Australian Government
Australian Radiation Protection and Nuclear Safety Agency

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Regulatory Assessment Report
Facility Licence Application A0309

Applicant: Australian Nuclear Science Technology Organisation (ANSTO)

ANSTO Nuclear Medicine Facility

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Executive summary

On 7 April 2017, the CEO of ARPANSA received an application (A0309) from the Chief Executive Officer (CEO) of the Australian Nuclear Science and Technology Organisation (ANSTO), for authorisation to operate a controlled facility, namely the ANSTO Nuclear Medicine (ANM) Facility.

The proposed facility will be used for the large-scale production (about twice the current production level) of molybdenum-99 (Mo-99). Technetium-99m (Tc-99m), the daughter of Mo-99, is currently used in about 80% of all nuclear medicine procedures. ANSTO states that the proposed ANM Mo99 Facility will be an export scale nuclear medicine manufacturing plant, which will secure Australia's ability to produce Mo-99 and increase capacity to meet a significant proportion of the world's needs.

When considering the licence application and making a decision as to whether to issue a licence, the CEO of ARPANSA is required to take into consideration certain matters prescribed in the Australian Radiation Protection and Nuclear Safety Act 1998 (the Act). The ARPANSA assessor prepared this Regulatory Assessment Report (RAR) for the CEO of ARPANSA to address these matters.

This RAR is based on the assessment of the information described in the application A0309, additional supporting material provided by ANSTO and discussions with facility representatives to clarify the application. The plans and arrangements for safety and security and other relevant information about the operation of the facility have been reviewed against applicable guidelines, e.g. the ARPANSA Regulatory Guide: Plans and arrangements for managing safety. These regulatory documents are based on national and international recommendations and guidance for radiation protection and nuclear safety. In addition, relevant international standards and guidance, particularly those published by the International Atomic Energy Agency (IAEA) have been applied for the assessment of the application for operating the ANM Facility.

The application describes operational aspects of the facility, plans and arrangements for managing safety, construction of the facility, final safety analysis, operating limits and conditions, arrangements for commissioning, and arrangements for operation. In assessing the application, ARPANSA took into account relevant design and operational aspects of the proposed facility. This included the production process, waste generated, and similar practices in other countries. ARPANSA's assessment also considered the matters identified in the assessment of the siting and construction licence applications that were required to be addressed in the licence application to operate the facility.

Considering the plans and arrangements for managing safety, and the safety analysis, it is expected that the proposed ANM Facility at the ANSTO Lucas Heights Science and Technology Centre (LHSTC) will not result in the introduction of any significant risks.

ARPANSA's assessment has identified some areas where results of routine operational experiences and hot commissioning are required to enhance the safety and to further reduce the risks in operation of the facility, and to demonstrate the effectiveness of the items important for safety. The ARPANSA assessor has recommended relevant licence conditions to address these areas.

The ARPANSA assessor finds that the application has satisfactorily addressed the matters that must be taken into account by the CEO of ARPANSA in deciding whether to issue a facility licence. He concludes that, based on the application, the facility may be operated without undue risk to the health and safety of people and the environment

The ARPANSA assessor recommends that the CEO of ARPANSA issue a facility licence to ANSTO authorising the operation of the proposed facility subject to the licence conditions set out in section 5.1 of this report. The ARPANSA assessment concludes that:

- the facility is constructed in accordance with the design approved in the construction licence (F0285) and subsequent approval of construction of items important for safety under regulation 54
- the results of the assessment of design, testing and cold commissioning show that the facility structure, systems and components important for safety during normal operation are inherently safe, and design objectives have been achieved. The results also show that the facility can be operated safely without undue risk to the health and safety of people and the environment
- the plans and arrangements for managing safety including operating arrangements, qualified and trained personnel, and security provisions are adequate to ensure safe and secure operation of the facility
- the radiological consequences from a broad spectrum of postulated reasonable accidents will not have any significant impact outside the facility. However, the reference accident i.e. the most conservative accident (design extension conditions) would have radiological consequences outside the facility within the site but no off-site consequences
- the operating limits and conditions, derived from the safety analysis, defining the safety envelope of the facility, are such that there is reasonable assurance that the facility will be operated safely and reliably
- there is reasonable assurance that the magnitude of the individual doses, the number of people exposed and the likelihood that exposure will happen during operation of the facility will be as low as reasonably practical
- there is reasonable assurance that the licence holder has the capacity to comply with the regulations and relevant licence conditions
- the applicant has demonstrated that there is net benefit from the proposed conduct, that is, the benefit outweighs the detriment of exposure to radiation
- international best practice has been applied to the design and construction, and operating arrangements for the facility.

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1. Introduction

The applicant, Australian Nuclear Science and Technology Organisation (ANSTO) has applied for a facility licence under section 32 of the Australian Radiation Protection and Nuclear Safety Act 1998 (the Act) [1] to operate the nuclear installation known as the ANSTO Nuclear Medicine (ANM) Facility.

The ANM is a nuclear installation as defined in regulation 11 of the Australian Radiation Protection and Nuclear Safety Regulations 1999 (the Regulations) [2] and further described in Item 24 in Schedule 3A of the Regulations.

1.1 Application

In accordance with the requirements of the Act, the CEO of ANSTO submitted an application for a facility licence on 7 April 2017. The application is in an acceptable form and the prescribed application fee has been received.

As required by regulation 40, the CEO of ARPANSA published a notice in The Australian newspaper and in the Australian Government Gazette (C2017G00473) on 28 April 2017, notifying the receipt of a facility licence application from ANM Pty Ltd and of his intention to make a decision on the application.

On 22 June 2017, ARPANSA organised a community information session to

- outline the process ARPANSA will use to assess and decide the application including the way in which the Agency seeks and takes into account public submissions
- inform the community of the nature and details of the application
- address issues raised through public submissions
- record any further issues that may arise from this session as new submissions.

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

1.2 Scope and purpose of the RAR

This Regulatory Assessment Report (RAR) includes the assessment of the information contained in the licence application to operate the ANSTO Nuclear Medicine Facility.

The purpose of this report is to document the assessment of information contained in ANM Pty Ltd.'s application against the requirements of the Act and Regulations, and to make recommendations to the CEO about a decision on the application. This document summarises the results of the regulatory assessment of the ANM facility by verifying that the facility has been constructed in accordance with the design approved through Facility Licence F0285 followed by approval of construction of items important for safety under regulation 54 [2].

Consideration is given to the matters to be taken into account by the CEO under section 32(3) of the Act [1], that is, international best practice in radiation protection and nuclear safety, and those matters set out in regulations 39 and 41 [2].

1.3 Regulatory assessment process

The ARPANSA assessment takes into account the following:

- the information contained in the initial application (Appendix 1)
- information obtained from the applicant following receipt of the application
- meetings and discussions with the applicant
- content of the public submissions
- other documents referred to in the body of this report
- results of site visits and inspection (Appendix 2)

The above information has been assessed against the requirements of the Act [1] and Regulations [2] and applicable international standards and guidance referred to throughout this report. Under the Act [1] and the Regulations [2], the licence holder must develop and follow their own plans and arrangements for managing safety. This requirement is consistent with Principle 1[1] of the International Atomic Energy Agency's Fundamental Safety Principles SF-1 [3]. ARPANSA *Regulatory Guide: Plans and arrangements for managing safety* [4] describes regulatory expectations in developing the plans and arrangements for managing safety.

Considering that the ANM Facility is akin to a fuel cycle facility, the submitted information has also been assessed against the relevant requirements for Safety of Nuclear Fuel Cycle Facilities, SSR-4 [5].

The assessment has mainly been performed by the assessors of Regulatory Services Branch. ARPANSA assessors possess high-level technical competency and extensive experience in technical assessment, inspection and compliance monitoring of a wide range of nuclear facilities including research reactors, spent fuel management and radioactive waste management facilities and radioisotope production facilities. Further, the ARPANSA lead assessor possesses operating experience in such facilities.

Expert advice has also been obtained in specific areas from other Units of ARPANSA as required. Such areas include emergency arrangements, modelling of accident analysis and legal advice. Since the application is for operating a nuclear installation, the content of public submissions has been included in the assessment. During the assessment process, ARPANSA maintained an open and transparent communication process to receive and provide information in accordance with ARPANSA's communication policy.

The ARPANSA assessment has also been subject to independent review by the Nuclear Safety Committee, which provides independent advice to the CEO of ARPANSA on nuclear safety matters in accordance with section 26 of the Act [1]. ARPANSA's regulatory process is subject to international peer review such as the IAEA IRRS[2] (Integrated Regulatory Review Service) mission.

ARPANSA's assessment and regulatory process utilises expert advice, internal independent review, use of content of public submissions and international independent review, which demonstrates that the ARPANSA's regulatory system is based on multiple layers and components. These multiple layers describe the regulatory Strength-in-Defence (SiD) system in accordance with international best practice [6]. Due to these multiple layers and components for the regulatory SiD system, ARPANSA assessment process ensures a robust institutional strength in depth (ISiD) embedded into ARPANSA's regulatory process. Similar

[1] Principle 1: Responsibility for safety

'The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risk'.

[2] There was a full-scope IAEA IRRS Mission to Australia in 2007 and a follow-up mission in 2011 to review ARPANSA's regulatory process. Another full-scope IAEA IRRS mission will be held in November 2018.

approach has been applied to assess whether the applicant has a robust ISiD in place and that the public, society and the environment is secured at all times. Details of ARPANSA's assessment are presented in the following sections.

2. Review and assessment of specific aspects of safety of operations

This section describes the review of information provided in the application and subsequently received from the applicant.

2.1 General information and purpose of the facility

Dr Adrian Paterson, Chief Executive Officer of ANSTO, made the application on behalf of ANSTO. ANSTO is part of the Department of Industry, Innovation and Science Portfolio. Ms Jayne Senior, General Manager, ANSTO Nuclear Medicine, is named as the nominee. The required information was provided about the applicant's Radiation Safety Officer.

The facility is located at Lucas Heights Science and Technology Centre, Lucas Heights, NSW.

Purpose of the facility

The proposed facility will be used for the large-scale production (about twice the current production level) of molybdenum-99 (Mo-99) from low enriched uranium (LEU) targets irradiated at the OPAL reactor. Technetium-99m (Tc-99m), the daughter of Mo-99, is currently used in about 80% of all nuclear medicine procedures. ANSTO states that the proposed ANM Mo99 Facility will be an export scale nuclear medicine manufacturing plant, which will secure Australia's ability to produce Mo-99 and increase capacity to meet a significant proportion of the world's needs.

Conclusion

The general information and the purpose of the facility described in the application provide a suitable general account of the facility.

2.2 Description of the facility and its site

The facility is a purpose-designed facility for extraction of Mo-99 from LEU targets irradiated at the OPAL reactor. The key systems and features of the facility include:

- hot cells for the processing of Mo-99 including for dissolution, purification, dispensing and packaging
- waste management systems for solid, liquid and gaseous wastes generated from the operation of the facility
- process control systems
- a control room housing the process control and building monitoring systems
- a truck bay and crane for deliveries, despatch and removing waste and a plant room housing main switchboards, plant and equipment
- ventilation systems to supply clean air to and extract potentially contaminated air from production equipment and areas
- laboratory activities which will integrate with the existing laboratories on site
- storage areas and active maintenance areas.

The main operational areas will be on the ground floor. The basement level of the building is reserved for an off-gas management system. The mezzanine floor will have an air-handling plant, some process related equipment, instrumentation and control cabinets and the communication room.

The quality control (QC) laboratory, although located separately, is considered part of the ANM facility because product samples from the ANM facility will be checked for QC in this laboratory. The QC laboratory is in an existing building (Building 2, B2) that was refurbished in 2010 for use as a dedicated active QC laboratory. Building fixtures were replaced during the refurbishment to meet Building Code of Australia standards and the technical specifications for the active QC laboratory. The dedicated B2 active laboratory ventilation system has been designed to the requirements of the ANSTO Active Ventilation Manual, which is also applied across the site for other facilities dealing with radioactive material. This laboratory has not previously been under an ARPANSA facility licence held by ANSTO.

Structures, systems and components of the facility are described in section 2.3.1.

The facility is within ANSTO's main fenced site at Lucas Heights, NSW, in the reactor precinct near the existing OPAL research reactor. Details of site characteristics were assessed for the siting licence, and the ARPANSA assessment concluded that characteristics affecting, or potentially affecting the facility and the effects that the facility has, or may have, on its surroundings were adequately addressed. The results of that assessment have been recorded elsewhere (R13/10687).

Conclusion

The facility description includes the location of the facility, the layout and main components comprising the facility and the operating envelope of the facility. The ARPANSA assessor considers that the description of the facility is adequate in terms of the site, engineering, infrastructures, and processes involved in the operation of the facility.

2.3 Information for authorisation to operate

2.3.1 A description of the structure, components, systems and equipment of the controlled facility as they have been constructed

Structures, components, systems and equipment include the items important for safety. All items important for safety have been classified on the basis of their safety functions and their safety significance as required by international standards [5]. Details of the classification of the items important for safety were documented in the Preliminary Safety Analysis of the facility, and were assessed in granting the construction licence for the facility (F0285). The classification of the items important for safety was mainly based on the operating experience in the current Mo-99 production facility, and on probabilistic analyses where appropriate. In classifying the items important for safety the following factors have been considered:

- safety functions to be performed by the item
- the consequences of failure to perform a safety function
- the time following a postulated initiating event at which, or the period for which, the item will be called on to perform a safety function.

Considering the safety significance of structures, systems and components, twenty-nine (29) items were identified as items important for safety. These items were grouped into fourteen requests for approval (RFA) under regulation 54 of the Regulations [2].

ID	Description	Sub-systems
RFA01	Basement shielding – decay tanks and enclosures, HEPA/SIAMs/Shielding; concrete walls, floor and roof shielding	As described in column 2
RFA02	Liquid waste decay tank system shielding – basement low level liquid waste system/shielding/containment; outside decay tanks and enclosures/shielding containment	As described in column 2
RFA03	Concrete shielding for dissolution hot cell, hydrogen conversion hot cell and solid waste (intermediate level and low level) hot cells	As described in column 2
RFA04	Lead shielding for purification hot cell, evaporation hot cell, dispensing hot cell, packaging hot cell and in-process sampling hot cell	As described in column 2
RFA05	Rear of cells crane	-
RFA06	Other cranes	-
RFA07	Ground floor shielding	• Container handling and despatch (all rooms) /shielding • Quality control laboratory, retention samples and other dose area/shielding • Intermediate level liquid waste (ILLW)) valve room/ shielding

ID	Description	Sub-systems
RFA08	Hot cell (HC) and liquid waste containment system (CS)	• Dissolution HC/CS • Hydrogen converter HC/CS • Purification HC/CS • Evaporation HC/CS • Dispensing HC/CS • Solid waste HC/CS • Other hot cell/CS • ILLW/CS • Low level liquid waste (LLLW)/CS
RFA09	Active ventilation system	• Process off-gas extraction subsystem (dissolver and hydrogen converter off-gas extraction) • Service hot cell extraction subsystem • Hydrogen converter hot cell extraction subsystem • Containment box extraction subsystem
RFA10	Remaining shielding elements	• Dissolution hot cell shielding • Purification hot cell shielding • Flask shielding • PADIRAC cask shielding • Basement concrete walls, floor and roof shielding
RFA11	Radiation monitoring system	
RFA12	Process containment (PC)	• Dissolution HC/PC Process control (related to dissolver, hydrogen converter, gas delay tanks, Hydrogen detection)
RFA13	Safety interlocking system	Flasks, PADIRAC, B(U) containers/interlocks
RFA14	Criticality assessment	-

RFA01: Basement Shielding – decay tanks and enclosures, HEPA/SIAMs/shielding; concrete walls, floor and roof shielding

RFA 01 addresses the gaseous and liquid waste management systems incorporating the following structures/components:

- carbon columns
- active ventilation SIAM filters

- active ventilation HEPA filters
- as delay tanks
- SIAM filters
- ILLW holding tank
- LLLW holding tank

The carbon columns, SIAM and HEPA filtration systems are connected to the Active Ventilation System (AVS) to control the gaseous and particulate emission for safe operation of the facility. Details of the AVS are described below.

Gaseous waste containment system: Operation of the ANM facility will generate fission gases. There are two sets of gas decay tanks. One set of gas decay tanks each of 120 L capacity is for dissolver off-gas storage and the other set of gas decay tanks each of 160 L capacity is for filtration off-gas storage prior to their release through the AVS red primary exhaust. One of the gas decay tanks for dissolver off-gas is dedicated at any point in time as a pressure relief tank and is connected directly from the dissolver vessels via bursting discs rated at 1050kPa; without any valves in between to ensure process containment is maintained in the event of a dissolver over-pressure. The tanks are pressure vessels and are designed and constructed to AS 1210 class 1 requirements. After a suitable decay period, the gases are pumped out using a vacuum pump and passed through carbon columns before release to atmosphere via the stack.

Liquid waste containment system: Operation of the ANM facility will ILLW and LLLW. These wastes will be contained in an appropriately designed containment system as described below:

ILLW holding tanks: Intermediate level liquid waste produced from the dissolution process will be transferred from the hot cell to a dedicated ILLW temporary holding tank. Following a decay period of at least two weeks in the holding tank, the ILLW will be transferred to ILLW decay tanks. The tanks are made from 316L stainless steel. The tanks form the containment boundary. The ILLW holding tanks have bunds to contain any leakage (up to the full volume of the tank). The bunds will be provided with a leak detection system and piping to allow sampling and recovery of any leaked fluid.

LLLW holding tanks: Low level liquid waste resulting from the purification process of Mo-99 product will be transferred from the hot cells to a dedicated LLLW temporary holding tank. Following a decay period of at least two weeks the LLLW will be transferred to the LLLW decay tanks. The tanks are made from 316L stainless steel. The LLLW holding tanks have bunds to contain any leakage (up to the full volume of the tank). The bunds will be provided with a leak detection system and piping to allow sampling and recovery of any leaked fluid.

The liquid and off-gas management systems are located in the basement of the building. In approving this RFA, the shielding of these structures, systems and components was modelled using the computer code Microshield which was used to estimate the dose taking into account the following aspects:

- suitable source terms and geometry
- selection of shielding materials
- build up factors.

Considering the safety function of this system during routine operation of the facility the dose-rate design objectives at appropriate locations were calculated for construction purposes. During construction, specifications of structural materials were verified. Following construction, dimensions of shielding were measured and verified. As part of testing and commissioning, achievement of the dose-rate design objectives was verified by measuring the dose rates at strategic locations using appropriate radiation sources, and by examining specifications of the structural materials. ARPANSA's assessment on whether the design objectives have been achieved are discussed below in this section (p34- 40).

RFA 02: Liquid waste Decay Tank System Shielding – basement low-level liquid waste system/shielding/containment; outside decay tanks and enclosures/shielding containment

RFA 02 addresses the construction of Liquid Waste Decay Tank System Shielding and includes the following structures/components:

- liquid waste decay tanks (ILLW and LLLW)
- pipelines to the liquid waste decay tanks
- pipeline to SyMo
- valve and sampling room
- pipeline from the hot cells to the holding tanks.

The ILLW will be transferred to temporary holding tanks and will be allowed to decay for about two weeks followed by transfer to the ILLW decay tanks where the ILLW will be allowed to decay for a minimum of two years. Then the decayed ILLW will be transferred using vacuum suction to the SyMo facility [note: SyMo facility is currently under siting and construction licence, F0266] for further treatment. The LLLW will be transferred from the hot cell to temporary holding tanks for decay for at least two weeks. Then the LLLW will be transferred to the LLLW decays tanks. After appropriate decay the LLLW will be transferred to ANSTO Waste Operations for treatment, which is operating under Facility Licence F0260.

The decay tanks are located in a designated area outside the building but within the perimeter of the facility. The main structural material for shielding is normal density and medium density concrete. Lead is used for outside shielding around pipelines from hot cells (ground floor) to holding tanks (basement) (for maintenance access). Similar to RFA 01, computer code Microshield was used to estimate the dose rates at appropriate locations taking into account the following factors:

- suitable source terms and geometry
- selection of shielding materials
- build up factors.

Considering the safety function of this system, the dose-rate design objectives at appropriate locations were calculated for construction purposes. During construction, it was verified that structural materials met

the specifications. Following construction, dimensions of shielding were measured and verified. As part of testing and commissioning, achievement of the dose-rate design objectives was verified by measuring the dose rates at strategic locations using appropriate radiation sources, and by examining specifications of the structural materials. ARPANSA's assessment on whether the design objectives have been achieved are discussed below (p 27–33).

RFA 03: Concrete hot cells

RFA 03 addresses the construction of hot cells for the following structures/components and/or processes:

- dissolver hot cell shielding
- hydrogen converter hot cell shielding
- intermediate level solid waste (ILSW) hot cell shielding
- low level solid waste (LLSW) hot cell shielding.

Dissolver hot cell: The dissolver hot cell will house the dissolver where the irradiated target will be dissolved for processing Mo-99.

Hydrogen converter hot cell: The function of the hydrogen converter hot cell will be to condition the target dissolution process off-gas stream flowing from the two adjacent dissolution hot cells.

ILSW hot cell: The ILSW hot cell will have the function of providing storage, handling and transfer of longer lived solid wastes generated during the dissolution and purification processes. Wastes generated in the Dissolver Hot Cell will be transferred via the PADIRAC system to the Intermediate Level Waste Hot Cell.

LLSW hot cell: The LLSW hot cell will have the function of providing storage, handling and transfer of the shorter-lived solid wastes generated during the Mo-99 processing operations. Wastes generated in the evaporation and dispensing hot cells will be transferred via the PADIRAC system to the low level waste hot cell.

High-density concrete was used as shielding material and lead glass was used for cell windows for construction of these concrete hot cells.

The dose rates at appropriate locations were estimated by applying computer code Microshield. The following factors were considered for estimation of doses:

- suitable source terms and geometry as input data
- selection of shielding materials
- build up factors.

Considering the safety function of these hot cells, the dose-rate design objectives at appropriate locations were calculated for construction purposes. During construction, it was verified that structural materials met specifications. Following construction, dimensions of shielding were measured and verified. As part of testing and commissioning, achievement of the dose-rate design objectives was verified by measuring the dose rates at strategic locations using appropriate radiation sources, and by examining specifications of the structural materials. ARPANSA's assessment on whether the design objectives have been achieved are discussed below (p 27–33).

RFA04: Lead hot cells

The following processes will be undertaken in lead hot cells:

- purification
- evaporation
- dispensing
- packaging
- in-process sampling.

Purification hot cell: The eluate from the resin columns in the dissolution hot cell will be subject to chemical processing for purification. The purified Mo-99 solution will be transferred to the evaporation hot cell.

Evaporation hot cell: The Mo-99 eluate from the purification hot cell will be transferred to the Evaporation Hot Cell for evaporation. After evaporation to dryness, the Mo-99 residue will be reconstituted to form the final active pharmaceutical ingredient (API). This final solution will be transferred to the adjacent dispensing hot cell.

Dispensing hot cell: The reconstituted Mo-99 API solution from the evaporation hot cell will be transferred into the dispensing hot cell for measurement and calculation of the specific activity. The solution will then be returned to a stock storage bottle in the Evaporation Hot Cell. QC samples will be dispensed as required for each batch and transferred via PADIRAC to the rear cell area. These samples will then be transported to the QC laboratory (B2) for analysis.

Packaging hot cell: This hot cell will house the packaging equipment for loading the assembled product into the depleted uranium shielded transport container.

In-process sampling hot cell: This hot cell will provide a work area for sampling and diluting of the in-process product samples as required. It will have a posting port for transfer of sampling equipment and containers into and out of the cell. The in-process sampling cell will be used for extracting samples from different stages of the process. These samples generally require dilution before the resultant solution can be transferred to the active chemical/instrument laboratories for analysis.

The cells are constructed from lead cased in stainless steel and the bottoms of the cells are constructed from standard density concrete. Lead glass is used for the cell windows.

The computer code Microshield was utilised to model the dose rates at appropriate locations for construction of these hot cells. For estimation of the dose rates, the following factors were taken into account:

- suitable source terms, geometry
- selection of shielding materials
- build up factors.

Considering the safety function of these hot cells, the dose-rate design objectives at appropriate locations were calculated for construction purposes. Specifications of structural materials were verified during construction. Following construction, dimensions of shielding were measured and verified. As part of

testing and commissioning, achievement of the dose-rate design objectives was verified by measuring the dose rates at strategic locations using appropriate radiation sources, and by examining specifications of the structural materials. ARPANSA's assessment on whether the design objectives have been achieved are discussed below (p 27–33).

RFA 05: Rear of cells crane

A 12 tonne dangerous goods rated (DGR) rear of cell overhead gantry crane will be used to undertake the following operations:

- load the target flask containing irradiated uranium targets from the transfer truck arriving in the loading dock to the dissolver hot cell via the mezzanine floor hatch
- move the empty target flask from the top of the dissolver hot cell to the truck in the ground floor loading dock, via the mezzanine floor hatch
- move the retrievable waste flask from the top of the ILSW hot cell via the ground floor hatch to the basement loading dock
- move the plant items for maintenance from the ground floor rear of cell via the ground floor hatch to the basement loading dock
- move PADIRAC casks between hot cell rear doors
- remove the top plug/lid of all hot cells and then lower to ground level to allow maintenance work to be carried out in the hot cells
- remove the hot cell containment box from the lead hot cells and lower to ground floor level
- move the spent uranium filter (SUF) flask from the top of the ILSW hot cell via the ground floor hatch to the basement loading dock.

During construction, materials and components specifications were verified. As part of testing and commissioning the design objectives were verified by load tests and by using the target transfer flask, the ILSW retrievable flask and the SUF flask. ARPANSA's assessment on whether the design objectives have been achieved are discussed below (p 27–33).

RFA 06: Other cranes

This RFA addresses 14 cranes and hoists. The cranes and hoists will be used for the following operations:

- packing cell fixed hoist: It will be used to lift the lid onto the package
- ILW cell hoist mounted on a cantilevered beam: The in-cell hoist will be used to lift waste bins, containing waste material, into a retrievable bin
- cantilevered beam wall mounted hoists (JCR-01-04): A& B will be used for lifting B(U) containers; C&D will be for lifting BU containers containing radioactive material on and off the conveyor
- front of cell crane (GCR-02): The front of cell crane will be used during hot cell maintenance to remove the manipulators for planned/breakdown maintenance and lower to the ground floor front of the cell area
- MR-01: This will include three monorails with each having their own individual hoist that will be used for installation or removal of the three contaminated LLW/ILW empty liquid waste system

tank-shielding lids and components in the case of maintenance from the shielded enclosure into the corridor for transport

- MR-02: Carbon columns monorails hoists will be used for carbon columns installation and maintenance
- MR-03: Level 1 plant room monorail hoist will be used to load or remove plant and equipment from the plant room and to externally load the components on a truck in the external loading dock
- MR-04: Maintenance room monorail hoist will be used to load or remove process plant from trolleys, i.e. such as manipulators for maintenance
- MR-05: Rear of cell monorail hoists will be used to install or remove hot cell inner containment boxes in the concrete hot cells in the case of deep maintenance
- JCR-01 and JCR-04: These jib cranes will be used to move the B(U) flasks from the conveyor system coming out of the dispatch room to a pallet on the ground floor of the loading dock in preparation for loading into a truck. These cranes will also be used to move the returned empty BU flasks from a trolley in the Receipting Room on to the conveyor system in the receiving room
- JCR-02: This jib crane will be used to move the empty type B(U) flasks from the conveyor system in the dispatch room to trolleys to take the B(U) flasks to the packaging hot cell. This crane will also be used to move the B(U) flasks with the product from the trolley with the B(U) flask coming back from the dispensing hot cell and to load the B(U) flask onto the conveyor system in the dispatch room
- JCR-03: This jib crane will be used to move the empty B(U) flasks from the conveyor system in the container handling cleaning room to trolleys for cleaning the flask, and to move the empty B(U) from the trolley with the B(U) flask coming back from the cleaning process. This crane will also be used to load the B(U) flask onto the conveyor system in the container handling cleaning room.

