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1. INTRODUCTION

Commonwealth entities that undertake activities involving controlled facilities, controlled apparatus or controlled material must comply with the requirements of the Act [1] and the Regulations [2].

The object of the Act is to protect the health and safety of people and the environment from the harmful effects of radiation.

Under the Act, a controlled person (which includes a Commonwealth entity) must not prepare a site for a controlled facility, construct, possess or control, operate, or decommission, dispose of or abandon a controlled facility unless the person is authorised to do so by a facility licence or is exempt.

A facility licence is a licence issued by the CEO of ARPANSA.

In the case of this application, the applicant, Dr Adrian Paterson, the CEO of ANSTO seeks a facility licence under sub-section 32(1) of the Act to site the controlled facility known as the ANSTO Nuclear Medicine Mo-99 Facility (ANM Facility).

The Act defines a controlled facility as either a nuclear installation or a prescribed radiation facility. The ANM Facility is a nuclear installation as defined in regulation 11.

1.1 Receipt of Application

In accordance with the requirements of the Act, the CEO of ANSTO submitted an application for a facility licence on 25 October 2012. The application is in an acceptable form. The appropriate application fee has been paid.

As required by the Regulations, the CEO published a notice in *The Australian* newspaper and in the *Australian Government Gazette* (C2013G00696) on 8 May 2013, notifying the receipt of a facility application from ANSTO and his intention to make a decision on the application.

Additional information subsequently obtained from the applicant forms part of the application.

1.2 Purpose and Format

The objective of this report is to document the assessment of information contained in ANSTO's application against the criteria set out in the Act and Regulations. Consideration is given to the matters to be taken into account by the CEO under sub-section 32(3) of the Act, that is, international best practice in radiation protection and nuclear safety as it relates to the application, those matters set out in regulation 41 and information obtained under Part 1 of Schedule 3 to the Regulations.

Section 2 of this report details the review of information contained in the application. The conclusions of the ARPANSA assessor appear in Section 4 and inform the assessment of matters to

be taken into account by the CEO in making a decision on the application. Section 5 sets out the assessor's recommendations to the CEO regarding the issue of a licence and any licence conditions.

The assessor has relied on the following documents and information in developing his recommendations to the CEO:

- The information contained in the initial application (A0270).
- Additional information obtained from the applicant following receipt of the application.
- Meetings and discussions with the applicant and/or their representatives.
- Issues raised and questions asked during public consultation, including the community information session held at the Engadine Community Centre on 16 May 2013.
- Other documents referred to in the body of this report.

1.3 Assessment Process

The following documents have been used in the assessment of this application:

- *Australian Radiation Protection and Nuclear Safety Act 1998*[1]
- Australian Radiation Protection and Nuclear Safety Regulations 1999[2]
- Australian Radiation Protection and Nuclear Safety Agency, *Regulatory Guide: Plans & Arrangements for Managing Safety* v4 (RG) (January 2013) [3]
- Australian Radiation Protection and Nuclear Safety Agency, *Regulatory Assessment Principles for Controlled Facilities* (RAPS), ARPANSA, RB-STD-42-00, Revision 1, October 2001 [4]
- International Atomic Energy Agency, IAEA, *Site Evaluation for Nuclear Installations, Safety Requirements* (SR), NS-R-3, 2003 [5]
- International Atomic Energy Agency, IAEA, *Safety Aspects in Siting for Nuclear Installations* (draft DS433, 2013) [6]
- 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 [7]
- Australian Radiation Protection and Nuclear Safety Agency, *Regulatory Assessment Criteria for Design of New Controlled Facilities and Modifications to Existing Facilities* (DC), RB-STD-43-00, Revision 1, October 2001 [8]

1.4 Legislative Framework

Under sub-section 30(1) of the Act, a controlled person must not prepare a site for a controlled facility, construct, possess or control, operate, or decommission, dispose of or abandon a controlled facility unless authorised to do so by a facility licence, or unless the controlled person is exempted in relation to the conduct concerned under the Regulations.

Sub-section 32(3) of the Act states:

“In deciding whether to issue a licence under subsection (1), the CEO must take into account the matters (if any) specified in the regulations, and must also take into account international best practice in relation to radiation protection and nuclear safety.”

In addition to international best practice in radiation protection and nuclear safety, the CEO must also take into account the following matters listed in sub-regulation 41(3):

- (a) whether the applicant includes the information asked for by the CEO; and*
- (b) whether the information establishes that the proposed conduct can be carried out without undue risk to the health and safety of people and to the environment; and*
- (c) whether the applicant has shown that there is a net benefit from carrying out the conduct relating to the controlled facility; and*
- (d) 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; and*
- (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; and*
- (f) whether the application has been signed by an office holder of the applicant, or a person authorised by an 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.*

Sub-regulation 39(2) permits the CEO to request information from the applicant relating to the conduct for which the licence is sought. The following information (as listed in Part 1 of Schedule 3 to the Regulations) was requested by the CEO in guidelines published to assist a controlled person make an application for a licence to prepare a site for a controlled facility:

General Information

- Item 1** The applicant’s full name, position and business address
- Item 2** *A description of the purpose of the facility that is to be authorised by the facility licence*
- Item 3** *A detailed description of the controlled facility and the site for that facility*
- Item 4** *Plans and arrangements describing how the applicant proposes to manage the controlled facility to ensure the health and safety of people and the protection of the environment including the following information:*
 - (a) the applicant’s arrangements for maintaining effective control;*
 - (b) the safety management plan for the controlled facility;*
 - (c) the radiation protection plan for the controlled facility;*

- (d) *the radioactive waste management plan for the controlled facility;*
- (e) *the security plan for the controlled facility;*
- (f) *the emergency plan for the controlled facility.*

Authorisation for preparing a site for a controlled facility

- Item 5 A detailed site evaluation establishing the suitability of the site.*
- Item 6 The characteristics of the site, including the extent to which the site may be affected by natural and man-made events.*
- Item 7 Any environmental impact statement requested or required by a government agency, and the outcome of the environmental assessment.*

2. REVIEW OF INFORMATION

This section describes the review of information provided in the application and subsequently received from the applicant with respect to the matters to be taken into account by the CEO, particularly:

- a. The letter from the CEO of ANSTO dated 24 October 2012
- b. ANSTO Facility Licence Application, A0270 (OS-LA-FORM-240C, NI v6)
- c. Documents listed in Appendix 1

2.1 General Information

2.1.1 Applicant information [Item 1]

Item 1 of Part 1 of Schedule 3 of the Regulations requires the applicant to provide details of the Applicant.

The Application was made by the CEO of ANSTO, Dr Adrian Paterson, and signed on 24 October 2012. The person nominated to be in effective control of the facility is Mr Andy Garcia, Project Director, ANSTO.

Conclusion

The ARPANSA assessor considers that the applicant information described in the application is satisfactory.

2.1.2 Description of the purpose of the facility [Item 2]

Item 2 of Part 1 of Schedule 3 of the Regulations require the applicant to provide a description of the purpose of the facility.

The proposed facility will be used for the large scale production (about four times the current production level) of molybdenum-99 (Mo-99). Technetium-99m (Tc-99m), the daughter of Mo-99, is currently used in about 80% of all nuclear medicine procedures. ANSTO states that the proposed ANM Facility will be an export scale nuclear medicine manufacturing plant, which will secure Australia's ability to produce Mo-99 and increase capacity to meet a significant proportion of the world's needs.

Conclusion

The description of the purpose of the facility described in the application is considered adequate by the ARPANSA assessor.

2.1.3 Detailed description of the facility and site [Item 3]

Item 3 of Part 1 of Schedule 3 of the Regulations require the applicant to provide a detailed description of the facility and site for the proposed facility.

Facility History

The proposed facility is a new facility. The existing facility for the production of Mo-99 is similar to the proposed new facility, but with a production level of 3-4 times lower.

Location of the Facility

The application states that the proposed site for the new building and facility is within ANSTO's main fenced site at Lucas Heights, NSW, in the reactor precinct near the existing OPAL research reactor. This ANSTO fenced site is in bushland 28 km southwest of the centre of Sydney. The ARPANSA assessor notes that the site was extensively assessed for its suitability as the location of a nuclear installation while licensing the OPAL reactor (Licence F0157). The site is established and is currently used for existing similar licenced operations. ANSTO is making use of the following characteristics of the site:

- The 1.6 km bush corridor outside the site and the security perimeter fence with site access controlled by Australian Federal Police.

- Infrastructure including power, water supply, waste services, transport and communications.
- Support services including safety and engineering.
- An established environmental monitoring programme.

The proposed location within the ANSTO fenced site is in an area called the 'Reactor Precinct'. This area is near the OPAL reactor and identified in ANSTO's long-term infrastructure plan as the preferred area for operations related to the reactor. Considering the interface of various processes, the ANM Facility will be close to the OPAL Reactor, the proposed SyMo Facility utilising the SynRoc or synthetic rock technique that will condition liquid intermediate level waste generated from the ANM Facility (which is under separate licence application assessment) and the ANSTO Health Tc-99m generator assembly plant.

ANSTO states that the close proximity of the facilities would minimise the risks associated with transport of irradiated material. The ARPANSA assessor notes that, since the proposed facility will be adjacent to OPAL, the transport of irradiated targets will provide some advantage in terms of time of transport and better operational controls for transport.

The ARPANSA assessor considers that the location of the proposed facility has been adequately addressed.

Description of the Facility

ANSTO states that the technology is based on the proven alkaline fission product Mo-99 production process. It will incorporate appropriate elements from both the existing ANSTO plant and the NTP Radioisotopes Pty Ltd (NTP) plant in South Africa. The ARPANSA assessor notes that similar processes are used in large-scale radioisotope production facilities around the world including the facility in the Netherlands. The current Mo-99 facility also utilises the alkali-based fission product processing.

The facility will incorporate:

- Hot cells for the processing of Mo-99 including dissolution, purification, dispensing and packaging.
- A control room housing the process control and building monitoring systems.
- A truck bay and crane for deliveries, dispatch and removing waste.
- A plant room housing main switchboards, plant and equipment.
- A system to ensure decay of dissolver off-gases.
- Ventilation systems for the supply of air and extract of potentially contaminated air including a stack to discharge and dilute exhaust air.
- Laboratory facilities which will integrate with the existing laboratories on site.
- Storage areas and active maintenance areas.
- Staff amenities.

The ANM Facility will include provision for waste storage to allow decay but will not incorporate final waste stream processing.

The waste management/waste minimisation features within the facility will include:

- Uranium waste management process.
- Transfer equipment for transfer of intermediate level liquid waste to a neighbouring waste treatment facility.
- Interim intermediate and low level liquid waste handling facilities.
- A stack monitoring system.
- Collection and treatment of low level radioactive liquid wastes in the ANSTO Lucas Heights system.
- A central control room housing the process control and building monitoring systems.

Conclusion

The facility description includes the location of the facility, the main components comprising the facility and the operating envelope of the facility. The ARPANSA assessor notes that, since the detailed design information is not yet available, this will be further assessed when assessing the construction and operation licence applications for the facility. The ARPANSA assessor considers that the description of the facility and its site as given in the application is acceptable for the proposed conduct, namely the preparation of the site for the facility.

2.2 Plans and Arrangements for Managing Safety

Item 4 (Part 1 of Schedule 3 to the Regulations) of the general information that may be requested by the CEO refers to plans and arrangements for managing safety of the controlled facility to ensure the health and safety of people and protection of the environment.

2.2.1 Arrangements for maintaining effective control [Item 4(a)]

In applying for a facility licence, the applicant may nominate a person or position that would control the conduct for which a licence is sought, and demonstrate how the nominee would maintain that control. The nominee must have appropriate responsibility, with adequate authority and control of material, human and financial resources to ensure safety of the conduct. Ultimate accountability remains with the applicant [3].

The arrangements for effective control have been assessed using the guidelines described in Section 1 of the RG [3] and regulatory assessment principles described in relevant RAPS [4] as given below.

Accountability of applicant

The licence holder is responsible for maintaining control over all aspects of conducts and dealings and may authorise people to carry out certain actions but the licence holder remains ultimately accountable (RG 1.1-1.4) [3].

The CEO of ANSTO signed and submitted the application, and Mr Andy Garcia, Project Director, ANSTO is the nominee. The CEO has the ultimate responsibility to maintain effective control and for ensuring compliance with the Act and the Regulations. The nominee is responsible for day to day work and for assisting the CEO in ensuring compliance with legislative requirements. Resources required to perform the engineering design and to undertake safety evaluation to satisfy regulatory requirements have been approved through ANSTO's project funding process. ANSTO states that a project steering committee comprising senior management will oversight progress of the project. In addition, ANSTO will follow ARPANSA's reporting requirements.

The ARPANSA assessor considers that the information submitted in relation to accountability of the applicant is acceptable.

Organisational arrangements

The licence holder must describe the organisational arrangements for managing the safety of the conduct and dealings to ensure the health and safety of people and the protection of the environment. This should include a description of responsibilities and lines of authority, and information on a quality system covering all activities that may impact on safety (RG1.5-1.20) [3].

The organisation structure related to the ANM Facility shows the lines of responsibility for all activities [ANM-Mo99-S-LA-D1] noting that ultimate responsibility rests with the CEO of ANSTO. ANSTO states that once the facility is constructed and operational, there will be an ANM production team that will operate the facility. However, ARPANSA will consider this in the next phase of assessment. Staff from the Engineering and Capital Programs (E&CP) division and other divisions of ANSTO have been seconded to the project team. In E&CP the Strategic Asset Programs Office (SAPO) set the project standards for governance and is central to the system for monitoring by senior management of projects during execution. Specialist groups in E&CP are located in the Nuclear Mechanical Services Unit which provides design and specialist services. Systems Safety and Reliability section has safety specialists who will conduct the detailed safety assessment.

