FACILITY LICENCE APPLICATION

NUCLEAR INSTALLATION

Use this form to apply for a facility licence for a nuclear installation under section 32 of the Australian Radiation Protection and Nuclear Safety Act 1998. Applicants should refer to Regulatory Guide: How to Apply for a Facility Licence for a Nuclear Installation when completing this form.
<table>
<thead>
<tr>
<th>DEPARTMENT OR COMMONWEALTH BODY:</th>
<th>ANSTO Nuclear Medicine Pty Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>PORTFOLIO:</td>
<td>Department of Industry, Innovation, Science, Research and Tertiary Education</td>
</tr>
<tr>
<td>PERSON MAKING THE APPLICATION:</td>
<td>(Department Secretary, CEO or other authorised delegate)¹</td>
</tr>
<tr>
<td>NAME:</td>
<td>Dr Adrian Paterson</td>
</tr>
<tr>
<td>POSITION:</td>
<td>Chief Executive Officer</td>
</tr>
<tr>
<td>BUSINESS ADDRESS:</td>
<td>Locked Bag 2001 Kirrawee DC NSW 2232</td>
</tr>
<tr>
<td>PH:</td>
<td>02 9717 3702</td>
</tr>
<tr>
<td>EMAIL:</td>
<td><a href="mailto:adi.paterson@ansto.gov.au">adi.paterson@ansto.gov.au</a></td>
</tr>
<tr>
<td>FAX:</td>
<td>0297176111</td>
</tr>
<tr>
<td>NOMINEE (where applicable):</td>
<td></td>
</tr>
<tr>
<td>NAME:</td>
<td>Jayne Senior</td>
</tr>
<tr>
<td>POSITION:</td>
<td>General Manager, ANSTO Nuclear Medicine</td>
</tr>
<tr>
<td>BUSINESS ADDRESS:</td>
<td>Locked Bag 2001 Kirrawee DC NSW 2232</td>
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<tr>
<td>PH:</td>
<td>02 9717 3653</td>
</tr>
<tr>
<td>EMAIL:</td>
<td><a href="mailto:jayne.senior@ansto.gov.au">jayne.senior@ansto.gov.au</a></td>
</tr>
<tr>
<td>FAX:</td>
<td>n/a</td>
</tr>
<tr>
<td>RADIATION SAFETY OFFICER (or contact person)</td>
<td></td>
</tr>
<tr>
<td>NAME:</td>
<td>Robin Foy</td>
</tr>
<tr>
<td>POSITION:</td>
<td>Manager, Radiation Protection Services</td>
</tr>
<tr>
<td>BUSINESS ADDRESS:</td>
<td>Locked Bag 2001 Kirrawee DC NSW 2232</td>
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<tr>
<td>PH:</td>
<td>02 9717 9787</td>
</tr>
<tr>
<td>EMAIL:</td>
<td><a href="mailto:robin.foy@ansto.gov.au">robin.foy@ansto.gov.au</a></td>
</tr>
<tr>
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</tbody>
</table>

DECLARATION (To be signed by the person making the application)

I hereby declare that the information provided on this form and in support of this application is, to the best of my knowledge, complete and true in every particular.

Signed: [Signature]  
Date: 7/4/17

¹A copy of the instrument of authorisation must accompany the application if it has been signed by an authorised delegate.
## SECTION B – KIND OF NUCLEAR INSTALLATION & TYPE OF AUTHORISATION

*Indicate the kind of nuclear installation and type of authorisation for which a licence is sought*

