Australian Government

ANSTO

Statement of Evidence to the Parliamentary Standing Committee on Public Works Nuclear Medicine Facility

ANSTO

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Contents

1 Purpose of Works

The purpose of this Statement of Evidence is to provide information to the Australian public to comment on, and the Parliamentary Standing Committee on Public Works to enquire into, proposed works under the Nuclear Medicine Facility Project.

1.1 Proposed Works

Australia has long-benefited from the sovereign manufacture and local supply of the nuclear medicine products used to diagnose and treat cancer. Replacement of the main manufacturing facility (the project) is now required to continue to meet community needs.

The project will help to secure the long-term supply of vital nuclear medicines through the construction of a modern nuclear medicine manufacturing facility at Lucas Heights. The Replacement Facility will enable production of existing products and facilitate future demand growth of existing and new products.

The project is expected to offer the following benefits:

- Meet domestic demand for technetium, lutetium and iodine and provide the flexibility to respond to market and technological changes in relation to the production of other nuclear medicine products.
- Deliver a more reliable supply of reactor-based radioisotopes for Australia. This includes being able to produce of nuclear medicines.
- Support academic and private sector medical researchers, by providing an accessible centre of expertise and contract manufacturing areas for the development of emerging nuclear medicine products.

1.2 Project objectives

The Replacement Facility will need to manufacture three ‘core’ products in sufficient quantities to meet demand. This section identifies the products and volumes before specifying the infrastructure required.

The core product requirements are described are given below:

- Technetium: Production of between 200 and 400 generators per week to reliably meet local needs and provide an ability to export surplus product / capacity.
- Lutetium: Production capacity of 20TBq[1] per week in order to meet the expected demand from growing export markets.

[1] TBq (Becquerel) is a measurement used to describe radioactivity.

- Iodine: Production capacity of 25TBq per week which is in line with the current arrangements.

In addition, the Replacement Facility will need to provide space for the future production of emerging nuclear medicine products.

As noted within Section 3 Need for Works, the Existing Facility is not well-placed to safely and reliably manufacture the required products over the medium- to long-term. As a result, the project team and their technical advisors began working on a design for a Replacement Facility several years ago. Since then, the design for the Replacement Facility has been refined to ensure that it will best meet the country's needs.

The final design contemplates a 12,700m^2 building located directly across from the OPAL reactor which accommodates:

- generator development suites
- hot cell packaging lines and dispatch facilities
- aseptic suites (contract manufacturing of alpha and beta emitting therapeutic products)
- development suites (for final research and development)
- handling and processing suites
- manufacturing suites
- production and quality control spaces
- ancillary facilities (for waste, warehousing, maintenance, plant, etc.)
- office space for staff.

Further detail on the design is contained in Section 4 Scope of Works.

2 Need for Works

2.1 Identified need for works

Australia has long-benefited from the sovereign manufacture and local supply of the nuclear medicine products used to diagnose and treat cancer. Replacement of the main manufacturing facility (the project) is now required to continue to meet community needs.

The project will:

- Provide safer, more reliable, improved performance and enhanced operability of our nuclear medicine manufacturing, distribution and production capabilities to meet the ongoing demand for nuclear medicine products in Australia (**Problem 1 – Asset condition and future compliance issues**)
- Ensure the continued supply of nuclear medicine products, protect patient health outcomes and secure our sovereign production capabilities (**Problem 2 – Australian sovereignty and patient health outcomes**)
- Provide futureproofing capacity and capabilities to meet future nuclear medicine manufacturing needs and emerging production technologies (**Problem 3 – Asset futureproofing and innovation opportunities**).

2.2 Deficiencies in current existing facilities

ANSTO's existing nuclear medicine facility (Building 23) at Lucas Heights plays a vital role in Australia's healthcare sector through the benefits that the community receive from the products that are manufactured there. Almost 80% of nuclear medicine isotopes used in Australia are manufactured from this facility, enabling over 700,000 patient procedures each year diagnosing and treating cancer (amongst other things).

The Existing Facility is approaching the end of its useful life and has been deemed by regulators and independent experts to be in urgent need of replacement. To address this, ANSTO have been planning a Replacement Facility for the past five years. Over this period, the Commonwealth has made several major decisions and provided in-principle support for the project.

2.3 Historical Background

The following reports and decisions have been made in recent years:

- A **Feasibility Study** prepared in **2016** assessed the longevity of the Existing Facility. It concluded that it is not fit for purpose beyond the medium-term and that it cannot be refurbished, and as a result, it recommended the replacement of the facility. The study also included a cost plan and a concept design for a Replacement Facility (which is consistent with the current design). Based on this,

the ANSTO Board endorsed further planning work to justify the need for a Replacement Facility. This instigated the development of the Initial Business Case (see next dot point).

- An **Initial Business Case** was prepared by ANSTO and submitted to the Commonwealth in **2020**. This business case thoroughly examined all available options to secure the supply of nuclear medicine products, ranging from the full import of products to domestic supply via either a retrofitted or a replacement facility. The business case recommended that the preferred option is the replacement of the Existing Facility with a modern version, including futureproofing features for the life of the facility (described here as the project). On the basis of this document, the Commonwealth provided ANSTO with $30m to undertake the planning and design of the Replacement Facility.
- **Numerous reports from the industry regulators** have confirmed that the existing, ageing facility is not fit for purpose in the long-term and that a replacement facility is required not only to meet Australia's future needs for nuclear medicine products, but also to ensure their safe production. These key industry regulators and assurance bodies include the Therapeutic Goods Administration (TGA), Auditor-General and Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

3 Options Considered

3.1 Options Analysis

A series of project options have been examined to meet the above requirements. This section summarises that analysis before going on to describe the approach to the analysis and the assessment outcomes.

3.1.1 Summary of the Options Analysis

A thorough examination of various supply options was undertaken as part of the options analysis. The options ranged from the full import of these products to domestic supply via a replacement facility. (refer Figure 3.1)

Figure 3.1: Potential options(1)

Options (in order of preference)		Description / key characteristics
	**Replacement Domestic Manufacturing Facility– Core Products**	The preferred option is to construct a replacement domestic manufacturing facility capable of providing the core products Manufacturing these products locally minimises the risks that they will not be available to meet the needs of local patients
	**Replacement Domestic Manufacturing Facility– Technetium Only**	This option involves the construction of a smaller facility Under this option, only technetium will be manufactured locally. With the remaining products imported, there is a risk, albeit small, that they will not be available to patients as and when required
	**Import Only – All Products**	This option involves moving to an importation model for all products It presents a higher risk to reliable patient access to nuclear medicine products and involves a higher overall cost

Note: *(1) Retro-fit options were excluded because they fail to meet the regulatory requirements in relation to safety and GMP.*

3.2 Reasons for adopting the proposed course of action

A Replacement Facility capable of producing the core products emerged as the preferred project option after detailed analysis. It provides both the best value for money and the most reliable access to the required product lines.

The preferred option is also consistent with the sector objectives in the most recent Commonwealth Budget – i.e. to develop key medicines locally and to rebuild Australia's industrial base. Medical science is considered one of the seven priority areas to revitalise industry and build economic resilience.

4 Scope of Works

4.1 Site Selection and project location

4.1.1 Project location

The Replacement Facility will be located on an under-utilised site within the secure area of the Lucas Heights Precinct.

4.1.2 Project Scope

The project will help to secure the long-term supply of vital nuclear medicines through the construction of a modern nuclear medicine manufacturing facility at Lucas Heights. The Replacement Facility will enable production of existing products and facilitate future demand growth of existing and new products.

The project is expected to offer the following benefits:

- Meet domestic demand for technetium, lutetium and iodine and provide the flexibility to respond to market and technological changes in relation to the production of other nuclear medicine products.

- Deliver a more reliable supply of reactor-based radioisotopes for Australia. This includes being able to produce of nuclear medicines.

