Australian Government
Australian Radiation Protection and Nuclear Safety Agency

arpansa

FACILITY LICENCE APPLICATION

Nuclear installation

Applicants should refer to REGULATORY GUIDE: How to apply for a licence for a nuclear installation to complete this form

REGULATORY SERVICES

ARPANSA-FORM-1802 v9.5

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Section A: Applicant information

Department or Commonwealth entity:	Australian Nuclear Science and Technology Organisation
Portfolio:	Department of Industry, Science and Resources
[redacted]	

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.

Print name: [redacted]

Sign: [redacted]

Date:

[1]A 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

Select from the table below

ITEM	KIND OF NUCLEAR INSTALLATION AND TYPE OF AUTHORISATION REQUIRED	CHECK
1	Preparing a site for a nuclear reactor designed: (a) for research or production of radioactive materials for industrial or medical use (including critical and subcritical assemblies); and (b) to have maximum thermal power less than 1 megawatt	☐
2	Constructing a nuclear reactor designed: (a) for research or production of radioactive materials for industrial or medical use (including critical and subcritical assemblies); and (b) to have maximum thermal power less than 1 megawatt	☐
3	Possessing or controlling a nuclear reactor: (a) for research or production of radioactive materials for industrial or medical use (including critical and subcritical assemblies); and (b) with maximum thermal power less than 1 megawatt	☐
4	Operating a nuclear reactor: (a) for research or production of radioactive materials for industrial or medical use (including critical and subcritical assemblies); and (b) with maximum thermal power less than 1 megawatt	☐
5	Decommissioning, disposing of or abandoning a nuclear reactor that: (a) was used for research or production of radioactive materials for industrial or medical use (including critical and subcritical assemblies); and (b) had maximum thermal power less than 1 megawatt	☐
6	Preparing a site for a nuclear reactor that is designed: (a) for research or production of radioactive materials for industrial or medical use (including critical and subcritical assemblies); and (b) to have maximum thermal power of at least 1 megawatt	☐
7	Constructing a nuclear reactor that is designed: (a) for research or production of radioactive materials for industrial or medical use (including critical and subcritical assemblies); and (b) to have maximum thermal power of at least 1 megawatt	☐
8	Possessing or controlling a nuclear reactor: (a) for research or production of radioactive materials for industrial or medical use (including critical and subcritical assemblies); and (b) with maximum thermal power of at least 1 megawatt	☐
9	Operating a nuclear reactor: (a) for research or production of radioactive materials for industrial or medical use (including critical and subcritical assemblies); and (b) with maximum thermal power of at least 1 megawatt	☐
10	Decommissioning, disposing of or abandoning a nuclear reactor that: (a) was used for research or production of radioactive materials for industrial or medical use (including critical and subcritical assemblies); and (b) had maximum thermal power of at least 1 megawatt	☐
11	Preparing a site for a plant for preparing or storing fuel for use in a nuclear reactor of a kind mentioned in any of items 1 to 9	☐
12	Constructing a plant for preparing or storing fuel for use in a nuclear reactor of a kind mentioned in any of items 1 to 9	☐
13	Possessing or controlling a plant for preparing or storing fuel for use in a nuclear reactor of a kind mentioned in any of items 1 to 9	☐
14	Operating a plant for preparing or storing fuel for use in a nuclear reactor of a kind mentioned in any of items 1 to 9	☐

15	Decommissioning, disposing of or abandoning 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	☐
16	Preparing a site for: (a) a radioactive waste storage facility that is designed to contain controlled materials with an activity greater than the applicable activity level prescribed by Section 10 of the Regulations; or (b) a radioactive waste disposal facility designed to contain controlled materials and have an activity greater than the applicable activity level prescribed by Section 11 of the Regulations	☐
17	Constructing: (a) a radioactive waste storage facility designed to contain controlled materials and have an activity that is greater than the applicable activity level prescribed by Section 10 of the Regulations; or (b) a radioactive waste disposal facility that is designed to contain controlled materials and have an activity greater than the applicable activity level prescribed by Section 11 of the Regulations	☐
18	Possessing or controlling: (a) a radioactive waste storage facility that contains controlled materials that has an activity greater than the applicable activity level prescribed by Section 10 of the Regulations; or (b) a radioactive waste disposal facility that contains controlled materials that has an activity greater than the applicable activity level prescribed by Section 11 of the Regulations	☐
19	Operating a controlled facility, being: (a) a radioactive waste storage facility that contains controlled materials that has an activity greater than the applicable activity level prescribed by Section 10 of the Regulations; or (b) a radioactive waste disposal facility that contains controlled materials that has an activity greater than the applicable activity level prescribed by Section 11 of the Regulations	☐
20	Decommissioning, disposing of or abandoning: (a) a radioactive waste storage facility that formerly contained controlled materials and had an activity greater than the applicable activity level prescribed by Section 10 of the Regulations; or (b) a radioactive waste disposal facility that formerly contained controlled materials and had an activity that was greater than the applicable activity level prescribed by Section 11 of the Regulations	☐
21	Preparing a site for a facility to produce radioisotopes, that is designed to contain controlled materials and have an activity greater than the applicable activity level prescribed by Section 12 of the Regulations	X
22	Constructing a facility to produce radioisotopes, that is designed to contain controlled materials and have an activity greater than the applicable activity level prescribed by Section 12 of the Regulations	☐
23	Possessing or controlling a facility producing radioisotopes and containing controlled materials that has an activity greater than the applicable activity level prescribed by Section 12 of the Regulations	☐
24	Operating a facility producing radioisotopes and containing controlled materials that has an activity greater than the applicable activity level prescribed by Section 12 of the Regulations	☐
25	Decommissioning, disposing of, or abandoning a facility that formerly produced radioisotopes, contained controlled materials and had an activity greater than the applicable activity level prescribed by Section 12 of the Regulations	☐