<table>
<thead>
<tr>
<th>ITEM</th>
<th>KIND OF NUCLEAR INSTALLATION AND TYPE OF AUTHORISATION REQUIRED</th>
<th>CHECK</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Preparing a site for a controlled facility, being a nuclear reactor that is designed: (a) for research or production of nuclear materials for industrial or medical use (including critical and subcritical assemblies); and (b) to have maximum thermal power of less than 1 megawatt</td>
<td>☐</td>
</tr>
<tr>
<td>2</td>
<td>Constructing a controlled facility, being a nuclear reactor that is designed: (a) for research or production of nuclear materials for industrial or medical use (including critical and subcritical assemblies); and (b) to have maximum thermal power of less than 1 megawatt</td>
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<td>3</td>
<td>Possessing or controlling a controlled facility, being a nuclear reactor: (a) for research or production of nuclear materials for industrial or medical use (including critical and subcritical assemblies); and (b) with maximum thermal power of less than 1 megawatt</td>
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<tr>
<td>4</td>
<td>Operating a controlled facility, being a nuclear reactor: (a) for research or production of nuclear materials for industrial or medical use (including critical and subcritical assemblies); and (b) with maximum thermal power of less than 1 megawatt</td>
<td>☐</td>
</tr>
<tr>
<td>5</td>
<td>De-commissioning, disposing of or abandoning a controlled facility, being a nuclear reactor that: (a) was used for research or production of nuclear materials for industrial or medical use (including critical and subcritical assemblies); and (b) had maximum thermal power of less than 1 megawatt</td>
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<tr>
<td>6</td>
<td>Preparing a site for a controlled facility, being a nuclear reactor that is designed: (a) for research or production of nuclear materials for industrial or medical use (including critical and subcritical assemblies); and (b) to have maximum thermal power of 1 megawatt or more</td>
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<td>Constructing a controlled facility, being a nuclear reactor that is designed: (a) for research or production of nuclear materials for industrial or medical use (including critical and subcritical assemblies); and (b) to have maximum thermal power of 1 megawatt or more</td>
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<td>Possessing or controlling a controlled facility, being a nuclear reactor: (a) for research or production of nuclear materials for industrial or medical use (including critical and subcritical assemblies); and (b) with maximum thermal power of 1 megawatt or more</td>
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<td>9</td>
<td>Operating a controlled facility, being a nuclear reactor: (a) for research or production of nuclear materials for industrial or medical use (including critical and subcritical assemblies); and (b) with maximum thermal power of 1 megawatt or more</td>
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<td>De-commissioning, disposing of or abandoning a controlled facility, being a nuclear reactor that: (a) was used for research or production of nuclear materials for industrial or medical use (including critical and subcritical assemblies); and (b) had maximum thermal power of 1 megawatt or more</td>
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<tr>
<td>11</td>
<td>Preparing a site for a controlled facility, being a plant for preparing or storing fuel for use in a nuclear reactor of a kind mentioned in any of items 1 to 9</td>
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</tr>
</tbody>
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2 Source: Table in clause 1 of Schedule 3A to the Australian Radiation Protection and Nuclear Safety Regulations 1999 (the Regulations)
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<tr>
<td>12</td>
<td>Constructing a controlled facility, being a plant for preparing or storing fuel for use in a nuclear reactor of a kind mentioned in any of items 1 to 9</td>
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<tr>
<td>13</td>
<td>Possessing or controlling a controlled facility, being a plant for preparing or storing fuel for use in a nuclear reactor of a kind mentioned in any of items 1 to 9</td>
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<tr>
<td>14</td>
<td>Operating a controlled facility, being a plant for preparing or storing fuel for use in a nuclear reactor of a kind mentioned in any of items 1 to 9</td>
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<tr>
<td>15</td>
<td>De-commissioning, disposing of or abandoning a controlled facility, being a plant that was used for preparing or storing fuel for use in a nuclear reactor of a kind mentioned in any of items 1 to 9</td>
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<tr>
<td>16</td>
<td>Preparing a site for a controlled facility, being: (a) a nuclear waste storage facility that is designed to contain controlled materials with an activity that is greater than the applicable activity level prescribed by regulation 7; or (b) a nuclear waste disposal facility that is designed to contain controlled materials with an activity that is greater than the applicable activity level prescribed by regulation 8</td>
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<td>Constructing a controlled facility, being: (a) a nuclear waste storage facility that is designed to contain controlled materials with an activity that is greater than the applicable activity level prescribed by regulation 7; or (b) a nuclear waste disposal facility that is designed to contain controlled materials with an activity that is greater than the applicable activity level prescribed by regulation 8</td>
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<td>Operating a controlled facility, being: (a) a nuclear waste storage facility that contains controlled materials with an activity that is greater than the applicable activity level prescribed by regulation 7; or (b) a nuclear waste disposal facility that contains controlled materials with an activity that is greater than the applicable activity level prescribed by regulation 8</td>
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<td>20</td>
<td>De-commissioning, disposing of or abandoning a controlled facility, being: (a) a nuclear waste storage facility that formerly contained controlled materials with an activity that was greater than the applicable activity level prescribed by regulation 7; or (b) a nuclear waste disposal facility that formerly contained controlled materials with an activity that was greater than the applicable activity level prescribed by regulation 8</td>
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</tr>
<tr>
<td>21</td>
<td>Preparing a site for a controlled facility, being a facility to produce radioisotopes, that is designed to contain controlled materials with an activity that is greater than the applicable activity level prescribed by regulation 11</td>
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<tr>
<td>22</td>
<td>Constructing a controlled facility, being a facility to produce radioisotopes, that is designed to contain controlled materials with an activity that is greater than the applicable activity level prescribed by regulation 11</td>
<td>☐</td>
</tr>
<tr>
<td>23</td>
<td>Possessing or controlling a controlled facility, being a facility producing radioisotopes and containing controlled materials with an activity that is greater than the applicable activity level prescribed by regulation 11</td>
<td>☐</td>
</tr>
<tr>
<td>24</td>
<td>Operating a controlled facility, being a facility producing radioisotopes and containing controlled materials with an activity that is greater than the applicable activity level prescribed by regulation 11</td>
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</tr>
<tr>
<td>25</td>
<td>De-commissioning, disposing of, or abandoning a controlled facility, being a facility that formerly produced radioisotopes and contained controlled materials with an activity that was greater than the applicable activity level prescribed by regulation 11</td>
<td>☐</td>
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</tbody>
</table>
SECTION C – FACILITY DETAILS