- Support academic and private sector medical researchers, by providing an accessible centre of expertise and contract manufacturing areas for the development of emerging nuclear medicine products.

The project team developed a detailed functional design brief on the basis of the above needs and a range of other performance criteria. This document formed the basis of the detailed design development undertaken at this stage of the project.

The project involves the construction of a two storey building on land adjacent to OPAL nuclear reactor and other buildings that supply the active ingredients for the nuclear medicine products. The types of activity undertaken on each level of the building includes:

- Basement (4,250m^2): The lower level is where all materials will enter and exit the facility. The quantity of active materials, including waste, that will be staged here warrants isolation from the other functions in the building.

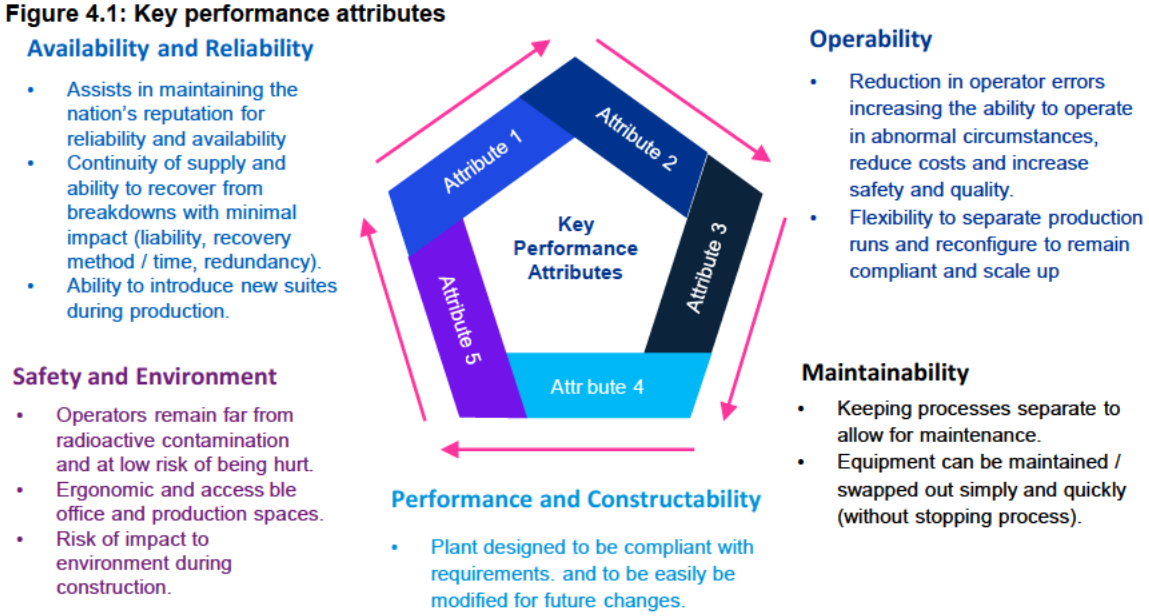
- Ground Floor (6,200m^2): The ground floor level is dedicated to the production of nuclear medicine. The production manufacturing suites, the quality assurance spaces as well as the offices are located on this level.

- Rooftop Level (2,250m^2): The rooftop level houses a number of plant functions and is linked to lifts and stairs for the vertical movement of maintenance personnel, equipment and materials. Photovoltaics are also planned for the rooftop level.

4.1.3 Key Design Criteria

ANSTO developed key performance attributes (in alignment with the project risks) to inform the design requirements for the Principal Consultant. Figure 4.1 outlines the key performance attributes used to develop the concept designs.

Figure 4.1: Key performance attributes



Source: *ANSTO, Key Performance Attributes.*

4.1.4 Facility Functions

Table 4.1 lays out the functions included in the Replacement Facility before indicating the expected benefit from that function.

Table 4.1: Facility Required Functions

Function	Brief Description	Functional Requirement (Including Benefit Provided)
Warehouse – Raw Material	The raw materials area of the warehouse is primarily used for the receipt of incoming materials, including active and non-active materials, personal items, and the return of generators and lead pots.	All raw materials for production are staged and organised here to facilitate safe, secure and timely access for manufacturing to maintain production schedules. GMP requires that incoming raw materials be segregated from shipping of waste and dispatch of finished products
Waste	The waste area of the warehouse is responsible for the preparation of non-active waste materials for disposal and the storage and treatment of active waste materials until they are safe to be disposed of.	An outcome from manufacturing is waste. Active waste must be held to allow for decay before it can be disposed of properly. GMP requires that shipping of waste be segregated from incoming raw materials and dispatch of finished products.
Warehouse – Dispatch	The warehouse dispatch area is for final packaging and shipment of all items out of the building. The products will then move to a large, open area for packaging and the final preparation of products to be shipped.	The final product will arrive from manufacturing in their shielded secondary container. Here it will be further packaged (boxed) and labelled to make it compliant for shipping over public roads. Orders will be filled and shipped. GMP requires that dispatch be segregated from incoming materials and waste.
Production Preparation	The production preparation rooms are primarily used for the preparation of equipment and chemicals prior to entering the production suites. These spaces also handle the decontamination of some equipment.	As part of the raw material sequence prior to use in production, all non-active raw materials, components and equipment must receive preparation before entering and use in the clean production environment.
Maintenance	The maintenance area of the building is a series of rooms that support the production areas by repairing and maintaining equipment, storing parts and equipment (including space for decay and decontamination and a mock-up trial lab space).	Maintenance of active and non-active equipment will be an ongoing and continuous activity needed to support manufacturing. All equipment leaving the production suites are potentially radioactive requiring time for decay prior to maintenance. Allows for maintenance without entering rooms that are radioactive which is compliant with GMP.
Plant Room	The plant room contains the large-scale, major utilities for the building. While the majority of these utilities will be located in the basement, some will be located on the rooftop level and some may be located outside of the building footprint.	The size and quantity of plant equipment is driven by the requirements of facility, production equipment, GMP and radiological requirements for the production suites.
Prod. Suite Technetium	The purpose of this area is to produce a generator device for extraction of technetium from the molybdenum solution that is received from the ANSTO nuclear medicine facility. The new generator device and production lines will provide a catalyst for a new technetium generator design that can improve the reliability of supply.	The technetium generator is expected to be ANSTO's most critical product and a crucial for nuclear imaging and therapeutic modalities that are central for the public health of Australia. Because of the importance of this product it is critical that product is manufactured weekly and the supply is secure. The size / configuration of the suite is the result of the equipment and GMP requirements. A stand-by line provides for maintenance shutdowns and potential additional / future capacity for domestic and export growth.
Production Suite Tellurium Based Iodine	This production area covers the manufacturing of tellurium-based Iodine 131 (I-131 tellurium-based), which is currently produced at the Lucas Heights campus and is of a higher quality and value compared to other iodine products produced overseas and extensively used for treatment in other countries. The production area has been designed to provide higher levels of reliability and capacity than what is currently achieved with one production line (e.g. inclusion of additional hot cell).	Tellurium based Iodine 131 is currently produced at the OPAL facility at the Lucas Heights site. There are higher costs involved in producing iodine in this way, however the resulting radioisotope is of a higher quality compared to other iodine products. This product is better suited for the domestic market and/or international markets where higher costs for the product can be justified. The size and configuration of the suite is the result of the required process equipment and GMP requirements.
Production Suite Lutetium	This area will be composed of the main Grade C production space, with an adjacent technical space with access to the back of the hot cells. Appropriate	Lutetium-177 is currently the most commonly used radiometal for targeted radionuclide therapy due to its commercial availability and the clinical success of 177Lu-based peptide

