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NUCLEAR MEDICINE MANUFACTURING PROGRAM

NMMF Radiation Protection Plan

For Siting Licence

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1. Purpose

The purpose of this Radiation Protection Plan is to describe the organisational arrangements for the control of exposure to ionising radiation under the siting and development phase for a new Nuclear Medicine Manufacturing Facility (NMMF) at the ANSTO Lucas Heights Science and Technology Centre (LHSTC).

The plan outlines the processes used in selection of the proposed site and to ensure compliance with the relevant legislation, including the Australian Radiation Protection and Nuclear Safety (ARPANS) Act [Ref: (1)] and Regulations [Ref: (2)]. This is an integral part of the ARPANSA Siting Licence Application for the NMMF.

ANSTO is committed to maintaining and enhancing the high standards of radiation safety recommended by the International Atomic Energy Agency (IAEA) and required by ARPANSA and Safe Work Australia. The plan is consistent with international best practice, a defence in depth strategy and in accordance with the IAEA standards and guidelines on protection against the effects of ionising radiation, specifically IAEA Safety Standard Series No. GSR Part 3, [Ref: (3)] and IAEA Safety Standard Series No. GSG Part 7 [Ref: (4)].

This plan should be read in conjunction with the Nuclear Medicine Manufacturing Program (NMMP) Safety Analysis Report (SAR) [Ref: (5)] other Plans and Arrangements supporting the Siting Licence Application.

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

2. Scope

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The scope of this plan is focused on the radiation protection requirements for the NMMF. This plan covers the safety aspects referred to in the ARPANSA licensing guidelines and plans and arrangements for managing safety [Ref: (6)].

During the NMMP development phase there is no intention for radioactive materials to be introduced onto the NMMF site prior to commissioning.

This plan does focus on radiation protection as a key feature in the siting and design aspects of the NMMF from a human centred design perspective. This plan applies key elements of the Design Guide – Safety in Design Strategy NMMP-0710-PM-0001 [Ref: (7)]. From a radiological protection perspective, the design guidance integrates technical aspects of exposure justification, optimisation, and dose limitation with human factors assurance and human factors design support.

This plan lists and briefly describes the systems and procedures for the control of exposure to ionising radiation which is reflective of the primary nature of materials and processes being utilised in the NMMF. Other and different sources of radiation including non-ionising are addressed through the ANSTO procedure AG-2471 Safe Management of ARPANSA Controlled Material and Controlled Apparatus [Ref: (8)].

3. Responsibilities

The Chief Executive Officer (CEO) of ANSTO is the applicant to ARPANSA for the NMMF Siting Licence. The CEO has overall responsibility for safety in accordance with the ANSTO Act [Ref: (9)], Work Health and Safety Act [Ref: (10)] and Regulations [Ref: (11)], and the ARPANS Act [Ref: (1)] and Regulations [Ref: (2)].

The CEO of ANSTO will delegate responsibility for the NMMF to a Nominee who is assisted by a Facility Officer, and Radiation Safety Officer (RSO). The details of these responsible officers will be recorded and maintained on the ANSTO intranet. Further details of the organisational structure are in the NMMF Safety Analysis Report [Ref: (5)] and Effective Control Plan [Ref: (12)].

3.1. Nominee

During the siting and development phase of the NMMP, the Group Executive, ANSTO Maintenance and Engineering will be responsible as the nominee. It is expected the nominee will change as the Program approaches operational readiness.

3.2. Facility Manager

The Nominee will appoint a Facility Manager for the NMMP during the siting and development phase of the Program. The Facility Manager will be responsible for understanding the scope of works, operational requirements, and processes to be applied during the NMMP lifecycle including identification and management of associated hazards and controls. The Facility Officer is responsible for demonstrating safety leadership by coordinating implementation of the ANSTO WHS Management System, AP-2300 ANSTO WHS Management System Overview [Ref: (13)].

3.3. Workers, Contractors and Visitors

Recognising that no radioactive materials will be introduced during the siting and development phase of the NMMP, all workers, contractors, and visitors have the responsibility to implement the ANSTO Work Health and Safety Management System (WHS MS) as per AP-2300 ANSTO WHS Management System Overview [Ref: (13)] and to follow all related procedures and instructions. Compliance with the WHS MS will ensure that radiation exposures remain As Low As Reasonably Practicable (ALARP) and within the limits and constraints of the licence.