The General Manager of Safety, Environment and Radiological Assurance (SERA) is responsible for setting the safety standards and providing safety advice and support, including radiation protection. The Regulatory Affairs Manager of SERA is responsible for liaising with ARPANSA on all regulatory matters.

The Application states that the General Manager of SERA is also Chair of the Safety Assurance Committee (SAC), and that all the significant processes are subject to SAC approval. The SAC approval process provides an internal independent review of the project plans and submissions to ARPANSA. ANSTO states that the organisational arrangements are reviewed periodically.

Following the submission of the application, ANSTO informed ARPANSA in a communication dated 11 February 2013 (D133292) of the following organisational changes:

- A new group, namely, Nuclear Services has been formed.
- Health physics services, and environmental monitoring and instrument calibration will be provided by Radiation Protection Services (RPS) in place of the former SERA.
- Former Manager of SERA is the Manager of the newly formed Nuclear Services.
- Waste Operations (of ANSTO Nuclear Operations) will report through Nuclear Services.
- The Head, Nuclear Services is also the Chief Nuclear Officer (CNO) who is the Chair of the SAC – the CNO reports to the CEO in order to maintain effective independence from Waste Operations and the Reactor.
- Work Health and Safety will report to the General Manager Human Resources now designated General Manager Human Resources and Work Health and Safety.
- The Emergency Response staff will report to General Manager Security and Safeguards.
- Regulatory and Safety Assurance will move into the Governance Risk and Compliance function in the office of the CEO.

The ARPANSA assessor notes that though there are some changes to the reporting line the functions remain unchanged.

ANSTO characterised this organisational change as a Regulation 52 change (no prior approval required) and ARPANSA accepted this characterisation on the basis that there were adequate controls to maintain functional independence of safety from operational responsibilities (R13/01787).

The ARPANSA assessor considers that the information provided in relation to organisational arrangements shows clear lines of responsibility and functions to exercise effective control.

Management system

The management system should be consistent with current AS/NZS ISO Standards and clearly documented policies and procedures should be in place (RG 1.21-1.25) [3], (RAPS 13-14)[4].

Through the ANSTO Occupational Health, Safety and Environmental (OHSE) Policy, the organisation has given a commitment to occupational health, safety, the environment and sustainability. The application also refers to other policies, including those for security, quality, human resources and business and together provide a comprehensive framework for the management system. These policies are not reviewed in this assessment report as they are part of a site-wide approach and have already been assessed for existing facilities.

The documents supporting the policies are certified under the AS/NZS ISO 9001 quality management systems and the AS/NZS ISO 14001 environmental management system. These systems ensure that there are procedures for document control and records management. The safety standards and requirements are contained in the Workplace Health and Safety (WHS) Management System which is also certified under the SERA division's AS/NZS ISO 9001 system. The management systems are

subject to monitoring and audit (both internal and external) to determine the effectiveness as required by ISO certifications.

Referring to the ANSTO Business Management System, ANSTO states that it has in place comprehensive project management and governance arrangements. This system prescribes, based on the size and complexity of the project, the safety, environmental, procurement and other requirements at each stage. It also prescribes, for each project, the degree of scrutiny by ANSTO senior management through a 'stage gate' approval process. The ANM Mo99 project will be subject to these project management and governance arrangements.

The ARPANSA assessor considers that the elements of the Management System described in the application are acceptable. Further details will be considered in future regulatory assessments for construction and operating licences.

Resources

The licence holder is responsible for ensuring that adequate and appropriate human, financial and material resources are available (RG 1.26-1.30) [3].

The application states that safety resource requirements are identified at several levels. For each potentially hazardous process or activity, a hazard identification and risk assessment is performed following the ANSTO WHS standard Risk Management procedures which identify the required equipment, including Personal Protective Equipment (PPE).

Referring to the ANSTO Capital Process (ANSTO AR 2682), the application states that the ANSTO project management and approval processes ensure there is sufficient funding available for the necessary equipment and people resources. The funding is approved in stages by the ANSTO Capital Investment Committee (CIC) comprising senior management and the projects are monitored throughout their lifecycle by the CIC.

The ARPANSA assessor considers that arrangements for resources described in the application are acceptable.

Conclusion

The application describes the lines of responsibility and functions in maintaining control over all aspects of conduct related to preparation of the site. Arrangements for effectively control technical, administrative and human factors, the ISO certified management system and adequate human, financial and material resources will be applied to the proposed conduct. The arrangements for maintaining effective control of the proposed conduct are acceptable.

2.2.2 Safety management plan [Item 4(b)]

The application should include a safety management plan that demonstrates that safety management practices are in accordance with internationally accepted principles and practices and duty of care obligations [3].

The arrangements for managing safety in the facility have been assessed against the guidelines described in the RG [3] and the principles 1, 7-9 in the RAPs [4].

2.2.2.1 Safety culture

The licence holder is responsible for establishing safety as the organisation's highest priority consisting with international best practice, and positive safety attitudes are encouraged by senior management (RG 2.1 2.19) [3], (RAPS 1, 3,6-9)[4].

ANSTO states that the ANM project will formulate and execute the project activities in compliance with the ANSTO Work Health and Safety Management System (WHSMS) which implements the safety requirements of the strategic plan and safety policy. The safety policy and safety arrangements are readily available to and accessed by staff on the ANSTO intranet and are subject to regular review.

ANSTO states that it encourages questioning attitudes and adopts a rigorous and prudent approach to work incorporating conservative decision making. ANSTO provides appropriate training and awareness instilled by safety briefings, toolbox talks, safety inspections and use of the STAR (Stop, Think, Act, Review) principle. These measures help to engender a safe approach to work. The ARPANSA assessor notes that safety briefings, toolbox talks and the STAR approach are in place for other ANSTO Health facilities. ANSTO states that through the independent SAC approval process ANSTO ensures that implementation of safety requirements are not subject to inappropriate commercial pressures.

The Application states that the ANSTO WHSMS have several layers of protection for staff, contractors and the environment. The ANSTO Standard Radiation Safety [AS2310] uses defence-in-depth as a main strategy in radiation protection. ANSTO's CEO holds regular forums for all staff which include safety related themes. ANSTO Engineering and Capital Projects (E&CP) division has a regular forum at which safety is discussed. There is significant consultation with workers including staff and contractors in aspects of safety through the Central Safety Consultative Forum, the Workgroup Health and Safety Committees and the Health and Safety Representatives and deputies. All committees referred to here have terms of reference set out in the WHSMS. Safety indicators for activities and processes are monitored to improve operational and safety performance within the E&CP Business Management System (BMS).

ANSTO has given a commitment to undertake all activities in accordance with procedures, and to report all safety events/incidents and investigation according to the WHS Management System.

The Radiation Protection Plan submitted with the application is referenced as part of ANSTO's defence-in-depth strategy, which is assessed elsewhere in this report.

ANSTO states that safety indicators for activities and processes are monitored to improve operational and safety performance within the E&CP Business Management System (BMS). Assessment of E&CP BMS does not form part of this report as this is a site-wide approach and applies to all ANSTO projects and it has been assessed previously (e.g. Camperdown Facility.)

Safety issues and learning are communicated both informally and by reports through line management and a Facility Officer. Toolbox talks and regular staff meetings will be used to reinforce safety during the proposed construction stage.

The application states that ANSTO conducts surveys on safety culture at the organisational level. The SERA division reports monthly on the events raised and their types, severity and lost time frequency and gives monthly feedback to divisions on safety training and housekeeping inspections.

The elements of safety culture described in the application are acceptable. ANSTO has given a commitment to the highest level of safety, and has in place mechanisms for consultation, contractor supervision, and communication of safety matters.

2.2.2.2 Administrative Arrangements

The licence holder is responsible for ensuring that the organisation has recognised its responsibility for ensuring the health and safety of people and protection of the environment (RG 2.20-2.29) [3].

ANSTO states that the proposed conduct will follow the arrangements for occupational health and safety in WHSMS, which will be supplemented by local arrangements. No details of local arrangements (e.g. rules, instructions) and procedures have been provided with the application for the siting licence. The ARPANSA assessor understands that these local arrangements will be developed and submitted for assessment with the application for the construction and operation licences. This is acceptable to the ARPANSA assessor.

ANSTO states that some project work during the siting licence stage may be performed by contractors under the supervision of ANSTO staff. Contractors will be managed following ANSTO procedures. If necessary, any field work they perform will be assessed by SWMS reviewed by ANSTO which will identify the hazards and specify the safety controls.

Other administrative arrangements related to restriction on working with radiation and planning and control of exposure are referred to in the Radiation Protection Plan, which is assessed under that section of this report.

ANSTO safety requirements are disseminated to staff and contractors, principally through training requirements. These include appropriate induction training and safety specific training. Implementation of safety requirements is ensured through supervision.

The ARPANSA assessor considers that the administrative arrangements for lines of responsibility in ensuring health and safety of people and the environment are acceptable for the purpose of a siting licence. This matter will be further assessed when assessing the application for construction and operation.

2.2.2.3 Safe Premises, Building and Equipment

The licence holder is responsible for providing a safe working environment including considering appropriate standards and conservative proven design and engineering practice in design and construction (RG 2.30-2.37) [3], (RAPS 10-12) [4].

ANSTO states that the facility will be designed to modern standards specifically for the purpose of Mo-99 production. As this application is for siting the ANM Facility, no detailed design information is available at this stage. However, concept design information suggests that the proposed facility will use technology similar to that used in the current Mo-99 process with improved design features. It is expected that the plant and equipment of the proposed facility will be in accordance with state of

the art technology. ANSTO states that ANSTO Guidance on categorisation of Structures, Systems and Components (ANSTO/T/TN/2008-11 Rev 1) will be applied during the design phase. Some aspects of design features related to radiation protection are presented in Section 2.2.3 of this report. Hazard categorisation of the facility is assessed in Section 2.4 of this report. ANSTO states that appropriate standards and codes will be applied in design and construction of the facility. ARPANSA is satisfied that this aspect has been adequately addressed by ANSTO. This aspect will be further assessed when assessing the applications for the construction and operation licences.

2.2.2.4 Competency, Training and Supervision

The licence holder is responsible for ensuring the arrangements are in place for identifying and transferring knowledge and skills needed to ensure that all activities are undertaken by competent and authorised staff, and appropriate supervision is in place (RG 2.38-2.55) [3].

ANSTO states that recruitment of staff and long-term contractors is based on technical and personal selection requirements of the role that includes qualifications, knowledge and experience appropriate for the work.

ANSTO states that the Radiation Protection Adviser (RPA) is recruited with necessary knowledge, skills and experience or is trained and authorised within ANSTO. The Health Physics Surveyors (HPS) are given comprehensive theoretical and practical training and are authorised within ANSTO. The ARPANSA assessor notes that ANSTO provides training and consultancy services to external stakeholders.

ANSTO also states that it provides training to staff through appropriately qualified staff including task-specific training prior to assigning the job. Training records are maintained in the ANSTO training management system. The ARPANSA assessor notes that the agency monitors training arrangements for operation of a similar facility (the current Mo-99 facility).

The ARPANSA assessor considers that the arrangements for identifying skill and competency requirements, training, and supervision of staff, contractors and visitors are acceptable.

2.2.2.5 Visitors, Contractors and Other Persons

The licence holder is responsible for ensuring safety of anyone entering a workplace including contractors, their employees and visitors (RG 2.55-2.62) [3].

ANSTO treats long-term contractors as equivalent to staff in terms of the application of safety training and requirements. Special arrangements exist for short-term contractors and visitors.

The site Security Plan (ANM-Mo99-S-LA-D5) is assessed in Section 2.2.5 of this report. Access to the Lucas Heights site is controlled by ANSTO Security and the Australian Federal Police and through the ANSTO security swipe card system. Only trained staff and approved contractors are given unaccompanied access. Visitors must be escorted by trained staff.

ANSTO states that there are comprehensive safety training requirements in place for contractors and these are described in Work Health and Safety Training Needs Analysis [AG-2364]. For short-term contractors these include contractor induction training and a radiation safety course. ANSTO requires contractors to:

2.2.3.5 Classification of Work Areas

It is expected that areas are classified in accordance with the levels of exposure involved, and there is appropriate delineation of areas by appropriate means. Accesses to the areas are controlled by local rules and procedures, use of personal protective equipment and appropriate warning signs are in place (RG3.24-3.36) [3].

ANSTO Guide 2509 (Radiation safety - Radiation and Contamination Control) describes the classification of radiation and contamination areas on the basis of exposure levels and the requirements to be followed. The areas are classified as red, blue and white depending on the levels of radiation.

The application (section 5.1 of Radiation Protection Plan) states that the classification for the various operational areas will be reviewed during and immediately following commissioning and thereafter periodically and will be adjusted if needed. Barrier procedures will be implemented to ensure that contamination is contained within classified areas. Access and egress of all persons to classified areas will be via the appropriate change barrier. Appropriate dosimeters and Personal Protective Equipment (PPE) will be worn according to the classification of the area. The barrier procedures will enforce monitoring for potential personal contamination prior to exit from any contaminated area. The ventilation system will be designed to ensure that there is no potential cross-contamination from radiological areas.

