Australian Government

Australian Radiation Protection and Nuclear Safety Agency

Statement of Reasons

Decision by the CEO of ARPANSA on

Facility Licence Application A0285 from the

Australian Nuclear Science and Technology Organisation (ANSTO)
to Construct the

ANSTO Nuclear Medicine Molybdenum-99 Facility

27 June 2014

This Statement of Reasons does not form part of Facility Licence F0285 and in the event of any inconsistency between the Licence and the Statement, the requirements and licence conditions in Facility Licence F0285 will prevail.

Contents

1 The Licence Decision

On 27 June 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 *construct* 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). Under regulation 11 of the *Australian Radiation Protection and Nuclear Safety Regulations 1999* (the Regulations), the proposed facility is a *nuclear installation*.

The licence application, signed by the Chief Executive Officer (CEO) of ANSTO, Dr Adrian Paterson, is dated 22 November 2013

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. While I am satisfied that ANSTO has adequately demonstrated over-all feasibility of the concept and design to allow me to authorise ANSTO to *construct* the *ANM Facility*, a number of safety-related items require specific consideration in the construction phase. This is captured in regulation 54. In addition to the safety category 1 and safety category 2 items identified in the Preliminary Safety Analysis Report (PSAR), and normally captured under regulation 54, I consider some additional safety-related items require specific attention. I have therefore imposed the following condition of licence:

> *The licence holder must seek the approval of the CEO of ARPANSA for construction of any hot cells/cell containment, hydrogen gas and detection system and any cranes along with items identified as safety category 1 and safety category 2 in the Preliminary Safety Analysis Report (PSAR).*

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 Background

This application is the second in a sequence of applications where ANSTO seeks authorisation to: 1) *prepare a site* for the *ANM Facility*; 2) *construct* the *ANM Facility*; and, 3) to *operate* the *ANM Facility*.

A licence to *prepare a site* for the *ANM Facility* (Facility Licence F0270) was granted to ANSTO on 4 October 2013. The Regulatory Assessment Report (RAR) as well as my Statement of Reasons for the decision is available from ARPANSA's website[1].

The present Statement of Reasons builds on the earlier decision. It therefore focuses on the elements that are relevant to the construction of the facility; for details already considered at the

[1] http://www.arpansa.gov.au/News/MediaReleases/mr1_041013.cfm

siting stage I refer to the documentation underpinning the licence to *prepare a site* for the *ANM Facility* (see footnote 1).

2.2 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) R14/05724[2,3].

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. the Radiation Protection Series suite of documents developed to support and promote national uniformity in radiation protection and nuclear safety across Australian jurisdictions;
e. 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[4]; the draft RAR developed by the ARPANSA assessors in support of this decision was reviewed by NSC members and was extensively discussed at the NSC meeting held 20 June 2014; and,
f. submissions received during the public consultation period including issues raised during the community information session regarding the application to *prepare a site* for the *ANM Facility*, organised by ARPANSA at the Engadine Community Centre, Sutherland, on 16 May 2013; transcripts are available on ARPANSA's website[5]; an invitation for submissions regarding the application to *construct* the *ANM Facility* was posted on the ARPANSA website on 6 January 2014 (to be closed 31 January) alongside application information; no submissions were received.

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

Sub-section 32(3) of the Act mandates consideration of international best practice (IBP) in licensing decisions. I reviewed fundamental issues in relation to the question of what constitutes IBP, and took into account IBP as appropriate, in my decision to authorise ANSTO to *prepare a site* for the *ANM Facility* (see footnote 1).

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[2] Lead reviewer was Dr Samir Sarkar, Regulatory Services Branch. Mr Martin Dwyer, Branch Head, Regulatory Services Branch, and Mr John Ward, Regulatory Services Branch, were involved in the review of the application and development of the RAR. Other ARPANSA officers in the Legal Office, the Office of the CEO and in the Radiation Health Services Branch contributed and/or were consulted as necessary.

