Australian Government

ANSTO

NUCLEAR MEDICINE MANUFACTURING PROGRAM

NMMF Safety Analysis Report

For Siting Licence

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Executive Summary

Australian society benefits from the production of radiopharmaceuticals domestically for better medical outcomes. The production of these isotopes at the Australian Nuclear Science and Technology Organisation (ANSTO) ensure improved and timely access to care, a more reliable supply chain and cost benefits when compared to importing nuclear medicine products. Australia's current nuclear medicine production facility, located at ANSTO, is one of only a few facilities world-wide capable of assembling molybdenum-99/technetium-99m generators, which is used in tens of millions of diagnostic procedures per year globally. The existing facility was constructed during the 1950s and has since undergone five major refurbishment projects within the last 30 years, however it is approaching the end of its lifespan and therefore a replacement facility is required.

Leveraging decades of experience researching, manufacturing, and handling radioactive materials, ANSTO is well positioned to continue to safely and effectively manage the manufacturing of nuclear medicine products well into the future through the establishment of a new Nuclear Medicine Manufacturing Facility (NMMF). The current Concept Design of the NMMF will ensure production of technetium-99m generators, iodine-131 products, lutetium-177, as well as the development and distribution of niche products, ensuring Australia remains a leader in global nuclear medicine advancements.

This facility Safety Analysis Report (SAR) has been prepared to demonstrate good safety practices and provides information intended to facilitate safety and regulatory approval by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) for the siting licence application. This document gives facility specific information and should be read in conjunction with the plans and arrangements.

A safety and security consequence analysis for the bounding case accident in the NMMF was undertaken to determine potential radiological impacts for the airborne release of radioactive material outside the facility. The bounding case accident was determined to be a fire event in the NMMF, [redacted] This analysis, a robust safety in design strategy, as well as international best practice and regulatory requirements will inform the detailed design of the facility. Further NMMF-specific risk assessments and hazard identification studies will be conducted at a future stage of the Nuclear Medicine Manufacturing Program (NMMP).

The projected doses and assessed hazards in the safety and security consequence analysis resulted in the NMMF being classed as an Emergency Preparedness Category II and as such establishes the basis for a graded approach to the application of safety requirements and for developing generically justified and optimised arrangements for preparedness and response for a nuclear or radiological emergency at the NMMF.

A siting stage evaluation was performed, and the Site Characteristics and Site Related Design Bases analysis concluded that the site was generally suitable. There are credible events and accidents that could cause damage to plant and equipment resulting in contamination and exposure events. However, the likelihood of these events is acceptable, and the consequences are able to be managed effectively. Alarm and protection systems allow abnormal and emergency situations to be detected and action taken to mitigate the situation.

The design of the facility and its intended operations have been examined in this document and compared against relevant standards and criteria. These comparisons have indicated that the facility design is adequate for its intended purpose. The safety management systems that will be used to control operations within the facility have been described and shown to provide appropriate levels of control. This SAR shows that the design of this facility and its intended operations are such that it can be operated and maintained safely and within dose limits and does not pose issues for ultimate decommissioning.

This report is to be submitted as part of the siting licence application to ARPANSA and is reflective of the current design stage. This analysis will become more detailed as the Program proceeds and will be reviewed, updated, and resubmitted with each subsequent licence application.

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1. Introduction

The Australian Nuclear Science and Technology Organisation (ANSTO) is responsible for radiopharmaceutical manufacture, research, specialised advice, and products. Providing more than 85 percent of diagnostic radiopharmaceuticals used in Australia every year through partnerships with over 220 imaging centres, ANSTO's facilities are a critical component to the national healthcare system. The ongoing Australian manufacture of these radiopharmaceuticals delivers more than 10,000 doses of potentially life-saving medicines every week.

ANSTO's Nuclear Medicine Production Facility Building 23 (B23), is one of only a few facilities world-wide capable of assembling molybdenum-99/technetium-99m generators, which are used in tens of millions of diagnostic procedures per year globally. The facility was constructed during the 1950s and has since undergone five major refurbishment projects within the last 30 years, however it is approaching the end of its lifespan and therefore a replacement facility is required.

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

This facility will build upon Australia's sovereign capability to manufacture nuclear medicines for medical treatment of Australian citizens by securing sovereign supply of nuclear medicine products to enhance patient health outcomes, provide safe and reliable operability of radiopharmaceutical manufacturing, and futureproof nuclear medicine manufacturing by leveraging emerging production technologies.

Additional key benefits include reducing Australia's reliance on costly foreign supply chains, enhancing Australia's international reputation in the medical sector, improving access to life-saving medicines, and providing jobs in the STEM sector.

The current Concept Design of a new nuclear medicine facility will support the:

- Production of technetium-99m generators (and support any expected growth). They are an essential requirement for majority of diagnostic nuclear medicine procedures representing over 80% of all nuclear medicine procedures in Australia.
- Production of iodine-131 products (and support any expected growth). Iodine-131 is a well-proven and vital therapeutic product for the treatment of thyroid cancer.
- Production of lutetium-177 (and support any expected growth). Lutetium-177 is an increasingly important product for systemic therapies which are growing in demand.
- Development and distribution of niche products, ensuring Australia remains a leader in global nuclear medicine advancements.

The Nuclear Medicine Manufacturing Facility (NMMF) will be designed to meet domestic demand for technetium-99m, lutetium-177, and iodine-based products and will have the flexibility to ensure Australians will benefit from innovation in the development of nuclear medicines to support diagnosis and treatment of diseases for generations to come.

To address, manage, monitor, and report upon the interactions that ANSTO has with the environment, the ANSTO Environmental Sustainability Strategy [Ref: (1)] has been developed. This high-level document communicates ANSTO's strategic direction towards minimising emissions, water consumption, waste generation, and to improve biodiversity outcomes for sites and managed bushland.

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Please note for clarity, NMMF refers to the Nuclear Medicine Manufacturing Facility, i.e., the physical structure. NMMP is the Nuclear Medicine Manufacturing Program which includes the NMMF, and the Program of works required to deliver the NMMF.

1.1. Style

This NMMF Safety Analysis Report (SAR) follows the format developed by ANSTO which leverages the International Atomic Energy Agency (IAEA) guidelines for the Safety Assessment for Research Reactors and Preparation of the SAR [Ref: (2)] as well as the Australian Radiation Protection and Nuclear Safety Agency's (ARPANSA) guide on the Preparation of the SAR for Non-reactor Facilities [Ref: (3)].

This report is a factual, objective description of the facility, its intended operations, and the identified hazards and controls. It is developed to be informative and readable, and to maximise utility to all relevant stakeholders.

1.2. Purpose / Objectives

The aim of this document is to demonstrate that the NMMF will be capable of safe and effective siting in compliance with all relevant safety regulations and requirements of ARPANSA throughout all phases of its lifecycle.

This is a living document that will be revised and developed as the facility progresses through its lifecycle. Revision of this document is subject to change management processes including assessments and approvals as required by ANSTO and its regulators.

1.3. Scope

The scope of this SAR covers all the activities taking place in the NMMF and the impacts of those activities to the site. It should be read in conjunction with Site Characteristics and Evaluation Report NMMF-0410-RT-0002 [Ref: (4)], Safety and Security Consequence Analysis NMMP-0410-RT-0003 [Ref: (5)], and AG-2430 LHSTC Site Description [Ref: (6)], which provides general information common to the ANSTO Lucas Heights campus, and the NMMF plans and arrangements prepared for the Siting Licence.

This SAR includes consideration of:

- Site characteristics
- Safety structures, systems, and components
- Hazards and accidents, including risk assessments
- Operating limits and conditions
- Operational experience
- Plant condition
- Radiation protection
- Radioactive waste management
- Decommissioning
- Emergency planning and preparedness
- Management systems.

This report is to be submitted as part of the siting licence application to ARPANSA and is reflective of the current design stage. This report will become more detailed as the Program progresses and will be reviewed, updated, and resubmitted with each subsequent licence application.

1.4. Facility Overview

The general purpose of the NMMF is to handle and produce radiochemicals and radiopharmaceuticals and to distribute radioisotopes for domestic and international customers. Liquid and solid radioactive starting materials manufactured on site or imported from overseas suppliers, will be used in the NMMF to produce these products.

This section provides an overview of the design decisions and how they meet relevant ANSTO requirements, codes, and standards.

1.4.1. Responsibilities

Details on the relevant roles and responsibilities for the NMMF are available in NMMF Effective Control Plan NMMP-0410-PM-0001 [Ref: (7)].

The CEO of ANSTO is the applicant to ARPANSA for the siting, construction, and operating licences for the NMMF. The responsibility for maintaining effective control and for ensuring compliance with the ARPANS legislation will be formally delegated to the Licence Nominee. The Nominee is assisted by a Facility Officer and a Licensing Officer. The names of these officers will be recorded and kept up to date on the ANSTO intranet in AG-1666 ANSTO Nuclear Installations, Prescribed Radiation Facilities and Source Licences [Ref: (8)].

The Nominee will be responsible for the management of plans and arrangements and the overall control of the proposed facility. The Nominee will ensure that local procedures and instructions for achieving regulatory compliance are in place, appropriately maintained, and all staff are aware of their respective accountabilities and responsibilities. Licence-specific roles and responsibilities for the NMMF are aligned with AG-5445 Guide on ARPANSA Requirements [Ref: (9)] have been provided in Table 1.

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Role	Responsibility
Licence Nominee	• Appoint a Licencing Officer and Facility Officer. • Management of plans and arrangements. • Overall control of the proposed facility. • Ensuring that local procedures and instructions relevant to achieving regulatory compliance are in place and appropriately maintained.
Licensing Officer	• Providing general advice to Responsible Officers, Facility Officers, and Line Managers on reporting requirements. • Preparing quarterly reports for the facility. • Preparing reports for ARPANSA on abnormal operations or breaches in conjunction with the Manager, Regulatory Affairs and Compliance, and the Facility Officer. • Assisting, when required, in the preparation of regulatory submissions for the facility. • Acting as a point of contact for conducting inspections. • Coordinating the review of plans and arrangements for the facility in accordance with Section 61 of the ARPANS Regulations. • Moderating and authorising requests to make changes to the facility.

Role	Responsibility
Facility Officer	• Will be responsible for development of the safe operations and maintenance arrangements for the facility. Their general responsibilities include: • Providing general advice to staff and line management on regulatory requirements appropriate to the facility. • Managing the workload of staff. • Assisting in the preparation of quarterly reports when required. • Preparing annual reports when required. • Preparing reports for ARPANSA on abnormal operations or breaches in conjunction with the Manager, Regulatory Affairs and Compliance, and the Licensing Officer. • Assisting with the preparation of regulatory submissions for the facility. • Acting as a point of contact for conducting inspections of the facility. • Conducting reviews of the plans and arrangements for the facility in accordance with Section 61 of the ARPANS Regulations.
Radiation Safety Officer (RSO)	The RSO is an experienced and recognised radiation protection specialist who is responsible for ensuring that ANSTO radiation protection advice, including relevant guides and arrangements, reflect current relevant Australian radiation protection legislation and international radiation protection best practice. The RSO also ensures that Radiation Protection Services (RPS) staff are adequately trained and experienced to fulfil their duties.

Table 1: Licence-specific Roles and Responsibilities for the NMMF

A proposed facility organisational chart for the siting stage is depicted in Figure 1 and will be updated, as deemed appropriate, through subsequent stages of the Program. More details on the roles and responsibilities for the NMMF are available in Table 2 and NMMF Effective Control Plan [Ref: (7)].

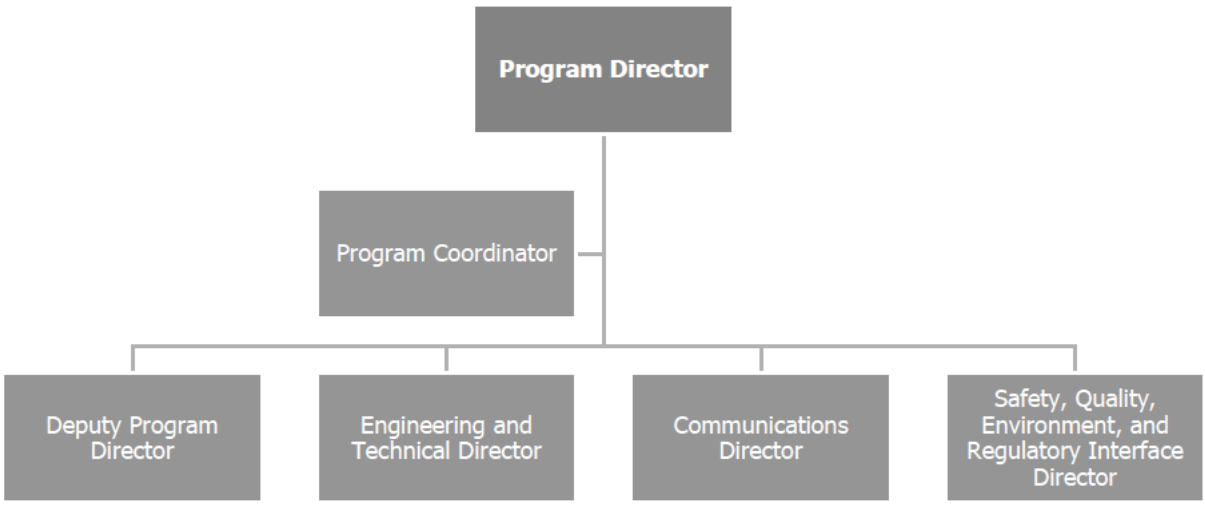


Figure 1: NMMF Organisation Chart

Role	Description
Program Director	Program development and stakeholder engagement lead for the NMMF Program.
Program Coordinator	Coordination of stakeholder working groups and interface with the Program Leadership Group (PLG).
Deputy Program Director	Development and implementation oversight of the NMMF Program.
Engineering and Technical Director	Oversees engineering management processes to ensure compliance with relevant engineering standards and industry best practice when delivering the scope of the Program and the associated NMMP User Requirements Specification [Ref: (10)].
Communications Director	Develops and oversees the internal and external communications strategies and process for the NMMF. The Stakeholder and Communications Management Plan NMMP-0010-PM-0005 [Ref: (11)] effectively describes, how, when, and by whom information and data will be administered and disseminated.
Safety, Quality, Environment and Regulatory Interface Director	Manages Subject Matter Experts (SMEs) interfacing across Good Manufacturing Practice (GMP), quality, regulatory, safety, and environment stakeholders.
Workers	All personnel, including contractors and service providers working on the NMMF will complete a NMMF-specific induction. The induction will communicate worker responsibilities for work health and safety as described under the WHS Act [Ref: (12)] and Regulations [Ref: (13)] and radiological safety requirements for the project as described in the NMMF Radiation Protection Plan NMMP-0410-PM-0003 [Ref: (14)].

Table 2: NMMF Role Descriptions

1.5. Facility Description

The NMMF is to be constructed on the Lucas Heights campus [redacted]

The primary function of the building is to replace the existing B23 on the site with a modern building that is better designed to meet ANSTO's current and future needs, meet reliable supply, adhere to compliance regulations and requirements, and enable a larger scale of production of just-in-time supply radiopharmaceuticals. With an efficient layout, ANSTO operations will be optimised for an improved process workflow in an order that is logical from incoming goods to outgoing final products.

The primary operations within the NMMF are:

- To act as a receiving point, from the Open Pool Australian Light-water (OPAL) Reactor or elsewhere, for radioactive material to be despatched (with the exception of NTD silicon and ANM manufactured molybdenum-99).
- To process molybdenum-99 (Mo-99) received from the ANSTO Nuclear Medicine (ANM) Facility or imported from other international suppliers, to manufacture Mo-99/Tc-99m generators.
- Handling and distribution of industrial sources, such as, but not limited to iridium-192 (Ir-192).
- Manufacture radiopharmaceuticals and radiochemicals.

- Conduct testing of radiopharmaceutical and radiochemical products in compliance with quality systems and established product specifications.
- Packaging of all radioactive products for transport to customers.
- Triage radiological waste streams for further processing.

The main planned work functions in the NMMF are:

- Operations: to conduct work associated with the manufacture of radiopharmaceutical and radiochemical products in hot-cells and technical spaces located in the GMP licensed areas of the facility.
- Compliance and Quality: to oversee the quality control and assurance of the manufactured products in compliance with Therapeutic Goods Administration (TGA) requirements and to maintain a quality system compliant to the International Organization for Standardization (ISO) requirements.
- Supply Chain: to control stock inventory and despatch of products.
- Engineering Support: to oversee maintenance work.
- Commercial: for customer interactions and customer support.
- Safety: health physics and radiation protection support.

A1 1.6. Facility Structure

The NMMF will be a multi-storey building with a footprint of approximately 6,700 m^2 which can easily expand to an additional 1,400 m^2 in the future for additional production space if required. The total area of the building is currently designed to be 13,000 m^2. The building has an angled façade on the western face to integrate aesthetically with the adjacent OPAL building. The NMMF concept design defines a multi-storey building and the associated manufacturing equipment for technetium, iodine, and lutetium-based products, along with a new product introduction capability:

- Logistics area where raw materials will be stored and finished products packaged and despatched. The floor also includes several ancillary functions such as waste storage.
- Production area where radiopharmaceuticals will be manufactured and tested. This level also includes an office wing. The production spaces will have an interstitial level.
- 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.

Proposed internal and external materials for the construction of the building and façade of the building include concrete, cement, stone veneer, aluminium composite materials, glass, and wood, and is aligned with ANSTO's Environmental Sustainability objectives [Ref: (1)]. Concept designs for the exterior of the NMMF is provided in Figure 2 and Figure 3. More details on the chosen materials will be available at a future licencing stage.

Figure 2: Concept Design Image for the NMMF (Ground Level)

Figure 3: Concept Design Image for the NMMF (South-West Facing)

1.6.1. Building and Structures

At the current stage of design, the main functional areas proposed within NMMF are:

- Cleanroom Production Suites)
- QC Laboratories
- Raw Material Warehouse
- Packaging and Despatch
- Utility and Plant Rooms
- Waste Segregation and Processing
- Offices.

All supply chain activities occur in the basement. This includes the receipt of non-radioactive and radioactive goods and packaging and despatch of final goods, see Figure 4. Most of the radioactive materials received in this area will be sent up to the production area on the ground floor. Additional activities on this level include storage and processing of all the radioactive waste, primary exhaust filtration, and the location of the filter bank.

With many of these activities requiring truck access, this level will be cut slightly into the hillside so the floor elevation level is similar in height to Bragg Avenue where all the trucks will approach the building from. Trucks will be able to back directly into the building to optimise loading and unloading, and the perimeter overhead doors will be closed for security purposes. While approximately half of the basement level will be below grade, the ground floor will be entirely above grade, this allows for direct sunlight, exterior views, and exterior access around the entire perimeter of the building.

