ARPANSA assessor notes that the information on radiological baseline for the proposed site is required as it will be used during the construction, operation and decommissioning of the facility to assess its impacts on the environment and the effectiveness of decommissioning activities. The information on radiological baseline is acceptable. ANSTO has undertaken a survey of the construction site and has provided the results of the survey to ARPANSA.

ANSTO states that the facility is likely to be well maintained and cared for over its lifetime. Thus it is likely that decontamination of dismantled equipment will be possible and that the building could be demolished or refurbished as required. ANSTO further states that a decommissioning Safety Analysis Report indicating waste to be removed will be prepared as part of the decommissioning licence application.

The ARPANSA assessment found that ANSTO has considered the following key aspects in the design of the facility to facilitate decommissioning:

- space and accessories for installation of removable biological shield for working in high radiation areas

- provisions for remote decontamination of systems and components
- selection of components and structures for easy decontamination and dismantling
- selection of surface finishes for easy decontamination
- provisions for adequate lifting and transport devices to facilitate the removal of decommissioned material including radioactive waste
- the exit route for removing decommissioned material including radioactive waste

The ARPANSA assessor further notes that for other nuclear installations operating at the Lucas Heights site, ANSTO adopts an approach to minimise exposure and waste generation by selecting suitable construction materials and also uses a facility layout that is suitable for decommissioning. This matter will be further considered when assessing the licence application for operation.

3.1.4 Construction

The design of the facility has been assessed against the ARPANSA regulatory assessment criteria[7] for design of controlled facilities which requires that an applicant implement principles of defence-in-depth, use of physical barriers, independency and diversity between levels of defence in depth and greatest emphasis on the first level of defence. Section 3 of the SyMo (PSAR) describes the safety principles followed in the design of the facility. ANSTO described each level of the defence-in-depth principle and stated that the defence-in-depth approach was adopted to ensure that the design and operation of the plant incorporates multiple and diverse levels of protection against the emissions of radioactive materials.

The key systems involved in the SyMo process include:

- transfer of wastes from the ANM Mo-99 facility
- storage tank
- transfer waste room (TWR)
- process system room (PSR)
- filling hot cells (FHC)
- evacuation bake-out and sealing hot cells (EBSHC)
- unloading hot cell (UHC)
- Hot Isostatic Press (HIP) hot cell (HHC)
- auxiliary system (off-gas/active ventilation/instrumentation)

The ARPANSA assessor considers that the HAZOP analysis and the risk assessment study for the *SyMo facility* needs to be reworked to include more details and also extended to cover maintenance and recovery phases as well as normal operation prior to authorisation for operation of the facility. The key aspects of the application were discussed at the ARPANSA Nuclear Safety Committee (NSC) meeting in November 2013[8]. The NSC advised that it was important that more detailed risk, hazard and engineering assessments (such as HAZOPs) are updated and developed during actual construction of the facility, especially for safety significant structures, systems and components (SSCs). Therefore, the HAZOP analysis and risk assessment for the *SyMo facility* needs to be revised and submitted to ARPANSA with the application for a licence to operate the facility. The HAZOP

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[7] Australian Radiation Protection and Nuclear Safety Agency, *Regulatory Assessment Criteria for Design of New Controlled Facilities and Modifications to Existing Facilities*, RB-STd-43-00, Revision 1, October 2001

[8] Minutes of Nuclear Safety Committee, 22 November 2013, D1318751

analysis is acceptable to ARPANSA for the proposed conduct subject to the following recommended licence condition:

> *The licence holder must not construct items of plant that will come into direct contact with the radioactive waste material during the Synroc process without the prior written approval of the CEO of ARPANSA. The submission must demonstrate that the design is informed by comprehensive risk identification and hazard assessment process and that construction will be undertaken in accordance with an appropriate quality management system.*

This approach is also supported by the NSC through a letter to the CEO of ARPANSA dated 21 March 2014.[9]

ARPANSA's assessment has taken into account whether design of the facility is based on technologies and engineering practice that are proven by testing and experience. The assessment has found that the technology of the Synroc process is based on established scientific and engineering principles and the practical application of this technology has been adequately demonstrated. Further details are described in section 2.4.1.2 of the RAR. The assessment also notes that the proposed *SyMo Facility* represents a very significant scale up of the application of Synroc technology.