[3] http://www.arpansa.gov.au/pubs/regulatory/ansto/RAR-ANM.pdf

[4] http://www.arpansa.gov.au/AboutUs/Committees/nscmt.cfm

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

I have made further considerations of IBP as it relates to the specifics of construction, 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 Matters arising from the decision to authorise ANSTO to *prepare a site* for the *ANM Facility*

I did not issue any specific licence conditions (other than on quarterly reporting) in my decision to authorise ANSTO to *prepare a site* for the *ANM Facility*. However, in my Statement of Reason for the decision I foreshadowed information I would require for my assessment of the application to *construct* the *ANM Facility*, *viz*:

- *Waste Management*
  - *Operational waste and contingencies*
  - *Decommissioning and management of decommissioning waste*
- *Accident analysis – further analysis*

I have taken these matters into account in my decision as set out in section 3.1.4.

2.2.4 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 guidelines to applicants applying for a licence to *construct* a *controlled facility*. Those guidelines comprise requests for an applicant to provide the relevant information described in Schedule 3, Part 1 of the Regulations.

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.

For the purpose of my Statement of Reasons, the phrase '*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 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 below. Consideration is given to IBP and to other matters detailed in Schedule 3, Part 1 of the Regulations, as and when relevant. The Statement of Reasons mainly considers matters not previously included in my Statement of Reasons supporting the decision to authorise ANSTO to *prepare a site* for the *ANM Facility* (see footnote 1).

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

As discussed in the decision to authorise ANSTO to *prepare a site* for the *ANM Facility* (see footnote 1), 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, as outlined in schedule 3, Part 1 of the Regulations. The discussion referred to ARPANSA's considerations in relation to management of radioactive waste[6]. 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. I here consider general aspects and aspects relating to the purpose of the proposed facility, its siting and its construction, and matters arising from the earlier authorisation to *prepare a site* for the *ANM Facility.*

3.1.1 Purpose and general outline of the facility

The *ANM Facility* is a proposed purpose built facility at ANSTO LHSTC to manufacture molybdenum-99. No other purpose has been stated by the applicant or is considered in ARPANSA's review of the licence application.

This plant will be built within a new building. The plant is designed to increase the production of molybdenum-99 up to approximately four times the current production levels. The molybdenum-99

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

will be manufactured by neutron irradiation of low enriched uranium (LEU), i.e. uranium with less than 20% content of fissile uranium-235. The use of LEU is considered a major contributor to enhancing international efforts to prevent proliferation of fissile material and can from this perspective be considered international best practice for reactor-based radiopharmaceuticals production. Internationally, there remain a number of significant molybdenum-99 manufacturers yet to move to LEU.

The *ANM facility* is based on established engineering design and operational experience. NTP Radioisotopes of South Africa is a collaborative partner of this project and NTP has almost 20 years of experience of utilising this technique.

The application outlines the processes for manufacturing molybdenum-99 from irradiated uranium targets. The key systems include: hot cells for processing of irradiated target material including dissolution, purification, dispensing and packaging. The facility also has a control room for process control and monitoring, truck bay and crane for deliveries and dispatch and waste removal, plant room for switchboards and plant and equipment, systems for decay of dissolver off-gasses, ventilation systems for supply and extraction of air and contaminated air, laboratory facilities which will be integrated with existing laboratories, storage and active maintenance areas. The design has incorporated defence-in-depth principles and is inherently conservative.

Liquid intermediate level waste[7] will, according to ANSTO's plans, be processed in the *SyMo Facility* for which ARPANSA granted ANSTO a licence in May 2014 to *prepare a site* for, and to *construct*[8]. The plant will utilise the so-called Synroc technique to immobilise the radioactive substances in a ceramic matrix. Completed Synroc cans will be moved as a batch inside shielded flasks from the new facility to existing solid intermediate level waste storage pits in Building 27 for on-going management by ANSTO Waste Operations. The waste store in Building 27 is operated under ARPANSA licence F0260. The purpose and characteristics make this waste store facility a *nuclear installation* under regulation 11.

Consideration is given to the implications of the operations on site and outside the perimeter of the LHSTC.