3.4. ANSTO Radiation Protection Services

ANSTO's Radiation Protection Services (RPS) section includes an appointed RSO and will provide radiological protection assistance across all phases of the program. This includes the appointment of Health Physicists (HP), Radiation Protection Advisors (RPA), and Health Physics Surveyors (HPS) as required.

3.4.1. Radiation Safety Officer

The RSO is an experienced radiation protection specialist who is responsible for ensuring radiation protection advice reflects current radiation protection legislation and international best practice. The RSO ensures ANSTO's radiation protection guides, plans and arrangements are appropriate to meet current Australian National Standards and Codes, the ARPANS Act and Regulations, and international best practice. The RSO also ensures that RPS staff are adequately trained and experienced to fulfil their delegated duties.

3.4.2. Health Physicist / Radiation Protection Advisor

The HP or RPA is an experienced professional trained in radiation protection and will provide advice and guidance to program personnel on radiation safety and technical aspects of radiation protection including safe working practices, human factors, relevant standards, and optimisation of design and operational radiation protection measures, including but not limited to.

- Radiological safety assessments
- Shielding advice
- Monitoring arrangements
- Handling and storage of radioactive materials and sources.
- Development and modification of work procedures and processes.
- Management of the radioactive waste.
- Transport, movement and transfer of radioactive materials.

3.4.3. Health Physics Surveyor

The HP or RPA is supported, at an operational level, by Health Physics Surveyors (HPS) who perform assurance radiation monitoring surveys of areas identified by the HP within the work site. The HPS has the authority to suspend work if the radiological conditions have significantly deviated from the expected standards and practice.

3.5. Regulatory Authority

The regulatory authority, ARPANSA, is responsible for ensuring that the radiation protection strategies for the safe handling and use of radioactive material or apparatus adopted for the NMMP are appropriate and in accordance with the relevant codes and recommendations.

4. ALARA and ALARP Terminology

The terms As Low As Reasonably Achievable (ALARA) and As Low As Reasonably Practicable (ALARP) are commonly used in safety legislation and radiation safety documentation [Ref: (14)] and [Ref: (15)]. ANSTO recognises that regardless of the terminology used, the emphasis is on what is “reasonable” and justification on what is “achievable” or “practicable” in the context of the risk and the net benefits of the work, as such the definitions and guidance on what is “reasonably” achievable and practicable are closely aligned.

For the purposes of the NMMP Safety Analysis Report and Radiation Protection Plan, the terms ALARA and ALARP are aligned and considered interchangeable to describe the risk based approach to optimisation of protection, the implementation of the hierarchy of controls and the concept of “reasonably practicable” as defined by the WHS Act and Regulations and in the context of societal and economic factors. It is confirmed that in the ANSTO Work Health & Safety Management System neither term places any additional constraints or requirements relative to the other [Ref: (16)].

5. Principles of Radiation Protection

ANSTO manages radiation risks through the application of a wholistic set of Radiation Protection Principles which contribute to a high level of protection for personnel, the public and environment. The objective being to minimise the detrimental effects of radiation exposure without unduly limiting human activities associated with nuclear medicine production and other research activities at the LHSTC.

The AE-2310 ANSTO Radiation Safety Standard [Ref: (17)] will be applied throughout the entire lifecycle of the facility and utilised during preparation of the NMMP siting licence. The ANSTO Radiation Safety Standard will also be used during the design and development phases of the NMMP, particularly with respect to establishing optimal design criteria for radiation safety. To this end the Radiation Safety Standard is a fundamental element of the NMMF Safety Analysis Report (SAR) and Plans and Arrangements.

The NMMP has also developed a Design Guide – Safety in Design Strategy [Ref: (7)] to establish processes to minimise exposure to ionising radiation utilising a defence in depth approach and building a strong generative safety culture.

The ANSTO Radiation Safety Standard describes the radiation protection principles for:

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

These principles are fundament and strengthened through the:

- Development and maintenance of a strong safety culture, and
- Managing exposures using a graded approach for both radiological and non-radiological aspects of the prevailing circumstances, whilst applying defence-in-depth to protective measures.