3.1.5 Conclusions

I am satisfied that the evidence before me, including the RAR and the supplementary material requested and received from ANSTO during the course of the review, provide sufficient information to proceed with reaching a decision on authorisation to *prepare a site* and to *construct* the *SyMo Facility*.

I note that DSEWPaC has determined that the proposed facility does not constitute a controlled action under the EPBC Act.

With regard to whether the information provided in the application includes information asked for by the CEO:

I consider the purpose of the *SyMo Facility* has been satisfactorily stated; that sufficient evidence is before me regarding the basic elements of its design and operations to understand, broadly, the safety implications of the conduct; and that sufficient evidence is before me regarding the characteristics of the site on which it is planned to be constructed to enable me to proceed with reaching a decision on authorisation *to prepare a site* and to *construct* the controlled facility. I consider the inclusion of a licence condition requiring specific authorisation from the CEO of ARPANSA relating to final design and operation information for the hot cell equipment is a prudent approach to construction of this facility.

[9] Letter to the CEO of ARPANSA from Chair of the NSC, 21 March 2014, D1318579

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

The issue here is whether the applicant has demonstrated that there are systems in place to control and limit the risks associated with the proposed conduct, to allow me to conclude that the proposed conduct can be carried out without undue safety risks.

I consider the systems for control and limitation of risks below; the health and environmental implications of the proposed conduct are considered in section 3.4.

3.2.1 Plans and arrangements for managing safety

In accordance with Schedule 3 Part 1 of the Regulations, the CEO may request information on plans and arrangements for safety when reviewing an application for a facility licence. The plans and arrangements outline how the applicant intends to plan and operate the facility whilst achieving satisfactory safety outcomes. ARPANSA has issued comprehensive guidelines in this area[10]. More detailed plans and arrangements for operation will be assessed when considering the application for an operating licence.

The RAR assesses the plans and arrangements for safety as they have been submitted by ANSTO, *inter alia*, the safety management plan (RAR section 2.2.2), the radiation protection plan (RAR section 2.2.3), the radioactive waste management plan (RAR section 2.2.4), the security plan (RAR section 2.2.5) and the emergency plan (RAR section 2.2.6). The RAR also considers the arrangements in relation to the relevant regulatory assessment principles laid out in the *Regulatory Assessment Principles for Controlled Facilities*[11]. It should be noted that an overarching system for plans and arrangements are already applied across the LHSTC and are monitored by ARPANSA as part of the Agency's compliance monitoring of ANSTO.

Whilst it is important that each licence application and regulatory assessment be considered on its own merits, I note that as an organisation, ANSTO has built and successfully sought licences from ARPANSA for several major nuclear and radiation facilities.

As the facility is constructed, and particularly as the full scale trial is undertaken, I expect to see more detailed plans and arrangements relevant to operation. These will be subject to review during evaluation of an application for licence to operate this facility.

I do not reiterate in detail the findings of the ARPANSA assessors. I limit myself here to commenting briefly on safety culture, security, and transport.

3.2.1.1 Safety culture

Safety culture refers to the shared values and beliefs for safety that are prevalent in an organisation. Integration of these values and beliefs into the plans and arrangements is important to prioritise safety appropriately against other organisational goals and thus driving safety performance to the

[10] http://www.arpansa.gov.au/Regulation/guides.cfm
[11] http://www.arpansa.gov.au/Regulation/guides.cfm

highest possible levels. Importantly the integration of human and organisational factors with technological systems contribute to holistic safety.[12]

ANSTO states that it encourages a questioning attitude and adopts a rigorous and prudent approach to work incorporating conservative decision making. ANSTO provides appropriate training and awareness instilled by safety briefings and safety inspections; the use of the STAR (Stop, Think, Act, Review) principle supports a good attitude to safety at work. ANSTO states that through the independent Safety Assurance Committee approval of processes, it ensures that implementation of safety requirements is not subject to inappropriate commercial pressures.