3.1.2 The site

The site information review was largely completed during assessment of the application for an authorisation to *prepare a site* for the *ANM Facility*. The ARPANSA assessors noted that 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. ANSTO has undertaken a survey of the construction site

[7] The waste classification scheme to be applied in all jurisdictions is outlined in the Safety Guide *Classification of Radioactive Waste,* Radiation Protections Series No 20, ARPANSA 2010, http://www.arpansa.gov.au/Publications/Codes/rps20.cfm Waste is mainly classified on the basis of the requirements for disposal; for intermediate level waste RPS 20 states as follows: *Waste that, because of its content, particularly of long lived radionuclides, requires a greater degree of containment and isolation than that provided by near surface disposal. However, ILW needs little or no provision for heat dissipation during its storage and disposal. Intermediate level waste may contain long lived radionuclides, in particular alpha emitting radionuclides, which will not decay to an activity concentration acceptable for near surface disposal during the time for which institutional controls can be relied upon. Therefore waste in this class requires disposal at greater depths, in the order of tens of metres to a few hundred metres.*

[8] http://www.arpansa.gov.au/News/whatsnew/news1_140513.cfm

and has provided the results of the survey to ARPANSA. The information on radiological baseline is acceptable.

3.1.3 Construction

The design of the facility has been assessed against the ARPANSA regulatory assessment criteria for design of controlled facilities which requires that an applicant implement principles of defence-in-depth, use of physical barriers, and independency and diversity between levels of defence in depth. Section 3 of the 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 elements to prevent/reduce emissions of radioactive substances.

The key systems of the *ANM Facility* include:

Ground floor

- Dissolution hot cell
- Hydrogen converter hot cell
- Purification hot cell
- Evaporation hot cell
- Dispensing hot cell
- Packaging hot cell
- Liquid waste sampling hot cell
- In-process sampling hot cell
- Solid intermediate level waste store and decay hot cell
- Solid low level waste store and decay hot cell
- Truck airlock (flask receipt and despatch)
- Quality control and sample laboratories
- Truck bay for deliveries
- Ancillary equipment such as type B(U) containers and cranes

Furthermore, there will be liquid intermediate level waste and liquid low level waste tanks and bund/shielding enclosures on the north side of the building.

Basement

- Gaseous waste treatment (active ventilation, standard iodine adsorption module (SIAM) filters, carbon column, gas delay tanks).
- Active exhaust system.
- Liquid waste transfer (initial capture and delay with subsequent transfer from holding tanks to decay tanks).
- Truck airlock (maintenance access and waste flask collection).

Mezzanine

- Rear of cells mezzanine (access to top of hot cells, storage, floor hatch through to truck airlock below).

- Mezzanine plant room for instrumentation and control (I&C), uninterrupted power supply (UPS), communications, hydraulics, and mechanical plant and equipment.

The ARPANSA assessors consider that the HAZOP analysis and the risk assessment study for the *ANM Facility* is satisfactory and sufficient for the granting of a construction licence.

3.1.4 Information related to matters arising from the assessment of the application for an authorisation to *prepare a site* for the *ANM Facility*

In my decision to authorise ANSTO to prepare a site for the *ANM Facility* I requested ANSTO to consider a number of factors ahead of, or as part of, the application for an authorisation to *construct* the *ANM Facility* (see footnote 1); these are dealt with below.

3.1.4.1 Waste management

My Statement of Reasons accompanying the licence to *prepare a site* for the *ANM Facility* identified the following two issues with regard to waste management (sections 3.3.2 and 3.1.2):

> *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 3.1.2). 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.*

In relation to the first issue, I note that ARPANSA has now granted a licence to *prepare a site* for, and to *construct*, the *SyMo Facility* (see footnote 8). However, I also requested ANSTO explain their contingency plans should the *SyMo Facility* be delayed or fail. The ARPANSA assessors reported on this in the RAR (section 3.1) and found the contingency plans to be adequate. I agree that a number of options are available, including prolonged storage in existing facilities and alternative solidification techniques.

In relation to the second issue, I have considered the features of the design to facilitate decommissioning; details of design features for decommissioning are presented in the RAR (section 3.2). 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 assessors further note 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.

I agree with the ARPANSA assessors that ANSTO has given end-of-life aspects of the *ANM Facility* reasonable consideration.

3.1.4.2 Accident analysis

My Statement of Reasons accompanying the licence to *prepare a site* for the *ANM Facility* further identified the following issue with regard to accident analysis (section 3.4.3):

> *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.*

ANSTO performed accident analyses for this facility which were included in the PSAR as required by Part 1 of Schedule 3 of the Regulations; this is reviewed in section 2.4 of the RAR. ANSTO considered that the bounding case accident for off-site dose is an unspecified energetic event causing damage to the dissolver tank and bunker.