Function	Brief Description	Functional Requirement (Including Benefit Provided)
	allowances have been for the production of this product in accordance with the requirements of ANSTO's private sector licensor for this product (ITM).	receptor radionuclide therapy for the treatment of neuroendocrine tumours and prostate cancer. The size and configuration of the suite is the result of the required process equipment and GMP requirements. This is a core product and a stand-by line provides for maintenance shutdowns and potential additional / future capacity. Of the two major products it is potentially one of the fastest growing (domestically and internationally). It can serve a number of different purposes and from an industry market share perspective it is an important market for ANSTO to be in.
Aseptic Suites (Contract Manufacturing Use)	It is acknowledged that by the very nature of new product introduction, the exact product details are not known in advance, but the general facility capabilities and range of materials can be reasonably foreseen. ANSTO is anticipating future contract manufacturing of niche / innovative alpha and beta emitting therapeutic products. This includes a sufficient footprint for manufacturing both Lu-177PSM and Dotatate	The two aseptic suites will be fitted out with equipment in the future. A standard room configuration has been provided to allow for future aseptic processed products anticipated to be alpha and beta emitting isotopes. This addresses the issues of needing to retro-fit a building to undertake development of theranostics.
Development Suite	This suite will support the development of new nuclear medicine, radioisotope production and radioactive medical device products, within a GMP environment for Phase 1 Clinical Trials.	This suite is for the research and development of new nuclear medicine and radioisotope production requiring scale up to clinically relevant production levels of radioactive quantity and concentration, and/or requiring preparation within a GMP environment. This is a flex ble space that includes its own dedicated Preparation and Quality Control. It is a commercially important suite because it allows early involvement.
Generator Develop. Suite	The Generator Development Suite which will be used to manufacture future medical device radioisotope generators of similar configuration to technetium. Because of this, it is important to allow space (but not necessarily the equipment) to meet the needs of what could be a major product in the medium- to long-term.	This suite is for the manufacture of future medical devices or radioisotope generators of future products or new model Tc99m. Once equipped (separate project), the suite provides the ability to get isotopes to market (replacing technetium). This is a flexible space that allows for the addition / removal of equipment.
Prod. Space (Non-Active)	These production spaces (non-active) are for testing non-radioactive materials and keeping records for quality control purposes.	This production and quality control area (non-active) is a GMP requirement for quality control of products manufactured in the facility to ensure they are safe and efficacious for use.
Qual. Control Sp. (Active)	These quality control spaces (active) are for testing radioactive products and batch managed materials against specifications.	This quality control area (active) is a GMP requirement for quality control of the products manufactured in the facility to ensure they are safe and efficacious for their use in humans.
Personnel Support	The personnel support rooms are used for proper gowning in the facility and clean change prior to entering the production spaces.	These support spaces are a GMP requirement to ensure proper control and hygiene of personnel working in the manufacturing clean rooms.
Office Space	The office will be the primary working location for most of the staff in the building.	Beside the personnel working in the manufacturing suites, there are numerous additional departments that are needed to support this work. These are personnel who require an office environment for a significant part of their time and are required late at night, overnight or in the early morning (in addition to standard office hours).

Sources: *Principal Consultant, Functional Design Brief Report*

4.1.5 Details of site selection

The Replacement Facility will be located on an under-utilised site within the secure area of the Lucas Heights Precinct. Its location is in general alignment with ANSTO's 2035 Masterplan for the Lucas Heights Precinct, including:

- The establishment of a new roundabout in front of OPAL.
- Extending Mendeleeff Avenue to intersect with Bragg Avenue.
- The elimination of Aston Avenue.

Located in the Reactor Zone, the proposed location affords ready access to both OPAL and ANM where the radio-isotopes used in production originate.

4.1.6 Site description

The facility is also situated to leverage the 6-metre grade change between Bragg Avenue and OPAL to create a 2-storey building where the active and non-active materials can enter the building at a lower level directly from Bragg Avenue and vertically feed the production suites immediately above on the second level.

The second level roughly aligns with the entrance to OPAL and relates directly with all the other buildings in the Reactor Precinct. A "milling area" is created by the form of the Replacement Facility and HIFAR providing opportunities for pedestrian friendly landscaping (refer circular paved areas on the west side of the building).

4.1.7 Information on zoning and approvals

All project elements are located within the boundaries of Commonwealth owned and ANSTO controlled land. No civilian authority design or construction approvals are required, although the works will comply with the relevant standards and regulations (where applicable). No land acquisitions are associated with this proposal.

4.1.8 Details of applicable codes and standards

The following legislation, standards, codes and guidelines are applicable:

- Environmental Protection and Biodiversity Conservation Act 1999 (Cth);
- Fair Work (Building Industry) Act 2012 (Cth);
- Work Health and Safety Act 2011 (Cth);
- Disability Discrimination Act 1992 (Cth);
- Fair Work Act 2009 (Cth);

- National Construction Code - Building Code of Australia;
- Relevant Australian Standards;
- ANSTO Building Code;
- Building and Construction Industry Improvement Amendment (Transition to Fair Work) Act 2012 (Cth); and
- IAEA Safety Standards Seismic Design for Nuclear Installations;
- ARPANSA's Code on Radiation Protection.

An accredited Building Certifier will certify the compliance of the design and the compliance of the completed works.

4.2 Planning and design concepts

The following principles were established to meet the design objectives:

- Segregation of people, materials, waste movements with dedicated maintenance routes to meet GMP and safety requirements;
- Promotion of natural light into the production suites, laboratories and office areas.
- Clear planning of circulation and egress routes for wayfinding
- Ease of construction and improved construction efficiency through the standardisation of key building components;
- economies of scale for building components and furniture, fixtures and equipment; and:
- a centralised facility management approach with Whole of Life benefits and maintenance benefits.

This will be accommodated by the use of simple materials, construction methods and finishes selection with robust façade & roof detailing that can be built by most contractors and requires minimal maintenance.

4.2.1 Structure

Superstructure

The replacement structure will be four stories. The lowest level will be a partial basement built into the existing sloping site. The structure will consist of concrete floor systems supported by concrete columns and walls.

The structures teams are exploring several options for structural floors ranging from post-tension slabs to precast slab & beam and hybrid options.

The structural design relies on utilising lift shafts and stair cores constructed from in-situ concrete to provide lateral stability to the superstructure.

Substructure

The substructure utilises a combination of shallow pad footings and concrete bored piles founded on Sandstone. Basement columns and walls will be supported by shallow pad footings founded on very low to low strength sandstone. The office area, where rock is anticipated to be 2.5m below the proposed floor level, columns and walls will be supported by concrete bored piles founded on medium to high strength sandstone.

Design Life

The design life of the structure is anticipated to be 50 years.

Seismic Design

For seismic design the structure will be designed in accordance with Australian Standards AS1170.4 and International Atomic Energy Agency Safety Standards No. SSG-67.

Fire Rating Levels

The building is classified as a mixed-use building comprising of areas classified as Class 5 (offices), Class 7 (storage and parking), Class 8 (business operations – manufacturing), and Class 9a (healthcare related).

A 120-minute fire rating level will be required in offices and 240-minute fire rating level will be required in manufacturing area.

Future Flexibility

To allow future flexibility the western wing between Grid 4-14,A-E has been designed for a 10tonne/m2 live load. The 10tonne/m2 design load will allow for total flexibility of hot cell and Gentech room configuration as well as unit replacement pathways.

4.2.2 Materials and furnishings

Materials and furnishings will be selected from those readily available locally for their functionality and ability to meet GMP / clean room requirements, durability, low maintenance, ecologically sustainable design properties.

4.2.3 Hydraulic Services

The hydraulic services systems proposed for this development will comprise the following:

- Potable cold water supply

- Non-potable cold water supply
- Reverse osmosis and demineralised water (including Water for Injection)
- Potable hot water supply
- Non-potable hot water supply
- Sewer drainage systems
- D-Line waste effluent (Active liquid waste system)
- B-Line waste effluent
- C-Line waste effluent
- Roof rainwater downpipe systems
- Roof rainwater collection, treatment and re-use

Water Supply Infrastructure

A new extended water main along Mendeleeff Avenue and Bragg Avenue is proposed alongside with the new road to the West of the building. The building shall be supplied with domestic cold water via a meter connected to the BMS with associated backflow prevention to the ANSTO Building Code.

