Australian Government | ANSTO

NUCLEAR MEDICINE MANUFACTURING PROGRAM

NMMF Effective Control Plan

For Siting Licence

File Number: NMMP-0410-PM-0001

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1. Purpose

The purpose of this Effective Control Plan is to describe the organisational effective control arrangements 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 plan is an integral element of the ARPANSA Siting Licence Application.

ANSTO is committed to maintaining and enhancing the high standards of safety controls 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 IAEA standards and guidelines on leadership and management for safety, specifically IAEA Safety Standard Series No. GSR Part 2 [Ref: (3)].

This plan should be read in conjunction with the NMMF Safety Analysis Report (SAR) [Ref: (4)] and 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

The scope of this plan includes statutory and regulatory compliance, management commitment, accountabilities and responsibilities, resources, communication, process implementation and documentation, and document control as per the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Regulatory Guide – Plans and Arrangements for Managing Safety [Ref: (5)].

This includes:

- The processes or systems that will allow all relevant and applicable statutory and regulatory requirements to be identified. (Refer: Section 3).
- How important statutory and regulatory compliance aspects will be shared and communicated to relevant personnel (Refer: Section 7).
- How all operations and functions will be in compliance with the identified requirements (Refer: Section 5).
- How the Licence holder will ensure the plan stays up to date with applicable regulatory requirements (Refer: Section 3).

3. Statutory and Regulatory Compliance

As a major licence holder, ANSTO is in regular communication with ARPANSA regarding statutory requirements and provides stakeholder comments to ARPANSA on planned changes. The Regulatory Affairs and Compliance Manager disseminates information obtained through these processes to Nominees, Facility Officers, and Licensing Officers. This includes information regarding regulatory updates to ensure the organisation stays up to date with applicable requirements.

Compliance with requirements is monitored by ANSTO's Risk and Audit Committee (RAC) as per AB-2098 ANSTO Board – Risk and Audit Committee Charter [Ref: (6)]. The RAC is responsible for providing independent oversight, advice, and assurance to the ANSTO Board on the appropriateness of risk oversight and management systems, financial reporting processes, performance reporting arrangements, systems of internal control, and systems to ensure compliance with relevant laws and policies. This is executed through an Internal Audit function, detailed in AG-2148 ANSTO Internal Audit Charter [Ref: (7)], which involves a Chief Risk and Assurance Officer (CRAO) to oversee Enterprise Risk, Project Risk and Assurance, and Internal Audit teams as well as reports to the ANSTO Chief Executive Officer (CEO).

ANSTO's AB-0009 Risk and Compliance Policy [Ref: (8)] establishes a uniform enterprise-wide approach to ensure compliance with all applicable laws, regulations, standards, codes of conduct, agreements, and work practices. ANSTO is committed to complying with all relevant internal and external compliance requirements, including relevant legislation, regulations, policies, procedures, and any other obligations relevant to, or being imposed on, the organisation. The compliance program is based on best practice and is consistent with AS ISO 37301:2023 - Compliance Management Systems [Ref: (9)] which provides principles and guidance for designing, developing, implementing, maintaining, and improving an effective compliance program. ANSTO is committed to identifying and implementing the highest standard of compliance to meet regulatory obligations.

While undertaking its research activities and operations, ANSTO engages with a wide range of regulatory bodies including, but not limited to:

- ARPANSA
- Australian Safeguards and Non-Proliferation Office (ASNO)
- Comcare
- Therapeutic Goods Administration (TGA).

The ANSTO Board is responsible for ensuring that the organisation complies with all applicable laws and regulations and considers adherence to non-binding rules, codes, and standards. The CEO, as the Licence holder, will nominate a Licence Nominee for the NMMF and is jointly accountable to the Board for implementation of an effective compliance framework and related processes.