The ARPANSA assessor considers that the elements for classification of areas described in the application are acceptable. Classification of areas will further be assessed when undertaking the assessment for ANSTO's applications for licences to construct and operate the ANM Facility.

2.2.3.6 Local Rules and Procedures

The licence holder is responsible for ensuring that local rules and procedures are in place and are implemented to provide an adequate level of protection, safety and supervision for controlled persons and visitors (RG 3.37-3.47) [3].

The application is to prepare a site for the proposed ANM Facility. Local rules and procedures are related to the controlled areas and the conducts to be undertaken in those areas. Therefore, this aspect will be considered when undertaking the assessment for ANSTO's applications for licences to construct and operate the ANM Facility.

2.2.3.7 Personal Protective Equipment

The licence holder is responsible for ensuring that there is provision of adequate and appropriate personal protective equipment (RG 3.48- 3.52) [3].

The application states that EPDs (Electronic Personal Dosimeters) will be used in controlled areas. The ANSTO OHSE Guide AG 2521 (Radiation Safety- Exposure Monitoring & Health Surveillance) provides guidance on requirements and responsibilities of wearing personal dosimeters. ANSTO

OHSE Guide AG 2511 (Radiation- Radiation and Contamination Control) provides guidance on clothing to be worn in controlled areas.

Section 6.1 of the Radiation Protection Plan (ANM-Mo99-S-LA-D3) states that the nature of the hazard and the work that is being undertaken will determine the level of PPE required in radiological classified areas. PPE will be supplied at the barriers to any radiological classified area.

Radiological classification of areas dictates the personal protective equipment to be used and since no detailed information on design and classification of areas is available at this stage, this matter will be considered when undertaking the assessment for ANSTO's applications for licences to construct and operate the ANM Facility.

2.2.3.8 Monitoring of Workplace

The licence holder should have a documented workplace monitoring program supported by procedures and rules (RG 3.53-3.60) [3].

Section 7 of the Radiation Protection Plan (ANM-Mo99-S-LA-D3) states that radiation monitoring programs will be in place to confirm adequate protection and optimisation of radiation protection measures.

Routine area monitoring will be performed to confirm the classification of controlled areas and that the dose rates and contamination levels within and around the controlled areas are within agreed values. There will also be a survey program in the facility based on an assessment of the radiological hazards within the facility. Task-based radiological monitoring will also be performed within the ANM Facility by use of appropriate procedures and with 'pass/fail' criteria.

As the siting of the facility will not involve any radiological monitoring of the workplace, this criterion will be assessed when undertaking the assessment of applications for the construction and operation licences for the facility when detailed design information will be available.

2.2.3.9 Monitoring of individuals

The licence holder should have arrangements to monitor individuals including visitors and contractors and to record the results of monitoring and report abnormal dose results if there are any (RG 3.61-3.71) [3].

Section 7.2 of the Radiation Protection Plan states that occupationally exposed persons will be monitored as part of the routine dosimetry program. ANSTO OHSE Guide AG 2521 (Radiation Safety- Exposure Monitoring & Health Surveillance) describes the monitoring of individuals and surveillance including investigation levels. Visitors and contractors are subject to monitoring depending on the tasks. The dose results are maintained by the Radiation Protection Services. ANSTO provides ARPANSA with dose results quarterly. Section 2 of the ANSTO OHSE Standard-Radiation Safety, AS 2310, describes record keeping arrangements related to exposures to individuals.

The ARPANSA assessor considers that the arrangements for monitoring individual and exposure control are acceptable. This will be further considered when undertaking the assessment for ANSTO's applications for licences to construct and operate the ANM Facility.

2.2.3.10 Monitoring the Environment

The licence holder is responsible for ensuring appropriate arrangements for monitoring the environment (RG 3.72-3.77) [3].

Section 7.4 of the Radiation Protection Plan states that the radioactive discharges to the environment from the ANM Facility will be subject to notification levels. The notification levels will be determined by ARPANSA on the basis of operational limits and conditions to be derived taking into account the on-site and off-site radiological consequences. The current Mo-99 production facility operates subject to specified notification levels for various radionuclides discharged to the atmosphere. Radioactive liquid wastes are managed according to a site-wide approach by ANSTO Waste Operations. Any discharge from the site is subject to compliance with statutory limits.

The proposed conduct to prepare the site for the facility will not involve any radiological discharge to the environment. Therefore, this aspect will be considered when undertaking the assessment for ANSTO's applications for licences to construct and operate the ANM Facility.

2.2.3.11 Transport

The licence holder is responsible for ensuring appropriate arrangements for on-site and off-site transport of radioactive material in accordance to legislative requirements (RG3.37-3.50) [3].

In Section 9 of the Radiation Protection Plan, ANSTO gives a commitment to comply with the ARPANSA Code of Practice for Safe Transport of Radioactive Material for off-site transport of radioactive material. Items and waste products leaving the facility or moving between contamination controlled areas require health physics monitoring and clearance.

ANSTO OHSE Guide-Radiation Safety- Movement and Transport, AG 2515 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.

It is expected that the proposed conduct to prepare the site will not involve the transportation of radioactive material. However, the ARPANSA assessor notes that due to the increase in production of Mo-99 by three to four times to that of the current level the volume of transport will also increase and this aspect will be assessed in future when the applications for licences to construct and operate the facility are received.

Conclusion

It is expected that the preparation of the site for the proposed ANM Facility will not involve any notable exposure to radiation. However, the application describes relevant arrangements for radiation protection including principles of radiation protection, expected design controls and radiation monitoring programs to be in place. The ARPANSA assessor considers that the arrangements for radiation protection for the siting of the ANM Facility are acceptable. The ARPANSA assessor notes that a detailed radiation protection plan will be assessed when undertaking the assessment for ANSTO's applications for licences to construct and operate the ANM Facility.

2.2.4 Radioactive waste management plan [Item 4(d)]

The arrangements for managing radioactive waste have been assessed against the guidelines of section 4 of the RG [3] and the principles 68, 69, 73-76 of the RAPs [4].

2.2.4.1 Management of Radioactive Waste

The applicant must provide arrangements to protect the health and safety of people and to protect the environment from hazards arising from the handling, treatment, storage, discharge and disposal of any radioactive waste expected to arise from any conduct. The arrangements should address appropriate codes and standards; the physical, chemical and radiological characteristics of the waste; methods of minimising the volumes and activities of radioactive wastes generated; the treatment, storage, disposal and discharges of radioactive wastes; and the control, monitoring, recording and reporting of wastes (RG 4.1-4.18) [3], (RAPs 68, 69, 73-76) [4].

It is expected that the siting process will not generate any radioactive waste. However, operation of the ANM Facility will generate solid, liquid and gaseous wastes.

The solid wastes to be generated include intermediate level solid waste (ILSW) and low level solid waste (LLSW). The ILSW will comprise solid uranium waste from the primary separation process and other solid wastes from the secondary separation process. The uranium waste will be encapsulated and removed in the transfer flask to be stored at ANSTO Waste Operations Facility. The secondary solid wastes will be collected in cells and will be removed by the retrievable flask. The LLSW will be collected and managed by ANSTO Waste Operations.

The intermediate level liquid waste arising from the proposed ANM Facility will be conditioned into an immobilised form at the SyMo Facility. The licence application for siting and construction of the SyMo Facility will be assessed separately (R13/10192). The low level liquid waste to be generated will be solidified at ANSTO Waste Operations Facility (F0260). The liquid discharges from the ANSTO Lucas Heights Science and Technology Centre (LHSTC) are managed under the ANSTO Waste Operations licence (F0260).

The radioactive gaseous wastes generated will be stored in evacuated tanks to decay for a certain period prior to release to the atmosphere. The radioactive gaseous discharges will be subject to

specific notification levels for radionuclides by use of the approach similar to the current Mo-99 production facility.

ANSTO states that the processes and equipment will be designed to minimise waste, recognising that the requirements for maximum product recovery and the required radionuclidic purity, and the use of consumables.

ANSTO has provided the following initial estimates of the amount of wastes to be generated annually:

		Amount of Annual Wastes
Dissolver cell (ILW ¹)	Spent uranium filter cups	450 filter cups
	Solid waste	24 standard deck bins
	Liquid waste	4400 litres
Purifications Cells (LLW ²)	Solid waste	200 of 20 litres containers
	Liquid waste	2250 litres
Cell Equipment (ILW)	Pumps, heaters, stirrers, tanks etc.	16 standard deck bins

The management of radioactive waste will be further assessed during the next stages of licence applications for construction and operation when detailed design of all equipment and processes are available.

2.2.4.2 Limiting Exposure to Radioactive Waste

It is expected that preparing a site for the ANM Facility will not involve any exposure to radioactive waste. ANSTO states that it will incorporate appropriate design features to limit the exposure pathways when the facility becomes operational. These include hot cells equipped with an active ventilation system, filtration system, shielded tanks for collection of wastes, shielded transfer flask system, area radiation monitoring system etc. In addition, appropriate procedures will be developed to handle radioactive waste.

This matter will be considered when undertaking the assessment for ANSTO's applications for licences to construct and operate the ANM Facility.

¹ ILW: Intermediate level waste

² LLW: Low level waste

2.2.4.3 Packaging and Containment of Radioactive Waste

The proposed conduct to prepare a site for the ANM Facility will not require any packaging and containment of radioactive waste. The ARPANSA assessor notes that all the solid wastes including ILSW and LLSW will be contained in the hot cells and placed in appropriate containers. They will be removed by use of appropriate transfer flask and/or equipment.

This matter will be further assessed when undertaking the assessment for ANSTO's applications for licences to construct and operate the ANM Facility.

2.2.4.4 Interim Storage of Radioactive waste

It is expected that the proposed conduct will not involve any interim (medium and longer term) storage of radioactive waste. ANSTO states that when the facility becomes operational the gaseous wastes will be stored in evacuated tanks for a certain period to decay prior to release to the atmosphere. The liquid wastes will be stored in shielded tanks for certain period to decay followed by conditioning of the waste (ILLW) at the SyMo Facility and/or solidification of the waste (LLLW) at ANSTO Waste Operations. The uranium wastes in filter cups will be stored inside the cell for a certain period to decay followed by encapsulation and storage at ANSTO Waste Operations Facility operating under ARPANSA licence F0260.

The interim storage arrangements for solid, liquid and gaseous wastes will be considered in the assessment for construction and operation of the facility taking into account the detailed design features.

2.2.4.5 Documentation of Radioactive Waste

The licence holder is responsible for ensuring that documentation detailing the nature of any radioactive waste is appropriately maintained (RG 4.47-4.51) [3].

It is expected that no radioactive waste will be generated from the preparation of the site. However, ANSTO foreshadowed the expected arrangements in Section 6 of the Radioactive Waste Management Plan (ANM-Mo99-S-LA-D4), which states that any wastes within the ANM Facility will be recorded to enable proper management. The ANM Facility procedures will be maintained within the ANSTO Quality System, which will ensure review and audit.

2.2.4.6 Routine Discharge of Radioactive Waste to the Sewer

The proposed conduct will not involve routine discharge to the sewerage systems. The ARPANSA assessor notes that any discharge from the site is managed by ANSTO Waste Operations (F0260) and subject to statutory discharge limits.

This matter will be further considered in future assessment of the licence applications for construction and operation.

2.2.4.7 Routine Discharge of Radioactive Waste to the Atmosphere

No radioactive gaseous waste will be generated during the preparation of the site. There will be discharges when the facility becomes operational. The airborne discharges from the current Mo-99 facility are monitored on-line. The airborne discharges from the ANM Facility will be subject to statutory notification levels, which are in place for the current Mo-99 production facility.

In correspondence following receipt of the licence application, ANSTO indicated their intention to incorporate additional design features such as activated charcoal columns to reduce gaseous discharges.

This matter will be further assessed when detailed design and process information are available in future assessment of the licence applications for construction and operation of the ANM Facility.

2.2.4.8 Routine Discharge of Solid Radioactive Waste to Municipal Tip

ANSTO does not discharge solid radioactive waste to the municipal tip.

2.2.4.9 Routine Discharge of Radioactive Waste by Incineration

This does not apply to this facility.

Conclusion

Considering that the proposed conduct to prepare a site for the ANM Facility will not result in radioactive waste, the ARPANSA assessor considers that the expected arrangements for managing radioactive waste foreshadowed in the application are satisfactory. This matter will be further considered when assessing the licence applications for the construction and operation of the facility.

2.2.5 Security plan [Item 4(e)]

The arrangements for security have been assessed against relevant guidelines of section 6 of the *Regulatory Guide: Plans & Arrangements for Managing Safety v3* (October 2011) [3] and the provisions of the *Code of Practice for the Security of Radioactive Sources* (2007) (RPS 11).

2.2.5.1 Security Procedures

The licence holder is responsible for *arrangements for security of controlled material or apparatus that includes arrangements to prevent sabotage, theft or unauthorised use (RG 6.1-6.9) [3]*.

The arrangements for security have been assessed against relevant guidelines of section 6 of the *Regulatory Guide: Plans & Arrangements for Managing Safety v3* (October 2011) [3] and the

provisions of the *Code of Practice for the Security of Radioactive Sources (2007) (RPS 11)* and ASNO's (Australian Safeguards and Non-Proliferation Office) National Design Basis Threat (NDBT), issued in 2012.

The joint ARPANSA-ASNO Physical Protection and Security Working Group (PPSWG) established terms of reference for the review of the proposed and existing security arrangements of the facility. On 8 May 2013, the PPSWG and ANSTO met to discuss the security risk assessment being developed to ensure that it is consistent with all requirements and expectations.