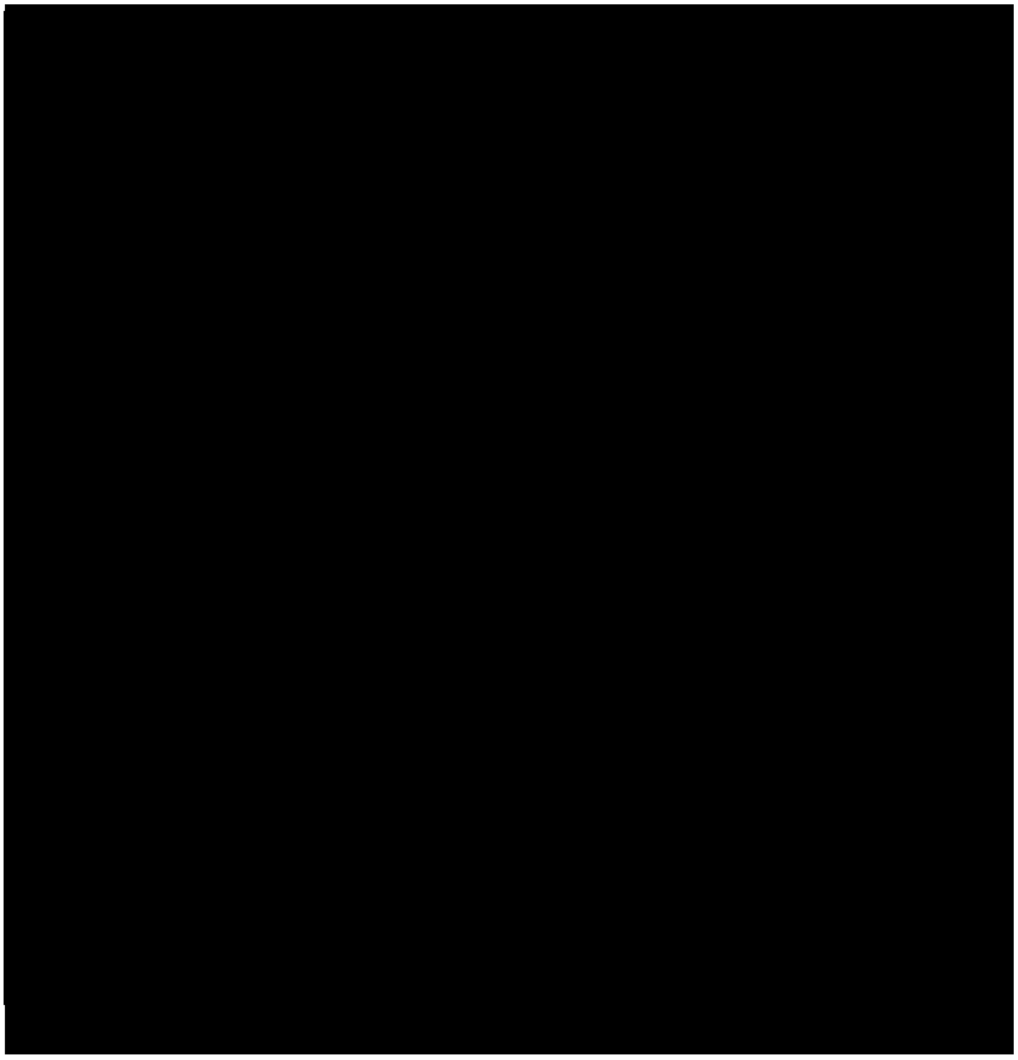
In contrast with the basement, the ground floor will host offices, laboratories, and production spaces. This level of the building will be laid out as an L shape, with the production spaces running east to west on the northern edge of the building and the office turning south at the western edge of the production areas, see Figure 5. This layout provides greater light and views to the office area and helps to delineate between the two programs.

Most employees will enter the building through the office area which also includes public spaces for employees to use as a break room/ cafeteria room. Employees not working in the offices will go to work via the Quality Control laboratory personnel airlock, or via the Production personnel airlock (that leads to cleanroom suites, or the basement).

Production personnel airlock and associated change room and health physics barrier will be the central access pathway to the following functional areas:

- Radiopharmaceutical manufacturing clean rooms.
- Cleanrooms for intermediate material preparation.
- Service rooms for radiopharmaceutical product packaging and maintenance.
- Basement (to access Raw Material Warehouse, Packaging and Despatch, Utility and Plant Rooms, or Waste Segregation and Processing).

To keep production suites as clean as possible, walkable ceilings will allow maintenance and replacement of fixtures, equipment, and utility components to occur without entering cleanrooms directly. This walkable ceiling level is known as the interstitial level and will be accessed via the rear of hot cell service rooms.



The plant level holds large mechanical equipment such as filter banks, air handling units, and a strobic fan system. To meet ANSTO's renewable energy requirements, additional solar panels will be housed on the roof over the plant level and offices. The spatial organisation of the facility is driven by operational and material flows, as well as room functions.

1.6.2. Plant and Equipment

The following major plant and equipment have been identified for use in the NMMF at the current stage of design. This will be updated as more information is available for future licensing stages.

1.6.2.1. Hot Cells

Hot cells will be used for the receipt of radioactive materials and the production of the nuclear medicine. The hot cells are an industry-standard component that provides safe containment for operating radiological equipment, by separating operators from radioactive materials.

1.6.2.2. Active Ventilation System

The basement houses a waste filtration room where exhaust air from the production suites will be ducted to. This will be where the primary stage of exhaust filtration occurs. After this air will be ducted to the plant level where secondary stage filtration will occur.

There will be multiple plant filter rooms located on the plant level of the building, to align with the NMMF ventilation zones. They will be utilised for secondary waste filtration after the primary exhaust filtration has occurred in the basement. The exhaust filters will be in a common header arrangement and feature bag-in bag-out filters.

All air extracted in the facility will be passed through HEPA (High-Efficiency Particulate Air) filters. In addition, any air with a risk of radioactive iodine contamination will be passed through charcoal filters (Standard Iodine Adsorption Module – SIAM filters). Charcoal filters (SIAM filters) are required to trap volatile radioactive materials such as I-131 in a gaseous phase.

[redacted]

1.6.2.4. Fire Protection Devices and Alarm Systems

Fire detection and alarm system will be installed throughout the facility to AS1670.1-2018 Fire detection, warning, control and intercom systems - System design, installation and commissioning, or equivalent at the time of construction.

Photoelectric type smoke detectors and thermal detectors will be provided in general areas and Multipoint Aspirating Smoke Detection (MASD) will also be provided in Comms Room and Electrical Switch Rooms, etc. as per AG-3219 ANSTO Building Code [Ref: (15)].

An addressable Fire Indicator Panel (FIP) with a graphics interface/ monitor will be located at Ground Floor Level main entrance lobby (considered as Designated Building Entry Point) or as nominated by the Building Certifier/ Principal Certifying Authority (PCA), and fire brigade authority. The FIP shall be networked with fire alarm connection back to the ANSTO Security Operations Centre (ASOC) and will have the ability to be remotely accessed by Emergency Response Team (ERT) on site.

The fire detection and protection systems within the NMMF shall be self-contained but shall be monitored via the site wide fire alarm system. An incoming water service will be extended into the new building from the existing site water system and have the facility to be connected to a future dedicated fire water service. More details on the fire protection devices and alarm systems are available in Fire Protection Strategy and Basis of Design NMMP-2820-RT-0001[Ref: (16)].

[redacted]

1.6.3. Radiological Designation of Areas

The initial plant concept and decisions on how safety is engineered into the design and access requirements drives the layout and nature of operations. As the design progresses, the designation of areas will be conducted with the following considerations:

- Areas are designated separately for radioactive contamination and ionising radiation risks, and the designation scheme will generally break up the controlled area designation into sub-designations. The greater the radiation or contamination related risk the greater the need to control access to that zone to ensure compliance with optimisation of individual personal radiation exposures and dose constraints.
- The radiological designation of areas will be determined in conjunction with ANSTO radiation protection advice and AG-2509 Classification of Radiation and Contamination Areas [Ref: (18)].

The designation levels for radiation and contamination areas, including associated monitoring requirements, are detailed in the NMMF Radiation Protection Plan [Ref: (14)]. Table 3 and Table 4 summarises the area radiation and contamination designations.

Fraction of a Dose Limit (average daily dose rate if exposed for 8 hours/day, 50 weeks/year)	***Potential Effective Occupational Doses**	**Radiation Designation of Area**	
≥3/10 occupationally exposed worker (≥24µSv/day)	> 20 mSv/year	Exclusion	Red
	6 mSv/year to 20 mSv/year	Controlled	Red
<3/10 occupationally exposed worker limit (4µSv/day to 24µSv/day)	2 mSv/year to 6 mSv/year	Controlled	Blue
	1 mSv/year to 2 mSv/year	Controlled	Blue
<1/20 occupationally exposed worker limit (4µSv/day)	< 1 mSv/year	Supervised	White
Nil occupational doses	Nil occupational exposure	Non-designated	N/A

* The potential effective dose is the total of the potential external radiation exposure plus the potential internal exposure. (Assumes a standard working year of 2000 hours and relevant occupancy factors determined in conjunction with the area RPA).

Table 3: Summary of Area Radiation Designations

Radioactive Work in Area^	Surface Contamination ($Bq.cm^{-2}$)		Radiological Designation of Area	
	α	βγ		
Medium or greater risk of spreading radioactive contamination outside of radioactive containment	> 6	> 500	Exclusion	Red
	0.6 ≤ 6	50 ≤ 500	Controlled	Red
Low risk of spreading radioactive contamination outside of radioactive containment	0.06 ≤ 0.6	5 ≤ 50	Controlled	Blue
Buffer area e.g., for monitoring of persons and items from a radioactive contamination controlled area	≤ 0.06	≤ 5	Controlled	Blue
Small sealed-sources or work only with "exempt" * quantity of radioactive material or less in an area.	Nil detectable		Supervised	White
No radioactive work	Nil detectable		Non-designated	N/A

^ The terms "Medium" and "Low" in the table are as defined in AG-2395 ANSTO Risk Analysis Matrix [Ref: (19)].

* "Small quantities of unsealed radioactive materials" for the purposes of designating a controlled area are those that are defined as "exempt" in the ARPANS regulations 2018 [Ref: (20)]. Refer to Part 1 Schedule 1 of those regulations.

Table 4: Summary of Area Contamination Designations

The operator gowning strategy for GMP cleanrooms and radiologically classified areas will be commensurate with contamination levels, GMP grade and local risks.

Personal monitoring using Electronic Personal Dosimeters (EPDs) and Thermo-Luminescence Dosimeters (TLDs) will be mandatory for staff within any area with a radiological designation. To minimise the possibility of transfer of contamination from the area, access control will be implemented along with barrier monitoring. Personal monitoring and decontamination equipment will be provided at that point.

More details on the designation process and a summary of the area radiation designations are available in NMMF Radiation Protection Plan [Ref: (14)] and Design Guide - Safety in Design Strategy [Ref: (21)].

[redacted]

[redacted]

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1.7. Process Description

The key operational functions that will be based within the NMMF are:

- Cleanroom Production
- QC Testing
- Raw Material Warehousing
- Packaging and Despatch
- Waste Segregation and Processing.

The operational flow within the facility is provided in Figure 6. This flow represents the operational philosophy of the current concept design stage and is subject to change during detailed design. This flow will be updated for a future licencing stage.

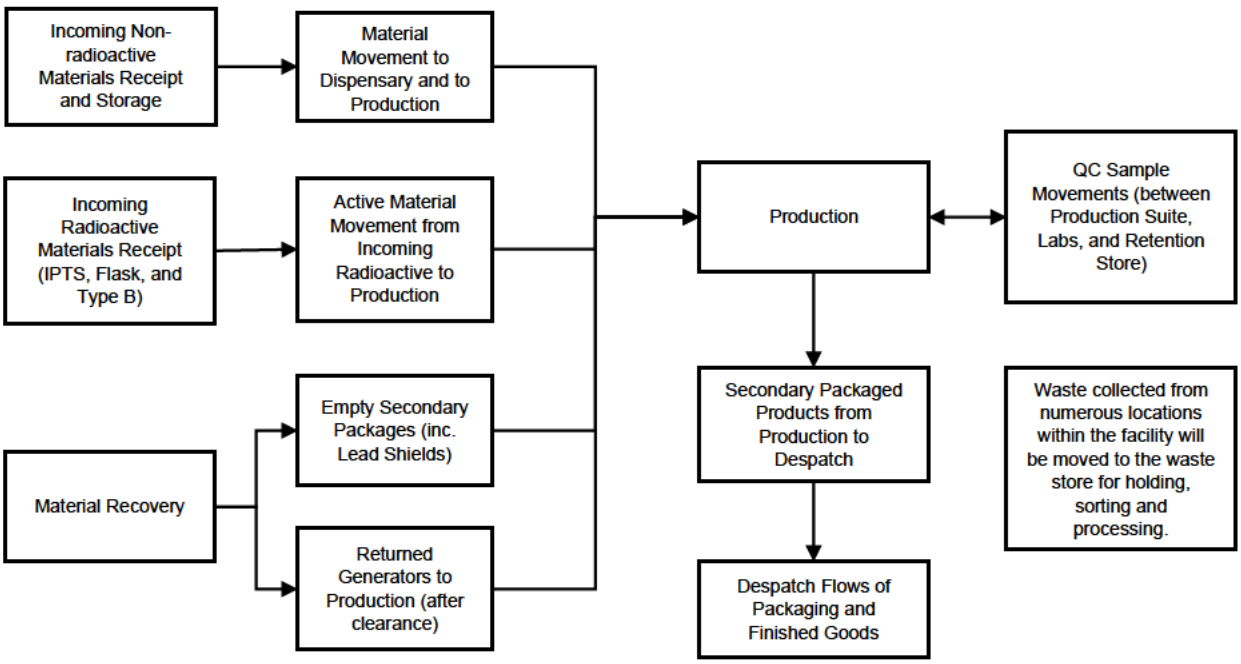

Figure 6: Operational Flow of the NMMF

1.7.1. Interfaces

The NMMF, when operational, will interface with various ANSTO divisions. These include:

- Waste Management Services (WMS) for solid and liquid waste collection and management.
- ANM Operations for the provision of Mo-99 raw material supply.
- Reactor Operations for the provision of irradiated targets via pneumatic transfer or shielded containers.
- ANSTO Maintenance and Engineering (AME) for:
  - Provision of general engineering support and program delivery
  - Provision of general facility maintenance support
  - Engineering equipment approvals officers.
- ANSTO IT for information management support
- Safety for:
  - Emergency Response Team - provide all hours first emergency response
  - Emergency management oversight
  - Work Health and Safety (WHS) support and advice
  - Health physics and radiation protection/ radiation optimisation support.
- Nuclear Science and Technology (NST) for environmental stack discharge reporting.
- Regulatory Affairs and Compliance for liaison with ARPANSA
- People, Performance and Capability (PPC) for human resources
- Nuclear Safety, Security and Stewardship (NSSS) and the Chief Security Officer for general building, site security, and site access control responsibility.

1.7.2. Similar Facilities

The NMMF will incorporate lessons learned from existing operational facilities, including the current B23, ANM, OPAL, and international licenced generator facilities with regulated safety regimes, into the design.

Separate SAR documents are in place for OPAL, ANM, and Waste Operations, as these facilities will interface with the NMMF. These documents cover the general WHS and radiation protection arrangements that are in place for activities taking place routinely in these facilities.

2. Site Characteristics

This section provides information on the site characteristics for the development of the NMMF. Details on external natural and human induced events that could have a significant impact on safety is also provided in this section. Where a significant natural or human induced hazard is identified, an evaluation of the characteristics is documented to support the argument that the facility will not pose an unacceptable risk to individuals, the surrounding population and environment, for the life cycle of the facility. More detailed information is available in the NMMF Site Characteristics and Evaluation Report [Ref: (4)].

2.1. Location

The NMMF development site is located on the ANSTO Lucas Heights campus [redacted]

The NMMF will be a two-story building constructed at the site location indicated.

[redacted]

2.2. Geological

The geography of the development site is notionally the same as for the Lucas Heights campus described in the AG-2430 ANSTO LHSTC Site Description [Ref: (6)]. The predominant rock outcropping at Lucas Heights is medium to coarse quartzose sandstone. Minor components of dark grey shale, siltstone, and sandstone/ siltstone makes up about 5% of the total. The sandstone units are composed mainly of medium-coarse quartz grains bound by a secondary quartz-siderite cement with a clay matrix. Generally, the soil cover over rock is very shallow and consists of sandy loam, gravel, clay, and ironstone. The top layers of sandstone are often soft and underlain by clay seams of varying thickness. Water is often encountered during excavation.

The NMMF development site is in the south-western portion of the Lucas Heights campus. The site is [redacted] an irregular shaped area of 1.6 ha. The maximum north-south and east-west dimensions are 130 m and 120 m respectively and is currently made up of a series of roads and grassed areas. The surface levels fall 6 m (RL 157 m to 151 m) to the north with an average slope generally within the range 8° – 9°. The site slopes to a series of internal roads, carparks, and batters.

The general subsurface profile encountered, following the geotechnical investigation conducted by Douglas Partners for the NMMF site [Ref: (26)], includes a fill layer, a natural layer, and a sandstone layer. More details on the geology of the NMMF site is available in NMMF Site Characteristics and Evaluation Report [Ref: (4)].

2.3. Seismological

The Lucas Heights campus is located on a sandstone plateau in the Sydney Basin. The current earthquake hazard map of south-eastern Australia [Ref: (27)] shows the Sydney Basin to lie in a low intensity seismic zone. While there are a number of geological features in the Sydney Basin, indicative of past earthquake activity, no seismically active geological structures have been identified, and there are no major faults within 35 km of the Lucas Heights campus, as described in the OPAL SAR [Ref: (28)]. From a global tectonic perspective, Australia is regarded as an intraplate setting, thousands of kilometres from an active plate boundary.

In 2001, the seismic hazard at the Lucas Heights campus was assessed and the results were documented in AG-2430 ANSTO LHSTC Site Description [Ref: (6)].

A Hazard Factor (Z) of 0.08 would be appropriate for the NMMF site in accordance with Australian Standard AS 1170.4 – 2007 Structural design actions – Part 4: Earthquake actions in Australia [Ref: (29)]. The site sub-soil class would be Class B. Additional details on seismology is available in NMMF Site Characteristics and Evaluation Report [Ref: (4)].

2.4. Hydrological

Geophysical and hydrogeological investigations of the Lucas Heights campus have been conducted periodically. The most significant having been undertaken for the OPAL Reactor site during the site assessment in June 1998. The geophysical study was undertaken to provide information on the subsurface conditions and any structures which may influence groundwater in the region. The reports of these investigations [Ref: (30), (31)] were submitted with the siting licence application for the OPAL Reactor as supporting documents.

Further details on the surface and groundwater hydrology are provided in NMMF Site Characteristics and Evaluation Report [Ref: (4)].