Section C: Facility details

Address of the nuclear installation

Australian Nuclear Science and Technology Organisation (**ANSTO**)
New Illawarra Road, Lucas Heights, NSW, 2234.

(Planned location of the nuclear installation is bounded by Mendeleev Avenue to the West, Bragg Avenue to the North, Meitner Street to the East, and Buildings 89 to the South.)

Detailed description of the purpose of the nuclear installation

This licence application and the supporting Safety Analysis Report (**SAR**) is for siting of a new Nuclear Medicine Manufacturing Facility (**NMMF**) at the ANSTO Lucas Heights Science and Technology Centre. The NMMF will be a purpose-built nuclear installation to reinforce Australia's sovereign capability to manufacture nuclear medicines for medical treatment of Australian citizens.

ANSTO provides specialised advice, research, and nuclear medicine manufacturing capabilities for more than 85 percent of diagnostic radiopharmaceutical products used every year in Australia. ANSTO works in partnership with more than 220 imaging centres nationally and internationally. The sovereign capability to manufacture and deliver more than 10,000 doses of potentially life-saving medicines every week is a critical component of Australia's national healthcare system.

The NMMF is an essential asset to achieve the Australian Government's mandate for the ANSTO Nuclear Medicine Manufacturing Program (**NMMP**) to deliver the following goals:

1. Secure sovereign supply of nuclear medicine products to enhance patient health outcomes.

2. Provide safe and reliable operability of radiopharmaceutical manufacturing capabilities.

3. Futureproof nuclear medicine manufacturing capability to leverage emerging product technologies.

ANSTO's current radiopharmaceutical manufacturing facility Building 23 (B23), is one of only a few facilities internationally and capable of assembling Mo-99/ Tc-99m generators and producing I-131 and Lu-177 medications. The purpose of the NMMF is to meet increasing demand for the current radiopharmaceutical products produced by ANSTO and to provide the capability for new product development.

On 30 September 2021, the Australian Government announced that it was safeguarding Australia's sovereign capability to produce vital nuclear medicines by launching a program to design and construct a new world-leading manufacturing facility to be built at Lucas Heights in Sydney.

Siting of the NMMF at Lucas Heights recognises the distinct advantages of being a stable secure site, in proximity to active input materials, and existing effective support infrastructure. The benefits include reducing Australia's reliance on foreign supply chains, enhancing Australia's international reputation in the medical sector, improving access to life-saving medicines, and enhanced development of roles in the STEM sector, as well as enhancing nuclear medicine products and production technologies.

Detailed description of the nuclear installation and the site

The NMMF will be a multi-storey building with a footprint of approximately 6,700 m2. The total area of the building is currently designed to be 13,000 m2. The NMMF concept design includes associated manufacturing equipment for technetium, iodine, and lutetium-based products, along with the capability to manufacture radiopharmaceuticals that may be developed in future. This includes a:

- logistics area where raw materials are stored and finished products are packaged and despatched. The floor also includes several ancillary functions such as waste storage;
- production area where radiopharmaceuticals are manufactured and tested. This level also includes an office wing. The production spaces have an interstitial level with utility services i.e. HVAC; and
- plant room/ area.

In addition to a manufacturing space, the building will house several laboratory spaces, a large, open concept office space for roughly 130 employees, receive incoming radioactive and non-radioactive goods, despatch final products, and store and process radioactive waste. The building is being designed not just for ANSTO's current needs, but with flexibility to accommodate the anticipated needs of the next forty-plus years, when required. By future proofing the design, the building will be able to adapt and meet the requirements of the ever-evolving field of nuclear medicine.

Section D: Safety analysis report

*For each activity to be authorised the applicant must provide a safety analysis report (SAR that is as **complete as possible**. Include a description of the SAR document in the relevant space below (version number, date of approval etc).*

Note: Where an activity is not applicable to this application mark as 'N/A' or delete. If applying for authorisation to prepare a site and construct in the same application then reference to the SAR must be included under both headings.