During construction, materials and components specifications were verified. As part of testing and commissioning, achievement of the design objectives was verified by load tests including the use of the Type B(U) flask. ARPANSA's assessment on whether the design objectives have been achieved are discussed below (p 27–33).

RFA 07: Ground floor shielding

The ground floor shielding relates to the following structures, systems and areas:

- liquid waste sampling hot cell
- valve room
- helium leak station
- pallet loading storage station
- dispatch area
- receipting area
- active ventilation plant room filters
- rear of cells areas
- maintenance room, lead castle

- blue waste storage room
- ventilation stack.

Liquid waste sampling hot cell: The function of this hot cell will be to provide the means to sample the waste stored within the ILLW and LLLW storage system. Liquid wastes will be subjected to analysis for uranium content. The shielding material for this hot cell is lead.

Valve room: The valve room contains the process valves controlling the operation of the ANM liquid waste system. This system conveys liquid waste from the hot cells to the decay tanks in the storage bunker, as well as allowing transfers for processing or removal of the waste. This room is shielded with thick concrete walls, and while it has access available for maintenance purposes it will be unoccupied during active fluid transfers.

Helium leak test station: The helium leak test station is located in the production cell face room near the despatch area, and provides a staging point for testing the B(U) package for leaks. The test apparatus is located behind an operator shield.

Pallet loading storage station: Shielded product containers may be stored on storage pallets in the truck air lock room whilst awaiting transport. This is a designated area which has three shielded walls, and the other open to the truck bay for access.

Dispatch area: The transport index station is located within the dispatch room. In this area, the product removed from the packaging hot cell will be placed prior to sending out for transport via the truck air lock.

The final production station is on the boundary of the dispatch room and the truck air lock, and is a holding point prior to loading of assembled pots prior to dispatch.

Localised lead shielding will be in place at each point in the assembly and dispatch process to protect operators. Further, concrete walls around the area will provide shielding to the rooms adjacent to the transport index station.

Receipting area (room): The receipting room will be used to receive packages on return from the customers. The area provides a hold point for documentation processes, prior to handing over to the container handling cleaning rooms for processing of the B(U) containers.

Active ventilation plant room filters: The gaseous wastes generated from the processing of irradiated targets will be passed through combinations of HEPA and SIAM filters, located in the active ventilation plant rooms, to remove particulates and any radioiodine. Gaseous wastes will also be passed through carbon columns to control the release to the environment.

The banks of HEPA filters servicing the secondary active ventilation system are located in the plant rooms.

Rear of cells area: The rear of cell area will be used for the transfer of materials into and out of the hot cells, for some maintenance activities, and for storage of cell components.

Maintenance room, lead castle: Maintenance on activated or contaminated equipment will be conducted in the active maintenance area. The active objects will be temporarily stored in a lead castle in this room.

Blue waste storage room: Low level solid waste from outside the hot cells will be placed in ANSTO standard plastic drums and stored in the Blue Waste room. This room is adjacent to the truck airlock, and provides convenient interface location for ANM and Waste Operations crews.

Ventilation stack: The gaseous wastes passing through the filter banks will be discharged via the stack. The stack will be continuously monitored for activity as part of the environmental monitoring program. The

stack is associated with the plant rooms, and is adjacent to the active ventilation plant room, outside of the building structure.

The materials used for construction of shielding include stainless steel lining, lead, lead glass, standard and medium density concrete as required.

Computer code Microshield was used to model the dose rate at appropriate locations for construction of the structures and systems described above. The dose rate calculations have considered the following:

- suitable source terms and geometry as input data
- selection of shielding materials
- build up factors.

The calculated dose rates include the contact dose rate on the outer layer of shielding and the dose rate at a distance from shielding as required.

Considering the safety function of the ground floor shielding, the dose-rate design objectives at appropriate locations were calculated for construction purposes. During construction, structural materials' conformance to specifications were verified. Following construction, dimensional correctness, correctness of concrete, and short-path were measured and verified. As part of testing and commissioning, achievement of the dose-rate design objectives was verified by measuring the dose rates at strategic locations using appropriate radiation sources and by examining specifications of the structural materials. ARPANSA's assessment on whether the design objectives have been achieved are discussed below (p 27 – 33).

RFA 08: Hot cell and liquid waste containment system

The hot cell and liquid waste containment system comprises the following structures, systems and components:

- dissolution hot cell
- purification hot cell
- evaporation hot cell
- dispensing and packaging hot cell
- hydrogen converter hot cell
- in-process sampling hot cell
- ILSW hot cell
- LLSW hot cell
- liquid waste sampling hot cell
- ILLW holding tanks
- ILLW decay tanks
- LLLW holding tanks

- LLLW decay tanks.

Each hot cell consists of two fundamental parts:

1. An inner containment box fabricated from 316 L stainless steel (9.52 mm thick for the dissolution, hydrogen converter, ILSW and LLSW hot cells, and 4.74 mm for all other hot cells)

2. A structurally independent gamma ray biological shield structure assembled from high density concrete, lead, steel or a combination of these materials.

The clear separation of containment and shielding functionality allows the containment box to be modified or, if necessary, even replaced. The containment boxes and biological radiation shielding are designed and constructed structurally independent of one-another to enable future exchange or modification of the containment boxes. The containment boxes are sealed to minimise the likelihood of leakage of contamination. This also reduces the quantity of air needed to be extracted through the ventilation systems to achieve a set pressure depression.

Dissolution hot cell: The targets irradiated at OPAL will be dissolved in a dissolver placed in the dissolution hot cell for processing of Mo-99. Gases generated during the dissolution process are cooled in a vapour condenser and all non-condensable gases, mainly hydrogen and noble gases are passed to the adjacent hydrogen conversion hot cell. The Mo-99 solution will be transferred to the purification hot cell for further processing.

The ILLW generated during processing of Mo-99 will be transferred under gravity to dedicated liquid waste holding tanks located below the cells in the basement area. The ILSW including SUF cups generated from processing of Mo-99 will be transferred to the ILSW hot cell after a certain period of decay.

The dissolution hot cell is designed to provide containment of the airborne radioactive materials released from any residual or spilt solid and liquid radioactive materials during the production runs. The nominal operating pressure for the dissolution cell is –500 Pa. The dissolution hot cell includes a top loading port to transfer the irradiated targets using a transfer flask.

Purification hot cell: The Mo-99 solution from the dissolution hot cell will be purified in this hot cell. The LLLW generated from the purification process will be transferred under gravity to liquid waste holding tanks located below the hot cells. The purification hot cell is designed to provide containment of the airborne radioactive materials and the nominal pressure for operating this hot cell is -400 Pa.

Evaporation hot cell: The Mo-99 solution from the purification hot cell will be transferred to the evaporation flask where the purified Mo-99 solution is evaporated to dryness. The Mo-99 residue will be reconstituted to form the final active pharmaceutical ingredient. The evaporation hot cell is designed to provide containment of the airborne radioactive materials released from any residual or spilt liquid radioactive materials. The nominal operating pressure for the evaporation cell is –350 Pa.

Dispensing and packaging hot cell: The reconstituted Mo-99 solution from the evaporation hot cell will be transferred to the dispensing hot cell for measurement of activity. The dispensing and packaging hot cell is designed to provide containment of the airborne radioactive materials released from any residual or spilt liquid radioactive materials. The nominal operating pressure for the dispensing cell is –300 Pa.

The nominal operating pressure for the packaging hot cell is -350 Pa. The hot cell includes a bottom loading port to allow the product out of the hot cell line via a type B(U) transport container. This port is used through an interlock system.

Hydrogen converter hot cell: The hydrogen converter unit is placed in this hot cell and process off-gas from the dissolver from the adjacent dissolution hot cell will be passed through the hydrogen converter for conditioning. After the dissolution is complete, the hydrogen converter vessel will be isolated from the process line. The hydrogen converter hot cell is designed to provide containment of the airborne radioactive materials released from any residual or spilt gaseous or liquid radioactive materials during the production runs, and of routine emissions generated during the regeneration of hydrogen converters. The nominal operating pressure for the dissolution cell is –400 Pa. The hydrogen converter hot cell includes a top loading port to allow hydrogen converters to be removed from the hot cell for maintenance.

In-process sampling hot cell: The in-process sampling hot cell will provide a work area for sampling and diluting of the in-process product samples as required. The transfer of sampling equipment and containers into and out of this sealed hot cell will be via the rear of cell utilising the PADIRAC transfer system. The in-process sampling hot cell is designed to provide containment of the airborne radioactive materials released from any residual or spilt liquid radioactive materials during the sampling process. The nominal operating pressure for the in- process sampling hot cell is –200 Pa.

ILSW hot cell: The ILSW hot cell will be used for storage, handling and transfer of longer lived solid wastes generated during the dissolution and purification processes. Wastes generated in the dissolution hot cell will be transferred via the PADIRAC system to the ILSW hot cell. There will be no processing of materials in this cell. The ILSW hot cell is designed to provide containment of the airborne radioactive materials released from any residual contamination or spilt liquid radioactive materials on the spent uranium filter cups, or other solid waste from the dissolver hot cell. The nominal operating pressure for the ILSW cell is -200 Pa. This hot cell includes a top loading port for using SUF flask and the removable waste bin flask.

LLSW Hot Cell: The LLSW handling hot cell will be used for storage, handling and transfer of the shorter-lived solid wastes generated during the Mo-99 processing operations. Wastes generated in the Evaporation and Dispensing hot cells will be transferred via the PADIRAC system to the LLSW hot cell. There will be no processing of materials in this cell. The LLSW hot cell is designed to provide containment of the airborne radioactive materials released from any residual contamination or spilt liquid radioactive materials on the solid waste from the non-dissolver or purification hot cells. The nominal operating pressure for the dissolution cell is –200 Pa.

Liquid waste sampling hot cell: This hot cell will provide the means to safely sample the waste stored within the ILLW and LLLW storage system. The liquid waste sampling hot cell is designed to provide containment of the airborne radioactive materials released from any residual contamination or spilt liquid radioactive materials from the sampling of the liquid waste decay tanks. The nominal operating pressure for the liquid waste sampling hot cell is –120Pa.

ILLW holding tanks: The ILLW produced from the dissolution process will be transferred from the hot cell to a dedicated ILLW temporary holding tank. Following a decay period of at least two weeks in the holding tank, the ILLW will be transferred to ILLW decay tanks. There are three ILLW holding tanks of 1700 L capacity each. The tanks are made from 316 L stainless steel. The tanks form the containment boundary. Each tank has a pair of valves connected to them, a pressure relief valve and a vacuum break valve to ensure the internal pressure of the tanks does not exceed the design pressure limits of -20k Pa to +45 kPa. The non-tank side of these valves is connected to the active ventilation lines between the dissolution cells and the first stage iodine absorption filters. The ILLW holding tanks have bunds to contain any leakage (up to the full volume of the tank). The bunds will be provided with a leak detection system and piping to allow sampling and recovery of any leaked fluid.

ILLW decay tanks: The ILLW will be stored in the decay tanks for a minimum period of two years before transferring to the SyMo facility for conditioning the ILLW into immobilised form. The SyMo Facility is under construction (F0266). There are four tanks of 7200 L capacity each. The tanks are made from 316 L stainless steel and they form the containment boundary. The tanks are double-skinned to ensure that in the event of a failure of the inner tank, the liquid will be contained. The outer skin will have a system of detecting liquid within it. These tanks are contained within a concrete bunker, designed to provide both shielding and an additional layer of containment, which also has a liquid detection system.

LLLW holding tanks: The LLLW resulting from the purification process of Mo-99 product will be transferred from the hot cells to a dedicated LLLW temporary holding tank. Following a decay period of at least two weeks the LLLW will be transferred to the LLLW decay tanks. There are three LLLW holding tanks of 1590 L capacity each, which are made from 316 L stainless steel. Each tank has a pair of valves, a pressure relief valve and a vacuum break valve. These valves are to ensure the internal pressure of the tanks does not go beyond the design pressure limits of -20k Pa to +45 kPa. The non-tank side of these valves is connected to the active ventilation lines between the dissolution cells and the first stage iodine absorption filters. The LLLW holding tanks have bunds to contain any leakage (up to the full volume of the tank). The bunds will be provided with a leak detection system and piping to allow sampling and recovery of any leaked fluid.

LLLW decay tanks: The LLLW will be stored in the decay tanks prior to transfer to ANSTO Waste Operations for treatment. There are three identical decay tanks of 7200 L capacity made from 316L Stainless Steel. The tanks are pressure vessels and are designed and constructed to AS 1210 class 1 requirements. The tanks are double skinned to ensure that in the event of a failure of the inner tank, the liquid will be contained. The outer skin will have a system of detecting liquid within it. These tanks are contained within a concrete bunker, designed to provide both shielding and an additional layer of containment, which also has a liquid detection system.

Considering the safety function of the hot cell containment system and liquid waste containment system the design objectives in terms of the functionality of the containment system including pressure tests, use of correct structural materials and dimensional correctness were examined. ARPANSA's assessment on whether the design objectives have been achieved are discussed below (p 27 – 33).

RFA 09: Active ventilation system

There are three separate active ventilation systems treating radiological classified areas. Each of these has a dedicated supply air system. There are also non-radiation 'white' support areas that have separate conventional air-conditioning and ventilation systems. All systems operate continuously.

The hot cells are classified red for contamination and have a ventilation system categorised as "'primary' as radioactive contamination is a normal occurrence. The rear of cells area is also classified as a red area, but the ventilation is classified as 'secondary' as radioactive contamination is an abnormal occurrence. The blue ventilation system operates in a similar principle to the red secondary but capturing exhausts from blue classified areas. Therefore, the active ventilation system comprises red/primary, red/secondary and blue systems. Facility areas radiologically classified as forbidden (basement areas) are ventilated through the red/primary ventilation system.

Red primary (RP) exhaust system: The RP system provides ventilation from the hot cells that enables a negative containment pressure barrier for each cell. This system consists of the following four sub-systems:

- RP1 from the dissolution cell process off-gas: RP1 comprises two sub-systems, RP1a and RP1b. RP1a is from the dissolution vessel itself and RP1b is the off-gas after passing through the hydrogen converter
- RP2 from the dissolution cell's internal containment box: RP2 provides extract from the dissolution cell containment box to maintain a negative pressure and remove heat from the dissolver cell to keep the cell environment below the allowable maximum temperature limits
- RP3 from the hydrogen converter cell and other production hot cells: RP3 provides extract from the hydrogen conversion, purification, evaporating, dispensing and packaging production hot cells inner containment box to maintain cell negative pressure
- RP4 from the four service hot cells and waste tank system: This system provides extract from the maintenance, sampling and waste hot cells, a glove box and the waste tank vacuum exhaust system.

Red Secondary ventilation system: This system provides zone and building radiological containment by maintaining negative pressures within the rear of cell areas. It removes potential contaminants from the extract air with HEPA filtration and provides a safe ventilated working environment for personnel in the rear of cells areas, and ongoing containment during an accident condition, such as a fire or a contamination spill.

Blue secondary (BS) ventilation system: This system provides zone and building radiological containment by maintaining negative pressures within the front of cell areas. It removes potential contaminants from the extract air with HEPA filtration and provides a safe ventilated working environment for personnel in the front of cells areas, and ongoing containment during an accident condition such as a fire or a contamination spill.

As part of testing and commissioning, the following have been undertaken:

- evidence of correct installation
- functional tests and inspections
- checks for pressures and leak tightness
- checks for stack velocity.

ARPANSA's assessment on whether the design objectives of these instruments have been achieved are discussed below (p 27- 33).

RFA 10: Remaining shielding elements

This RFA addresses the shielding elements for the following the structures, systems and components:

- Flask shielding: Retrievable waste bin flask, SUF flask, target transfer flask, PADIRAC flask (horizontal transfer flask), liquid waste transfer flask
- AVS room door
- SIAM filter room door
- Valve room door

- Purification hot cell rear door
- Dissolution hot cell rear and top doors
- B(U) container trolley
- AVS trench covers
- Carbon columns top plate
- ILLW/LLLW holding tanks top cover.

Target transfer flask: This flask will be used for transferring irradiated targets from the OPAL reactor to the ANM facility. Currently this flask is used for transferring irradiated targets from the OPAL reactor to Building 54 (B54) that houses the current fission Mo-99 facility. The flask is equipped with appropriate design safety features including shielding and interlocks. ANSTO has significant experience in operating this flask and the flask is operated following standard procedures. This flask will be used only for on-site transport.

SUF cup flask: The SUF cup flask will be used for transferring the SUF cups to be generated from the ANM facility. This flask is currently used for transferring SUF cups generated from the Mo-99 production process at B54 to ANSTO Waste Operations. The SUF cups (up to nine at a time) are placed into double containment and transferred to the B41 high activity handling cells, where the assembly containing the SUF cups is encapsulated in a stainless steel storage vessel. This storage vessel is then transferred to Building 27 ANSTO Waste Operations for storage. The flask is designed with appropriate safety features including shielding and interlocks.

Retrievable waste flask: Two (2) retrievable solid waste (RSW) flasks (the existing and a new version) will be used to transfer solid active wastes from the ANM Mo-99 waste hot cells to Waste Operations. This flask is designed with appropriate design safety features including interlocks, shielding and controls for operation. The ARPANSA assessor witnessed the commissioning of the retrievable waste flask and observed that the flask was successfully commissioned.

Horizontal transfer flask: The PADIRAC flask will be used for removing radioactive material from the hot cells and for inter-cell transfers of radioactive material. This type of flask is commercially available and used in the nuclear industry around the world. This flask will only be used for on-site movement of radioactive material. The ARPANSA assessor observed the commissioning tests of the PADIRAC flask, which were performed satisfactorily.

Type B(U) container: The ANM facility will use a 'Beatrice' container, which is a Type B(U) package for off-site transport of product (Mo-99). The package is designed by NTP, South Africa. This type of package is currently used at ANSTO Health and in South Africa. The use of this package has been approved by ARPANSA in accordance with the ARPANSA Code: Safe Transport of Radioactive Material, RPS C-2 (2014). The Type B(U) container trolley will be used for transferring the product from dispatching hot cell to the dispatch area followed by off-site transport.

The construction materials for the above structures, systems and components include lead, steel, iron and concrete.

The computer code Microshield was used to model the dose rates at appropriate locations for construction of the structures and systems described above. The dose rate calculations have considered the following:

- suitable source terms and geometry as input data
- selection of shielding materials
- build up factors.

The calculated dose rates include the contact dose on the outer layer of shielding, and the dose at a distance from shielding as required.

Based on the safety function of the remaining shielding elements, the dose-rate design objectives at appropriate locations were calculated for construction purposes. During construction, specifications of structural materials were verified. Following construction, dimensional correctness, correctness of concrete, and short-path were measured and verified. As part of testing and commissioning, achievement of the dose-rate design objectives was verified by measuring the dose rates at strategic locations using appropriate radiation sources, and by examining specifications of the structural materials. ARPANSA's assessment on whether the design objectives have been achieved are discussed below (p 27- 33).

RFA 11: Radiation monitoring system

The radiation monitoring system includes the following:

- Radiation Air Sampler Monitoring System (RAMS) detecting airborne radioactive contamination in selected locations in the facility
- alpha/beta counters (beta castle) in selected locations in the facility.
- local area radiation monitors to indicate the radiation levels in selected locations in the facility
- radiation monitors used for safety interlocking or for alarms preventing accidental radiation exposure to personnel
- process radiation monitors that directly and continuously monitor the radiation/contamination levels associated with the production and waste management processes, including the active ventilation system
- radiation monitors associated with stack discharge monitoring
- contamination monitors used for personnel monitoring, e.g. hand and foot contamination monitors and walk through monitors.

Although the safety category of the contamination monitors used for personnel monitoring (Safety Category 3) do not come under regulation 54, they were considered in the approval for completeness.

Radiation Air Sampler Monitoring System (RAMS): Radiation air sampler monitors are installed at locations where there is potential for airborne contamination. There are 21 air sampling monitors at appropriate locations. The radiation monitors will detect an abnormal radiation level, and if it is greater than the alarm set point, will raise an audible and visual alarm, and relay it to the ANSTO Site Operation Centre (ASOC). Such an alarm leads to the evacuation of the facility. In addition, the air samplers will also provide early warning of process failures e.g. leaks of radioactive gases whether or not personnel are present at that location.

Local area radiation monitors: There are thirty-nine (39) local area radiation monitors installed in various selected locations of the facility to indicate the radiation levels in the facility. The alarm setting of these monitors will depend on the location which will be determined by the Radiation Protection Adviser (RPA) during hot commissioning. The radiation monitors will indicate the radiation levels and raise audible and visual alarms if the radiation is above the set alarm levels. These alarms will not be relayed to the ASOC but will be available within the facility through the human machine interface (HMI) screens.

Local area radiation monitors will provide the following functions:

- monitoring of radiation levels under normal operating conditions in the various locations of the facility to help to meet the routine dose limits and constraints
- detecting above normal radiation levels under accident conditions to provide warning to personnel in the vicinity to minimise the risk of radiological consequence
- providing a historical record of the radiation levels in the facility at various locations to facilitate trouble shooting and incident investigations.

During operation of the facility the radiation levels will vary from location to location and areas are radiologically classified in accordance with such levels. Appropriate administrative controls will be in place for access to certain areas.

Process radiation monitors: Sixteen (16) radiation monitors are installed at selected locations to detect abnormal levels of radioactivity in the process and within the AVS. These monitors will detect normal and abnormal conditions in the production processes and off-gas management system. They will monitor the following specific air streams:

- RP4 exhaust from three hot cells and a glove box i.e. waste tank vacuums exhaust, sampling hot cell and MPB/IPC hot cell, and a glove box
- RP4 exhausts from the four hot cells i.e. LLSW hot cell, ILSW hot cell, in-process sampling hot cell and maintenance hot cell
- RP3 exhaust from the purification cell, evaporation hot cell, dispensing hot cell and the packaging hot cell
- radiation monitors on the inlet and outlet of the bank of carbon columns.

These monitors will raise a local alarm when the pre-set alarm level is exceeded.

Radiation monitors used for safety interlocking and/or alarms: There will be four (4) task specific monitors at selected locations that will provide safety interlocking and/or alarms required for safety-instrumented functions (SIF) to prevent accidental exposure to personnel. These radiation monitors will only provide indication of the radiation levels with some warning of unsafe radiation levels. Alarms will be set in accordance with the type of activities undertaken at these selected locations (e.g. packaging, liquid waste sampling etc.).

Alpha/beta counters: There will be two (2) alpha/beta counters at two (2) fixed locations in the facility. These monitors will be routinely used for measuring removable surface contamination on the shielded pots to be despatched from the facility. These counters will have local alarms that will indicate an elevated level of contamination.

Stack discharge monitor: There will be an on-line monitor to measure the discharged gaseous activities. The detecting system will be an NaI detector. A separate and redundant high purity germanium (HPGe) detecting system will also be available.

Radiation/Contamination monitors: There will be five (5) hand and foot contamination (HFC) monitoring systems at selected locations to detect any possible personal contamination. In addition, there will be two walkthrough monitors at the points of entry and exit into the facility on the ground floor.

These instruments are commercially available and therefore, cold commissioning of these instruments involve:

- calibration by ANSTO's Instrument Calibration Facility
- checks of pressure and leak tightness
- checks of duct air flows and velocities
- functional checks of correct instrument operation.

ARPANSA's assessment on whether the design objectives of these instruments have been achieved are discussed below (p 27- 33).

RFA 12: Process containment

The process containment system comprises a number of sub-systems and the key sub-systems include:

- dissolver vessels
- filtrate collection vessel and associated valves
- gas management vessel, connected between the dissolver vessel and the hydrogen conversion system
- hydrogen converters
- dissolver off-gas decay tanks and filtration gas decay tanks
- hydrogen leak detection system
- control and protection system

Dissolver vessels: Irradiated targets will be dissolved in a dissolver vessel in the dissolution hot cell. There are two (2) dissolver vessels. A similar dissolver vessel is used at the current ANSTO Mo-99 production facility. The dissolver vessel is connected to the gas management system, hydrogen converter and gas storage tank. The dissolver is constructed from high grade stainless steel 304 L. A stainless steel frit filter is attached to the base of the dissolver to remove the solid waste containing uranium and fission products. This filter cup is referred to as the SUF cup. The operation of the dissolver is controlled by an external control system from the cell front.

Filtrate collection vessel: The filtrate collection vessel is connected to the dissolver vessel to draw and collect the filtrate of the dissolution and filtration process by vacuum transfer. This vessel is constructed from stainless steel 316 L. It has four manually operated valves for various operations related to the filtrate.

Gas management vessel: The gas management vessel will act as a liquid separation trap between the dissolution and hydrogen conversion and will provide a fission gas management function. It is constructed from stainless steel 316 L.

Hydrogen converters: The dissolver off-gas will be passed through the hydrogen converter to convert the hydrogen into water. There will be four (4) hydrogen converters in the hydrogen conversion hot cell. The construction material is Inconel alloy 625. Only one hydrogen converter will be connected to the dissolution process for a given batch.

Gas decay tanks: There are two sets of gas decay tanks. One set of gas decay tanks each of capacity 120 L is for dissolver off-gas storage. The other set of gas decay tanks each of 160 L is for filtration off-gas storage. The off-gas will be released in sequence after a certain decay period through the AVS red primary exhaust. These tanks are rated for a design pressure of 1200 kPa. One of the gas decay tanks for dissolver off gas is dedicated as a pressure relief tank and is connected directly from the dissolver vessels via bursting discs without any valves in between. If the dissolver becomes pressurised during a dissolution run due to any reason then the bursting disc of the corresponding line connecting the dissolver to this gas tank will rupture (as per design provision) and the gases will be directed to this dedicated gas tank, and will be contained within the process containment. The construction material of these tanks is stainless steel 316L.