A number of minor recommendations on the risk assessment framework being developed, the risk assessment elements to be covered and the description of risk treatment measures were provided by ARPANSA to ANSTO on 29 July 2013.

The PPSWG has been provided with the revised risk assessment matrix, which complies with the expectations of ARPANSA and ASNO against the NDBT, RPS 11 and national requirements covered under the Attorney-General's Department Protective Security Policy Framework.

ARPANSA conducted a siting security inspection for the proposed facility on 9 August 2013, which satisfied ARPANSA's expectations. During this inspection it was noted that some modifications to the boundary fence will be required during the preparation of the site, and it has been communicated to ANSTO that interim security measures must be implemented in order to preserve the integrity of the protective security system during this phase.

2.2.5.2 Proposed and Existing Security Procedures

The licence holder is responsible for *arrangements for security of controlled material or apparatus that includes arrangements to prevent sabotage, theft or unauthorised use (RG 6.1-6.9) [3]*.

No security enhanced radioactive materials will be in use in preparing the site.

Conclusion

The ARPANSA Assessor notes that ANSTO has satisfied all ARPANSA and ASNO requirements regarding proposed and existing security measures to be implemented in order to reduce risks to an acceptable level for a facility in operation. Nevertheless, ARPANSA will observe and verify that these measures are implemented throughout any construction, should a licence to construct be granted by ARPANSA in the future. During the preparation of the site, ANSTO's current site-wide security plan is acceptable, providing that interim security measures are in place to preserve the integrity of the protective security system at the boundary.

2.2.6 Emergency plan [Item 4(f)]

The applicant must have emergency plans and procedures that address all foreseeable emergencies to ensure the protection of personnel, the public and the environment. Adequate facilities and equipment must be available and an appropriate state of preparedness maintained [3].

The emergency plans related to the proposed conduct have been assessed against the guidelines of the RG [3] and principle 54(d) of the RAPs [4].

2.2.6.1 Emergency plans

The licence holder is responsible for providing detailed emergency plans based on the assessment of consequences of reasonably foreseeable accidents aiming to minimise the consequences and ensuring the protection of on-site personnel, the public and the environment (RG 7.1-7.21) [3].

Section 2 of the Emergency Plan (ANM-Mo99-S-LA-D6) states that during the siting activities, the project engineers are responsible for ensuring the emergency arrangements are in place and all those involved are trained in their roles. ANSTO will develop an assessment of the risks during construction and operation and submit it for review and approval during the later stages of the project. ANSTO also refers to the siting Safety Management Plan, and the Security Plan, for supplementary information related to emergencies.

It is expected that no radiological emergency will be involved during the siting process.

2.2.6.2 Emergency procedures

The licence holder is responsible for ensuring that comprehensive procedures are prepared according to the emergency plan (RG 7.22-7.35) [3]

The following procedural aspects have been described in the application:

If an incident or accident occurs, the ANSTO emergency response arrangements will be invoked. The ANSTO Site Control Centre (SCC) will be the focal point for communications in the event of an emergency. All security alarms and safety alarms are monitored and all calls to the ANSTO emergency number are notified to this centre.

Referring to the arrangements of ANSTO SOP 05 *Duty Safety Co-ordinator (DSC) – Role in Emergencies* ANSTO states that the next level of emergency response is managed by an on-call role known as the Duty Safety Coordinator. This role is staffed 24/7 by a senior ANSTO safety officer who is contactable by phone or pager. This officer is experienced in the emergency arrangements and has the necessary authority to take control of the emergency and command further ANSTO resources if required. The DSC ensures that the response is sufficient and where necessary, escalates the emergency.

It is expected no radiological emergency will occur during the siting stage. This matter will be further considered when assessing the licence applications for the construction and the operation of the facility. The ARPANSA assessor considers that the procedural aspects for emergency described in the application are acceptable for the proposed conduct.

2.2.6.3 Emergency preparedness

The licence holder is responsible for ensuring that all relevant agencies are prepared for such emergencies and adequate facilities and equipment are available and maintained (RG 7.36-7.42) [3], (RAPS 16, 54(d), 123)[4].

Section 4 of the Emergency Plan (ANM-Mo99-S-LA-D6) states that the ANSTO SCC, which is the emergency communications point, is monitored 24/7 by the AFP. The DSC roles are rostered 24/7. If for any reason, the DSC is unavailable, the SCC has standing orders to notify the next rostered DSC.

ANSTO states that emergency personnel are trained and that there are exercises of the emergency arrangements. There will be emergency exercise drills when the work teams are in place during construction and commissioning. The higher-level response arrangements involving all aspects of ANSTO's emergency management and response are exercised regularly and many of these exercises involve the external emergency services. The ARPANSA assessor notes that the agency oversees some all-agency emergency exercises. The emergency arrangements are continually updated, including updating of the contact lists and safety alarm responses.

The ARPANSA assessor considers that the arrangements for emergency preparedness are acceptable noting that this matter will be further assessed when undertaking the assessment of ANSTO's applications for licences to construct and operate the facility.

Conclusion

The ARPANSA assessor considers that the plans and procedures described in the application taking into account the accident scenarios of the current Mo-99 facility during routine operation and anticipated occurrences are acceptable noting that a more detailed risk assessment related to emergencies will be provided in the applications for the licences to construct and later to operate the facility reflecting the results of the Reference Accident (section 2.4).

2.3 Authorisation for Preparing a Site

2.3.1 Detailed site evaluation [Item 5]

Item 5 of part 1 of Schedule 3 of the Regulation requires the applicant to provide a detailed site evaluation for the proposed controlled facility.

The purpose of the site evaluation for a nuclear installation is to protect the public and the environment from the radiological consequences of radioactive releases during accidents and normal operation [5]. The site evaluation needs to consider:

- (a) The effects of external events occurring in the region of the particular site.

- (b) 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.
- (c) 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.

In addition, 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]. The accident at the Fukushima Daiichi nuclear power plant that occurred on 11 March 2011 has increased the focus on extreme natural events such as seismicity and associated events, e.g. tsunamis (see e.g. the report from a recent IAEA International Experts Meeting)[7]. The issue has particular implications for safety when multiple facilities are collocated on the same site (specifically, the collocation of a new facility at an existing site).

Assessment

Section 7 of the ANM Mo99 Site Characteristics and Evaluation (ANM-Mo99-S-LA-C4ab) states that the requirements of SR [5] have been extensively considered in the OPAL site evaluation process and they are relevant to the ANM Facility as this facility will be in the OPAL reactor precinct.

In Section 2.4 of this report, ARPANSA has considered a Reference Accident following input from ANSTO which considers the potential risk to the population and the environment from a very unlikely but high consequence accident. The Reference Accident incorporates projected population growth to 2046.

With regard to additional risks associated with the collocation of this facility and other facilities on the LHSTC site such as the OPAL reactor, the assessor notes that this new facility replaces an existing Mo-99 manufacturing facility and that its location proximate to the reactor will minimise the risks associated with the transport of radioactive material. The ARPANSA assessor also notes that the OPAL reactor is an F3 (hazard category) facility and the ANM Facility is an F2 (hazard category) facility. It is expected that the construction and operation licence applications will provide detailed information on how the risks of collocated facilities will be addressed.

ANSTO states that a comprehensive ANSTO environmental monitoring program remains in place and serves as a baseline for existing radioactivity levels. This aspect will be further assessed when undertaking the assessment of the licence applications to construct and operate the facility

The location of the proposed ANM Facility is satisfactory with respect to all of the matters relevant to siting described above.

Conclusion

The ARPANSA assessor notes that a detailed assessment of the site was performed during licensing of the OPAL reactor for the suitability of the site. Details of Reference Accident analysis are presented in Section 2.4. The ARPANSA assessor considers that the site is suitable for the proposed conduct subject to the conclusion of Section 2.4.

2.3.2 Site Characteristics [Item 6]

Item 6 of part 1 of Schedule 3 of the Regulation requires the applicant to provide the site characteristics for the proposed controlled facility.

Assessment of the site characteristics is to describe those characteristics that would influence the facility's safety and potential impacts of normal operation and accidents on people and the environment, and to identify the design bases that would take account of these characteristics (RAP 54) [4], (SR 2.2) [5].

2.3.2.1 Radiological baseline

Before any work may be commenced on the proposed ANM Facility, it is important that the radiological baseline of the site is established. This information would be used during the construction, operation and decommissioning of the facility to assess the impacts of these activities on the environment and ultimately, the effectiveness of decommissioning activities (SR 4.15) [5].

Section 4.5 of the ANM Mo99 Site Characteristics and Evaluation [ANM-Mo99-S-LA-C4ab] refers to Chapter 3 of the OPAL SAR. ANSTO refers to the on-going environmental monitoring regime including monitoring the stack monitoring, creek water and sediments. The ARPANSA assessor notes that the selected site is adjacent to the OPAL reactor and there are no nuclear facilities operated at that location. ANSTO provides the results of liquid discharges measurements from the site on a monthly basis and the discharge levels are below the statutory limits. ANSTO also provides the results of airborne discharges from the site along with the estimated effective dose at 1.6 km, and the results show that the doses are below the ANSTO annual ALARA objective of 20 μSv for the site. It is expected that no elevated levels of radiation will be present at the site. ANSTO provided the results of radiological surveys and these results show that the radiation level is at the background level. This radiation level will be used in future assessment as the baseline to assess the impact the future activities to be undertaken at this facility.

2.3.2.2 Geography

Geographical information including creeks, rivers, lakes, mountains, valleys, and any topography and details of present and projected land and water usage and ecology should be provided (SR 4.4-4.9, 4.14) [5].

Surface water

Considering that the operation of the facility will involve radioactive liquid waste, the facility design features will ensure that the radioactive liquid wastes are contained in purpose designed pipelines and vessels (section 4.2, ANM Mo-99-S-LA-C4ab). These will be housed inside shielded containment cells as a secondary or tertiary barrier and the storage vessels will be located so that possible leakage into the surface water (stormwater) runoff is not possible. All of these plant areas will have contained active drainage systems which under normal operations contain no significant activity. Should a significant leak occur it will be contained. Any discharge of liquid from the site is subject to the licence conditions in ANSTO Waste Operations Licence (F0260).

ANSTO states that given this facility design and arrangements, there are no pathways by which a significant quantity of active materials could be transported by surface water flow outside the building.

Groundwater

ANSTO assessed that for a significant quantity of fission products to enter the groundwater systems, there would need to be firstly a leak from the pipelines or tanks and secondly a further leak from the backup containment system. The safety features and mitigation factors for the groundwater leakage scenario are discussed in the Reference Accident Assessment.

Section 3.3.2 of the facility reference accident states that intermediate level liquid wastes will be contained in tanks in a secure bounded system when the facility is approved for operation. Safety features and accident mitigation factors considered include:

- Tanks designed to minimise the risk of leakage.
- Tanks will be contained in robust shielded enclosures with leak detection and containment which will prevent leakage into the surface water (stormwater) runoff.

Referring to the OPAL siting licence, ANSTO states that the highest ground water velocity estimates from ANSTO's monitoring program is 7.36 metres per year, and the hydrological study for the OPAL siting licence quoted a shallow aquifer at moving at a speed of 0.05 m/d (18 m/y) at OPAL. At the highest rate, should a spill of intermediate level liquid waste into the ground water occur, it would take approximately 6 years to leave the fenced area, and around 20 years to reach the first watercourse (Molong Creek), which is a more than an adequate amount of time to undertake appropriate remediation. Therefore, leakage of radioactive liquid waste into the groundwater is not considered in the accident scenario.

This aspect will be further assessed when undertaking the assessment of the applications for licences to construct and operate the facility.

Land use

Section 4.4 of the AM Mo99 Site Characteristics and Evaluation [ANM-Mo99-S-LA-C4ab] describes the land and water uses, referring to Chapter 3 of the OPAL SAR.

ANSTO states that the site is surrounded by a 1.6 km radius bush area which is owned by the Commonwealth except for a small section on the eastern side of the Woronora River which is NSW Crown land. Under the Sutherland Shire Local Environmental Plan (SSLEP) (Sutherland Shire Council, 2006), land within the ANSTO 70 ha fenced area is zoned 12 (Special Uses – Research and Technology) and the 1.6 km area outside the perimeter fence is zoned 12 (Special Uses - Military). There are small areas on the western perimeter of the 1.6 km area that are zoned 13 – Public Open Space.

The bush corridor is used for recreational purposes including bushwalking and bike riding. Part of it is leased to Waste Service NSW which operates the Lucas Heights Waste Management Centre. Other areas are leased to public entities in an area called the Business and Technology Park and to the United Pistol Club.

The residential suburbs of Barden Ridge and Engadine are located in the north-east to south-east sectors adjacent to the 1.6 km boundary. The suburban area of Menai is located some 3 km further to the north-east.

The public occupancies closest to the ANSTO perimeter fence are the ANSTO canteen which is open during the day and the Stevens Hall motel which has 24 hour occupancy and these occupancies are considered in the Reference Accident Assessment.

There is no farming in the bush corridor and very little mixed farming within 5 km of the site. The ANSTO Reference Accident includes projected demography to 2036 however ARPANSA has considered the public occupancy and the projected population to 2046 in its assessment of the Reference Accident.

ANSTO states that the proposed ANM Facility operations will not affect these on-going land uses since the beyond-design-basis accident will not result in contamination of land outside the boundary. Further details are described in the Reference Accident in Section 2.4 of this report.

2.3.2.3 Radiological assessment

For the proposed site the potential radiological impacts in operational states and in accident conditions on people and to the environment need to be evaluated (SR 2.12) [5].

