Australian Government

Australian Radiation Protection and Nuclear Safety Agency

Statement of Reasons

Decision by the CEO of ARPANSA on Facility Licence Application A0270 from the Australian Nuclear Science and Technology Organisation (ANSTO) to Prepare a Site for the

ANSTO Nuclear Medicine Molybdenum-99 Facility

4 October 2013

This Statement of Reasons does not form part of Facility Licence F0270 and in the event of any inconsistency between the Licence and the Statement, the requirements and licence conditions in Facility Licence F0270 will prevail.

Contents

1 The Licence Decision

On 4 October 2013, 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 a *controlled facility* at the ANSTO Lucas Heights Science and Technology Centre (LHSTC), namely, the ANSTO Nuclear Medicine Molybdenum-99 Facility (referred to as the *ANM Facility* in this Statement of Reasons). The licence application, signed by the Chief Executive Officer (CEO) of ANSTO, Dr Adrian Paterson, is dated 25 October 2012. Under regulation 11 of the *Australian Radiation Protection and Nuclear Safety Regulations 1999* (the Regulations), the proposed facility is a *nuclear installation*. 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 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) R13/08434[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 13 December 2012 (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

[1] Lead reviewer was Dr Samir Sarkar, Regulatory Services Branch. Mr Martin Dwyer, Branch Head, Regulatory Services Branch, Mr Jim Scott, Regulatory Services Branch, Mr Selva Kumar, Legal Advisor, and Dr Rick Tinker, Mr Blake Orr and Dr Marcus Grzechnik, Radiation Health Services Branch, were involved in the review of the application and of the RAR. Other ARPANSA regulatory officers were consulted as necessary. A mature draft of the RAR was reviewed by Mr Robert Lyons, member of the Nuclear Safety Committee.
[2] http://www.arpansa.gov.au/AboutUs/Committees/nscmt.cfm

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 *ANM* Facility is at its *front end* dependent on the Open Pool Australian Lightwater Reactor (OPAL) to provide the neutron irradiation of the uranium targets required to produce, through nuclear fission, molybdenum-99 (Mo-99), a precursor to technetium-99m (Tc-99m) that is used in a variety of medical procedures. The operation of the OPAL reactor itself has not been considered in the RAR or in my decision. It operates under a licence first issued by the then CEO of ARPANSA, Dr John Loy, on 14 July 2006. Reactor operations are monitored through ARPANSA's compliance monitoring activities. Following on from one of the licence conditions imposed by Dr Loy, ANSTO is currently implementing actions that address issues identified in the first Periodic Safety Review (PSR) of the reactor and its operations. Reviews of security, and of emergency preparedness and response, specific to OPAL operations as well as LHSTC-wide, are ongoing.

As to the *back end* of the *ANM Facility*, the liquid waste arisings are planned to be treated and solidified in an inert matrix using what is referred to as the synthetic rock, or SynRoc, technique. I received, on 6th August 2012, an application from ANSTO to authorise the preparation of a site and the construction of a facility at LHSTC to treat liquid intermediate level waste generated from the *ANM Facility* operations utilising this technique. The application for this so-called *SyMo Facility* is currently under regulatory review. It is a *prescribed 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* (see section 3.6). The details of the proposed facility were presented at the previously mentioned 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 in his Statement of Reasons[4] underpinning the decision to licence ANSTO to operate the 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;

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

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 nuclear 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;
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.

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 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* for the controlled facility.

3.1.1 Implications of a staged licensing process

It is implicit in 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 different purposes of a licence, 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 for 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 is suitable for the proposed conduct (section 3.1.2); and
b. with respect to the siting aspect *per se*, does the application provide necessary and sufficient information (section 3.1.3)?

3.1.2 Purpose and general outline of the facility

The purpose of the *ANM Facility* is to produce Mo-99, a precursor to Tc-99m used in radiopharmaceutical applications. The *ANM Facility* is intended to replace the radiopharmaceutical production facility already in operation at LHSTC. The product will be marketed in Australia as well as internationally. The Mo-99 will be produced by nuclear fission using low enriched uranium (LEU), irradiated in a neutron field generated by the OPAL reactor. The purpose and characteristics make the 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. I agree with the ARPANSA assessors, that the purpose has been adequately described. Any future modification or addition to the purpose would need to be considered under the Regulations; potentially, such changes have implications for safety and would in accordance with regulation 51 require prior approval of the CEO of ARPANSA.