ADDRESS OF THE NUCLEAR INSTALLATION

ANM Mo-99 Facility - Building 88
QC Active Laboratory - Building 2, Rooms 0142 and 0143
Lucas Heights Science and Technology Centre, New Illawarra Road, Lucas Heights, NSW 2234

PURPOSE OF THE NUCLEAR INSTALLATION

To extract and purify radioisotope Molybdenum-99 from uranium target plates irradiated in ANSTO’s OPAL reactor for the production of Technetium 99m generators.

DESCRIPTION OF THE NUCLEAR INSTALLATION AND ITS SITE

The nuclear installation is a purpose built facility, where Mo-99 is extracted from irradiated targets, processed, packaged and dispatched to the Tc-99m generator assembly plants. Part of the Mo-99 produced will go to the existing ANSTO Tc-99m generator production facility currently operated by ANSTO Health under ARPANSA licence F0262 and the remaining Mo-99 will be despatched to Tc-99m generator plants overseas.

SITE OF THE INSTALLATION

The site for the new 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 site has been investigated extensively in the safety assessments and ARPANSA licence applications for other Nuclear Installations including the OPAL reactor (ARPANSA licence F0157) and has proved to be a suitable location for this facility with siting licence F0270 being granted.

The site is established and is currently used for existing similar licensed operations. This area is near the OPAL reactor and has been identified in the long-term infrastructure plan as the preferred area for operations related to the reactor. The ANM Mo99 production facility is close to the OPAL Reactor, the SyMo liquid waste processing plant (planned to use the ANSTO Synroc technology) and the ANSTO Health Tc-99m generator assembly plant. The close proximity to these associated facilities optimises operations and minimises risks when transporting irradiated targets and waste streams between the facilities.

PROCESS DESCRIPTION

The technology is based on the proven alkaline fission product Mo-99 production process. It will incorporate desirable elements from both the existing ANSTO plant and the NTP Radioisotopes Soc Ltd (NTP) plant in South Africa.

The ANM Mo99 facility includes:
- 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, despatch and removing waste and a plant room housing main switchboards, plant and equipment.
- A system to ensure capture and decay of dissolver off-gasses.
- Ventilation systems to supply clean air to and extract potentially contaminated air from production equipment and areas.
- Laboratory activities which will integrate with the existing laboratories on site.
- Storage areas and active maintenance areas.

Further description of the process and equipment are given in P-50098 ANM Mo99 Facility Safety Analysis Report.