Prepare a site

The NMMF SAR for Siting Licence, (Document Number NMMP-2040-RT-0001) (Revision A1, approved on the 13 November 2024) has been prepared to evidence good safety practices and provides information to support the fact that the proposed Lucas Heights site is suitable, safe, and secure for design and development of the NMMF.

The SAR demonstrates and documents how siting activities that are subject to this submission are suitable, safe, and secure. The planned activities for the facility are based on production and assembly of Mo-99/Tc-99m generators, I-131 products and a Lu-177 product. The concept design for the NMMF also includes arrangements for receipt of radioactive targets. Support activities include reuse of Tc-99m generator secondary casings, quality control management and product packaging and despatch. The SAR also conceptually describes how systems and processes will be applied during later stages of the NMMP including construction, commissioning, operation through to decommissioning.

Key elements of the SAR include the following:

1. **Conceptual Facility Description** describing the physical building structure (SAR Section 1.6) including the Building Structure (Section 1.6.1), Plant and Equipment (Section 1.6.2), Radiological Designation of Areas (Section 1.6.3), Security Arrangements (Section 1.6.4) and Process Descriptions (Section 1.7).

2. **Site Characteristics** for the Location (Section 2.1) including Geological, (Section 2.2), Seismological (Section 2.3), Hydrological (Section 2.4), Metrological (Section 2.5), Site Services (Section 9.6), Surrounding Land Use (Section 2.7), Surrounding Population Distribution (Section 2.8) and Baseline Radiological Levels.

3. **Safety Structures, Systems and Components (SSCs)** describing the Design Codes and Standards to be used, SSC Classification (Section 3.3), Qualification and Operability (Section 3.4), Design Methods (Section

3.5), Design for Safety (Section 3.6), Design for Nuclear Safety and Nuclear Security (Section 3.7), Design for Radiological Safety (Section 3.8), Design for Chemical Safety (Section 3.9), Industrial Safety (Section 3.10), External Events (Section 3.11), Fire Protection (Section 3.12) and Design for Decommissioning (Section 3.13).

4. **Hazard and Accident Analysis** detailing the hazard identification and risk assessment processes used and to be used, including Hazard Identification and Categorisation (Section 4.1), Design Basis Accident Analysis (Section 4.2), Initiating Events and Hazards in the Facility (Section 4.3), Protection Systems (Section 4.4), Risk Management (Section 4.5), Safety Analysis for Normal Operation (Section 4.6), Safety Analysis for External Events (Section 4.7), Emergency Preparedness Categorisation (Section 4.8), Analysis of Environmental Impact (Section 4.9) and Work Health and Safety (Section 4.10).

5. **Safety Management** describing the safety management arrangements specific to the facility, including, ANSTO Safety Policy (Section 5.1), Legal Requirements (Section 5.2), facility Management Structure and Responsibilities (Section 5.3), Safety Approval System (Section 5.4), Quality Assurance Program (Section 5.5) and Control of Normal Operations (Section 5.6).

6. **Operating Limits and Conditions** covering applicable instructions, procedures, or management limits, including Safety Limits and Safety System settings (Section 6.1), Limiting Conditions for Safe Operation (Section 6.2), Surveillance (Section 6.3), Administration (Section 6.4) and Assessment of Operating Limits and Conditions (Section 6.5).

7. **Review of Operating Experience** to develop a culture of continuous improvement the NMMP has considered a number of improvements and recommendations gained through operational experience and the Independent Review of B23 including, Commissioning Program (Section 7.1), Commissioning Report (Section 7.2) History since Commissioning (Section 7.3), Review of Radiological Monitoring Results (Section 7.4), Dose Uptake by workforces (Section 7.5), Waste Quantities arising from operations (Section 7.6), Description of Incident and Accidents (Section 7.7), and Audit and Inspection findings (Section 7.8).

8. **Review of Plant Condition** to be considered during design development and major equipment supply (Section 8.0).

9. **Radiation Protection** measures as detailed in the NMMF Radiation Protection Plan (NMMP-0410-PM-0003) detailing the Principles of Radiation Protection (Section 9.1) and Radiation Protection Program (Section 9.2).

10. **Radioactive Waste Management** arrangements as detailed in the NMMF Waste Management Plan (NMMP-0410-PM-0004) including Policy and Requirements (Section 10.1), Design for Radioactive Waste Management (Section 10.2), Waste management systems (Section 10.3), and Waste Classification and Disposal (Section 10.4).

11. **Decommissioning** describing the steps required for eventual decommissioning of the facility as detailed in the NMMF Decommissioning Plan (NMMP-0410-PM-0007) including Baseline Radiological Characterisation (11.1), Decommissioning Strategy (Section 11.2), and Design for Decommissioning (Section 11.3).