2.4.1. Surface Hydrology

The surface hydrology is relevant to the safety aspects of the NMMF, because radioactive material deposited in or above the ground may find its way into drainage channels, creeks, or rivers through surface runoff. There are no known private dams that could be fed by runoff from the area surrounding the Lucas Heights campus. The nearest major dam owned by a public utility and is used for public consumption, is the Woronora Dam approximately 7 km south-east of the campus. Neither dams nor groundwater bores are within a ground water catchment that could be directly influenced by runoff from the Lucas Heights campus and hence form a possible dispersion pathway.

2.4.2. Groundwater Hydrology

The groundwater flow around the Lucas Heights campus is characterised by the local topography. The campus is situated on top of a gently north-sloping ridge. On the eastern side, several steep gullies drain into the Woronora River, and on the west are the shallow depressions forming the headwaters of Bardens and Mill creeks.

The groundwater hydrology is complicated by weathering and features of the Hawkesbury sandstone. The unweathered sandstone has a very low primary or intergranular permeability while the weathered sandstone has a considerably higher primary permeability.

A detailed baseline groundwater investigation for the Lucas Heights campus is documented in the OPAL SAR Chapter 3 Site Characteristics [Ref: (28)]. Standing groundwater levels are known for the northern area of the Lucas Heights campus and for the Little Forest Legacy Site. The overall hydraulic gradient is to the north although locally the gradient is strongly influenced by structural and topographical features. Reported investigations indicate a shallow groundwater zone between 6 m and 10.7 m and a deeper regional zone between 12.4 m and 19.7 m below the surface [Ref: (28)].

Based on the geotechnical investigation conducted by Douglas Partners for the NMMF site [Ref: (26)] groundwater seepage was observed in some of the test pits (TP) at depths in the range of 0.2 m (reduced level (RL) 154.6 m, Australian Height Datum (AHD)) to 1.4 m (RL 153.7 m, AHD). The observations of groundwater levels within the bedrock profile encountered within boreholes were precluded given the introduction of water during coring. Ephemeral seepage may occur from along the soil and rock interface following heavy rainfall and may also occur along bedding planes and fractured zones in the rock. It should be noted that groundwater levels are transient and that fluctuations may occur in response to climatic and seasonal conditions.

It is considered that from a geotechnical perspective, effective control of ground water at NMMF site will be readily achievable, provided appropriate design, site preparation, implementation of earthworks control procedures, and sound engineering and construction practices are adopted.

2.5. Meteorological

ANSTO operates a meteorology laboratory (Building 34) on the Lucas Heights campus which has been recording data since 1968. The data captured includes wind speed and direction, relative humidity, atmospheric pressure, and rainfall and is available on ANSTO's website [Ref: (32)]. An extended table with more statistics about the rainfall is available through the Bureau of Meteorology [Ref: (33)]. Meteorological conditions for the NMMF site is the same for the Lucas Heights campus and is described in the AG-2430 ANSTO LHSTC Site Description [Ref: (6)] and NMMF Site Characteristics and Evaluation Report [Ref: (4)].

2.5.1. Winds

The natural hazard presented by severe winds at the Lucas Heights campus is documented in the OPAL SAR Chapter 3 [Ref: (28)], noting an annual exceedance frequency of 1.82×10^{-2} for a wind velocity of 75 mph. The HIFAR Probabilistic Safety Assessment (PSA) produced a tornado hazard analysis which determined an annual exceedance frequency of 1×10^{-4} at wind speed of 75 mph [Ref: (34)]. Based on data from the HIFAR PSA, the fastest mile wind speed is 105 mph (170 km per hour) for the Lucas Heights campus. At a similar exceedance level, the highest tornado-type wind speed is 85 mph (135 km per hour).

The Site Design Basis – Stage 1 [Ref: (17)] report for the NMMF considered wind pressure effects, gusting effects, pressure drops, and projectile effects in the case of the tornado-type winds. This data will be applied during detailed design of the NMMF.

2.5.2. Rainfall

Statistical data relating to rainfall at the Lucas Heights campus for the years 1958 to 2022 has been recorded by the Bureau of Meteorology [Ref: (35)] and is presented in NMMF Site Characteristics and Evaluation Report [Ref: (4)].

Two aspects of rainfall have the potential to impact on the NMMF site:

- Rainfall and wind distribution
- High rainfall and flooding.

High rainfall and flooding are recognised as a natural hazard with some areas of the Lucas Heights campus which is potentially prone to localised flooding. Impacts from flash floods can be affected by localised topography and drainage routes and there is always the potential for some facilities to be affected by run-off in extreme rain events. The potential for local external flooding has been considered as part of the NMMF design.

2.5.3. Bushfire Weather

The Lucas Heights campus is located near bush fire prone land. The risk of bushfire in the vicinity of the NMMF site (as with the rest of the campus) increases during dry weather and peaks on days of high temperature, low humidity and strong winds.

The following bushfire protection measures for the Lucas Heights campus are already in place:

- An internal 8-meter, two-way sealed perimeter road between the NMMF development site and the forest vegetation to the south and west.
- External fire trail with turning areas.
- Hydrant points both internal and external to the security fence at regular intervals.
- Electricity to the NMMF site will be located underground.
- Fixed building fire detection and protection systems.
- Management of internal landscaping to Asset Protection Zone (APZ) standards.

The main design considerations with the NMMF for avoiding or minimising hazards from bushfire include compliance with relevant Australian building standards, use of appropriate construction materials, appropriate design to avoid the collection of combustible material on or near buildings (e.g., leaves settling in guttering, roof, or eaves), and maintaining recommended fire hazard reduction distances from bushland.

Based on the existing measures, it was determined that no additional bushfire protection measures were required for the NMMF as the facility falls beyond a 140 m buffer zone, see Site Design Basis – Stage 1 [Ref: (17)].

2.5.4. Atmospheric Dispersion of Radioactivity

The important parameters for dispersion modelling of atmospheric releases are wind speed and dispersion stability category. The recorded information on wind direction, speed, and Pasquil Stability Category for the Lucas Heights campus is summarised in the OPAL SAR Chapter 3 [Ref: (28)].

The Safety and Security Consequence Analysis [Ref: (5)] considers future 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 doses and thyroid doses for exposure of adults, children, and infants at various distances from NMMF.

[redacted] potential bounding case accidents were considered:

- Building fire
- Seismic event

[redacted]

It is assessed that a large-scale building fire, which has the potential to result in the airborne release of all the available radioactive materials stored in the facility, represents the bounding case accident with respect to releases to the environment. This analysis and assumptions will be revisited when the facility design is more mature to provide a more realistic assessment of consequences.

Based on the NMMF Safety and Security Consequence Analysis [Ref: (5)], a total loss building fire is used as the most significant reference accident scenario for the facility.

While compartmentation was not used as a control measure and released activity is calculated on the total maximum licensable limit, there is significant conservatism in quantifying the projected dose to public.

Conservatively the projected dose (effective) for exposure to adults, children, and infants at various distances from the NMMF allows for a comparison with generic criteria to categorise the NMMF from an emergency preparedness perspective as category II [Ref: (36)].

Considering the most restrictive group (infant daytime, inhalation) the projected thyroid equivalent dose for 50-years exceeds generic intervention levels (GILs) within approximately 1.3 km of the NMMF and beyond the Lucas Heights site boundary and could give rise to exposure to people off-site which may warrant early protective action.

2.6. Site Services

The nominated site for the NMMF will utilise several services currently in place to service adjacent buildings and facilities. Interruption to these services (such as power, communications, water, compressed air, and drainage) should be minimal.

These services are described in sections 2.6.1 to 2.6.6.

[redacted]

2.6.2. Wastewater

Infrastructure is currently in place at the Lucas Heights campus for the treatment and discharge of low-level liquid wastes (B-line wastewater), trade wastes (C-line wastewaters), and non-radioactive sewage. Wastewater is managed by ANSTO WMS. The NMMF will require additional collection pipelines, effluent treatment plant upgrades for the treatment of facility effluent. The design for new effluent holding and treatment facilities will be incorporated into the SAR and assessed during the next stage of the Program. It is not envisaged that there will be any requirement to alter existing wastewater or trade waste agreements with Sydney Water.

2.6.3. Stormwater

Stormwater runoff from the Lucas Heights campus does not contribute to any public drinking water supply. It drains to three main discharge points and a few smaller stormwater drainage outlets, see NMMF Site Characteristics and Evaluation for more information [Ref: (4)]. There is no requirement to monitor stormwater during the siting phase, however, silt and sediment control will be closely managed and monitored during the construction phase of the NMMF. Stormwater control during the Facility operational phase will be incorporated into the NMMF detailed design.

2.6.4. Electricity

[redacted] The NMMF design incorporates additional backup and uninterruptable power supplies.

2.6.5. Compressed Air Supply

General usage compressed air is supplied from ANSTO on-site compressors through a reticulation system. A back-up compressed air system is provided within NMMF to ensure continuity of supply in the event the site supply is not in operation. Backup or additional compressed air services, as in the case of the NMMF will involve specific facility plant and equipment to meet air quality requirements and will be assessed in the detailed design phase.

2.6.6. Communications/ Data Services

The communications system at the Lucas Heights campus consists of the following components:

- Public Address (PA) System: The PA system provides site wide coverage and is used for major broadcasts to staff including emergency announcements. The existing site PA system will be extended to cover all areas of the NMMF.
- Facility SCADA: The Facility SCADA shall contain safety and plant alarms, triggered from a network of alarm sensors which detect events such as changes in the status of safety and plant systems, including those associated with Structures, Systems and Components (SSCs). Details of these for the NMMF are explored in section 3.
- Telecommunications: The telephone system consists of a network of in-ground cables. The network is based on distributed Private Automatic Branch Exchange (PABX) systems linked via optical fibre cables to form a single virtual PABX with enhanced reliability. The network covers the whole of the Lucas Heights campus including all occupied and unoccupied buildings and structures. The telecommunications network will be extended and incorporated into the NMMF.
- Computer Network: The ANSTO computer network and data communication system consists of an extensive network [redacted] General computer requirements for the NMMF will be met by extending the existing Ethernet network system through underground fibre-optic cables.
- Security System: The main security system provides for the physical protection [redacted] in accordance with national and international obligations. [redacted]

A1 2.7. Surrounding Land Use

A wide range of activities take place on the Lucas Heights campus, typical of a small industrial facility or university campus. These include various research activities in nuclear, health, minerals, materials, environmental and industrial applications, including the production, manufacture, and distribution of nuclear medicines, neutron beam analysis, ion beam analysis, accelerator mass spectrometry, silicon and gamma irradiation, and radiative waste treatment and management activities.

The land surrounding the NMMF is used for workshop areas [redacted] offices [redacted]. HIFAR (High-Flux Australian Reactor) is also [redacted] currently undergoing decommissioning.

[redacted]

Nearby industrial facilities include the ANSTO Innovation Precinct, located on the northern side of the main Lucas Heights campus area, which is leased to various private companies and the Lucas Heights Resource Recovery Park [redacted]

The army takes great care to ensure that all practices using live ammunition at the Holsworthy Military Training Area are carried out safely. [redacted]

Details of facilities and activities at the Lucas Heights campus and industrial and military facilities can be found in the NMMF Site Characteristics and Evaluation Report [Ref: (4)] as well as AG-2430 ANSTO LHSTC Site Description Ref [(6)].

A1

2.8. Surrounding Population Distribution

The estimated population for land surrounding the Lucas Heights campus at 1.6 km to 25 km from ANSTO is 2,064,774, based on GeoScience Australia National Exposure Information System data for 2020, and is documented in AG-2430 ANSTO LHSTC Site Description [Ref: (6)].

This population is dominated at the north-east, east, and east-south-east of the site (this represents Barden Ridge, Engadine, and surrounding suburbs). Further from the site, the main population concentrations are to the north and north-east (towards Menai). The population is relatively low to the south of the site. The population projection of annual average growth rate every five years to 2041 for the Sutherland Shire Local Government Area (LGA) is around 1% [Ref: (6)].

Growth of off-site population will be updated and reassessed upon revision of the SAR and as additional data becomes available.

2.9. Baseline Radiological Levels

Baseline radiological levels are background (~1 mSv/ year) within the general vicinity of the NMMF . For further information regarding baseline radiological levels on the Lucas Heights campus, refer to the AG-2430 ANSTO LHSTC Site Description [Ref: (6)].

A baseline radiological survey for the site will be available during a future licencing stage.

3. Safety Structures, Systems, and Components (SSCs)

A safety SSC relevant for radiological safety, for the purpose of safety categorisation, is defined as an engineered system, structure, or component whose failure could lead to a radiological consequence minor or higher as determined by AG-2395 ANSTO Risk Analysis Matrix [Ref: (19)].

3.1. General Building

The NMMF is being designed in alignment with the current Australian Standards, National Construction Code (NCC) Building Code of Australia (BCA) [Ref: (38)], and ANSTO's Building code, see AG-3219 ANSTO Building Code [Ref: (15)]. The concept design of NMMF will be supported by the safety-related characteristics incorporated across the ANSTO site.

3.2. Design Codes, Standards, and Guides

All buildings, plants, and equipment associated with the NMMF are to be constructed to the current standards, or equivalent at the time of execution. The building will be reviewed periodically throughout its life to ensure that compliance with current codes and standards is maintained.

The design related standards applicable to new work and equipment at ANSTO are detailed in Table 5. These standards related to civil structures, laboratory design and safety, mechanical engineering, electrical systems, plumbing and drainage, fire protection, and pharmaceutical production environments. Additional standards and guidelines are outlined in NMMF Applicable Codes, Standards and Guidelines NMMP-0080-PM-0006 [Ref: (39)].

Standard Number	Title
AS/NZS 1170 all parts including	Minimum design loads on structures (SAA Loading Code)
AS/NZS 1170.2	Structural design actions – Wind actions
AS/NZS 1170.4	Earthquake loads
AS/NZS 1200	Pressure equipment
AS 1418 (Set)	Cranes, hoists, and winches
AS/NZS 1668, Part 2	The use of ventilation and air-conditioning in buildings - Ventilation design for indoor air contaminant control
AS 1670	Fire detection, warning, control, and intercom
AS 1940	The storage and handling of flammable and combustible liquids
AS/NZS 2243	Safety in laboratories, incl. fume cupboards
AS/NZS 2293	Emergency escape lighting and exit signs for buildings
AS 2419, 2441, 2444, 2665	Standards relating to fire fighting and protection systems
AS/NZS 2430	Classification of hazardous areas
AS 2982	Laboratory design and construction - General
AS 3000	Electrical installations – Buildings, structures and premises
AS/NZS 3013	Electrical installations
AS 3100	General requirements for electrical equipment
AS 3500	Water supply systems, plumbing and drainage systems, and rainfall and runoff
AS/NZS 3666	Air handling and water systems – microbial control
AS 3700	Masonry structures
AS 3780	The storage and handling of corrosive substances
AS 3959	Construction of buildings in bushfire prone areas
AS 4024	Safety of machinery
AS/NZS 4452	The storage and handling of toxic substances
N/A	AME Active Ventilation: • AG-2906 Active Ventilation System (AVS) Manual [Ref: (40)] • AP-3084 AME Active Ventilation [Ref: (41)]
PIC/S 2022	PIC/S Code of GMP for Medicinal Products

Table 5: Design-related Standards Applicable to New Work at ANSTO

3.3. Classification of Systems, Structures, and Components

A complete explanation and application of the categorisation is provided in AG-2494 Guidance on the Radiological Safety Categorisation of SSCs [Ref: (42)]. This aligns with the risk management framework outlined in AP-2301 Work Health & Safety Risk Management [Ref: (43)], ALARP principles, as well as supports defence-in-depth.

The categorisation of SSCs to be adopted for the facility will focus on the following safety functions:

- Limiting radiation exposure to both occupationally exposed individuals and to members of the public.
- Minimising radioactive contamination in the working and external environments; it is expected that the latter would be bound by protection of members of the public.
- Limiting exposure to chemical hazards.
- Protection from non-radiological risks.

Operator evaluation of the facility will be against categories assigned based on the dose impact associated with a particular SSC. Guidance on how SSCs are categorised is summarised in Table 6 and Table 7.

Category	Description
I	Items whose failure could lead to a radiological exposure exceeding 100 mSv (for occupationally exposed individuals) or 5 mSv (for a member of the public), considering other protective measures, with some degradation. Based on the above, any structures, systems, and components that forms a primary means of ensuring radiation safety generally is a Category I SSC.
II	Items, other than Category I items, that failure of could lead to a radiological exposure exceeding 20 mSv (for occupationally exposed individuals) or 1 mSv (for a member of the public), considering other protective measures, with some degradation. Based on the above, any structures, systems. and components that makes an important additional contribution to radiation safety is assigned as Category II SSC.
III	Any structures, systems, and components that is not allocated to Safety Category I or II.

Table 6: SSC Categories

Role of SSC	Credible worst case radiological consequence			
	Catastrophic	Severe	Major	Moderate or lower
Primary	I	I	II	III
Secondary	I	II	II	III
Tertiary	II	III	III	III

Table 7: Tabular Representation of the SSC Categorisation System

The SSCs for the NMMF will be classified according to this scheme in the safety assessments for each functional area identified in sections 1.6 and 1.7. These may include equipment such as active ventilation systems, interlocks, fire detection/ suppression systems, and radiation monitoring equipment.

A radiological safety assessment identifies and classifies safety systems as critical controls or controls that support maintaining risks ALARP and support defence in depth.

The NMMF Structures, Systems and Components Register NMMP-2040-SC-0001 [Ref: (44)] is used to document the SSCs nominated for use. This document will be updated and maintained to reflect all SSCs implemented in the NMMF during detailed design. When Original Equipment Manufacturer (OEM) data becomes available, the OLCs for each SSC will be defined. A nominal listing of SSCs from similar operational environments has been provided in Table 8. Note: the category for these nominated SSCs are yet to be determined (TBD) as they are subject to OEM and OLC design data required from the final supplier.

SSC	Category	Worst Case Radiological Consequence	Primary Safety Function
Transfer Flask - Molybdenum	TBD	Damage to flask with direct exposure to radioactive Mo-99.	Shielding
Molybdenum Active Receipt Flask Hoist	TBD	Failure of hoist, with damage to receipt flask and exposure to Mo-99.	Lifting, support and movement of radioactive materials.
Active Receipt Bay - Rear of Cell Hoist	TBD	Failure of hoist, with damage to receipt flask and exposure to target.	Lifting, support and transfer of radioactive materials.
Active Receipt Bay - Front of Cell Hoist	TBD	Failure of hoist, with damage to B(U) and Type A containers resulting in exposure to targets.	Lifting, support and transfer of radioactive materials.
Active Receipt Molybdenum - Hot Cells	TBD	Catastrophic failure of hot cell shielding due to seismic event results in radiation exposure to personnel in the hot cell area.	Shielding & hatch interlock.
Active Material Transfer Carts (AMTCs)	TBD	Tipping over and fall of generators or pots to floor resulting in exposure to radioactive source.	Secure transfer of radioactive materials.
Hot Cells Tc-99m (Line 1 and 2)	TBD	Catastrophic failure of hot cell shielding due to seismic event results in radiation exposure to personnel in the hot cell area.	Shielding & hatch interlock.
Autoclave Tc-99m (Line 1 and 2)	TBD	Heat and pressure control system failure resulting in pressure release of radioactive material.	Heat and pressure control.
Hot Cells Iodine-131 Sterile and Non-sterile	TBD	Catastrophic failure of hot cell shielding due to seismic event results in radiation exposure to personnel in the hot cell area.	Shielding & hatch interlock.
Hot Cells Lutetium-177 (Line 1 and 2)	TBD	Catastrophic failure of hot cell shielding due to seismic event results in radiation exposure to personnel in the hot cell area.	Shielding & hatch interlock.
Liquid Waste Bunded Area	TBD	Containment of unplanned release of radioactive liquid waste.	Shielding, isolation and containment.