Considering the present and projected population, ANSTO refers to Geoscience Australia data using their National Exposure Information System (NEXIS) database on the population outside the site's 1.6 km bush corridor. This database provides information aggregated at the building level and takes account of extensive non-urban areas such as bushland, river escarpments, and water bodies. These data have been developed in a form that is directly usable by the PC Cosyma modelling tool to allow estimation of collective doses.

ANSTO used NSW Statistical Local Populations Projections, 2006-2036.

ARPANSA used ARGOS (Accident Reporting and Guidance Operational System) to model the radiological consequences in the Reference Accident taking into account the projected population until 2046. This matter is considered in the analysis of Reference Accident in Section 2.4 of this report.

2.3.2.4 Design basis external events

The characteristics of the proposed site that would influence the design of the facility or the radiological impact of operations or accidents needs to be taken into account. These include seismology, meteorological events, flooding, geotechnical hazards and external human induced events. While the design base will be considered in detail as part of the design stage of the project, it is important that any design-basis external events that may result in design problems for a proposed facility be identified early in the project, at the siting stage (SR 2.7), SR 3.1-3.50) [5].

The design basis external events are described in Section 3 of the ANM Site Characteristics and Evaluation (ANM-Mo99-S-LA-C-4ab).

Seismology

Based on the site location on the sandstone plateaus of Sydney Basin, which is a low seismic hazard zone, ANSTO states that there are no major faults within 35 km of the site. The application refers to an extensive field study undertaken during siting of OPAL and states that only a few minor faults with several vertical displacements of 0.3 m or less were found. Referring to a probabilistic seismic hazard analysis by the Institute of Geological and Nuclear Sciences (IGNS) in 2001, the application presented a summary of the predicted mean peak ground accelerations and response spectral accelerations for return periods. Based on these results and the OPAL siting study ANSTO concludes that the proposed facility can be safely designed with respect to seismology.

The ARPANSA assessor notes that the worst case scenario with the potential for off-site consequences would be an earthquake resulting in release of significant amounts of fission gases, which is considered in the Reference Accident for the facility. The ARPANSA assessor considers that the information on the site characteristics and other relevant information on seismology are adequate for the proposed conduct and the information provided suggests that the safety of the site will not be affected by seismic events.

Meteorological events

ANSTO states that there is extensive weather data from the ANSTO Lucas Heights monitoring station which has been operating since 1958.

Regarding meteorological events the application refers to the OPAL siting study documented in Chapter 3 of the OPAL SAR. For rainfall and temperatures data the application refers to the Bureau of Meteorology website and infers that lightning is a known hazard and will be considered in the design and in the risk assessment. The likelihood of bushfire is considered to be low taking into account the site maintenance and the fire loading to be present in the facility. The details of the risks of bushfire have already been considered in the OPAL siting application.

Based on the tropical cyclones data available on the BOM website the application considers two potential scenarios by which tropical cyclones may affect the Lucas Heights. ANSTO states that relevant meteorological data will be taken into account in the engineering design. This matter will further be considered in future assessments for the construction and operation stages.

The ARPANSA assessor considers that the site characteristics and relevant information on meteorology for the proposed conduct is adequate and the information provided suggests that the safety of the site will not be affected by meteorological events.

Flooding

Section 3.3 of the ANM Mo99 application: Site Characteristics and Evaluation states that the Lucas Heights site is located on a ridge with a far higher elevation than the surrounding regions and drains naturally to the surrounding terrain. The river and the creek systems are also described in this section. ANSTO concludes that due to the topography of the site and surrounding area, it is not possible for the proposed site to be flooded from any water ingress from external areas.

The application also describes the controls in place for stormwater on the Lucas Heights site. ANSTO states that flooding due to earthquake and tsunami is not possible. ANSTO refers to Chapter 3 of OPAL Reactor SAR for a detailed study of flooding at the Lucas Heights site. The ARPANSA assessor considers that the site characteristics and relevant information on flooding for the proposed conduct is adequate and the information provided suggests the safety of the site will not be affected by flooding.

Geotechnical hazards

An extensive study undertaken during OPAL siting is referred to for geotechnical characteristics of the site. This included drilling boreholes to examine subsurface conditions and establishing a water monitoring program.

The application refers to a recent preliminary geotechnical assessment of the proposed site of the ANM Facility by Coffey Geotechnics in 2011. ANSTO states that further data will be obtained as needed for the detailed design.

The application states that the proposed ANM Facility site is at the western end of the Lucas Heights site. The facility will occupy a plot running approximately 55 m in the north-south direction and 45 m

in the east-west direction. It is gently sloping with approximately a 2 m drop in elevation over the length. Based on the available information including borehole core sample data from within the proposed site, Coffey have developed a preliminary geotechnical model of the subsurface units, and the results are summarised in Table 5 of Section 3.4 of the ANM Facility Site Characteristics and Evaluation [ANM-Mo-99-S-LA-C-4ab]. The results suggest that the site is not subject to potential land or rock slides.

The ARPANSA assessor considers that the geotechnical data considered in the siting is adequate.

Human induced events

The application has considered the following human induced events:

- Civil and military aircraft activity
- Transport of dangerous goods by road and rail
- Army training

Various controls including restrictions on flight path, distance of the proposed site from roads and rail, and communication with the military camp are in place to manage the risk associated with the above activities.

Considering the controls in place, ANSTO has assessed the risk of these human induced events having an adverse effect on the proposed facility as 'extremely low'. The application states that on-site events including loss of external power, on-site transport and incidents at adjacent facilities will be considered in the detailed design of the ANM Facility.

The ARPANSA assessor considers that the human-induced events that may have an adverse impact on the safety of the proposed facility have been adequately addressed in relation to the proposed conduct of preparing the site for the ANM Facility.

2.3.2.5 Operational radiation doses

The assessment of the site for a controlled facility should consider the implications of the site characteristics for the radiological impact of the controlled facility on the surrounding population and the environment during normal operation, and anticipated operational occurrences. (SR 2.22 -2.24) [5].

Considering the concept design and the intended production level of Mo-99, it is expected that the exposure to operators during normal operation is likely to be similar to the doses received by operators of the current Mo-99 production facility. It is also expected that the radioactive gaseous discharges during normal operation will remain at the level similar to the current Mo-99 facility

taking into account the improved design features of the ANM Facility. This information needs to be assessed in terms of the detailed design safety features of the facility. The ARPANSA assessor notes that ARPANSA will require detailed analysis of radiological consequences of radioactive discharges during routine operations and anticipated operational occurrences. The radiological consequences due to the Reference Accident are presented elsewhere in this report. ARPANSA will consider the radiological consequences from operation of the facility when it undertakes assessment of the applications for licences to construct and operate the facility.

2.3.2.6 Suitability of the site

Acknowledging that siting considerations and engineering are coupled, any unreasonable introduction of special design requirements to compensate for a poor site should be discouraged (DC 18-19) [8].

In assessing suitability of the site ANSTO and ARPANSA considered a range of extreme accidental and malicious events superimposed upon plant design and operational vulnerabilities. The analysis also builds in the projections for population increases for the region out to 2046 as developed by the NSW Government. The worst case scenario considered beyond-design-basis accident is called the Reference Accident and it is by its very nature extremely unlikely to eventuate. Further details of the Reference Accident are presented in section 2.4 of this report.

The overall assessment of the site characteristics did not identify any significantly deficient aspect of the site. The ARPANSA assessor considers that the design requirements foreshadowed in the application are adequate and reasonable noting that this matter will be considered further when ARPANSA assesses applications for licences to construct and operate the facility.

2.3.2.7 Decommissioning

The impact of a site on the decommissioning of a controlled facility requires detailed design information not available at the siting stage. However, for a complete description of the site assessment process, consideration should be given to all direct and indirect exposure pathways, for all anticipated activities during decommissioning, including the handling, interim storage, transportation and disposal of radioactive waste.

The proposed conduct is for siting and no detailed information about the design, construction and operation of the facility is available. However, the arrangements for managing radioactive waste and transportation are described in section 2.2.4 of this report. The ARPANSA assessor notes that for other nuclear installations operating at the Lucas Heights site, ANSTO adopts an approach to minimise exposure and waste generation by selecting suitable construction materials, and also uses a facility layout that is suitable for decommissioning. This aspect will be further considered when it undertakes assessment of the applications for licences to construct and operate the facilities.

2.3.3 Environmental impact statement [Item 7]

Item 7 of part 1 of Schedule 3 of the Regulations requires the applicant to provide any environmental impact statement requested or required by a government agency, and the outcome of the environmental assessment.

ANSTO referred the proposal to construct the ANM Facility to the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) for a determination on whether an Environmental Impact Statement (EIS) was required. ARPANSA provided DSEWPaC with its observations in terms of the increase in production level (3-4 times the current level), radiological exposure and lack of details of the design. DSEWPaC decided that the proposed siting of the ANM Facility is not a controlled action under the EPBC Act. Copies of ARPANSA's advice to DSEWPaC and the decision by DSEWPaC are in Appendices 2 and 3.

DSEWPaC requires the siting to be undertaken in accordance with:

- ARPANSA licences issued for the proposed facility.
- ANSTO Nuclear Medicine Mo99 Facility Siting Licence Waste Management Plan, September 2012.
- ANSTO Nuclear Medicine Mo99 Facility Siting Licence Environment Protection Plan, September 2012.
- ANSTO Nuclear Medicine Mo99 Facility Site Characteristics and Evaluation, September 2012.

Conclusion

The ARPANSA assessor notes that no EIS was required for the proposed conduct.

2.4 Reference Accident

The use of the 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 (RAP 118) [4]. The Reference Accident is specific to the controlled facility or reference design if the detailed design of the facility is not known. It involves the identification of a severe hypothetical accident, beyond the design bases of the facility, and assessing its radiological consequences against the criteria intended to protect the people and the environment. The Reference Accident must be proposed by the applicant and agreed by ARPANSA.

2.4.1 Principles

The ARPANSA principles are based on an internationally accepted strategy of 'defence in depth' for achieving safety. This involves the use of layers of protection that are independent and different, so that a loss of safety at any level is compensated by the protection provided by the next layer (RAP 2) [4].

In assessing the radiological suitability of the proposed site for the ANM Facility, ARPANSA requires that the consequences of a hypothetical severe accident be compared to the siting criteria. ARPANSA's principles (RAPs 117-121) [4] require that following the Reference Accident:

- The implementation of emergency interventions would be feasible at the intervention levels adopted by ARPANSA.
- The contamination of the environment would not be so extensive as to restrict the long-term use of land around the site.

Protective measures designed to ensure that the radiation doses to individuals or to a collective population are minimised are described in *Recommendations: Intervention in Emergency Situations Involving Radiation Exposure, Radiation Protection Series No. 7* (ARPANSA 2004). For urgent protective measures for the general public the Generic Intervention Levels are:

- Sheltering at avertable dose of 10 mSv
- Evacuation at avertable dose of 50 mSv
- Iodine prophylaxis at avertable doses (to the thyroid) of 100 mGy (adults) or 30 mGy (children)

The purpose of the Recommendations is to provide guidance on radiation protection criteria for use in mitigating the consequences of emergencies involving radiation exposure. The application of this guidance is intended to ensure that suitable actions are taken to reduce any adverse health effects, by preventing deterministic effects and minimising the stochastic risk to both members of the public and workers.

The ARPANSA assessor has considered both individual and collective effective doses from a severe hypothetical accident scenario at ANSTO's proposed new Mo-99 production facility against the Generic Intervention Levels and the collective dose.

2.4.2 Choice of Accident

Although the detailed design of the facility is not available, ANSTO relied on the current processes in the existing Mo-99 facility and the anticipated plant and equipment similar to the current facility as described in Sections 2.1 to 2.4 of ANM Mo99 Reference Accident (ANSTO/T/TN/2012-07). The ANM Mo99 Reference Accident is based on the most conservative assumptions.

ARPANSA performed an independent analysis of the Reference Accident using the same inventory used by ANSTO with different release scenarios.

ARPANSA accepts the ANSTO's Reference Accident for assessing the suitability of the proposed site. This matter is discussed below under Consequence of Reference Accident. This aspect will be further considered in future assessments for the construction and operating stages since during those stages detailed engineering design features would be available.

2.4.3 Frequency and Severity of the Reference Accident

ANSTO states that the frequency of the Reference Accident would be between 10^{-5} and 10^{-6} per annum. Considering the conservative assumptions in the Reference Accident, the ARPANSA assessor considers that the frequency of the accident is sufficiently low and the accident represents a suitable bounding case for the siting assessment.

The assumed failures of plant and procedures in selecting and analysing the Reference Accident ensure that it is of sufficient severity to assess the site as the last level of defence in depth, which satisfies Principles 2 and 17 [4].

This aspect will be further considered when assessing the licence applications for construction and operation of the facility.

2.4.4 Conservatism of analyses

Principle 11 [4] suggests using realistic assessments of the consequences of beyond-design-basis accidents. Considering that the detailed design information is not available at the siting stage, it is appropriate that the Reference Accident be based on conservative assumptions as described in Principle 118 [4], and ARPANSA expects a comprehensive assessment of design-basis and beyond-design-basis accidents at the detailed design stage, in the PSAR in support of the application for construction of the ANM Facility.

The ARPANSA assessor considered the results of the ARPANSA analysis of the Reference Accident in this assessment. The ARPANSA assessor also considers that ANSTO should be advised to use the same assumptions in the reference accident analysis and to revise the Reference Accident in the application for construction of the ANM Facility.