Sewer Drainage Infrastructure

A new extended sewer main along North of Bragg Avenue is proposed to serve the NMMF building as part of a different project. The building shall have an overflow relief gully to prevent any surcharge into the building should the remaining campus have a blockage further downstream.

Purified Water

An in-house purified water (PFW) system shall be provided to supply the manufacturing facility and laboratory areas for component washing, autoclave sterilisation and reagent preparation processes PFW shall also be used to produce ultrapure water, feeding the UPW Milli-Q IQ units located in various locations.

Active Liquid Waste

The manufacturing suites handling radioactive material shall have an independent liquid waste collection and drainage system, known as active liquid waste ‘D-Line’ system, separate from the sewer drainage system.

General Quality Requirements

Reverse Osmosis (RO) water that is in contact with or have the potential to come into contact with raw materials, in-process materials, APIs, other clean utilities or components must be designed to reduce the risk to product contamination. The RO water quality shall be monitored and verified as part of a quality management program; and shall include regular sampling of the water to test for purity compliance.

Mechanical Services

The mechanical systems proposed for this development will comprise the following:

- Chilled Water plant consisting of:
    - Air cooled Chillers (4 pipe for heating hot water
- Heating Hot water plant inclusive of:
    - 4 pipe Air Cooled Chillers
- Cleanroom Air Handling Plant including pre-conditioning units;
- Radiological Active Ventilation and GMP exhausts throughout the building;
- Quality Control Laboratory Air Handling Plant including pre-conditioning units and exhaust systems;
- Office VAV Air Handling Systems and fan coil units;
- Loading dock and Basement exhaust systems
- General Ventilation & Exhaust Systems;
- Mechanical Services Switchboards
- Building Management System and Environmental Management System (BMS & EMS)
- Environmental Discharge Monitoring Systems (EDMS)
- Radiological monitoring systems (RMS)
- Pneumatic Transfer Systems (PTS and IPTS)

4.2.4 Electrical Services

The scope of the electrical services works for the facility includes:

- Modify and extend the existing 2 x HV underground feeders to add the new load,
- Construct cable routes (underbore/trenching, conduits, backfill, pulling and joint pits) and install Cables
- 2 x Kiosk Substations consisting of HV Switchgear, Transformer and LV Switchgear compartment
- HV Protection relay and DC Supply
- Standby Power Generation System Including Permanent On-site Load Bank
- Mains Cabling
- Main Switchboards (MSB)
- Power Factor Correction (PFC)
- Active Harmonic Filters (AHF)
- Uninterruptable Power Supply (UPS)
- Electrical Energy Metering
- Sub-main Cabling
- Cable Containment Systems
- Distribution Boards
- Final Sub-Circuit Cabling
- General Power, Power to Other Services and Power to Specialist Equipment
- Photovoltaic (PV) System
- Earthing and Bonding System
- Lightning Protection System and Surge Protection
- Lighting (Internal and External)

- Lighting Control System
- Emergency Lighting and Exit Signs
- Incorporation of Ecologically Sustainable Design (ESD) Requirements

Maximum Demand

The preliminary maximum demand for the building is approximately 1,200kVA based on an allowance of 100VA/m2 for the main building areas (basement floor and ground floor) and 8VA/m2 for plant levels / areas (interstitial floor and plant floor).

Final maximum demand to be determined during the detailed design stage of the project once equipment details are available.

Substation Including HV and LV Equipment

The ANSTO site is currently supplied by many 11kV underground (UG) feeders emanating from the ANSTO privately owned zone substation. Based on a maximum demand 2 x 1,500kVA kiosk substations ‘A’ & ‘B’ are proposed. The Kiosk substation's locations are adjacent to the new building.

Photovoltaic (PV) System

A 260kW Photovoltaic (PV) System is proposed to be roof mounted The system will be zero export to the external building electrical network with any PV power generated used within the predominately by the building mechanical services.

Plant Availability

The new building will be supplied from a minimum of two separate kiosk substations connected to the

campus HV network. The substations will be arranged such that failure / planned maintenance of one substation will not impact production or lab areas. A bus-tie will be installed between building Main Switchboards.

An external standby diesel generator system will provide generator backed power to building life safety services and building critical equipment for a 12-hour period

4.2.5 Acoustics

Objectives

The following overarching acoustic design objectives will guide the development of acoustic performance criteria and design requirements:

- Internal sound insulation design to control airborne noise transfer between spaces and provide speech privacy.
- Room acoustic design to support effective spoken communication and general user comfort.
- Control of internal noise levels from building services, external noise ingress via the building envelope, rain noise, and floor impact noise to suit the particular use of each space.
- Control of operational noise (plant noise and activity noise) egress to external areas on the ANSTO site, to nearby ANSTO buildings, and to nearby off-site receivers.
- Control of internal vibration levels for general user comfort.

Design criteria

The acoustic design criteria and acoustic concept design is based on:

- ANSTO Building Code, which includes qualitative acoustic requirements only.
- Audio Security Level zone requirements (per ASIO Technical Note 1-15)
- No Audio Security zone requirements for this project.
- Process equipment does not include any high noise generating equipment (>80 dBA Lw) and does not have any specific vibration sensitivities requiring consideration in the design.

Environmental Noise Emission

- Given the site is owned and managed by the Australian Government, the Project is therefore not subject to a Development Application approval process. Notwithstanding this, operational noise from the new facility to be designed to comply with operational noise criteria at nearby noise-sensitive premises (off-site) in accordance with the NSW Noise Policy for Industry, as is standard practice for new developments in NSW

4.2.6 Landscaping

Landscaping works will restore areas disturbed during construction. Precautions will be taken to avoid compromising existing environmental sensitivities by adopting landscaping practices in keeping with local environmental conditions. Landscaping design will have regard to minimising potable water usage and will promote designing with Country.

4.2.7 Civil Works

The existing ground surface is to be levelled to provide a suitable building pad. This will require documentation of a raised earthworks pad above the existing sloped ground profile or otherwise cut into the existing surface to provide as level building surface.

The stormwater drainage system will consist generally of a piped collection and disposal system which discharges stormwater runoff towards an outfall at the western boundary of the campus. The building will be subject to a minor overland flow from the south which will be piped and directed around the new building.

The new building will have vehicle and pedestrian servicing requirements which will include loading and refuse vehicles directly servicing the building. The existing road network will be upgraded at the building perimeter to comply with the ANSTO Building Code requirements for road widths. The documentation will include surface grading, stormwater drainage design, services coordination and pavement selection/detailing.

4.3 Environmental Sustainability

4.3.1 Energy targets

Relevant background documentation, including available concepts and studies for the proposed development, existing site details, planning controls, and other relevant reports and policies have been reviewed in the development of the ESD strategy for the project to date. This includes appreciation for the relevant ANSTO requirements for sustainability, with specific attention to the ANSTO Building Code.

JV3 modelling has demonstrated that the building envelope with Section J DTS-compliant services can meet the requirements of Part J1 of the NCC and the ANSTO Building Code 20% improvement on insulation requirements when compared to a reference building of the same layout and use.

Opportunities for ESD initiatives have been identified and documented at a high level commensurate with the concept design stage of this project.

Building materiality and passive design opportunities in the functional requirements have been reviewed, with consideration of broader site scale initiatives relevant to the project and ANSTO policy drivers for ESD. Energy efficiency measures will be included to ensure that the facility does not utilise energy unnecessarily when in operation.