The application outlines in general terms the methodology for separating the Mo-99 from the targets by use of proven technology (currently in use at ANSTO and overseas facilities). Consideration is given to the implications of the operations on site and outside the perimeter of the LHSTC, site characteristics have been considered and a reference accident scenario and analysis have been provided.

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) and the accident analysis (RAR section 2.4).

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

For all the aspects mentioned above, the ARPANSA assessors concluded that sufficient information is provided. I agree for the purpose of the siting licence, but note that information about decommissioning and the management of decommissioning waste, i.e. the *end-of-life aspects* of the facility, is scarce. ARPANSA has received information that the planned operational life-span of the facility is 30 years. I expect ANSTO to give decommissioning and other matters related to end-of-life of the facility further detailed consideration ahead of applying for a construction licence, or as part of a construction licence application.

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 accident at the Fukushima Daiichi nuclear power plant that occurred on 11 March 2011 and evolved over the following days and weeks has increased the focus on extreme natural events such as seismicity and associated events, e.g. tsunamis (see for example, the report from a recent IAEA International Experts Meeting[7]).

The site evaluation should consider:

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
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.

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

[7] Protection against Extreme Earthquakes and Tsunamis in the Light of the Accident at the Fukushima Daiichi Nuclear Power Plant. International Experts Meeting, 4-7 September 2012, International Atomic Energy Agency, Vienna, 2012.

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 worst case scenario with the potential for off-site consequences is considered to be an earthquake resulting in release of significant amounts of fission gases. The overall assessment of the site characteristics did not identify any poor aspect of the site.

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* for the *ANM Facility*. The information suggests 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.

3.1.4 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* for the *ANM 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 *ANM 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* for the Controlled Facility.

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 proponent 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 proponent intends to plan and operate the facility whilst achieving satisfactory safety outcomes. ARPANSA has issued comprehensive guidelines in this area[8].

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*[9]. It should be noted that the plans and arrangements are to a substantial extent already applied across the LHSTC and are monitored by ARPANSA as part of the Agency's compliance monitoring of ANSTO.

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

The plans and arrangements consider safety culture, which concerns all the human factors that govern safety; this includes managerial systems, behavioural, organisational, cultural and psychological factors that, together with the performance of the technical systems, contribute to *holistic safety*[10]. Most importantly, safety has priority over production.

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 currently operating 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

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

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[11] and the IAEA INFCIRC/225/Rev.5[12] 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 will be carried out at the ANSTO premises (and also at ARPANSA) in the second half of 2013. During the IPPAS mission, the physical protection system will be reviewed and compared with international guidelines (INFCIRC/225/Rev.4[13]) 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 one of the main concerns of many stakeholders. Naturally, the volume of radiopharmaceuticals being transported will increase as a result of the increased production capacity.

Section 9 of the Radiation Protection Plan gives a commitment to comply with the ARPANSA Transport Code[14] for off-site transport of radioactive material. ANSTO guidance on Radiation Safety - Movement and Transport provides step by step guidance on responsibilities and requirements to be followed for safe transport of radioactive material. This includes controls in movement, packaging, labelling, contamination levels, reporting of incidents/accidents, and non-conformance control. The safety record for transport of this kind of material in Australia as well as globally is satisfactory.

3.2.2 Conclusions

The RAR concludes that the application to site the *ANM Facility* has included information that establishes acceptable controls for the proposed conduct, which includes 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* for the *ANM 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 *ANM Facility* to enable me to proceed with reaching a decision on authorisation to *prepare a site* for a controlled facility.

[11] Code of Practice: Security of Radioactive Sources. Radiation Protection Series No. 11, ARPANSA 2007
[12] http://www-pub.iaea.org/books/IAEABooks/8629/Nuclear-Security-Recommendations-on-Physical-Protection-of-Nuclear-Material-and-Nuclear-Facilities-INFCIRC-225-Revision-5
[13] http://www.iaea.org/Publications/Documents/Infcircs/part12.shtml
[14] Code of Practice: Safe Transport of Radioactive Material, 2008 Edition. Radiation Protection Series No. 2, ARPANSA 2008

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[15], in the 2007 Recommendations of the International Commission on Radiological Protection (ICRP)[16] and in the guidelines on security referred to above. This framework can be considered IBP.