Hydrogen leak detection system: The hydrogen detection system will provide part of the defence in depth for safe operation of the facility. The hydrogen leak detection is provided in the following locations in the AVS Red primary exhaust ducting to detect leakage of hydrogen from process containment:

- red primary exhaust piping of dissolution hot cell 1 (DCELL 1) (RP2)
- red primary exhaust piping of dissolution cell 2 (DCELL 2) (RP2) [DCELL 2 will not be used at this stage]
- red primary exhaust piping of the hydrogen conversion Cell (HCELL) (RP3)
- red primary exhaust piping of the hydrogen regeneration process (RP1b).

The detection system has two alarm levels typically set at the following values:

- alarm Level 1 - 20% LEL (lower explosive limit) for hydrogen (8000 ppm)
- alarm Level 2 - 40% LEL for hydrogen (16000 ppm).

In the event of reaching alarm level 2 for hydrogen concentration the circulation of chilled water into the dissolver vessel jacket will be activated to slow down the dissolution chemical reaction. Fission gases are also released along with hydrogen during the dissolution process. Radiation monitoring instruments are available at various locations in the AVS exhaust piping to provide a redundant and diverse method of detecting leaks of radioactive off-gases from process containment during dissolution, and hence indirectly to also detect leaks of hydrogen.

Control and protection system: A Programmable Logic Controller (PLC) system will be used for control of various process transfers through process containment as appropriate including the control of vacuum pumps and valves, and interlocks. This control system is part of the overall process control system (PCS) for the Mo-99 production process. Operator control will be implemented via a HMI.

A separate PLC driven system will be employed for some of the control and interlock functions associated with the process containment, which will be implemented as part of the AVS. The PCS PLC and the AVS PLC will share information via a communications link. The control and interlocking functions of the AVS related process containment include the sequential selection of gas decay tanks for dissolver off-gas and filtration off-gas for a given dissolution run, control of over-pressurisation of the gas tank, and selection of decay tank.

A separate and independent PLC system will control the hydrogen converter selection for dissolution runs, regeneration of hydrogen, temperature and pressures in various tanks, hydrogen leak detection and detection of over-pressurisation of the dissolver.

As part of testing, acceptance and commissioning the following have been considered:

- evidence of correct material supply
- pressure vessel design certificates and registration
- pressure tests
- evidence of correct installation and operation
- evidence of inspections, examinations and tests
- checks of pressure and leak tightness
- functional checks of correct SCADA (supervisory control and data acquisition)/HMI operation.

ARPANSA's assessment on whether the design objectives of these instruments have been achieved are discussed below (p 27- 33).

RFA 13: Safety interlocks

These safety interlocks will perform roles in the following operations:

- transfer of irradiated low enriched uranium target plates from the irradiated target transfer flask to the dissolution hot cell (DCELL) via the top loading port
- transfer of ILSW and the SUF cups from the ILSW hot cell to the RSW flask and the SUF flask respectively via the shielded doors of the ILSW hot cell on the top of the hot cell
- transfer of various materials (both radioactive and non-radioactive) between PADIRAC casks and each of production, service and waste storage hot cells via the hot cell doors located at the rear of cells. The PADIRAC casks are used to transfer materials between all hot cells

Following are various safety interlocking functions that control the transfer of radioactive material between shielded flasks and hot cells.

Interlocks for the transfer of irradiated targets to the dissolution hot cell: The transfer of irradiated targets to the dissolution hot cell from the top port of the hot cell is subject to the following interlock functions:

- interlocking the flask ball valve with the overhead crane

- interlocking the shield door and gate valve operation with the presence of flask and crane disablement.

Interlocks for the transfer of radioactive items from the intermediate level solid waste hot cells: The safety interlocks for the transfer of radioactive material from the ILSW are similar to the DCELL (Interlocks for the transfer of irradiated targets to the dissolution hot cell). The transfer operations related to ILSW will involve one of the following flasks:

- transfer of SUF cups by the SUF flask
- transfer of ILSW by the RSW flask.

Mechanical interlocks for the transfer of radioactive items using the PADIRAC casks between hot cells: The PADIRAC system is used to transfer various radioactive items between hot cells. The system is designed with appropriate shielding to prevent inadvertent exposure and to maintain a depression in the cell containment boxes relative to the external room pressure, thereby maintaining confinement and preventing migration of material from the containment boxes to the room environment. Such a system is widely used in the nuclear industry around the world to transfer radioactive material.

Safety Interlocks for the B(U) Port in the Packaging Cell: The B(U) container is used to despatch Mo-99 solution from the packaging cell. The B(U) port loading system consists of a number of sub-systems. The safety interlocks use various sensors, limit switches and actuating devices.

The ARPANSA assessor witnessed the functionality tests and commissioning of these safety interlocks. ARPANSA's assessment on whether the design objectives of these instruments have been achieved are discussed below (p 27- 33).

RFA 14: Criticality assessment

Criticality assessment involves the dissolver, dissolution hot cell, liquid waste containment system, and the ILSW hot cell. The design of these systems has taken into account the experience with the current Mo-99 production facility. The design and construction of these systems have taken into account the geometry and selection of process and material in this regard. Further, the maximum amount of fissile material present at any one time is stipulated by operational limits and conditions following criticality assessment using a computer code. ANSTO's criticality officer issued criticality certificate, CCT/187, based on detailed analysis of the process, design features and anticipated accident conditions, applying the American Nuclear Society Standard: Nuclear Criticality Safety in Operations with Fissionable Material outside Reactors, ANSI/ANS-8.1-2014. The criticality certificate stipulates that the subcritical limit, and that specific process requirements and administrative controls will be in place. Compliance with this criticality certificate is part of ANM plans and arrangements.

As part of inspection, testing and commissioning the following aspects have been considered:

- evidence of correct dimension and construction materials
- pressure vessel design certificate
- functionality checks of the liquid waste system
- cold run using the un-irradiated target.

ARPANSA's assessment on whether the design objectives of these instruments have been achieved are discussed below.

Verification and assessment

The facility was constructed by the contractor 'Watpac' and it was a requirement of the contract that all construction works must comply with AS/NZS ISO 9001 for quality management as ANSTO operates under an ISO-accredited quality system. The design specifications and related safety objectives for construction of the items important for safety have been verified in accordance with ANSTO's quality system following appropriate acceptance criteria. As part of acceptance, ANSTO signed-off all relevant construction records for structures, systems and components of the facility and the ARPANSA assessor sighted such records during site visits.

ARPANSA has verified the design objectives of the items important for safety have been achieved taking into account the following:

- as built drawings
- testing results
- specifications
- visual inspections
- material data records
- photographs
- results of commissioning including cold commissioning.

In undertaking such verification, the ARPANSA assessor has examined the drawings, inspection and test records and results, and manufacturing data records. Site visits were conducted to witness commissioning tests. Planned inspections were also conducted to verify whether the items important for safety have been constructed in accordance with the approved design.

While approving the construction of items important for safety under regulation 54, ARPANSA's assessment took into account international best practice as described in ARPANSA *Regulatory Guide: Construction of an item important for safety - regulation 54* [7]. As part of international best practice ARPANSA's assessment considered the fundamental principle of defence in depth that provides a high degree of confidence that accidents in facilities will be prevented, and ensures that the radiological consequences of any design-basis accidents would be minor and within prescribed limits. Defence in depth ensures that the likelihood of any reference accident i.e. the most conservative accident (design extension conditions) that could have serious radiological consequences is extremely small. In the design and construction of the item important for safety, defence in depth has been implemented in the form of a hierarchy of diverse levels of equipment and procedures. Defence in depth will afford substantial protection against performance failures, including common cause failures.

ARPANSA's assessment has concluded that the following principles and criteria have been used in construction of the items important for safety:

- conservative proven design and engineering practice applied at defence in depth levels 1 through 3 so that safety functions are performed at an appropriate level
- appropriate codes and standards have been applied to the design, manufacturing, construction, installation, commissioning, quality assurance, testing and inspection of structures, systems and components
- provision of physical and functional independence and diversity between the levels of defence in depth to reduce common cause failures of structures, systems and components
- the failsafe design safety features of the structures, systems and components
- an appropriate program of design verification and validation is in place that confirms that the design is adequate and in accordance with the design specifications
- items important for safety have been designed and constructed in such a way that they can be tested, inspected and maintained before operation and throughout the operational lifetime of the facility to assure that the intended design objectives are achieved and any deficiencies are identified and dealt with appropriately to prevent failures, including common cause failures
- effective management of ageing so that the safety functions are delivered throughout the period needed.

Shielding

Verification of shielding for the various items described below are combined since they were subject to similar testing, inspection and acceptance criteria. The items are:

- basement shielding (RFA 01)
- liquid waste decay tank system shielding (RFA 02)
- concrete shielding for dissolution hot cell, hydrogen conversion hot cell, solid waste hot cell (RFA 03)
- lead shielding for purification of hot cell, evaporation hot cell, dispensing hot cell, packaging hot cell and in-process sampling hot cell (RFA 04)
- ground floor shielding (RFA 07)
- remaining shielding elements (RFA 10).

The RFAs covering these shielding items are described in the preceding pages.

The following criteria have been used for verification and commissioning:

- evidence of dimensional correctness i.e. overall thickness
- evidence of correct concrete, lead and/or steel density
- evidence of correct concrete, lead and/or steel placement
- satisfactory test for radiation short paths (minimum path length through shielding) with radioactive sources
- visual inspections

- commissioning results.

The ARPANSA assessor sighted and examined the concrete test reports issued by the NATA accredited certifier in accordance with applicable standards such as AS 1012.1, AS 1012.8.1, AS 1012.9 to confirm that specifications have been met. Photographs, as-built drawings, commissioning results and site visits have also been used to verify that the structures, systems and components have been constructed in accordance with the approved design, and that design objectives have been achieved. Apart from the specifications of the shielding items (density, thickness, material supplied), dose rate design objectives were verified at appropriate locations using suitable radioactive sources by short path testing. The measured results confirm that no short path was detected at the locations considered for the design objectives, and the measured dose rates are within the expected dose rates considered in the design. The ARPANSA assessor notes that the flasks (irradiated target transfer, SUF cup, retrievable waste bin) of the 'Remaining Shielding Elements' are currently in routine use at the B54 Mo-99 production facility.

In order to verify the accurate performance of the shielding during routine operation the shielding items require hot commissioning testing using the full-scale irradiated targets which will be considered in the assessment of hot commissioning results.

Rear of cell cranes (RFA 05) and other cranes (RFA 06)

In order to verify that the construction and installation of the rear of the cell cranes and other cranes were in accordance with the approved design, and that design objectives have been achieved, the ARPANSA assessor undertook the following:

- witnessed the operation of the rear of cell crane
- examined as built drawings
- examined site acceptance test (SAT) inspection reports
- reviewed commissioning results
- conducted visual inspections and examined photographs.

The ARPANSA assessor considers that the test reports provide a systematic methodology for detailing the results of the tests performed. The vast majority of the tests were performed without problem. A small number of the tests required further follow-up to be performed. However, all discrepancies and deficiencies that were observed during the initial testing phase have since been reviewed, rectified and formally signed-off. There are no outstanding issues with any of the 12 cranes described within RFA-05 and RFA-06. The test results and the observations of the ARPANSA assessor show that the cranes have been constructed and commissioned in accordance with the approved design and the design criteria have been met.

Hot cell and liquid waste containment system (RFA 08)

For hot cell containment the material data records, results of hot cell leak test, and calibration of pressure gauges were examined along with as built drawings and photographs. During a site visit the ARPANSA assessor confirmed that the negative pressure is maintained with primary active ventilation system in operation.

Material data records, welding test results, pressure vessel design certificate (for class B), pressure test results and functionality test results along with as built drawings and photos were examined for the hot cell and liquid waste containment system to confirm whether these systems have been constructed as per design and whether design objectives have been achieved. All the liquid waste tanks have been constructed in accordance with pressure vessel requirements. Only the design of the 'Class B' pressure vessel requires registration with the Safe Work NSW and the external liquid waste decay tanks come under such category. Safe Work NSW has issued the design certificate for this class vessel. This design certificate is recognised by Comcare. During the site visit the ARPANSA assessor witnessed the functionality tests of the liquid waste containment system and hot cell containment system and observed that design criteria for these systems have been met.

Examination of the aforementioned information, commissioning results and results of site visits suggest that the hot cell and liquid waste containment systems have been constructed as per approved design and that the design objectives have been achieved. The commissioning results demonstrate that the hot cell containment system will withstand the design internal pressure in order to contain radioactive material that might otherwise be released. Hot commissioning of these items will reconfirm the performance of these safety systems during routine operation.

Active Ventilation System (RFA 09)

ARPANSA conducted a site visit on 10 November 2017 (Apendix-2) specifically on the commissioning of the AVS system. Particular attention was given to the configuration of the two fans, two HEPA filters and the stack configuration as built. Observations during the site visit confirmed the configuration of the fan and stack components of the AVS to be consistent with documentation provided as part of the application to operate.

Following this site visit ANSTO provided the final results of the AVS commissioning in late November 2017 (R17/13051). These results explained that although testing and acceptance criteria had been subject to minor alterations this could be justified in terms of optimising the as-installed performance and reliability of the AVS. ARPANSA accepts these minor justifiable changes to the testing criteria noting that there was no negative impact on safety.

The AVS was verified as being installed as per as-built drawings for the facility and the ductwork leak tested to meet AS4254.2 and ISO 10648-2. ARPANSA examined the raw measurement data of leak test results which clearly show measured leakage airflow well below maximum design air leak rates. In addition, ARPANSA conducted a site visit to observe the commissioning and pre-commissioning tests which were undertaken in accordance with ANSTO's Commissioning Method Statement.

The facility has been designed to have directional airflow through specific zones within the facility. ANSTO has measured and tested pressures within these zones. Results measured are well within the design criteria. Commissioning results and the observations during a site visit suggest that the active ventilation system has been constructed in accordance with the approved design criteria and that design objectives for the ventilation have been achieved. The commissioning results demonstrate that directional airflows and pressures within the facility zones are in accordance with the design objectives. Conformance to standards mentioned above is considered appropriate to the kind of ventilation as designed and as-built. Acceptance

testing to demonstrate compliance with ISO 10648-2 indicates that the ventilation system has considered international best practice in the design and operation of the AVS.

During a site visit on 11 January 2018, the ARPANSA assessor witnessed the cold commissioning run using un-irradiated targets during which it was confirmed by observation of ventilation parameters that the design criteria for the AVS have been met.

Radiation monitoring system (RFA 11)

For radiation monitoring system (RMS) installation records, inspection of locations through site visits, review of as-built drawings and calibration certificates have been used to verify whether the system has been constructed, installed and commissioned as per approved design and plan. The ARPANSA assessor notes that during installation and commissioning, the locations of some monitors have been changed for better monitoring. This has been undertaken in accordance with the documented 'change control procedure' that formed part of the plans and arrangements for construction of the facility. Even at the end of the construction phase, it was confirmed that some monitors/detectors will need to be relocated once the actual work space is occupied – for example, there are two monitors and detectors set up in the active workshop. However, the most appropriate place for this equipment cannot be adequately determined until work is completed. The available information shows that the RMS has been constructed in accordance with the design and that design objectives have been achieved. The accuracy of response of the RMS will be verified during hot commissioning using the dissolution of irradiated targets for processing of Mo-99.

Process containment (RFA 12)

The process containment system is also linked with the AVS and the hot cell containment system. In order to verify that the structures, systems and components have been constructed in accordance with the approved design and that design objectives have been achieved the following have been examined:

- records of material supply
- results of pressure tests and leak tightness tests, and functionality tests
- design certificate of registration for the pressure vessel
- as built drawings and photos .

All the off-gas tanks are classified as pressure vessels 'class B' and Safe Work NSW issued the certificates of registration for the pressure vessels. The ARPANSA assessor visited the facility during construction of the process containment system and witnessed the commissioning tests and functionality tests (Appendix-2). In addition, for hydrogen detection and functionality tests for the dissolver vessel a number of full-scale cold runs involving un-irradiated targets were undertaken. Based on ARPANSA's examination of records, results, site visits, and witnessing commissioning and functionality tests it is concluded that the process containment system has been constructed in accordance with the approved design, and that design objectives have been achieved. Based on the aforementioned results and observations the ARPANSA assessor considers that the facility could proceed to hot commissioning. Further, verification of the performance of this item will be confirmed by witnessing hot commissioning using irradiated targets.

Safety interlocking system (RFA 13)

The construction, installation and commissioning of the safety interlocking system have been verified through the following mechanisms:

- witnessing functionality tests including those using a radioactive source
- witnessing the cold commissioning of critical plant and equipment using un-irradiated targets
- review of as-built drawings
- checking commissioning record sheets
- checking the commissioning method statement
- use of photographic records.

The ARPANSA assessor considers that the safety interlocking system has been constructed, installed and commissioned in accordance with the approved design and following appropriate procedures. The functionality and cold commissioning tests demonstrated that the interlocks provided intended safety functions which provides confidence in moving to hot commissioning phase of the facility.

Criticality assessment (RFA 14)

ARPANSA examined the as built drawings, material data records, inspection test results for the liquid waste system, and witnessed water runs (without un-irradiated targets) and cold commissioning using un-irradiated targets. The ARPANSA assessor observed that relevant structures, systems and components have been constructed and installed according to the approved design and the commissioning method statement. Evidence of pressure vessel test and registration for Class B was sighted. This includes design certificates issued by Safe Work NSW which are recognised by Comcare. During cold commissioning, the ARPANSA assessor witnessed the dissolution of un-irradiated targets, the management of solid and liquid waste, and observed that the operation was undertaken in accordance with approved design and safety criteria and limits. These aspects will be further verified during hot commissioning.

Conclusion

The design and construction of the structures, components, systems and equipment of the ANM facility have incorporated the principle of defence in depth that will provide a graded protection against a variety of operational occurrences and accidents, including those that might originate from equipment failures and human error, and events that initiate outside the facility. Defence in depth provisions incorporated in the design will provide substantial protection against common cause failures, including performance failures. The structures, components, systems and equipment have been constructed in accordance with the appropriate standards and codes.

The design basis for each item important for safety has been systematically justified and documented to ensure safe operation and maintenance of the facility, and if necessary, allow replacement or substitution by an equivalent item meeting the design intent and functional requirements of the original item. All items important for safety have been designed and arranged in such a way to facilitate the cold commissioning process.

The structures, systems and components have been constructed in accordance with the approved design, and the design objectives and criteria of all the items important for safety have been achieved. No issues have been identified that may preclude the hot commissioning of the safety related systems. The ARPANSA assessor concludes that the structures, components and equipment of the ANM Facility will provide adequate safety during operation. The results of the commissioning tests provide confidence to proceed to hot commissioning. The performance and functionality will be further verified during hot commissioning using irradiated targets.

2.3.2 A final safety analysis report that demonstrates the adequacy of the design of the controlled facility, and includes the results of commissioning tests

Item 16 of part 1 of Schedule 3 of the Regulations requires the applicant to provide a final safety analysis report that demonstrates the adequacy of the design of the controlled facility, and includes the results of commissioning tests.

The operating organisation shall demonstrate the safety of its facility through a set of documents known as the licensing documentation (or safety case). The licensing documentation shall include an adequate safety analysis report and the operational limits and conditions, as well as any other information required by the regulatory body [5].

The criteria for judging safety specified in the international standard [8] and the guidance on safety analysis for accidents are described in relevant international guidance [9].

The application is supported by the ANM Facility *Final Safety Analysis Report* (FSAR), P-50098, Revision 2. A revised version of this document (Revision 3) was provided later with revised operational limits and conditions (OLCs) taking into account ARPANSA's feedback on better clarity required on the bases of OLCs including safety system settings and process parameters. The FSAR is supported by HAZOP (Hazard and Operability) studies and a risk assessment of the operation of the facility.

ARPANSA's assessment has considered the following key aspects of the safety analysis:

- design principles
- safety classification of items important for safety and application of defence in depth
- hazard analysis and risk assessment
- accident analysis
- operational limits and conditions.

It is noted that ARPANSA assessed the preliminary safety analysis report (PSAR) and was satisfied with the PSAR in granting the licence to construct the ANM Facility (F0285). The FSAR includes the updated status of the facility taking into account the operating arrangements and OLCs of the facility to describe the safe operating envelope. Details are described below.

2.3.2.1 Design principles

Design for nuclear safety: The following key principles have been considered in the design for nuclear safety:

- use of single parameter sub-critical limits so that the accumulative amount of uranium (in all forms) at all stages of the process remains less than the single parameter sub-critical limits for all normal and abnormal conditions
- no single process failure could credibly go undetected and lead to a deviation beyond these sub critical limits
- primary criticality safety measures are passive
- secondary criticality safety measures (both passive and active) are incorporated as defence in depth to further ensure safety through redundancy and diversity.

Design for radiological safety: The following key principles have been applied to the design for radiological safety:

- justification of radiological exposures: benefits outweigh the risks
- optimisation of radiation protection: implementation of controls, use of dose constraints and application of ALARA
- dose limits and constraints: use of statutory requirements and international best practice
- defence in depth: incorporation of multiple containment barriers and redundancy and diversity in safety systems.

Design for chemical safety: The key principles applied to the design for chemical safety include:

- use of robust containment systems
- use of appropriate instrumentation and control systems
- application of the ANSTO Workplace Health and Safety (WHS) Chemical Standards and Australian Standards for Good Manufacturing Practice (GMP)
- use of chemical resistant material.

Design for industrial safety: The design for industrial safety includes the following:

- application of relevant Australian standards for lifting devices incorporating appropriate load safety margin and controls
- application of appropriate national and international standards for pressure vessels and pressurised pipe systems
- fume cupboards (for Quality Control Laboratory) are designed in accordance with the relevant Australian standard.

Design for external natural and man-made events: The following hazards have been identified and considered in the design of the facility:

- external events including: bushfires, drought, localised flooding, high summer temperature, lightning, seismic activity, extreme winds
- man-made events including: missiles from high-energy equipment (kinetic energy, pressure energy, chemical energy, electrical energy), on-site activities including at OPAL and SyMo, road accidents

- reasonable combinations of events, including earthquake causing bushfire, fire, loss of power, loss of water supply and localised flooding.

Details of the design principles and features were considered in the assessment of the licence application for construction of the facility, and in the approvals for construction of items important for safety under regulation 54 [2]. The ARPANSA assessors considered that the design principles applied to the facility are appropriate to the scope of operation and in accordance with international standards [5]. The key structures, systems and components (SSCs) are described in section 2.3.1.

2.3.2.2 Safety classification of items important for safety

Items important for safety have been classified according to the safety functions provided by such items. Categorisation of the structures, systems and components was assessed in granting the licence to construct the facility (F0285). Results of such assessments are recorded elsewhere (R14/05724). Twenty-nine (29) items were identified as items important for safety. These were constructed under separate regulatory approval under regulation 54[3] [2]. Classification of the items was primarily based on deterministic methods which were complemented by probabilistic methods as required. The following factors were taken into account:

- safety functions to be performed by the item
- consequences of failure to perform a safety function
- the frequency with which the item will be called on to perform a safety function
- the time following a postulated initiating event at which, or the period for which, the item will be called on to perform a safety function.

In approving construction of items important for safety, ARPANSA considered the necessary capability, reliability and functionality for the relevant operational states, for accident conditions arising from internal and external hazards, to meet the criteria specified in ARPANSA's Regulation 54 Guideline [7]. ARPANSA's assessment has taken into account the application of defence in depth, through a combination of several layers of protection (i.e. physical barriers, systems to protect the barriers, and administrative procedures), in design and construction of the facility to ensure a high level of safety in operation of the facility. The adequacy and the availability of defence in depth have been tested in the accident analysis as described below. ARPANSA has applied the following principles and criteria for approving the construction of items important for safety [7]:

Conservative proven design and engineering practice: whether conservative design, with safety margins, applied at defence in depth levels 1 to 3 have been incorporated in the design of structures systems and components that have safety functions at these depth levels.

[3] **Approval required to construct safety item**

The holder of a licence, or a person covered by a licence, must not construct an item that is important for safety, and that is identified in a safety analysis report, as part of the construction of a controlled facility, unless the CEO has given the holder, or the person, approval to construct the item.

Codes and standards: whether appropriate codes and standards have been applied to the design, manufacturing, construction, installation, commissioning, quality assurance, testing and inspection of structures, systems and components that are important for safety.

Redundancy, independence and diversity: whether provisions of physical and functional independence and diversity between the levels of defence in depth have been considered to reduce the uncertainties and the susceptibility of structures, systems and components to reduce the probability of common cause failure.

Reliability: whether inherent safety features in the design of the structures, systems and components have been duly considered.

Validation and verification: whether an appropriate system is in place for verification and validation to confirm that the design is adequate and in accordance with the design specification.

Testing, inspection and maintenance: whether appropriate provisions have been considered in the design and construction of items important for safety so that they can be tested, inspected and maintained before operation and throughout the operational lifetime of the facility.

Ageing and degradation: whether ageing management has been considered in the design of the structures, systems and components so that the safety functions are delivered throughout the period needed.

Quality assurance: whether an ISO-accredited (ISO 9001) quality assurance system has been applied to the design of the structures, systems and components that are important for safety at all defence in depth levels, including process control systems, safety systems and modifications.

Plant layout and access: whether the design and layout have considered the access requirements to the structures, systems and components that contribute to the significant safety function in operating the facility, and there is minimum lifting of loads and movement of equipment above the items important for safety.

Conclusion

Verification of the construction of items important for safety, and performance and functionality has been performed through examination of as built-drawings, records of tests and inspections, physical inspection of the items, site visits, witnessing commissioning tests and cold commissioning, and review of commissioning results. Based on observations and assessments the ARPANSA assessor considers that the design objectives and criteria have been met. Further details are described in section 2.3.1.

2.3.2.3 Hazard analysis and risk assessment

The safety analysis of the facility is supported by the analysis of potential hazards associated with the facility and the activities to be performed at the facility. Based on the design of this facility and operational experience in operating a similar Mo-99 production facility ANSTO undertook a series of hazard and operability (HAZOP) studies following Australian Standard (AS IEC 61882) which form part of the application. Results of the ANSTO HAZOP analyses are recorded in ANSTO report (ANSTO_FACL_SAFE_TN_0326_A). The HAZOP studies addressed:

- movement of active materials between hot cells using the PADIRAC flask
- loading/unloading materials
- operation of the ANM Facility AVS system including extraction systems (includes fans, HEPA and carbon filtration) and maintenance of pressure regimes
- delay and release of active gases
- liquid ILW and LLW removal from hot cells and transfer to tanks
- operation of storage tanks including transfer of decayed liquid ILW to the Synroc plant
- removal of liquid LLW
- receipt and management of returned B(U) containers
- despatch of Mo-99 product
- dissolution and purification
- hydrogen conversion and active gas capture
- product recovery and dispensing.
- movement of irradiated targets using the target flask from OPAL to inside the dissolution hot cell
- removal of SUF cups from the waste hot cell in the SUF Cup flask to Waste Management Services control
- removal of active solid wastes from the waste hot cells in the retrievable waste flask (RWF) to Waste Management Services control
- external and internal fires and explosions
- other external natural and human induced events such as bushfire, flooding, seismic activity and onsite activities HAZOP of the Building 2 Quality Control Laboratory.