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

5.1. Justification

There will be no radiological materials introduced or handled during the siting and construction phases of the NMMP. Construction tasks will be conventional, other than the requirement to use calibration or check sources at the commissioning phase for radiation monitors and with high activity sources for hot cell integrity testing and validation of specific ARPANSA approvals to Construct an item important for safety.

As the program evolves a key feature of the NMMF will be designed to optimise potential radiological exposures to workers and to ensure activities are where practicable within agreed dose constraints. Such exposures are only considered to be justified on the basis the operation of the NMMF will ensure that Australia meets the increasing demand for, and delivers, the public healthcare benefits of nuclear medicine.

ANSTO will continue to be a reliable domestic and international supplier of nuclear medicine products, including:

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

5.2. Optimisation of Protection

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All radiological activities associated with the NMMP will be assessed and where the benefit and potential risk is justified the activity will be included under the program. The protection measures will be optimised to provide the best level of protection that can be achieved under the prevailing circumstances. ANSTO is committed to reducing the likelihood of incurring exposures by limiting the number of people who may be exposed and reducing the magnitude of each individuals' dose to ALARA. The optimisation of radiation protection takes into consideration economic and societal factors, in line with recommendations by the International Commission on Radiological Protection's (ICRP) 2007 [Ref: (14)].

Optimisation of radiation protection at ANSTO aims to achieve the best level of protection under the prevailing circumstances through an ongoing and iterative process that involves:

- Evaluation of the exposure situation, including any potential exposures (the framing of the process).
- Selection of appropriate values for the constraints or reference levels.
- Identification of possible process and protection options.
- Selection of the best option under the prevailing circumstance.
- Implementation of the selected option.

For the NMMP particularly during the design and development phase, ANSTO will use dose criteria to define boundaries within which optimisation processes take place. The types of dose criteria that ANSTO use dose review levels, dose constraints, and dose limits.

Optimisation of protection during design is a forward-looking iterative process aimed at preventing or reducing future exposures, essentially during operations. ANSTO considers both technical and socio-economic developments and using a graded approach requires both qualitative and quantitative assessments.

The graded approach and decision-making tools for optimisation of radiation protection for the NMMP are described in the ANSTO Radiation Safety Standard AE-2310 [Ref: (17)].

5.3. Dose Limitation

For the NMMP the individual dose to personnel, particularly during planning for operations, the combination of exposures from all regulated ANSTO activities must be considered and shall not exceed the specified effective dose limits and equivalent dose limits for planned exposure situations as stated in the ARPANS Regulations [Ref: (2)].

The NMMP considered that limits are insufficient in themselves to ensure the best practicable protection under the prevailing circumstances, and both the optimisation of protection and the limitation of doses and risks to individuals are necessary to achieve the highest standards of safety.

The principle of dose limitation and constraints are described in detail in [Ref: (17)] and are the same for men and women in public and occupational exposure situations.

5.4. Safety Culture

ANSTO promotes and seeks to maintain a safety culture which guides the attitudes and behaviour of all personnel to realise optimal safety and radiation protection objectives by:

- Promoting individual and collective commitment to protection and safety at all levels across ANSTO.
- Providing information and training on the effects of radiation and means of minimising potential exposure.
- Ensuring a common understanding of the key aspects of a generative safety culture within ANSTO.
- Providing the means to support individuals and teams to carry out their tasks safely and successfully in collaboration with others.
- Encouraging participation of workers and their representatives in the development and implementation of safety and radiation protection policies, rules procedures and practices.
- Adopting and encouraging a conservative decision-making approach.
- Ensuring accountability of ANSTO and of individuals at all levels for protection and safety.
- Encouraging open communication regarding protection and safety within ANSTO and with relevant parties, as appropriate.
- Encouraging a questioning and learning attitude and discouraging complacency regarding protection and safety.
- Encouraging the reporting of all safety related incidents.
- Providing means by which ANSTO continually seeks to develop and strengthen its safety culture.

A strong safety culture, incorporating the measures above, will be promoted and maintained through all phases of the NMMF development.

5.5. Defence in Depth

ANSTO applies a multilevel (defence-in-depth) system of sequential, independent approaches to safety and radiation protection controls. This approach is commensurate with the likelihood and magnitude of potential exposures and sources for which ANSTO is authorised. Details of the defence-in-depth approach is described in ANSTO AE-2310 Radiation Safety Standard [Ref: (17)] and applied through the Design Guide – Safety in Design Strategy [Ref: (7)].