4.3.2 Measures to reduce energy and water use

The ANSTO Environmental Sustainability Strategy includes specific objectives for the reduction of energy consumption, water consumption and emissions. It maps core ESD initiatives and targets to the United Nations Sustainable Development Guidelines (UN SDGs).

The following table sets out the applicability of the goals and objectives to this project and within the ESD strategy developed to date.

Table 4.2: ANSTO Environmental Sustainability Strategy application to project

Strategy Goal	Scope and Applicability	ESD Supporting Initiatives
1 Reduce our energy emissions	Organisation & Building Applicable	Building electrification, PV provision, energy efficient design, performance envelope JV3 assessment demonstrating compliance with ANSTO Building Code target for 20% improved insulation levels over Section J DTS requirements
2 Increase our water resilience	Organisation and building scale	Rainwater capture and reuse, high fixture and fitting efficiency.
3 Manage pollution responsibly	Site and Building Applicable (Civil)	Stormwater discharges and pollutant levels to be addressed through Civil design.
4 Low emission vehicle fleet	Organisation, Site and Building	Provision for EV chargers and/or infrastructure at this building location on site
5 Sustainable site renewal and design	Organisation, Site and Building	Energy, water and waste initiatives are defined in the ESD strategy. While the intent of this goal is broadly applicable, the building does not qualify for formal rating under NABERS on the basis of its space uses. Benchmarking to NABERS or Green Star to the extent that the metrics for energy, water and waste under these schemes can be applied, is an element of additional scope to consider in subsequent design development phases
6 Sustainable and ethical procurement	Organisation and Building Indirect	Procurement practices and modern day slavery requirements should form part of tender requirements. Scope-3 emissions reductions are indirectly supported in material life cycle considerations initiatives
7 Eliminating and minimising waste	Organisation and Building Applicable	Recommendation to undertake operational waste management assessment and design Materials and product selection initiatives to reduce waste impacts up front
8 Preserving our biodiversity and heritage	Organisation N/A to project	
9 Establishing green campuses	Organisation N/A to project	
10 An effective, efficient and integrated EMS	Organisation N/A to project	

Efficient water use is a key aspect of the design. Key water saving measures will include where practical:

- 100kL rainwater harvest and reuse storage capacity has been nominated for the NMMF building, provisionally sized in line with typical allowances for a building of this scale
- High efficiency fixtures and fittings (i.e. high WELS-rated taps, toilet cisterns, urinals and shower heads)
- Water efficient appliances such as kitchen dishwasher facilities
- Elimination or reduction of non-essential water intensive uses e.g. reuse of lab and process garments (where appropriate) to cut down laundering-related water use.
- Alternative water supply from captured rainwater for non-potable uses including landscape irrigation, amenities flushing, HVAC cooling tower make up water
- Consideration of process-related water uses in the manufacturing facility and identification of candidates for use of alternative water supply

4.3.3 Re-use of existing structures

There are no existing structures on the site that will be suitable to be retained for the future facility. Where possible sections of the inground IPTS system will be retained.

4.3.4 Demolition and disposal of existing structures

The new facility necessitates the demolition of the eastern extension of Mendeleeff Avenue and the adjacent accessible parking area. The existing Aston Avenue, between Mendeleeff Avenue and Rutherford Avenue will also be demolished. There are seven buildings within the area of the future building footprint that will also require demolition to make room for the new Manufacturing Building. These buildings are beyond the end of their economic life and are not fit for reuse or refurbishment. This demolition work is required to allow the construction of the new Facility.

A new road is to be constructed to connect Mendeleeff to Bragg Avenue, which will provide north to south access through the entire reactor precinct.

4.3.5 Compliance with local, state/territory and Commonwealth water and energy policies.

The Facility will be designed, constructed, operated and maintained in order to use energy and water as efficiently as possible and to comply with the following statutory and ANSTO requirements, this includes:

- Section J of the National Construction Code;

- Commonwealth Ecologically Sustainable Development Guidelines
- Commonwealth Sustainable Procurement Guide
- ANSTO Environmental Sustainability Strategy
- Energy Efficiency in Government Operations Policy (EEGO)
- Sutherland Shire Environmental Specifications for materials

Materials selection to optimise internal environment quality, reduce resource depletion and sustainable procurement including recycled products and materials as identified on the Department of Climate Change, Energy, the Environment and Water website.

4.4 Master and site planning

4.4.1 Master and site planning, including details of future developments

The proposed site for the facility is located in the Reactor Zone in accordance with the ANSTO Masterplan. The location affords ready access to both OPAL and ANM where the majority of source materials originate. This close proximity minimizes roadway risk. In addition, the remainder of the materials that come from off-site will enter the campus from the adjacent secure entrance. This again affords a convenient proximity to the new facility via Bragg Avenue.

The orientation of the facility allows future flexibility for the facility to expand to the east in the future.

4.4.2 Provision for people with disabilities

Access for people with disabilities will be provided in accordance with the National Construction Code 2016, Australian Standard AS14285, the Disability Discrimination Act. This includes designated parking for people with disabilities in accordance with AS1158 Category P12, and Unisex sanitary facilities in accordance with AS1428.1-2001.

4.4.3 Childcare provisions

There is no requirement for childcare facilities under this project given there is currently a facility onsite.

4.4.4 Security Measures

In accordance with Government initiatives to improve physical security arrangements across Government departments, advice from both the engaged specialist SCEC-endorsed security design consultants and the designated security authorities has and will continue to be incorporated in the design solutions for the proposed works.

Site-specific security threat assessments and security risk assessments have been completed, and appropriate security protection will be provided in accordance with ANSTO Security requirements and other specific project requirements including ASIO technical notes and ARPANSA Radiation Protection Series No. 11 - Code of Practice for the Security of Radioactive Sources and Protective Security Policy Framework (PSPF).

The security threat assessment will be reviewed during the detailed design phase and the facilities would be secured as appropriate to the classification level required for activities conducted within.

4.4.5 Fire protection including bushfire protection measures

All fire protection requirements will, as a minimum, be in accordance with the provisions of the Building Code of Australia, the Manual of Fire Protection Engineering and all other applicable codes and standards.

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

The new facility is such that it falls beyond a 140m buffer zone. The following bushfire protection measures for the ANSTO Lucas Heights campus are already in place:

- External fire trail with turning area;
- Hydrant points both internal and external to security fence at regular intervals;
- Electricity to the proposed development site is located underground;
- Gas services to ANSTO facilities are installed and maintained in accordance with Australian
- Standard AS/NZS 1596 ‘The storage and handling of LP Gas’; and Management of internal landscaping to Asset Protection Zone (APZ) standards

4.4.6 Work health and Safety

The Australian Government is committed to improving work health and safety outcomes in the building and construction industry. The proposed Joint Information Warfare Facility will comply with the requirements of the Work Health and Safety Act

2011(Cth), Work Health and Safety (Commonwealth Employment – National Standards) Regulations and relevant ANSTO policies.

In accordance with the Building and Construction Industry (Improving Productivity) Act 2016, project contractors will also be required to hold accreditation from the Office of the Federal Safety Commissioner under the Work Health and Safety Accreditation Scheme.

Safety aspects of the proposed redevelopment have been addressed during the design development process and have been documented in a Safety in Design Report and HAZID reports. A Work Health Safety Plan will be required to be developed for the construction phase prior to the commencement of any construction activities.

The construction site will be secured appropriately to prevent public access, or access by unapproved ANSTO personnel, during the construction period. No special or unusual public safety risks have been identified.

The design and subsequent operation of facilities, equipment and processes, using a risk management approach, must consider the interface with humans and unintended consequences at all stages of the facility lifecycle from concept-design to decommissioning.

The concept design needs to meet these safety requirements by incorporating:[2]

- Work Health and Safety Act's Management of Safety in Design Principles
- ARPANSA Holistic Safety Guidelines and Human Factors
- ARPANSA's Code on Radiation Protection.