2.4.5 Consequence of Reference Accident

In the consequence analysis, ANSTO used projected population until 2036 but ARPANSA used projected population until 2046 to estimate the collective dose (man-Sv) to the population.

The ARPANSA analysis shows that the maximum total and thyroid doses for all ages at the 0.5 km ANSTO boundary approach 20 mSv and 200 mGy respectively. The estimate of projected dose at the ANSTO site exceeds the intervention level of 10 mSv for sheltering in place and the projected thyroid doses exceed the 30 mGy intervention level for consideration of iodine prophylaxis.

At the 1.85 km population boundary the modelled total effective age-dependent doses do not exceed 5 mSv. Thyroid dose estimates at the 1.85 km population boundary for a 1 year-old were estimated to be up to 50 mGy, above the 30 mGy intervention level for consideration of iodine prophylaxis. Based on the results of this assessment, urgent protective measures including sheltering for the general public would be recommended. In the release scenario considered the evacuation intervention level would not be reached.

The ARPANSA analysis shows that the maximum collective dose calculated was 23 person-Sv (to the North-East sector), and was projected to increase to 29 person-Sv by 2046.

Based on ARPANSA's analysis of the Reference Accident, the ARPANSA assessor considers that there is significant consequence outside the facility and therefore, the hazard category of the ANM Facility is F2³.

The ARPANSA assessor also considers that ANSTO should be advised to use the same assumptions in the reference accident analysis and to revise the Reference Accident in the application for construction of the ANM Facility.

Conclusion

The ARPANSA assessor considers that the Reference Accident selected by ANSTO to evaluate the proposed site for the ANM Facility is acceptable as relevant siting criteria and principles including use of a conservative inventory of fission gases, loss of defence in depth and conservatism in assumptions have been considered in the selection of this accident.

The ARPANSA assessor considers that the assumptions in the Reference Accident should be the most conservative in line with the assumptions considered in the ARPANSA analysis.

The analysis performed by ARPANSA indicates very limited radiological consequences from a hypothetical and conservative exposure scenario. Coupled with the low probability of the accident scenario, the resulting risk to people at the population boundary is extremely small.

The results show that there would be no long-term disruption to land use following the Reference Accident.

The ARPANSA assessor notes that ANSTO undertook to provide further analyses at the construction application stage for the facility as detailed information on engineering features would be available at that stage. This is considered acceptable.

³ Hazard Category F1: where there is no potential for significant consequences outside the facility

Hazard Category F2: where there is potential for significant consequences on the site outside the facility, but not outside the site.

The ARPANSA assessor considers that the Reference Accident should be reviewed, adopting the most conservative approach, in the licence applications for construction and operation of the ANM Facility. This review should incorporate additional information and details on the design and operational features as they mature during the design phase. Based on ARPANSA analysis of the Reference Accident, the ARPANSA assessor considers that the hazard category of the facility is F2.

The ARPANSA assessor also considers that ANSTO must consider the results of the Reference Accident while developing the plans and arrangements for managing safety, and considering the design features of the facility for the licence applications for construction and operation of the facility. ANSTO will be advised to revise the Reference Accident adopting the same conservative assumptions used in the ARPANSA analysis.

2.5 Other Matters for Consideration

2.5.1 Whether the information establishes that the proposed conduct can be carried out without undue risk to the health and safety of people, and to the environment [paragraph 41(3)(b) of the Regulations]

The application to site the ANM Facility has included information that establishes acceptable controls for operating activities by identifying the hazards and assessing the safety and risks of the proposed activities. The application has been assessed against the relevant matters to be taken into account by the CEO, as described in sections 2.1 to 2.3 of this report. The Reference Accident has also been considered in the assessment. Based on this assessment, the ARPANSA assessor is of the opinion that the information contained within the application can establish that the proposed conduct of siting the ANM Facility can be carried out without undue risk to the health and safety of people, and to the environment and therefore will satisfy the requirement of Regulation 41(3)(b).

2.5.2 Whether there is a net benefit from the conduct [paragraph 41(3)(c) of the Regulations]

The facility will be used for production of Mo-99, which is the precursor of Tc-99m the radionuclide used in 80% of the medical diagnostic procedures. ANSTO states that apart from ensuring domestic supply of Mo-99-Tc-99m, the proposed facility will have the capacity to export, which will help the future global supply. If the facility is approved for operation it will most likely involve limited exposure to operators but the benefit that millions of patients will receive will outweigh the risk associated with the operation of the facility.

The ARPANSA assessor considers that the facility will provide a net benefit once it becomes operational.

2.5.3 Whether the doses are as low as reasonably achievable, having regard to economic and social factors [paragraph 41(3)(d) of the Regulations]

The dose constraint for operators of the facility is 15 mSv/year. In addition, ANSTO has an annual ALARA objective of 2 mSv as part of further optimisation of radiation protection. Since the siting will not involve dealing with radioactive material the doses for the proposed conduct will be ALARA. However, the doses for the operating stage must be assessed taking into account detailed design information and operational arrangements and controls. The Radiation Protection Plan foreshadowed the expected arrangements for radiation protection to be in place if the facility is approved for operation, and is assessed in Section 2.2.3. Considering the dose profile of the current Mo-99 plant it is expected that the doses will be acceptably low if the facility is approved for operation. This matter will be further considered when assessing the licence applications for construction and operation of the facility.

2.5.4 Whether the Applicant can comply with the regulations and the licence conditions [paragraph 41(3)(e) of the Regulations]

The applicant is the CEO of ANSTO. ANSTO is licensed by ARPANSA to operate numerous nuclear installations and prescribed radiation facilities and it has been proven that ANSTO is capable of complying with the ARPANS Act and Regulations and licence conditions.

2.5.5 Whether the Application has been signed by an authorised person [paragraph 41(3)(f) of the Regulations]

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

2.5.6 If the Application is for a facility licence for a nuclear installation - the content of any public submissions [paragraph 41(3)(g) of the Regulations]

Regulation 40 requires the CEO of ARPANSA to advertise receipt of the site licence application for the ANM Facility and to invite submissions from the public in the Australian Government Gazette and a national newspaper. ARPANSA published the following notices in accordance with regulation 40:

- A notice in the Australian Government Gazette on 8 May 2013.
- A notice on the ARPANSA website from 8 May 2013.
- A notice in The Australian newspaper on 8 May 2013.
- Notices in the St George and Sutherland Shire Leader newspapers in editions from 8 - 16 May 2013.
- Notice in the Liverpool Leader on 8 May 2013.

Copies of the siting licence application submitted by ANSTO were made available to the public along with the advice on to how make a submission.

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.

ARPANSA received 30 submissions; 17 of which addressed the ANM Facility, three submissions addressed the processing of the radioactive liquid waste to be generated from the ANM Facility and 10 submissions addressed the Interim Waste Store (IWS). Submissions addressing the processing of radioactive liquid waste and the IWS are considered under separate licence applications (A0266 and A0277).

Submissions on the ANM Facility raised the following issues:

- Radioactive liquid waste from the proposed facility
- Evaluation of an alternative technology for Mo-99 production
- Information about proliferation of Pu-239 suspected to be generated in the Mo-99 production process
- Information about accumulation of Pu-239 in the waste from Mo-99 production process
- Amount of Pu-239 to be produced in the Mo-99 process
- ANSTO long term road map for non-fission based methods for production of Mo-99
- Concern about use of the proposed facility for facilitating nuclear weapons development
- Transporting radioactive waste to overseas
- Risks of transportation of radioactive waste
- ANSTO may be given the go-ahead to produce more radioactive waste than necessary
- Cost of the expansion of the production facility
- Resourcing in the State Emergency Services, ANSTO contribution to the need for increased services, and inclusion of this in the cost analysis
- Inadequate addressing of security aspects
- Compensation for public health, property or environmental damage resulting from a serious accident
- Support for this industry while the scientific community lacks funding for non-invasive and safe treatments
- Production of Mo-99 beyond Australia's needs that are for overseas distribution, as the wastes to be generated from the excess production will be stored at ANSTO Lucas Heights Facility
- Demographic changes

The ARPANSA assessor considered the public submissions in relation to ANSTO's application to prepare a site for the ANM Facility. The submissions along with ANSTO's responses and ARPANSA's comments are presented in Appendix-4.

Issues about the construction and operation of the ANM Facility will be considered further in the assessment of applications for licences to construct and operate the facility. Several public submissions raised issues about Government policy in nuclear science research and radioactive waste management which ARPANSA was not able to address in its assessment.

2.5.7 International Best Practice

Sub-section 32(3) of the Act requires the CEO, in making a decision on a facility licence, to take into account international best practice in relation to radiation protection and nuclear safety.

ARPANSA has developed a set of Guidelines [3] and Principles [4] which are based on international standards and recommendations, particularly those of the International Atomic Energy Agency (IAEA), and the contemporary practices in the radiation and nuclear safety industries of developed countries. The IAEA standards and recommendations have been developed by consensus of member countries and represent the distillation of best practice of their cumulative radiation and nuclear safety experience.

The ARPANSA assessor notes that the technology expected to be incorporated in the proposed facility is also used in Argentina, Belgium, Netherlands and South Africa for the production of Mo-99 through the fission process. Therefore, similar technology is used in other countries.

To address sub-section 32(3) of the Act, the assessor took into account assessments of the application against the *Regulatory Guide: Plans & Arrangements for Managing Safety v3* (October 2011) [3] and RAPs [4].

The dose limits considered in the siting of the facility are in accordance with the RPS 1 (Radiation Protection series No. 1) [9], which is based on the 1991 Recommendations of the International Commission on Radiological Protection (ICRP) in its Publication 60 [10], superseded by ICRP Publication 103 [11]. RPS 1 is currently being revised to take into account ICRP Publication 103 [11]; the changes are not material to the review of this application.

Conclusion

The information contained in the application refers to relevant IAEA safety Standards (GSR Part 3, BSS) [12] and ICRP recommendations (ICRP Publication 103) [11]. The facility has incorporated internationally applicable principles in the siting of the facility. Similar technology and processes are used in other countries for the production of Mo-99, including Argentina, Belgium, the Netherlands and South Africa. The ARPANSA assessor notes that more than 98% of Mo-99 is produced from HEU (high enriched uranium) targets but the proposed facility will utilise LEU (low enriched uranium) targets. The ARPANSA assessor considers that the adoption of international best practice in designs and technology and radiation protection as described in the application is acceptable.

3. OVERALL CONSIDERATIONS

In assessing this application, the ARPANSA assessor has taken into account the following:

- The proposed facility will use similar technology to that used in the current Mo-99 production plant and therefore, operational procedures and operator training will be quite similar and ANSTO will be able to use their long experience in operating such a facility. In addition, operational experience will also be useful in improving the design of the proposed facility and in developing procedures and arrangements for the facility.
- The proposed facility will have the capability of producing about four times the current production level.
- Design features at the construction and operating stages will take into account the use of improved technology so that the airborne emission levels do not increase significantly although the production level will increase by about 4-fold.
- Design features incorporate state-of-the-art technology.
- Design provisions will reduce manual handling.

4. CONCLUSIONS

The matters set out in sub-regulation 41(3) that the CEO is required to take into account in making a licensing decision, have been described in this report in section 2.5 Other Matters for Consideration. The application and information provided in support of the application provide evidence that:

- The application was in a form approved by the CEO under sub-regulation 39(1), including payment of the relevant application fee (section 1.1).
- The applicant included all of the information required by the CEO under section 34 of the Act (sections 2.1 to 2.3).
- The information establishes that siting of the ANM Facility poses no undue risk to the health and safety of people or to the environment; this has been considered for both anticipated normal operation and potential accident scenarios if the facility is approved for operation in future (section 2.5.1).
- The applicant has shown a net benefit from siting of the ANM Facility (section 2.5.2)
- Reasonably achievable efforts have been proposed to optimise protection taking into account available information of the magnitude of individual doses, the number of people exposed and the likelihood that exposure will occur (section 2.5.3).
- The applicant has shown a capacity for complying with the regulations and licence conditions (section 2.5.4).
- The application was signed by the requisite office holder (section 2.5.5).

The contents of public submissions were considered in section 2.5.6 of this report.

The regulatory review documents relied on in the licence assessment and preparation of this report (section 1.3) reflect current international best practice in relation to radiation protection and nuclear safety. Further, the standards and practices considered in the concept design of the facility and the existing operating practices have also been considered as part of international best practice.

5. RECOMMENDATIONS

5.1 Issue of Licence

It is recommended that Facility Licence F0270 be issued to ANSTO in respect of licence application A0270 authorising the siting of a controlled facility, namely the ANSTO Nuclear Medicine Mo-99 Facility and the organisation advised to provide the following:

- A revised Reference Accident for the ANM Facility using the same assumptions made in the ARPANSA Reference Accident analysis with the construction licence application and incorporating the details of design and operational features of the proposed facility.