The defence-in-depth measures applied during the NMMF design and development program include, but are not limited to:

- Optimisation of radiation exposures through both engineered and administrative controls.
- Minimising radioactivity and radioactivity concentrations where possible.
- Preference for passive rather than active controls.
- Radiation and contamination control measures.
- Maintenance of engineered control systems.

- Safety and Reliability Assurance (SRA) and approvals process.
- Validation of control measure effectiveness.
- Safe and secure movement and transport of radioactive materials.
- Safe and secure management of radioactive wastes.
- Exposure monitoring.
- Radiation safety training.

The NMMP Team will use defence-in-depth measures to minimise the potential for failure of safety and radiation protection control measures.

AG-7082 Risk Management Tool Risk Response & Control Effectiveness [Ref: (18)] provides further guidance regarding risk response options, identifying critical controls, and determining the strength of controls. [Ref: (17)].

6. Design of the Workplace: Radiological Hazards and Controls

No radiological hazards or potential exposures have been identified to be received by workers during the siting and development phase of the NMMP. During planning and design a rigorous program to identify radiological hazards and develop controls will be established and maintained to ensure conformance with international standards and leveraging best practice guidelines.

ANSTO has developed a Design Guide – Safety in Design Strategy [Ref: (7)] which specifically incorporates guidance on the principles for radiation protection:

- Justification
- Optimisation
- Dose Limitation.

The standards and guides on radiation protection within the ANSTO WHS MS [Ref: (13)] focus on minimising the risks of radiological hazards associated with radioactive sources. Preliminary design features that will impact on design features are detailed in the Design Guide – Safety in Design Strategy [Ref: (7)] and include:

- Area radiological designation and access control
- Component layout
- Health physics related design features
- Material characteristics from a radiological protection viewpoint
- Airborne emissions
- Shielding
- Human factor hazards associated with processes and materials movement
- Dose rate design objectives for radioactive operational and waste areas.

Optimisation of controls to minimise radiation exposure both to personnel and members of the public are developed during the Optioneering Process (ALARP Study). By applying the ALARP principle several of the following defence in depth design techniques can be applied:

- Engineering design of interlocks, ventilation, radiation, and contamination monitors.
- Isolation of the radioactive source by containment, distance and / or limiting time exposure to the source.
- Remote handling techniques.
- Shielding radioactive materials using hot cells, shielding containers, lead bricks, shielding flasks during transport, movement and transfer, and other equivalent techniques.
- Delay and decay of short-lived isotopes.

- Administrative controls such as training and procedures.
- Suitable equipment and personal protective equipment.
- Effective work planning to minimise the dose received by staff members.
- Appropriate characterisation and monitoring to ensure the disposal of exempt waste and routine discharge of gaseous or effluent waste are within regulatory limits.
- Emergency plans to mitigate the consequence of significant spillage of radioactive materials to the environment.

During the later detailed design stages of the NMMF, a detailed safety assessment on the facility and processes will be undertaken to ensure the level of radiation protection is optimised for each source and activity potentially involving exposure to ionising radiation.

7. Radiological Classification of Work Areas

The classification of contamination and radiation areas is undertaken according to the process described in AG-2509 ANSTO Classification of Radiation and Contamination Areas [Ref: (19)] and in conformance with AE-2310 ANSTO Radiation Safety Standard [Ref: (17)]. The radiological classification of areas is employed to control, prevent, limit, and review occupational exposure (actual or potential) to ionising radiation. This system of radiological classification supports occupational dose limits and dose constraints not being exceeded and is part of the process of ensuring that doses to individuals are optimised.

Area classifications will be reviewed and adjusted as required, with any changes being performed in accordance with AG-2509 Classification of Radiation and Contamination Areas [Ref: (19)]. For radiation contamination areas, the internal radiation hazard is determined by the potential internal radioactivity levels in Bq/cm^2 and Bq/m^3. The classification levels for radiation and contamination areas are summarised in Table 1 and Table 2.