Concerns have been raised, in some cases publicly, over past shortcomings of the safety culture in the current radiopharmaceuticals production facility. This relates to events that occurred at least five years ago and ANSTO has agreed that the safety culture at the time fell short of expectations. I consider the current situation to be satisfactory and that there is a clear commitment from senior management to promoting and continuously improving the safety culture.

3.2.1.2 Security

With regard to physical security, a joint ARPANSA-Australian Safeguards and Non-Proliferation Office (ASNO) working group (the Physical Protection and Security Working Group, PPSWG) has been established to review the proposed and existing security plans and arrangements of the facility. The PPSWG was established under a joint Terms of Reference to ensure that licence holders such as ANSTO are effectively regulated from a security perspective, and that they are afforded the best possible guidance and advice in complying with the relevant Code of Practice[13] and the IAEA INFCIRC/225/Rev.5[14] international requirements enforced by ASNO. The working group has already provided specific guidance to ANSTO on security issues and will continue to provide this guidance as the project advances. I also note that an International Physical Protection Advisory Service (IPPAS) mission has been carried out at the ANSTO premises (and also at ARPANSA) in late 2013. During the IPPAS mission, the physical protection system was reviewed and compared with international guidelines (INFCIRC/225/Rev.4[15]) and internationally recognised best practices. Based on this review, further recommendations for improvements may be provided including follow-up activities and assistance.

3.2.1.3 Transport

Transport of radioactive material continues to be a concern for many stakeholders. Location of the *SyMo Facility* adjacent to the proposed *ANM Facility* will reduce transport for the liquid waste between the two facilities. An underground transfer system is being proposed. Transfer of liquid waste from Building 54 will be via flasks. There will be no offsite transport of radioactive material to

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12 See ARPANSA's Holistic Safety Guidelines and Sample Questions (November 2012)
http://www.arpansa.gov.au/pubs/regulatory/holistic/HolisticSafetyGuidelines.pdf
http://www.arpansa.gov.au/pubs/regulatory/holistic/HolisticSafetyGuidelinesSampleQuestions.pdf

13 Code of Practice: Security of Radioactive Sources. Radiation Protection Series No. 11, ARPANSA 2007

14 http://www-pub.iaea.org/books/IAEABooks/8629/Nuclear-Security-Recommendations-on-Physical-Protection-of-Nuclear-Material-and-Nuclear-Facilities-INFCIRC-225-Revision-5

15 http://www.iaea.org/Publications/Documents/Infcircs/part12.shtml

or from the *SyMo Facility*, other than when immobilised waste is eventually transported to a National Radioactive Waste Management Facility[16].

3.2.2 Conclusions

The RAR concludes that the application to prepare a site and to construct the *SyMo Facility* has included information that establishes acceptable controls for the proposed conduct, which include measures to limit and monitor exposures of the workforce, the public and the environment; and, that the security provisions are satisfactory. I agree with the conclusions reached by the ARPANSA assessors. Based on evidence submitted in support of the application before me, I can proceed with reaching a decision on ANSTO's application for an authorisation to *prepare a site* and to *construct* the *SyMo Facility*.

With regard to whether the information establishes that the proposed conduct can be carried out without undue risk to health and safety of people, and to the environment:

I consider enough evidence is before me regarding the plans and arrangements for safety at the proposed *SyMo Facility* to enable me to proceed with reaching a decision on authorisation to *prepare a site* and to *construct* a controlled facility.

3.3 Has the applicant shown that there is a net benefit from carrying out the conduct relating to the controlled facility?

The issue of net benefit relates to the principle of *justification* in the international framework for safety. The basic elements of the framework as such are laid out in the IAEA Safety Fundamentals[17], in the 2007 Recommendations of the International Commission on Radiological Protection (ICRP)[18] and in the guidelines on security referred to above. This framework can be considered IBP and is reflected in ARPANSA's Fundamentals: Protection against Ionising Radiation[19].