The NMMF Licence Nominee will appoint a Facility Officer, who will be responsible for managing compliance with ARPANS regulations and any licence conditions for the facility. The Facility Officer maintains operational and functional oversight of the design, construction, commissioning, and operational activities of the NMMF. The Nominee will also appoint a Licensing Officer who will be responsible for reporting to ARPANSA regarding compliance with the ARPANS Act [Ref: (1)] and Regulations [Ref: (2)] and the facility licence conditions. It is the responsibility of the persons filling these positions to provide advice to the organisation and staff on the operating requirements to ensure continuing compliance and communicate new or changed requirements as they occur.

All information pertaining to statutory and regulatory compliance aspects will be communicated to staff at regular meetings and through written procedures which are easily accessible through the ANSTO intranet. All staff with a role relating to an ARPANSA licence are to complete training to ensure that they are aware of the regulatory requirements and know where and how the relevant information can be accessed. All operations and functions of the proposed facility will be reviewed regularly to ensure that they comply with the identified requirements.

Throughout the NMMF lifecycle, including design, construction, operations, and decommissioning, as part of the management of change process, all relevant statutory and regulatory requirements will be identified through formal review of the ARPANS Act [Ref: (1)] and Regulations [Ref: (2)], International Atomic Energy Agency (IAEA) guidance, and guides on ARPANSA requirements, facilitated by the Regulatory Affairs and Compliance Manager.

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4. Management Commitment

ANSTO Management supports, promotes, and endorses all plans and arrangements submitted as part of this siting licence application. ANSTO management is committed to ensuring compliance with statutory and regulatory obligations (as discussed in Section 3), allocating adequate resources to safety, security, and maintaining control over the proposed NMMF throughout its lifecycle.

ANSTO's Project and Budgetary processes for the NMMF Program are described in NMMP Project Management Plan NMMP-0010-PM-0016 [Ref: (10)]. The NMMP Leadership Group (PLG) is responsible for the allocation of human and financial resources to ensure that the proposed facility can be safely and effectively managed throughout all phases of program delivery. Resources for the proposed NMMF will be fully funded by ANSTO through government appropriations.

Management's commitment to regulatory compliance, available resourcing for holistic safety and security, and overall control for the facility is maintained by direct appointment of an ANSTO Program Director and Contractor Supervisor to oversee day-to-day activities on the site.

Management is committed to the principles of holistic safety, consistent with the requirements of the IAEA General Safety Requirements [Ref: (3)] for leadership and management for safety. The PLG will ensure that the human, organisational, and technological aspects are all considered, controlled, and integrated to ensure the highest level of safety is achieved. This includes:

- Promoting the strong safety culture of the organisation which aims to ensure that safety is integral to everything that everyone does and that it is demonstrated in the values, attitudes, beliefs, and behaviours of all workers.
- Ensuring that human factors risk assessments are considered when designing equipment, tools, systems, and work processes to enhance safety, reduce errors, enhance comfort, and increase productivity, as detailed in NMMP Design Guide – Safety in Design Strategy NMMP-0710-PM-0001 [Ref: (11)].
- Developing a Design Risk Assessment (DRA) upon completion of a design package that identifies potential hazards and risks associated with a system, sub-system, or component design and elements of the design or operation that mitigate against them as detailed in NMMP Design Guide – Safety in Design Strategy [Ref: (11)].
- Promoting continual learning and development through online and face to face training, accessed via the Learning and Development (L&D) system for both technical and non-technical skills.
- The use of a systematic, explicit, and proactive Work Health and Safety Management System (WHS MS), as detailed in AP-2300 ANSTO WHS MS Overview [Ref: (12)], which is compliant with ANSTO legislative obligations and ISO 45001 [Ref: (13)].
- Applying defence in depth methodology to ensure that any technology used during operations is safe.

ANSTO promulgates health and safety information to all staff and contractors through the ANSTO, Safe, Secure and Sustainable initiative. This program was initiated in 2014 to embed ANSTO's values of Working Together, Curiosity, Excellence, Leadership, Trust + Respect. The ANSTO Board reaffirmed the Safe, Secure and Sustainable initiative in June 2022 to continue development of "Our Culture" as a mindset and behaviours driven by "Our Values".