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

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

Table 1: Summary of Area Radiation Classifications

AREA CONTAMINATION DESIGNATION				
Radioactive Work in Area[1]	Surface Contamination ($Bq.cm^{-2}$)		Radiological Designation of Area	
	α	βY		
Medium or greater risk of spreading radioactive contamination outside of radioactive containment	>6	>500	Exclusion	Red
	0.6 ≤ 6	50 ≤ 500	Controlled	Red
Low risk of spreading radioactive contamination outside of radioactive containment	0.06 ≤ 0.6	5 ≤ 50	Controlled	Blue
Buffer area e.g. for monitoring of persons and items from a radioactive contamination controlled area.	≤0.06	≤5	Supervised	Blue
Small sealed-sources or work only with "exempt"[2] quantity of radioactive material or less in an area.	Nil detectable		Supervised	White
No radioactive work	Nil detectable		Non-designated	NA

Table 2: Summary of Area Contamination Classifications

During the siting and development phase of the NMMP and as the design matures the radiological designation of specific areas in the facility will be determined, this will include a room specific breakdown of the classification of contamination and radiation areas.

7.1. Safety Hazard Notification

Potential safety hazards, including radiological, present during the conduct or dealing are identified and illustrated graphically on hazard notice boards in accordance with the AG-2414 Safety Hazard Notice Board Process [Ref: (20)].

8. Local Rules and Procedures

During the siting and development phase of the NMMP local rules and procedures will be established for the site. The local rules will be commensurate with work activities and the level of protection, safety, and supervision for controlled persons and visitors as detailed in AP-2511 Radiation Protection Requirements in Radiological Controlled Areas [Ref: (21)]. When appropriate the local rules will be upgraded to include requirements for entry and exit into radiologically designated areas within the facility, responsibilities and accountabilities for sources and processes, as well as emergency and incident reporting and investigation procedures. The procedure for Radiation Protection Requirements in Radiological Controlled Areas [Ref: (21)] also describes the radiological protection requirements for individual and workplace monitoring, calibration and maintenance of equipment, contamination detection, response measurement and investigation level should it be exceeded, and clearance of items from radiological classified areas. Procedures and work instructions for all conducts and dealings associated with the NMMF will be developed prior to its operation.

Additionally, Radiation Safety Guides located within the ANSTO WHS MS will also form part of the local rules for the facility.

[1] The terms "Medium" and "Low" in the table are as defined in the AG-2395 ANSTO Risk Analysis Matrix.
[2] "Small quantities of unsealed radioactive materials" for the purposes of designating a controlled area are those that are defined as "exempt" in the ARPANS regulations 2018. Refer to Part 1 Schedule 1 of those regulations.

9. Personal Protective Equipment

Personal Protective Equipment (PPE) for conventional safety hazards during the siting and development phase will be required, there will however be no activities involving radioactivity during this phase of the program.

During design of the facility, PPE requirements for gowning and clothing change procedures will be considered for entering and leaving contamination classified areas, and radiological classified areas as described in AP-2511 Radiation Protection Requirements in Radiological Controlled Areas [Ref: (21)]. PPE may include but is not limited to: All workers and visitors within the facility are required to wear applicable PPE prior to entering radiological designated areas. The PPE required is determined against the nature of the hazard and the work that is being undertaken. PPE may include, but is not limited to:

- Protective clothing
- Protective respiratory equipment for which the protection characteristics are made known to the user (with adequate instruction and fit testing conducted).
- Protective aprons, gloves, and organ shields.

The PPE requirements will be based on both the classification of the radiological/contamination zone as well as Good Manufacturing Practice (GMP) cleanroom classification. Provision will be made for PPE to be stored and maintained in proper condition, including arrangements for laundering or disposal.

10. Radiation Monitoring Programs

Monitoring is the collection of information about radiological conditions in the workplace and the evaluation of this information (workplace and area monitoring). This, together with information on exposures to individuals (dosimetry results), assists in confirming that safe working practices and engineering standards have been successfully implemented and that the radiological hazards are under effective control.

As part of the design and development process for the facility, monitoring programs that will be developed to confirm the adequacy of protection and optimisation of protection measures during operations. The radiation monitoring program will be developed under the supervision of a HP or RPA.

ANSTO has detailed guidance on monitoring in AG-5507 Radiation and Contamination Monitoring of the Workplace [Ref (22)].

10.1. Workplace and Area Monitoring

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

Routine area monitoring and assurance monitoring is performed for the purposes of confirming dose rates and contamination levels within and around the classified areas of the facility are within agreed parameters.