Assessor			
NAME: Samir Sarkar	SIGNATURE:	<i>ORIGINAL SIGNED</i>	DATE: 3 / 10 / 2013
Branch Head			
NAME: Martin Dwyer	SIGNATURE:	<i>ORIGINAL SIGNED</i>	DATE: 3 / 10 / 2013

6. REFERENCES

- [1] *Australian Radiation Protection and Nuclear Safety Act 1998*
- [2] *Australian Radiation Protection and Nuclear Safety Regulations 1999*
- [3] *Regulatory Guide: Plans & Arrangements for Managing Safety v3* (October 2011)
- [4] Australian Radiation Protection and Nuclear Safety Agency, *Regulatory Assessment Principles for Controlled Facilities*, RB-STD-42-00, Revision 1, October 2001
- [5] International Atomic Energy Agency, IAEA, *Site Evaluation for Nuclear Installations, Safety requirements*, NS-R-3, 2003
- [6] International Atomic Energy Agency, IAEA, *Safety Aspects in Siting for Nuclear Installations* (draft DS433, 2013) [6]
- [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 [7]
- [8] Australian Radiation Protection and Nuclear Safety Agency, *Regulatory Assessment Criteria for Design of New Controlled Facilities and Modifications to Existing Facilities*, RB-STD-43-00, Revision 1, October 2001.
- [9] Australian Radiation Protection and Nuclear Safety Agency, *Recommendations for Limiting Exposure to Ionizing Radiation (1995) and National Standard for Limiting Occupational Exposure to Ionizing Radiation* (republished 2002)
- [10] International Commission on radiological Protection, ICRP, Publication 60, *The 1990 Recommendations of the ICRP*
- [11] International Commission on radiological Protection, ICRP, Publication 103, *The 2007 Recommendations of the ICRP*
- [12] International Atomic Energy Agency, IAEA, *radiation Protection and safety of Radiation Sources: International Basic safety Standards, Interim Edition, General Safety Requirements Part 3*, 2011

APPENDIX-1

1. ANSTO Nuclear Medicine Mo99 Facility Site Characteristics and Evaluation, ANM-Mo99-S-LA-C4ab, September 2012
2. ANSTO Nuclear Medicine Mo99 Facility Reference Accident Assessment, ANSTO/T/TN/2012-07 rev 0, September 2012
3. ANSTO Nuclear Medicine Mo99 Facility Siting Licence Effective Control Plan, ANM-Mo99-S-LA-D1, September 2012
4. ANSTO Nuclear Medicine Mo99 Facility Siting Licence safety management Plan, September 2012
5. ANSTO Nuclear Medicine Mo99 Facility Siting Licence Radiation Protection Plan, ANM-Mo99-S-LA-D3, September 2012
6. ANSTO Nuclear Medicine Mo99 Facility Siting Licence Waste Management Plan, ANM-Mo99-S-LA-D4, September 2012
7. ANSTO Nuclear Medicine Mo99 Facility Siting Licence Security Plan, ANM-Mo99-S-LA-D5, September 2012
8. ANSTO Nuclear Medicine Mo99 Facility Siting Licence Emergency Plan, ANM-Mo99-S-LA-D6, September 2012
9. ANSTO Nuclear Medicine Mo99 Facility Siting Licence Environmental Protection Plan, ANM-Mo99-S-LA-D7
10. Additional Information provided on 30 April 2013 in response to the questions on 26 March 2013, R13/05413
11. ANSTO Responses on Public Submissions, R13/07151
12. ANSTO communication dated 12 August 2013, R13/08946
13. ANSTO Radiation Protection services Baseline Radiological Survey ANM MO99 & SYNROC, ANSTO/RPS/TN/2013-1, September 2013, R13/10205

APPENDIX-2



Australian Government

Australian Radiation Protection and Nuclear Safety Agency

D12016473

7 November 2012

Ms Mahani Taylor
 Director
 New South Wales Section
 South-Eastern Australia Assessment Branch
 Department of Sustainability, Environment, Water, Population and Communities
 GPO Box 787
 CANBERRA ACT 2601

Dear Ms Taylor

Thank you for your letter of 26 October 2012 to the Parliamentary Secretary for Health and Ageing, The Hon Catherine King MP, inviting comment on referral EPBC 2012/6598 ANSTO Nuclear Medicine Mo-99 Facility, Lucas Heights, NSW. The Parliamentary Secretary has asked me to respond on her behalf.

The Australian Radiation Protection And Nuclear Safety Agency (ARPANSA) is the licensing authority for radiation production facilities proposed to be established by a Commonwealth entity or contractor under the *Australian Radiation Protection and Nuclear Safety Act 1998 (ARPANS Act)*.

On 26 October 2012, ARPANSA received a siting licence application from the Australian Nuclear Science and Technology Organisation (ANSTO) for a facility to produce molybdenum-99 (Mo-99). The proposed action by ANSTO represents a major expansion of ANSTO's Mo-99 production capacity with a planned increase of three to four times the capacity of the existing Mo-99 production facility in the ANSTO campus at Lucas Heights. It will be a new facility requiring a separate siting licence. The activity level of the material to be manufactured causes the facility to be classified as a nuclear action under the *Environment Protection and Biodiversity Conservation Act 1999* (the EPBC Act). Provided I grant ANSTO a siting licence, the project will still require licences from ARPANSA for the construction and operation of the facility.

I note that in 2003 the Parliamentary Secretary for Health and Ageing commented on a referral (EPBC 2003/1114) under the EPBC Act for an extension of the existing Mo-99 production facility. At that time, our advice to the Parliamentary Secretary was that the extension was a nuclear action under the EPBC Act as it significantly modified a nuclear installation. In that instance, ANSTO applied to the CEO of ARPANSA for approval under Regulation 51 of the *Australian Radiation Protection and Nuclear Safety Regulations 1999* to make a change with significant implications for safety.

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 the existing environmental discharge limits set for the

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existing smaller Mo-99 plant. ANSTO's present application is only for the siting of the proposed facility and this licence is not required to include sufficient information about whether the current environmental discharge limits are likely to be compliant when the proposed Mo-99 production facility is in operation. We will receive more comprehensive information in this respect when ANSTO applies for its construction and operation licences at a later stage of this process.

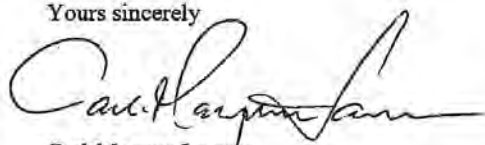
You will also note from page 4 of ANSTO's referral ('001 Referral of proposed action v Nov 10') that the disposal pathway for intermediate level liquid radioactive wastes in the proposed Mo-99 production facility will involve the use of a proposed radioactive waste treatment facility (SyMo) using ANSTO's Synroc technology. We have received a separate licence application from ANSTO for the siting and construction of SyMo. The proposed SyMo facility does not require consideration under the EPBC Act as a nuclear action as it is a 'prescribed radiation facility' and not a 'nuclear installation' under the ARPANS Act. However, in view of the connection between Mo-99 production and the proposed waste facility, and considering the SyMo facility will involve high temperatures and pressures, we have requested ANSTO seek your view on whether SyMo might also justify scrutiny under the EPBC Act. Nevertheless, we note SyMo's potential to greatly reduce the volume of physical waste generated by the proposed Mo-99 production facility.

The new Mo-99 facility will render the existing Mo-99 facility redundant and we would expect to receive advice from ANSTO in the near future about its plans to decommission, remove or re-use this facility. We have not currently received advice from ANSTO on the redundant Mo-99 facility.

ARPANSA's assessment of ANSTO's application for a siting licence for the proposed Mo-99 production facility under the ARPANS Act will include technical assessments of the safety of the proposed facility. Guidance to applicants is given in documents available on our website at <http://www.arpansa.gov.au/pubs/regulatory/guides/OS-LA-SUP-240G.pdf>. These documents detail the issues for consideration when making the licensing decision for this type of facility. Also, as part of our assessment, there will be public consultation, opportunity for public submissions and comments and public forum discussion. Comments received during public consultation will be considered by ARPANSA in its assessment of the licence application.

I hope this information is helpful to your Department as you consider ANSTO's application under the EPBC Act.

Yours sincerely



Carl-Magnus Larsson
CEO of ARPANSA

APPENDIX-3

NOTIFICATION OF REFERRAL DECISION – NOT CONTROLLED ACTION IF UNDERTAKEN IN A PARTICULAR MANNER

ANSTO Nuclear Medicine Mo99 Facility, Lucas Heights, NSW (EPBC 2012/6598)

This decision is made under sections 75 and 77A of the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act).

Proposed action

person named in the referral	Australian Nuclear Science and Technology Organisation (ANSTO) ABN: 47956969590
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proposed action	The construction, commissioning and operation of a facility to manufacture the medical radioisotope molybdenum-99 (Mo-99), at Lucas Heights Science and Technology Centre (LHSTC) on Einstein Avenue, Lucas Heights, NSW (See EPBC Act referral 2012/6598).
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Referral decision: Not a controlled action if undertaken in a particular manner

status of proposed action	The proposed action is not a controlled action provided it is undertaken in the manner set out in this decision.
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Person authorised to make decision

Name and position	Tessa Bird Acting Assistant Secretary South-Eastern Australia Environment Assessments
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signature	
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date of decision	13 December 2012
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manner in which proposed action must be taken	The following measures must be taken to avoid significant impacts on <ul style="list-style-type: none"> • Nuclear actions (sections 21 & 22A) • Commonwealth land (sections 26 & 27A) • Commonwealth action (section 28)
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1. The action must be undertaken in accordance with:
 - any Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) licences issued for the proposed facility; and
 - the following industry standard or code of practice (as amended from time to time):
 - ANSTO Nuclear Medicine Mo99 Facility Siting Licence Waste Management Plan, September 2012;
 - ANSTO Nuclear Medicine Mo99 Facility Siting Licence Environment Protection Plan, September 2012; and
 - ANSTO Nuclear Medicine Mo99 Facility Site Characteristics and Evaluation, September 2012.

APPENDIX-4

Responses to questions and comments from public submissions re: IWS, ANM Mo99 and SyMo applications

Question/comment	ANSTO Response	ARPANSA Comment
<p>1. Of primary concern is a mixture of highly radioactive fission products ('molywaste') generated from ⁹⁹Mo is stated by ANSTO to comprise the majority of radioactivity to be stored at Lucas Heights, surprisingly more than spent fuel rods and considerably more than the waste returning from France. Molywaste, particularly in its liquid form represents the most hazardous material at Lucas Heights, both for ANSTO workers and surrounding residents.</p>	<p>The licence applications do not make this statement.</p> <p>The OPAL reactor at Lucas Heights is designed for 20MW with 300 days operating time per year. This requires burning 6.3Kg of U-235 per year with the corresponding fission products. The ANM Mo-99 plant running at its design capacity will use only 0.35Kg of U-235 per year generating a correspondingly significantly smaller amount of fission products.</p>	<p>ARPANSA assessor considers that ANSTO comment is acceptable as it relies on the proposed purpose and corresponding design. ARPANSA will consider further details when assessing the licence application for construction and operation of the facility.</p>
<p>2. Why has ANSTO not evaluated non-fission alternatives to avoid generation of molywaste? Serious consideration should be given to alternatives that use accelerators to produce ⁹⁹Mo or ⁹⁹Tc-m by selective reaction without fission-product waste.</p>	<p>ANSTO has evaluated non-reactor alternatives for the production of Mo-99 and Tc-99m. Such evaluation has also been undertaken by international bodies, in particular the OECD Nuclear Energy Agency (NEA). The NEA report (http://www.oecd-nea.org/med-radio/reports/Med-Radio-99Mo-Prod-Tech.pdf) noted that no such alternative technologies are currently in use anywhere in the world, and expressed strong doubts as to whether they could ever substitute for reactor technologies. Given that, it would be grossly irresponsible for ANSTO to risk the health of Australians on unproven technology.</p>	<p>The application is for production of Mo-99 in commercial scale. Based on the available information on production of Mo-99 in the literature ARPANSA assessor notes that accelerator production of Tc-99m is not used for any commercial scale production facilities.</p>

<p>3. Little has been said about the alternate proliferation risk of plutonium created as a by-product of 99Mo production and potentially separable from molywaste by altering the chemical treatment of the waste stream.</p>	<p>In a typical production year, the ANM Mo99 facility operating at capacity will produce approximately 6.2 g of Pu-239, which is less than 1/1000 of the amount that would be of significance from a safeguards perspective. Furthermore, that Pu-239 will be mixed with other materials and will therefore be unusable for any purpose.</p> <p>Further, the facility will be under IAEA safeguards, including regular inspections, to ensure that any material of concern could not be diverted from the declared activities. We also note that sub-section 5(2) of the ANSTO Act provides: “The Organisation shall not undertake research or development into the design or production of nuclear weapons or other nuclear explosive devices”.</p>	<p>ARPANSA will consider sampling requirements and possible OLCs in this regard.</p>
<p>4. Insufficient details have been given to assess whether the quantity of Pu239 in accumulating molywaste is likely to be a proliferation concern. The isotope ratio is likely to be weapons-compatible.</p>	<p>See response to question 3.</p>	<p>See 3 above</p>
<p>5. Just how much plutonium will be produced in the waste stream for the new facility? ANSTO is requested to publish an accurate calculation of the mass of 239Pu created for each batch of 99Mo and the mass to thus accumulate over the course of the planned 99Mo production program.</p>	<p>See response to question 3.</p>	<p>See 3 above</p>

6. ANSTO is asked to provide a long term road map for the development of non-fission based methods for the production of ⁹⁹ Tc-m regardless of the outcome of the current application.	See response to question 2.	See 2 above
7. There is concern that the proposed radioisotope production facility might potentially facilitate nuclear weapons development at Lucas Heights.	See response to question 3.	See 3 above
8. If the Synroc system is so safe then why have there been so many successful legal challenges to moving the waste from Lucas Heights to a permanent repository?	<p>There have been no successful legal challenges to moving the waste from Lucas Heights to a permanent repository. There is currently an unresolved court case (in which ANSTO is not involved) regarding the nomination of Muckaty Station in the Northern Territory as a possible site for a National Radioactive Waste Management Facility (NRWMF), but that case is based around provisions of the Land Rights Act, not any hazard which might be posed by radioactive waste.</p> <p>In any event, the waste to be stored in the IWS is not in synroc form but the majority of the waste is vitrified and a small amount of waste is cemented (i.e. technological wastes). The waste from the IWS will be moved to a NRWMF when it becomes available.</p>	ARPANSA is not aware of any legal challenge in transferring waste from Lucas Heights.
9. Is Synroc being used anywhere else in the world? If it is successful in dealing with nuclear waste why did we need to transport our waste overseas if we had this technology at the time?	Synroc is being investigated by many governments around the world and it has been shown to be cost effective for certain wastes. The Synroc HIP technology has been chosen by the UK for Pu-wastes and in the USA for calcined waste in	

Idaho.