Considering the hazards, accidents were postulated and analysed and the results of the risk assessments form part of the application. Details of the risk assessment analyses are recorded in ANSTO report (ANSTO/T/TN/2015-20 rev 2). Seventy-one (71) scenarios have been identified and analysed that may have radiological consequences and ten (10) accident scenarios have been identified associated with industrial hazards. Considering the design safety features and controls in place the likelihood of eight (8) scenarios related to radiological consequence have been assessed as being of very low probability and were not considered further. The remaining sixty-three (63) scenarios have been further analysed to assess the associated risks. The results of risk analysis show that the off-site consequences from the analysed scenarios would be insignificant. The ARPANSA assessor considers that the scenarios are based on operational experience, and adequate consideration has been given to potentially hazardous scenarios. In addition, ARPANSA's independent verification of the reference accident i.e. the most conservative accident (design extension conditions) that could lead to more severe consequences suggests that there are no significant off-site consequences from such an incident. Therefore, the activities covered in the ANSTO's hazard and risk analyses are sufficiently comprehensive.

A total of seven (7) of sixty-three (63) postulated accidents have been subjected to detailed assessment for onsite radiological consequences because of the likelihood and consequence of these 7 postulated accidents. The assessment has taken into account the frequency of the particular type of operation or activity, the radionuclide inventory, design safety features, reliability of structures, systems and

components, engineering and administrative controls in place, and operator experience and training. The assessment shows that the risk associated with these scenarios is low to very low. The ARPANSA assessor considers that the risk assessment has adopted a systematic analysis taking into account the appropriate elements of risk analysis such as types and sources of risks, targets of risks and dimensions of health and environmental risks. The methods and techniques adopted for health and environmental risks analyses are in line with the IAEA recommended approach [10]. Considering the risk management framework in place the ARPANSA assessor considers that there is reasonable assurance that the activities could be undertaken safely.

The risk assessment of the B2 QC laboratory[4] where the QC activities will be undertaken shows that one scenario (contamination due to QC handling process) will result in high risk. Particular attention has been paid to this scenario due to a recent overexposure event involving a similar QC handling process, and taking into account the issues identified from the analysis of that event. As part of ANSTO's risk management framework the risk assessment analysis recommended additional controls to this high-risk activity to reduce the risk to be as low as reasonably practicable (ALARP). In addition, it was recommended to investigate the automation of the QC process, and ANSTO undertook to address this recommendation by investigating the process re-engineering options, which will be submitted to ANM Management and ANSTO Executive by November 2018. The ARPANSA assessor concludes that in order to have practical understanding about the magnitude of the risk it is important to obtain operational data on the activities and revise the risk assessment for the QC laboratory. Relevant licence conditions have been recommended related to risk assessment of the QC process.

Assessment of external hazards: Hazards associated with external natural and human induced events were assessed in granting the licence to prepare a site (F0270) and for construction of the facility (F0285). Such hazards include meteorological, hydrological, geological and seismic events, and all reasonable combinations thereof, were considered in the design. Human induced external hazards arising from nearby facilities and transport routes were also addressed. The hazards considered in the design are in accordance with international standards [5].

There are a number of nuclear installations and prescribed radiation facilities operating at the ANSTO site. The results of the accident analyses for all facilities including the reference accident i.e. the most conservative accident (design extension conditions) show that in almost all cases there is no significant radiological consequences outside the facility except for the OPAL reactor. The OPAL accident analysis shows that there could be significant radiological consequence on-site outside the facility but no off-site significant consequences. Further, the ANM facility is adjacent to the OPAL reactor and therefore, special attention has been paid to potential impacts of an accident at the OPAL on the ANM facility.

The OPAL reference accident used a conservative assumption that 25% of the reactor core would be damaged due to reactivity insertion. The damage was also assumed to occur immediately following the initiating event. The reference accident assumes that the reactor building containment would fail and as a result fission product release would occur. This is a conservative assumption as it will overestimate the amount of fission products released to the atmosphere compared with a confinement system. The reference accident assumed that the containment was degraded and would leak at 3% volume per day. A further conservatism was introduced in the timing of the ventilation shutdown of the reactor building with the assumption that the building ventilation system would operate for two minutes after release of fission products and that these fission products would be vented directly and unfiltered into the atmosphere at

[4] Building 2 Quality Control Laboratory is situated at a separate location on the site.

ground level. The rate of ventilation during this time was taken as two building volume changes per hour, a value typical of research reactors.

The computer code PC-COSYMA was used to estimate radiological consequences and the results of calculation show that there are no significant off-site radiological consequences. ARPANSA independently performed the calculation using the computer code PC-COSYMA and found that the results were consistent. The calculations indicate that the most conservative accident of the OPAL reactor would not have significant impact on the safety of the ANM facility taking into account the safety design features and availability of the items important for safety at the ANM facility. This aspect was also considered in approving the siting and construction of the ANM Facility.

The design features of the ANM facility have taken into account these external hazards and the ARPANSA assessor has verified relevant safety functions to deal with such hazards during site visits, commissioning tests and cold commissioning. Based on observations the ARPANSA assessor considers that the design criteria have been met.

ARPANSA conducted site visits to witness the commissioning and functionality tests, and cold commissioning of items important for safety. In addition, the ARPANSA assessor has reviewed as built drawings, manufacturing records, inspection and test records, commissioning results and cold commissioning (use of un-irradiated targets) results of the items important for safety. ARPANSA's review shows that the design provisions of the ANM facility will ensure that all items important to safety are capable of withstanding the effects of the external hazards considered and/or provision of other safety features such as passive safety features will protect the facility and will ensure that the main safety functions will be achieved. The design has considered adequate margins to protect items important to safety against levels of external hazards more severe than those selected for the design basis as derived from the site hazard evaluation.

2.3.2.4 Accident analysis

In addition to the postulated accident analysis described above, ANSTO presented a deterministic safety assessment as part of the safety analysis. The following scenarios including the reference accident have been considered:

- Nuclear safety involving criticality safety
- Target plate melt during transfer
- Reference accident – unspecified energetic release

Nuclear safety: Criticality control in operation of this kind of facility is a key requirement in accordance with international standards [5], and consideration of criticality accidents in the deterministic safety analysis is recommended in international guidance [11].

Criticality safety is assured for routine and abnormal conditions by adhering to single parameter sub-critical limits including on concentration of U-235 in ILLW, on accumulation of uranium precipitate in process tanks and vessels, and on the mass of dry uranium oxide in SUF (spent uranium filter) cups. Considering the design features, process controls and administrative controls in place the criticality safety aspect will be strictly controlled through specific OLCs and a strict monitoring program. Specific conditions are stipulated in the Criticality Certificate for operation of the facility. The provisions considered in the criticality safety assessment are in line with those recommended in international guidance [11]. The criticality safety

analysis has also taken into account ANSTO's operational experience with the current Mo-99 production facility. The ARPANSA assessor has reviewed all relevant parameters, functions, design consideration and concludes that the single parameter sub-critical limits adopted in the design and operation of the facility are adequate to maintain criticality safety in operation and during anticipated operational occurrences.

Target plate melt during transfer: Short-lived fission products resulting from the irradiation of target plates generate significant decay heat, and there is potential for melting the target plate cladding if they were to be removed from the reactor immediately following irradiation. The current fission Mo-99 facility is using the same number of targets per flask and the same flask for transport of irradiated targets from the OPAL reactor. There are a number of engineering and administrative controls in place to prevent target melt during transfer. Considering the engineering controls and administrative controls in place this event is considered being of very low probability and the ARPANSA assessor concurs with ANSTO's assessment.

Reference accident- unspecified energetic release: For the purposes of future emergency planning and preparedness, a generic scenario namely, 'unspecified energetic event', has been postulated. This event is considered to cause massive damage to the dissolver(s) and building. The inventory of two dissolvers is assumed to be affected resulting in a rapid release of radionuclides into the atmosphere which occurs at ground level. This assumption is highly conservative because in routine operation only one dissolver will be used, which is an OLC for the facility.

A combination of dispersion modelling, dose modelling and data on meteorological conditions and the surrounding population were considered to assess the consequence of the release. ANSTO's assessment shows that all the consequences are below levels requiring intervention (sheltering or provision of stable iodine), i.e. the release could be managed with the existing counter-measures in place within ANSTO and with the external emergency services. The maximum effective dose to a member of the public was calculated to be 0.83 mSv at Stevens Hall and 4.2 mSv to a worker on site. The maximum collective dose was calculated to be 1.64 person-Sv.

The event does not need the implementation of protective countermeasures in order to protect people or the environment. Independent modelling by ARPANSA indicates that intervention levels offsite are not triggered in the case of an emergency release of this magnitude under the scenario assumptions made for modelling the energetic event.

The ARPANSA assessor considers that the scenario considered is more conservative than the reference accident and the results of ANSTO's analysis of the unspecified event are in agreement with ARPANSA's independent verification.

Design extension conditions: ARPANSA's assessment has considered the design extension conditions required by international standards [5]. The assessment has taken into account the design safety features, functions of the items important for safety and the postulated events noting that ANSTO's accident analysis did not explicitly address the design extension conditions. ARPANSA's assessment concludes that the features of the facility as built, and as planned to operate, demonstrate considerable capacity to prevent and withstand accidents and their progression, in line with the principle of defence in depth. This aspect has been captured under periodic safety review in section 2.3.2.7 and a licence condition is recommended.

Control of abnormal events and emergency arrangements: The ANM will apply local emergency arrangements to deal with abnormal occurrences/accidents as identified in the safety assessment. These

local arrangements form the ANM Building Management System (BMS). For example, Spill Response (instructions), I 50101. However, the ANSTO Emergency Response Team (ERT) will remain the first responder in the event of an emergency. Further, certain alarms will be sent to the ASOC, and the ASOC will function as a communication centre for all emergency response situations. All abnormal events in the facility will be reported in accordance with ANSTO procedure WHS Event Reporting AG 2372. An assessment of the adequacy of such local emergency arrangements is described in section 3.6.

2.3.2.5 Operational limits and conditions

The postulated initiating events have been used to derive the OLCs taking into account the performance requirements for the items important for safety. The OLCs aim to prevent situations arising that could lead to anticipated operational occurrences or accident conditions, and to mitigate the consequences of such events if they do occur. Details of the OLCs are described in section 2.3.3.

2.3.2.6 Periodic safety review

It is considered essential to carry out systematic periodic safety reviews of such a facility throughout its lifetime, taking into account ageing, modifications, human and organisational factors, operating experience, technical developments, new information on site evaluation and other information relating to safety from other sources [5].

ARPANSA's regulatory oversight of controlled facilities and applicable international standards [5] suggest that modifications including changes to procedures and arrangements are anticipated to be carried out throughout the operational lifetime of such a facility. These modifications along with ageing of the facility can have effects on the safety of the facility. Therefore, periodic safety reviews provide the opportunity to confirm that the safety analysis report and other documents (such as those on OLCs and on maintenance and training) remain valid and consistent with the current state of the facility. Periodic safety reviews can also identify where improvements may be necessary. Such periodic reviews should take into account changes in the site characteristics, including changes in operation of other nearby facilities, the cumulative effects of ageing and modifications, changes to procedures, feedback from operating experience and technical developments. The regular review of modifications made to a facility also ensures that the combined effects of a number of modifications with minor safety significance do not have unforeseen effects on the overall safety of the facility [9]. In accordance with international standards, the frequency of undertaking periodic safety review for this kind of facility is typically ten (10) years [5]. In line with the international standard, the ARPANSA assessor considers that undertaking periodic safety review of the ANM facility would ensure that the current engineered provisions and operational practices are such that protection and safety is optimised, and therefore, a licence condition is recommended relating to periodic safety review. Considering that the hot commissioning activities and early stage operational experience will provide insight into the performance of the items important for safety in responding to abnormal occurrences, the ARPANSA assessor recommends that the first periodic safety and security review be submitted after gaining five years of operational experience.

Conclusion

The ARPANSA assessor concludes that the FSAR has taken into account detailed design, functions of the safety systems, operating arrangements, operational limits and conditions, routine operational conditions and potential accident conditions in assessing safe operation of the facility. The ARPANSA assessment utilised the approach to judging safety analysis described in relevant international standards [8]. The

methods and assumptions for safety analysis for accident conditions considered in ANSTO's safety analysis are in line with international standards [5, 9]. The safety analysis of the facility shows that the maximum potential consequences of the reference accident (unspecified energetic event) to the most exposed members of the public would be less than the threshold at which emergency intervention would be required. It is concluded that there is potential for significant consequence outside the facility but no potential for off-site consequences that is in agreement with ARPANSA's independent verification. This aspect is further assessed in section 3.6.

The risk assessment for B2 QC laboratory resulted in identifying a high-risk scenario related to an event during QC sample handling. In order to control the risk to ALARP the risk assessment team had recommended two additional controls. Based on observations of the plant and equipment, cold run of QC and the review of risk assessment and operating procedures, the ARPANSA assessor considers that ANSTO should revise the risk assessment of the QC laboratory taking into account operational experience so that practical aspects of operational risks are captured. Further, the risk assessment recommended introducing automation in handling QC samples to reduce the risk to the operators. This is considered appropriate by the ARPANSA assessor to reduce the risk associated with QC sample handling.

Recommended licence conditions

Based on the above assessment the ARPANSA assessor recommends the following licence conditions as they relate to the safety analysis of the facility to provide a higher degree of assurance for safe and reliable operation of the facility.

- Routine operation of the facility must not commence until:
    a) the licence holder has analysed automation of the QC procedure for high activity Mo-99 liquid samples as part of the optimisation under the radiation protection plan (section 3.3)
    b) the licence holder has provided a plan, including times for completion of actions, based on the 28 recommendations of the risk assessments for the ANM Facility and the Building 2 QC Active Laboratory, and justification of alternative actions to achieve the same outcome in case such alternatives are preferred
    c) the licence holder has reassessed all scenarios that lead to 'moderate' or more severe consequences from the radiation protection perspective regardless of likelihood including "incredible" scenarios; and analysed opportunities to improve management of radiation risks through reducing the likelihood of an event leading to such consequences, or reducing the consequence should an event occur, or both
    d) the licence holder has reassessed the contribution of human factors to the likelihood of events occurring, and to the mitigation of risks, in the assessment under (c).

- The licence holder must undertake the first Periodic Safety and Security Review (PSSR) of the ANM facility after gaining five years of operational experience from the finalisation of commissioning activities. The PSSR must:
    a) summarise the operational experience including any abnormal occurrences as well as provide an account of contributing factors to such occurrences, risk mitigation,

occupational radiation exposures including contamination events, and public radiation exposures

b) review the capability of the safety functions under a range of design extension conditions agreed by ARPANSA

c) consider the security of the facility

d) include an plan for implementation of actions identified during the course of the review

The PSSR report must be submitted to ARPANSA by 31 December 2024 or at a time agreed by the CEO of ARPANSA.

2.3.3 The operational limits and conditions of the controlled facility

Item 17 of part 1 of Schedule 3 of the Regulation requires the applicant to provide operational limits and conditions of the controlled facility.

The facility requires to be operated within a comprehensive set of operational limits and conditions (OLCs) to prevent situations arising that could lead to anticipated operational occurrences or accident conditions and to mitigate the consequences of such events if they do occur [5].

The application is supported by a document entitled 'Operating Limits and Conditions', P-50099, which refers to the FSAR for derivation of such OLCs. ANSTO's approach conforms to the international standard [5] and guidance [9, 12]. The OLCs are developed taking into account the following aspects:

- analysis of the safety categorisation of the facility and identify any inherent specific limits in the physical design of the facility
- results of accident analysis and the controls managing the risk of accidents
- operational experience with the current Mo-99 production facility.

Compliance with the OLCs will protect the facility, workers, members of the public and the environment from undue exposure to radiation. In deriving the OLCs, the safety analysis has taken into account the functional capability and performance levels of equipment, safety related items and personnel.

For each parameter for which a safety limit is required, and for other safety related parameters (e.g. AVS parameters), appropriate systems have been installed to monitor and control the parameters for the process, plant and equipment so that the safety limits are not exceeded. The safety system settings have been established to ensure automatic actuation of safety systems before limits are reached. The ARPANSA assessor observed such actuation during commissioning of the SSCs and cold commissioning. For example, actuation of the safety interlocks for transfer of targets and dispatch of finished product (which is simulated using a radioactive source). Further details are described in the assessment of construction and verification of structures, systems and components above.

The specifications of safety systems and the corresponding parameters are set to maintain the safety margins in operation of the facility. These specifications and parameters are clearly captured in the operating instructions to ensure that the operators have a clear understanding of the safety significance of the systems and parameters during operation of the facility.

The limiting conditions have been established taking into account the lowest functional capability or performance level of equipment or values of parameters that need to be adhered to during startup, operation and shutdown of the facility. These limiting conditions include limits on operating parameters, requirements for minimum operable equipment and the rules to follow in the event that the systems are unavailable. These limiting conditions are also reflected in the operating instructions so that the operators have a clear understanding of the significance of such limiting conditions. In addition, operators are trained in OLCs.

Since specific OLC requirements are related to the modes of operation of the facility, the following modes of operation for the facility have been considered:

Mode	Description
Production	The operation of plant and equipment associated with separation, purification and reconstitution of Mo-99.
Regeneration	When the task of hydrogen converter regeneration is performed.
Packaging	The stage of operation once production and dispensing of Mo-99 have been completed. It is solely performed in the Packaging Cell.
Suspended (safe mode)	When production has been stopped and the plant has been placed in a safe mode.
All other modes	Any other activity or plant status, other than “Production” or “Regeneration” including: • Maintenance, or • Plant preparation prior to the commencement of a production run, or • Waste Transfer.

The OLCs derived from the safety analysis are in the following areas:

- containment systems including ventilation system
- handling of LEU targets and wastes containing LEU
- operational radiation protection
- instrumentation and control system
- operating personnel
- auxiliary systems and equipment.

Each OLC is supported by surveillance requirements and the basis of operational limiting conditions is described in a standalone document ‘Operating Limits and Conditions, P-50099’ and in Table 4 of section 11 of the SAR.

The ARPANSA assessor witnessed the implementation of a number of the OLCs during cold commissioning of the facility as they relate to the containment system, handling fissile material, operating personnel, and the instrumentation and control system. The ARPANSA assessor considers that ANSTO has adopted a graded approach in deriving the OLCs, design objectives, safety limits, safety systems settings and limiting conditions for safe operation. Compliance with these OLCs would prevent situations arising that could lead

to anticipated operational occurrences or accident conditions and would mitigate the consequences if they did occur. In addition, adherence to the limiting conditions would help to avoid the undesirable actuation of safety systems.

Conclusion

The ARPANSA assessor concludes that the derived OLCs would provide a high degree of assurance that the facility will be operated safely and reliably subject to strict adherence to these OLCs and the corresponding surveillance requirements. The OLCs will be further assessed during review of the hot commissioning results.

2.3.4 The arrangements for commissioning the controlled facility

Item 18 of Part 1 of Schedule 3 of the Regulation requires the applicant to provide the arrangements for commissioning the facility.

Submission of an adequate commissioning program to the regulatory authority describing stages of commissioning and the results of commissioning is also required by the international standard [5].

The following information has been assessed related to arrangements for commissioning:

- Commissioning Plan of Safety Related Systems, Mo99_COMM_SAFE_PL_1573
- Commissioning Plan for Mo-99 Production Process, Mo99_COMM_PROC_CTP_1174_B
- Cold commissioning results for items important for safety
- Cold Commissioning Report Mo-99 Production Process, Mo99_COMM_PROC_ER_8156

Commissioning Plan of Safety Related Systems

This document outlines the plan for the commissioning of the safety related items of the ANM facility. The roles and responsibilities related to commissioning are described in this document. The safety related systems that were subject to commissioning were identified in the PSAR for construction of the facility. Construction of these items were approved under regulation 54 [2] recognising that design principles and criteria recommended in the ARPANSA Regulatory Guide [7] were met.

Roles and responsibilities for commissioning

Roles and responsibilities related to commissioning of the safety related items are described in section 4 of the ANM Mo99 Commissioning Plan. ANM project staff and the contractor (Watpac Construction Pty Ltd) are undertaking commissioning tasks while utilising expertise of other relevant ANSTO staff.

The ANM Technical Manager is responsible for overseeing the commissioning activities and reviewing the results of the commissioning tests.

Arrangements for testing and commissioning

Commissioning arrangements include factory acceptance testing, cold commissioning and hot commissioning.

Factory acceptance testing (FAT): Factory acceptance testing was performed for key equipment items prior to consignment and installation at ANSTO. This includes the hot cell containment and interlock systems.

Major equipment and systems were also subject to site acceptance testing (SAT) or commissioning by the vendors/contractors.

Details of the FAT and SAT protocols were considered in the assessment of the licence application to construct the ANM Facility (F0285) and were found acceptable (R14/05724).

Cold commissioning: All the safety related items were cold commissioned in accordance with the protocols and arrangements considered in the assessment of the licence application to construct the facility (F0285).

Cold commissioning was undertaken using cold commissioning protocols and the commissioning method statement. The ANSTO responsible officer (project engineer) witnessed the commissioning tests and verified that design criteria specified in the commissioning method statement have been achieved. The ANSTO responsible officer signed off the commissioning test results as part of acceptance process. The ARPANSA assessor witnessed a number of cold commissioning tests including:

- transfer of un-irradiated targets (not using irradiated material)
- transfer of ILSW
- operation of the PADIRAC flask
- test of the AVS
- use of type B(U) package for transfer of radioactive material off-site.

During commissioning, functionality of critical components (e.g. safety interlocks) that provide defence-in-depth for safe operation of the safety systems were also tested. The ARPANSA assessor observed that all the commissioning tests were performed satisfactorily in accordance with the commissioning method statement.

Hot Commissioning: Hot commissioning involves the use of a significant amount of radioactive material, and use of significant radioactive materials at the ANM facility requires ARPANSA approval. The results of cold commissioning along with the operating arrangements have been assessed in this report to determine whether the facility can proceed to hot commissioning. The results of hot commissioning will be assessed by ARPANSA for approval to proceed to routine operation.

Commissioning Plan for Mo-99 Production Process

This commissioning plan describes the commissioning activities, understanding the design intent, functional testing of the equipment and start-up of the chemical process associated with the Mo-99 production process in the hot cells. Relevant commissioning methods and instructions are referred to in this document. Further documentation related to construction and installation, testing and commissioning to be followed are presented in Appendix B of the commissioning plan.

The roles and responsibilities of persons involved in the design, installation, testing and commissioning of the systems being tested are described in Section 5. The document states that it shall be acceptable for one person to act in more than one role e.g. the technical manager may also act as the tester and it may be beneficial for the manager to do so.

The technical manager, in association with the lead project engineer, is responsible for overall management of commissioning activities, and supervision of other technical and engineering personnel and subcontractors required for inspection, testing and commissioning tasks; and for ensuring the implementation of any design modifications.

The following key process-related systems were subject to cold commissioning:

- dissolver system in hot cell
- hydrogen conversion system
- nitrogen gas supply system
- instrumentation and Control (I & C) system
- gaseous waste system
- liquid waste system
- solid waste system
- solution filtering system
- purification system
- transfer and storage of low level and intermediate level liquid waste
- evaporation process
- dispensing and packaging
- stack monitoring
- cold production run for Mo-99.

Details of the commissioning of the sub-systems and the key performance parameters are presented in Section 7 of the commissioning plan. Prior to commissioning (pre-commissioning), the expected values for parameters important for safety to be measured during commissioning were established, which conforms to international standards [9].

The ARPANSA assessor observed a number of commissioning tests such as transfer of target to dissolution hot cell, dispatch of final product, transfer of solid waste (SUF Cup), ventilation system etc. and found that these systems were successfully commissioned according to the commissioning methodology.

The ARPANSA assessor notes that the facility is designed to incorporate two dissolution hot cells, and one dissolution hot cell is commissioned, which will be subject to operation. The ARPANSA assessor observed that the second dissolution hot cell is still under construction and is not commissioned, and therefore, hot commissioning of this hot cell will be subject to approval from ARPANSA under regulation 51.

The ARPANSA assessor witnessed the water run (without use of un-irradiated targets) and cold commissioning run involving un-irradiated targets. ANSTO provided ARPANSA with the results of cold commissioning. These results have been assessed taking into account the observations of the ARPANSA assessor during site visits witnessing the water run and cold commissioning. Further details of examination and verification of construction of items important for safety are described in section 2.3.1.

During cold commissioning two deviations occurred, namely, incorrect connection to a dissolver during a dissolver backflush resulting in liquid in a gas-holding tank and a slight change in the colour of the final

product. Causes of both deviations have been rectified to prevent recurrence and the work instructions have been revised to reflect the improvement. Neither of these deviations had any significant safety impact on the performance of the safety functions of the items important for safety. The water run and cold commissioning provided opportunities to further improve the operating instructions and to set the process parameters more accurately.

Conclusion

In summary, the commissioning tests and cold commissioning runs performed were:

- confirm the performance of the shielding and containment systems
- confirm the effectiveness of the engineering controls, e.g. safety interlocks
- confirm the effectiveness of effluent controls
- confirm the performance of criticality control measures to some extent
- demonstrate the performance of the emergency shutdown systems
- demonstrate the performance of systems for fire detection
- demonstrate the availability of the emergency power supply
- demonstrate the availability of other support systems, e.g. chiller.

ARPANSA's assessment of the cold commissioning results along with the observations during commissioning tests and cold commissioning concluded that all the safety related systems and the process related systems were successfully commissioned according to the commissioning methodology, and the design intent was achieved. The elements and structure considered in the commissioning plans are in line with international standards [9].

The hot commissioning results will confirm performance of some structures, systems and components that could not be verified from cold commissioning whether the design objectives and criteria have been achieved for safe and reliable routine operation of the facility. Therefore, ANSTO must submit the hot commissioning results to ARPANSA for further assessment and for approval prior to commencing routine operation of the facility. The results of commissioning and cold commissioning provide assurance that the facility can be subject to hot commissioning.

The arrangements for commissioning the facility provide reasonable assurance for proceeding to hot commissioning and the results of the hot commissioning are essential to demonstrate the effectiveness of the operating arrangements. Therefore, the following licence condition is recommended.

Recommended licence condition

The licence holder must not commence operation of the facility until the structures, components, systems, material, equipment and processes have been tested using irradiated target plates in accordance with the approved program for 'hot' commissioning, and the test results have been analysed and approved by the CEO.

2.3.5 The arrangements for operating the controlled facility

Item 19 of Part 1 of Schedule 3 of the Regulations requires the applicant to provide the arrangements for operating the facility.