A Hazard Identification workshop, facilitated by the Principal Consultant during the concept design stage, acted as the primary source of hazard information. The workshop involved representatives from ANSTO to identify the key risks to be addressed over the building's lifecycle. The Hazard Identification workshop supported the development of the Safety in Design, Nuclear Safety Assessment and Product Quality Risk Assessment. One of the key outcomes from these workshops was the need for two generator production lines to meet the safety requirements and plant availability and reliability objectives.

4.4.7 Associated plans and drawings

The project floorplans have been designed to meet the requirements of the Functional Design Brief, in particular the key performance attributes (availability and reliability, operability, maintainability, performance and constructability, and safety and environment) provided by ANSTO.

[2] Other legislation and guidance is also relevant – i.e. Australian Radiation Protection and Nuclear Safety Act (1998), Australian Radiation Protection and Nuclear Safety Regulations (2018) and Regulatory Guide: Applying for a License for a Nuclear Installation.

The Replacement Facility will be a two-storey building with a site footprint of approximately 6,500m^2. The gross floor area (GFA) of the building is 12,700m^2 in total. As a specialist building, there is a further requirement for 3,000m^2 of interstitial space – i.e. the walkable space for maintenance that exists above the ceiling of the ground floor.

Basement Plan – 4,250m2

The lower level is where all materials will enter and exit the facility. The quantity of active materials, including waste, that will be staged here warrants isolation from the other functions in the building. Heavy vehicles are easily accommodated when they come off Bragg Road. Materials are moved from the basement to the ground floor via lifts and 'dumb waiters.'

Ground Floor Plan – 6,200m2

The ground floor level is dedicated to the production of nuclear medicine. The production manufacturing suites, the quality assurance spaces as well as the offices are located on this level. This is where the majority of staff spend their time in the building. The building is 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. This level has opportunities for windows on all sides of the building and provides for a formal entrance across from OPAL's public engagement.

Rooftop Level Plan – 2,250m2

Many necessary plant functions are housed on the rooftop level with the inclusion of elevators and stairs for the vertical movement of maintenance personnel, equipment and materials. Photovoltaics are also planned for the rooftop level space.

4.4.8 Project Scale

Figures 4.2 and 4.3 provide 3D massing diagrams which give an indication of the size, scope and scale of the proposed Replacement Facility. Each side of the site / building is shown in the diagrams.

Figure 4.2: 3D massing diagram – south-west perspective (from above)

Source: *Principal Consultant, Facility and Architectural Descriptive Report*

Figure 4.3: 3D massing render – north-east perspective (from ground level)

Source: *Principal Consultant, Facility and Architectural Descriptive Report*

4.5 Below-the-line works

There are no below-the-line works nominated for the project.

5 Other issues

5.1 Key Legislation

Key industry regulators and assurance bodies include the Therapeutic Goods Administration (TGA), Auditor-General and Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

5.1.1 Quality Requirement

The design, construction and commissioning of the facility and the associated utilities and process equipment and laboratories needs to be compliant with the current code of GMP and the TGA guidelines. The GMP practices are multifaceted, and the concept design will consider and provide solutions that are suitable for such a facility.

ANSTO are ultimately responsible for the quality of the product produced from this facility and cannot contract out this responsibility. However, they have contracted the design of the facility and the scope of the design is to provide suitable quality considerations in this functional brief.

5.2 Heritage or Geographical assessments

There are no National Heritage matters within the project site. The nearest heritage site listed on the Commonwealth Heritage List is occurs within the wider locality being the Cubbitch Barta National Estate Area. This area is a large bushland area which has been identified for its outstanding Indigenous cultural heritage and natural values. The Cubbitch Barta National Estate Area is located adjacent to the Lucas Heights site to the south and west. At its closest point, the area is around 500 metres to the south of the project site (on the south side of Heathcote Road).

The project area is located on Dharawal Country within the Illawarra region of NSW. Traditional Dharawal people's lands are primarily confined to the area south of Botany Bay, extending as far south as the Nowra area, across to the Georges River in Sydney's west. As described in relation to Commonwealth heritage places overseas, the Cubbitch Barta National Estate Area is located adjacent to the Lucas Heights site to the south and west and, among other attributes, has been identified for its outstanding Indigenous cultural heritage.

An Aboriginal Heritage Information Management System (AHIMS) search undertaken in 8 September 2022 did not identify any known Aboriginal sites within the project site (which has previously been extensively disturbed as part of the development of the ANSTO facility). Four previously recorded Aboriginal sites were however identified in the bushland area to the south of the project site between the boundary of the Lucas Heights campus and Heathcote Road.

5.3 Environmental Impact Assessments

An EPBC referral has been prepared for the project advising the existing site for the project is currently disturbed and does not contain any existing vegetation, the construction and operation of the proposed facility is unlikely to have direct or impacts.

The proposed facility is expected would be designed to meet (or improve upon) existing emissions releases from Lucas Heights. It is therefore not expected that there would be any significant impacts to the any threatened species or threatened ecological communities.

5.4 Impacts on local Community

ANSTO has conducted rigorous assessments to identify potential environmental and local community impacts and propose suitable mitigation measures. These include:

- **Visual Impacts:** An architectural location plan was completed as part of the preparation into this Statement of Evidence; indicating that there are no visual impacts as the facility will not be readily visible to the public.
- **Noise Impacts:** Given the site is owned and managed by the Australian Government, the Project is therefore not subject to a Development Application approval process. Notwithstanding this, operational noise from the new facility to be designed to comply with operational noise criteria at nearby noise-sensitive premises (off-site) in accordance with the NSW Noise Policy for Industry, as is standard practice for new developments in NSW.
- **Traffic, Transportation and Road Impacts:** During construction, there will be an increase to the number of large vehicles entering Harman delivering materials to site and undertaking construction activities. The effects of this increase on the internal and external road networks will be mitigated through the development of a Traffic Management Plan, ongoing and regular coordination of all construction activities with local authorities, and de-confliction with peak traffic times such as ANSTO personnel work starting and finishing time.
- **Relevant Local Facilities:** There will be no impact on local facilities as part of this project.
- **Heritage Impacts:** There are no buildings of heritage value identified within the proposed Project Area. Based on a preliminary assessment of the Project Area and associated works against the Indigenous heritage values of the base, there will be no impacts to the identified Indigenous heritage values within the site.

5.5 Consultation with Key Stakeholders

5.5.1 Overview

A Stakeholder and Communication Management Plan has been prepared and implemented by ANSTO. The purpose of the Plan is to define and document the approach, strategies and processes to effectively perform and / or manage communication with the stakeholders for the project.

5.5.2 Stakeholder Engagement Strategy and consultation

The project director and team recognise the importance of a well-planned approach to all project-related communications and the need for the early establishment of a good relationship between the project team, the project sponsor and appropriate relevant stakeholders.

Given the nature of the project, effective stakeholder engagement will be critical to successful delivery. Effective engagement increases the likelihood of the project succeeding and minimises the risk of failure that can occur through a lack of understanding of the operations, concerns and impacts for stakeholders.

Table 5.1 identifies the key stakeholders on the project. This includes the Department of Industry Science and Resources (DISR) who are responsible for sponsoring the project.