The *Environment Protection and Biodiversity Conservation Act 1999* and the *Australian Radiation Protection and Nuclear Safety Act 1998* prohibit the development of nuclear fuel reprocessing facilities in Australia. It is therefore not possible to use Synroc in fuel re-processing.

10. A cost/benefit appraisal of Synroc and its reliability are missing from the public information.

A cost/benefit appraisal was developed in preparing the business case for the ANM projects. This has been subject to detailed scrutiny through the Cabinet process and the subsequent application to the Public Works Committee (PWC).

11. Are we still going to transport any waste overseas for reprocessing?

Spent fuel from the OPAL reactor will be returned either for reprocessing in Europe or for permanent storage in the US.

There is no current intention to send any wastes arising from the ANM facility overseas for reprocessing.

Any such conduct will be subject to ARPANSA scrutiny.

12. What are the risks of transportation of radioactive waste?

The safety record of the transport of radioactive material is very strong. The international regulations ensure the protection of people and the environment in all credible accident scenarios.

The safety of transport packages is assessed against the requirements of the ARPANSA Code of Practice for the Safe Transport of Radioactive Material 2008 (RPS 2) which is based on the IAEA Regulations for the Safe Transport of Radioactive Material. The transport containers are heavily engineered and extremely robust. This, coupled with the immobilised nature of the waste make the risks associated with transport of radioactive waste

		extremely low.
13. ANSTO may be given the go ahead to produce more nuclear waste than may be necessary.	One of the fundamental principles of radioactive waste management is that of waste minimisation and ANSTO is committed to this principle. A strong factor in the selection of the Synroc process is that it minimises the volume of waste for later handling and storage. There are also comprehensive features in the ANM Mo99 plant for safely handling and minimising gaseous and other wastes.	ARPANSA has in the decision requested ANSTO to further detail their waste management plan and contingencies.
14. There is no information on the cost of the expansion of the production facilities, the IWS or the decommissioning of HIFAR.	We are not sure how this is relevant to the safety and security of the facilities. This application is not relevant to the decommissioning of HIFAR.	
15. State Emergency Services are already suffering a lack of resources. Does ANSTO contribute to the need for increased services? Is this included in the costs?	ANSTO has long established liaison arrangements with the NSW Emergency Services. These include joint meetings and joint exercises. In terms of the requirements for support and cooperation with these services, the new ANM Mo99 and Synroc facilities are similar to the existing facilities on the ANSTO Lucas Heights site which include the OPAL reactor, the existing Mo99 production facility and waste facilities. There will be no need for changes to these arrangements.	
16. Security has not been adequately addressed.	ANSTO has a comprehensive security system, based on Australian and internationally required standards, to guard its nuclear materials, radioactive sources and facilities. All people and vehicles entering the site are subject to inspection by Australian Federal Police (AFP) Protective	Assessment of arrangements for Security has been assessed as required by Item 4(a) of Part of Schedule 3 of the Regulations. The results of assessment are presented in Section 2.2.5 of this report.

Service officers, who guard the site 24 hours a day. AFP and ANSTO officers also regularly patrol the entire site and the buffer zone. There are regular reviews by expert agencies, including the Australian Security Intelligence Organisation and the Australian Safeguards and Non-Proliferation Office, to ensure security continues to meet the stringent national and international physical security protection standards. In addition, agency inspectors from the Australian Radiation Protection and Nuclear Safety Agency can require access to ANSTO's sites at any time to conduct security inspections. ANSTO's security risk assessments are supported by information provided by the Australian Security Intelligence Organisation and other government departments and agencies. The Australian Federal Police are on site to provide an armed, high level and professional service that deters, prevents and effectively manages security threats through a proactive, flexible, robust and intelligence driven approach. The Australian Federal Police have a 24 hour presence at ANSTO with support from NSW Police and the Australian Defence Force as appropriate. Whilst armed Australian Federal Police is a strong deterrent there are a range of other of other sophisticated security controls involving people, technology, operations and processes. For each transport of radioactive materials a security transport plan is developed in conjunction with law enforcement agencies who provide security support to such movements.

17. There is no legal compensation commitment for public health, property or environmental damage resulting from a serious accident.

On the issue of legal liability, ANSTO's liability would flow in accordance with usual legal principles of negligence applicable in NSW. This means that if ANSTO is proven to have caused personal injury or death to persons or property damage or environmental damage due to a release of ionising radiation, whether directly or indirectly, or due to other negligence, then it will be legally liable to compensate such persons or owners of such property. ANSTO has commercial insurance in place to cover this potential liability, as well as supplementary cover under a Deed of Indemnity from the Commonwealth of Australia.

The commercial insurance policy covers liability arising out of ANSTO's responsibility for : (a) managing, storing and conditioning Ionising Radiation (as defined) emitting material and waste; (b) transporting nuclear waste and materials for disposal both within Australia and overseas; and (c) transporting radioactive materials including radioisotopes.

18. Why is such an industry supported when the scientific research community is crying out for funds for non-invasive and safe treatments?

The beauty of nuclear medicine is that it is indeed non-invasive and safe – which is recognised by doctors and by organisations such as the Cancer Council. ANSTO supplies some 10,000 doses of radioisotopes per week for use in nuclear medicine procedures across Australia. One in two Australians in their lifetime will receive a nuclear medicine treatment from OPAL. ANSTO-produced radioisotopes are used for the diagnosis of heart disease and a range of

cancers and skeletal injuries both in Australia and internationally.

19. Why is ANSTO producing Mo-99 beyond Australia's needs that are for overseas distribution, as the wastes to be generated from the excess production will be stored at ANSTO Lucas Heights Facility?

The Global supply of nuclear medicine is currently under threat, with reactors responsible for around 70 per cent of the world's current Mo-99 production due to close between 2015 and 2020. Further with medical modernisation in developing countries, global demand for Mo-99 is increasing by up to 10 per cent a year.

The production of Mo-99 is dependent on highly specialised infrastructure e.g. a reactor and Mo-99 production facility. As a result, every country cannot be expected to produce its own supply. Australia has benefited from international cooperation in the past when we needed to rely on imports of Mo-99 and has also contributed to world supply during shortages.

Australia is well placed to help meet the increasing demand for Mo-99 and as a member of the community of nations and a significant player in the region has a responsibility to do so.

Australia is also in a unique position of being able to produce Mo-99 exclusively using low enriched uranium (LEU). Currently, most of the global Mo-99 supply is produced in reactors fuelled by highly enriched uranium (HEU) and using HEU targets. HEU can be used in nuclear weapons. Consequently, alternative manufacturing processes are highly desirable.

For example, the US has put measures in place to favour Mo-99 produced in reactors fuelled by proliferation proof LEU, such as that used in Australia's OPAL reactor. The development of ANSTO's new Mo-99 facility will therefore contribute to global nuclear security and non-proliferation, and was identified by the former

This matter has been considered in the decision and ANSTO is requested to further develop their waste management plan including contingencies

Prime Minister at the 2012 Nuclear Security

Summit as a major contribution by Australia to global nuclear security.

Importantly, the co-located Synroc waste treatment plant will use the Australian innovation, Synroc, to convert the necessary waste into a stable, synthetic rock suitable for transportation to the National Radioactive Waste Management Facility for long term storage once it is operational. The new Synroc plant will reduce the volume of nuclear byproducts by 90 to 95 per cent compared to existing waste treatment methods, resulting in a smaller volume of waste being temporarily stored at ANSTO’s Lucas Heights campus. The costs of waste treatment will be included in the price charged for Mo-99, meaning that there will be no subsidy to overseas patients.

20. Where and when is a ‘National Radioactive Waste Management Facility’ going to be constructed?

There is bipartisan support for a NRWMF and it will be the Government who decides its location. The site currently under study is Muckaty station in the Northern Territory, however other sites may be considered. It is expected that a facility will be available by the end of the decade.

The *National Radioactive Waste Management Act 2012* makes provision to site, construct and operate a NRWMF subject to environmental and radiation protection regulatory approvals. The Department of Resources, Energy and Tourism (RET) has responsibility for management of the Commonwealth’s radioactive waste and as part of this responsibility is implementing the Government’s policy to establish a permanent facility.

21. The analysis given at 2.2.1 of “Siting Safety Assessment. Site Characteristics and Site Related

As stated in the Siting Safety Assessment (section 2.2.1), there are no credible accident scenarios that could cause

For the three ANSTO licence applications, the projected population out to 2046 has been

Design Bases” about population around LHSTC looks really superfluous. There is a reference to quite out-dated “OPAL Safety Analysis Report (INVAP/ANSTO 2004)” (which is not provided) whereas the analysis about population density and population distribution is required.

any conceivable risk to the surrounding population. It was thus considered unnecessary to include such population data in this application. However, ANSTO has developed decade projections of population from the ABS 2006 Census data, and the NSW Department of Planning data for another licence application

considered by ARPANSA; in particular, in its analysis of the Reference Accident of ANM Mo99 Facility.

22. The general requirement of the IAEA is low density area around a waste storage site. A multimillion population urban area in Sydney metro area cannot be considered low density. Location near the Woronora River, a major water supply, adds to the hazards.

That is not correct. The siting process is a risk-based one. To cite text from IAEA, the siting of nuclear installations “...is concerned with the evaluation of those site related factors that have to be taken into account to ensure that the site– installation combination does not constitute an unacceptable risk to individuals, the population or the environment over the lifetime of the installation.” IAEA Safety Requirements No. NS-R-3, Nov 2003. Given the robust nature of the transport / storage containers and the immobilised nature (vitrified and cemented) of the waste, the risks associated with storage at Lucas Heights are negligible. Although the Woronora River is a water supply source, Lucas Heights is well downstream of the Woronora Dam. In any case, this is not relevant as there are no liquid, gaseous, or soluble wastes to be stored in the facility and therefore no credible release scenario is considered.

For the three ANSTO licence applications the projected population out to 2046 has been considered by ARPANSA; in particular, in its analysis of the Reference Accident of ANM Mo99 Facility.

23. The risks of possible large bushfire are too high (every 8 – 12 years). The deserted location looks much better.

Extensive studies have been undertaken in relation to the bushfire risk to the OPAL reactor. This has led to a detailed analysis of the different pathways that would constitute a risk to the public or to the environment. It has been

concluded that there is no credible risk of the release of radiation from the OPAL reactor. The IWS is well enveloped within the risk assessment for the OPAL reactor. There is much less radioactive material associated with the IWS, and the TN81 transport/storage container in which the vitrified waste will be housed is rated to withstand temperatures of 800°C for 30 minutes. Hence there is no credible radiation risk from the IWS as a result of bushfire.

24. What is to become of the decommissioned reactor? Is it to be cut up and buried at Lucas Heights?

This is a separate issue, and its regulatory approval process will be dealt separately but when the permanently shut-down reactor HIFAR is decommissioned, it will be dismantled in a safe manner. The radioactive waste arising from the decommissioning operation will be appropriately conditioned, packaged and sent to the NRWMF.

Decommissioning of HIFAR reactor is subject to ARPANSA regulatory approval.

25. I was required to sign an indemnity for the Australia Government before I could buy my house and when I raised that issue at the information session my veracity was challenged. So what is it that ANSTO is trying so hard to conceal? Whatever happened to transparency?

ANSTO is not aware of the basis for this statement, and cannot comment without seeing the document referred to. The applications for this facility – like ANSTO's operations generally - are open and transparent.

26. ANSTO and the Government should negotiate deferral of planned return shipment until a suitable national repository is available.

Any attempt to renegotiate the time scale for return of the waste could damage Australia's international reputation in relation to our global nuclear obligations. It is important to meet our obligations to France otherwise it raises uncertainty and may have negative financial impacts on future reprocessing services.

27. What assurances are there that Lucas Heights will not become a permanent waste store?	The ANSTO Act prevents that occurring.	The <i>ANSTO Act 1987</i> prohibits the permanent storage of radioactive waste at ANSTO.
28. I understand that the waste returning from France and the UK will carry the same amount of radioactivity as the original material sent from Australia.	This fact has been public since the 1990s.	This is correct, however there is a substitution contract for the waste from the UK, which means that the cement waste will remain there and an equivalent amount of more stable and lesser volume of vitrified waste will be returned.
29. Is there any high level waste resulting from decommissioning of HIFAR?	There will be no high level waste resulting from the decommissioning actions of HIFAR. ANSTO does not generate High Level Waste.	
30. What is the impact on the increased local population?	The safety assessment of the IWS (ANSTO/T/TN/2021-03 Rev 2) concluded that there are no credible scenarios which could impact on people or the environment.	The projected population until 2046 has been considered in ARPANSA analysis of the reference Accident of the ANM Mo99 Facility. ARPANSA analysis shows that there are no significant radiological risk to the people and environment.