The assurance survey program will be based on a risk assessment of the radiological hazards within the facility, with the frequency of survey being based upon the magnitude of the hazard, the potential for exposure of a worker, and the potential for the conditions to change.

10.2. Monitoring of Individuals

Individual monitoring (dosimetry) is the measurement, assessment, and evaluation of radiological exposure to an individual. Occupationally exposed employees, including those normally or occasionally employed to work in a controlled area, will be monitored as part of the routine dosimetry program supervised by RPS.

Routine external monitoring using Thermo-luminescent Dosimeters (TLDs) (or other appropriate personal dosimeter) for the measurement of effective dose (β/γ exposure to the whole body) and to the extremities (β/γ) will be carried out during the operational phase of the NMMP. The routine dosimetry program will be as detailed in AG-2521 Personal Dosimetry [Ref: (23)]. The strategy for radiological monitoring will be addressed during the design phase of the program to ensure appropriate processes and infrastructure is in place for personal dosimetry issue and assessment, Electronic Personal Dosimeter (EPD) monitoring of individuals in relation to radiation and contamination classification areas described in Table 3.

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Area Classification		Dosimetry Requirements
RED (Controlled)	Radiation	TLD and EPD
	Contamination	TLD and EPD Internal Dosimetry
BLUE (Controlled)	Radiation	TLD and EPD
	Contamination	TLD Internal Dosimetry
WHITE (Supervised)	Radiation	Not required, use if available
	Contamination	Not required, use if available
NON-DESIGNATED AREA		Not required

Table 3: Minimum dosimetry requirements for ANSTO workers working in radiological controlled areas

Any NMMP workers classified as occupationally exposed persons will undergo baseline and final whole-body monitoring. Persons entering the classified contamination areas may also be required to undergo routine whole-body monitoring and/or additional monitoring depending on their tasks. Periodic review and reporting of dose results is performed.

10.3. Radiation Monitoring Instrumentation

The radiation monitoring equipment to be used in the facility consists of a combination of fixed and portable instrumentation designed to monitor the radiological conditions and the workers in the facility as outlined Table 4.

Instrumentation Type	Description and Use Case
Fixed Radiological Monitoring Instrumentation	• Installed area instrumentation measures and registers external gamma dose rates in relevant areas. • Fixed air samplers for airborne contamination • Provides real time data to RPS workers through intelligent, digital, software operated detector arrays. • Data gathered includes logging the level, status, and alarms from all area radiation monitors. • Have local displays and trigger visual and audible alarms if dose rates are higher than the pre-determined values.
Portable Radiological Monitoring Instrumentation	• Used to reduce the possibility of contamination spread, measure potential external contamination on workers. • Measurement is routinely performed as close as possible to the contamination source by means of portable equipment. • They complement/ validate the information provided by fixed detectors and survey specific operations or procedures, including gamma and neutron dose rate and surface and airborne contamination monitors. • Portable instruments are also used to measure items leaving areas where contamination is expected, as well as to release material to users outside the facility.

Table 4: Radiation Monitoring Instrumentation

Specific installed and portable radiation monitoring equipment to be used in the facility will be determined and procured following a detailed assessment of the facility design, human factors task analysis, and best available equipment market assessment.

10.4. Monitoring of the Environment

There are no identifiable routes of discharge of radiological material into the environment as well as no identifiable exposure pathways to wildlife in their natural habitats during the siting and development phase activities of the Program. Additional details on monitoring of the environment during subsequent stages of the facility, is available in NMMP Environment Protection Plan NMMP-0410-PM-0006 [Ref: (24)].

11. Transport

During the siting phase of the NMMP, no movements of radioactive materials are expected to occur.

The movement of radioactive materials internally within ANSTO is in accordance with AG-2515 Safe Movement and Transport of Radioactive Material [Ref: (25)]. Movement of radioactive materials outside of the ANSTO Lucas Heights Science and Technology Centre will be in accordance with ARPANSA RPS C-2 Code for the Safe Transport of Radioactive Material [Ref: (26)], Radiation Protection Series No. 11 [Ref: (27)], Australian Code for the Transport of Dangerous Goods by Road and Rail [Ref: (28)], Australia Post Dangerous & Prohibited Goods & Packaging Guide [Ref: (29)], and the International Air Transport Association's Dangerous Goods Regulations (DGR) [Ref: (30)].