As part of operating arrangements for this kind of facility international standards [5] require the following:

- documented structures, functions, roles and responsibilities for operation of the facility
- sufficient qualified personnel
- operation in accordance with the set of operational limits and conditions
- an effective ageing management program for items important for safety
- adequate provisions for control of modifications to the facility
- a system for records and reports
- operating procedures for normal operation, anticipated operational occurrences and accident conditions
- a program to ensure criticality safety in operation
- a program for radiation protection and waste management
- an accident management program and local emergency arrangements
- a program to learn from events at the facility and events from other similar facilities
- an initial decommissioning plan.

The facility will be operated following the Safe and Secure Operations Manual (P-50100). The manual describes the procedure for safe and secure operation of the ANM Facility and is supported by other applicable procedures and work instructions.

Structures, functions, roles and responsibilities: The 'Effective Control Plan' (Q-50081) describes the organisational structure of ANM Pty Ltd. The General Manager of the facility is the nominee, and the CEO of ANSTO is the licence holder. The General Manager reports to the Board and to the CEO. The General Manger is responsible for managing safety of the facility during routine operation by implementing safety plans and arrangements.

The operations manager is the facility officer and is responsible for:

- planning and managing resources, ensuring that operating personnel are adequately trained and qualified
- ensuring that operations and maintenance of the facility are carried out in accordance with appropriate procedures, standards and regulatory requirements
- undertaking duties delegated by the general manager.

An operator is assigned the role of a building warden as an additional duty to undertake the responsibilities specified in the WHS Standards and Practices Standard Operating Procedure (AG-2362).

The building manager is responsible for ensuring that the WHS management system is followed and for other specific duties listed in in AG-3212 Role of Building Manager.

Since fissile materials are used in the facility, an authorised safeguards officer is responsible for the duties required by the ANSTO Nuclear Material Control & Safeguards System, AS-1318.

The high reliability officer is responsible for ensuring that a safety culture is established and that incidents are reported, investigated, trended and reviewed for improvements, and for developing training matrices and monitoring training programs for staff. In addition, he/she is responsible for ensuring identified risks are reviewed and safe operation of the facility is maintained.

The senior operator acts as operations manager in his/her absence, ensures safe operation of the plant during shift conditions, and is responsible for diagnosis of faults during abnormal conditions, for supervising process operators and for ensuring adequate staff level for day-to-day operation.

Process operators undertake routine shift operations under the supervision of the senior operator, and an operator trained as senior operator acts as senior operator in his/her absence.

The role of authorised isolator is to isolate the equipment during shutdown periods and to return the isolated equipment safely to service.

Further details on structure, roles and responsibility are described in section 3.1.

The functional responsibilities, lines and authorities, and lines of internal and external communications are clearly described in the Safe and Secure Operations Manual. This document is supported by more details of functional responsibilities, roles and responsibilities in the associated ANM BMS that includes Management Responsibility (P-50052), Quality and Reliability Responsibilities and Production (P-50054), Technical and supply responsibilities. There is a comprehensive set of documents defining the organisation structure and the arrangements for discharging responsibilities specifying all the roles that are important for safe operation of the facility. Proper implementation of the described structures, functions, roles and responsibilities will provide reasonable assurance in performing the duties and responsibilities for safe operation of the facility. Roles and responsibilities of Operations Manager, Senior Operator, Process Operator and Authorised Isolator were verified while witnessing the cold commissioning water run and using un-irradiated targets and found to be in conformance with the documented procedure.

Sufficient qualified personnel: All the ANM staff are trained and qualified, and their qualifications and skill sets are described in the position descriptions. Senior staff members such as general manager, operations manager and supervisors are responsible for ensuring adequate training for all operating personnel. The ARPANSA assessor has verified the training matrix for the ANM operators and noted that eight (8) operators including operations manager and senior operator are fully trained for the ANM facility and other operators are in the process of training. The training matrix includes the understanding, knowledge and application of the ANM BMS system for operation of the facility. Training was undertaken during the water run and cold commissioning processes. During the water run and cold commissioning run, the ARPANSA assessor observed that the operators, including the senior operator, had demonstrated their ability to operate the plant and equipment in compliance with the operating procedure.

Operation in accordance with the set of operational limits and conditions: Operational limits and conditions have been derived from the safety analysis of the facility and define the safety envelope of the facility. Ensuring compliance with the OLCs is the responsibility of the operations manager as specified in the Safe and Secure Operation Manual (P-50100). In order to comply with the OLCs, safety system settings and normal operating values are set in the computerised operation control panel, and operators are required to confirm such parameters and record them in the manufacturing record [Manufacturing Record- Sodium Molybdate (Mo-99) Solution, Part-I, 1001728]. The record of such information is checked by one operator

and verified by the senior operator or vice versa. The computerised control system does not allow the operator to change any safety system settings, and the operator cannot proceed to the next step without confirming the pre-set values by three repetitions. This shows strong provisions of defence in depth. The ARPANSA assessor verified compliance with a number of OLCs when witnessing the cold commissioning run. These included minimum staffing level, number of target plates per run, AVS parameters, process containment parameters, availability of specific area radiation monitors and air sampler radiation monitors.

Effective ageing management program for items important for safety: Ageing and degradation were considered in the design criteria for construction of items important for safety under regulation 54 [2]. In approving the construction of items important for safety, ARPANSA considered the ageing and wear-out mechanisms, radiation induced degradation and thermal effect on the structures, systems and components. Adequate margins were established between the intended operational life and the predicted safe working life of the items important for safety. The ANM facility will use the Maintenance Manual (I-50206) supported by the Maintenance Procedure (P-50138) and other references listed in these documents. The manual and procedure describe the responsibilities associated with various positions for maintenance and the frequency of maintenance for various items important for safety. These documents also describe the required frequency of replacement of various structures and components. The procedure refers to planned and unplanned maintenance instructions and all maintenance records will be maintained in the ANSTO SAP system. The manual and procedures describe comprehensive arrangements for maintenance to deal with ageing and degradation of items important for safety.

Adequate provisions for control of modifications to the facility: The ANM BMS contains Change Control Procedure (P-50003) that describes the system for managing changes to the facility. This procedure describes the responsibilities for change and the application of the Risk Management Procedure (P-50005) while undertaking changes. A systematic approach will be in place to evaluate change, categorise change depending on safety significance, and approve changes by the internal safety committee (Safety Assurance Committee) as required prior to seeking regulatory approval. Verification of implementation of change and close out provisions are also specified in this procedure, and a change control register will be maintained for recording all modifications. It is noted that changes with significant implications for safety require prior approval from ARPANSA under regulation 51 [2]. The arrangements for control of modifications demonstrate that adequate and sufficient safety provisions are in place to control the potential hazards both during and after the modification.

Operating procedures for normal operation, anticipated operational occurrences and accident conditions: Production batch record (M-1001728, M-50161) forms part of the operating procedures that support the ANM BMS. The batch record provides step-by-step instructions for the production process. The batch record was applied during the cold commissioning run using un-irradiated targets, which the ARPANSA assessor witnessed. The results of the cold commissioning run demonstrated that there are multiple layers of administrative controls for the production process. The procedures specify the verification of safety system settings, and compliance with OLCs to prevent anticipated operational occurrences. The operating procedures have been developed based on operating experience with the current Mo-99 production facility and refined using the results of cold commissioning.

The ANM BMS includes the ANM Facility Incident Response Procedure (I-50275) which identifies incident scenarios involving hazardous activities and describes the safe recovery process to be followed. The roles and responsibilities of various positions related to incident response are clearly described in this document. Thirty (30) postulated incidents and associated recovery processes have been described and all operators are trained and assessed in this procedure. Based on observation of cold commissioning and review of the

procedures the ARPANSA assessor considers that they are user-friendly and cover all operational states and potential hazardous incident scenarios.

Criticality safety in operation: The facility operation is subject to Criticality Certificate (CCT/187) that specifies the procedures to be followed and limits to be adhered to during hot commissioning and subsequent operation. This includes limits on the amount of fissile material present in various locations at any one time and required sampling analyses for uranium content. Single-parameter subcritical limits are specified as OLCs and contained in the operating procedures. Operators are trained on the conditions of the criticality safety, and the operations manager is responsible for ensuring compliance with the conditions of the criticality safety certificate. Criticality safety will be verified during hot commissioning of the facility, and based on the results of the hot commissioning the criticality safety certificate will be revised if necessary. Acknowledging that a number of safety parameters and OLCs can only be verified by hot commissioning, a licence condition has been recommended that requires ARPANSA approval of hot commissioning results prior to moving to routine operation (section 2.3.4).

Program for radiation protection and waste management: The adequacy of arrangements for radiation protection and radioactive waste management are described in sections 3.3 and 3.4.

Although the arrangements for radioactive waste management are considered adequate for short to medium term, this aspect has been further assessed in terms of national policy and plans for complete life-cycle management of radioactive waste. The operation of the ANM facility will generate intermediate level solid and liquid wastes along with low-level solid and liquid waste. The ILLW will be processed at SyMo facility into a stable immobilised glass form applying Synroc technology. The rate of generation of the radioactive waste will depend on the levels of Mo-99 production that will be determined by the demand of this product. Any delay or difficulties associated with the SyMo facility will result in implementation of the contingency plan for management of ILW considered in the construction licence for this facility.

The Government's policy is that Commonwealth radioactive waste and the waste holdings of states and territories as these jurisdictions see fit and as feasible, is to be managed in a National Radioactive Waste Management Facility (NRWMF), established at an appropriate site in accordance with the site selection process laid out in the *National Radioactive Waste Management Act 2012.* The purpose of the NRWMF is to allow for disposal of solid LLW and storage of solid ILW.

Work is progressing on the site selection for the NRWMF. Regarding the policy for radioactive waste management the Australian National Report (2017) on Joint Convention states:

> *The overall policy objective of the Australian Government with respect to radioactive waste is to ensure the safe and secure management of Australia's legacy and future radioactive waste, noting the waste minimisation efforts of waste producers.*
>
> *Implementation of this policy objective will be through the development of a national facility that is based on best industry practice, conforms to international treaty obligations, and can accept the highest achievable proportion of Australia's legacy and future radioactive waste. The preferred approach for the National Radioactive Waste Management Facility is to have appropriate functionality for:*
>
> - *low level waste (LLW) disposal to cater for the volume of waste reasonably foreseeable for the next 100 years, with a sufficient period of institutional control without causing undue reliance on future generations or harm to the environment*

- *ILW storage for a period of time sufficient for the Government to establish a permanent disposal facility.*

As part of its commitment to the safe and secure life-cycle management of all of Australia's radioactive material, the Government will develop a final disposal facility for Australia's intermediate-level waste in the coming years.

Further, the CEO of ARPANSA received a correspondence from the former Deputy Prime Minister and Minister for Resources and the Northern Territory, The Hon. Barnaby Joyce MP, stating:

The Australian Government is also committed to identifying and developing a permanent disposal pathway for ILW. As part of the work to establish the NRWMF, over the next two years, the department is committed to developing relevant policy and institutional arrangements to effectively manage the full life cycle of waste in Australia, from generation to disposal. A separate process for the disposal of ILW will commence once this work is completed, noting it will occur at a different and geologically suitable site to the NRWMF.

The policy and commitment of the Government provide confidence that both LLW and ILW have been captured in the plans for full life-cycle management of all radioactive waste. The ARPANSA assessor recommends a licence condition to capture the full life-cycle management of ILW.

Accident management program and local emergency arrangements: The procedure for managing radioactive or chemical spill at the facility are described in ANM Spill Response Procedure (I-50101). The procedure describes the roles and responsibilities of various positions to respond to such an incident including corrective actions to be taken and decontamination and monitoring provisions to be followed in the event of radioactive or chemical spill. The Safe and Secure Operation Manual (P-50100) describes details of the arrangements for response to events resulting in loss of a criticality safety system, radiological events, security events, non-radiological events, major natural disasters, loss of communication and medical emergencies. Details of the on-site arrangements for responding to an emergency are described in Section 3.6 below. The emergency arrangements have addressed applicable requirements of GSR Part-7 [13]. The effectiveness of implementation of emergency preparedness will be verified through an emergency exercise during hot commissioning. This is recommended as a licence condition.

Program to learn from events at the facility and events from other similar facilities: As described in section 11 of the FSAR for the ANM facility, lessons from the operating experience with the current Mo-99 production facility including incidents have been incorporated in the operating arrangements for the ANM facility. The key example is the recent over-exposure accident at B23 while handling a QC sample. The ANM QC risk assessment has incorporated the lesson learnt from that accident and improved the design and procedure for handling QC samples at B2 QC laboratory. Based on the results of the risk assessment ANSTO undertook to investigate automation of the QC dispensing and testing processes. Process-reengineering options will be presented to ANM management and ANSTO executive by November 2018.

Considering that a high-risk scenario has been identified in the ANSTO risk assessment of the B2 QC laboratory, the ARPANSA assessor has recommended a licence condition to revise the risk assessment incorporating operating experience with the ANM facility. Further, through the Non-conformance, Corrective and Preventative Action Procedure (P-50007) that forms part of the ANM BMS, ANSTO gives a commitment to incorporate the results of investigations of incidents including the results of root cause analysis in the procedures and arrangements to ensure continuous improvement. The High Reliability Officer of the ANM facility is responsible for ensuring improvements in the ANM operations based on the results of investigations and trend analysis of safety incidents. The arrangements for incorporating lessons learnt from events give reasonable assurance for safe operation of the facility.

Initial decommissioning plan: For a new facility, planning for decommissioning begins at the design stage, and the decommissioning plan needs to be prepared and maintained throughout the lifetime of the facility [5]. The requirements for decommissioning of facilities are specified in the international standard, GSR Part-6 [14]. The ARPANSA regulatory guide [15] provides guidance in addressing the requirements for planning, conducting and completing the decommissioning of facilities.

Decommissioning of the ANM facility was considered in the assessment of the application for construction and the results of the assessment have been recorded elsewhere (R14/05724). ARPANSA's assessment found that the design features considered in the facility were suitable to facilitate decommissioning.

All aspects of the facility's operation must be taken into account in the decommissioning plan [5]. Section 13 of the Safety Analysis Report (P-50098) provides an overview of the key aspects of decommissioning including the decommissioning hazards involved, design considerations, selection of construction materials for facilitating decommissioning, dismantling considerations, decommissioning methods and the estimated amount of decommissioning wastes. The effectiveness of operating arrangements that would facilitate safe decommissioning can only be evaluated after gaining adequate routine operational experience. Further, throughout the lifetime of the facility, the facility will be subject to modifications and safety reviews that will need to be taken into account for the final decommissioning plan. The ARPANSA assessor recommends a licence condition to prepare an initial decommissioning plan based on several years routine operating experience and to submit this plan to ARPANSA. The recommended licence condition on the initial decommissioning plan is presented below.

Operational readiness plan and transitioning plan

The ANM Operational Readiness Plan (Q-50028) describes the arrangements in place for full operation of the facility, and allocation of staff and resources. The key elements of operational readiness plan include staffing and training, and operational and quality systems documentation. It also shows the organisational structure for the ANM facility and responsibilities arising from the operational readiness plan. A training matrix for various job positions including operators, supervisors and the production manager is also included in this plan. As of 11 January 2018, eight staff members including the operations manager were trained in the ANM BMS. These trained operators cover two runs per week and other operators are in the process of training.

The ARPANSA assessor examined the training records and witnessed the cold commissioning operation and was satisfied with the adequacy of the training. Further details are described under *sufficient qualified personnel* above. Training of certain number of operators was completed in accordance with the target schedule provided in the plan. Operational and quality systems documentation has been updated using results of commissioning and functionality tests of structures, systems and components, and plant and equipment. Documentation was updated based on the results of testing and commissioning of plant and equipment. The updated documentation was applied to the cold commissioning of the facility using un-irradiated targets. The ARPANSA assessment of cold commissioning is described above (section 2.3.4).

Currently Mo-99 production is undertaken in B54 and the associated QC process is undertaken in B23 under facility licence F0262. It is important to consider the arrangements that are in place for moving the production process from B54 to the ANM facility at Building 88 and the associated QC process to Building 2.

An adequate number of staff (8) is trained to operate the ANM facility for two (2) runs per week. Other staff from B54 are currently undertaking training at the ANM facility to familiarise themselves with the new plant and equipment. This will continue until all B54 operators are trained. Once the ANM operating arrangements are confirmed through hot commissioning and the facility is authorised to move to routine

operation, the following operating arrangements (percentage of the current total production capacity, per week as a four week average, until the B54 ceases operation) will be progressively put in place to ensure stability in operation of the two facilities until ANM becomes operational to its full capacity.

- 20% ANM vs. 80% B54
- 40% ANM vs. 60% B54
- 60% ANM vs 40% B54
- 80% ANM vs 20% B54

This arrangement will also ensure that the total Mo-99 production does not exceed 100% of the current production capacity. A licence condition is recommended in this regard.

Hot commissioning followed by operation of the ANM facility will result in radioactive gaseous discharges, and simultaneous operation of the B54 facility will also result in gaseous discharges. The EIS (environmental impact statement) for the OPAL reactor stipulates that airborne discharges from the radiopharmaceuticals production facilities at Lucas Heights must not exceed the current gaseous discharge levels regardless of the increase in production of radiopharmaceuticals. Therefore, the ARPANSA assessor recommends relevant licence conditions related to simultaneous operation of both facilities and levels of gaseous discharges.

Arrangements for safe shutdown[5]

The situations that necessitate a shutdown of the facility process and putting the facility into a safe and stable state, with no movement or transfer of chemicals and/or fissile material, should be analysed. In order to maintain the facility in a safe state, some systems should operate continuously or should be restarted within a defined delay period if they become unavailable [9]. Examples of such systems are:

- exhaust ventilation systems that ensure dynamic containment of radioactive material
- dilution (gas flow) systems used to prevent hazardous concentrations of hydrogen
- safety significant I & C systems and utility supply systems.

The key aspect of the processing of Mo-99 involves alkali dissolution of the irradiated LEU targets followed by purification applying appropriate procedures. The dissolution process will take place in the dissolver. The dissolution and purification processes will be performed inside the hot cell. The dissolution process will generate small quantities of hydrogen gas, which will be converted to water using a hydrogen converter. There are no ignition sources within the process vessels and piping and the potential for static build up is minimal due to the predominant use of metal components. The process equipment is purged with nitrogen and evacuated prior to use to ensure that oxygen is removed and that the concentration in the dissolver is maintained below the Lower Explosive Limit (LEL). A continuous flow of nitrogen is maintained to the dissolver during operation. The design and operating parameters of the extract ventilation rate through the hot cells ensure that any leaked hydrogen would be dispersed maintaining concentrations below the lower flammability range within the hot cell and ventilation extract ducts.

If these defences fail, there is a hydrogen leak detection system that alarms at low levels of hydrogen and trips out all sources of ignition in the hot cells on detection of concentrations of hydrogen that are

[5] A safe shutdown state implies there is no movement of radioactive material or liquids, with ventilation and (essential) cooling only

approaching the LEL. This system also triggers a process control to circulate chilled water into the dissolver vessel jacket to slow down the dissolution reaction.

Furthermore, if hydrogen is leaking out of the vessels fission products will also leak out. In that case, the stack monitors would alert the operators to a potential leak even if hydrogen detectors failed or the concentration at the detection point was still below the alarm level.

There are no other flammable materials in the hot cells. The quantities of combustible materials, such as columns, tubing and plastic vessels are limited or shrouded in stainless steel to reduce the fire load within the hot cells.

The facility is equipped with standby power supply in the event of failure of normal site power supply. The standby power supply covers the entire facility load except for some heavy usage components of the ventilation systems e.g. the chillers. All safety systems are supplied by standby power. In addition, the PLCs controlling the I&C systems ventilation, fire detection in the ventilation system and the fire suppression system in the SIAM filters are provided with uninterruptible power supplies (UPS). This provision will maintain operation to enable the safe shutdown of systems in a predetermined manner if ongoing operation is required during a site power outage.

As part of administrative controls a list of actions are specified for the operators to be performed in the event of a process deviation and shutdown including the involvement of ANSTO ERT (Emergency Response Team) and ASOC. Operators are trained in such actions and the ARPANSA assessor verified this aspect during site visits. Details of the actions are described in section 8 of the ANM Safe and Secure Operations Manual (P-50100). Following an emergency relevant safety systems will be restored to normal operating status with all alarms reset prior to safe return to operations. During commissioning of the facility the ARPANSA assessor observed an exercise involving restoration to normal operating conditions after failure of power supply and found that the procedures were suitable.

ANM Maintenance Procedure (P-50138) will be applied to relevant maintenance activities. A safe Work Method & Environment Statement (SWMES) will be required to assess the hazards involved in the maintenance for recovery to normal operation. Following completion of the maintenance, the routine operating procedure including pre-start checklist will be applied to restart the facility to normal operation.

ARPANSA's assessment suggests that the arrangements for safe shutdown and for return to normal operation are adequate to commence hot commissioning leading to operation.

Interface between safety and security

The interfaces between safety, security and control of nuclear material must be managed throughout the lifetime of the facility [5].

The design features have taken into account provisions for nuclear criticality control including engineering and administrative controls. Configuration of the system, geometry, structural components and process control instrumentation have been considered. Effectiveness of the controls were verified by witnessing commissioning tests and the cold commissioning runs involving un-irradiated targets. Administrative controls including procedures for handling nuclear material and conditions of the criticality certificate will be followed.

Appropriate standards such as the American Nuclear Society Standard, ANSI/ANS 8.1-2014 (Nuclear Criticality safety in Operations with Fissionable Materials outside Reactor) and ANSI/ANS 8. 19-2014

(Administrative Practices for Nuclear Criticality safety) have been applied to the criticality safety analysis. An authorised safeguards officer will be responsible for implementing the requirements described in ANSTO Nuclear Material Control & Safeguards System (AS-1318). Further, the ARPANSA assessor has considered the recommendations provided in the IAEA INFCIRC 225/Rev.5[6] and NSS 14[7] and found that such recommendations have been reflected in the design and operation of the facility. More details of assessment of the security arrangements are presented in section 3.5.

The ARPANSA assessor concludes that the technical and administrative measures in place will provide a strong safety and security interface so that neither are compromised.

Conclusion

The arrangements for operation of the ANM Facility are supported by a comprehensive set of procedures and work instructions. The arrangements demonstrate that the management structure, provisions for resources, suitably trained and qualified staff, operating procedures and work instructions, control of modifications, maintenance and inspection, accident management and local emergency arrangements, and continuous improvement in operation are adequate.

The arrangements for moving the operation from B54 to the ANM facility suggest smooth transition of operation to the ANM facility. However, licence conditions are recommended to ensure that the total production from the two facilities does not exceed the full production capacity of the existing facility thus avoiding an increase in the radioactive gaseous discharges.

The arrangements for safe shutdown provides a satisfactory level of assurance that the facility can be shut down safely and maintained under control, should an unforeseen event with safety implications occur during hot commissioning.

The measures for managing the safety and security interface complement each other.

The ARPANSA assessor concludes that proper implementation of these arrangements will provide reasonable assurance for safe and reliable operation of the facility. Implementation of the operating arrangements will be subject to ongoing compliance monitoring by ARPANSA.

Considering the transition plan for moving operations from B54 to the ANM facility, the ARPANSA assessor recommends the following licence conditions:

Recommended licence conditions

- The licence holder must, by 30 June 2020, provide a report to the CEO of ARPANSA on:
    a) holdings of intermediate level waste (ILW) at the ANM Facility
    b) projected future generation of ILW at the facility

[6] International Atomic Energy Agency (IAEA), Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities, IAEA Nuclear Security Series No. 13, IAEA, Vienna (2011)

[7] International Atomic Energy Agency (IAEA), Nuclear Security Recommendations on Radioactive Material and Associated Facilities, IAEA Nuclear Security Series No. 14, IAEA, Vienna (2011)

c) plans for treatment of the ILW generated at the facility including projected treatment in the SyMo Facility

d) plans for storage and disposal of the ILW that take into consideration the national policy and plans for full life-cycle management of radioactive waste

e) contingency plans should one or several components of the ILW management system not eventuate or fail.

- The licence holder must submit a decommissioning plan for the ANM facility after gaining five years of operational experience from the finalisation of commissioning activities. The decommissioning plan must be submitted to ARPANSA by 31 December 2024 or at a time agreed by the CEO, taking into consideration the national policy and plans for full life-cycle management of radioactive waste.
- The licence holder must not commence operation of the facility until:
  a) the licence holder has demonstrated operational readiness in terms of staffing numbers, competence, training, arrangements for emergency preparedness and response, and provisions for safe and secure production of Mo-99 in both B54 and in the ANM Facility during the initial phase of routine operations of the ANM Facility
  b) the licence holder has developed plans for possess and control of the facility in case operations have to be discontinued for other than planned or short-term unplanned outages
  c) the licence holder has provided a plan for phasing out routine Mo-99 production in B54.
- During initial routine operations of the ANM Facility with simultaneous Mo-99 production in B54: the total production of Mo-99 must be capped at 2400 six-day curie per week as a four-week average, and not increased beyond that level until production in B54 has ceased and operational experience of the ANM Facility provides evidence of safe operations.
- For a period of 18 months after cessation of routine operations in Building 54, and contingent on ARPANSA's approval, Mo-99 production in Building 54 must only take place under special circumstances such as during short-term outages in the ANM Facility.
- The licence holder must report the airborne discharges from Mo-99 production at the Lucas Heights Science and Technology Centre to the CEO annually as percentages of the notification levels set out in the following table:

Annual airborne discharge notification levels for Mo-99 production

Annual Notification Levels											
Kr-85m (TBq)	Kr-87 (GBq)	Kr-88 (GBq)	I-131 (GBq)	I-132 (GBq)	I-133 (GBq)	Xe-135 (TBq)	Xe-135m (TBq)	Xe-133 (TBq)	Gross alpha (MBq)	Gross beta (MBq)	Total all other radionuclides (MBq)
10	300	400	10	7	2.15	400	100	1350	When detected	1000	500

3. Plans and arrangements

Item 4 of the general information that may be requested by the CEO refers to plans and arrangements for managing safety of the controlled facility to ensure the health and safety of people and protection of the

environment. It is expected that there are plans and arrangements that describe how the applicant proposes to manage the controlled facility.

3.1 Effective control arrangements

It is expected the applicant describes the organisational arrangements for managing safety of the conduct and dealings to ensure the health and safety of people and the protection of the environment. This should include a description of responsibilities and lines of authority, and information on a quality system covering all activities that may impact on safety [4].

Statutory and regulatory compliance

The application is supported by an ANSTO Guide (AG – 5445) on addressing ARPANSA's requirements. This document describes the roles and responsibilities for complying with ARPANSA's regulatory requirements. Section 10 of this document describes responsibilities including:

- nominee
- licensing officer
- facility officer
- responsible officers
- regulatory affairs manager.

The nominee ensures that local procedures and instructions for achieving regulatory compliance are put in place, where applicable, and are appropriately maintained. The procedures and instructions should be focussed on the particular requirements for the controlled material and controlled facilities managed by the division or institute. For ANM, the general manager is the nominee. The high reliability officer of the ANM facility is the licensing officer for the facility and the operations manager is the facility officer. ANSTO has an organisational regulatory affairs manager who is the main contact point for all regulatory matters and will be supported by relevant ANM officers to ensure compliance with regulatory requirements.