A key element of the Safe, Secure and Sustainable initiative is the internal communications strategy to promote ANSTO management's commitment to the principles of holistic safety, from the Board and operational leadership to all personnel and contractors.

The Safe Secure Sustainable initiative encompasses communication through team meetings, working groups hazard alert notices, a dedicated SharePoint site, safety stories, podcasts and targeted safety events i.e., psychological wellness and health promotion.

The NMMP Leadership team will utilise the Safe Secure Sustainable resources to develop a program safety culture and communicate safety information through induction and training programs, toolbox talks, meeting safety moments and targeted safety items during progress meetings. Relevant information and supporting documents will be readily available through the NMMP document management system and program intranet site.

5. Accountabilities and Responsibilities

ANSTO has specific roles and responsibilities in place to ensure compliance with the ARPANSA requirements as detailed in AG-5445 - ANSTO Guide on ARPANSA Requirements [Ref: (14)]. The CEO of ANSTO is the applicant to ARPANSA for the siting, construction, and operating licences for the NMMF. The responsibility for maintaining effective control and for ensuring compliance with the ARPANS legislation will be formally delegated to the Licence Nominee. The Nominee is assisted by a Facility Officer and a Licensing Officer. The names of these officers will be recorded and kept up to date on the ANSTO intranet in AG-1666 ANSTO Nuclear Installations, Prescribed Radiation Facilities and Source Licences [Ref: (15)].

The Nominee will be responsible for the management of plans and arrangements and the overall control of the proposed facility. The Nominee will ensure that local procedures and instructions for achieving regulatory compliance are in place, appropriately maintained, and all staff are aware of their respective accountabilities and responsibilities.

The Licensing Officer, Facility Officer, and Radiation Safety Officer (RSO) roles are summarised in Table 1.

Role	Responsibility
Licensing Officer	• Providing general advice to Responsible Officers, Facility Officers, and Line Managers on reporting requirements. • Preparing quarterly reports for the facility. • Preparing reports for ARPANSA on abnormal operations or breaches in conjunction with the Manager, Regulatory Affairs and Compliance, and the Facility Officer. • Assisting, when required, in the preparation of regulatory submissions for the facility. • Acting as a point of contact for conducting inspections. • Coordinating the review of plans and arrangements for the facility in accordance with Section 61 of the ARPANS Regulations. • Moderating and authorising requests to make changes to the facility.
Facility Officer	Will be responsible for development of the safe operations and maintenance arrangements for the facility. Their general responsibilities include: • Providing general advice to staff and line management on regulatory requirements appropriate to the facility. • Managing the workload of staff. • Assisting in the preparation of quarterly reports when required. • Preparing annual reports when required. • Preparing reports for ARPANSA on abnormal operations or breaches in conjunction with the Manager, Regulatory Affairs and Compliance, and the Licensing Officer. • Assisting with the preparation of regulatory submissions for the facility. • Acting as a point of contact for conducting inspections of the facility. • Conducting reviews of the plans and arrangements for the facility in accordance with Section 61 of the ARPANS Regulations.
Radiation Safety	The RSO is an experienced and recognised radiation protection specialist who is responsible for ensuring that ANSTO radiation protection advice, including relevant guides and arrangements, reflect current relevant Australian radiation protection legislation and international radiation protection best practice. The

Role	Responsibility
Officer (RSO)	RSO also ensures that Radiation Protection Services (RPS) staff are adequately trained and experienced to fulfil their duties.
Supervisors	They are responsible for the day-to-day operations of their area once the NMMF becomes operational.

Table 1: Licence-specific roles and responsibilities for the NMMF

During siting, the Facility Officer and Licencing Officer role will be fulfilled by a member of the PLG. The PLG will engage other ANSTO divisions under service level agreements to provide ongoing and specialised services. Responsibility delegations for the proposed facility are summarised in Table 2.