3.3.1 Benefit of the conduct

Justification is about whether the proposed conduct does more good than harm. From a societal perspective, the determination of whether a conduct is justified involves values, policies and priorities. The *ANM Facility* is an Australian Government initiative. The facility will be used for production of Mo-99, which is the precursor of Tc-99m, used in a large number of medical procedures carried out in Australia. The beneficiaries would be all people in Australia that undergo, or will undergo, such procedures using the radiopharmaceuticals produced at the proposed facility over its operational life-span. In a global market where much of the supply currently and in the foreseeable future is satisfied through the operation of reactors that are near to the end of their operational life-span, and/or from reactors using highly enriched uranium (HEU) for Mo-99 production, the main benefit may be the *sustainability* of Mo-99 (Tc-99m) supply, using only LEU. In view of the ageing fleet of reactors globally, a sizeable portion of the international market may also be accessible to ANSTO.

3.3.2 Operational risks and waste management

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

As demonstrated in the plans and arrangements for managing safety, dealt with 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 within 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. A four-fold increase in the production of Mo-99 will also lead to increased generation of intermediate level liquid radioactive waste, destined for conditioning in the planned *SyMo Facility*, currently subject to a separate regulatory assessment. I note that ANSTO has not identified any contingency plans in case the *SyMo Facility* does not go ahead or if it for some reason 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 waste management facility comes on line.

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

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

I do not consider ANSTO's contingency plans to be satisfactory; however I also do not consider the contingency plan to be critical for a decision to authorise ANSTO *to prepare a site* for a controlled facility. I expect ANSTO to detail its contingency plans ahead of, or as part of, a future application to construct the *ANM Facility*.

With regard to waste management, I further note that Sutherland Shire Council, in its submission to ARPANSA during the public consultation process, supported the new facility going ahead provided its production be constrained to only support the Australian market. The Council noted that production for the international market by necessity increases the waste holdings on site beyond what would happen if the production was limited to the Australian market, in particular if there are further delays in the establishment of a National Radioactive Waste Management Facility (NRWMF).

With regard to the NRWMF, enabling legislation (the *National Radioactive Waste Management Act 2012)* is in place. I am not speculating here when a NRWMF may become operational (which, *inter alia*, involves approval of the CEO of ARPANSA for all stages of the licensing process). It is, however, unlikely to start receiving waste earlier than 2020 and will require extensive consultation with a variety of stakeholders during the licensing process. It is possible that an increase in waste holdings at LHSTC, as noted by the Council, will be the result of an expanded production capacity.

I consider that the issues raised by the Council should be addressed by ANSTO as part of its contingency planning for management of the radioactive waste, in particular the management of intermediate level waste, ahead of or as part of, an application for a licence to construct the facility. This will form the basis for future conditions – if any – that I may impose on waste generation and management. I do not consider it being critical to an authorisation to *prepare a site* for a controlled facility.

The issue of decommissioning waste was mentioned under section 3.1.2

3.3.3 Alternatives

Alternatives that may be considered include: supply of radiopharmaceuticals through importation, alternative techniques for production, and alternative sites (in Australia) for production.

On the point of supporting the Australian demand through importations, Dr Loy reasoned in his Statement of Reasons to grant a licence to operate the OPAL reactor in 2006 as follows:

> *"I accept that it would be feasible for Australia to rely upon imports for reactor-produced radioisotopes. There would be some consequences in terms of the availability of some pharmaceuticals and certainly some risks of the disruption from time to time. The Government has chosen not to accept these limitations and risks and this is properly a decision for Government. The production of isotopes for medical application – both diagnosis and treatment – is a benefit to Australia. When weighed against the radiological risks arising from normal operation of the reactor and the management of its radioactive waste, which I believe ANSTO has established to be small, there is clear net benefit to Australian society as a whole."*

Alternative techniques for production of Mo-99 and an alternative site for production may now be not relevant. Most likely minimal - if any - risk reduction would be achieved by use of alternative techniques and sites, and the investment necessary to achieve this would be very considerable in

relation to what is needed in order to utilise and expand the infrastructure at LHSTC. However, the issue of collocation of new facilities with old facilities is an issue that needs consideration, as mentioned in section 3.1.3. In the specific case of the *ANM Facility,* it should be noted that this is a *replacement facility*, albeit with a four-fold increased production capacity compared to the facility that will become obsolete. I therefore do not consider it being a major consideration in a decision to authorise ANSTO to prepare a site for the facility; it will become a consideration in the review of a construction licence application, in the context of all operations at the LHSTC.