Design processes for the NMMP will take into account the movement of waste products leaving the facility or moving between contamination classified areas that require radiological monitoring and clearance. Clearance arrangements are described in ANSTO procedure AG-2514 Clearance of Items from Classified Areas [Ref: (31)] (32)].

12. Training

Specific training for the NMMP will be commensurate with the responsibilities of the role an individual is performing.

All workers enrolled on the ANSTO personal dosimetry service attend the Basic Radiation Safety training course and the Radiation Protection Workshop, conducted by RPS, prior to working in classified areas. The AG-2058 Work Health & Safety Training Handbook [Ref: (33)] provides information on the WHS training available at ANSTO. The handbook is a reference to assist managers and workers in determining the relevant WHS and Radiation Protection training and resourcing needs to fulfil their position requirements considering the site's risk profile.

Health physics monitoring in the facility will be performed by an HPS. All HPS at ANSTO undergo a training program that includes theoretical and practical training. An assessment is conducted at the conclusion of the training program to determine the individual's competence in performing the duties of an HPS. The HPS will be familiar with the operations, instrumentation, and radiological requirements of the facility.

13. Record Keeping

All documents pertaining to the NMMP are managed under NMMP Document Management Plan NMMP-0010-PM-0013 [Ref: (34)] and will be managed in accordance with the ANSTO AR-1041 Management System Controlled Document Process [Ref: (35)] and ANSTO AR-1477 Records Management Process [Ref: (36)], as appropriate. Such documents may include, but are not limited to:

- Approvals, licenses and authorisations granted by the Regulatory Authority.
- Approved NMMF Plans and Arrangements, including this Radiation Protection Plan.
- Design specification and drawings
- Safety and Radiation Protection Hazard and Risk Assessment reports
- Details of training courses provided to and attended by workers.
- Any radiological survey reports.
- Reports of any incidents or accidents involving exposure to ionising radiation.

14. Review and Audit of Radiation Protection Plan

Review and update of this Radiation Protection Plan will be carried out following:

- Planning for the introduction of radioactive materials to the facility.
- Significant changes to planned operating parameters involving radiation protection controls.
- Any modification that has the potential to change the radiological conditions of the facility.
- In the event of an emergency, accident, or incident.

Under Section 61 of the ARPANS Regulation, ANSTO requires its licenced facilities to perform a review of their Plans and Arrangements documents to assure ongoing compliance and accuracy of the documents at least once every 3 years. This review is undertaken in line with AF-3417 Review of Plans and Arrangements for ARPANSA Licences [Ref: (37)].

14.1. Performance Indicators

Performance indicators used to measure the effectiveness of radiological control measures include:

- Occupational exposure to individuals.
- Monitoring results from routine radiological surveys.
- Event/ Incident Reports.

14.2. Occupational Exposure

ANSTO use dose criteria which serve as boundaries within which the optimisation process takes place and serve to reduce inequities of exposure. The types of dose criteria that ANSTO use are Dose Review Levels, Dose Constraints and Dose Limits. The process of optimisation with the use of constraints or review levels is applied in planning protective actions and in establishing the appropriate balance between individual exposures and group/society benefits. Further details on this approach are provided in AE-2310 Radiation Safety Standard [Ref: (17)].

14.3. Monitoring Results

RPAs will review the radiological conditions within the facility, as measured during planned assurance or special surveys, and will make recommendations to NMMP management, as needed, to remedy the following situations:

- The radiological classification of the area is incorrect.
- There is a trend towards increasing radiation or contamination levels in an area.
- There is a specific radiological concern.

14.4. Event/ Incident Reports

Events or incidents will be investigated by the NMMP Program Director (with additional expertise made available from the ANSTO resources, as required). The frequency and magnitude of radiological events will be considered an indicator of the effectiveness of this plan and its implementation.

15. Emergency Response and Event reporting

Emergency response arrangements for the facility have been developed and are described in NMMF Emergency Management Plan NMMP-0410-PM-0005 [Ref: (38)].