12. **Emergency Planning and Preparedness** outlining the emergency planning and response arrangements to mitigate any incident at the NMMF including during construction and how the NMMF Emergency Plan (NMMP-0410-PM-0005) is integrated into the ANSTO Lucas Heights Emergency Plan, including Policies and

Procedures (Section 12.1), Emergency Response (Section 12.2) Control of Abnormal events and Emergency Arrangements (Section 12.3).

13. Management System details the management system procedures to ensure specific requirements are fulfilled and covering areas of Management Responsibility (Section 13.1), Resource Management (Section 13.2), Process Implementation (Section 13.3) and Change Management (Section 13.4).

The SAR sets out the basis for:

A. Acceptability of the Site Location and Design (Section 14.1)

B. Acceptability of Normal Operations (Section 14.2)

C. Acceptability of Residual Risk Associated with Abnormal Operation (Section 14.3)

D. Adequacy of Emergency Arrangements, Procedures and Exercises (Section 14.4)

E. Maintenance, Inspection and Testing of Safety related Items (Section 14.5)

F. Action Planning for future stages (Section 14.6)

G. Justification for Continued Operation (Section 14.7).

The conclusion drawn in the SAR is that based on the site characteristics, geotechnical and demographic information as well as specific site-related design considerations, development of the NMMF at the proposed site can be done safely with the proposed engineering specifications.

Construct

Not Applicable

Possess or control

Not Applicable

Operate

Not Applicable

Decommission

Not Applicable

Dispose of or abandon

Not Applicable

Section E: Plans & Arrangements

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

Effective control arrangements

Effective control of the site will be maintained by plans and arrangement which include detailed processes for ensuring:

- clearly defined accountabilities and responsibilities for key stakeholders are specified and documented;
- appropriate resources are in place;
- change management processes are clearly documented; and
- processes are in place to support effective communication between relevant stakeholders on matters of facility safety and security.

The NMMF Effective Control Plan (Document Number NMMP-0410-PM-0001) has the following key elements:

A. Accountabilities and Responsibilities, of key stakeholders with specified roles (Section 5)

B. Resources, including financial, human, equipment and material resources as well as resource monitoring processes (Section 6)

C. Communication with relevant stakeholders through the ANSTO and NMMP communication network (Section 7)

D. Process Implementation, particularly with respect to Change Management (Section 8)

E. Documentation and Document Control, linking the ANSTO Business Management System with the NMMP Document Management Plan (Section 9).

Safety Management Plan

Safe management of the site will be maintained through plans and arrangements which include detailed processes for ensuring safety risks are identified and managed efficiently and effectively. This includes ensuring that:

- clearly defined accountabilities and responsibilities are specified and documented;
- safety policy objectives are measured and monitored;
- change management is embedded into decision making; and
- processes are in place for training, education and continuous improvement.

The plans and arrangements explaining how ANSTO will maintain safety of the site are set out in the NMMF Safety Management Plan (Document Number NMMP-0410-PM-0002). The key elements of the NMMF Safety Management Plan are:

A. Responsibility for safety by the ANSTO CEO and delegated nominees (Section 3)

B. Safety Policy and Objectives describing ANSTO's holistic approach and demonstrated values (Section 4)

C. Monitoring and Measurement of performance indicators including incident, response, notification, and investigation (Section 5)

D. Risk Management and Mitigation describing safety risk identification and assessment processes as well as stakeholder involvement and consultation (Section 6)

E. Change Management including Governance, Change Control Assessment, Configuration Management, Regulated Structures, Systems and Components, implementation, and review process (Section 7.1-7.6)

F. Learning and Continuous Improvement through inspection, audit verification and validation (Section 8)

G. Training and Education to ensure potentially hazardous work is performed and supervised by trained and competent personnel (Section 9)

H. Review Process where systems and processes are reviewed periodically to assure ongoing compliance, accuracy and continual improvement. (Section 10)

Radiation protection plan

Radiation protection of the site will be maintained by plans and arrangements which include detailed processes for ensuring:

- responsibilities of nominated delegates of the ANSTO CEO;
- application of the principles of radiation protection;
- application of ALARP principles to achieve optimisation in design of radiological hazard controls; and,
- development of local rules and procedures commensurate with work activities.

The plans and arrangements explaining how ANSTO will maintain radiation protection at the site are set out in the NMMF Radiation Protection Plan (Document Number NMMP-0410-PM-0003). The key elements of the NMMF Radiation Protection Plan are:

A. Responsibilities of ANSTO CEO and nominated delegates, workers and radiation protection services (Section 3.1- 3.4).

B. Principles of Radiation Protection including Justification (Section 5.1), Optimisation of Protection (Section 5.2), Dose Limitation (Section 5.3), Safety Culture (Section 5.4) and Defence in Depth (Section 5.5).

C. Design for Workplace Radiological Hazard Control including application of ALARP principles to achieve optimisation of controls (Section 6).