3.3.4 Conclusions

I consider the prospect of sustained production of Mo-99 over the next few decades for the Australian and global market to be a tangible benefit for patients in Australia and overseas that require medical procedures based on Tc-99m availability. At this stage, and for the purpose of *preparing a site* for the *ANM Facility*, I consider that enough information is before me to conclude that there is net benefit from the conduct. I note that reactor-based production of radiopharmaceuticals was a significant component of Dr Loy's statement with regard to net benefit of the operation of the OPAL reactor:

> *"I find that there is a net benefit to Australian society arising from the proposed utilization of the OPAL reactor. The detriment that it may cause from increased exposures to radiation to the workers and to the public near the site ……. are small and are far outweighed by the benefit arising from the production of radioisotopes and other applications and the carrying out of research using neutrons."*

I consider the proposed *ANM Facility*, as far as can be judged today, would have negligible (if any considering the *ANM Facility* is a replacement facility) additional impact during normal operations and that Dr Loy's statement, as regards radiopharmaceuticals production, is still valid.

With regard to whether the applicant 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 *ANM Facility* and that 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* for 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; the principle of *optimisation* and the principle of *dose limitation*. They 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[17]; 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; they are unchanged despite the planned four-fold increase in production of molybdenum-99 at the site.

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.

ANSTO states that radiological exposures to workers during the operation of the *ANM Facility* will be within set dose constraints and are expected to be similar to those for the existing Mo-99 production facility. Considering the concept design and the intended production level of Mo-99, it is expected that the *actual* radiation doses to operators during normal operation are likely to remain similar to the doses incurred in the currently operating Mo-99 production facility.

The application states that visitors and short-term workers who may be required to enter and/or perform work within radiological classified areas for periods shorter than one month shall be considered members of the public for the purposes of limiting radiological exposures.

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 30 µSv per year, i.e. about 3% of the statutory dose limit or in the order of 1% 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 constraint and objective are highly restrictive. It is expected that the *actual* discharges of noble gases may increase but stay within the operational limits already established.

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

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

With regard to off-site releases and radiological consequences, and subject to further regulatory review, I had already formed the preliminary view that the new facility may operate within existing limits. This was expressed in a letter to DSEWPaC on 7 November 2012 (Appendix 2 of the RAR):

> *"In relation to the potential for off-site release and radiological consequence, the currently available equipment and technology, if employed and operated correctly, could enable the proposed facility to operate within existing environmental discharge limits set for the existing smaller Mo-99 plant."*

The referral decision of DSEWPaC, informed by my letter of 7 November 2012, was that the proposed facility was not a controlled action if undertaken in a particular manner; including if: "*undertaken in accordance with any Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) licences issued for the proposed facility."*

The preliminary review did not consider accidents, which had not been analysed in any detail by ARPANSA at the time the Agency had to provide the preliminary view to DSEWPaC. I turn to accidents in the next section.

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.

Following discussions between ARPANSA and ANSTO, the ARPANSA assessors have considered a scenario involving an event with serious degradation of the safety systems. The probability for an event of this kind is estimated by ANSTO to be between 1/1 000 000 and 1/100 000 per year. The consequences are determined by the factors governing dispersion and deposition at the time of the hypothetical accident. For the purpose of the ARPANSA review, deliberately pessimistic assumptions were used. In all, this provides a 'bounding scenario', beyond design basis. It is unlikely that a real accident would have worse consequences. However, the issue will have to be revisited against the backdrop of detailed knowledge of the design of the facility which I expect will accompany the construction licence.

3.4.3.1 Doses to members of the public

The accident analysis demonstrates that this scenario may lead to levels of airborne radioiodine for which the estimates of thyroid absorbed dose for a child at the population boundary exceed by a small margin the operational intervention level for iodine prophylaxis, which in Australia is set to 30 mGy[18]. The effective dose may reach values, again at the population boundary, that could lead to recommendations to those living or working close to the facility, to stay indoors during plume passage. The long-term effects, in terms of land use and health implications at the population boundary, would be very small and cause minor, if any, disruption to normal life. Current ANSTO

[18] Recommendations: Intervention in Emergency Situations Involving Radiation Exposure. Radiation Protection Series No. 7. ARPANSA 2004.

emergency plans, while developed for a reactor accident, provide adequate arrangements for the protection of the public for this scenario.