3.3.1 Benefit of the conduct

The proposed facility will apply Synroc technology to process the current alkaline ILLW from fission Mo-99 production plant, future alkaline ILLW from *ANM Facility* and legacy acidic ILLW into a stable immobilised ceramic and glass form. The proposed process will reduce the volume of the waste and facilitate safe disposal of radioactive waste and will lower the environmental risk. The technology to be used is an innovative approach developed by ANSTO based on the research of a number of years. Therefore, this facility makes significant contributions to the national innovation and research program and supports a broad range of research that is of benefit to the general public and scientific community. Once the facility is approved for operation it will involve occupational exposure to ionising radiation that has harmful effects. Considering the engineering and administrative controls to be in place the risk to such harmful effect of radiation is low. The benefits of the facility outweigh the low risks involved in operation of the facility.

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16 For the national plan for management of radioactive waste, see the 4th National Report of the Commonwealth of Australia, submitted October 2011 and reviewed at the Review Meeting under the Terms of the Convention in 2012, http://www.arpansa.gov.au/Regulation/collaborations/jointconv.cfm

17 IAEA Safety Standards: Fundamental Safety Principles. Safety Fundamentals SF-1. International Atomic Energy Agency, Vienna, 2006.

18 The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Annals of the ICRP Volume 37 Nos. 2-4, 2007.

19 Radiation Protection Series (RPS) F-1; http://www.arpansa.gov.au/pubs/rps/rpsF-1.pdf

The ARPANSA assessors consider that there is net benefit from the proposed conduct in the area of radioactive waste management and reduction of environmental risk.

3.3.2 Operational risks and waste management

As noted earlier, DSEWPaC determined that no environmental assessment was required.

As demonstrated in the plans and arrangements for managing safety, discussed in section 3.2.1, the radiation protection plan describes the principles of radiation protection including justification of the conduct, optimisation of radiation protection and limiting the doses to operators and to members of the public.

The plan demonstrates that activities will be carried out well within exposure levels defined in the IBP framework for safety; aspects related to *optimisation* of protection, including accidents, are addressed in section 3.4.

A further consideration is waste management. The *SyMo Facility* is noted in the *ANM Facility* licence application as an important interface for dealing with waste generated through nuclear medicines manufacture. A four-fold increase in the production of Mo-99 will lead to increased generation of intermediate level liquid radioactive waste, destined for conditioning in the planned *SyMo Facility*. I note that ANSTO has not identified any contingency plans in case the *SyMo Facility* does not go ahead or if, for some reason, it becomes inoperable. Requested to explain why such contingency plans have not been presented, ANSTO has referred to its confidence in the technology and that the storage tanks would account for several years of production of liquid waste, if necessary, while the *SyMo Facility* comes on line. This issue was dealt with in the Statement of Reasons relating to the *ANM Facility*. I expect ANSTO to detail its contingency plans ahead of, or as part of, a future application to construct the *ANM Facility*.

3.3.3 Alternatives

Alternatives to the production of Mo-99 are dealt with in the licensing decision Statement of Reasons relating to the *ANM Facility* and I will not repeat them here. Alternatives to the *SyMo Facility* largely rely on a continuation of the current arrangement of long term storage of large volumes of liquid waste from Mo-99 production. This alternative is not considered desirable.

3.3.4 Conclusions

The conclusion of a net benefit relating to Mo-99 production by ANSTO at Lucas Heights was fully explained in the Statement of Reason for the *ANM Facility* siting licence decision. In light of that licence decision, there is also a significant net benefit resulting from the improved conditioning of liquid waste resulting as a consequence of Mo-99 production.

With regard to whether the applicant has shown that there is a net benefit from carrying out the conduct relating to the controlled facility:

I consider enough evidence is before me regarding benefits and risks associated with the proposed *SyMo Facility.* The information as such, provides sufficient reassurance at this stage of net benefit resulting from the conduct to enable me to proceed with reaching a decision on authorisation to *prepare a site* and to *construct* a controlled facility.