Responsibility	Delegations
Safety	All personnel are responsible for their safety, as well as others, in alignment with regulatory obligations under the Work Health and Safety Act [Ref: (16)] and Regulations [Ref: (17)]. Advice, co-ordination, and monitoring of safety responsibilities will be provided by the ANSTO High Reliability Group including a Work Health and Safety (WHS) Adviser and a Health Physicist. Changes or upgrades to the facility that could potentially impact safety are assessed through the ANSTO Safety and Reliability Assurance (SRA) process to facilitate relevant safety approvals.
Security	General Security is the responsibility of ANSTO Security and Safeguards.
Statutory and Regulatory Compliance	Statutory and regulatory compliance responsibilities remain with the Licensing Officer and Facility Officer, liaising with the ANSTO Regulatory Affairs and Compliance Manager, who ultimately reports to the Chief Operating Officer (COO).
Resources	Management of the resources available and utilised for the Program is the responsibility of the Program Director with input and oversight by the NMMP Program Control Group (PCG) and the ANSTO Capital Committee, as detailed in NMMP-0010-PM-0016 Project Management Plan [Ref: (10)].
Process Implementation	The Engineering and Technical Director will monitor and ensure safety and system hazard control processes and measures are implemented through a verification and validation process.
Management of Plans and Arrangements	The Nominee is responsible for the overall management of the plans and arrangements.
Maintaining Control of the Facility	The Nominee and Program Director (during the siting phase only).

Table 2: Responsibilities for the NMMF

A proposed facility organisational chart is shown in Figure 1 and will be updated, as deemed appropriate, prior to the NMMF becoming operational. Role descriptions have been provided in Table 3.