SSC	Category	Worst Case Radiological Consequence	Primary Safety Function
Uninterruptible Power Supply (UPS)	TBD	Loss of power to safety critical systems i.e. ventilation.	Power supply to safety critical systems.
Fire Detection and Alarm Systems	TBD	Failure of fire detection system during fire event leading to larger fire event and release of radioactive materials to atmosphere.	Fire detection and alarm.
Fire Suppression Systems Extinguishers/ Hose Reels / Fire Doors	TBD	First attack fire control and suppression.	Fire suppression
Active Ventilation System – HEPA and Filters (SIAM)	TBD	Release to atmosphere of volatile radioactive vapour, fume, or dust.	Control of airborne radioactive materials.
[redacted]			
Radiation Monitors - Hand and Foot	TBD	Failure of hand and foot monitor leading to potential for extended exposure to radioactive material contamination.	Radiation contamination exposure monitoring/ alert.
Radiation Monitors - Area	TBD	Failure of area monitor, with potential for unknown/ extended radiation exposed to personnel.	Radiation exposure alert
Radiation Monitors - Access	TBD	Out of calibration or incorrect reading portable access monitor (EPD) resulting unknown/ extended radiation exposure.	Radiation exposure alert
Radiation Monitors – Portable and Contamination	TBD	Out of calibration or incorrect reading portable radiation monitors resulting unknown/ extended radiation exposure to personnel.	Radiation exposure alert

Table 8: Nominal SSCs for the NMMF

General hot cell design and operational arrangements of the cells will be driven by the total facility wide isotope activity limit. The expected isotope inventory has been provided in Appendix A: .

3.4. SSC Qualification and Operability

Formally qualified components within the facility include items that are subject to special quality assurance during manufacture or installation in order to withstand demanding operational conditions. Qualified components are to be scheduled for inspection, certification, and maintenance as part of the verification and validation process described in Project Validation Master Plan NMMP-8000-RT-0001 [Ref: (45)].

The System and Sub-System Quality Level NMMP-0300-PR-0001 [Ref: (46)] procedure has been developed to determine the level of design quality assurance, change control management, and commissioning required. Three quality levels are identified: A, B and C where Level A has the most stringent requirements. These are assigned based on an assessment of their safety, seismic category, reliability and availability, GMP, and complexity factor, as detailed in the procedure.

Major plant equipment has been selected with the consideration of the suitability of materials to resist degradation from environmental factors and process conditions. These items meet the standards for the type of equipment (where specific standards exist) and are also scheduled for maintenance according to the required frequency as indicated in SAP.

The basic handling equipment of the facility such as shielded hot-cells and their associated ventilation systems are those typically used in the nuclear industry. Components used in the facility such as autoclaves (certified pressure vessels) and cranes conform to the requirements outlined in ANSTO WHS Management System (WHS MS), see AP-2300 ANSTO WHS Management System Overview [Ref: (47)]:

- AG-2497 Lifting Equipment Process [Ref: (48)] and AP-3059 Lifting Equipment/ Lifting Devices [Ref: (49)].
- AG-2501 Pressure Equipment Process [Ref: (50)] and AP-3058 Pressure Equipment [Ref: (51)].
- AP-2928 Piped Gas Systems Process [Ref: (52)].

Details on the operability of the selected SSCs will be available once the detailed design for the NMMF matures.

3.5. Design Methods

The NMMF will allow for efficient, compliant, and safe production. The design of the facility provides organisational flexibility to allow for future changes in customer demand.

As a multiproduct radiopharmaceutical facility, it is structured to allow growth and changes without impacting the basic building organisation and workflows thereby helping to ensure compliance throughout its lifecycle. The design of the facility will optimise material and personnel workflows, the appropriate segregation of processes, the necessary segregation of cleanrooms, plus segregation in radiological designations to create a safe facility for staff.

During the design phase, a suite of Engineering Design Safety Principles (EDSPs) have been identified which are to be applied to the NMMF. These EDSPs have been derived through review of Australian regulatory guidance and consideration of the United Kingdom Office for Nuclear Regulation Safety Assessment Principles as an additional source of Relevant Good Practice (RGP). These principles are provided in Table 9.

Engineering Design Safety Principle	Description
Fit for Purpose Design	The design should be fit for purpose, follow appropriate national and international codes and standards, conventions, protocols, and be commensurate with the safety significance of the defined safety functions.
Hazard Identification	Potential hazards from the operation of the proposed plant should be identified in a systematic and comprehensive manner. The design should eliminate these hazards as far as reasonably practicable in all modes of operation and across all stages of the facility lifecycle.
Significant Faults	The sensitivity of the plant to potentially significant faults, and the frequencies and consequences of any resulting hazards, should be minimised.

Engineering Design Safety Principle	Description
Defence In Depth	Plant should be designed to have defence-in-depth, making appropriate use of redundancy, diversity, and segregation, commensurate with the safety significance of the potential hazard, and reflecting the preference for safety measures to sit at the highest possible level on the hierarchy of controls.
Minimise Reliance on Human Action for Safety	When designing safety systems, the allocation of safety actions between humans and technology should be optimised. The dependence on human action to maintain a safe state should be minimised.
Primary Containment	Damage to primary containment should be minimised. The plant should be designed such that damage to the primary containment will not result in the release of a significant inventory of radioactive material from the subsequent containment barrier under the most onerous credible operational and fault conditions.
Radiation Protection	Protection against radiation and contamination resulting from normal operation, and the consequences of fault conditions, should be provided in all parts of the plant to which access is required or can reasonably be gained. Protection through engineered controls and design features should be preferred over protection by administrative or procedural controls requiring human action. Adequate devices, suitably located, should be provided for monitoring radiological conditions. Doses should be minimised as far as is reasonably practicable.
Industrial Safety	General industrial safety should be ensured by designing the plant such that it can be constructed, operated, maintained, and decommissioned in accordance with legislation and ANSTO requirements covering safety, health, and the environment.
Fail Safe Systems	SSCs important to safety should be designed to be inherently safe or to fail in a safe manner.
Safety Systems Robust Against Any Single Failure	No single random failure assumed to occur anywhere within the safety systems provided to perform a safety function should prevent that function being performed during any normally permissible state of plant availability.
Independent Safety and Control Systems	Safety systems (systems designed to protect against fault conditions) should be independent of control systems (systems designed to control normal planned processes and operations).
Define Safety Working Life	The safe working life of all SSCs which are important to safety should be defined.
Design for Full Operating Life	SSCs should be qualified to perform their required safety functions throughout their operational lives, under the operational, environmental, and accident conditions specified in the design.
Basis for Reliability Claims	The reliability claimed for any SSC important to safety should consider its novelty, the experience relevant to its proposed environment, potential common cause failures, uncertainties in operating and fault conditions, physical data, and design methods.
Monitoring, Inspection, and Maintenance	Provision should be made for monitoring, inspection and maintenance of SSCs important to safety, prior to service, in service, and at intervals throughout the plant life, commensurate with the performance requirements.

Engineering Design Safety Principle	Description
Access Control	The design should aim to prevent unauthorised access to or interference with systems important to safety.
Accident Management	Plant should be designed to facilitate accident management and recovery.
Robust Support Services	Support services and facilities such as access roads, water supplies, fire mains, and site communications important to the safe operation of the plant should be designed and routed so that in the event of any credible incident sufficient capability to perform their emergency functions will remain.
Monitoring of Plant State	Sufficient indicating and recording instrumentation and controls should be available to the plant operator to provide adequate monitoring of the state of the plant, warning of any safety related change of state, and the means of identifying, initiating, and confirming all necessary safety actions, including those required for accident management and recovery.
Human Factors and Ergonomics	The design of all interfaces between operating personnel and the plant should follow good human factors and ergonomics practice.
Detection and Management of Containment Breach	Means should be available to detect, locate, monitor, and manage leakage from containment which could indicate a potentially unsafe condition or give rise to a significant radiological effect.
Design for Decontamination	Containment structures, vessels, pipework, plant, equipment, and facilities housing them, which may become contaminated with radioactive material, should be designed to facilitate an appropriate level of decontamination.
Containment and Control	The design of facilities should be adequate for the safe containment and control of radioactive material.
Storage and Use of Hazardous Materials	The use and storage of hazardous material should be kept to a practicable minimum, controlled, and located so that any accident to or release of the materials will not jeopardise establishing safe conditions on the plant or site.
Minimise Impact of Waste	Plant should be designed to be operated and maintained such that the impact on people and the environment of solid, liquid, and gaseous wastes is minimised.
Modelling	Models should be employed where necessary in support or confirmation of the design or as a means of describing safety related conditions in the plant.
Suitability of the Site	The site should be assessed to determine the suitability of the characteristics of the site for the design conditions specified for normal operation and fault conditions.
Fire Safety	Fire-loading in the plant should be quantified and the choice of materials and the firefighting provisions provided justified. The design must take due account of relevant building regulations.
Build, Commission, Decommission, and Dismantle	Plant should be designed to facilitate safe build, commissioning, decommissioning, and dismantling.
Safety Management Arrangements	At each phase in the life of the plant, suitable management arrangements should be established and implemented.
Equipment and Staffing Levels	Guidance on minimum equipment and staffing levels necessary for the design to achieve safety performance requirements should be specified. This guidance should be adequately justified.

Engineering Design Safety Principle	Description
Safety Analysis	Analysis of normal operation and fault conditions should be carried out to identify safety functional requirements and justify the adequacy of the plant design and system of operation.

Table 9: Description of Engineering Design Safety Principles for the NMMF Design

3.6. Design for General Safety

Across all stages of the design phase, consideration of safety, including Human Factors (HF), will be inherent. As outlined in section 2 and in section 18 of the WHS Act 2011 [Ref: (12)], it is incumbent upon a Persons Conducting a Business or Undertaking (PCBU), to do whatever is 'reasonably practicable' to ensure health and safety of workers and others at the workplace. This Duty extends to designers, manufacturers, importers, suppliers, installers, constructors and those commissioning structures or plant. These duty holders must eliminate hazards where possible and minimise risks, using AG-2407 ANSTO Hierarchy of Risk Controls [Ref: (53)], to implement solutions that are considered reasonably practicable.

In relation to a duty to ensure health and safety, reasonably practicable means that which is or was at a particular time, able to be done to ensure health and safety, considering and weighing all relevant matters including:

- The likelihood of the hazard or the risk occurring.
- The degree of harm that might result from the hazard or risk.
- What the person concerned knows, or ought to reasonably know, about:
  - The hazard or the risk.
  - Ways of eliminating the hazard or minimising the risk.
- The availability of ways to eliminate or minimise the risk.
- After assessing the extent of the risk and the available ways of eliminating or minimising the risk, the cost associated with available ways of eliminating the risk, including whether the cost is grossly disproportionate to the risk.

The Design Guide - Safety in Design Strategy [Ref: (21)] details the NMMF EDSPs to be applied throughout the design process and to all structures, systems, and components. Any design which does not apply relevant EDSPs must be fully justified in terms of the benefits of the design versus the associated risks, demonstrating that the risks are still reduced to ALARP. Appendix C of this strategy also outlines the Human Factors Integration Plan (HFIP). The HFIP will include details of the human factors (HF) deliverables that are specific to the design stage that the HFIP is being developed for.

3.7. Design for Nuclear Safety and Nuclear Security

No nuclear material (IAEA definition) is used or stored in the facility. [redacted] Design for nuclear safety is not relevant to this SAR.

[redacted]

[redacted]

3.7.2. Criticality Control

As there are no nuclear materials used or stored in the facility, there are no criticality control requirements for the NMMF.

3.8. Design for Radiological Safety

The ANSTO requirements relating to radiological safety are discussed in AE-2310 Radiation Safety Standard [Ref: (54)]. The whole-body effective radiation exposure limit for workers is 20 mSv annually (averaged over 5 years) and 50 mSv in any one year. However, ANSTO has work-area specific dose constraints which take into account the radioactive work being done. Currently, these are between 1mSv/year and 5mSv/year but the specific dose constraints for each work area within the new facility will be determined at a later, detailed stage in the design. These area specific dose constraints are reviewed annually.

The facility shall be designed in such a way to ensure compliance with the AE-2310 Radiation Safety Standard [Ref: (54)] and its associated guidance documentation within the WHS MS, as well as all other relevant ARPANSA codes and practices, including but not limited to:

- Code for Radiation Protection in Planned Exposure Situations (Radiation Protection Series C-1 Rev 1) [Ref: (55)].
- Code for the Safe Transport of Radioactive Material (Radiation Protection Series C-2 Rev 1) [Ref: (56)].
- Guide for Radiation Protection in Existing Exposure Situations (Radiation Protection Series G-2) [Ref: (57)].
- Guide for Radiation Protection of the Environment (Radiation Protection Series G-1) [Ref: (58)].
- Fundamentals for Protection Against Ionising Radiation (Radiation Protection Series F-1) [Ref: (59)].
- Guide for Classification of Radioactive Waste (Radiation Protection Series G-4) [Ref: (60)].

In particular, the facility should be designed in such a way to ensure doses during normal operations remain within the local dose constraints for the facility, with these dose constraints forming the basis for the dose objective for the facility.

Any equipment handling radioactive material will be designed to provide measures sufficient to ensure radiation exposures to workers are optimised and with appropriate levels of containment to minimise the risk of release of radioactive material to the working environment.

Expected Nominal SSCs for radiological safety, including shielding, radiation monitoring, radioactive contamination monitoring, and alarms have been detailed in section 3.3. Details on radiation protection within the NMMF is provided in NMMF Radiation Protection Plan [Ref: (14)].

3.9. Design for Chemical Safety

Various chemicals will be used for processing operations in the manufacturing suites and for product testing within the QC testing in both radioactive and non-radioactive laboratories located in the NMMF. The manufacturing suites, chemical storage areas (including Dangerous Goods licence), and laboratories will be designed to appropriate laboratory codes and standards. The standards relevant for establishing the laboratories and systems, detailed in Table 5, include:

- AS 1940-2017 The storage and handling of the flammable liquid
- AS 3780-2008 The storage and handling of corrosive substances (Dangerous Goods)
- AS/NZS 4452-1997 The storage and handling of toxic substances
- AS/NZS 2243-2010 Safety in Laboratories, parts 1 – 10 as applicable.

The AG-2441 ANSTO Storage of Chemicals [Ref: (61)] guide will be followed during detailed design and compliance auditing with future results reported using AF-4003 Chemical Management Compliance Tool [Ref: (62)].

3.10. Design for Industrial Safety

The codes and standards at the time of construction will be the basis for the industrial safety design for the facility. All mechanical and electrical equipment will be selected and installed to comply with the relevant Australian standards for industrial safety listed in Table 5.

All civil, mechanical, and electrical construction projects will be undertaken in compliance with ANSTO's WHS MS, see AP-2300 ANSTO WHS Management System Overview [Ref: (47)], which incorporates all applicable WHS and radiological legislations, codes, and standards. This includes applying risk management practices ISO 31000, AG-3062 ANSTO Safety in Design [Ref: (63)], and other applicable sections of the ANSTO Work Health and Safety Management system.

3.11. Design for External Events

Lucas Heights campus-related external events generally, are explored in AG-2430 ANSTO LHSTC Site Description [Ref: (6)]. The potential for hazards associated with external events to affect the facility have been assessed in the NMMF Site Characteristics and Evaluation report [Ref: (4)]. This report concluded that the site does not have any negative features which cannot be eliminated or controlled and as such is suitable for the NMMF.

As detailed in Design Guide - Safety in Design Strategy [Ref: (21)], the implementation of defence-in-depth in design provides a graded protection against a wide variety of operational occurrences and accidents, including those events that initiate outside a facility. Details of external events, including the design basis events, are detailed section 4.7.

3.12. Design for Fire Protection

The NMMF will be designed and constructed to meet the fire protection requirements of the NCC [Ref: (38)], considering the nature of the facility. This includes smoke and thermal (rate-of-rise) based fire detection systems as required under the code. Manual fire extinguishers will be provided throughout the building as per the code, with the type of extinguisher chosen based upon the potential fire loads. Automated fire suppression systems including sprinklers and/or gaseous systems will be considered as per requirements of the code. Fire sprinklers or gaseous fire suppression systems, if used, will be designed to contain and mitigate the risk of radiological contamination spread.

Additional details on the design for fire protection is available in Fire Protection Strategy and Basis of Design [Ref: (16)].

3.13. Design for Decommissioning

The design of the NMMF follows a 'whole-of-life' approach that will facilitate the safe decommissioning and dismantling of structures, systems, components, plant, and equipment. Whilst the detailed decommissioning strategy will be made in the future; it is expected that decommissioning will leverage the skills and facility knowledge of operational personnel through a post operational clean out. More details on the decommissioning strategy is available in section 11 and in the NMMF Decommissioning Plan NMMP-0410-PM-0007 [Ref: (64)].

4. Hazard and Accident Analysis

This section details the hazard identification and risk assessment process used to provide an assessment on the safety of the facility. For the licencing stage, a NMMF Safety and Security Consequence Analysis Report [Ref: (50)] and a NMMF Site Characteristics and Evaluation report [Ref: (4)] has been prepared to identify preliminary risks. This section will be updated as the design of the facility matures.

4.1. Hazard Identification and Categorisation

A detailed hazard identification and categorisation of relevant facility hazards across all NMMF processes, using the AG-2395 Risk Analysis Matrix [Ref: (19)] will occur at a future licencing stage.

An initial Program Hazard Log has been developed to document and describe all hazards within the facility. The relevant risk scenarios from Safety and Security Consequence Analysis [Ref: (5)] include:

- Building fire
- Seismic event
- [redacted]

The scenario analysis for these events have been provided in Appendix B: . As the facility design matures, the Program Hazard Log and this SAR section will be updated to reflect NMMF-specific scenarios.

4.2. Design Basis Accident Analysis

Bounding case accident scenarios were identified through the NMMF Safety and Security Consequence Analysis Report [Ref: (5)]. These included major building fire, security, and seismic events which have been addressed when considering the effects of potentially significant natural or human induced external events. It is assessed that a large-scale building fire, which has the potential to result in the airborne release of all the available radioactive materials stored in the facility, represents the bounding case accident with respect to releases to the environment.