3.4 Has the applicant 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 economic and social factors?

The issue considered under this heading relates to the two principles of radiation protection that have to be considered once a conduct involving radiation has been deemed justified, namely, the principle of *optimisation* and the principle of *dose limitation*. These principles rest on the international framework for safety referred to in section 3.3. The principles of radiological protection are considered by ANSTO in the radiation protection plan.

The *optimisation* principle in essence means that all reasonable effort (from cost and societal perspectives) should be made to reduce doses, the number of people exposed and the likelihood of exposure; exposures should be *as low as reasonably achievable,* or ALARA. In order to mitigate any negative consequences for individuals, doses must be maintained within dose limits. To further guide protection, a *dose constraint* can be derived that is lower than the dose limit by an appropriate margin; it would be considered unacceptable to *plan* a conduct so that the constraint is exceeded.

Optimisation applies to all exposed categories of people. Limits and – when defined – constraints, are different for workers and members of the public. For wildlife, ICRP has defined *derived consideration reference levels* that may guide efforts to optimise protection[20]; these and elements of other international frameworks for protection of wildlife have been considered in ARPANSA's Regulatory Guide on waste facilities (see footnote 5).

ANSTO's commitment to the constraints and objectives stated in the radiation protection plan relate to the impact of all activities within the LHSTC.

Optimisation is considered here as relevant to *workers*, to the *public and the environment*, and to exposures from *accidents*.

3.4.1 Workers

The limit for effective dose to workers is, as laid out in the Regulations, 20 mSv annually as an average over five consecutive years, although the dose in a single year can be 50 mSv as long as the five-year average remains the same. As part of the optimisation process, ANSTO has defined a dose constraint of 15 mSv/year effective dose for occupational exposure and an annual 'ALARA objective' of 2 mSv. In addition, ANSTO has implemented an 'investigation level' for effective dose of 1 mSv per month.

The ARPANSA assessor has identified defence-in-depth principles in accordance with the ARPANSA safety principles in the design of the plant and equipment and the facility. This includes use of multiple barriers, monitoring and alarm systems to control abnormal operation and detection of failures, and provisions of control of design basis accidents. The application refers to various types of safety systems and their classifications.

As further final detailed design is completed, it should be subjected to a detailed hazard identification process including the consideration of possible maintenance and repair situations so as to modify and develop the design, operating procedures and maintenance procedures that will

[20] Environmental Protection: the Concept and Use of Reference Animals and Plants. ICRP Publication 108. Annals of the ICRP Volume 38 Nos. 4-6, 2008

ensure that exposure doses to staff are kept to a minimum. This will be an important consideration in evaluation of an operating licence application evaluation.

3.4.2 The public and the environment

ANSTO is obliged under the Regulations to comply with an *effective dose limit* for members of the public of 1 mSv per year. ANSTO has further defined a dose constraint of 300 µSv per year, i.e. about 30% of the statutory dose limit or in the order of 15% of the average annual dose received by any member of the Australian public from all sources. The ALARA objective for members of the public is 20 µSv per year.

The liquid and gaseous discharges from the proposed facility would be below concern for the purpose of protection of wildlife.

ANSTO referred the proposal to site and construct the *SyMo Facility* to the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) for a determination on whether an Environmental Impact Statement (EIS) is required. ARPANSA provided its observations in terms of the processing the intermediate level liquid waste generating from the proposed *ANM Facility*. DSEWPaC decided that the proposed siting and construction of the *SyMo Facility* is not a controlled action under the EPBC Act.

3.4.3 Exposures from accidents

The use of a *reference accident* allows the radiological suitability of a site for a proposed controlled facility to be assessed at the conceptual planning stage, largely independently of the detailed design and before the detailed design of the facility is known. It involves the identification of a severe hypothetical accident, beyond the design basis of the facility, and the assessment of its radiological consequences.

ANSTO considered the bounding case accident for off-site dose. The ANSTO analysis shows that there is no scenario with significant consequences outside the facility and therefore, suggests that the facility comes under hazard category F1. The ARPANSA assessor notes that ARPANSA RAPs recommends a Reference Accident only for a facility of category F2 or F3; therefore, a Reference Accident is actually not required for this facility.