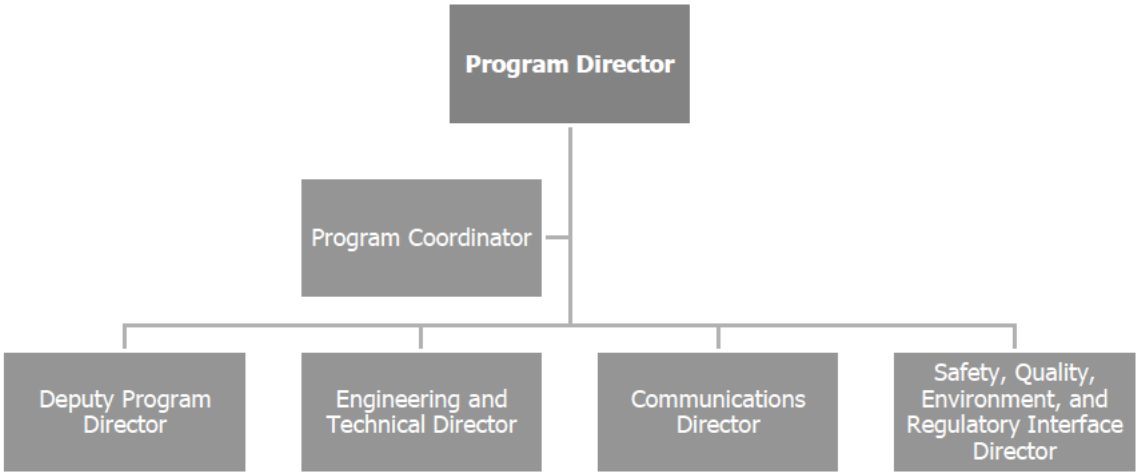

Figure 1: NMMF Organisation Chart

Role	Description
Program Director	Program development and stakeholder engagement lead for the NMMF Program.
Program Coordinator	Coordination of stakeholder working groups and interface with the PLG.
Deputy Program Director	Development and implementation oversight of the NMMF Program.
Engineering and Technical Director	Oversees engineering management processes to ensure compliance with relevant engineering standards and industry best practice when delivering the scope of the Program and the associated NMMP User Requirements Specification [Ref: (18)].
Communications Director	Develops and oversees the internal and external communications strategies and process for the NMMF. The Stakeholder and Communications Management Plan NMMP-0010-PM-0005 [Ref: (19)] effectively describes, how, when, and by whom information and data will be administered and disseminated.
Safety, Quality, Environment and Regulatory Interface Director	Manages Subject Matter Experts (SMEs) interfacing across Good Manufacturing Practice (GMP), quality, regulatory, safety, and environment stakeholders.
Workers	All personnel, including contractors and service providers working on the NMMF will complete a NMMF-specific induction. The induction will communicate worker responsibilities for work health and safety as described under the WHS Act [Ref: (16)] and Regulations [Ref: (17)] and radiological safety requirements for the Program as described in the NMMF Radiation Protection Plan NMMP-0410-PM-0003 [Ref: (20)].

Table 3: NMMF Role Descriptions

6. Resources

Resource planning for the NMMF is conducted during review of the budget and described in the NMMF Project Management Plan NMMP-0010-PM-0016 [Ref: (10)]. The budgeting needs for operations and safety arrangements are identified and assessed through the resource planning process. The Project Management Plan [Ref: (10)] describes how the PLG allocates adequate and appropriate financial, human, equipment, and material resources to successfully implement the plans and arrangements for the safe and effective control of the facility.

6.1. Financial Resources

The ANSTO project management and approval processes for projects ensure there is ongoing and sufficient funding available for the necessary equipment and people resources for any new processes and changes. This is assessed and managed through the AG-8192 ANSTO Capital Committee Charter [Ref: (21)] which describes the capital works and funding process. The funding is allocated by the Capital Committee, comprised of senior management, and projects are monitored throughout their lifecycle by the Investment Review Committee (IRC).

Once approved, the funds are made available to the Program Director and staff. All external purchases of items and services, including additional training, are through the ANSTO Procurement division and follow the requirements of the AG-2881 Procurement Guideline - Purchasing Principles [Ref: (22)].

6.2. Human Resources

The ANSTO processes for identifying the safety resource requirements are at several levels. For each potentially hazardous process or activity, a hazard identification and risk assessment, following AP-2301 Work Health & Safety Risk Management [Ref: (23)], is performed which identifies required equipment such as personal protective equipment (PPE). During consequential stages of the Program, this will be conducted through the preparation of Safe Work Method and Environmental Statements (SWMES). This detailed planning will ensure there are sufficient workers assigned to each task.

The NMMF Radiation Protection Plan [Ref: (20)] identifies the necessary involvement by radiation specialists, and it also recommends constraints for the allowable involvement of radiation workers. The risk assessments and plans are reviewed internally through the SRA process where appropriate.

6.3. Equipment and Material Resources

Prior to the operation of the proposed NMMF, a risk assessment will be developed. For each potentially hazardous process or activity, a hazard identification and risk assessment following AP-2301 Work Health & Safety Risk Management [Ref: (23)] will be performed. This will assist in identifying the critical controls including all required equipment, materials, and PPE for the facility. The details relating to the employment of all safety related resources will be developed during the detailed work planning for the subsequent licence applications, i.e., construction and operation of the facility.

6.4. Resource Review and Monitoring

The NMMP Program Control Group (PCG) forms part of the supportive governance group with membership drawn from the Program Leadership Team, governance groups, and input from the RAC. This group monitors Program performance and resourcing requirements. Where a shortfall in performance or resourcing requirements is identified, including those impacting on safety and security, the PCG will make operational decisions relating to delivery of the Program within its delegation and work stream. Decisions falling outside the PCG's delegated authority are elevated to the Capital Committee.

7. Communication

Communication during all phases of the Program will be vital to its success. The processes for personnel communication and the communication network within the facility are described in the NMMP Project Management Plan [Ref: (10)].