As requested in the Statement of Reasons supporting the authorisation to *prepare a site* for the *ANM Facility*, the initial reference analysis has been updated to incorporate further understanding of the plant design. Conservative analysis, and independent modelling by ARPANSA, indicated that intervention levels offsite (beyond the LHSTC boundary fence) were not triggered even by an energetic release of a very large source term to the atmosphere. Population and demographic projections up to the year 2046 have been considered in this analysis. I consider sufficient analysis has been performed of reference accident consequences for the current stage in the licensing process.

3.1.5 Conclusions

The RAR developed by the ARPANSA assessors has considered the material submitted by ANSTO in support of the application. The ARPANSA assessors generally concluded that sufficient information is provided. I agree with the ARPANSA assessors' conclusions for the purpose of the construction licence.

I note that some technical information on safety-related items is lacking in detail. This is captured by regulation 54 as applied in a condition of licence accompanying this decision, which is further discussed in section 4.

With the proviso above I am satisfied that the evidence before me, including the RAR and the supplementary material requested and received from ANSTO as part of the application and during

the course of the review, provide sufficient information to proceed with reaching a decision on authorisation to *construct* the *ANM Facility*.

I note that the then Department for Sustainability, Environment, Water, Population and Communities (DSEWPaC; now Department of the Environment) has determined that the proposed facility does not constitute a controlled action under the *Environmental Protection and Biodiversity Conservation Act* (EPBC Act)[9].

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; to enable me to proceed with reaching a decision on authorisation to *construct* a controlled facility. I consider the remaining details of safety-relevant installations should not impede the commencement of construction works; however, I consider the inclusion of a licence condition requiring specific authorisation from the CEO of ARPANSA for specified safety-related items is a prudent approach.

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. The systems were reviewed in the relation to the application for an authorisation to *prepare a site* for the *ANM Facility*, and further review has been performed in relation to the application before me (see the RAR; footnote 2). I agree with the ARPANSA assessors' conclusions as regards the information contained in the application. My references to IBP and my conclusions in the Statement of Reasons (see footnote 1) underpinning my decision to authorise ANSTO to *prepare a site* for the *ANM Facility* still stand.

3.2.1 Conclusions

The RAR concludes that the application to *construct* the *ANM 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 *construct* 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:

[9] Notification of Referral Decision- Not Controlled Action if Undertaken in a Particular Manner, ANSTO Nuclear Medicine Mo99 Facility, EPBC 2012/6598

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 *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[10], in the 2007 Recommendations of the International Commission on Radiological Protection (ICRP)[11] and in the IAEA guidance on security[12]. This framework can be considered IBP and is reflected in ARPANSA's *Fundamentals: Protection Against Ionising Radiation*[13].

3.3.1 Conclusions

The issue of net benefit was discussed at some length in my decision to authorise ANSTO *to prepare a site* for the *ANM Facility*. I note that the ARPANSA assessors consider that there is net benefit from the proposed conduct as documented in the RAR (see footnote 2). I conclude that no information has come to light in the application before me that make me reconsider my position documented in the Statement of Reasons regarding the application to *prepare a site* for the *ANM Facility* (see footnote 1).

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 *ANM 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 *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

[10] IAEA Safety Standards: Fundamental Safety Principles. Safety Fundamentals SF-1. International Atomic Energy Agency, Vienna, 2006.
[11] The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Annals of the ICRP Volume 37 Nos. 2-4, 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] Radiation Protection Series (RPS) F-1; http://www.arpansa.gov.au/pubs/rps/rpsF-1.pdf

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[14]; these and elements of other international frameworks for protection of wildlife have been considered in ARPANSA's Regulatory Guide on waste facilities (see footnote 6).

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

3.4.1 Conclusions

The ARPANSA assessors consider information contained in the application to be satisfactory. I note that protection of workers, the public and the environment under *normal operations* were discussed in my decision to authorise ANSTO to *prepare a site* for the *ANM Facility*. The request for additional information on exposures following *accidents* was discussed in section 3.1.4.2 of this Statement of Reasons. I consider my conclusions to be still valid and further supported by information contained in the application before me.