The reference accident analysis for the *ANM Facility* is considered a bounding case study relevant and applicable to the *SyMo Facility*.

3.4.4 Conclusions

The exposures of the public from normal operation of the facility would, on the basis of the evidence presently before me, be very small; the worker doses would be well within statutory limits and current constraints.

Nevertheless, in order to show worker doses are ALARA, particularly with respect to plant recovery and maintenance, I expect ANSTO to further develop a detailed risk identification review of the *SyMo Facility* ahead of, or as part of, the next step(s) in the licensing process.

With regard to 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 economic and social factors:

I consider enough evidence is before me regarding on-site and off-site radiological consequences of the proposed *SyMo Facility* under normal operations, and that the information as such provides sufficient reassurance at this stage of adequate protection of people and the environment from the harmful effects of radiation; that the beyond design basis scenario for accident analysis is appropriate; that the consequences of the reference accident (bounding case accident) scenario are limited and manageable in the long term; and that the evidence before me at this stage enables me to proceed with reaching a decision on authorisation to *prepare a site* and to *construct* a controlled facility.

3.5 Has the applicant shown capacity for complying with these regulations and the licence conditions that would be imposed under section 35 of the Act; whether the application has been signed by an office holder of the applicant, or a person authorised by an office holder of the applicant?

The capability of ANSTO, being the only nuclear operator in Australia and under ARPANSA's surveillance with regard to its compliance with the Regulations and all licence conditions imposed by ARPANSA, is assessed in the RAR as satisfactory. I agree and have little doubt that ANSTO is capable of complying with the Regulations and with the licence conditions that I may impose under section 35 of the Act for the conduct specified in the licence application before me.

The application was signed by the CEO of ANSTO, Dr Adrian Paterson.

Whether the applicant has shown capacity for complying with these regulations and the licence conditions that would be imposed under section 35 of the Act; and whether the application has been signed by an office holder of the applicant, or a person authorised by an office holder of the applicant:

I consider enough evidence is before me with regard to the capability of ANSTO, represented by the CEO for the purpose of this application, of carrying out the conduct defined in the application in a manner that is compliant with the Regulations and with the licence conditions I may impose, to enable me to proceed with reaching a decision on authorisation to *prepare a site* for and to *construct* a controlled facility.

3.6 The content of submissions made by members of the public about the application

3.6.1 Process

Whilst the *SyMo Facility* is not a nuclear installation, it has been considered in conjunction with both the *ANM Facility* and *Interim Waste Store* licence applications and was included in the public consultation process required under regulation 40 of the Regulations.

The public was advised of the application, and submissions were invited in the following ways:

a. through a notice published in the Australian Government Gazette on 8 May 2013;

b. by posting information on the ARPANSA Website from 8 May 2013;
c. through an advertisement in The Australian newspaper on 8 May 2013;
d. through an advertisement in the St George and Sutherland Shire Leader and the Liverpool Leader on 8 May 2013 (and further advertisements in the St George and Sutherland Shire Leader); and
e. at a community information session held at the Engadine Community Centre on 16 May 2013 (attended by approximately 40 community participants).

Copies of the licence application submitted by ANSTO were made available to the public, along with the advice as to how and when submissions could be made. The consultation covered the application for the *ANM Facility*, and applications for a licence to site and construct a facility for the storage of radioactive waste arising from reprocessing of fuel used for the High Flux Australian Reactor (HIFAR), and, finally and as previously mentioned, the application for a licence to site and construct the *SyMo Facility*.

In making a decision on the licence application, paragraph 41(3)(g) of the Regulations requires the CEO of ARPANSA to take into account any submissions received from the public about the application. Section 2.5.6 of the RAR summarises the questions/comments raised in written submissions and during the community information session, and the responses from ANSTO and/or ARPANSA. In view of the relatively small number of submissions and that no fundamentally new or previously unknown issue was raised, the CEO of ARPANSA decided to *not* organise another public forum to discuss the applications in the light of submissions received.