**TYPE OF AUTHORISATION (complete relevant section)**

**PREPARE A SITE FOR A NUCLEAR INSTALLATION**

1. *Provide a detailed site evaluation establishing the suitability of the site*

2. *Describe the characteristics of the site, including the extent to which the site may be affected by natural and man-made events*

3. *Provide information about any environmental impact statement requested or required by a government agency, and the outcome of the environmental assessment*

**CONSTRUCT A NUCLEAR INSTALLATION**

1. *Describe the design of the controlled facility, including ways in which the design deals with the physical and environmental characteristics of the site*

2. *Describe any fundamental difficulties that will need to be resolved before any future authorisation is given*

3. *Describe the construction plan and schedule*
4. Provide information about the preliminary safety analysis report that demonstrates the adequacy of the design of the facility and identifies structure, components and systems that are safety related items (include copy)

5. Describe the arrangements for testing and commissioning safety related items

**POSSESS OR CONTROL A NUCLEAR INSTALLATION**

1. Describe the arrangements for maintaining criticality safety during loading, moving or storing nuclear fuel and other fissile materials at the controlled facility

2. Describe the arrangements for safe storage of controlled material and maintaining the controlled facility

**OPERATE A NUCLEAR INSTALLATION**

1. Describe the structures, components, systems and equipment of the controlled facility as they have been constructed

   The facility has been constructed under ARPANSA license F0285 granted to construct a Nuclear Installation, known as the ANM Mo99 facility. A description of the structures, components, systems and equipment are provided in Structures, Systems, Componenets and Equipment of ANM (Q-50395) Design safety principles, process, and hazard and protection systems are discussed in the ANM SAR (P-50098).

2. Provide information about a final safety analysis report that demonstrates the adequacy of the design of the controlled facility, and includes the results of commissioning tests (include copy)

   The Safety Analysis Report (SAR) is provided with this application;
   P-50098 r2 Safety Analysis Report.pdf

   The SAR is based on final as-built design information, safety assessments, Cold and Hot commissioning plans and will form the safety basis for the ongoing operation, periodic review and any future modifications to the facility including the proposed establishment of the second production line.

   This SAR describes the building, plant and production processes and presents the assessed safety and environmental impacts associated with these. It includes information on the design principles for nuclear, radiation and general safety protection and an overview of the key safety management considerations and systems in place for the full lifecycle of the facility.
No significant process or inventory modifications have been made since the preliminary SAR was issued and a construction licence approved. The main improvement made to the facility since the construction licence was issued and as a result of the detailed design engineering and assessment processes is the inclusion of over-pressure and vacuum breakers to each hot cell to protect the sealed Hot Cell structures in the unlikely event of a maximum achievable over or under pressure respectively. A change from the PSAR is that the product Quality Control (QC) facilities are not being installed or commissioned within Building 88 at this stage. Consequently this SAR now describes a new QC Blue Laboratory (including process and associated safety assessment information) being commissioned exclusively for ANM Mo-99 product sample QC analysis in Building 2.

This SAR demonstrates that the ANM Mo-99 facility, as built, configured, managed and maintained can be operated without posing any undue risk to either the workforce or members of the public or the environment.

The results of cold commissioning tests will be provided as they become available.

3. **Describe the operational limits and conditions of the controlled facility**

The operating limits and conditions are described in

P-50099_r3 Operating Limits and Conditions.pdf

4. **Describe the arrangements for commissioning the controlled facility**

The commissioning plans for the facility are described in;

Mo99_COMM_PROC_CTP_1174 rB Commissioning Plan - Process.pdf

Mo99_COMM_SAFE_PL_1573 rB Commissioning Plan - Systems.pdf

5. **Describe the arrangements for operating the controlled facility**

The arrangements are described in the facility plans and arrangements provided with this application. The management of plans and arrangements and overall control of the facility is the responsibility of the licence Nominee, the General Manager, ANM. Specific procedures are in place which describe the processes employed to ensure the facility is operated in a controlled and adequately resourced manner, ensuring the safety and security of the facility. Standards and systems are maintained to meet and exceed all relevant legislated and other safety requirements. Key procedures for the safe operation of the plant are the Safe and Secure Operations (P-50100) and Operating Limits and Conditions ( P-50099), also provided with this application. Position descriptions describe the responsibilities for each position within ANM, including responsibilities for safety and security. Staff are required to be familiar with, and competent to undertake, processes within their area of responsibility. Records of training in the processes and related procedures are maintained.

Service level agreements have been developed for services provided by ANSTO in the areas of radiation and work health and safety, waste management, engineering and maintenance, human resources, information technology, finance, security and emergency services as follows:

NUCLEAR SERVICES
- Radiation protection advice
- Environmental and stack emission monitoring
- Meteorology & plume transport modelling
- Regulatory Affairs support

WASTE SERVICES
- Conditioning, management and storage of low and intermediate level solid waste and low level liquid waste from the manufacturing process of Mo-99.
- Storage of SyMo treated ILLW
- Effluent collection and discharge from the facility

SECURITY and EMERGENCY
- Nuclear safeguards for the facility
- Security services
- Emergency arrangements

ENGINEERING, CAPITAL PROGRAMS and FACILITIES
- Technical services for engineering and capital programs within ANM and decommisioning services for plant and equipment
- Maintenance and management of utilities and facilities
- Management of assets used or owned by ANM.