16. Definitions

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

Term	Definition
ALARA	As Low As Reasonably Achievable
ALARP	As Low As Reasonably Practicable
ANSTO	Australian Nuclear Science and Technology Organisation
ARPANS	Australian Radiation Protection and Nuclear Safety
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
CEO	Chief Executive Officer
DGR	Dangerous Goods Regulations
EPD	Electronic Personal Dosimeter
GMP	Good Manufacturing Practice
HP	Health Physicist
HPS	Health Physics Surveyors
I-131	Iodine-131
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
Lu-177	Lutetium-177
NMMF	Nuclear Medicine Manufacturing Facility
NMMP	Nuclear Medicine Manufacturing Program
OPAL	Open Pool Australian Light-water Reactor
PPE	Personal Protective Equipment
RPA	Radiation Protection Advisor
RPS	Radiation Protection Services
RSO	Radiation Safety Officer
SRA	Safety and Reliability Assurance
SWMES	Safe Work Method and Environmental Statement
Tc-99m	Technetium-99m
TLD	Thermo-luminescent Dosimeter
WHS	Work Health and Safety
WHS MS	Work Health and Safety Management System

17. References

The following items are referred to in this document or were used in its creation.

1. Australian Radiation Protection and Nuclear Safety (ARPANS) Act. s.l. : Cth, 1998.
2. Australian Radiation Protection and Nuclear Safety (ARPANS) Regulations. 2018.
3. IAEA Safety Standards, GSR Part 3, General Safety Requirements. Vienna : International Atomic Energy Agency, 2014.
4. IAEA Safety Standards, GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency. Vienna : International Atomic Energy Agency, 2015.
5. NMMF Safety Analysis Report. NMMP-2040-RT-0001.
6. ARPANSA-GDE-1735 ARPANSA Regulatory Guide - Plans and Arrangements for Managing Safety. 2023.
7. NMMP-0710-PM-0001 Design Guide - Safety in Design Strategy.
8. AG-2471 Safe Management of ARPANSA Controlled Material.
9. Australian Nuclear Science and Technology Organisation Act 1987.
10. Work Health and Safety Act 2011.
11. Work Health and Safety Regulations Cth 2011.
12. NMMF Effective Control Plan. NMMP-0410-PM-0001.
13. AP-2300 ANSTO WHS Management System Overivew.
14. ICRP Publication 103, 2007. s.l. : International Commission on Radiological Protection. 103.
15. ARPANSA Radiation Protection Series RPS C-1 Code for Radiation Protection in Planned Exposure Situations . s.l. : ARPANSA, 2020.
16. ANSTO. ANSTO Memorandum: Independent Review Implementation Plan, Enhancing the WHS Management System, Recommendation 68 - The relative roles of ALAR and ALARP. s.l. : Cth, 26/03/2020.
17. AE-2310 Radiation Safety Standard.
18. AG-7082 ANSTO Risk Management Tool Risk Response & Control Effectiveness.
19. AG-2509 Classification of Radiation and Contamination Areas.
20. AG-2414 Safety Hazard Notice Board Process .
21. AP-2511 Radiation Protection Requirements in Radiological Controlled Areas.
22. AG-5507 Radiation and Contamination Monitoring of the Workplace.
23. AG-2521 Personal Dosimetry .
24. NMMP-0410-PM-0006 NMMF Environment Protection Plan.
[redacted]
26. ARPANSA Radiation Protection Series RPS C-2 (Rev.1) Code for the Safe Transport of Radioactive Material. s.l. : ARPANSA.
27. ARPANSA Radiation Protection Series No. 11 Code of Practice for the Security of Radioactive Sources. 2019. RPS No. 11.
28. Australian Code for the Transport of Dangerous Goods by Road and Rail. Edition 7.8.
29. Australia Post Dangerous and prohibited goods and packaging guide. s.l. : Australia Post, 2020.
30. IATA Dangerous Goods Regulations (DGR Edition 65). s.l. : IATA.
31. AG-2514 Clearance of Items from Classified Areas.
32. AF-2357 ANSTO Contamination Clearance Certificates .
33. AG-2058 ANSTO WHS Training Handbook.
34. NMMP-0010-PM-0013 Document Management Plan .
35. AR-1041 ANSTO Management Controlled Document Process.
36. AR-1477 ANSTO Records Management Process. AR-1477.
37. AF-3417 Reviewing Plans and Arrangements for ARPANSA Licences Form.
38. NMMP-0410-PM-0005 NMMF Emergency Management Plan .
39. AG-2378 Work Health and Safety Definitions.

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