Details of the mechanisms for reporting compliance are described in Sections 11 and 12 of the ANSTO Guide including mechanisms of reporting potential non-compliances.

The requirements for managing ARPANSA-related statutory and regulatory compliance is well described in the guide and meets ARPANSA requirements. Primary responsibility for reporting to ARPANSA is through the High Reliability Officer via the ANSTO Regulatory Affairs Manager.

Management commitment

Management's commitment to maintaining safe and secure operations is generally well documented in the effective control plan and in lower level procedures. Management commitment to ensure compliance with statutory and regulatory obligations and adequate resource allocation are described in the document ANM Management Responsibilities (P-50052).

Through the ANSTO Work Health, Safety and Environment Policy (2013), ANSTO commits the organisation to undertake its work activities in a manner that:

- places the protection of human health and safety and the environment, as its highest priority

- promotes a positive safety culture and environmental awareness throughout all levels of the organisation
- strives for continual improvement in safe work practices, reducing environmental impact and the prevention of pollution
- empowers its people for ownership of safety
- facilitates continual learning from experience, both its own and others.

The roles and responsibilities in undertaking the above commitments are described in ANM Management Responsibilities (P-50052).

Although the effective control plan did not explicitly describe the principles of holistic safety relating to human aspects and human performance, these factors and principles were given due consideration in the design and layout of the plant and equipment. These factors and principles were considered in approving the construction of items important for safety under regulation 54.

There are procedures for the control of documentation and changes that detail the requirements to be met including the requirement to categorise a change and undertake risk assessment of the change. The commitment provided by management demonstrates the attributes of leadership for safety by managers as specified in international standards [16].

Accountabilities and responsibilities

The organisational structure of the ANM facility, and how it fits within the overall ANSTO organisation is outlined in the effective control plan and includes reporting arrangements and some key accountabilities. The document, ANM Management Responsibilities (P-0052) describes the responsibilities of ANSTO Nuclear Medicine Management in the maintenance of the ANM BMS and compliance with TGA, ARPANSA and WHS statutory and regulatory requirements. Further details on accountabilities and responsibilities are described in the Safe and Secure Operations Manual (P-50100) and Operating Limits and Conditions (P-50099, Rev 4). Further details of these aspects are described in section 2.3.5. A notable feature of ANSTO procedures is a section titled Responsibilities, which describes the accountabilities for all staff. In support of the effective control plan ANSTO has provided the copies of relevant service level agreements with internal service providers. These service level agreements describe the terms of reference and scope of the services provided by other divisions. Details of the services to be provided are described in section 6.9 of the ANM Management Responsibilities (P0052).

Resources

ANSTO as an organisation has significant technical and financial resources through a mixture of government appropriation and commercial services. The ANM structure has approximately 60 professional and technical staff and the ability to access further ANSTO resources through service level agreements and other ANSTO internal systems. Other divisions of ANSTO provide services through service level agreements such as radiation protection services and engineering maintenance services.

Communication

Communication expectations and procedures are well documented, particularly in the ANM Communication Procedure (P-50096 Rev 0). This procedure requires all staff to communicate in an effective

and appropriate manner using the pathways and formats described therein. The procedures describe the principles, pathways, forums and contents. There are multiple methods of communication relating to the multidirectional transfer of information and instructions (i.e. up, down and sideways). The communication routes for certain specific events such as radiological events and regulatory submissions are also defined. Specific events communication paths are detailed in Table 2 of this document.

Process implementation

The applicant states that all new processes and changes to existing processes at the ANM facility are managed through the change control system described in Change Control Procedure (P-50003) which forms part of the ANM quality management system. Changes in operations and processes are subject to the ANSTO internal review process including review and approval by the ANSTO Safety Assessment Committee (SAC) depending on the types of change. Changes requiring regulatory approval are submitted to the regulatory authority following appropriate procedures. There is a process in place for verification of completion of actions.

Documentation and document control

The applicant states that both the ANSTO and ANM BMS have been designed to meet the requirements of ISO 9001:2008 and ISO 14001:2004. It is ANSTO's policy that all processes are reviewed and documented to ensure they are well understood, current and available for use. The ANM BMS describes specific operations within the ANM facility. The procedures and instructions describe the step-by-step process for specific operations. Relevant checklists support these documents. The documents are accessible to staff and the document control process ensures that the latest versions are available to users. An internal audit process is in place to check the effectiveness of the document control process. In addition, the ANSTO's management system is subject to ISO audit and TGA audit in accordance with the good manufacturing practice.

Conclusion

The above arrangements describe the manner in which the applicant proposes to maintain effective control of the facility. The arrangements show that there is an established system for clear roles and responsibilities, resource allocation, peer review, internal independent review, internal approval process, accredited quality system, and clear communication system. These characteristics conform to the SiD recommended by international best practice [6]. Given the applicant's first priority is safety and there are multiple layers of screening applying the principles of SiD, the ARPANSA assessor considers that a strong ISiD is in place to ensure safe operation of the facility [6].

The application of these arrangements were observed during planned inspections, site visits and cold commissioning of the facility. Proper implementation of these measures will provide a reasonable assurance that an adequate level of effective control will be maintained for safe and secure operation of the facility.

3.2 Safety management plan

The application should include a safety management plan that demonstrates that safety management practices are in accordance with internationally accepted principles and practices and duty of care obligations [4].

Safety policy and objectives

The ANSTO Work Health, Safety and Environment Policy gives the following commitments:

- places the protection of human health and safety and the environment, as its highest priority
- promotes a positive safety culture and environmental awareness throughout all levels of the organisation
- strives for continual improvement in safe work practices, reducing environmental impact and the prevention of pollution
- empowers its people for ownership of safety
- facilitates continual learning from experience, both its own and others.

In order to achieve these commitments ANSTO implements relevant WHS standards and guides, an internal safety approval system and quality management system. Details of the elements that demonstrate commitment towards strong safety culture are described in section 5.5 of the ANM Radiation Protection Plan (Q-50083, rev. 5). For fostering safety culture ANSTO emphasises sound management practices, good engineering and laboratory practices, attention to quality assurance, implementation of a comprehensive safety assessment, monitoring and review, effective communication, consultation and cooperation, and feedback from lessons learned, and experience and research. These elements are in line with the provisions of fostering a culture of safety specified in international standards [16].

The safety management plan pulls together specific safety arrangements for the ANM facility, deferring to the requirements of the overarching ANSTO Occupational Health, Safety and Environment Management System (OHSE) where appropriate. This approach promotes integration across divisional boundaries to support corporate uniformity and learning. Specific operational requirements are addressed through the ANM BMS system.

The safety management plan describes ANSTO's safety and security values through the ANM safety policy and objectives. This includes promoting a questioning attitude through the use of the STAR principle (Stop, Think, Act, and Review). The responsibility on all staff to maintain vigilance and act in the event of safety, security or process non-conformance is clearly reinforced in supporting documents such as the ANM Mo-99 Facility Safe and Secure Operations Manual (P-50100 Revision 3) and the Non-conformance, Corrective and Preventive Action Procedure (P-50007, Revision 0). ANSTO gives commitment to implement the safety and security provisions through lower level procedures forming the ANM BMS system. For example, the Operations Manager is responsible for ensuring that local safety arrangements are maintained and implemented, the Radiation Protection Adviser is responsible for implementing radiological protection services under a Service Level Agreement (SLA) and the Safeguards Officer ensures appropriate security provisions for nuclear material. The non-conformance procedure describes the arrangements for dealing with deviations, corrective and preventative actions to be taken, closing out corrective actions, reporting, and the corresponding responsibilities. These arrangements demonstrate that a systematic approach will be in place to manage effectively the processes and activities, and is consistent with international standards [16].

In order to improve the operational and safety performance of the facility ANSTO has considered a number of safety indicators including number of events, types of events, number of opportunities for improvement identified, number of corrective actions closed out, and number of safety and/or housekeeping inspections conducted. The comprehensive set of safety performance indicators will be considered once the facility becomes operational, and will be subject to regulatory compliance.

The safety management plan clearly states the high level management accountabilities for safety, an attribute of safety culture. This drives the message to staff at all levels that safety is an important value and in this regard leadership for safety is clear. ARPANSA will need to monitor how leadership delivers this on a day to day basis once operations commence. The accountabilities are more clearly defined in the ANM Facility Safe and Secure Operations Manual (P-50100 Revision 3). This is an operational document and provides information and instructions that will help to promote an effective safety culture in the facility workforce. Application of this document was verified during cold commissioning of the facility demonstrating that responsibilities and accountabilities are clearly defined for safe operation of the facility.

Monitoring and measurement

The safety principles considered in the design of the facility including layout, structures, systems and components have taken into account safety performance in terms of exposure to the operators during normal operation. The design objectives of most of the structures, systems and components have been confirmed through cold commissioning. The design objectives of some structures, systems and components could not be verified from cold commissioning, for example, the active ventilation system. Hot commissioning will verify whether design objectives of such systems have been achieved. ANSTO has utilised the safety data obtained from operational experience with the current B54 Mo-99 production facility. The safety management plan broadly describes ANSTO's system for Event Management. ANSTO defines an event as the occurrence of something that has caused, has the potential to cause, or may be perceived to cause consequences that may affect the health and safety of people or impact on the environment, plant or property. ANM will use the ANSTO Event Reporting System that provides a risk informed graduated process. Verification of the effectiveness of engineered safety systems or administrative controls that are mitigated by other layers of defence are described in the FSAR. Further, in the Radiation Protection Plan ANSTO gives commitment to review the doses to operators of various working groups quarterly to optimise the radiation protection. A licence condition is recommended in this regard (see Radiation Protection Plan below).

Risk assessment and mitigation

This aspect is covered in the section 3.1, Effective Control Plan and in section 2.3.2, Final Safety Analysis Report.

Managing change

The application refers to the ANM Change Control Procedure (P-50003) that describes the process of managing changes involving production, process, operations, plant and equipment and relevant aspects that may affect the safety of operation of the facility and the product. All changes are subject to formal risk assessment and the internal approval processes. A change control register will be maintained to capture such changes, and the results of reviews and any follow up actions are also reported in the monthly change control system. Any changes requiring regulatory approvals are undertaken following the appropriate procedures and the ANSTO Guide. The change management process forms part of the ANM BMS system and ANSTO quality system.

Learning and continuous improvement

The safety management plan refers to the overarching ANSTO WHS for learning and continuous improvement. These are delivered through the Human Resources and WHS division along with the ANM Quality System and rely on audits and workplace inspections. These systems are valuable and their performance elsewhere at ANSTO suggests they will be effective at ANM. ANM has utilised the operating

experience with the B54 Mo-99 production. It is expected that the ANSTO policy objective of learning and continuous improvement will be implemented at the ANM facility during its operation, and will be subject to regulatory oversight. Further details are described in section 2.3.5 above.

Training and education

ANM has its own training procedure (P-5009) that will follow ANSTO processes under a service level agreement with ANSTO HR and WHS Division. These ensure that hazardous work is performed and supervised by authorised and qualified workers. Each worker is assigned an individual training plan associated with their work tasks. Training programs are provided for induction, work specific tasks, ongoing, refresher, job change and competency based training. Training is managed through the ANSTO Learning Management System. Training requirements extend to contractors for training needs associated with their work. ANSTO has effective contractor supervision arrangements in place. The ANM operators have been trained during the cold commissioning process so that they receive practical experience with the state of the art technology. They applied routine operating procedures for the cold commissioning process. The ARPANSA assessor observed the operators performance during cold commissioning and found that they are appropriately trained in operation of plant and equipment. The ARPANSA assessor also noted that during training at the ANM facility the operators used audio-visual technology to record their operating performance. This was subsequently shared with other operators and was viewed by the supervisor and the same operator. This ensures learning from each other and provides opportunity to reflect on one's own performance. This interactive process of training demonstrates ANSTO's commitment to continuous learning and development. Further details of sufficient qualified personnel are described in section 2.3.5 above.

Conclusion

The above arrangements describe the safety management measures that the applicant proposes to implement. The implementation of a significant part of these arrangements for managing safety were observed during site visits to observe the cold commissioning and the cold commissioning run using un-irradiated targets. These measures should provide reasonable assurance that an adequate level of safety management will be maintained. The provisions for management of processes and activities provides confidence in achieving the organisation's goal without compromising safety.

3.3 Radiation protection plan

The applicant is responsible for ensuring that arrangements are in place for meeting their responsibilities towards radiation protection and nuclear safety [4].

Principles of radiological protection

In order to provide an appropriate level of protection ANSTO applies the principles of justification (of a practice), dose limitation and optimisation of protection.

The risk from the controlled exposure situation of the ANM facility has been justified on the basis that there is net societal benefit from the production of Mo-99 for application to medicine.

Regarding optimisation ANM has committed to the fundamental radiation protection principle of optimisation by keeping the likelihood of incurring exposures, the number of people exposed, and the

magnitude of their individual doses as low as reasonably achievable, taking into account economic and societal factors (the ALARA principle).

The application states that the ALARA principle will be formally applied to the ANM facility and Building 2 QC Active Laboratory, as appropriate, by:

- use of task-specific dose constraints (also referred to as radiation dose review levels in Safe Work Method and Environmental Statements) to ensure an appropriate balance between individual exposures and group/society benefits
- identification of activities with a radiological risk and completion of a Safe Work Method and Environmental Statement and a Radiological Risk Assessment by the person planning the work with input from various stakeholders including Radiation Protection Services staff to assess the expected doses from the task and optimise the controls. Once optimisation measures have been identified and implemented, the expected dose may be considered ALARA
- conducting qualitative and quantitative ALARA assessments where it is shown or expected that the annual effective dose as a consequence of planned exposure situations is greater than the levels specified in the ANSTO WHS Radiation Safety Standard (AE-2310)
- application of the ANSTO occupational exposure and public exposure investigation levels as detailed in the ANSTO WHS Radiation Safety Standard (AE-2310).

According to the ANSTO Standard (AE-2310) an ALARA assessment will be conducted where it is shown or expected that the annual effective dose as a consequence of planned exposure situations is greater than:

- 2 mSv to any occupationally exposed person
  or
- 0.1 mSv to any member of the public within ANSTO controlled sites
  or
- 0.02 mSv to any member of the public outside ANSTO controlled sites.

The application further states if a radiological risk assessment demonstrates that the annual radiation exposures are predicted to be less than these annual effective doses, dose reduction measures will be in place, where reasonable. Once a situation has been shown to be optimised this will be reviewed periodically to ensure that it is still appropriate for the prevailing circumstances.

As part of optimisation of protection the following dose constraints will be in place as a site wide approach:

- annual effective dose constraint of 15 mSv for an occupational worker
- annual effective dose constraint of 0.75 mSv for any member of the public within the site
- annual effective dose constraint of 0.3 mSv for any member of the public outside the site
- for occupational exposure of persons 16 to 18 years of age who are being trained for employment involving radiation and for exposure of students of age 16 to 18 who use sources in the course of their studies, the dose constraints are as required for members of the public within ANSTO sites.

As a parameter of performance measure the annual ALARA objective for an occupational worker will be 2 mSv and that for a member of the public outside the controlled site will be 0.02 mSv.

Investigation levels will also apply for optimisation of protection. For occupational exposure the following investigation levels will apply for any single dosimetry reporting period (in this case monthly):

- 1 mSv effective dose
  or
- 1.5 mSv equivalent dose to the lens of the eye
  or
- 40 mSv equivalent dose to the skin or hands and feet.

All investigations will include the following actions:

- ascertain the source of the exposure
- determine whether the dose was actually received by the person
- determine if the exposure was justified and optimised
- reduce future radiological exposure, where reasonable.

For public exposure, the monthly investigation level within the site will be 0.05 mSv applying the same process as described above for occupational exposure. For a member of the public outside the controlled site the investigation level for effective dose per calendar quarter will be 0.005 mSv (5 µSv), applying the same process.

The statutory dose limits specified in the ARPANS Regulations will apply to individual doses resulting from the activities associated with facilities.

The application states that doses calculated in the supporting document (Mo99_FACL_OPER_TN_0329_B: Dose Assessment) will initially serve as the dose constraints for the various groups identified in this document. Considering that expected individual doses are below ANSTO's ALARA objective of 2mSv/yr, ANSTO did not consider further dose reductions to be justified from an economic perspective. However, the ANM will review the doses received by individuals and work groups quarterly during the first year of full operation as part of the continuous monitoring and review process to ensure the assumptions made (e.g. times taken, worker position, dose rates etc.) are verified during the early stages of routine operations.

Planning and design of workplace

Planning and design of the workplace was considered in the assessment of the licence for construction of the facility followed by the approval of construction of items important for safety under regulation 54. Design features and applicable standards were considered when issuing the licence for construction of the facility and were found to be adequate to minimise the exposure to the workers (R14/05724). Appropriate engineering controls including ventilation, interlocks, shielding and selection of appropriate radiation monitoring systems were considered when approving construction of items important for safety under regulation 54.

Appropriate engineering controls have been incorporated in the design including fixed shielding, movable shielding, interlock systems on hot cells and access doors, and HVAC and gas management systems in line with the principle of defence in depth. Further details are described in 6.1 of the Radiation Protection Plan (Q-50083).

Radiation safety officer

ANSTO's Radiation Protection Services (RPS) section will provide health physics service to the ANM Facility under a service level agreement. An ANSTO Radiation Safety Officer (RSO) will be appointed for the ANM Facility who will be supported by Health Physicists (HP) and Health Physics Surveyors (HPS).

The application states that the RSO is an experienced, recognised radiation protection specialist who is responsible for ensuring that ANSTO's radiation protection advice reflects current relevant Australian radiation protection legislation and international radiation protection best practice. The RSO will ensure that the ANSTO radiation protection guides and arrangements are appropriate to meet current Australian National Standards and Codes, the ARPANS Act and Regulations, and international best practice. The RSO will also ensure that RPS staff are adequately trained and experienced to fulfil their duties. The HP will assist workers with improvements in radiation safety at a practical operational level through the review of working practices and input into working procedures for all activities where radiological safety assessment is required. The HPS will perform radiation monitoring surveys of areas identified by the HP within the work site. The HP and the HPS have the authority to suspend work if the radiological conditions have significantly deviated from the expected operational levels or it is believed that radiological conditions present an unacceptable risk either to workers or to members of the public.

Radiation Safety Committee

ANSTO Radiation Protection Services provide all relevant radiation safety advice to ANSTO facilities. In addition, all new operations and changes with significant safety implications are subject to an ANSTO internal committee, namely, Safety Assurance Committee (SAC) approval. The SAC meets at a regular interval and discusses relevant matters that require approval or advice. The SAC receives advice from Radiation Protection Services regarding radiation safety matters and use the results of review of SAC submission by radiation protection experts in granting approval of certain activities. For the operation of the facility the ANM General Manager will have overall responsibility for radiological safety. The General Manager will delegate actions for implementing the Radiation Protection Plan to the ANM Operations Manager. The ANM operations manager will be responsible for implementing systems, procedures and technologies to ensure compliance with radiation safety standards, and optimising radiation protection of workers and the public, whilst ensuring all radiological exposures are ALARA.

Classification of the work areas

The work areas have been radiologically classified on the basis of exposure levels and the requirements to be followed. The areas are broadly classified as contamination class and radiation class. Further, based on exposure levels and access controls, work areas are classified as forbidden, red, blue and white. Details of the work areas, their locations and classifications are described in section 7 of the Radiation Protection Plan (Q-50083). The application states that certain areas in the ANM facility have been designed to allow for a change in contamination and radiation area classifications based on the type of work to be performed.

Local rules and procedures

The application refers to ANSTO Guide (AG-2511) Radiation Protection Requirements in radiologically Classified Areas, for local rules and procedures. The guide describes access and exit requirements, rules to be followed in radiologically classified areas, use of personal protective equipment (PPE), use of radiation and contamination monitors etc. Further, task specific rules and procedures (e.g. spill response, inventory control etc.) are described in the ANM BMS system.

Personal protective equipment

The application states that all workers and visitors within the ANM facility and B2 QC laboratory will require wearing personal protective equipment (PPE) prior to entering radiological classified areas.

Details of the PPE requirements and clothing change procedures when entering or leaving contamination classified areas and entry and exit to the radiological classified areas are described in ANSTO Guide

AG2511. The ARPANSA assessor notes that ANSTO submits the personal dose results to ARPANSA quarterly. These are subject to ARPANSA assessment for trend analysis and compliance monitoring.

Monitoring of the workplace

The application states that the ANM facility workers will perform monitoring of the radiological conditions of the work place routinely, with assurance monitoring performed by RPS workers to a survey program. The facility is equipped with fixed and portable radiation monitoring systems. The area monitors are located at strategic locations and the results of the area monitors will be displayed on the SCADA system and will be available to the operators at the working areas. Construction of the radiation monitoring system was subject to ARPANSA approval under Regulation 54 [2]. The air of the cell face area will be continuously monitored using an air sampler. Details of the radiation monitoring instrumentation are presented in section 11.3 of the Radiation Protection Plan (Q-50083).

The ARPANSA assessor notes that records of surveys and any radiological incidents are maintained within an ANSTO's electronic system in a quality format. Trends in surveys and incidents will be tracked by the RSO and HP. Incidents will be investigated depending on their nature.

Monitoring of individuals

The application states that occupationally exposed employees will be monitored as part of the routine dosimetry program. This will include the supply of dosimetry devices, analysis of returned devices and a dose record keeping service provided by RPS.

Routine external monitoring using thermo-luminescent dosimeters (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 TLDs will be assessed either monthly or quarterly based on the exposure. Electronic personal dosimeters (EPD) will also be used as part of dose control measures.

The ANM facility workers will undergo baseline and periodic whole body monitoring. Persons entering the classified contamination areas will also be required to undergo routine whole body monitoring and/or additional monitoring depending on their tasks.

The following performance indicators will be monitored to measure the effectiveness of radiological control measures:

- occupational exposure to individuals
- monitoring results from routine radiological surveys
- event/incident reports.

The application states that ANM management and RPS will review and audit these performance indicators to maintain the continuous improvement towards the reduction of radiological exposures to workers at ANM.

Depending on the exposure levels, RPS may undertake investigations. Details of investigation levels are presented under principles of radiological protection above.

Monitoring of the environment

The operation of the facility will generate solid, liquid and gaseous wastes. Solid waste will be transferred to ANSTO Waste Operations facilities for management under Facility Licence F0260. Some low level liquid

wastes will be discharged offsite through ANSTO Waste Operations following further processing. The discharged wastes are subject to compliance with statutory requirements and limits. The airborne discharges from the ANM facility will be subject to ARPANSA notification levels, which are based on conservative modelling to ensure that there is no undue risk from such discharges. Details of notification levels are described in the Waste Management Section. The gaseous wastes will be discharged through the stack and monitored by an on-line monitoring system. Further details of the environmental monitoring program are described in the Environmental Protection plan. The discharge of gaseous waste from the facility is subject to a licence condition.

Transport

Operation of the facility will involve onsite transport of radioactive material, including irradiated target material, solid and liquid wastes, to and from the ANM facility. The application states that the movement of radioactive material to and from the facility will be in accordance with ANSTO Guide AG2515 Safe Movement and Transport of Radioactive Material.

The ANSTO Guide describes the controls and measures that will be in place for safe transport of radioactive material within the controlled site. These include use of appropriate packages, limits on package surface dose rates, use of a designated vehicles, limits on vehicle speed, requirements for health physics escort, need for contamination clearance certificate, and maintenance of appropriate records. The ARPANSA assessor notes that any offsite transport of radioactive material will be subject to *ARPANSA Code: Safe Transport of Radioactive Material, Radiation Protection Series RPS C-2* (2014).

Conclusion

The above description of arrangements for radiation protection describes measures that the applicant proposes to implement. The above arrangements suggests that all activities involving radiation exposure or potentially involving exposure are planned, supervised and carried such that exposure is minimised. However, the ARPANSA assessor has found that the optimisation process of radiation protection mainly focussed on the ‘ALARA principle’, which is not consistent with international best practice. The optimisation process should include, but not limited to, comparison of alternative systems and methodologies, analysis of interdependencies and assessment costs. Further, there is reference to the ALARA objective for annual effective dose of 2 mSv, and it is not clear how this objective supports the optimisation process. Further, the ARPANSA assessor notes that the dose constraint referred to in the application is not based on an operational dose assessment using the measured data of the current Mo-99 production facility and should be revised. Therefore, the ARPANSA assessor recommends two licence conditions in this regard.

The ARPANSA assessor considers that the arrangements for radiation protection will provide reasonable assurance to minimise the exposure subject to the following recommended licence condition.

Recommended licence conditions

The licence holder must not commence operation of the facility until:

a) the licence holder has defined a dose constraint for occupational exposures to radiation in the ANM Facility and in the Building 2 QC Active Laboratory, provided an analysis of optimisation of radiation protection that outlines how different options have been evaluated in order to manage radiation risks, and provided a plan including a time-line for implementation of reasonable

measures to reduce the radiation exposures, the number of exposed individuals and the likelihood of exposures

b) the licence holder has analysed automation of the QC procedure for high activity Mo-99 liquid samples as part of the optimisation under (a).

3.4 Radioactive waste management

Appropriate arrangements should be in place for safe management of radioactive waste [4]. The arrangements should take into account the physical, chemical and radiological characteristics of the waste; methods of minimising the volumes and activities of radioactive wastes generated; the treatment, storage, disposal and discharges of radioactive wastes; and the control, monitoring, recording and reporting of wastes [4].

Management of radioactive waste

Operation of the ANM facility will generate solid, liquid and gaseous wastes. Low and intermediate level solid and liquid waste will be produced from the production process of Mo-99. The plans and arrangements for managing radioactive waste interface with those of ANSTO Waste Operations, which is operating under Facility Licence F0260. ANSTO Nuclear Services will provide waste management services to ANM under a service level agreement. ANM has applied the ARPANSA/IAEA classification system for radioactive waste. Local procedures and instructions that comprise the ANM BMS also apply. For example, Solid Waste Decay and Transfer between Cells using PADIRAC (I-50187), Liquid Waste Tanks Operations Manual (I-50235).

Through the Waste Management Policy ANSTO gives a commitment to the following objectives:

- safely treat and store ANSTO's radioactive wastes in preparation for final disposal, minimising exposures while considering economic factors
- minimise radioactive waste generation and provide custodianship of waste from source to storage and final disposal.

During the design and construction of the facility suitable materials were selected to minimise the generation of radioactive waste. Technical and administrative controls have been incorporated in operation of the facility including use of minimal manual handling in operations.

Since the facility will use fissile material, a criticality assessment has been performed using appropriate analysis and specific operational limits and conditions have been derived in this regard. Further, operation of the facility is subject to the conditions of the criticality certificate. The ARPANSA notification levels for gaseous discharges from the facility and the discharge limits specified in the Trade Waste Agreement for the site will apply.