3.6.2 Responses to the submissions

The submissions often covered more than one, sometimes all three, facilities currently subject to regulatory review by ARPANSA. The issues raised in the submissions, ANSTO's response and comments from the ARPANSA assessors have been posted on ARPANSA's website[21].

The submissions relevant to the *SyMo Facility* can be grouped as follows:

a. **If the Synroc system is so safe then why have there been so many successful legal challenges to moving the waste from Lucas Heights to a permanent repository? (question /comment 8):** I consider ANSTO's responses satisfactory. Whilst I note that there is an unresolved court case related to the nomination of Muckaty Station in the Northern Territory as a possible site for a National Radioactive Waste Management Facility (NRWMF), but that case is based around provisions of the Land Rights Act, not any hazard which might be posed by radioactive waste. ARPANSA is not aware of any legal challenge in transferring waste from Lucas Heights.
b. **Is Synroc being used anywhere else in the world? If it is successful in dealing with nuclear waste why did we need to transport our waste overseas if we had this technology at the time? (question/comment 9):** There are literature reports on the use of similar form for managing HLW in other countries. Australian spent nuclear fuel was transported overseas

[21] http://www.arpansa.gov.au/Regulation/Branch/consultation.cfm

for reprocessing. As part of contractual obligation Australia will accept the returned waste arising from reprocessing of Australian spent nuclear fuel. Transformation of liquid waste into highly stable immobilised glass ceramic and/or ceramic form is a technique and that has been around for some time.

c. **A cost/benefit appraisal of Synroc and its reliability are missing from the public information (question/comment 10):** I consider ANSTO's response satisfactory. The issue is commercial in nature and not related to the regulatory assessment.

3.6.3 Conclusions

I conclude that the public submissions (verbally during the community information session and in writing) have raised issues that require monitoring and further consideration in the subsequent stages of the licensing process, and that they correspond to issues identified in the regulatory review. No fundamentally new or previously unknown issue has been identified.

With regard to the content of submissions made by members of the public about the application:

I consider the public consultation has identified issues associated with the application for the proposed *SyMo Facility* that correspond to issues identified during the regulatory review, and reinforces their importance. These issues need further consideration in subsequent licensing stages but are not critical to the stages covered by the application; I may thus proceed with reaching a decision on authorisation to *prepare a site* and to *construct* a controlled facility.

4 Matters for ANSTO to consider

In this Statement of Reasons I have identified issues that require further work and information. I anticipate ANSTO will in the future submit an application for a licence to operate the *SyMo Facility*. Ahead of, or as part of, an application to operate the *SyMo Facility*, ANSTO need to further elaborate on the following:

a. Waste management. This involves further consideration of the following two issues:
   - Operational waste and contingencies (see 3.3.2). This applies in particular to the continued production of intermediate level waste in the case that the *SyMo Facility* does not go ahead or becomes - for whatever reason - inoperable; and, in the case that there are further delays in the establishment of the National Radioactive Waste Management Facility. (Also requested for the ANM Facility)
   - Decommissioning and management of decommissioning waste (see 3.1.3). I consider it IBP to consider the end-of-life aspects of a facility already at the planning stage, i.e. to consider the management of waste before the waste arises. Whilst the proposed facility may only be a small part of the decommissioning activities at the LHSTC, consideration of these aspects at the planning stage is important to avoid the creation of legacy situations.

b. Detailed hazard identification (see 1.0, 3.1.2, 3.4.1). The HAZOP analysis and the risk assessment study for the *SyMo Facility* predates the final design of various elements of the facility and this matter should be resolved once the final design is fixed and prior to authorisation for *Operation* of the facility.

c. Full-scale trial. ANSTO will perform a full scale trial using non-radioactive material as part of testing and commissioning of the plant and equipment of the facility. A full scale trial of plant and equipment will facilitate confirmation of the design objectives and routine operational aspects of the facility, and results of such full scale trial with non-radioactive material will be important in assessing the application for full operation of the facility.

I suggest the information specified above is submitted as part of a safety case (all information and material in support of the safety of the proposed facility) for the operation of the *SyMo Facility*. It will be considered in the review and decision on whether to grant a licence for operation.