D. Radiological Classification of Work Areas for area radiation and contamination designation (Section 7).

E. Local Rules and procedures commensurate with work activities and level of protection for safety (Section 8).

F. Personal Protective Equipment for radiological protection and product safety with Good Manufacturing Practice (GMP) (Section 9).

G. Radiation Monitoring Programs for personnel, work area and environmental monitoring including instrumentation (Section 10.1- 10.4).

H. Transport movement of radioactive targets and transfer of product within the facility (Section 11).

I. Training from Basic Radiation Safety through to specialised task-based training programs (Section 12).

J. Record Keeping for required records of authorisation, risk assessment and survey reports (Section 13).

K. Review and Audit of the Radiation Protection Plan to update performance indicators, monitoring results event and incident reports (Section 14).

Radioactive waste management plan

Radioactive waste management at the site will be maintained by plans and arrangements which include detailed processes for ensuring:

- management of radioactive waste, classification, minimisation, movement and transfer;
- arrangements for solid, liquid and gaseous waste; and
- long term disposal arrangements.

The plans and arrangements explaining how ANSTO will manage radioactive waste for the site are set out in NMMP-0410-PM-0004 NMMF Waste Management Plan. The key elements of the NMMF Radioactive Waste Management Plan are:

A. Management of Radioactive Waste (Section 4) including Classification of waste (Section 4.2), Waste Minimisation (Section 4.3), Codes of Practice (Section 4.4), Limiting Exposure to Radioactive Waste (Section 4.5), Packaging and Containment of Radioactive Waste (Section 4.6) Holding Storage of Radioactive Waste in Facility (Section 4.7), Movement and Transfer of Waste (Section 4.8), Record Keeping and Documentation (Section 4.9) and Training of Personnel (Section 4.10).

B. Solid Waste Management (Section 5) including Contact Handled Solid Waste and Remote Handled Solid Waste (Section 5.1 and 5.2), Limiting Exposure to Solid Waste (Section 5.3) Monitoring and Characterisation of Solid Waste (Section 5.4).

C. Liquid Waste Management (Section 6) including Contact Handled Liquid Waste and Remote Handled Liquid Waste (Section 6.1 and 6.2) Non-Active Liquid Waste (Section 6.3), Limiting Exposure to Liquid Waste (Section 6.4) and Monitoring and Sampling of Liquid Waste (Section 6.5).

D. Gaseous Waste (Section 7) describing the Monitoring and Characterisation of airborne discharges (Section 7.1)

E. Long Term Disposition (Section 8.1) discussing arrangements for Miscellaneous Waste, Remote Handled Liquid Waste, Contact Handled Solid Waste (Section 8.3) Contact Handled Liquid Waste (Section 8.4) Liquid Disposal via B-Line (Section 8.5) and Non-Radioactive Wastes (Section 8.6)

Security plan

[redacted]

[redacted]

Emergency plan

Emergency management of the site will be maintained by plans and arrangements which include detailed processes for ensuring:

- arrangements are consistent with Emergency Preparedness Category II;
- responsibilities for multi-agency response are clearly documented;
- local emergency procedures and preparedness are considered; and,
- emergency management arrangements are coherent with the ANSTO Site Emergency Management Plan.

The plans and arrangements explaining how ANSTO will manage emergency events at the site are set out in the NMMF Emergency Management Plan (Document Number NMMP-0410-PM-0005). The NMMF Emergency Plan contains information about:

A. Applicability of Emergency Preparedness Category II (Section 3).

B. Responsibilities of nominated ANSTO personnel supporting a multi-agency response (Section 4).

C. Emergency Arrangements for Support Plant and Services (Section 5.1) Local Emergency procedures (Section 5.2) and Emergency Preparedness (Section 5.3).

D. Best practice arrangements consistent with NSW emergency services and international codes and standards (Section 6).

Environment protection plan

Environmental protection arrangements for the site will be maintained by plans and arrangements which include detailed processes for ensuring:

- systems and processes for management of environmental aspects;
- preserving wildlife, and natural habitat;
- commitment to maintain high standards of environmental protection; and,
- recognition of international standards (e.g. International Atomic Energy Agency (**IAEA**)).

The plans and arrangements explaining how ANSTO will manage environmental protection at the site are set out in the NMMF Environment Protection Plan (Document Number NMMP-0410-PM-0006). The key elements of the NMMF Environment Protection Plan are:

A. Environmental Management System (Section 3) covering Policy and Strategy, Aspects, Compliance Obligations, Audit and Review (Section 3.1-3.5).

B. Responsibilities for the environment of ANSTO personnel and NMMF Program team (Section 4).

C. Areas of Environmental Impact in terms of the site and adjacent land area (Section 5).

D. Design Criteria for waste control and atmospheric discharge (Section 6).

E. Monitoring of airborne, surface water and groundwater releases (Section 7).

F. Protection of Wildlife including vegetation and native animals (Section 8).

Decommissioning plan

Decommissioning arrangements for the site and facility will be maintained with plans and arrangements which include detailed processes for:

- maintaining commitments to international (IAEA) best practice;
- maintaining and enhancing facility characterisation data; and,
- ensuring appropriate funding and financing for decommissioning.