Lines of communication at ANSTO are defined and established through regular meetings with both internal and external stakeholders. Key internal meetings will be maintained in the NMMF calendar. Meetings with external stakeholders such as suppliers, contractors, and subcontractors, will be arranged at regular intervals as appropriate to gather data on progress against the NMMF scope. Safety will be a key element across these meetings to develop a strong safety culture and to address safety issues in a timely manner. Key recurring and structured meetings for the Program, as detailed in Table 4, are further explored in Section 15 of the NMMP Project Management Plan [Ref: (10)].

Meeting	Objective/ Agenda
Regular Program Control Group (PCG)	Overall direction of the Program.
Regular Executive Status Review	• High-level monitoring and review of program status and performance against safety, cost, schedule, and quality. • Review of financial dashboard to ascertain expenditure against budget.
Contract Meeting	• To provide updates on progress to the customer. • To address NMMF issues. • To deal with other contractual issues as required.
Regular Design Review Meeting	Verify and validate requirements against design.
Regular NMMP Team Meeting	• To identify, document, and action any issues relating to the Program. • To provide updates on performance against safety, cost, schedule, quality, HR, risk, and technical key performance indicators.
Regular Production Meeting	• Production issues. • Commissioning planning.
NMMF Interface Meeting	Review of NMMF interface issues, against the Interface Plan.
Toolbox Meetings and Shift Handovers	Upon commencement of site works, Safety, “Start Right, Finish Right”, Daily work schedule, Field issues, and Near Miss reporting.

Table 4: NMMP Key Meetings

All ANSTO personnel and contractors involved in the NMMF will complete a NMMF specific induction training program. This program will include relevant information on radiation protection and nuclear safety. Delivery of the induction program and reporting arrangements will be through their Contractor/ Construction Supervisor who is accredited through the ANSTO WHS MS [Ref: (12)] as detailed in AP-2303 Safe Management of Contractors [Ref: (24)]. The Contractor Supervisor will maintain regular communications, including toolbox talks, with Contractors, Sub-contractors, and ANSTO workers. The Contractor Supervisor or Principal Contractor will ensure any change to, or new plant, equipment, materials, substances, working arrangements, or systems of work are included in all relevant risk assessments and communicated to all workers that may be impacted. All toolbox talks undertaken must be documented by the Contractor Supervisor.

Once the NMMF becomes operational, the communication between staff for maintaining a safe work environment will need to be efficient and timely. All appropriate staff will be inducted into the facility with all specific activities which have immediate implications for safety and operations being communicated. All relevant staff will be trained in key procedures relevant to activities occurring in the facility through the Learning and Development (L&D) system.

Communication channels available to staff will include management review, operational group meetings, monthly reporting requirements, staff forums, the intranet, phone calls, emails, and distribution of presentation notes or minutes from relevant meetings and forums.

The ANSTO Governance, Risk and Compliance (GRC) system [Ref: (25)] will be utilised for recording safety events, including those with radiation protection and nuclear safety aspects, and following up actions from these events. The system has a workflow component which will send information to the relevant staff members for corrective actions and follow up.

8. Process Implementation

Introduction of new process or safety significant changes to existing processes planned for the NMMF are managed through the NMMP Change Management Plan NMMP-0010-PM-0036 [Ref: (26)].

Structural, technological, behavioural, policy, and process changes within the ANSTO organisation are facilitated using the NMMP Change Management Plan [Ref: (26)] and through ANSTO's AF-6947 Change Management Plan [Ref: (27)]. This form guides the initiating person/s to ensure the objective of the change is clear and all aspects have been adequately considered. Additionally, the AF-6946 Change Management Checklist [Ref: (28)] should be used to ensure all required steps have been undertaken and sufficient consideration has been made to safely implement the change.

A summary of the process, which covers all phases of the change, is provided below:

- Description of and justification for the new or changed process
- Consultation with key stakeholders to determine impacts of the new or changed process.
- SRA approval where required.
- Evaluation of the impacts of the new or changed process on:
    - Equipment rated Safety Category 1 or 2 in the NMMF Safety Analysis Report.
    - Safety and radiation protection.
    - The status of regulatory approvals.
    - The environment.
- Approval from regulators, including ARPANSA, as required.
- Approval to prepare required changes in readiness for implementation.
- Approval to implement the new or changed process.
- Verification that all actions to implement the process are complete.