Limiting exposure to radioactive waste

The Radiation Protection Plan describes the arrangements for limiting exposure to radioactive waste. These are assessed in section 3.3 above.

Packaging and containment of radioactive waste

The wastes will be handled in dedicated hot cells depending on the production and purification processes. Liquid and gaseous wastes will be stored in purpose-designed tanks prior to transfer to other facilities for further processing and discharging to the atmosphere in compliance with appropriate operational limits and conditions. The movement of solid waste materials between hot cells in the facility will be undertaken

via a horizontal-loading shielded PADIRAC flask system which is designed to seal with the hot cells. The movement of solid wastes will be undertaken using PADIRAC, RSW flask and SUF flask. Currently the RSW flask and SUF flasks are used for transferring ILSW e and SUF cups from Building B54 Mo-99 production facility. The ARPANSA assessor witnessed the commissioning tests for PADIRAC®, retrievable flask and SUF slask. All were successfully commissioned in accordance with the documented procedure.

Storage of radioactive waste

The following arrangements will be in place for storage of radioactive waste:

- solid wastes will be stored in purpose-built hot cells, and waste stores operated by ANSTO waste operations under Facility Licence F0260
- Intermediate level liquid waste and low level liquid waste will be stored in purpose-built holding tanks and delay tanks
- gaseous wastes will be stored in gas delay tanks and will be released through carbon columns.

Details of the design features of these systems were considered in the assessment for construction under regulation 54.

Appropriate engineering controls such as active ventilation, shielding and radiation monitoring equipment will be in place; administrative controls including procedures and instructions will also be in place for safe storage of radioactive waste. Security provisions in line with the recommendations made in IAEA NSS 13 and NSS 14 will be in place (see Security Plan, section 3.5).

Documentation of radioactive waste

Records of radioactive waste will be maintained in accordance with the ANM BMS and ANM quality system. The ANM BMS system comprises procedures and instructions including Procedures for Packaging and Despatch (P-50162), and Good Documentation Practices (P-50233).

The Radioactive Waste Management Plan states that the following waste management services procedures will apply to the ANM Facility:

a) NWP 9.8.1: Low Level Solid Waste Procedure
b) NWP 9.8.2: Intermediate Level Solid Waste Procedure
c) NWP 9.6.1: Low Level Liquid Waste Procedure
d) NWI 9.7: Effluent Procedure
e) NWP 9.5: Laundry Procedure
f) NWP 9.2: Decontamination
g) NWP 9.11.1: Spent Uranium Filter Cups Management

Through ARPANSA inspection and compliance monitoring processes the above procedures have been found effective for safe management of radioactive waste.

Routine discharge of radioactive waste to the sewer

Radioactive discharges to the sewer is a site-wide matter as the discharge limits are imposed by the Trade Waste Agreement in accordance with the World Health Organisation (WHO) Drinking Water Guidelines. Compliance with the discharge limits of the Trade Waste Agreement (Sydney Water Corporation, Consent to Discharge Industrial Trade Waste Water #4423) is a condition of the ANSTO Waste Operations Facility Licence F0260.

Routine discharge of radioactive waste to the atmosphere

The existing notification levels applicable to the B54 Mo-99 production facility will apply to the ANM facility noting that the production level of this facility will be about two times higher than the current facility at B54. This is due to the ongoing Department of Environment's condition, resulting from the OPAL reactor licensing process, that the current airborne discharge levels from the radiopharmaceuticals facilities must be maintained regardless of any increase in production of radioisotopes. The existing discharge notification levels of B54 were derived based on discharge modelling using computer code PC- Cream and real time monitoring data. In order to verify the performance of the ANM facility discharge monitoring system hot commissioning of the facility is required, and ARPANSA will assess the results of hot commissioning.

Conclusion

The above arrangements describe the radioactive waste management measures that the applicant proposes to implement. The arrangements suggests that the waste management measures include suitable collection, characterisation, classification, processing, transport and storage of radioactive waste and the discharge of effluent waste. Suitable procedures are in place to undertake the aforementioned activities. The rigour and frequency of sampling and monitoring are based on the environmental impact of the waste and the environment applying a graded approach. The operational data on radioactive discharges from the ANM facility, along with the discharge profiles from other facilities at the site, should be used to model the radioactive airborne discharges from the ANM facility. The proposed arrangements for managing radioactive waste will provide reasonable assurance for safe operation of the facility.

3.5 Security Plan

Appropriate arrangements for the security of the controlled facility, controlled material or controlled apparatus to prevent unauthorised access, damage, theft, loss or unauthorised use should be in place [4].

ARPANSA's assessment has taken into account the following:

- the ANM Security Plan and accompanying documentation
- observations from a number of site visits of the facility during construction prior to cold commissioning of the facility
- results of security system commissioning by a Security Construction and Equipment Committee (SCEC) endorsed consultant.

ARPANSA's Security Advisers engaged with ANSTO security staff throughout the entire ANM facility licensing process to ensure a holistic approach to security design, operation and management was undertaken and that security was seamlessly integrated into the overall ANM operations.

The ANM facility utilises the international best practice method of production using LEU targets. As such the ANM nuclear and other radioactive material have been appropriately characterised in the ANM Security Plan ensuring the protective security system implemented is in accordance with international best practice. In addition, the LEU plates used in the ANM facility will be irradiated prior to use in the ANM facility, effectively introducing an intrinsic deterrent against theft of nuclear material. The radiation protection and nuclear safety design requirements during the transfer and processing of the irradiated target plates further requires LEU to be contained at all times within either robust containers or hot cells that further restrict access. These best practices and radiation protection and nuclear safety features collectively serve to reduce the attractiveness of this nuclear material to theft for malicious purposes.

The ANM facility's protective security encompasses ANSTO site-wide protective security measures that are set out in the ANSTO Security Plan and integrated with additional ANM facility-specific protection for designated restricted areas including at building vehicle entrances, that provide security 'defence-in-depth' to the ANM facility. The orientation of the ANM facility vehicle entry points in relation to OPAL provides additional protection of irradiated LEU against possible standoff attacks. Further, security by design features include the use of compartmentalisation, meaning the areas of greatest radiological consequence or risk for sabotage or theft (including cyber-attack) have been afforded greater protection.

The ARPANSA Security Advisers conclude that the combination of safety containment, ANM facility building design and orientation features and protective security measures have been implemented. The harmonised facility security plans and site security arrangements will ensure adequate security during the transfer of irradiated material between facilities along the site production chain, as well as while in use within the ANM facility and for the storage of waste prior to final disposal, where applicable.

ANSTO's IT security measures uses a risk-informed approach and have been designed to mitigate against domestic and international cyber-threat. The ANM facility IT system has incorporated the same measures. The ANM facility IT systems have adequate physical protection and access controls. There is sufficient dedicated back-up power supply to support the on-going safe operations of the ANM facility computer (network), I & C systems and electronic security systems in the event of an unexpected loss of external mains power supply.

ANSTO's risk-informed approach to protective security is based on the current design basis threat (DBT) considerations identified by the Australian government. The ANM facility protective security system is designed to be scalable with the DBT in mind, including the advice contained in the threat assessments received by ASIO. The ANM Security Plan is to be reviewed on an annual basis and more frequently in the event of a change in the threat level, refurbishment of the facility, change in security categorisation of the facility or a security incident, for example.

Nuclear security culture also plays an important role in ensuring individuals working in the ANM facility remain vigilant to prevent and combat the general threat of sabotage or use of nuclear or other radioactive material for malicious acts. An effective nuclear security culture is dependent on security training, awareness, roles and personal responsibilities, and nuclear security systems. The ANSTO Security Strategy and Plan, including relevant supporting documentation such as the ANSTO Security Manual, sets out ANSTO's organisational security requirements and responsibilities, annual security awareness training and security accountability and responsibilities, and reinforces security culture at the operational level. This information is articulated in the ANM Security Plan.

The range of radiological consequences associated with all potential risks identified in the ANM Security Plan was graded against preventive security controls and assessed for residual risk. In accordance with international best practice, where the potential radiological consequences of sabotage are less severe than the unacceptable radiological consequences, the operator should still protect safety related equipment and devices by controlling access to them and securing them. An inspection of the ANM facility during the final fit out on 16 June 2017 confirmed that the security access control measures, the safety control barriers for liquid and gaseous waste systems provide adequate levels of protection of the ANM facility safety related production and waste storage systems. Therefore, these controls and safety barriers will provide adequate measures to reduce and/or mitigate against the identified risks.

The ANM Security Plans and Arrangements are suitably interfaced with safety systems and measures during normal operation and are integrated into the ANSTO site emergency management framework. In addition,

the ANM facility Emergency Plan ensures that safety can be adequately managed in an emergency initiated by a security event.

In January 2018, ARPANSA's security advisers undertook a security system inspection of the ANM facility to ascertain the effectiveness of the design, installation and performance verification of the system in accordance with the approved design. It was observed that the design objectives and performance criteria of the security system have been achieved and that the system met the functional requirements of a compartmentalised facility, particularly related to movement from one security zone to the next, the levels of access control applied to each zone, the detection and assessment capabilities and expected response times.

Further to this verification exercise, ARPANSA's security advisers reviewed the ANM facility vulnerability assessment, the accompanying adversary sequence diagram and were provided with a PowerPoint presentation on the tabletop exercise conducted with relevant on-site staff (including the AFP). The ARPANSA security advisers assessed the current capability and capacity of ANSTO Security to undertake ongoing verification activities including the assessment of risks, to conduct vulnerability assessments, and to develop security incident scenarios such that the ANM facility will be adequately protected.

Conclusion

ARPANSA's assessment concludes that the ANM Facility Security Plan and the protective security measures applied, including the safety design features, would provide adequate assurance of a sustainable level of protective security for the ANM facility. The security arrangements will continue to be under regulatory oversight once the facility becomes operational.

3.6 Emergency plan

Emergency plans and procedures should address all foreseeable emergencies to ensure the protection of personnel, the public and the environment. Adequate facilities and equipment must be available and an appropriate state of preparedness maintained [4].

Emergency planning classification, hazard assessment and emergency response arrangements

The relevant international standard for reviewing ANM's arrangements is IAEA General Safety Requirements - Part 7*, Preparedness and Response for a Nuclear or Radiological Emergency* (2015).

The ANM arrangements for an emergency comprise a facility-specific plan, a site-specific plan and the relevant state plans all integrated to ensure that both on-site and off-site response personnel and decision makers act in a coordinated and harmonised manner to achieve the goals of emergency response.

The ANM facility is an Emergency Planning Category II (EP Cat II) [13] facility for which no urgent protective actions are likely to be warranted off-site. However, in an emergency, urgent protective actions and early protective actions may be needed on-site. ANSTO has classified the ANM facility as an EP Cat II. The submitted plans have comprehensively assessed a range of relevant accident scenarios in section 10 of the FSAR, including a bounding unspecified energetic event, in order to characterise the possible releases of radionuclides into the environment and to determine what protective actions might be required for both safety and security initiated events, respectively. These scenarios have also taken into consideration the entire life cycle and movement of the materials used and generated at the facility.

The following key information was detailed, consistent with IAEA GSR Part 7 [13]:

- nuclear and radiological inventory analysis and hazard assessment
- Facility Emergency Planning Hazard Categorization (EPC Cat II)
- clearly defined roles and responsibilities for both on-site and off-site response personnel
- a radiation protection strategy which includes:
    a) generic criteria (GC)
    b) operational intervention levels (OILs)
    c) emergency action levels (EALs) and other physical observables (OPOs)
    d) response time objectives (RTOs)
- communications plan and arrangements
- arrangements for the detection, emergency classification and notification
- arrangements for taking urgent protective actions
- arrangements for taking mitigation actions
- arrangements for managing a medical response
- arrangements for managing non-radiological consequences
- arrangements for managing radioactive waste generated in an emergency

The ARPANSA assessor considers that the facility emergency planning classification, hazard assessment and response arrangements have been performed consistent with international best practice.

C^3 and concept of operations

The submitted plans capture clear Command, Control and Coordination (C3) arrangements for personnel to operate under in the event of an emergency event. Communications and coordination between the ANSTO Security Operations Centre (ASOC), the Radiation Assessment Teams (RATs) and the Crisis Management Team (CMT) is evident. The role of the ASOC to facilitate and coordinate offsite assistance in a general emergency has also been established. ANSTO has demonstrated that they conduct regular and comprehensive emergency exercises, which tests and prepares all levels of the organisation to respond, be it a safety or security initiated event. Adequate infrastructure, equipment and capabilities are available on-site for emergency scenarios with additional support available from NSW emergency services, should the emergency exceed the capabilities available on-site.

The concept of operations described across the submitted plans includes all expected mechanisms to detect, assess, notify, activate, respond and terminate the emergency. The available technical equipment also includes an array of live radiation monitoring equipment both inside and outside of the facility, all supported by uninterruptable power systems, mobile and hand-held detection equipment, communications equipment, spill- and contamination-control equipment and other large plant equipment such as fire suppression systems and robust aerosol filtration devices. Responding personnel at ANSTO also have sufficient personal protective equipment and live dosimetry systems available.

A number of EALs and OPOs have been detailed in the submission, with further EALs to be established once additional operating experience is gained. This includes trigger points on the SCADA system and other I & C systems to detect the onset of abnormal conditions, in order to initiate actions to prevent an emergency.

ANSTO's demonstrated past performance provides confidence that that ANSTO will successfully establish additional EALs with operating experience with the ANM facility.

Conclusion

The submitted plans and arrangements conform to the requirements of IAEA GSR Part 7 and ANSTO has demonstrated that adequate preparedness is established for an effective response to an emergency. Moreover, efforts have been taken to ensure that safety and security are integrated into the plans and the entire life cycle of operation with hazardous materials has been considered. Considering that the efficacy of the emergency plan has not been tested the ARPANSA assessor recommends the emergency arrangements described in the application be validated during hot commissioning prior to commencing routine operation. Therefore, the ARPANSA assessor recommends the following licence condition.

Recommended licence condition

- The licence holder must not commence operation until a field emergency response exercise, observed by ARPANSA, has been carried out by ANSTO based on a scenario agreed with ARPANSA that demonstrates that the emergency response arrangements are commensurate with emergency preparedness category II, and that the ANM Facility's arrangements interact in a satisfactory manner with emergency response arrangements implemented site-wide.

3.7 Environment protection plan

The arrangements for protection of wildlife and their natural habitats should be consistent with the international best practice [4].

Protection of wildlife

Apart from the radiation protection for the operator and members of the public, the applicant described arrangements that will be in place for radiation protection of wildlife. The operation of the facility will result in airborne and liquid discharges which will be subject to compliance with the statutory requirements. ANSTO considers the following pathways by which radionuclides routinely discharged from ANSTO sites could result in possible exposure to members of the public or to the environment:

- airborne emissions causing external radiation doses from dispersing radioactive gases
- rain-out or deposition of airborne radionuclides entering the food chain leading to exposure due to drinking water or eating food
- discharge of low levels of radioactivity through the Sydney Water sewage treatment system and into the sea leading to exposure of workers at the sewage treatment plant, uptake by fish and accidental ingestion of seawater by swimmers
- contamination of groundwater used for drinking or soil used for food production, leading to exposure by ingestion and possibly inhalation (for example, of soil dust).

ANSTO has a routine environmental monitoring program in place for radiological assessment of nearby river water, ground water, and surface water comprising stormwater runoff and near-surface groundwater leaving the LHSTC. Environmental samples are collected and analysed according to the Environmental Monitoring Sampling Schedule, ANSTO Controlled Document G-300. ANSTO publishes the summary of results of environmental analysis in the ANSTO Annual Reports and the quarterly Buffer Zone Reports. The results of airborne discharge monitoring and liquid effluent discharges are provided to ARPANSA monthly

and quarterly. Waste water to be generated from the ANM facility will be transferred to Waste Management Services. Waste Management Services operates under Facility Licence F0260 and is responsible for ensuring that any liquid discharges from the ANSTO site are in compliance with statutory requirements8.

The gaseous radioactive discharges from the ANM Facility will be subject to ARPANSA notification levels and are subject to relevant licence conditions (see Waste Management Section above).

ANSTO has utilised the guiding principles for radiological assessment of wildlife populations and ecosystems described in ARPANSA RPS G-1, Guide for Radiation Protection of the Environment. This Guide builds on recent scientific and regulatory developments and international standards such as those of the IAEA and ICRP. It outlines the framework for protection of the environment from the harmful effects of ionising radiation and the practical aspects of the process through which protection can be demonstrated.

The current ANSTO environmental monitoring program measuring radioactivity levels in local environmental media including surface waters, ground waters, air, sediments, and in marine biota located near the ocean outlet of the Cronulla Waste Water Treatment Plant (CWTP) will apply to the operation of the ANM Facility. Cumulative annual effective dose from external radiation is monitored at the site perimeter fence, at the CWTP and nearby residences using environmental TLDs. Environmental gamma radiation is measured at a remote meteorological station located in the nearby suburb of Engadine, situated to the east of ANSTO, and the data are available on-line.

ANSTO has evaluated the dose rates to a range of marine biota in the receiving environment at Potter Point, near Cronulla, NSW using a conservative screening benchmark of 10 µGy/hr as recommended in RPS G-1. In 2017, screening evaluation was performed based on projected conditions (e.g. using increased projected discharge activity concentrations (1.5 times existing) and an expanded set of radionuclides). Dose rates were calculated using the ERICA-Tool for sea anemones, molluscs, crustaceans, polychaete worms, phytoplankton, macroalgae and pelagic fish, and ranged from 9.2E-3 to 2.2E+0 µGy/hr. ANSTO also performed a screening evaluation of dose rates to wildlife via air pathways including the noble gases in the gaseous discharges. This evaluation indicated dose rates of less than 3E-04 µGy/hr when considering exposure to grasses, trees, annelids, arthropods, reptiles and mammals.

Conclusion

The ARPANSA assessor considers that ANSTO's environmental monitoring program is adequate and the arrangements for radiological protection of wildlife are based on conservative assumptions and practical measurements of environmental samples. The arrangements for radiological protection of wildlife are consistent with international best practice.

4. Matters to be taken into account by the CEO

The following matters prescribed by the Act and Regulations are to be taken into account by the CEO in deciding whether to issue a facility licence.

[8] Sydney Water Corporation, Consent to Discharge Industrial Trade Waste Water #4423

4.1 International best practice

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

The review of this licence application took into account assessments of the application against regulatory guides, relevant standards and codes of practice. ARPANSA Guidelines [4, 7, 15] and Codes [17] are based on international standards and recommendations, particularly those of the IAEA, and the contemporary practices in the radiation and nuclear industries of developed countries. The IAEA standards and recommendations have been developed by consensus of member countries and represent distillation of best practice of their cumulative nuclear safety experience.

The dose limits considered in the siting of the facility are in accordance with the RPS C-1 (Radiation Protection Series No. 1) [17] which is based on relevant requirements of the IAEA's Basic Safety Standards GSR Part 3 [18] and the 2007 Recommendations of the International Commission on Radiological Protection (ICRP) in its Publication 103 [19].

ARPANSA's assessment has also considered relevant requirements as specified in the IAEA Safety Standard, Specific Safety Requirements for Nuclear Fuel Cycle Facilities, SSR-4 [5] since the ANM Facility is akin to a fuel cycle facility.

Conclusion

Considering that how international best practice has been incorporated into the arrangements for managing safety in the ANM facility as described above, the ARPANSA assessor has concluded that the applicant has considered international best practice with respect to operation of the proposed facility.

4.2 Information asked for by the CEO

Apart from the information specified in the ARPANSA Licence Application form (REG-LA-FORM-240C v9), ANSTO has provided other information during the course of the assessment of the licence application. This includes the revised FSAR, Radiation Protection Plan, Radioactive Waste Management Plan, Security Plan, Safe and Secure Operation Manual, ANM BMS. The applicant has provided all information asked for by the CEO.

4.2.1 Undue risk

The applicant must demonstrate that the radiation risks arising from the proposed conduct have been considered, including the probability and magnitude of potential exposures arising from accident scenarios or abnormal occurrences.

The application to operate the ANM facility has included the risk assessment analysing the hazardous scenarios and the associated risks during routine operation of the facility. No likely event was identified that could result in significant radiological dose outside the facility and off-site. ARPANSA has analysed the events considered in ANSTO's risk assessment taking into account the method of risk assessment and the design features and controls in place, and found it acceptable. The radiological risks associated with the Reference Accident were considered for the assessment of the application to construct the ANM Facility and were found acceptable. ARPANSA's assessment of risk analysis submitted in the application is

described above in section 2.3.2. ARPANSA's assessment resulted in two licence conditions to strengthen the risk control measures.

It is noted that the construction of each item important for safety was subject to ARPANSA approval under regulation 54. For the assessment of the request for approval under regulation 54, the ARPANSA assessor considered the safety function, safety margin and defence-in-depth. The ARPANSA assessor was satisfied that the design and construction of the safety items incorporated conservative design and technology and proven engineering practice. Further, based on the experience with the current facility for Mo-99 production, ANM facility design safety features, and the administrative and engineering controls that will be in place, maximum individual annual effective dose to operators will be about 1 mSv except for the dispatch/packaging operator whose annual average effective dose will be about 1.7 mSv. The statutory annual effective dose limit for members of the public is 1 mSv, and therefore, the routine operation of the ANM facility will not result in any radiation dose to operators that will be significantly higher than the annual dose limit for members of the public.

As part of compliance monitoring ARPANSA conducted twenty-six (26) site visits and two (2) planned inspections during construction and cold commissioning of the ANM facility. No significant safety and security issues were identified from the site visits, and no non-compliance was identified from the inspections. In addition, there have been regular quarterly meetings with ANSTO to follow up matters from the quarterly reports and to discuss relevant safety and regulatory matters related to the construction of the facility.

In assessing the undue risk, operation of the OPAL reactor has been considered as part of the front-end process. In compliance with the OPAL operating licence condition ANSTO submitted the first OPAL periodic safety review (PSR) in 2014 and ARPANSA reviewed that submission. ARPANSA's review suggested that the information provided by ANSTO has delivered assurance that the facility has been designed and is operating safely, and adequately conforms to the current safety standards and practices. It has also shown that there are plans and arrangements in place for continued safe operation for the period until the next periodic safety and security (PSSR) which is due in November 2021.

Following the first OPAL periodic safety review there are no significant safety or security actions or issues which remain outstanding. All other non-safety and non- security significant actions continue to be monitored to completion as part of the licence holder's mandatory quarterly reporting to ARPANSA. A plan for the next Periodic Safety and Security review that is to take place in 2021 is due to be submitted to ARPANSA by 2019.

Since the PSR was submitted to ARPANSA in August 2014:

- there have been 13 ARPANSA Inspections, the results of which have been reported to Parliament quarterly. There were no significant safety or security events identified from these inspections with the exception of one breach of the Act under Section 30(2) – Failure to comply with Licence Conditions in June 2016, relating to failure to update the Reactor Facility Security Plan. This has since been rectified. All other areas for improvement identified are monitored to completion by the Lead ARPANSA Inspector
- there have been no other breaches of the Act
- there have been 76 site visits by ARPANSA Inspectors to OPAL. No significant safety or security issues relating to operations or culture have been noted

- the average annual effective dose to operators was below 1 mSv, which is the annual statutory limit for members of the public. The gaseous radioactive discharges from OPAL were below the statutory notification levels
- the current OPAL Safety Analysis Report is updated on a regular basis to reflect the living nature of the document. ARPANSA no longer issues Regulation 51 approvals without an accompanying request for an update of the SAR document so any significant changes made since the 2014 PSR are captured in the current SAR
- there have been over 1000 events raised by OPAL with one (1) currently confirmed as an INES Rated 1 event (failure to comply with a criticality certificate – all actions to rectify are now completed). None of these events resulted in significant exposure to staff, public or environment
- OPAL has applied for eight modifications under Regulation 51 and received approval for all with no significant safety or security issues raised by ARPANSA. Of these eight, two are directly related to modifications required to support the operation of the ANM facility.

The ARPANSA assessment has also taken into account the overexposure accident during an ANSTO Health quality control process whereby an operator received a significant dose to the hands following a vial of Mo-99 being spilled. ARPANSA undertook an inspection of this event and recommended a number of actions for improvement. ANSTO incorporated lessons learnt from that event and incorporated the improvements in the ANM QC process. This aspect is further discussed in section 2.3.2 and three licence conditions have been recommended to manage the risks associated with the quality control process.

As part of the back end process the solid radioactive waste and low level liquid waste will be managed at ANSTO Waste Operations applying appropriate procedures. Intermediate level liquid waste generated from the ANM facility is intended to be processed at the SyMo facility which is under siting and construction (F0266). ARPANSA undertook three (3) planned inspections and four (4) site visits during the past three years. No significant safety and security issues were identified from the site visits. However, one non-compliance related to reporting a regulation 52 change was identified, and this non-compliance did not have any significant safety implication. Corrective actions were taken to ARPANSA's satisfaction to prevent recurrence. In addition, there have been regular quarterly meetings with ANSTO to follow up matters from the quarterly reports and to discuss relevant safety and regulatory matters related to the operation of ANSTO Waste Operations.

Based on the above evidence, ANSTO has demonstrated that the 'front end' and 'back end' of the ANM facility, namely the OPAL reactor and ANSTO Waste Operations, continue to be operated without undue risk to the health and safety of people and the environment.

Conclusion

The ARPANSA Assessor has concluded that the abovementioned arrangements provide a reasonable assurance that the dealing will not result in an undue risk that is, the probability and magnitude of potential exposures due to incidents and accidents are not unacceptable.

4.2.2 Net benefit

The applicant must demonstrate that the proposed conduct produces sufficient benefit to individuals or to society to offset the radiation harm that it might cause, that is, the conduct must be justified, taking into account social, economic and other relevant factors.

The facility will be used for production of Mo-99, which is the precursor of Tc-99m, the radionuclide used in 80% of medical diagnostic procedures. ANSTO states that apart from ensuring domestic supply of Mo-99/Tc-99m, the proposed facility will have the capacity to export, which will help the future global supply. In addition, the use of LEU targets for Mo-99 production will enhance controls related to security and non-proliferation of safeguards material. However, operation of the facility will generate low level and intermediate level solid and liquid waste. Low-level solid and liquid wastes are processed and managed by authorised ANSTO Waste Operations facilities. Intermediate level solid wastes are currently stored at designated storage facilities at ANSTO. The ILLW generated from the ANM Facility will be processed into a stable immobilised glass form applying Synroc technology. The proposed process will reduce the volume of waste, facilitate safe disposal of the radioactive waste and will lower the environmental risk. The technology to be used is an innovative approach developed by ANSTO based on research over a number of years. ARPANSA has issued the licence to prepare a site and construct the SyMo Facility where the intermediate level waste will be processed. Considering that this facility is first of its kind, the construction of structures, systems and components that will come in contact with radioactive material will require prior approval from ARPANSA as stipulated by licence conditions. Further, an identical full-scale demonstration plant will be constructed through which the conditioning of ILLW will be confirmed by simulation and operators will be trained in operation and maintenance. The application for operation of the SyMo facility will be subject to ARPANSA's regulatory assessment applying applicable international standards. Subject to regulatory approval, operation of the SyMo facility will involve risk of exposure to ionising radiation. Considering the engineering and administrative controls to be in place the risk due to such exposure is expected to be low. The benefits of the facility are considered to outweigh the low risks involved in operation of the facility.