For the purposes of safety assessment, it has been conservatively assumed that the building will not have separate fire compartments, hence a fire at any place of the facility is assumed to have to the potential to expand into a building fire, representing the bounding case accident. Release from any internal incidental event of a specific step of a process would be bounded by the identified building fire event. These assumptions will be revisited when the facility design is more mature, to provide a more realistic assessment of consequences.

A design risk assessment will be undertaken upon completion of the detailed design packages to identify potential hazards and risks associated with SSC design and elements of the design or operation that mitigate against them.

4.3. Initiating Events and Hazards in the Facility

Postulated initiating events, including human induced events, which could affect safety will be identified and evaluated including their effects both individually and in credible combinations, once the design of the facility has matured.

4.3.1. Initiating Events

A detailed risk assessment of initiating events across NMMF operation will be conducted at a future licencing stage.

4.3.2. External Hazards

External hazards have been identified based on AG-2430 ANSTO LHSTC Site Description [Ref: (6)] in the NMMF Site Characteristics and Evaluation report [Ref: (4)]. These will be captured in the Project Hazard Log as more details of the facility become available. A safety analysis for these hazards has been provided in section 4.7.

4.3.3. Nuclear Hazards

No fissile materials are stored or used in the facility and therefore there are no nuclear hazards identified for the facility.

4.3.4. Radiological Hazards

An assessment of the radiological impacts for the airborne release of radioactive material outside the facility as a result of a bounding case accident was conducted, see Safety and Security Consequence Analysis [Ref: (5)].

PC-Cosyma was used to assess the radiological hazard for identifying potential consequences of the release outside the facility. The analysis was performed reflecting day and night conditions for projected effective doses and thyroid doses for exposure of adults, children and infants at various distances from NMMF.

[redacted] potential bounding case accidents were considered:

- Building fire
- Seismic event

[redacted]

It is assessed that a large-scale building fire which has the potential to result in the airborne release of all the available radioactive materials stored in the facility represents the bounding case accident with respect to releases to the environment. Details of the inventory and release fractions are provided in section 3 of the Safety and Security Consequence Analysis [Ref: (5)].

A more detailed assessment for all radiological hazards in the facility will be undertaken during a future licencing stage.

4.3.5. Chemical and Biohazards

As detailed in section 3.9, there are various chemicals which will be used for processing operations in the manufacturing suites and for product testing within the QC laboratories located in the NMMF in both radioactive and non-radioactive laboratories. In these instances, appropriate training will be conducted, personal protective equipment (PPE) will be available accordingly, and they will be stored safely with current Safety Data Sheets (SDS) available.

A detailed risk assessment considering chemical hazards in the facility will be undertaken in the next phase of the NMMF.

The microbiology laboratory will keep microorganisms such as bacteria, endotoxins, and fungi which are compendial type organisms (British Pharmacopoeia, United States Pharmacopoeia, European Pharmacopoeia). After use, these microorganisms will be destroyed by autoclaving and/or incineration by an external contractor. Classification of the microbiology laboratory will be determined during a future stage of the Program lifecycle.

4.3.6. Industrial Hazards

Industrial risks will be considered as a part of the Hazard Log process and will be considered with reference to AP-2301 Work Health & Safety Risk Management [Ref: (43)] and comply with NSW Safe Design of Structures Code of Practice (2019) [Ref: (65)].

A detailed risk assessment considering industrial hazards in the facility will be undertaken in the next phase of the NMMF.

4.4. Protection Systems

Protection systems provide passive, automatic, or on-demand safeguarding functions to ensure the safe operation of the facility and, if required, a safe operational shutdown of the facility. SSCs relating to the protection of the facility, including their safety functions, are detailed in section 3.3.

4.4.1. Fire Alarm and Suppression

Fire alarm equipment has been detailed in section 1.6.2. Further details will be provided in future licencing stage as the facility design matures.

4.4.2. Instrumentation, Alarm, and Control Systems

Instrumentation alarm and control systems utilised within the facility will be considered with respect to a defined specification and assessed in terms of a nominated SSC. Nominal SSCs related to protection systems have been included in Table 8. Additional details on the instrumentation, alarm, and control systems will be included as part of the detailed design phase of the Program.

[redacted]

4.5. Risk Management

A detailed risk assessment which explores hazard scenarios identified and the corresponding mitigation actions will be undertaken during a future licencing stage. This assessment will explore Hazard Control, Protection and Damage Limitation Systems such as the use of relevant PPE, and Optimisation principles to identify scope for improvements.

4.5.1. Hazard Control

Hazard control measures refer to the operating strategies and procedures/ instructions that are in place to control known hazards. These are administrative measures as distinct from the hardware measures referred to in section 4.5.2.

ANSTO has various operating strategies, procedures, and instructions that are in place to control known hazards in the NMMF. NMMF-specific procedures and instructions will be developed to control identified hazards in the facility prior to operations. These procedures and work instructions will be risk assessed to ensure that all operators are adequately informed of the hazards during all operational activities. This process is described in AG-2397 Explanatory Notes for Safe Work Method and Environmental Statements [Ref: (66)].

ANSTO has comprehensive processes which collectively ensure that potentially hazardous work is performed by and supervised by properly trained, authorised, and qualified workers. This process is initiated by the recruitment process for employees and non-employees where the selection is based on the approved selection criteria for the role. The criteria include the qualifications, knowledge, and experience appropriate for the work to be performed. Further information on training and authorisation of workers can be found in section 5.6.6.

4.5.2. Protection and Damage Limitation Systems

Protection and damage limitation systems refer to the equipment and instrumentation that are in place to control known hazards. These are distinct from the administrative measures referred to in section 4.5.1.

Radiation monitoring systems are early detection protection systems which can prevent consequences from hazards. The NMMF will have an integrated radiation monitoring system which will include several key components and features designed to detect, measure, and manage radiation levels. These components work together to ensure accurate monitoring, safety, and compliance with regulatory standards. Systems such as local radiation monitors will be installed throughout the facility with an alarm set point for elevated dose rates. The radiation monitoring equipment types used in the NMMF is detailed in the NMMF Radiation Protection Plan [Ref: (14)].

Fire alarm and suppression equipment has been detailed in section 1.6.2.

4.5.3. Optimisation

The optimisation of radiation exposure to ANSTO staff and members of the public, will be achieved by applying the ALARP principle, using several of the following defence in depth design strategies:

- Isolation of the radioactive source by containment, distance and limiting time of exposure.
- Remote handling
- Shielding hot cells, shielding containers, shielding flasks during transport, and other equivalent techniques.
- Automation, where available
- Delay and decay of isotopes prior to intervention by staff
- Assessment of Best Available Technologies (BAT)
- Work planning to minimise the dose received by staff members. Administrative controls such as training and procedures.
- Personal protective equipment
- Emergency response plans to mitigate the consequence of significant spillage of radioactive materials to the environment.

During later stages of the NMMF, a detailed safety assessment on the facility will be undertaken to ensure the level of radiation protection is optimised for each radiation source and the exposure to ionising radiation. Additional details on radiation protection measures for the facility are available in NMMF Radiation Protection Plan [Ref: (14)].

4.6. Safety Analysis for Normal Operation

The NMMF will be managed and regularly reviewed to ensure that all regulatory, legal, safeguards, safety, and environmental requirements are complied with at all times during normal operation, reference AP-1094. Radiological monitoring of processes within the NMMF will be carried out on an ongoing basis in line with the NMMF Radiation Protection Plan [Ref: (14)]. Routine surveys will be undertaken to confirm radiation and contamination levels are within acceptable limits, with any abnormal levels to be flagged and followed up. The doses received by NMMF staff will be monitored by RPS and reviewed by facility management and the HP to ensure that they are ALARP.

Once operational, the NMMF will produce radioactive gases, dust, or other airborne emissions which will be controlled by the HVAC exhaust systems, inclusive of a carbon filtration unit, supported by routine stack discharge monitoring. Notification levels and discharge limits/ targets that apply for the facility will be defined further into the design process. Any wastewater that may be generated during operations, from the safety shower, eye wash, and hand washing facilities, will drain to the effluent treatment plant. This liquid would then be discharged off site in alignment with the Trade Waste Consent with Sydney Water Corporation.

The combined effects of direct radiation and of releases of radioactive material from the facility will be minimised and will not approach authorised limits to the public.

4.7. Safety Analysis for External Events

A site evaluation for natural and human induced external hazards are detailed in Table 10 and Table 11. Additional details are available in the NMMF Site Characteristics and Evaluation report [Ref: (4)].

External Natural Events	Site Evaluation
Seismic	The NMMF location is such that it can be safely designed with respect to earthquakes and surface faulting. The worst foreseeable seismic scenario with the potential for off-site consequences would be an earthquake leading to the release of significant radioactive material. The consequence is described as one of the bounding case accidents within the NMMF Safety and Security Consequence Analysis [Ref: (5)].
Meteorological	Meteorological data and characteristics are available in the NMMF Site Characteristics and Evaluation report [Ref: (4)]. Extreme meteorological phenomena such as wind, high and low temperatures, intense rainfall and hail, and lightning can all be managed and/or controlled for the NMMF site through the site design basis.
Hydrological	Hydrological conditions, including stormwater and groundwater, associated with the NMMF site can be managed via facility design to ensure active material does not enter waterways.
Geological	The geology of the NMMF site has been evaluated through a geotechnical investigation conducted by Douglas Partners [Ref: (26)] and described in the NMMF Site Characteristics and Evaluation report [Ref: (4)]. The geology of the NMMF site is stable and suitable for the planned structure.
Bushfire	The Lucas Heights campus is surrounded by bushfire prone land. Control measures associated with bushfire weather conditions are described in the NMMF Site Characteristics and Evaluation report [Ref: (4)]. The main design considerations for avoiding or minimising hazards from bushfire include compliance with relevant Australian building standards, the use of appropriate construction materials, appropriate design to avoid the collection of combustible material on or near buildings (e.g., leaves settling in guttering, roof, or eaves), and maintaining recommended fire hazard reduction distances from bushland.

Table 10: Site Evaluation for External Natural Events

Human Induced External Events	Site Evaluation
Aircraft Transport	The potential for an air traffic and transport event impacting on the NMMF site is discussed in the NMMF Site Characteristics and Evaluation report [Ref: (4)]. [redacted]
Road Transport	The primary road transport risk associated with the main road near the Lucas Heights campus is likely to be from hazardous chemicals transported along Heathcote and New Illawarra Roads. As detailed in the NMMF Site Characteristics and Evaluation report [Ref: (4)], the bounding scenarios for hazard chemical ignition or explosion would have no significant impact on the NMMF.

Human Induced External Events	Site Evaluation
Rail Transport Accident	The Illawarra railway line passes within 3 km of the OPAL Reactor and NMMF development site. Hazardous chemicals (ammonia, chlorine, or sodium cyanide) may be transported on this line in instances where there is a problem with the usual Sydney-to-Melbourne route. As detailed in the NMMF Site Characteristics and Evaluation report [Ref: (4)], the rail is considered too far away to affect the Lucas Heights campus in the event of an accident.
Nearby Industrial Activities	A review of sites licenced under the Dangerous Goods Act or nominated as Major Hazard Facilities within an 8 km radius of Lucas Heights, revealed that no oil refineries, chemical plants, plastic manufacturing plants, or any industrial complex that handle large quantities of hazardous materials are sufficiently close enough to the Lucas Heights campus to affect operations, even in the worst-case accident at these facilities.
[redacted]	[redacted]

Table 11: Site Evaluation for Human Induced External Events

4.8. Emergency Preparedness Categorisation

Radiological hazards have been identified for the NMMF and the potential consequences of an emergency have been assessed to provide a basis for establishing arrangements for preparedness and response for a radiological emergency. The emergency used for the assessment, detailed in Safety and Security Consequence Analysis [Ref: (5)] is a radiological release resultant from building fire within the facility.

The IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [Ref: (36)] groups assessed hazards in accordance with the Emergency Preparedness Categories (EPC) I - V.

Considering the most restrictive group (infant daytime, inhalation), the projected thyroid equivalent dose for 50-years exceeds Generic Intervention Levels (GILs) within approximately 1.3 km of the NMMF. This is beyond the Lucas Heights site boundary and could give rise to exposure to people off-site which may warrant urgent protective actions or early protective actions to achieve the goals of emergency response.

As such, the assessed hazard results in the NMMF being classed as Emergency Preparedness Category II. This is defined as facilities, such as some types of research reactor and nuclear reactors used to provide power for the propulsion of vessels (e.g. ships and submarines), for which on-site events, are postulated that could give rise to doses to people off the site that would warrant urgent protective actions or early protective actions and other response actions to achieve the goals of emergency response in accordance with international standards, or for which such events have occurred in similar facilities. Category II (as opposed to Category I) does not include facilities for which on-site events (including those not considered in the design) are postulated that could give rise to severe deterministic effects off the site, or for which such events have occurred in similar facilities.

This EPC establishes the basis for a graded approach to the application of safety requirements and for developing generically justified and optimised arrangements for preparedness and response for a nuclear or radiological emergency at the NMMF that impacts outside the facility. The EPC will be reviewed in line with the Safety and Security Consequence Analysis [Ref: (5)] as the facility design matures.

4.9. Analysis of Environmental Impact

There will be no volatile radioactive wastes, gases, dusts, or other airborne emissions generated during the siting of the new facility. There will be no radioactive or chemical discharge to the environment during the siting of the NMMF.

The ANSTO Corporate Plan prioritises the implementation of the AE-5362 ANSTO Environmental Sustainability Strategy [Ref: (1)], which states the objectives, targets, and actions by which ANSTO will minimise its direct and indirect impacts on the environment. Environmental management will be a standard item on the agenda of all NMMF management meetings. Staff members are encouraged to actively report environmental incidents through the ANSTO Incident Management System.

The ANSTO Stack Emission Radiation Monitoring System (ASERMS) will monitor gaseous emissions via the NMMF stack/s. The ASERMS will monitor the HVAC discharge air to environment, in order to monitor isotopic emissions from the facility. For more information, refer to NMMF Environment Protection Plan [Ref: (67)].

The most recent assessment of potential radiological impacts to wildlife from ANSTO facilities at the Lucas Heights campus was conducted for the ANSTO Nuclear Medicine Mo-99 Facility and is detailed in ANSTO-E-785 Screening Assessment of Dose Rates to Wildlife related to the Nuclear Medicine Mo99 Facility [Ref: (68)]. This assessment considered both airborne emissions and liquid discharge pathways and conservatively evaluated ANSTO's cumulative potential discharges. This assessment used methods from international best practice as laid out by the ARPANSA Guide: Radiation Protection of the Environment [Ref: (58)], which is consistent with current approaches set forth by the International Commission on Radiological Protection (ICRP) and the IAEA.

ANSTO has submitted a referral to construct and operate the NMMF at Lucas Heights. The referral was for a proposed action under Section 68 of the Environment Protection and Biodiversity Conservation Act 1999 (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 decision document (EPBC Notification of Referral Decision 2023/09748) [Ref: (69)].

Formal comments on the referral were received from:

- National Indigenous Australians Agency (NIAA)
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)
- Department of Industry, Science and Resources (DISR).

Geoscience Australia also concurred with ANSTO that construction of the NMMF is not likely to have a significant impact to the environment and should not be considered a controlled action.

During subsequent stages of the NMMF Program, an update to the existing screening assessment of dose rates to wildlife dose assessment will be conducted to include the operation of the NMMF.

Additional details are available in Environment Protection Plan [Ref: (67)].

4.10. Work Health and Safety

ANSTO is committed to ensuring the health, safety, and welfare for all workers, contractors, visitors, and members of the public. Central to this commitment is a proactive WHS MS [Ref: (47)] which supports ANSTO's Work Health and Safety and Environment policy, see AB-0002 Health, Safety, Community and Environment Policy [Ref: (70)]. The WHS MS provides a comprehensive system of policies, procedures and guides to assist ANSTO in meeting its strategic plans and legislative obligations.

The Work Health, Safety and Environmental Management Plan Delivery Phase NMMP-0010-PM-0003 [Ref: (71)] details the Work Health, Safety and Environment (WHS & E) Management System that will be incorporated into the management plans for the NMMF delivery. It details the roles and responsibilities as well as the principles such as the Stop, Think, Act and Review (STAR) safety guidance and the Safe Work Method and Environmental Statements (SWMES) to be used. Additional detail on WHS MS is available in the NMMF Safety Management Plan NMMP-0410-PM-0002 [Ref: (72)].

5. Safety Management

This section outlines the safety management arrangements specific to the facility. It covers the ANSTO current safety practices that the NMMF will be designed, constructed and operated under, and considers their extent and implementation, and details where safety management responsibilities lie. This section demonstrates that the new facility practices will be designed and optimised for safety and shows that effective feedback and review mechanisms are in place to facilitate continuous improvement. The NMMF Safety Management Plan [Ref: (72)] outlines the effective safety management plans and arrangements relevant to the NMMF.

A1 5.1. ANSTO Safety Policy

ANSTO has policies in place relating to all aspects of its operations. AB-0002 Health, Safety, Community and Environment Policy [Ref: (70)] states ANSTO's commitment to work health and safety, environment, and sustainability as well as ANSTO's actions to meet those commitments. Other policies, including those for security, quality, human resources, and business, provide a comprehensive framework. These policies are periodically reviewed.

There are several measures in place to ensure these policies are available and understood. They are provided at induction and available on the ANSTO intranet which is accessible to all staff. ANSTO promulgates health and safety information to all staff and contractors through the ANSTO, Safe, Secure and Sustainable initiative. A key element of the Safe, Secure and Sustainable initiative is the internal communications strategy to promote the ANSTO Health, Safety, Community and Environment Policy and management's commitment to the principles of holistic safety, from the Board and operational leadership to all personnel and contractors.

Supporting the Health, Safety, Community and Environment Policy are the radiation safety standards. AE-2310 Radiation Safety Standard [Ref: (54)] commits to as low as reasonably practicable (ALARP) principles to optimise radiation protection and safety and outlines the ANSTO source-related dose constraints.

There are objectives for general safety performance and the key performance indicators are monitored as per AP-7486 Planning to Achieve WHS Targets and Objectives [Ref: (73)]. ANSTO also has an environment monitoring program which has been detailed in section 4.8.

Operational and Project documents are developed in accordance with the ISO 9001 certification and in conformance to the ANSTO project governance framework described in AB-0117 Executive Policy Project Management Policy [Ref: (74)]. The ISO 45001 Occupational Health and Safety Standard certifies ANSTO's WHS MS, with other policies managed in accordance with ANSTO's ISO 9001 certified Quality Management System (QMS). Additionally, the ISO 14001 Environmental Management System certifies ANSTO's EMS to ensure there are procedures for document control and records management.