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 (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 *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.

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

3.5.1 Conclusions

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 capacity 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 *construct* a controlled facility.

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

3.6.1 Process

The application to *prepare a site* for the *ANM Facility* was subject to the public consultation process required under regulation 40. 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.

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 (the *IWS Facility*) for the storage of radioactive waste arising from reprocessing of fuel used for the High Flux Australian Reactor (HIFAR), and, finally, the application for a licence to *prepare a site* for, and to *construct*, the *SyMo Facility* for immobilisation of liquid intermediate level waste resulting from the radiopharmaceuticals production.

Following receipt of the application for authorisation to *construct* the *ANM Facility*, notice was published in The Australian newspaper and the Australian Government Gazette on 2 January 2014, with an invitation to make submissions. The invitation was posted on the ARPANSA website on 6 January 2014 alongside information on the licence application. No further submissions were received. However the submissions made in response to the application to *prepare a site* for the *ANM Facility* remain relevant. The submissions often covered more than one, sometimes all three, facilities subject to regulatory review by ARPANSA, and were relevant to different licensing stages such as siting, construction and operation. The issues raised in the submissions, ANSTO's response

and comments from the ARPANSA assessors have been posted on ARPANSA's website[15]. They were summarised in the Statement of Reasons underpinning the decision to authorise ANSTO to *prepare a site* for the *ANM Facility* (see footnote 1) and are not reiterated here.

3.6.2 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 and no additional submissions were received in relation to the application for an authorisation to *construct* the *ANM Facility.*

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. They are not critical to the stage covered by the application; I may thus proceed with reaching a decision on authorisation to *construct* a controlled facility.

4 Licence conditions

I have included the standard licence condition of quarterly reporting in my decision.

The *ANM Facility* is complex and some of the detailed design elements, particularly some of the 'in hot cell' equipment, are yet to be finalised. The ARPANSA assessors are satisfied with the design specifications used by ANSTO for the engagement of the construction organisation and are satisfied with the arrangements set out for the management of the construction process.

However, in light of the final detailed design elements being specified but not yet finalised, the assessors recommend, and I have issued, the following condition of licence:

> *The Licence Holder must seek the approval of the CEO of ARPANSA for construction of any hot cells/cell containment, hydrogen gas and detection system and any cranes along with items identified as safety category 1 and safety category 2 in the Preliminary Safety Analysis Report (PSAR).*

As a general rule, a regulator must be mindful to not issue a licence if there are doubts as to the safety of the operations, and refrain from compensating such doubts through issuing conditions of licence (i.e. the conditions of licence become surrogates for operator-implemented safety). However, an applicant must also be given reasonable opportunity to refine plans and design as a project proceeds. The ARPANSA assessors are of the view that such refinement can be made against the backdrop of a sound safety design and safety regime as outlined in the application.

I also note that regulation 54 states as follows:

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

54. Approval required to construct safety item

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

While regulation 54 applies generally, the licence condition indicated above further specifies its application to the construction of the *ANM Facility* and specifically identifies items not categorised as safety category 1 or 2 as being relevant to regulation 54.

5 Matters for ANSTO to consider

Just as the current radiopharmaceuticals production facility, the *ANM Facility* will generate noble gas emissions, where in particular emission of xenon-133 is of interest. At even the low (in terms of radiation dose) emission levels, the emissions are likely to be observed in the monitoring stations ARPANSA operates under the terms of the Comprehensive Test Ban Treaty (CTBT). This interference can reduce the efficacy of the CTBT network. To protect the accuracy and sensitivity of the CTBT network ANSTO should aim at incorporating improved technology and operating the *ANM Facility* such that there is no increase in xenon-133 emissions, despite the approximately four-fold increase in production.

When assessing the anticipated operating licence application, I expect plans and arrangements for managing safety at the *ANM Facility* to demonstrate that it will be operated safely and that, in the event of a process failure or equipment breakdown, can be brought safely to shut down and maintained in a safe shutdown state pending the development of a suitable maintenance recovery process. I expect that the plans and arrangements, including maintenance and recovery processes will be further developed during the commissioning process involving nonradioactive material.

I expect the information specified above to be submitted as part application for authorisation to *operate* the *ANM Facility*.