It is noted that the Department of Industry, Innovation and Science (DIIS) is pursuing plans for establishing a NRWMF, which will include a disposal facility for low level solid waste and a storage facility for intermediate level solid waste. It is imperative to consider the full life cycle of waste management while making recommendations for issuing a licence to operate a facility that generates intermediate level waste. In that regard the Government has given commitment that it is working towards a policy on the complete waste management cycle of intermediate level solid waste.

Considering the design safety features and engineering and administrative controls that will be in place for these facilities the radiological impact on health and safety of people and environment is expected to be negligible.

Conclusion

The ARPANSA assessor has considered the above claims with regard to benefit and detriment and has concluded that the applicant has suitably demonstrated that there is net benefit from the proposed conduct, that is, the benefit outweighs the detriment.

4.2.3 Optimisation of radiation protection – ALARA

The applicant must show that the magnitude of individual doses, the number of people exposed, and the likelihood that exposure will happen, are as low as reasonably achievable, having regard to economic and social factors.

ALARA is part of optimisation of protection that takes into account the level of protection and safety in terms of the magnitude of individual doses and the number of exposed individuals including members of the public.

The applicant states that the ALARA principle will be applied to the operation of the ANM facility by:

- use of task-specific dose constraints (also referred to as radiation dose review levels in Safe Work Method and Environmental Statements) to ensure an appropriate balance between individual exposures and group/society benefits
- identification of activities with a radiological risk and completion of a Safe Work Method and Environmental Statement, and a Radiological Risk Assessment by the person planning the work with input from various stakeholders, including Radiation Protection Services staff, to assess the expected doses from the task and optimise the controls
- conducting qualitative and quantitative ALARA assessments where it is shown or expected that the annual effective dose as a consequence of planned exposure situations is greater than the levels specified in the ANSTO WHS Radiation Safety Standard (AE-2310).

Once optimisation measures have been identified and implemented, the expected dose may be considered ALARA.

While the general arrangements for radiation protection are satisfactory, the optimisation aspect should be improved as described in section 3.3, and two licence conditions have been recommended in this regard.

ANSTO operates a number of nuclear installations and radiation facilities across the site. ANSTO uses a site wide dose constraint of 15 mSv/year for operators and an annual ALARA objective of 2 mSv as part of further optimisation of radiation protection. For members of the public the annual dose constraint is 300 µSv and the ALARA objective is 10 µSv.

ANSTO occupational exposure and public exposure investigation levels are applied as detailed in the ANSTO WHS Radiation Safety Standard (AE-2310).

Considering the design of the facility and the engineering and administrative controls to be in place the dose assessment shows that during routine operation of the facility the maximum annual average effective dose to the operator will be about 1 mSv except for the dose to the dispatch and packaging staff which is about 1.7 mSv. The ARPANSA assessor considers that the magnitude of estimated doses to the operators are low and there will not be any dose implications to the members of the public taking into account that the statutory annual effective dose limit to the members of the public is 1 mSv.

Conclusion

The above information provides a reasonable assurance that the magnitude of the individual doses, the number of people exposed and the likelihood that exposure will happen due to the proposed dealing will be low subject to improvement in the optimisation process, and two licence conditions have been recommended in this regard.

4.2.4 Capacity to comply

The applicant must demonstrate a capacity to comply with the regulations and any conditions likely to be imposed on the licence. This should include sufficient financial and human resources to manage the proposed conduct.

The applicant is the CEO of ANSTO. ANSTO is licensed by ARPANSA to operate a significant number of nuclear installations and prescribed radiation facilities and it has been proven that ANSTO is capable of complying with the ARPANS Act and Regulations and licence conditions. As a Commonwealth agency, ANSTO has adequate financial and human resources to manage the proposed conduct. In addition, compliance with the legislative requirements and licence conditions is verified by ARPANSA inspections.

Conclusion

The above arguments provide reasonable assurance that the applicant has the capacity to comply with the regulations and any conditions likely to be imposed on the licence.

4.2.5 Authorised signatory

The application must be signed by an officer holder of the applicant or a person authorised by an office holder of the applicant, and in the latter case, an instrument of authorisation must be provided.

The application was signed by Dr Adrian Paterson who is the CEO of ANSTO. Therefore, this fulfils the requirements of regulation 39(4)(b) of the Regulations.

4.2.6 Content of public submission

Regulation 40 requires the CEO of ARPANSA to advertise receipt of a facility licence application and invite public submission for a nuclear installation.

ARPANSA published the following notices:

- a notice in the Australian Government Gazette on 28 April 2017
- a notice on the ARPANSA website on 28 April 2017
- a notice in The Australian newspaper on 28 April 2017.

A copy of the operating licence application submitted by ANSTO was made available to the public along with advice on how to make a submission.

On 22 June 2017, ARPANSA organised a community information session to:

- outline the process ARPANSA will use to assess and decide the application including the way in which the Agency will seek and take into account public submissions
- inform the public of the nature and details of the application
- address issues raised through public submissions
- record any further issues that may arise on the night as new submissions.

ARPANSA received only one submission on this application. ARPANSA previously received thirty (30) submissions on the siting licence application and these submissions also included comments on operational aspects of the facility that were taken into account. The CEO took into account such submissions in making

the decision to issue a licence (F0270) to prepare a site for the facility and the corresponding Regulatory Assessment Report is available at:

https://www.arpansa.gov.au/sites/g/files/net3086/f/legacy/pubs/regulatory/ansto/RAR_Mo99.PDF

The submission on the operating licence application raised the following issues:

- public health harm associated with radioactive waste
- permanent disposal of intermediate level waste
- no public consultation by ANSTO about increasing nuclear waste production
- no licence for the Synroc facility
- radioactive waste burden from supplying Mo-99 to overseas customers
- fall in demand of Mo-99 supply
- production of Mo-99 using cyclotron
- increased production and retention of plutonium.

The submission along with ANSTO's responses are presented in Appendix 3.

Conclusion

ARPANSA's assessment has given due considerations to the content of the public submissions, most of which are related to the applicant and ANSTO have adequately addressed these matters. The issues related to public health harm and permanent disposal of intermediate level waste have been considered in this assessment under the headings 'Undue risk' and 'Net benefit'.

5. Conclusions

The application and information provided in support of the application provide evidence that:

1. the application was in a form approved by the CEO under Regulation 39(1), including payment of the relevant application fee
2. the application included all of the information required by the CEO under s34 of the Act
3. the application was signed by the requisite office holder
4. the facility is constructed in accordance with the design approved in the construction licence (F0285) and subsequent approval of construction of items important for safety through regulation 54
5. the results of the assessment of design, testing and cold commissioning show that the facility structure, systems and components important for safety during normal operation are inherently safe, and design objectives have been achieved, and the facility can be operated safely without undue risk to the health and safety of the people and to the environment
6. the plans and arrangements for managing safety including operating arrangements, qualified and trained personnel, and security provisions are adequate to ensure safe and secure operation of the facility

7. the radiological consequences from a broad spectrum of postulated reasonable accidents will not have any significant impact outside the facility. However, the reference accident i.e. the most conservative accident (design extension conditions) would have radiological consequences outside the facility within the site, but no off-site consequences
8. the operating limits and conditions, derived from the safety analysis, defining the safety envelope of the facility, are such that there is reasonable assurance that the facility will be operated safely and reliably
9. there is reasonable assurance that the magnitude of individual doses, the number of people exposed and the likelihood that exposure will happen during operation of the facility will be as low as reasonably practical
10. there is reasonable assurance that the applicant has the capacity to comply with the regulations and relevant licence conditions
11. the applicant has demonstrated that there is net benefit from the proposed conduct, that is, the benefit outweighs the detriment of exposure to radiation
12. international best practice has been applied to the design, construction, and operating arrangements for the facility

5.1 Recommendations

5.1.1 Issue of licence

It is recommended that a facility licence be issued to ANSTO Nuclear Medicine Pty Ltd in respect of licence application A0309 authorising the operation a controlled facility, namely the ANM Mo-99 Facility, subject to the licence conditions listed below.

5.1.2 Licence conditions

Apart from the standard licence conditions prescribed in the licence template the following licence conditions are also recommended:

operations for the stated purpose of the facility (routine operations) must not commence until:

a) the structures, components, systems, material, equipment and processes have been tested using irradiated target plates in accordance with the approved program for 'hot' commissioning, and the test results have been analysed

b) the licence holder has demonstrated operational readiness in terms of staffing numbers, competence, training, arrangements for emergency preparedness and response, and provisions for safe and secure production of Mo-99 in both Building 54 and in the ANM Facility during the initial phase of routine operations of the ANM Facility

c) the licence holder has developed plans for possess and control of the facility in case operations have to be discontinued for other than planned or short-term unplanned outages

d) the licence holder has defined a dose constraint for occupational exposures to radiation in the ANM Facility and in the Building 2 QC Laboratory, provided an analysis of optimisation of radiation protection that outlines how different options have been evaluated in order to manage radiation risks, and provided a plan including a time-line for implementation of

reasonable measures to reduce the radiation exposures, the number of exposed individuals and the likelihood of exposures

e) the licence holder has analysed automation of the QC procedure for high activity Mo-99 liquid samples as part of the optimisation under (d)

f) the licence holder has provided a plan, including times for completion of actions, based on the 28 recommendations of the risk assessments for the ANM Facility and the Building 2 QC Active Laboratory, and justification of alternative actions to achieve the same outcome in case such alternatives are preferred

g) the licence holder has reassessed all scenarios that lead to 'moderate' or more severe consequences from the radiation protection perspective regardless of likelihood including "incredible" scenarios; and analysed opportunities to improve management of radiation risks through reducing the likelihood of an event leading to such consequences, or reducing the consequence should an event occur, or both

h) the licence holder has reassessed the contribution of human factors to the likelihood of events occurring, and to the mitigation of risks, in the assessment under (g)

i) a field emergency response exercise, observed by ARPANSA, has been carried out by ANSTO based on a scenario agreed with ARPANSA that demonstrates that the emergency response arrangements are commensurate with emergency preparedness category II, and that the ANM Facility's arrangements interact in a satisfactory manner with emergency response arrangements implemented site-wide

j) the licence holder has provided a plan for phasing out routine Mo-99 production in Building 54

k) the licence holder has reported any other observation or occurrence with significance for safety, not covered by (a) to (j) above

l) (a) to (k) have been actioned to the satisfaction of the CEO of ARPANSA.

- during initial routine operations of the ANM Facility with simultaneous Mo-99 production in Building 54: the total production of Mo-99 must be capped at 2400 six-day curie per week as a four-week average, and not increased beyond that level until production in Building 54 has ceased and operational experience of the ANM Facility provides evidence of safe operations
- for a period of 18 months after cessation of routine operations in Building 54, and contingent on ARPANSA's approval, Mo-99 production in Building 54 must only take place under special circumstances such as during short-term outages in the ANM Facility
- the licence holder must report the airborne discharges from Mo-99 production at the Lucas Heights Science and Technology Centre to the CEO annually as percentages of the notification levels set out in the following table:

Annual airborne discharge notification levels for Mo-99 production

Annual Notification Levels											
Kr-85m (TBq)	Kr-87 (GBq)	Kr-88 (GBq)	I-131 (GBq)	I-132 (GBq)	I-133 (GBq)	Xe-135 (TBq)	Xe-135m (TBq)	Xe-133 (TBq)	Gross alpha (MBq)	Gross beta (MBq)	Total all other radionuclides (MBq)
10	300	400	10	7	2.15	400	100	1350	When detected	1000	500

- the licence holder must by 30 June 2020 provide a report on
    a) holdings of intermediate level waste (ILW) at the ANM Facility
    b) projected future generation of ILW at the facility
    c) plans for treatment of the ILW generated at the facility including projected treatment in the SyMo Facility
    d) plans for storage and disposal of the ILW that take into account the national policy and plans for full life-cycle management of radioactive waste
    e) contingency plans should one or several components of the ILW management system not eventuate or fail
- the licence holder must undertake the first Periodic Safety and Security Review (PSSR) of the ANM facility after gaining five years of operational experience from the finalisation of commissioning activities. The PSSR must:
    a) summarise the operational experience including any abnormal occurrences as well as provide an account of contributing factors to such occurrences, risk mitigation, occupational radiation exposures including contamination events, and public radiation exposures
    b) review the capability of the safety functions under a range of design extension conditions agreed by ARPANSA
    c) consider the security of the facility
    d) include a plan for implementation of actions identified during the course of the review.

The PSSR report must be submitted to ARPANSA by 31 December 2024 or at time agreed by the CEO.

- The licence holder must submit a decommissioning plan for the ANM facility after gaining five years of operational experience from the finalisation of commissioning activities. The decommissioning plan must be submitted to ARPANSA by 31 December 2024 or at a time agreed by the CEO and take into account the national policy and plans for full life-cycle management of radioactive waste.

References

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[19] International Commission on Radiological Protection, ICRP, Publication 103, the 2007 Recommendations of the ICRP.

Appendix 1

Documents forming part of the Application

(i) ANSTO Nuclear Medicine Operating Licence Application, April 2017, REG-LA-FORM-240C v9

(ii) ANSTO Nuclear Medicine, Structures, Systems, Components and Equipment of ANM Q-50395, rev 0

(iii) ANSTO Nuclear Medicine, ANM Mo99 Facility Safety Analysis Report, P-50098 (rev. 3)

(iv) ANM Mo99 Facility Operational Risk Assessment, ANSTO/T/TN/2015-20 (rev 2)

(v) Risk Assessment of the B2 Quality Control Laboratory, ANSTO/T/TN/2016-02 (rev. 2)

(vi) ANSTO Nuclear Medicine, Operating Limits and Conditions, P-50099 (rev. 4)

(vii) ANM Mo99 HAZOP of Production Process, Mo99_FACL_SAFE_TN_0326_A

(viii) HAZOP of the B2 Quality Control Laboratory ANSTO/T/TN/2015-07 rev 0

(ix) ANM Mo99 Facility, Hazard and Operability Study, Mo99_FACL_OTH_ER_2217

(x) ANSTO Nuclear Medicine, ANM MO-99 Facility Safe and Secure Operations Manual, P-50100 (rev. 3)

(xi) ANSTO Nuclear Medicine, ANM Operational Readiness Plan, Q-50028 (rev. 2)

(xii) ANSTO Nuclear Medicine, ANM Transition Plan, Q-50507 (rev. 0)

(xiii) ANM MO99 PROJECT, Commissioning Plan Mo-99 Production Process Mo99_COMM_PROC_CTP_1174_B

(xiv) ANM MO99 PROJECT, Commissioning Plan of Safety Related Systems, Mo99_COMM_SAFE_PL_1573

(xv) ANSTO Nuclear Medicine, ANM MO-99 Facility- Safe and Secure Operations Pre-Start Checks Mo-99 Production, F-50137 (rev. 1)

(xvi) ANSTO Nuclear Medicine, Maintenance Procedure, P-50138

(xvii) ANM MO99 PROJECT Mo99_FACL_OPER_TN_0329_B: Dose Assessment

(xviii) ANSTO Nuclear Medicine, Effective Control Plan, Q-50081 (rev. 3)

(xix) ANSTO Nuclear Medicine, ANM Safety Management Plan Q-50082 (rev. 3)

(xx) ANSTO Nuclear Medicine, ANM Radiation Protection Plan, Q-50083 (rev. 5)

(xxi) ANSTO Nuclear Medicine, Waste Management Plan Q-50084 (rev. 4)

(xxii) ANSTO Nuclear Medicine, ANM Emergency Plan Q-50086 (rev. 5)

(xxiii) ANSTO Nuclear Medicine, ANM Security Plan, Q-50085 (rev. 3)

(xxiv) ANSTO Nuclear Medicine, ANM Environment Protection Plan Q-50323 (rev. 0)

Appendix 2

Inspection and Site Visits to the ANM Facility

(i) ANM Site Visit, 6 August 2014 (observe excavation and construction works), R14/08956

(ii) ANM Site Visit, 13 May 2015 (observe progress of construction), R15/06786

(iii) ANM Site Visit, 12 August 2015 (observe the progress of construction), R15/11368

(iv) ANM Inspection (reporting and verification, configuration control, and training), 30 Nov- 4 December 2015, R15/16499

(v) ANM Site Visit, 19 February 2016(observe progress of construction of hot cells, gaseous discharge system), R16/01841

(vi) ANM Site Visit, 20 June 2016 (construction of hot cell, ventilation system, liquid waste containment system), R16/07326

(vii) ANM Site Visit, 5 September 2016 (construction of Valve room for ILLW, LLLW; Sampling hot cell for liquid waste; Liquid waste shielding; Lead hot cell shielding; Liquid waste transfer system from hot cells; Liquid and gaseous waste decay tanks; ILW waste cell; Rear of cell cranes; Dissolution hot cell; Installation of PADIRAC flask; Carbon columns and associated shielding), R16/10758

(viii) ANM Site Visit, 8 November 2016 (construction of hot cells; external liquid waste tanks; installation of monitoring equipment, active ventilation system; cranes), R16/13003

(ix) ANM Site Visit, 14 December 2016 (Site acceptance testing items; construction of liquid waste sampling hot cell; installation of in-cell plant and equipment), R16/14419

(x) ANM Site Visit, 8 February 2017, (overall construction, installation of in-cell plant and equipment), R17/02004

(xi) ANM Inspection (reporting and verification, configuration control, inspection, testing and maintenance and radiation protection), 2 June 2017, R17/06685

(xii) ANM Site Visit, 18 September 2017 (installation of structures, systems and components, commissioning tests, PADIRAC commissioning), R17/10217

(xiii) ANM Site Visit, 27 September 2017 (PADIRAC system operation including the functionality of safety interlocks; Operation of the safety features including interlocks and alarms; Operation of the ILSW flask for using retrievable waste bin; Functionality of the interlocks; Pre-commissioning tests for Active Ventilation System), R17/10492

(xiv) ANM Site Visit, 28 September 2017 (Irradiated transfer flask operation including the functionality of safety interlocks; Operation of the safety features including interlocks and alarms; Transfer of irradiated targets (not using any targets) to dissolution hot cell), R17/10734

(xv) ANM Site Visit, 23 October 2017, (Type B(U) package operation for transferring the final product from the packaging and dispatch hot cells including the functionality of safety interlocks; Operation of the safety features including interlocks including the inter-cell transfer system, and the radiation monitor; Testing the operational parameters for AVS), R17/11731

(xvi) ANM Site Visit, 26 October 2017 (commissioning tests for liquid waste system and AVS), R17/11935

(xvii) ANM Site Visit, 1 November 2017 (commissioning tests for the AVS (Red Primary)), R17/12187

(xviii) ANM Site Visit, 3 November 2017 (facility restart from loss of main and generator power supply), R17/12351

(xix) ANM Site Visit, 10 November 2017 (Commissioning of AVS), R17/13095

(xx) ANM Site Visit, 10 November 2017 (Verification of Radiation Monitoring System), R17/13130

(xxi) ANM Site Visit, 16 November 2017 (review of manufacturing, installation, inspection, testing and maintenance, commissioning records of the structures, systems and components

(xxii) ANM Site Visit, 8 January 2018 (water run to check the performance of plant and equipment), R18/00409

(xxiii) ANM Site Visit, 11 January 2018 (cold commissioning of the facility using un-irradiated target), R18/00408

(xxiv) ANM Site Visit, 17 January 2018 (plant and equipment of QC Laboratory, B2), R18/00694

(xxv) ANM Site Visit, 24 January 2018 (verification of ANM security system effectiveness), R18/02446

(xxvi) ANM Site Visit, 2 February 2018 (cold run demonstration of the quality control process in B2, verification of improvements in B2 in the light of B23 contamination), R18/01351

(xxvii) ANM Site Visit, 28 February 2018 (observe the suitability of items important for safety against design extension conditions), R18/03289

(xxviii) ANM Site Visit, 23 March 2018 (verification of labelling of systems, plant and equipment), R18/03502

Appendix 3

ANSTO's responses to questions and comments from public submissions. ARPANSA has commented on several of these items in different sections of the RAR

	Questions/Comments	ANSTO's Response
1	There are clearly significant public health harms associated with nuclear waste	ANSTO has safely managed radioactive waste resulting from the production of lifesaving nuclear medicines and research into areas of national priority for over 60 years. Radioactive waste is safe when appropriately managed and stored. In fact, it is safely and securely managed and stored all around the world using well established practice. Experience demonstrates that such storage does not pose any threat to public health. ANSTO's waste management practices and temporary storage facilities are subject to stringent scrutiny by several independent Commonwealth regulators, including ARPANSA and the Department of the Environment and Energy, to ensure no threat is posed to the safety of the environment or the community. The National Radioactive Waste Management Facility (NRWMF), where the waste arising from the operation of the ANM facility will ultimately be managed, will be subject to the same stringent regulations.
2	There is no permanent disposal plan for the Intermediate Level Waste produced by this proposal	The Government has said that once a National Radioactive Waste Management Facility (NRWMF) is established, providing a permanent location for low level waste disposal and intermediate level waste storage, they will commence the process to establish a permanent disposal facility for intermediate level waste, drawing upon overseas experience. It should be noted that intermediate level waste can be very safely stored for many decades, while this process is underway.
3	There has been no public consultation by ANSTO about increasing nuclear waste production	There has been extensive public consultation around ANSTO's new nuclear medicine facility undertaken by various organisations. 1. ARPANSA has run two full public consultation processes – one in 2013 as part of the siting licensing process (which involved public submissions and a community information session) and another in 2014 as part of the construction licensing process. 2. The Department of the Environment and Energy ran a public consultation process under the *Environment Protection and Biodiversity Conservation Act* in 2013. 3. The Parliamentary Standing Committee on Public Works undertook a public consultation process, and reported in 2013. ANSTO is committed to regular and proactive engagement with the public, and has maintained strong communication lines with the local community about the new facility through various channels, including a proactive media campaign, ongoing briefings for community leaders, website updates and social media
4	There is no license for the Synroc facility, and indeed no Synroc facility built yet to the process waste	On 13 May 2014, ARPANSA issued a license to ANSTO to prepare a site for, and construct a Synroc plant at its Lucas Heights campus. To ensure optimal design, ANSTO has chosen to establish a demonstration plant in an existing building. This demonstration plant will be used to refine the design of the final plant, which will not be required to be operable until sufficient waste has been produced and requires treatment. To elaborate, there is a necessary stepped approach towards becoming fully operational, involving filling of the tanks and allowance for appropriate decay prior to treatment. Initial fill of a single tank is conservatively estimated to take

	Questions/Comments	ANSTO's Response
		between 16 to 20 months at maximum production from the ANM facility. Optimal decay of the content needs to occur prior to being treated in the Synroc plant and this will take a further 24 months, post fill. Consequently, ANSTO is working towards an operational date in the fourth quarter of 2019. Additionally, as part of its approval of ANSTO's construction licence application for the new facility, ARPANSA provided approval for ANSTO's contingency plans should the Synroc facility be unavailable. These contingency plans include alternative solidification techniques, primarily cementation.
5	The vast majority of the nuclear waste burden from this plant will be created by sales to the overseas market, and leave Australia with the waste from ANSTO's overseas customers	The waste that will be generated during the production of Mo-99 will be treated with the state-of-the-art Synroc process. It will be temporarily stored at ANSTO until the establishment of the NRWMF. Importantly, for international sales the costs of waste management will be included in the price charged for Mo-99, meaning there will be no subsidy to overseas patients. The production of Mo-99 is dependent on highly specialised infrastructure i.e. a reactor and Mo-99 production facility. As a result, every country cannot be expected to produce its own supply. Australia has benefited from international cooperation in the past when we needed to rely on imports of Mo-99, and has also contributed to world supply during shortages. Australia is well placed to help meet the increasing demand for Mo-99, which is a vital component of all healthcare systems. Given its capacity to produce Mo-99, as a member of the community of nations and a significant player in the region it has a responsibility to do so. Australia is also in a unique position of being able to produce Mo-99 exclusively using low enriched uranium (LEU). Currently, most of the global Mo-99 supply is produced in reactors fuelled by highly enriched uranium (HEU) and using HEU targets. HEU can be used in nuclear weapons. Consequently, alternative manufacturing processes are highly desirable.
6	NEA 2017 projections for isotope production highlight a number of important issues, including a fall in demand of 25% from 2011-2015. It is likely that ANSTO's new facility will be facing an oversupplied market. There is no urgent global shortage	In terms of the NEA report, it shows a fall in demand of 10 per cent, not 25 per cent, over the past five years. That appears to be a consequence of the more efficient use of Mo-99, rather than any fall in the need for Tc-99m. It is important to remember that the report's predictions for coming years assume that there are no major outages from ageing reactors elsewhere in the world during this period. They also do not take into account likely increases in demand from developing countries (non-member states of the NEA) with ageing populations in our region. Akin to other markets, world demand for Mo-99 varies considerably from year to year. ANSTO expects to supply around 25 per cent of world demand, but that will change as demand fluctuates, as well as supply – in the short term as well as the long. Most importantly, ANSTO's new facility will secure domestic supplies of Mo-99 long into the future, providing stability in delivering life-saving medicine to Australian patients.
7	In Canada cyclotron production has been commercially licensed and the technetium so produced is currently undergoing routine clinical trials. Commercial levels of production have been demonstrated in January 2015 on three different	Both the IAEA and the NEA have examined alternative technologies for the production of Mo-99 or Tc-99m and expressed strong concern over the expense and practicality of these technologies substituting for reactor-based technologies. In terms of Canadian research into direct production of Tc-99m using cyclotrons, it has not yet demonstrated the feasibility of this production method to satisfy clinical demand. Nor has the manufactured product met purity and quality assurance criteria mandated by health regulatory bodies such as Australia's Therapeutic Goods Administration or the US Food and Drug Administration. Canada is in fact now importing Mo-99 from overseas suppliers, including ANSTO. The NEA and the International

	Questions/Comments	ANSTO's Response
	types of commonly used cyclotrons	Atomic Energy Agency (IAEA) regard the fully LEU-based production process that is used by ANSTO to be the gold standard of Mo-99/Tc-99m production, due to its proliferation resistance, easier availability of target material, and reduced security and safeguards burdens on transportation and processing. Given that, it would be grossly irresponsible for ANSTO to risk the health of Australians on unproven technology.
8	The increased production and retention of plutonium and uranium from target dissolution creates nuclear security concerns	In a typical production year, the ANM Mo99 facility operating at capacity will produce approximately 6.2 g of Pu-239, which is less than 1/1000 of the amount that would be of significance from a safeguards perspective. Furthermore, that Pu-239 will be mixed with other materials and will therefore be unusable for any purpose. Further, the facility will be under IAEA safeguards, including regular inspections, to ensure that any material of concern could not be diverted from the declared activities.