The plans and arrangements explaining how ANSTO will manage the decommissioning of the facility and site are set out in the NMMF Decommissioning Plan (Document Number NMMP-0410-PM-0007). The key elements of the NMMF Decommissioning Plan are:

A. Funding and analysis of appropriate financing mechanisms to enable decommissioning (Section 4).

B. Decisions affecting Characterisation and Decommissioning, i.e. Post Operative Clean-Out (Section 5).

C. Preliminary Facility/Site Investigation including historical site assessment, initial scoping survey and radiological baseline survey (Section 6).

D. Detailed Facility/Site Investigation covering facility and waste characterisation for disposal, hazardous material surveys and analysis, and **EPBC Act** referral (Section 7).

E. Facility Decommissioning Plan and Site Remediation Plan including Licence and regulatory approval, remediation planning, decommissioning risk assessment safety and security planning (Section 8).

F. Final Site Handover – Post decommissioning covering final site surveys, ongoing monitoring requirements and clearance certification (Section 9).

Section F: Extra information

Complete the Section(s) below corresponding to the proposed activity

Note: Where an activity is not applicable to this application mark as 'N/A' or delete.

Prepare a site for a nuclear installation

Provide a detailed site evaluation establishing the suitability of the site for the facility

ANSTO has prepared a Site Characteristics and Evaluation Report (Document Number NMMP-0410-RT-0002) which provides a detailed evaluation of key natural and human induced aspects that have been assessed to justify the suitability of the proposed site for development of the NMMF.

Based on the site characteristics, geotechnical and demographic information as well as specific site-related design considerations, it was concluded that development of the NMMF within the Lucas Heights Science and Technology Centre can be done safely with the engineering design, construction and operational competencies outlined in the Site Characteristics and Evaluation Report (Section 6).

The Site Characteristics and Evaluation Report considers the NMMF asset lifecycle for siting, design and development phases with consideration of operational and decommissioning phases of the program.

Key natural and human induced aspects of the Site Evaluation include:

A. Seismic Evaluation (Section 5.1.1).

B. Meteorological Evaluation covering wind, high and low temperature, intense rainfall, hail and lightning (Section 5.1.2).

C. Hydrological Evaluation covering surface water (stormwater) and ground water hydrology (Section 5.1.3).

D. Geological Evaluation (Section 5.1.4).

E. Bushfire Evaluation (Section 5.1.5).

F. Aircraft, Road and Rail Transport Risk Evaluation (Sections 5.2.1, 5.2.2 and 5.2.3).

G. Evaluation of Nearby Industries (Section 5.2.4).

[redacted]

I. Effect on On-site Activities and Further Work (Section 5.3.1-2).

Describe the characteristics of the site, including the extent to which the site may be affected by natural and human events.

The NMMF Site Characteristics and Evaluation Report (Document Number NMMP-0410-RT-0002) describes key natural and human induced characteristics or aspects which could impact on the suitability of the proposed NMMF development site (Section 3).

Key information on the natural and human induced aspects of the NMMF site include:

A. Location and Surrounding Land Use (Sections 3.1 and 3.2).

B. Demography, of both On-site and Off-site Population (Section 3.3).

C. Meteorology including winds, ambient temperature, ambient pressure, atmospheric turbulence, inversions, atmospheric mixing layers, rainfall and bushfire weather and atmospheric dispersion of radioactivity (Section 3.4).

D. Hydrology of surface and groundwaters (Section 3.5).

E. Geology and Soils including local geology and geology of the NMMF site (Section 3.6).

F. Seismology and seismic hazard factor (Section 3.7).

G. Site Services including water supply, wastewater, stormwater, electricity, compressed air, communications and data services (Section 3.8).

H. Adjacent Facilities at the Lucas Heights Science and Technology Centre, local industrial premises [redacted] (Section 3.10).

I. Transport Routes for air, road, rail and water transport (Section 3.10).

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

ANSTO has submitted a referral to the Department of Climate Change, Energy, the Environment and Water to construct and operate the NMMF. The referral was for a proposed action under Section 68 of the EPBC Act.

The delegate for the Minister for the Environment and Water has confirmed that the proposed action is not a controlled action, provided it is taken in the manner described in EPBC Act referral 2023/09748.