Table 5.1: Relevant stakeholders for the project

Type	Organisation	Description	Approach
The Commonwealth	Department of Prime Minister and Cabinet	Responsibilities for intergovernmental and whole of government policy coordination.	Via DISR
	Minister for Industry and Science – The Hon Ed Husic MP	ANSTO forms part of the Minister's portfolio.	Via both DISR and ANSTO
	Dept. of Industry Science and Resources (DISR)	DISR is the sponsoring department. ANSTO is a portfolio agency within DISR.	PCG monthly meeting Monthly update with ANSTO Govt. Affairs.
	Department of Climate Change, Energy, Enviro. & Water (DCCEEW)	Environment Protection and Biodiversity Conservation (EPBC) Act Referral will be assessed by DCCEEW. Administers EPBC Act.	Briefing to be initiated in the next phase.
	Parliamentary Standing Comm. on Public Works (PWC)	Works to the value of +$15m are referred to PWC. They report to Parliament on project need / value.	Via Department of Finance

Type	Organisation	Description	Approach
	Department of Finance (Finance)	Advises on arrangements for management & ownership of assets	Via DISR
	Department of Health (DoH)	Establishes standards for health products. Reg. group within DoH is Therapeutic Goods Admin. (TGA).	Monthly update with ANSTO Govt Affairs.
	Australian Federal Police	Provides protective services, onsite security and incident response force.	Briefed on concept design.
	Department of Foreign Affairs and Trade (DFAT)	Responsible for foreign policy and relations, international aid, consular services, trade and investment (inc. Australian Safeguards & Non-Proliferation Office -ASNO – a statutory office within DFAT)	To be initiated in the next phase of the project.
Regulators and industry bodies	Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)	ARPANSA regulates Commonwealth entities dealing with radiation.	Preliminary verbal advice and presentation of concept design and indicative timings to be initiated in the next phase.
	Therapeutic Goods Administration (TGA)	Regulates therapeutic goods. Part of the DoH. Goods must be registered before supply.	Presentation of concept design and indicative timeline to be initiated in the next phase.
	ASNO (Statutory office within DFAT)	Australia's safeguards and nuclear security regulator.	To be initiated in the next phase of the project.
	International Atomic Energy Agency (IAEA)	Promotes safe, secure and peaceful use of nuclear technologies.	To be initiated in the next phase of the project.
Neighbours and community	Sutherland Shire Council	ANSTO is surrounded by area under management of Council.	Briefed on concept.
	Reps from the Dharawal nation	The site is on the traditional lands of the Dharawal people.	Design will incorporate appropriate cultural recognition.
Nuclear Medicine Customers and Suppliers	Customers	Represented via the External Advisory Board. Advise on products and clinical needs.	Meetings held (x2). Voice of customer report completed February 2022.
	Suppliers	Supply chain partners in the manufacture of nuclear medicine products.	To be initiated in the next phase of the project.

Type	Organisation	Description	Approach
	ITM (Germany)	ANSTO licenses the ITM intellectual property for production of Lutetium.	Meetings held (x2).
State Authorities, State Depts. and Utilities	Sydney Water	Supply water, manage wastewater and stormwater drainage.	To be initiated in the next phase of the project.
	NSW Fire Brigade	Responsible for fire and rescue.	To be initiated in the next phase of the project.
	Ausgrid	Electricity distributor	To be initiated in the next phase of the project.
	NSW Dept. of Planning and Environment	Responsible for planning in the state of NSW.	The need for this is unlikely but is noted here for completeness.

Source: *Stakeholder and Communication Management Plan*

6 Cost-effectiveness and public value

6.1 Project Costs

The estimated out-turned cost of this project is $619.23 million, excluding Goods and Services Tax. This cost estimate includes construction costs, management and design fees, furniture, fittings and equipment, contingencies and escalation allowance.

6.2 Project Delivery Method

Approach

The delivery model analysis for the project was based on procurement guidance from the Department of Infrastructure, Transport, Regional Development, Communications and the Arts. A series of workshops involving senior officers from ANSTO and their advisors were also held to develop and confirm this analysis.

Packaging of Works

An analysis based on the above guidelines has identified the need for two packages:

- Specialist equipment works
- Main building works

Delivery Option Assessment

This analysis confirmed that the specialist equipment works should be delivered through ANSTO's existing commercial arrangements with specialist subcontractors. However, further work was required to assess which of three options should be progressed for the main building works (refer Table 6.1).

Table 6.1: Description of potentially suitable delivery models (main building works)

Model	Description
Design and Construct	This involves an integrated design and construction contract, with the Commonwealth procuring a contractor based on a design they developed.
Managing Contractor	The Commonwealth engage subcontractors to deliver the works and receive an agreed management fee plus reimbursement of subcontractor fees.
Early Contractor Involvement	This involves a two-stage contractual arrangement, where the Commonwealth procures a construction contractor to develop the design under a fixed price and when the project proceeds a different arrangement may be struck for the build.

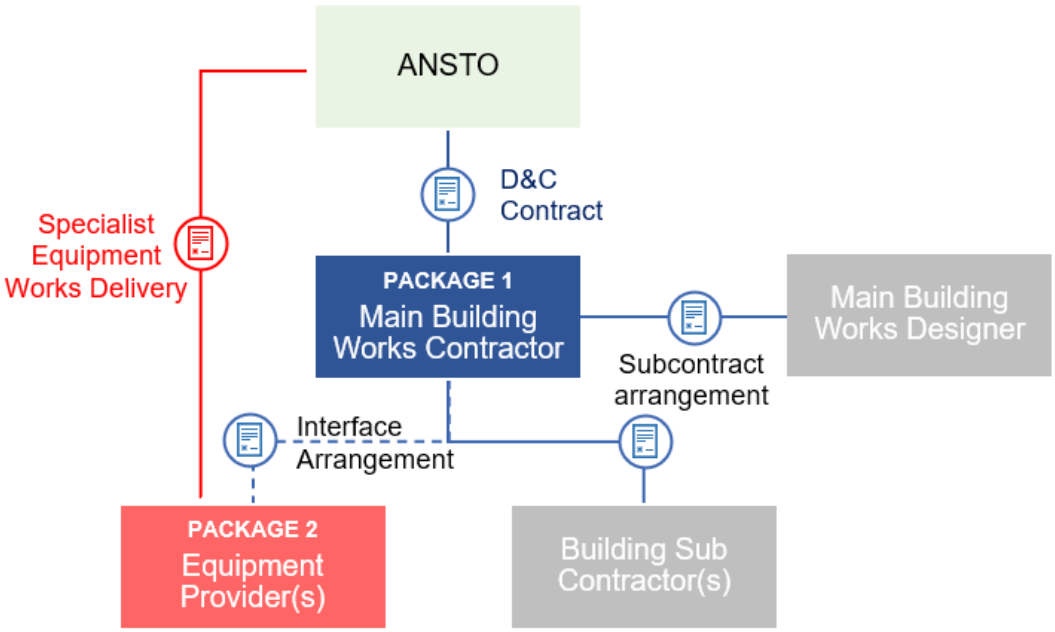
Source: *Detailed Business Case*

The assessment identified the Design and Construct Model as the most suitable option for delivery of the main buildings works package. The reasons for this were:

- **Timely approval and delivery and certainty of completion** – Both the Early Contractor Involvement Model and Managing Contractor Model theoretically provide an opportunity to obtain project approvals and appoint contractors early. However relative to other projects, there is less of a need to fast-track these processes.
- **Risk allocation and transfer** – The Design and Construct Model generally provides a higher degree of risk transfer to contractors when compared to other models.
- **Price certainty** – The Design and Construct Model generally provides a greater degree of price certainty to the Commonwealth when compared to both the Managing Contractor and Early Contractor Involvement Models.
- **Market interest and capability** – The Design and Construct Model is well understood by the market, whereas both the Managing Contractor and Early Contractor Involvement Models are less common for new building in metropolitan areas.

Based on the delivery model analysis and assessment, it is recommended that the building works be progressed via the Design and Construct Model. Furthermore, it is recommended that the ANSTO project team manage the production equipment portion with another contractor. The suitability of this delivery approach will be tested and confirmed with the market in 2023 prior to the development and release of the tender documents.