HUMAN RESOURCES and WHS SERVICES
- Personnel management, employee support, workforce planning
- Training and development
- WHS management systems and operational support
- Health centre access

BUSINESS SERVICES
- Access to IT systems and equipment.
- Service, support and maintenance of IT equipment and systems.
- Financial regulatory reporting
- Accounts payable and receivable
- Payment of taxes
- Tendering and contracts of goods and services
- Strategic external and government relations advice
- Communication, media liaison and promotion of ANM
- Legal services, including contracts and legal documentation.
- Risk, compliance and audit services

### DECOMMISSION A NUCLEAR INSTALLATION

1. **Describe the decommissioning plan for the controlled facility**

2. **Describe the schedule for decommissioning the controlled facility**

### ABANDON (CLOSE) A NUCLEAR INSTALLATION

1. **Provide results of decommissioning activities at the controlled facility**

2. **Provide details of any environmental monitoring program proposed for the site**

### SECTION D – PLANS & ARRANGEMENTS

*Describe the plans and arrangements for managing the facility and any associated sources in the space provided AND/OR provide clear references to where this information may be found within accompanying documentation.*

*Identify trusted international standards relevant to the proposed facility and describe how these will be applied or taken into account.*

#### EFFECTIVE CONTROL ARRANGEMENTS

Described in the Effective Control Plan - Q-50081, provided with this application

#### SAFETY MANAGEMENT PLAN

Described in the Safety Management Plan - Q-50082, provided with this application

#### RADIATION PROTECTION PLAN

Described in the Radiation Protection Plan, Q-50083, provided with this application

#### RADIOACTIVE WASTE MANAGEMENT PLAN

Described in the Waste Management Plan, Q-50084, provided with this application
**SECURITY PLAN**

Described in the Security Plan, Q-50085, provided with this application

**EMERGENCY PLAN**

Described in the Emergency Plan, Q-50086, provided with this application

**ENVIRONMENT PROTECTION PLAN**

Described in the Environment Plan, Q-50323, provided with this application

**SECTION E – ASSOCIATED SOURCES**

Is there controlled material and/or controlled apparatus used in connection with the facility?

- **NO** - proceed to Section G
- **YES** - describe in the space below.

If Yes: identify codes and standards relevant to the source(s) and describe how compliance with the requirements of the codes and/or standards will be achieved.

Radioactive sources are used in B2 Blue QC laboratory (Building 2 room 0142) for the calibration of laboratory instruments. A source is used in B88 for calibration of the in-cell ion chamber. A source inventory workbook will be maintained and is attached to this application, with source details. Testing will be performed where relevant according to the ARPANSA Guidelines on Wipe testing of Sealed Sources & Use of Sealed Sources Beyond Recommended Working Life. Movement of these sources, for example to another ANSTO division or for disposal, will be performed according to ANSTO internal procedures, compliant with ARPANSA’s Guide for Transfer or Disposal of Sources.

**SECTION F – SOURCE DETAILS**

Complete the Excel Spreadsheet known as the Source Inventory Workbook (SIW) for any sources used in connection with the facility [Click here for template]

Note: For sealed sources, a copy of any source certificate or special form certificate should accompany the application as per item 5(d) of Part 2 of the Regulations.

**SECTION G – MATTERS TO BE TAKEN INTO ACCOUNT BY THE CEO**

INTERNATIONAL BEST PRACTICE IN RADIATION PROTECTION AND NUCLEAR SAFETY

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3 Under regulation 42 of the Australian Radiation Protection and Nuclear Safety Regulations 1999, the CEO will also take into account the content of any submissions made by members of the public about the application, pursuant to a notice issued under regulation 40.
Describe how international best practice in radiation protection and nuclear safety will be considered with respect to the facility.

ANSTO has adopted the appropriate guidelines for operating the ANM Mo99 facility. In relation to process Operations, the project has followed the IAEA safety requirements in their Evaluation for Nuclear Installation (No. NS-R-3).