Construct a nuclear installation

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

Not Applicable

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

Not Applicable

Describe the construction plan and schedule

Not Applicable

Describe the arrangements for testing and commissioning safety related items

Not Applicable

Possess or control a nuclear installation

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

Not Applicable

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

Not Applicable

Operate a nuclear installation

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

Not Applicable

Describe the operational limits and conditions of the facility

Not Applicable

Describe the arrangements for commissioning the facility

Not Applicable

Describe the arrangements for operating the facility

Not Applicable

Describe the results of a field exercise to respond to a scenario that involves an emergency and has been agreed with the CEO

Not Applicable

Decommission a nuclear installation

Describe the schedule for decommissioning the facility

Not Applicable

Dispose of or abandon a nuclear installation

Describe the results of decommissioning activities at the facility

Not Applicable

Provide details of any environmental monitoring program proposed for the site

Not Applicable

Section G: Associated sources

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

☒ *NO - proceed to Section H* ☐ *YES – describe in the space below*

If yes, identify the codes and standards relevant to the source(s) and describe how compliance will be achieved

Include relevant details from the Sealed Sources (from Section H). - N/A

Section H: Source details

Complete the Excel Spreadsheet known as the source inventory workbook (SIW) for any sources used in connection with the facility. The SIW template is available here. Include a copy of any source certificate for sealed sources.

Section I: Matters to be taken into account by the CEO

International best practice in radiation protection and nuclear safety

Describe how international best practice in radiation protection and nuclear safety will be considered with respect to the kind of facility and type of authorisation(s) sought

ANSTO has a robust radiation protection program based on the adotion of international best practice and continual process improvement. The NMMF program has adopted an international best practice stratagy in radiation protection both in design of the facility and its forward application to operational practice. This approach is described in the NMMF SAR (Document Number NMMP-2040-RT-0001) and NMMF Radiation Protection Plan (Document Number NMMP-0410-PM-0003)

These practices are in line with international standards and guides set by organisations such as the IAEA and the World Health Organization (**WHO**), ensuring that the facility operates within a globally recognised framework for safety and quality. ANSTO also maintains a quality system compliant to International Organization for Standardization (**ISO**) requirements.

The NMMF SAR follows the format developed by ANSTO which leverages the IAEA guidelines for Safety Assessment for Research Reactors and Preparation of the SAR (IAEA Safety Standard Series No. SSA-20) as well as the ARPANSA's guide on the Preparation of the SAR for Non-reactor Facilities (ARPANSA-GDE-1925). The most recent assessment of potential radiological impacts to wildlife utilises methods from international best practice as laid out in ARPANSA Guide: Radiation Protection of the Environment (Radiation Protection Series G-1), consistent with approaches adopted by the International Commission on Radiological Protection (**ICRP**) and the IAEA.

The NMMF Radiation Protection Plan is consistent with international best practice and is in accordance with the IAEA standards and guidelines on protection against the effects of ionising radiation, specifically IAEA Safety Standard Series No. GSR Part 3, and IAEA Safety Standard Series No. GSR Part 7, which includes stringent measures for monitoring and controlling radiation exposure, comprehensive training for all personnel, and the implementation of advanced safety protocols.

ANSTO has appointed a Radiation Safety Officer who is an experienced and recognised radiation protection specialist and is responsible for ensuring that ANSTO radiation protection advice is consistent with relevant guides and arrangements, reflects current Australian radiation protection legislation and international radiation protection best practice.

ANSTO leverages operational experience and lessons learned from other nuclear installations and facilities, including existing facilities including B23, ANM, OPAL, and international licenced radiopharacutical generator facilities into the design of the NMMF. The NMMP has adoted many engineering design safety principles drawn from national and international codes and standards, conventions, protocols commensurate with the significance of safety functions adopted for the NMMF.

Undue Risk

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

ANSTO will apply various systems and processes to ensure that the NMMF poses no undue risk to workers and the community. The NMMF Radiation Protection Plan (Document Number NMMP-0410-PM-0003) describes the arrangements and procedures to control of exposure to ionising radiation for the described conduct or dealing during operational activities at the NMMF.

ANSTO has conducted a detailed Safety and Security Consequence Analysis (Document Number NMMP-0410-RT-0003) for planned operations at the facility. Using the PC-Cosyma modelling tool, an analysis was performed to address potential consequences of a release outside the facility, reflecting day and night conditions for projected effective dose and thyroid dose for exposure of adults, children, and infants at various distances from the NMMF.

Key design features to be incorporated into the detailed design of the NMMF address the bounding case accidents described at (Section 2) of the Safety and Security Consequence Analysis. These include use of low or non-combustible materials to minimise and mitigate the potential risk of a building fire. In addition, seismic design aspects will be incorporated into the design of the building structure and high reliability systems and structures such as hot cells and radioactive material transfer systems. [redacted]

Net benefit

Provide information that demonstrates a net benefit from the proposed conduct

The net benefit of the proposed NMMF will be to provide and improve access to life saving nuclear medicines by the Australian community. Refer Section 1 of the NMMF SAR (Document Number NMMP-2040-RT-0001)

The NMMF will provide additional net benefit by:

A. Building upon Australia's sovereign capability to manufacture nuclear medicines for medical treatment.

B. Secure the sovereign supply of nuclear medicine products to enhance patient health outcomes.

C. Enhance Australia's reputation in the medical sector.

D. Reduce reliance on foreign supply chains for essential radiopharmaceutical medicines.

ANSTO provides radiopharmaceutical manufacture, research, specialised advice, and products to more than 220 imaging centres across Australia. ANSTO's partnership with these imaging centres and nuclear medicine products are critical to the national healthcare system.