A key element of the Organisational Change Management Plan [Ref: (27)] and process is establishing a communication strategy through a Consultation and Engagement Plan, as detailed in AF-6948 Consultation and Engagement Plan [Ref: (29)]. This plan must engage relevant personnel throughout the change development and implementation process.

Early engagement is essential for WHS consultation and contractor arrangements. In addition to internal and external contractor stakeholders, the change management process may also require involvement from NMMP configuration Working Groups, WHS Committees, and Health and Safety representatives.

During the implementation phase the following actions are required:

- Actions will be monitored against the change timeline.
- The NMMP Change Control Group (CCG) will meet on a regular basis to update the status of the change.
- Resistance to the change should be monitored and, if necessary, strategies should be implemented to gain understanding of the core issues and assist in resolving them.
- Training and support should be provided to ensure the change is as smooth as possible.
- Consultation with WHS representatives to assess any WHS issues associated with the setup of the change.

New changes to existing processes which have safety implications will require approval by the internal ANSTO SRA team and is evaluated through the AG-2434 Guidance for the Safety and Regulatory Screening Form [Ref: (30)]. Where the change has significant implications for safety, engagement with ARPANSA prior to implementation will be required. Changes that do not affect or improve safety are to be notified to ARPANSA in the quarterly report.

Following consultation and approval of the change, verification of any actions are to be documented to ensure that all actions have been completed to a satisfactory level. Processes are monitored through safety and quality data and validation for the process or equipment. Deviations from the approved design specification are managed through the quality notification and corrective and preventative action system and AI-3416 Reviewing Plans and Arrangements for ARPANSA Licences [Ref: (31)].

9. Documentation and Document Control

Safety and security practices, including radiation protection and nuclear safety, are documented in the ANSTO Business Management System (BMS) and periodically reviewed by the relevant custodian and department. Key documents include:

- AB-0003 Nuclear Security and Safeguards Policy [Ref: (32)]
- AB-0002 Health, Safety, Community and Environment Policy [Ref: (33)]
- AG-1028 ANSTO Security Manual [Ref: (34)]
- AP-2300 ANSTO Work Health & Safety Management System Overview [Ref: (12)]
- AE-2310 Radiation Safety Standard [Ref: (35)]

Specific procedures for the NMMF will be documented under the NMMP Document Management Plan (Delivery Phase) NMMP-0010- PM-0013 [Ref: (36)]. This plan describes the processes associated with the creation, review, approval, and archiving of all documents and records associated with the delivery of the Program.

ANSTO's BMS has been designed to meet the requirements of ISO 9001 and ISO 14001.

It is ANSTO policy that all processes are documented, reviewed, and integrated into the BMS to ensure that they are well understood, current, and available for use. Procedures and instructions are integrated across ANSTO through the AP-8125 Business Management System (BMS) Controlled Document Procedure [Ref: (37)] where associated processes are cross-referenced within documents for ease of use. During the documenting process, associated activities are reviewed to ensure consistency between procedures. Document templates are used to ensure consistency in the presentation of information in procedures and instructions for ease of reading by the end user.

All procedures are accessible to staff and contractors through ANSTO's intranet. The documents are controlled to ensure that only the latest revision is available to users. ANSTO documents are controlled by AR-1041 Business Management System (BMS) Controlled Document Process [Ref: (38)]. Documents generated during both commissioning and operations will be controlled according to these processes. This process ensures that documents are identified, created, reviewed, approved, and distributed to end users in a controlled manner.

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

10. Review Process

This effective control plan will be reviewed according to AI-3416 Reviewing Plans and Arrangements for ARPANSA Licences [Ref: (31)] to meet the requirements of relevant regulations. Should the plans and arrangements need to be reviewed for a specific reason outside the annual review period, additional reviews will be scheduled. The review will be recorded, and approval obtained from the Facility Nominee.