The effectiveness of these management systems is monitored and maintained by the audit programs required by the ISO certifications. These include both internal audits by ANSTO workers and external audits by the certifying organisation. Audit records are maintained, and non-conformances and corrective actions are managed through these processes.

5.2. Legal Requirements

ANSTO is considered the "person conducting a business or undertaking'" for the purposes of the Work Health and Safety Act (2011) [Ref: (12)], associated Regulations, and the Safety, Rehabilitation and Compensation Act (1988) [Ref: (75)]. ANSTO is considered the controlled person for the purposes of the ARPANS Act, 1998 and associated regulations.

5.3. Facility Management Structure and Responsibilities

Clear lines of responsibility in safety matters are defined in the following ANSTO WHS documents:

- AG-1682 ANSTO Financial Delegation Manual [Ref: (76)] and AP-2300 ANSTO WHS Management System Overview [Ref: (47)] documents the delegations at ANSTO, including safety delegations.
- AP-2300 ANSTO WHS Management System Overview [Ref: (47)] describes the risk management approach developed and implemented by ANSTO to assist management and workers to establish and maintain a healthy and safe workplace. This procedure provides an overview of the ANSTO WHS MS including the needs and expectations of workers and other interested parties and the scope of the WHS MS.
- AP-2362 WHS Accountabilities, Responsibilities and Actions [Ref: (77)] outlines the roles, accountabilities, and responsibilities of workers, managers, work groups, and nominated role holders at ANSTO, including guidance on the actions that demonstrates the conduct of these responsibilities.

The detailed management structure and control processes that have been established for the current stage of the facility is described in section 1.4.1 and the NMMF Effective Control Plan [Ref: (7)]. NMMF specific responsibilities and delegations have been summarised in Table 12.

Responsibility	Delegations
Safety	All personnel are responsible for their safety, as well as others, in alignment with regulatory obligations under the Work Health and Safety Act [Ref: (12)] and Regulations [Ref: (13)]. Advice, co-ordination, and monitoring of safety responsibilities will be provided by the ANSTO High Reliability Group including a WHS Adviser and a Health Physicist. Changes or upgrades to the facility that could potentially impact safety are assessed through the ANSTO Safety and Reliability Assurance (SRA) process to facilitate relevant safety approvals.
Security	General Security is the responsibility of ANSTO Security and Safeguards.
Statutory and Regulatory Compliance	Statutory and regulatory compliance responsibilities remain with the Licensing Officer and Facility Officer, liaising with the ANSTO Regulatory Affairs and Compliance Manager, who ultimately reports to the Chief Operating Officer (COO).
Resources	Management of the resources available and utilised for the Program is the responsibility of the Program Director with input and oversight by the NMMP Program Control Group (PCG) and the ANSTO Capital Committee, as detailed in Project Management Plan [Ref: (78)].
Process Implementation	The Engineering and Technical Director will monitor and ensure safety and system hazard control processes and measures are implemented through a verification and validation process.
Management of Plans and Arrangements	The Nominee is responsible for the overall management of the plans and arrangements.
Maintaining Control of the Facility	The Nominee and Program Director (during the siting phase only).
Operations	Responsibilities for the operation of the facility will be available at a future stage of the Program.

Table 12: Responsibilities for the NMMF

The core responsibilities listed below are further discussed in the following sections:

- Training and authorisation of facility workers (section 5.6.6)
- Maintaining the operating limits and conditions (section 6)
- Controlling maintenance (section 6.4.2)
- Special responsibilities in emergencies (section 12)
- The control of modifications system (section 13.4).

Details on ANSTO's policy, framework, and processes involving delegations of authority can be found in AG-1682 ANSTO Financial Delegations Manual [Ref: (76)].

A1 5.4. Safety Approval System

Introduction of new process or safety significant changes to existing processes planned for the NMMF are managed through the NMMP Change Management Plan NMMP-0010-PM-0036 [Ref: (79)].

Risk management underpins the decision-making process for evaluation and approvals of proposed changes. Assessment of the risk to personnel is a WHS Act requirement. Any identified hazards due to proposed changes must be analysed for its inherent and residual risks and impacts.

Changes have the potential to create new risks or alter the status of the risk and its impacts. It is therefore important that appropriate assessment of the risk of the proposed change is undertaken and documented. This assessment helps determine if the proposed change should be approved in its current form or rejected. For the assessment of the risks following matrix and guidance may be used:

- AG-2395 Risk Analysis Matrix [Ref: (19)]
- AF-2322 Safety and Regulatory Impact Screening [Ref: (80)]
- AF-2327 Independent Safety and Reliability Review [Ref: (81)]
- AF-2321 Safety Control Evaluation Checklist [Ref: (82)]
- Any organisation changes through AF-6947 Change Management Plan [Ref: (83)].

ANSTO's target for all safety risks is "Moderate" impact or lower. ANSTO does not accept safety risks with a residual impact of "Major" or higher irrespective of likelihood of occurrence. A safety risk not within the acceptable threshold must be escalated to the responsible ANSTO Executive with an appropriate sense of urgency by applying the ANSTO High Risk Escalation Process AR-7455. The manager of the area of the change must escalate the risks or impacts falling in this category using AF-7454 High Risk Identification and Notification Process [Ref: (84)].

In addition to the internal approvals process implemented by ANSTO, a proposed modification to an ARPANSA licensed facility or process must be assessed to decide if the change has significant implication(s) for safety under Section 63 of the ARPANS Regulations. Determination of the safety significance of the change shall be undertaken using AF-2322 Safety and Regulatory Impact Screening [Ref: (80)], and associated guide, AG-2434 Guidance for the Safety and Regulatory Screening Form [Ref: (85)].

All changes that are categorised to be safety significant and fall under Section 63 of the ARPANS regulations [Ref: (20)] are required to be assessed and endorsed as required using the Safety and Reliability Assurance process in line with AP-1094 Safety and Reliability Assurance [Ref: (86)]. Only after Chief Nuclear Officer (CNO) endorsement, can such changes be submitted to ARPANSA for approval. Request for ARPANSA approval for such changes is required to be made by the Nominee of the Facility.

5.5. Quality Assurance Program

The Quality Management Plan (QMP) NMMP-0010-PM-0002 [Ref: (87)] provides a framework for defining management goals, objectives and regulatory guidelines for carrying out work in the areas of research and development, design, purchasing, fabrication, manufacture, handling, packaging, shipping, storing, cleaning, installing, testing, inspection, maintenance, and technical support.

These specified requirements apply to all individuals and organisations involved in the development, design, construction, commissioning, validation, and operational implementation of the NMMF, including designers, suppliers, constructors, manufacturers, operators, and participants in the Program in general.

ANSTO Health Products is a GMP manufacturer licensed under the TGA with a well-established Pharmaceutical Quality System (PQS). Following the design qualification of the newly built facility and related utilities, systems, and process equipment, all validation and GMP-related tasks completed for the NMMF will fall under the jurisdiction of ANSTO's PQS. Examples of such activities include:

- Qualification of facility, equipment, and services, and validation of manufacturing, cleaning, and analytical and quality control processes, quality requirements for which will also be the subjects of the Project Validation Master Plan (PVMP) and workstream-specific Validation Plans (VPs).
- Implementation of procedural and related documentation for GMP relevant activities conducted within the NMMF.
- Training of personnel involved in GMP activities conducted within the NMMF.
- Ongoing management of the facility and its equipment during the validation and operational phases of the facility lifecycle.
- Management of deviations, changes, and non-conformances from the validated state and quality-approved procedures/ specifications.
- Management of GMP relevant materials including receipt, handling, status identification, release, and disposal.
- Management of the PQS itself.

5.5.1. Quality Policy

The NMMP shall be delivered in accordance with the NMMF Standards and Codes as detailed in NMMF Applicable Codes, Standards, and Guidelines [Ref: (39)]. The QMP reflects the ISO approach and the Code of Good Manufacturing Practice requirements to Quality Management throughout the Program lifecycle.

The NMMF Program has established a QMS in compliance to ISO 9001: 2015 Quality Management Systems – Requirements.

5.5.2. Management Review

The QMP is a controlled, approved document, and is approved by the Program Director. The document is controlled in accordance with Document Management Plan NMMP-0010-PM-0013 [Ref: (88)].

The QMP will be reviewed at various stages and in line with the phases of the Program. Triggers for review may include:

- Regulatory change or change relevant standard or code of practice.
- Non-conformance is detected against the QMP.
- The QMP no longer reflects the actual work practices or scope of work.
- ANSTO amends its project plan or project program.
- As a result of an incident and or emergency response.
- Third Party advice or recommendation is adopted.

5.5.3. Quality Systems

ANSTO and ANSTO contractors and suppliers shall adhere to the requirements of Quality Management Plan [Ref: (87)] to meet the following objectives for the design and delivery phase of the Program:

- Planning and controlling work processes, including any design activities.
- Careful selection of contractors and suppliers and confirming that their work complies with the requirements of the QMP.
- Acknowledging and rectifying any nonconforming work and improving work processes to prevent recurrence of nonconformances.
- Maintaining orderly records to demonstrate that contract activities have satisfied acceptance criteria.

The Quality Management Plan [Ref: (87)] details the relevant regulatory standards and guidelines for the facility, the project quality processes, design and development, change management, procurement/ supplier quality, audits, inspection and testing, and training competence and awareness for the NMMF.

5.6. Control of Normal Operations

The details for all aspects of normal operations are referenced in the following Plans and Arrangements:

- Effective Control Plan [Ref: (7)]
- Safety Management Plan [Ref: (72)]
- Radiation Protection Plan [Ref: (14)]
- Waste Management Plan [Ref: (89)]
- Emergency Plan [Ref: (90)]
- Environment Protection Plan [Ref: (67)]
- Security Plan [Ref: (25)].

This section is complemented by section 12.3 which covers abnormal events and emergency arrangements. Also, section 4.5 and 4.6 will discuss any risks associated with normal operations and assess the safety of normal operations.

5.6.1. Overall Responsibility

Refer to sections 1.4 and 5.3 for details about the responsibilities for the NMMF.

5.6.2. Local Control

Refer to sections 1.4 and 5.3 as well as the NMMF Effective Control Plan [Ref: (7)] and the NMMF Safety Management Plan [Ref: (72)] for details about the local responsibilities for the NMMF.

5.6.3. Use of Written Procedures

The quality systems in use impose a set of requirements on the facility and its operation, the staff, and the documentation of most activities within the facility. All operations are governed by written procedures and work instructions.

The Document Management Plan [Ref: (91)] details the document management system chosen for the management, control, and identification of documents for the Program. The procedure applies to all Program related formal documents developed by all ANSTO, consultants and contractor organisations.

Formal Program documents are version controlled and defined as those used to manage, design, construct, license, operate, or maintain the facility.

All operational procedures are accessible to staff through ANSTO's intranet. The documents are controlled to ensure that only the latest revision is available to users. ANSTO documents are controlled by the AR-1041 ANSTO Management Controlled Document Process [Ref: (92)]. Documents generated during both commissioning and operations will be controlled according to these processes. The processes ensure that documents are identified, created, reviewed, approved, and distributed to end users in a controlled manner.

5.6.4. Permits to Work

ANSTO has work permits including Safe Working Permit, Confined Space, Electrical Access Permit, and Excavation/ Penetration permits.

The use of these permits is outlined in:

- AP-2408 Safe Working Permits [Ref: (93)]
- AP-2401 Confined Space Risk Assessment and Entry Process [Ref: (94)]
- AF-2104 Electrical Access Permit [Ref: (95)]
- AG-2403 Excavations & Penetrations [Ref: (96)].

Permits must be initiated and open before these activities are undertaken in the facility. In general, the purpose of the Permit is to communicate the hazards associated with the task, the hazards associated with the work area, controls to be implemented for safe work and to ensure that affected persons are advised of upcoming works.

5.6.5. Handing Over of Responsibilities

During short-term and long-term absences, including holidays and retirements, ANSTO has a mechanism for people to act within a role and assume its responsibilities for a defined period of time. In addition, ANSTO has a succession planning and talent management process to upskill staff for roles within the organisation to streamline the handover of responsibilities during personnel changes.

When the facility is being transitioned into operations, a detailed handover process will be adopted in alignment with the practical completion of the facility and the commencement of commissioning. This section, and the interfaces detailed in section 1.7.1, will be updated to reflect the handover stage of the facility.

5.6.6. Training and Authorisation of Workers

ANSTO has comprehensive processes which collectively ensure that potentially hazardous work is performed and supervised by personnel with adequate training, authority, and qualifications. This process is initiated during recruitment where candidate selection is based on approved selection criteria for the role which includes consideration of the appropriate qualifications, knowledge, and experience for the work to be performed. Position descriptions for the role clearly outline the set of work responsibilities that are to be performed by the role holder. All NMMF position descriptions will be maintained by the HR division.

Radiation Protection Services (RPS) workers play an important safety role in radiation areas and controlled facilities providing radiation monitoring and advice during commissioning, construction, operation, and maintenance of the facility. RPS workers must be demonstrably Suitably Qualified and Experienced Persons (SQEP) to fulfil their respective roles. They are recruited with the necessary knowledge, skills, and experience required to undertake the role requirements or are trained, deemed competent, and authorised to act in this capacity within the ANSTO training framework.

ANSTO's Learning and Development (L&D) module, part of the SAP PeopleHub system, is the tool used to assign and facilitate any competency training required to support personal development and meet the changing needs of the organisation. Induction training will be provided to all new employees working within the NMMF with completion being tracked through PeopleHub.

Building Managers and Area Supervisors will be responsible for authorising and/or discontinuing work within their designated areas, ensuring that personnel performing tasks are properly trained, and appropriate risk assessments have been conducted.

ANSTO workers that are required to do specialised tasks involved in facilities, laboratories, and projects are provided area-specific inductions and task-specific training (if this training has not previously been completed). High-risk work licences must be available for inspection at all times.

Additional details on training and the authorisation of workers are available in the NMMF Safety Management Plan [Ref: (72)].

5.6.7. Control of Contractors, Tenants, and Visitors

Any visitors to the site must be registered, inducted at ANSTO reception, and always escorted by an authorised person. Any visitor entering construction work areas should hold a General Construction Induction Card and must be escorted by the Principal Contractor who will provide a local area induction and outline all required PPE required for entry. An overview is given in AP-2363 WHS Training Procedure [Ref: (97)]. Visitors and contractors working or staying for extended periods of time must undertake comparable induction and training and must be supervised as deemed necessary.

AP-2303 Safe Management of Contractors [Ref: (98)] details the role of an ANSTO Contractor Supervisor. This includes being responsible for all contactors and sub-contractors under their supervision and the compliance with WHS and security requirements associated with work. This includes facilitating the completion of a Safe Working Permit (SWP), as detailed in AP-2408 Safe Working Permits [Ref: (93)].

A full list of courses and retraining period requirements is provided in AG-2058 WHS Training Handbook [Ref: (99)].

More details on the control of contractors, tenants, and visitors are available in the NMMF Safety Management Plan [Ref: (72)].

NMMF-specific plans and procedures will be developed during a later phase of the Program.

6. Operating Limits and Conditions

Operating Limits and Conditions (OLCs) are instructions, procedures, or management limit that, if breached, could result in a serious unsafe condition. OLCs are derived from detailed risk assessment and define operational parameters that maintain safety margin(s) with ALARP risk acceptability criteria.

The classification of SSCs relevant to radiological safety is based on AG-2494 Guidance on the Radiological Safety Categorisation of SSCs [Ref: (42)]. This guide is primarily intended for the radiological safety categorisation of items in facilities other than nuclear research reactors and as such is applicable to the NMMF. A nominal list of SSCs for the facility has been provided in section 3.

According to the safety categorisation of the safety-related items, any SSCs within the NMMF which are categorised as Safety Category 1, OLCs will be required. For items categorised as Safety Category 2, OLCs may be required if the worst-case consequence is severe or higher. These will be reviewed in the detailed design stage.

6.1. Safety Limits and Safety System Settings

Safety Limits and Safety System Settings will be provided for a future licencing stage.

6.2. Limiting Conditions for Safe Operation

Limiting conditions for safe operation will be provided in subsequent phases of the NMMF project.

6.3. Surveillance

Surveillance requirements will be provided at a later phase of the NMMF project. The frequency and scope of periodic testing, calibration, or inspection activities to assure that necessary performance of systems and components is maintained, and facility operations remain within safety limits, safety system settings, and limiting conditions for safe operation will be described.

6.4. Administration

6.4.1. Minimum Staffing Levels

Minimum staffing level requirements for the facility will be determined at a later phase of the NMMF project.

6.4.2. Control of Inspection and Maintenance Activities

Asset management plans will be developed for the facility to define the examination, maintenance, inspection, and testing requirements for assets and components. Any assets critical to safety will be assigned to an asset owner/ custodian and registered in the asset management plan. This document will detail the specific objectives and specifies the activities, programs, resources, responsibilities, time scales, and specific measurable outcomes that are required for assets to achieve their set objectives.

6.5. Assessment of Operating Limits and Conditions

A detailed assessment of the OLCs, based on the safety categorisation of SSCs, will be undertaken at a later stage of the NMMF.

7. Review of Operating Experience

The Lucas Heights campus hosts a range of research and production facilities which includes several facilities with a potential nuclear or radiological hazard including:

- Research reactors comprising the 10MW HIFAR, which was operational between 1958 and 2007 and is currently undergoing decommissioning, and the 20MW OPAL reactor, which has been operational since 2007.
- The ANSTO Health business which manages and operates a range of facilities that provides the Australian and international community with a range of health-related products and services, including radioisotopes for therapeutic and diagnostic applications.

ANSTO actively strives for a culture of continuous improvement based on decades of operational experience and lessons learned. Notable improvements in safety have occurred in recent years in the current ANSTO Health product's facilities.

A key driver for the delivery of the NMMF project is the lessons learned from the operating experience from B23, including the recommendations from ARPANSA's Independent Review of B23. The NMMF project will review and consider the relevant operational experiences from B23, including recommendations from independent reviews of the facility and any events or incidents tracked in the GRC to develop a facility and processes which demonstrates ANSTO's commitment to providing a safe and healthy workplace for all of workers, including employees, contractors, students, volunteers and others as detailed in the WHS Act [Ref: (12)] as detailed in ANSTO response to the independent review [Ref: (100)].

As this is a siting licence application, the NMMF design is still maturing. ANSTO will leverage operational experience and lessons learned from other nuclear installations and facilities, including existing facilities and international best practice. The sections below will be updated during future SAR reviews to reflect the operational information available at that time.

7.1. Commissioning Program

A commissioning program will be developed that details the objectives, required organisation and training, the quality systems required, and the relevant procedures, instructions, and OLCs acceptable during the commissioning. Details will be provided after the construction of the facility at a future licence submission.

7.2. Commissioning Report

Once the commissioning program has been undertaken, commissioning reports will be prepared and detailed in a future licence submission.

7.3. History Since Commissioning

This section will be updated post commissioning of the NMMF for future licence submissions.

7.4. Review of Radiological Monitoring Results

Radiological monitoring results across all phases of the NMMF development will be included in this section for future licence submissions.