3.4.3.2 Doses to the workers and others on site

The analysis performed by ARPANSA assessors indicates that radiation doses incurred by staff on site during this accident scenario (either ANSTO staff or anyone else being present at the premises), may reach and go above the five-year average for an annual exposure of a radiation worker of 20 mSv. Any doses received by ANSTO staff, rescue workers and others present on site during the emergency would need to meet the requirements of the Australian recommendations on exposures in emergency situations (see footnote 18).

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. Actual doses are not likely to differ markedly from the doses incurred from operation of the existing production facility.

The accident scenario is of low probability and illustrative of a severe accident beyond design basis. The consequences are limited in the short term, and manageable in the long term. Nevertheless, I expect ANSTO to further develop and assess the accident scenarios 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 *ANM 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 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* for 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 a controlled facility.

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

3.6.1 Process

Regulation 40 requires the CEO of ARPANSA to advertise receipt of a licence application for a nuclear installation and to invite submissions.

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 siting and construction of a facility for 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 siting and construction of 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. Appendix 4 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, I decided to *not* organise another public forum to discuss the application(s) 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 are posted on ARPANSA's website[19].

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

a. **Alternative techniques for Mo-99 production, or for medical procedures (question /comment 2, 6, 14, 18):** I consider ANSTO's responses satisfactory. Alternatives (importation, production technique, and location of production facility) were discussed in section 3.3 where I reached the conclusion that, based on the evidence before me, there is net benefit from the proposed conduct, considering the small risks associated with the *ANM Facility* and the benefit from sustained radiopharmaceutical production to the Australian, and global, population. Submission 14 does not consider alternatives directly but the cost of the facilities, which is *one* consideration in establishing net benefit of a conduct.

b. **Generation of waste, particularly plutonium, and its implications for nuclear proliferation; and SynRoc technique for waste management (question/comment 1, 3, 4, 5, 7, 8, 9, 10, 13, 19, 20, 22, 24, 26, 27, 28, 29):** Many of the questions raised on waste management relate to the return of intermediate level waste from France and UK. This issue is considered in ARPANSA's regulatory review of the application from ANSTO to prepare a site for, and construct, an interim store for such waste at LHSTC, and is not directly relevant to the application considered in this Statement of Reasons. With regard to waste arising from operation of the *ANM Facility* I consider ANSTO's responses generally satisfactory. Waste generation and the waste management plan, including contingencies in the case the *SyMo* plant is inoperable and in view of the uncertainty as to when the planned NRWMF may become operational, were discussed in 3.3.2. I have there stated that improved contingency plans need to be developed ahead of, or as part of, an application to construct the *ANM Facility*. I have also requested further information on decommissioning and management of decommissioning waste (see 3.1.2).

c. **Security (question/comment 16):** I consider ANSTO's response satisfactory. Security was considered in section 3.2.1.2.

d. **Transport, emergencies and liabilities (question/comment 11, 12, 15, 17, 25):** I consider ANSTO's responses satisfactory. I expect to again consider the emergency arrangements following further analysis of the reference accident, ahead of or as part of an application to construct the *ANM Facility*.

e. **General aspect of the site, such as population density and risk for bushfires (question/comment 21, 22, 23, 30):** I consider ANSTO's responses satisfactory; however, I expect further consideration of demographic factors being part of the further analysis of the reference accident, as stated under (d) above.

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

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 *ANM 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 stage covered by the application; I may thus proceed with reaching a decision on authorisation to *prepare a site* for 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 near future submit an application for a licence to construct the *ANM Facility* and if a construction licence is granted, ultimately an application for a licence to operate the facility. Ahead of, or as part of, an application to construct the *ANM 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.
    - 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. Accident analysis (see 3.4.3). As the plans for the construction of the facility progress, further analysis of accident scenarios will be expected, involving a range of potential scenarios and mitigation. I expect these analyses to be performed in consultation with ARPANSA staff.

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 construction of the *ANM Facility*. It will be considered in my review and decision on whether to grant a construction licence.