11. Definitions

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

Term	Definition
ANSTO	Australian Nuclear Science and Technology Organisation
ARPANS	Australian Radiation Protection and Nuclear Safety
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ASNO	Australian Safeguards and Non-Proliferation Office
BMS	Business Management System
CEO	Chief Executive Officer
COO	Chief Operating Officer
CRAO	Chief Risk and Assurance Officer
DRA	Design Risk Assessment
GMP	Good Manufacturing Practice
GRC	Governance, Risk and Compliance
IAEA	International Atomic Energy Agency
IRC	Investment Review Committee
ISO	International Organisation for Standardisation
L&D	Learning and Development
NMMF	Nuclear Medicine Manufacturing Facility
NMMP	Nuclear Medicine Manufacturing Program
PCG	Program Control Group
PLG	NMMP Leadership Group
PPE	Personal Protective Equipment
RAC	Risk and Audit Committee
RPS	Radiation Protection Services
RSO	Radiation Safety Officer
SME	Subject Matter Expert
SRA	Safety and Reliability Assurance
SWMES	Safe Work Method and Environmental Statements
TGA	Therapeutic Goods Administration
WHS	Work Health and Safety
WHS MS	Work Health and Safety Management System

12. 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. Cth, 2018. .
3. IAEA Safety Standards, GSR Part 2, Leadership and Management for Safety. Vienna : International Atomic Energy Agency, 2016.
4. NMMF Safety Analysis Report. NMMP-0410-RT-0004.
5. Regulatory Guide: Plans and Arrangements for Managing Safety v5. s.l. : ARPANSA, 2014.
6. AB-2098 ANSTO Board - Risk and Audit Committee Charter.
7. AG-2148 ANSTO Internal Audit Charter.
8. AB-0009 ANSTO Risk and Compliance Policy.
9. AS ISO 37301:2023 Compliance management systems - Requirements with guidance for use.
10. NMMP-0010-PM-0016 Project Management Plan.
11. NMMP-0710-PM-0001 Design Guide - Safety in Design Strategy.
12. AP-2300 ANSTO WHS Management System Overivew.
13. ISO 45001 Occupational health and safety management systems — Requirements with guidance for use. 2018.
14. AG-5445 ANSTO Guide on ARPANSA Requirements.
15. AG-1666 ANSTO Nuclear Installation, Prescribed Radiation Facilities and Source Licences.
16. Work Health and Safety Act 2011.
17. Work Health and Safety Regulation 2017.
18. NMMP User Requirements . NMMP-0030-SW-0001.
19. NMMP-0010-PM-0005 Stakeholder and Communications Management Plan.
20. NMMP-0410-PM-0003 NMMF Radiation Protection Plan.
21. AG-8192 ANSTO Capital Committee Charter.
22. AG-2881 Procurement Guideline - Purchasing Principles .
23. AP-2301 Work Health & Safety Risk Management.
24. AP-2303 Safe Management of Contractors.
25. ANSTO Governance, Risk, Compliance (GRC) Cloud.
26. NMMP Change Management Plan. NMMP-0010-PM-0036.
27. AF-6947 Change Management Plan.
28. AF-6946 Change Management Checklist .
29. AF-6948 Consultation and Engagement Plan .
30. AG-2434 Guidance for the Safety and Regulatory Screening Form.
31. AI-3416 Reviewing Plans and Arrangements for ARPANSA Licences.
32. AB-0003 Nuclear Security and Safeguards Policy.
33. AB-0002 ANSTO Health Safety Community and Environment Policy.
34. AG-1028 ANSTO Security Manual.
35. AE-2310 Radiation Safety Standard.
36. NMMP-0010-PM-0013 Document Management Plan.
37. AP-8125 ANSTO Business Management System (BMS) Controlled Document Procedure.
38. AR-1041 Business Management System (BMS) Controlled Document Process.

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