7.5. Dose Uptake by the Workforce - Routine and Abnormal

There is no dose uptake expected by the workforce during the siting stage. This will be updated to reflect the operational stage of the NMMF in the future.

7.6. Waste Quantities Arising from Operations and Comparison with Operational Limits

During the siting stage there are no quantities of gaseous, liquid, and/or solid wastes expected to be generated.

7.7. Description of Incidents and Accidents

There are no incidents or accidents to describe as the facility has not been constructed.

7.8. Description of Audits and Inspections

As the facility is not constructed or operational, there are no historical audits and inspections to describe.

8. Review of Plant Condition

The building, plant, and equipment are yet to be constructed or procured. The facility is intended to be designed fit for purpose and in alignment with current standards. This section of the SAR will be updated at a later stage in the project with information on:

- Building, Plant, and Equipment Condition
- Security Systems
- Comparison with Regulatory Expectations
- Results of Facility Inspections
- Comparison with Current Standards
- Comparison with Modern Housekeeping and Maintenance Standards
- Identification of any Life-limiting Features
- Aging Management.

9. Radiation Protection

Radiation Protection details are documented in the NMMF Radiation Protection Plan [Ref: (14)]. The radiation protection measures during all phases of the facility fully comply with AE-2310 Radiation Safety Standard of the ANSTO WHS Safety Management System.

9.1. Principles of Radiation Protection

ANSTO manages radiation risks through the application of Radiation Protection Principles in order to contribute to an appropriate level of protection of people and the environment against the detrimental effects of radiation exposure without unduly limiting the human factor actions that may be associated with such exposure.

The AE-2310 ANSTO Radiation Safety Standard [Ref: (14)] is applicable to the NMMF and will be implemented through the application of the ANSTO WHS guide [Ref: (12)], and practices for radiation protection as well as this plan.

The ANSTO Radiation Safety Standard provides a description of the radiation protection principles:

- Justification of Practice
- Optimisation of Protection
- Dose Limitation.

These principles contribute to an appropriate level of protection of people and the environment against the detrimental effects of radiation exposure without unduly limiting the desirable human actions that may be associated with such exposure. These are strengthened through:

- The development and maintenance of a strong safety culture within ANSTO.
- Managing exposures using a graded approach to appropriately consider both radiological and non-radiological aspects of the prevailing circumstances, whilst applying defence-in-depth to protective measures.

The principle of justification and the principle of optimisation of protection apply equally to all controllable exposure situations, and the principle of dose limitation applies to public and occupational exposures in planned situations.

The NMMF shall be designed to provide radiation protection of workers, the public and the environment by providing appropriate shielding and containment of radioactive sources during production, transport, QC sampling and testing, and waste management and storage.

9.2. Radiation Protection Program

Radiation protection monitoring programs will be used to confirm adequate protection and optimisation of those protection measures during the operation stage of the NMMF, will be developed in conjunction with the RPA and are described in subsequent sections.

ANSTO has detailed guidance on monitoring in AG-5507 Radiation and Contamination Monitoring of the Workplace [Ref: (101)].

9.2.1. Workplace and Area Monitoring

Monitoring of the radiological conditions of the workplace will be performed routinely through standard operating procedures by NMMF workers, with assurance monitoring performed by RPS workers as part of a survey program.

Routine area monitoring and assurance monitoring is performed for the purposes of confirming:

- The dose rates and contamination levels within and around the classified areas of the NMMF are within agreed parameters.
- The current area classifications within the NMMF.

Workplace monitoring includes, as appropriate:

- Leak and wipe tests.
- External ionising radiation levels.
- Surface contamination levels.
- Airborne contamination monitoring levels.
- Readily accessible exposure levels for non-ionising radiation.

More details are available in the NMMF Radiation Protection Plan [Ref: (14)].

9.2.2. Monitoring of Individuals

Individual monitoring (dosimetry) is the measurement, assessment, and evaluation of radiological exposure to an individual. Occupationally exposed employees, including those normally or occasionally employed to work in a controlled area, will be monitored as part of the routine dosimetry program, detailed in AG-2521 Personal Dosimetry [Ref: (102)] guide, which includes the supply of dosimetry equipment, analysis of returned dosimetry equipment, and a dose record keeping service provided by RPS.

Routine external monitoring using TLDs for the measurement of effective dose (β/γ exposure to the whole body) and to the extremities (β/γ) will be carried out. The TLD issue/ assessment period is quarterly for each occupationally exposed worker. EPDs will be used to provide real time individual monitoring. The dosimetry requirements are dependent on the designated radiation and contamination classification areas.

10. Radioactive Waste Management

Radioactive Waste Management details are documented in the NMMF Waste Management Plan NMMP-0410-PM-0004 [Ref: (89)]. This plan outlines the organisational arrangements and responsibilities for radioactive waste management at the NMMF.

10.1. Policy and Requirements

The AB-0103 ANSTO Radioactive Waste Management Policy [Ref: (103)] and AG-2517 Safe Management of Radioactive Waste guide [Ref: (104)] provides a framework for managing radioactive waste at ANSTO. This policy states that all radioactive waste at ANSTO will be managed in a manner that protects human health and the environment both now and into the future.

10.2. Design for Radioactive Waste Management

As per the Safety in Design Strategy [Ref: (21)] the following engineering design safety principles are to be followed for the facility:

- The production, accumulation, storage and disposal of radioactive waste and process residues should be consistent with the strategy for their management on the site.
- Containment systems should limit radioactive releases to the environment in normal and fault conditions, such that the radiological consequences of discharges of liquid and gaseous wastes via unintended or non-engineered routes are reduced so far as is reasonably practicable.
- The positioning and design of discharge outlets for liquid and gaseous wastes should take into account the characteristics of the surrounding man-made and natural environment.
- The design should minimise the potential for the inadvertent discharge of waste, discharge of waste into an incompatible environment and discharge of waste via unintended or non-engineered routes.
- The design should minimise the quantity of radioactive waste, including secondary waste and scrap, arising at all stages of a plant's life.
- The accumulation of radioactive waste on site should be minimised.
- Radioactive waste should be characterised and segregated to facilitate its subsequent safe and effective management. Provision should be made for dealing with radioactive waste that does not meet existing processing, storage or disposal criteria.
- Waste should not be treated (e.g., by mixing) in a manner that would make it incompatible with its subsequent management.
- Radioactive waste generated should be in a form that minimises the hazards associated with its storage and is compatible with long-term storage, retrieval and disposal technology. It should be processed into a passively safe state as soon as is reasonably practicable.

10.3. Waste Management Systems

Waste management systems for gaseous, liquid, and solid waste generated in the NMMF is available in the NMMF Waste Management Plan [Ref: (89)].

10.3.1. Gaseous Waste/ Airborne Discharges

During the siting and development phase of the facility there will be no planned radioactive airborne releases to the atmosphere. Additional detail on potential operational discharges is available in section 4.6 and 4.9.

10.3.2. Solid Waste

Solid wastes generated from the NMMF will be managed used existing WMS infrastructure, processes, and expertise. The contact handled and remote handled waste generated at the facility will be managed by trained personnel using risk assessed instructions/procedures. All arrangements in place align with the waste management philosophy of minimisation and the principle of ALARP.

For contact handled solid waste:

- Short lived solid waste streams shall be decayed and scanned as Free Release waste.
- Lower activity solid waste streams from the process hot cells are envisaged to be transported in approved bins (flasks/ devices/ containers) to the Centralised Waste Decay area in the building's basement.
- Once decayed, solid waste will have capability to be moved within mega-bins or steel drums by hoist or forklift; or moved within wheeled 'Sulo' bins.

Remote handled solid waste (such as OPAL irradiation cans or tellurium crucibles) will be stored in a waste hot cell and periodically loaded into an Aluminium Retrievable Bin (ARB) for transport to Waste Management. Other high activity waste that will not decay within a 'reasonable time' for safe handling by alternate means (steel drums or mega bins) will also be transferred to the NMMF waste hot cell for periodic ARB transport to Waste Management.

Longer lived and/or highly active solid waste streams from the process hot cells are envisaged to be transported to a dedicated waste hot cell, in the Active Receipt area, either by direct inter-cell transfers or via approved shielded bins (flasks/ devices/ containers).

10.3.3. Liquid Waste

No remote handled liquid waste will be discharged from the NMMF. Contact handled liquid waste include:

- General Laboratory and Plant Room liquid waste from non-active areas will be classified as C-line waste.
- Laboratory liquid waste generated from active areas will be classified as B-line waste.
- Manufacturing process liquid waste contains trace levels of long-lived isotopes and it is unlikely to meet B-line entry limits. Hence, this waste will be treated as D-line waste.

The NMMF will have active process liquid waste streams from the manufacturing lines. These shall include dedicated B, C & D pipelines which where practicable are connected to the dedicated Centralised Waste Decay area within the facility's basement.

Active liquid waste streams (D-line) shall be piped to Waste Management for final treatment and disposition. A means for transport of liquid waste in approved vessels shall also be considered for a back-up or future products.

Active liquid waste streams (B-line) shall be piped to an external in-ground B-line pit tank, in the campus site network. Non-active liquid waste streams (C-line) shall be piped to an external in-ground C-line pit tank, in the campus site network.

The facility will be connected to ANSTO's B-line network to transport liquid to the site effluent treatment plant for processing and discharge. Effluent discharges to the sewer must comply with the current trade wastewater agreement between ANSTO and the Sydney Water Corporation (Consent to Discharge Industrial Trade Wastewater #4423 [Ref: (105)]) for treated discharges from the site. Sydney Water conducts independent testing of liquid effluent discharges to the sewer and the Trade Waste Agreement is periodically reviewed to provide assurance that ANSTO's discharges remain within authorised radiological and non-radiological limits and pose no threat to the environment.

10.4. Waste Classification and Disposal

Radioactive waste at ANSTO is divided into five main categories based on their physical form and emitted dose rate as below:

- Free Release Waste: waste that meets the criteria for exemption (activity concentration and activities of radionuclides).
- Contact Handled Solid Waste: radioactive solid waste that is above the exemption levels and has a radiation contact dose rate below 2 mSv/hr.
- Contact Handled Liquid Waste: radioactive liquid waste that is above the exemption levels and has a radiation contact dose rate below 2 mSv/hr.
- Remote Handled Solid Waste: radioactive solid waste that is above the exemption levels and has a radiation contact dose rate above 2 mSv/hr.
- Remote Handled Liquid Waste: radioactive liquid waste that is above the exemption levels and has a radiation contact dose rate above 2 mSv/hr.

ANSTO will manage radioactive waste in a manner that protects human health and the environment, both now and in the future. The organisation is committed to safely treat and store ANSTO's radioactive wastes in preparation for final disposal, minimising exposures while considering economic factors, and minimise radioactive waste generation and provide custodianship of waste from source to storage and final disposal.

11. Decommissioning

The NMMF Decommissioning Plan [Ref: (64)] describes the decommissioning plans and arrangements in place to identify the steps required for the characterisation and eventual decommissioning of the NMMF.

11.1. Initial Scoping Survey/s

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An initial Site Radiological Scoping Survey [Ref: (106)] has been performed to determine the extent of any surface radiological activity.

The Site Radiological Scoping Survey considers:

- Radiological activity measurements
- Any initial sampling -if required
- Radiological calculations – if required
- Radiological activity mapping
- Dose-rate measurements.

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The survey report will form part of the Historical Site Assessment.

11.2. Radiological Baseline Survey

A Radiological Baseline Survey will be performed during or near completion of the facility bulk excavations to determine and document the radiological state of the site prior to building construction works.

The Radiological Baseline Survey will add to and form part of the Historical Site Assessment.

11.3. Decommissioning Strategy

At the end of the operational phase of the facility, a decommissioning strategy will be prepared in compliance with the relevant regulatory requirements. The preferred and likely option for decommissioning the facility would be 'immediate dismantling' as stipulated in the IAEA's Decommissioning of Facilities General Safety Requirements Part 6 [Ref: (107)]. Whilst the final decision on the detailed decommissioning strategy will be made in the future, it is expected that decommissioning will leverage the skills and facility knowledge of operational personnel through a post operational clean out.

11.4. Design for Decommissioning

As per the safety in design principles detailed in Design Guide - Safety in Design Strategy [Ref: (21)] the plant should be designed to facilitate safe build, commissioning, and decontamination and dismantlement (D&D). As such, the design will ensure that:

- Build, commissioning, decommissioning, and dismantle can be conducted safely in accordance with approved procedures and relevant legislation.
- The choice of materials and construction will minimise eventual quantities of radioactive waste.
- Undesired accumulations of chemical or radioactive materials are avoided and processes that minimise and reduce the volumes of waste are utilised.
- Any important access facilities required for commissioning and decommissioning are provided.
- Access to process equipment, structures, systems, and large components are facilitated through designs such as dedicated exclusion zones.
- The choice of materials is likely to be compatible with future waste treatment, storage, and disposal routes.
- Account is taken of the need to make the facility passively safe at the end of its operational life before it enters care and maintenance prior to dismantling and decommissioning.

Many of the activities required during the early stages of characterisation and decommissioning will be dependent on the:

- Timeline to cease operations in the NMMF.
- Funding availability for characterisation and eventual decommissioning.
- Priority of project.
- Definition of the facility end-state and decommissioning boundary.
- Availability of information and records such as health physics records, facility drawings, plant and equipment details, and incident records.
- Availability of experienced operators for the planning of characterisation and decommissioning.
- Post Operative Clean-Out (POCO) including the completion of AF-7030 Preparing to Vacate a Building or Designated Hazardous Area [Ref: (108)].
- Development of strategies for specific radioactive material disposition including the disposal of mixed liquid waste, dismantlement and/or reuse of hot cells, removal of resulting waste, and the possibility of hazardous material including radiological and non-radiological contamination sources.

Additionally, the NMMF will have equipment and infrastructure such as hot cells, HVAC systems, and waste storage tanks which will require specific planning to execute dismantling and decommissioning.

11.5. Waste Management During Decommissioning

The development of a decommissioning Waste Management Plan (WMP) establishes the waste management criteria for decontamination, disposal, clearance/ release, and recycling. It also looks at the impacts on decontamination and dismantling methods, mainly the creation of secondary wastes from decontamination and dismantling methods.

The WMP identifies the system to be used for final waste management, identifies the release criteria, and establishes possible waste packaging (including waste conditioning). Existing waste management systems and processes will be leveraged to manage waste from future decommissioning. This plan will be developed as the facility approaches the end of its lifecycle.

12. Emergency Planning and Preparedness

The NMMF Emergency Plan NMMP-0410-PM-0005 [Ref: (90)] describes the emergency plans and arrangements in place to respond to and mitigate any incident arising from the NMMF. As per the Safety and Security Consequence Analysis [Ref: (5)], the emergency used for the assessment as the NMMF reference accident is a release resultant from building fire within the facility.

The IAEA) Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency (2015) groups assessed hazards in accordance with the EPCs.

As per NMMF Emergency Plan [Ref: (90)], the assessed hazard results in the NMMF being classed as Emergency Preparedness Category II, as detailed in NMMF Emergency Preparedness Categorisation NMMP-0410-PM-0009 [Ref: (109)]. Category II are facilities for which on-site events are postulated that could give rise to doses to people off the site that would warrant urgent protective actions or early protective actions and other response actions to achieve the goals of emergency response in accordance with international standards, or for which such events have occurred in similar facilities.

12.1. Policies and Procedures

The ANSTO Emergency Management Plan (EM Plan), documented in AG-5945 ANSTO Emergency Management Plan [Ref: (110)], defines the roles and responsibilities of nominated ANSTO personnel supporting a multi-agency response to on-site emergencies and in the provision of specialist advice, technical and practical assistance, and resources to assist external organisations' response to emergencies with off-site consequences. The following legislation applies to the ANSTO EM Plan:

- Australian Nuclear Science and Technology Organisation Act
- Australian Radiation Protection and Nuclear Safety Act and Regulations
- Work Health and Safety Act and Regulations
- NSW State Emergency and Rescue Management Act
- NSW Protection from Harmful Radiation Act
- NSW Public Health Act.

ANSTO will review and approve the NMMF Emergency Plan/s prior to their implementation and ensure an adequate level of emergency preparedness will be maintained during the entire period of siting and construction. All emergencies that occur at the Lucas Heights campus, including those at the NMMF, will be managed in accordance with the overarching ANSTO EM Plan. Threat-specific sub-plans have been developed for potential events that were identified during the risk assessment process for the Lucas Heights campus.

A1 12.2. Emergency Response

During the siting and construction phases, no operational activities are expected to occur on the site. Some site preparation activities may occur, following authorisation as part of the siting licence application with ARPANSA.

The AG-5950 ANSTO Emergency Management Plan: Lucas Heights Campus Emergency Plan [Ref: (111)] will apply at the NMMF site. The Site Construction Supervisor and Site Safety Officer will develop local emergency management arrangements for the NMMF site aligned with the nature and magnitude of risks.

12.3. Control of Abnormal Events and Emergency Arrangements

At the current stage of the facility, the NMMF will rely on local emergency arrangements for the Lucas Heights campus as defined in AG-5950 ANSTO Emergency Management Plan: Lucas Heights Campus Emergency Plan [Ref: (111)].

12.3.1. Incident Reporting Systems

When an incident occurs, including a near miss/ hit, it is immediately reported to local management and then reported through the ANSTO Incident Management System. For an incident requiring support outside the immediate area (i.e. ERT, RPS, or WHS), ASOC would be called immediately to engage required support.

All events and incidents are reported, monitored, and managed through the Governance, Risk, and Compliance (GRC) Cloud following the AR-6350 ANSTO Incident Management Process [Ref: (112)]. The GRC Cloud is a fully integrated system that assists ANSTO in securely managing its assurance activities, by recording all information pertaining to the investigation of the incident including:

- Impact
- Corrective/ preventative actions
- Any recommendations for improvement
- Verification of the effectiveness of any actions
- Incident close out.

More details on incident reporting and notifications are available in the NMMF Safety Management Plan [Ref: (72)].

12.3.2. Learning from Experience

ANSTO's approach to business resilience is based on a culture of continuous improvement and learning from experience (LfE). As a mechanism for continuous improvement, lesson learning reviews are a key element of AG-4532 ANSTO Business Resilience Program and Learning and Improvement Strategy. ANSTO's emergency, incident response, crisis management and business continuity arrangements are evaluated through periodic reviews, exercising, testing, post-incident reporting, and performance evaluations.

Lessons learned are integrated into training and exercises and following any minor/ major incidents or disruptions with the conduct of reviews, debriefs and investigations, and use of post-incident and post-exercise reports.