The proposed NMMF will provide safe and reliable operability of radiopharmaceutical manufacturing, and futureproof nuclear medicine manufacturing by leveraging emerging production technologies. The NMMF will also provide employment in the STEM sector.

Optimisation of protection

Provide information to show that radiation protection has been optimised

ANSTO has developed an Optioneering Process (ALARP Study) for the optimisation of the planned activities described in the SAR (that is, production of Mo-99/Tc-99m generators, I-131 and Lu-177 products as well as the movement and transfer of radioactive materials). The ALARP studies outline how radiation protection can be achieved with respect to the relevant activities.

ANSTO is committed to reducing the likelihood and extent of radiological exposures to ALARP. ANSTO also uses conservative dose criteria to define boundaries within optimisation processes to reduce inequities of exposure. The types of dose criteria that ANSTO use are Dose Review Levels, Dose Constraints, and Dose Limits. The process of optimisation with the use of constraints or review levels is applied when planning protective actions. To this end, the Recommendations and Principals of Radiation Protection described in ICRP 2007 have been adopted in the NMMF Radiation Protection Plan (NMMP-0410-PM-0003).

Technical, human and organisational factors

Provide information to show that the applicant has considered the interaction between technical and human and organisational factors in the management of safety

Human Factors inherent to the safe design of the NMMF's systems and processes have been applied at all stages of the NMMP. When designing structures, systems and components the allocation of safety actions between humans and technology will be optimised and dependence on human actions to maintain a safe state will be minimised.

The NNMP will develop a Human Factors Integration Plan (**HFIP**). The HFIP will include details of the Human Factor deliverables that are specific to the design and development phases and applicable to operational activities.

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

ANSTO has demonstrated skills and expertise in effective and safe operation of many different licenced nuclear facilities. The NMMP will be supported by management commitment to ensuring continuous improvement based on operational experience and a robust safety culture as described in the NMMF Safety Analysis Report (Document Number NMMP-2040-RT-0001) and Section 4 of the NMMF Effective Control Plan (NMMP-0410-PM-0001).

The Commonwealth Government has committed financial resources for ANSTO to deliver the NMMF Program, Refer Section 6 of NMMF Effective Control Plan.

ANSTO has established a dedicated project management team to design and deliver an effective safe and secure asset. The NNMP project team has engaged suitably qualified and experienced persons, many of whom have extensive experience in project management, radiopharmaceutical manufacture and radiological safety. The roles and responsibilities of key members of the NMMF project team are described in Section 5 of the NMMF Effective Control Plan.

The NMMP will regularly be subject to both internal and external management review, throughout the NMMF asset lifecycle to ensure regulatory and legal compliance.

The NMMF's safety in design strategy will incorporate lessons learned from existing operational facilities, including the current B23, ANM, OPAL, and international licenced generator facilities.

Authorised signatory

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

The application has been signed off by [redacted] the CEO of ANSTO and therefore an office holder of ANSTO which fulfils the requirements of the Regulations.

Application fee

Applicants should refer to Section 49 of the Regulations to determine the appropriate application fee.

The fee must be received before the application can be assessed. Accepted payment methods are EFT, credit card or BPAY – please see Payment methods | ARPANSA.

Submitting your application

Send application form and all supporting documents to licenceadmin@arpansa.gov.au.

Note: Applicants must also provide a version of the application suitable for public review. Documents for release must satisfy the Australian Government Web Accessibility guidelines.

CHECKLIST

	Item	Check	N/A
1.	Completed and signed Section A – Applicant information	☒	
2.	Instrument of authorisation for authorised person	☒	☐
3.	Organisational chart showing nominee	☒	☐
4.	Completed Section B – Kind of facility & type of authorisation	☒	
5.	Completed Section C – Facility Details	☒	
6.	Documents to support Section C	☒	☐
7.	Completed Section D – Safety Analysis Report	☒	
8.	Documents to support Section D	☒	☐
9.	Completed Section E – Plans and Arrangements	☒	
10.	Documents to support Section E	☒	☐
11.	Completed Section F – Extra Information	☒	
12.	Documents to support Section F	☒	☐
13.	Completed Section G – Associated Sources	☐	☒
14.	Documents to support Section G	☐	☒
15.	Completed Section H – SIW	☐	☒
16.	A copy of any sealed source certificates	☐	☒
17.	Completed Section I – Matters to be considered by the CEO	☒	
18.	Documents to support Section I	☒	☐
19.	A version of the application suitable for public review	☒	
20.	Appropriate application fee	☒	