The Mo99 production technology is based on the proven alkaline fission product process, which is the most widely used process worldwide. The ANM Mo99 process incorporates desirable elements from both the existing ANSTO plant and the NTP Radioisotopes Pty Ltd (NTP) plant in South Africa. ANSTO staff have made visits to the NTP plant and collaborated with NTP staff to develop a design under an IP agreement.

The facility has been designed to meet the required standards for buildings containing nuclear materials and high levels of radioactivity. The proposed process uses LEU targets as feed material which is preferred internationally because it greatly enhances safety relating to security and non-proliferation. Further these targets will be irradiated in the ANSTO OPAL reactor which itself uses LEU fuel.

Licence condition 3.7 (d) of the combined ANSTO Health licence requires that "The Licence Holder must include in the Safety Analysis Report consideration of Reference Accidents for each Radiopharmaceuticals Operations Facility."

The intent is that the conservatively determined consequences are not exceeded by any credible accident that it is possible to postulate for the facility. Assumptions made in the assessment are, by necessity, conservative.

The Reference Accident for the ANM Facility is a hypothetical scenario whose consequences bound all credible postulated accidents. International best practice indicates that the level of conservatism should not be excessive, otherwise plans are developed for a scenario that will in all likelihood, never happen, taking focus from more likely events.

The potential effect of this release on the site and surrounding suburbs was examined using a combination of best practice dispersion modelling, dose modelling and data on meteorological conditions and the surrounding population. The assessment showed that all the consequences are below levels requiring the consideration of intervention (sheltering or provision of stable iodine), i.e. the release could be managed with the existing counter-measures in place within ANSTO and with the external emergency services.

The existing ANSTO operations routinely comply with all requirements under the ARPANS legislation. These arrangements are implemented under certifications to current ISO 9001 management systems standards. ANSTO is committed to protecting the environment, as demonstrated by its certification to the current ISO 14001 international environmental management system standard. ANSTO maintains a high standard of monitoring of emissions to support this.

The arrangements for radiation protection and radiation safety are given in Radiation Safety [AS-2310, WHS Radiation Safety Standard.] and supporting practices which together form a comprehensive suite of arrangements consistent with international best practice. In the Operating licence application, arrangements for the planning and control of exposure to radiation are described in the Radiation Protection Plan [Q-50083].

All additional plans included within the submission [including Effective Control Plan (Q-50081), Safety Management (Q-50082), Waste Management Plan (Q-50084), Security Plan (Q-50085), Emergency Plan (Q-50086), and Environmental Protection Plan (Q-50087)] are compliant with the ARPANS Act and Regulations and with current Australian National Standards and Codes. The Plans are consistent with international best practice and is in accordance with the International Atomic Energy Agency (IAEA) standards and its guidelines on protection against the effects of ionising radiation (IAEA Safety Series No. 115, 1996 and Safety Guide No RS-G-1.1, ICRP 103).
INFORMATION ASKED FOR BY THE CEO

Confirm that all information asked for by the CEO has been provided.

The information requested by the CEO is contained within this application on the prescribed form and in the accompanying plans and arrangements which have been prepared following the ARPANSA guidelines.

UNDUE RISK

Provide information to show that there is no undue risk from radiation associated with the facility.

The ANM Mo99 Reference Accident Assessment (ANSTO/T/TN/2012-07) considered the radiological risk from severe accident scenarios to test that radiation doses are within criteria and that emergency interventions can be implemented if needed. The dose results for the worst accident scenarios were compared with regulatory criteria and these results satisfy the criteria with a safety margin. The report concluded that the proposed ANM Mo99 facility will be safe with respect to offsite effects. It will be an F1 category installation with no safety impact outside of the facility.

The ANM Mo99 Facility Operational Risk Assessment (ANSTO/T/TN/2015-20) assessed the risks of internal abnormal events to safety of the proposed operation of the ANM Mo99 facility. The report concluded that significant accidents are unlikely and that there is no significant off-site consequence from these events.

The Radiation Protection Plan (P-50083), provided with this application, describes measures in place to minimise the risk of exposure to ionising radiation as a result of operational activities at ANM. These measures ensure compliance with the ARPANS Act and Regulations and current Australian National Standards and Codes.

NET BENEFIT

Provide information that demonstrates a net benefit from the proposed conduct.