The following observations, assessments, and audits will be conducted at the NMMF:

- Routine review of safety documentation as required under the ARPANS Regulations.
- Management system audits.
- Regular workplace safety comments, suggestions, and housekeeping inspections, as per AG-2432 Workplace Safety & Housekeeping Inspections [Ref: (113)].
- External and independent audits conducted by SMEs for the Principal Contractor and ANSTO such as audits by High Reliability every 2 months to ensure contractors are meeting the requirements detailed in AF-1311 Contractor Onsite Inspection Checklist [Ref: (114)].
- Compliance checks through the Smartek Contractor Pre-qualification Compliance System which records the contractors' relevant insurance/s, safety management systems, licenses, and other compliance criteria assigned by ANSTO, as detailed in AP-2303 Safe Management of Contractors [Ref: (98)].

- Audits to identify discrepancies in actual conduct of operations compared to procedures.
- Safety surveys.

These processes will allow the Line Managers to identify and address hazards, monitor implemented control measures and local procedures, and to ensure a good safety culture is sustained. Any discrepancies in processes or areas found to be unsatisfactory will undergo changes to bring them to a satisfactory level.

An inspection schedule will be prepared for the facility dictating the required frequency of inspections/ audits based on the severity of the risks and the types of hazards involved. Reports generated from these processes will be entered into ANSTO's Governance, Risk, and Compliance (GRC) Cloud System with actions assigned as required and will be utilised to ensure learning and continuous improvement.

More details are available in the NMMF Safety Management Plan [Ref: (72)].

12.3.3. Emergency Arrangements

The general site arrangements detailed in the ANSTO EM Plan will be applicable for the NMMF. More details are available in the Site SAR emergency arrangements and the AG-5945 ANSTO Emergency Management Plan. Arrangements for the facility will be aligned GSR Part 7 Category II requirements.

The Area Supervisor is responsible for ensuring that local emergency arrangements are in place, that they are suitable for the sources used or stored in that location and all those involved are trained in their roles as described in AG-2952 Role of Area Supervisor [Ref: (115)].

The Building Warden is responsible for marshalling evacuees and securing the affected building as described in AG-2465 Building Wardens [Ref: (116)]. There are trained deputies for this role.

The Health Physics Surveyor (HPS) and Health Physicist have roles in radiation incidents as part of the ANSTO general emergency response arrangements.

Localised arrangements are detailed in NMMF Emergency Plan [Ref: (90)] which also details the roles and responsibilities for emergencies.

13. Management Systems

Details about the planning, implementation, and control of essential activities relating to the management system procedures to ensure that the specific requirements at each stage of the facility are correctly applied and fulfilled, including responsibilities, are detailed in the NMMF Effective Control Plan [Ref: (7)] and the NMMF Safety Management Plan [Ref: (72)].

13.1. Management Responsibility

For the siting stage, a clear hierarchy and description of responsibilities have been provided in Table 1, Table 2 and Figure 1. These have also been further described in the NMMF Effective Control Plan [Ref: (7)]. The roles and responsibilities within the plans and arrangements will be updated to reflect the status of the NMMF as it moves across licensing stages.

13.1.1. Safety Monitoring and Review

Section 12.3.2 discusses the observations, assessments, and audits that will be conducted at the NMMF relevant to safety monitoring and review. More details are available in the NMMF Safety Management Plan [Ref: (72)].

13.2. Resource Management

ANSTO has an ongoing commitment to quality of delivered product and service that is a fundamental part of the management objectives. This commitment is demonstrated in AB-0101 ANSTO Quality Policy [Ref: (117)] and in the form of quality products and service, delivered on time and within budget, through ensuring best available technology in plant, equipment and personnel skills with the provision of initial and ongoing competency assessment and training.

During the siting and design phase, the Quality Manager is responsible for quality and to identify necessary resources including personnel training and systems review and improvement as well as to ensure that deliverables are fit for purpose and compliant to regulatory requirements, relevant standards and in line with the requirements of ANSTO's QMS.

13.3. Process Implementation

Introduction of new process or safety significant changes to existing processes planned for the NMMF are managed through the NMMP Change Management Plan [Ref: (79)]. Structural, technological, behavioural, policy, and process changes within ANSTO are facilitated through ANSTO's AF-6947 Change Management Plan [Ref: (26)]. These documents offer guidance to the initiating person/s to ensure the objective of the change is clear and all aspects have been adequately considered.

13.4. Change Management

An efficient and effective Change Management process is critical to the safety of personnel and safe management of the NMMF throughout the facility lifecycle.

The NMMF will manage changes during the delivery phase including design and specification/ requirement development, construction, and commissioning up to the stage of operational readiness using the NMMP Change Management Plan [Ref: (79)].

The NMMP Change Management process identifies, assesses all Potential Controlled Changes (PCC) prior to authorisation to proceed. Proposed changes are reviewed in a structured manner and with a wholistic approach including assessing potential implications with respect to:

- Legislative Compliance
- Contractual Compliance
- Safety and Radiation Protection Impact
- Environmental Aspects
- Cost and cost phasing
- Schedule
- Project Risks
- Stakeholder consultation and engagement.

The Change Management process is managed through the Change Control Request (CCR) Form NMMP-0010-FR-0004 [Ref: (118)]. This form is used to formally register the change proposal, record initial details, articulate justification for the change, commence a preliminary assessment, formally prepare a Configuration Change Assessment and Verification/ Validation Plan. A schematic diagram of the NMMP change control process is described in Figure 9.

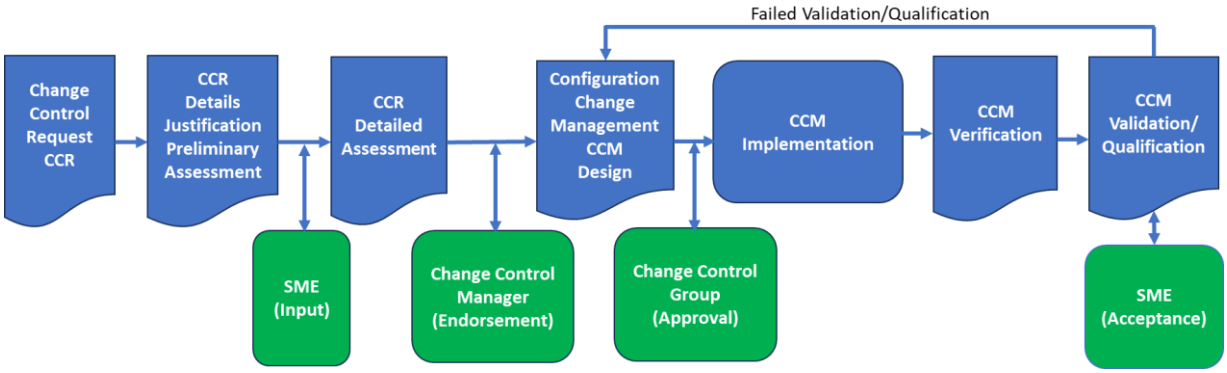

Figure 9: Schematic of the NMMP Change Control Process

14. Conclusions

14.1. Acceptability of Site Location and Design

Based on the site characteristics, geotechnical and demographic information as well as specific site-related design considerations, it is concluded that the development of the NMMF within the Lucas Heights campus, does not have any negative features which cannot be eliminated or controlled with a reasonably high standard of engineering design, construction and operation.

Foreseeable design basis external events with the potential to have a significant impact on the NMMF development site were identified through the NMMF Safety and Security Consequence Analysis Report [Ref: (5)] and bounding case accident scenarios for the facility.

Scenarios included major building fire, [redacted] and seismic events which have been addressed when considering the effects of potentially significant natural or human induced external events. The effect of these events will be further analysed during detailed design of the facility.

In summary, the ARPANSA Siting Licence application for the NMMF is considered safe and suitable and been selected because of the following features:

- The existing nuclear site has extensive security infrastructure [redacted]
- Existing mature and reliable infrastructure including power, water supply, waste services, and communications.
- Stable geological location with minimal history of seismic activity.
- Well contained natural surface and ground water systems, overlaying a purpose-built wastewater system.
- Existing staff with the expertise in the areas of radiation protection, maintenance and engineering, asset management, waste management, and emergency response capabilities.
- An established environmental monitoring program.

14.2. Acceptability of Normal Operations

ANSTO has demonstrated skills and expertise of operating nuclear facilities safely and effectively at Lucas Heights campus, this coupled with a strong management commitment to ensuring continuous improvement based on operational experience, and a robust safety culture all contribute to the development of the NMMF that will be managed and regularly reviewed to ensure that all regulatory, legal, safeguards, safety and environmental requirements are complied with at all times throughout its lifecycle.

The NMMF will be sited in line with ANSTO WHS MS standards and practices, which are consistent with accepted radiation and work health and safety practices in Australia. A set of Plans and Arrangements have been prepared for the siting phase of the facility.

14.3. Acceptability of Residual Risk Associated with Abnormal Operation

ANSTO has a deep understanding and experience in operating nuclear medicine facilities. The NMMF will have design features which mitigate various risks within the existing B23 facility. A detailed safety analysis for internal abnormal events will be prepared at a future phase of the project.

Section 4.7 details the safety analysis for potential for hazards associated with external events. A siting stage evaluation was performed and the NMMF Site Characteristics and Evaluation report [Ref: (4)] concluded that the site was generally suitable.

14.4. Adequacy of Emergency Arrangements, Procedures and Exercises

The main local emergency arrangement is the requirement to make safe and evacuate the building under some circumstances. Based on the earlier discussions in section 1.6.2.4, section 3.12, and section 4.4 above, it is considered that the facility will be well equipped with detection and protection systems, trained personnel and well supported by the ANSTO emergency personnel and procedures.

Radiological hazards have been identified for the NMMF at the ANSTO Lucas Heights campus, and the potential consequences of an emergency have been assessed to provide a basis for establishing arrangements for preparedness and response for a radiological emergency. The emergency used for the assessment is the NMMF reference accident provided in the Safety and Security Consequence Analysis of a release resultant from building fire within the facility.

The assessed hazard results in the NMMF being classed as Emergency Preparedness Category II. This EPC establishes the basis for a graded approach to the application of safety requirements and for developing generically justified and optimised arrangements for preparedness and response for a nuclear or radiological emergency at the NMMF that impacts outside the facility.

14.5. Maintenance, Inspection, and Testing of Safety Related Items

Asset management plans will be developed for the facility to define the examination, maintenance, inspection and testing required for assets and components. Any assets critical to safety will be assigned to an asset owner/custodian and registered in an asset management plan.

These systems will ensure that the maintenance, inspection, and testing of safety-related items will be implemented within the required frequencies to ensure that all items are functioning in their intended role in the overall safety system.

14.6. Action Plan

The following actions are considered for future stages of the Program:

- A preliminary risk assessment should be undertaken when the design of the facility matures to understand the operational risk profile of the facility and determine the appropriate SSCs and if OLCs are required to maintain and operate the NMMF safety.
- A Hazard Identification (HAZID) process should occur to understand the relevant hazards within the NMMF and propose mitigative actions implementing the hierarchy of controls to ensure risk is as low as reasonably practicable.

14.7. Justification for Continued Operations

Radiological exposures to workers during the operation of the NMMF are expected to occur and will be within the set dose constraints. These are expected to be similar to those of the existing radiopharmaceutical production facilities at ANSTO. These exposures are considered to be justified on the basis that the operation of the NMMF will ensure that Australia obtains the public health care benefits from nuclear medicine and will continue to be a reliable domestic and international supplier of nuclear medicine products.

These products include:

- Technetium-99m (Tc-99m) generators – the essential requirement for the majority of diagnostic nuclear medicine procedures. This needs security and reliability of supply to meet patient needs. It represents over 80% of all nuclear medicine procedures in Australia.
- Iodine-131 (I-131) – a well-proven and vital therapeutic product for the treatment of thyroid cancer.
- Lutetium-177 (Lu-177) – a growing and increasingly important product for systemic therapy.
- Irradiated Products – a range of industrial or pharmaceutical materials that are only repackaged within the facility for despatch as per the contract irradiation service at the OPAL Reactor.

Foreseeable design basis external events with the potential to have a significant impact on the NMMF development site were identified through the NMMF Safety and Security Consequence Analysis Report [Ref: (5)] and bounding case accident scenarios for the facility.

Scenarios included major building fire, [redacted] and seismic events which have been addressed when considering the effects of potentially significant natural or human induced external events. The effect of these events will be further analysed during detailed design of the facility.

15. Definitions

The following abbreviations/ definitions have been used in this document:

Term	Definition
AFP	Australian Federal Police
AHD	Australian Height Datum
ALARP	As Low As Reasonably Practicable
AME	ANSTO Maintenance and Engineering
AMTC	Active Material Transfer Cart
ANM	ANSTO Nuclear Medicine
ANSTO	Australian Nuclear Science and Technology Organisation
ARB	Aluminium Retrievable Bin
ARPANS	Australian Radiation Protection and Nuclear Safety
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ASOC	ANSTO Security Operations Centre
BAT	Best Available Technology
BCA	Building Code of Australia
B23	Building 23
CASA	Civil Aviation Safety Authority
CCR	Change Control Request
CCTV	Closed-Circuit Television
CEO	Chief Executive Officer
CNO	Chief Nuclear Officer
COO	Chief Operating Officer
D&D	Decontamination and Dismantlement
DU	Depleted Uranium
EDSP	Engineering Design Safety Principle
EM Plan	Emergency Management Plan
EPC	Emergency Preparedness Category
EPD	Electronic Personal Dosimeter
ERT	Emergency Response Team
FIP	Fire Indicator Panel
GIL	Generic Intervention Level
GMP	Good Manufacturing Practice
HAZID	Hazard Identification
HF	Human Factors

Term	Definition
HFIP	Human Factors Integration Plan
HIFAR	High-Flux Australian Reactor
HPS	Health Physics Surveyor
HVAC	Heating, Ventilation, and Air Conditioning
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IPTS	Inter Pneumatic Transfer System
ISO	International Organization for Standardisation
IT	Information Technology
L&D	Learning and Development
LAN	Local Area Network
LfE	Learning from Experience
LGA	Local Government Area
LHSTC	Lucas Heights Science and Technology Centre
MASD	Multipoint Aspirating Smoke Detection
NCC	National Construction Code
NMMF	Nuclear Medicine Manufacturing Facility
NMMP	Nuclear Medicine Manufacturing Program
NSSS	Nuclear Safety, Security and Stewardship
NST	Nuclear Science and Technology
OEM	Original Equipment Manufacturer
OLCs	Operating Limits and Conditions
OPAL	Open Pool Australian Light-water
PA	Public Address
PABX	Private Automatic Branch Exchange
PCA	Principal Certifying Authority
PCBU	Persons Conducting a Business or Undertaking
PCC	Potential Controlled Change
PCG	Program Control Group
PPC	People, Performance and Capability
PPE	Personal Protective Equipment
PQS	Pharmaceutical Quality System
PSA	Probabilistic Safety Assessment
PVMP	Project Validation Master Plan

Term	Definition
QA	Quality Assurance
QC	Quality Control
QMP	Quality Management Plan
QMS	Quality Management System
RGP	Relevant Good Practice
RL	Reduce Level
RPA	Radiation Protection Advisor
RPS	Radiation Protection Services
SAR	Safety Analysis Report
SDS	Safety Data Sheets
SIAM	Standard Iodine Adsorption Module
SME	Subject Matter Expert
SPMLF	Security Project Management Lifecycle Framework
SQEP	Suitably Qualified and Experienced Persons
SRA	Safety and Reliability Assurance
SSCs	Structures, Systems and Components
STAR	Stop, Think, Act and Review
SWMES	Safe Work Method and Environmental Statements
SWP	Safe Working Permit
TGA	Therapeutic Goods Administration
TLD	Thermo-Luminescence Dosimeter
TP	Test Pits
UPS	Uninterruptible Power Supply
VP	Validation Plans
WHS	Work Health and Safety
WHS & E	Work Health, Safety and Environment
WHS MS	WHS Management System
WMP	Waste Management Plan
WMS	Waste Management Services
Z	Hazard Factor

16. References

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Appendix A: NMMF Isotope Licence Limits

The Siting Licence shall be based upon the total facility wide isotope activity, at any one time. Table 13 lists the NMMF activity limits to be submitted for ARPANSA approval.

Limit (Total activity at any one time)	Form	Basis of Limit
275 TBq Mo-99	Liquid	5 off maximum batch inventories, with 3 off being in-process
60 TBq Lu-177	Liquid	3 off maximum batch inventory in-process or in transport package/s
120 TBq I-131	Liquid	3 off maximum batch inventory in-process or in transport package/s
1 TBq P-32	Solid	Forecast business demand
20 TBq Y-90	Solid	Forecast business demand
200 GBq I-123	Liquid	Forecast business demand
1 TBq Re-188	Liquid	Forecast business demand
1000 TBq Ir-192	Solid	Forecast business demand
1 TBq Ho-166	Solid	Forecast business demand
30 TBq Au-198	Solid	Forecast business demand

Table 13: NMMF Licence Limits

Appendix B: Risk from Ionising Radiation

Risk Scenario	Planned Controls (Based on standardised risk mitigation controls)	Risk with Existing Controls			Risk Treatment (Future risk mitigation strategies)
		Likelihood	Impact	Rating	
Building Fire: Large-scale building fire which has the potential to result in the airborne release of all the available radioactive materials stored in the facility. Assumptions entire fire load.	. Fire detection systems . Fire suppression equipment (Hose reel/Extinguishers) . Building design minimise fire risk/ BCA and codes . Building materials (low combustibility) brick/metal . Minimisation of flammable consumables . Buffer zone for bushfire control . Design to minimise collection of combustible materials near buildings . Building fire inspections/audits.	**C** **Very Unlikely** Event could occur in certain circumstances (moderate chance)".	**4.** **Major** Exceedance of legal limit for ionising radiation to a member of the public".	**Medium**	Reference: A. NMMP-0410-RT-0003-A0 ANSTO-SSR-FN-2024-03-Siting Licence _ Safety and Security Consequence Analysis Reference B. NMMP-0410-PM-0009-A0 NMMF Emergency Preparedness Categorisation

Risk Scenario	Planned Controls (Based on standardised risk mitigation controls)	Risk with Existing Controls			Risk Treatment (Future risk mitigation strategies)
		Likelihood	Impact	Rating	
Seismic Event: Considered to have the potential to release the NMMF inventory of liquid waste in addition to the potential airborne release of aerosols.	. Stable site, Ref seismic data NMMP-0410-RT-0002 . Safety of design with earthquakes and surface faulting . Seismic/Shock qualified critical controls . Designed buildings and structures . NMMF Emergency Management Plan . Seismic consideration with Structures Systems and Components (SSCs) . Deign for a Peak horizontal Ground Acceleration of 0.37g.	**B** **Highly Unlikely** Event could occur in exceptional circumstances (remote chance)".	**4** **Major** Radiation exposure less than legal limit for occupational exposure. Medium term environmental damage 1-3 years, Release confined to Buffer zone. Damage between $5-10M"	**Low**	"Reference: A. NMMP-0410-RT-0003-A0 ANSTO-SSR-FN-2024-03-Siting Licence _ Safety and Security Consequence Analysis
[redacted]					

Table 14: Risk from Ionising Radiation

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