Figure 6.1: Contract Structure



Source: *Detailed Business Case*

6.3 Construction program / project schedule

It is proposed that the preparation of the tender documentation for the main building works package will commence in late 2023 and be completed in mid to late 2024. Contract award for this package will occur shortly after the Construction License is issued (early 2025). The hot cells and process equipment will be procured, manufactured and installed between late 2024 and mid 2027. The final set of regulatory approvals are assumed to occur a four year period from mid 2028. After taking the timelines for each task into account and allowing for contingency, the project is assumed to be fully operational in mid 2032.

6.4 Revenue

The Facility expects to generate a significant revenue stream each year, however, under the base demand assumptions this is not forecasted to fully recoup all to construction, finance and operational costs over the next 40 years. The base demand scenario reflects a conservative domestic supply.

6.5 Public Value

The project will provide a range of social and economic benefits that are relevant to investment decision-making. It is important to note that these socio-economic benefits are not directly relevant to the option examined in the above financial and funding analysis. However, they are relevant to a qualitative comparison of the project and a do-nothing scenario.

Broadly, there are a number of health and economic related benefits that could be realised by investing in the nuclear medicine sector. A global assessment[3] of nuclear imaging and medicine showed substantial shortages in equipment and workforce capabilities, particularly in low and middle-income countries. The assessment showed that scaling-up the use of nuclear medicines would avert approximately 3.2% of the total 76m cancer deaths expected between FY20 and FY30. This would cost an additional US$6.84b over this period but could yield lifetime productivity gains of US$1.23t worldwide, a **net return of $179 per $1 invested** (in US$ terms).

Table 6.2 sets out the broader socio-economic benefits of developing a Replacement Facility by impacted stakeholder groups. The table below provides data showing the potential health and economic benefits through investing in the nuclear medicine sector.

Table 6.2: Project socio-economic benefits

[3] Hricak, Hedvig et al. “Medical imaging and nuclear medicine: a Lancet Oncology Commission.” *The Lancet. Oncology* vol. 22,4 (FY21): e136-e172. doi:10.1016/S1470-2045(20)30751-8.

Stakeholders	Benefit description
Industry 	• Reduce delays to industry partners and customers receiving much needed nuclear medicine. • Improve the ability of industry to secure current and future supply of nuclear medicine products. • Reduce reputational risks for industry partners caused by supply shortages. • Reduce the costs of production significantly by avoiding import costs during a shutdown period • Provide job retention and job creation benefits in a region with the fewest number of jobs in the metropolitan area. Includes opportunities in the fields of construction, maintenance and science. • Creation of advanced local expertise in nuclear medicine by utilising more state of the art equipment and automation.
Health care professionals 	• Decrease the reputational risk to medical professionals and staff through provision of nuclear medicine products to provide world class care. • Improved mental health and wellbeing of staff and physicians when organising and conducting medical procedures due to reliability. • Support health care providers to provide world class care. • Reduce the loss of income caused by referring patients to other institutions to receive treatment.
Patients 	• Reliable and timely treatment increasing probability of a positive health outcome. For example, a missed scan or dosage often requires the entire treatment program to be reset, impacting patient health outcomes. • Early detection and intervention increasing probability of a positive health outcome. • A global assessment[4] showed that scale-up of nuclear medicine and imaging would avert approximately 3.2% of the total 76m cancer deaths expected between FY20 and FY30. While costing US$6.84b over this period, this could yield lifetime productivity gains of US$1.23t worldwide, a net return of US$179 per US$1 invested.

[4] Hricak, Hedvig et al. "Medical imaging and nuclear medicine: a Lancet Oncology Commission." *The Lancet. Oncology* vol. 22,4 (FY21): e136-e172. doi:10.1016/S1470-2045(20)30751-8.

A: Glossary

This section describes the key terms and abbreviated terms in this document.

Term	Definition
ANSTO Nuclear Medicine (ANM)	ANSTO Nuclear Medicine (ANM) Pty Ltd, a majority subsidiary of ANSTO, who operate the current Molybdenum-99 (Mo-99) manufacturing facility to provide materials for Tc-99m generators manufactured by ANSTO and other suppliers.
Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)	The Commonwealth's primary authority on radiation protection and nuclear safety. ARPANSA is there to protect the people and the environment from the harmful effects of radiation
Australian Safeguards and Non-proliferation Office (ASNO)	ASNO's role is to ensure that the countries international obligations are met under the Nuclear Non-Proliferation Treaty and is a key body for ensuring that the correct safeguards are in place to protect Australia's security.
Computed tomography	A medical imaging technique that uses a computer to acquire a volume of x-ray-based images, generally reconstructed as two-dimensional (2D) or three-dimensional (3D) pictures of inside the body. These images can be rotated and viewed from any angle. Each CT image is effectively a single 'slice' of anatomy.
Department of Climate Change, Energy, Environment and Water (DCCEEW)	DCCEEW are responsible for ensuring that major projects on Commonwealth Land comply with the Environment Protection Biodiversity Conservations Act (1999) (EPBC Act).
Design & Construct (D&C)	The Design and Construct Model would involve ANSTO engaging a contractor that underwrites the delivery and cost of building design and construction. They will be provided with the concept design and a specification that spells out functional performance requirements as well as commercial terms and a proposed risk allocation. From this, they will develop a detailed design consistent with the concept design and provide a fixed price to construct the building
Diagnostic imaging (diagnostic scan)	Diagnostic imaging uses technologies such as x-ray, CT, MRI, ultrasound, PET and SPECT to provide physicians with a way to look inside the body without surgery. Diagnostic imaging is considered a non-invasive diagnostic technique, as opposed to a biopsy or exploratory surgery. PET, SPECT and some types of MR imaging also provide information about how certain tissues and organs are functioning.
Dept. of Industry Science and Resources (DISR)	DISR is the sponsoring department for the project. ANSTO is a portfolio agency within DISR.
***The Environment Protection and Biodiversity Conservation Act 1999* (EPBC)**	The Environment Protection and Biodiversity Conservation Act 1999 is Australia's national environmental legislation. It's the main law which focuses on protecting and conserving the country's important environmental ecosystems, including significant wildlife, plants, habitats and places.
Good Manufacturing Practice (GMP)	Good Manufacturing Practice is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any

	pharmaceutical production that cannot be eliminated through testing the final product.
Iodine (I-131)	Iodine is widely used to diagnose and treat various diseases associated with the adrenal gland and neuroblastomas. For example, iodine is widely used in treating thyroid cancer and in imaging the thyroid, and also in diagnosis of abnormal liver function, kidney blood flow and urinary tract obstruction.
Isotope	Atoms of a single element that have differing masses. Isotopes are either stable or unstable (radioisotope). Radioisotopes are radioactive: they emit particles (alpha, beta) or electromagnetic (gamma) radiation as they transform or decay into stable isotopes.
Lutetium (Lu-177)	This form of lutetium is emerging as a radioisotope of choice for targeted radionuclide therapy (e.g. small tumours, prostate cancer and potentially other types of cancers) due to its ideal parameters for therapy and minimal waste management requirements.
Radioactivity	The spontaneous decay or disintegration of an unstable atomic nucleus accompanied by the emission of radiation.
Radioisotope	A radioisotope is a radioactive version of an element. Radioactive isotopes differ from the stable versions of the same element in that they have either more or fewer neutrons. There is no chemical difference between the way the radioactive and non-radioactive versions of an element react.
Technetium (Tc-99m)	Technetium is the most important and commonly used nuclear medicine in Australia. It is used to diagnose a variety of heart, lung, cancer and skeletal conditions. The nuclear medicine processing and distribution facility supports the distribution of technetium and numerous other health products across Australia.
Theranostics	Theranostics is a nuclear medicine treatment technique that facilitates targeting of specific cancers using diagnostic imaging to identify if target receptors are present on cancer cells, followed by precision radiation treatment that target these receptors.
Therapeutic Good Administration (TGA)	Therapeutic Good Administration. As part of the Department of Health, the TGA safeguards and enhances the health of the Australian community through effective and timely regulation of therapeutic goods.