The facility is operated to produce Molybdenum-99 which is used in Technetium-99m generators. Technetium-99m is used in 90% of diagnostic nuclear medicine procedures around the world. The majority of the world's supply is currently produced by four reactors all of which are over 40 years old and reaching the end of their life. Also the existing Molybdenum-99 plant at ANSTO is nearing the end of its operating life. This poses significant challenges to the reliability of future production of Mo-99 as the current fleet of reactors is subject to longer and more frequent planned and unplanned shutdowns, as well as the potential for permanent shutdowns within the next 10 years. The ANSTO Nuclear Medicine facility will utilise Low Enriched Uranium (LEU) and has the capacity to supply 25 - 30% of the current global demand, ensuring both domestic and international supply is maintained and reduce the risk of a supply shortage.

ALARA

Provide information in relation to the proposed conduct to show that the magnitude of individual doses, the number of people exposed, and the likelihood that exposure will happen, are as low as reasonably achievable, having regard to economic and social factors.

The new ANM Mo99 facility meets the existing standards and requirements relating to radiation dose to staff and relating to the potential for exposure of members of the public in the event of releases to off-site.
A dose assessment (Mo99_FACL_OPER_TN_0329) has been performed for the activities proposed in the facility and associated activities and is provided with this application. The radiation protection plan (P-50083) further describes the organisational arrangements and procedures for the control of exposures to ionising radiation during all operational activities at the ANM Mo-99 facility. The plan outlines the systems and processes that ensure compliance with standards and regulatory requirements on radiation protection; the plan also outlines the application of optimisation of protection measures at the ANM Mo-99 facility.

The discussion and assessment of potential dose to members of the public is in the report ANM Mo99 Reference Accident Assessment (ANSTO/T/TN/2012-07) given in the previous siting application. The Reference Accident assumptions are reviewed in the SAR (P-50098) and are conservative.

**CAPACITY TO COMPLY**

*Provide information to show that the applicant has the capacity to comply with the Regulations and any licence conditions that may be imposed.*

ANM operates within ANSTO’s well established procedures for the management of controlled facilities. These facilities comply with ARPANS Regulations and licence conditions, as evidenced by the ongoing compliant operation of other Nuclear Installations and facilities, including the OPAL Reactor (licence F 0157) and the existing Mo-99 manufacturing facility (licence F 0262). As described in the Effective Control Plan, P-50081, ANM have engaged sufficient personnel to implement the commitments made in this licence submission, comply with the regulations and comply with any additional conditions which may be imposed.

**AUTHORISED SIGNATORY**

*Confirm that the application has been signed by an office holder of the applicant or a person authorised by an office holder of the applicant.*

The application has been signed by the CEO, ANSTO, the authorised signatory of the applicant.
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<thead>
<tr>
<th>CHECKLIST</th>
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<tr>
<td>ITEM</td>
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<tr>
<td>1. Completed and signed Section A – Applicant information</td>
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<td>2. Instrument of authorisation for authorised person</td>
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<td>3. Organisational chart showing nominee</td>
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<td>4. Completed Section B – Kind of facility &amp; type of authorisation</td>
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<td>5. Completed Section C – Facility Details</td>
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<td>6. Documents to support Section C</td>
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<td>7. Completed Section D – Plans and Arrangements (including relevant TIS)</td>
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<td>8. Documents to support Section D</td>
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<td>9. Completed Section E – Associated Sources (including relevant codes and standards)</td>
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<td>10. Documents to support Section E</td>
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<td>11. Completed Section F – SIW (on CD-ROM or email attachment)</td>
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<td>12. A copy of any Sealed Source or Special Form Certificates</td>
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<td>13. Completed Section G – Matters to be considered by the CEO</td>
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<td>14. Documents to support Section G</td>
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<td>15. CD-ROM of entire application including Section G (SIW) and all supporting documentation</td>
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<td>16. CD-ROM of application suitable for public review</td>
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<td>NOTE: The applicant must include alternative format of all documents (besides pdf) to satisfy Australian Government Web Accessibility guidelines</td>
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<td>17. Appropriate application fee</td>
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SUBMITTING THE APPLICATION

This application form, all accompanying documentation, any CDs, and the appropriate application fee should be sent to:

The CEO of ARPANSA
PO Box 655
MIRANDA NSW 1490

OR

licenceadmin@arpansa.gov.au

Note: If the email option is chosen, prior arrangements must be made for payment of the application fee either by cheque or electronic funds transfer before the application can be accepted. Arrangements should also be made for delivery of CDs.