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NUCLEAR MEDICINE MANUFACTURING PROGRAM

NMMF Safety Management Plan

For Siting Licence

File Number: NMMP-0410-PM-0002

Table of Contents

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1. Purpose

The purpose of this Safety Management Plan is to describe the organisational arrangements for providing safe systems of work under the siting and development phase for a new Nuclear Medicine Manufacturing Facility (NMMF) at the ANSTO Lucas Heights campus.

The plan outlines the processes used in site selection and to ensure compliance with the relevant legislation, including the Work Health and Safety (WHS) Act [Ref: (1)] and Regulations [Ref: (2)], ARPANS Act [Ref: (3)] and Regulations [Ref: (4)]. 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 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.

This plan should be read in conjunction with the NMMF Safety Analysis Report (SAR) [Ref: (5)] and 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

ANSTO is committed to implementing a structured and wholistic approach to safety and to achieve a consistently high standard of safety performance throughout the Nuclear Medicine Manufacturing Program (NMMP) lifecycle. The scope of this plan includes all safety and licencing requirements under the Work Health and Safety (WHS) Act [Ref: (1)] and Regulations [Ref: (2)], ARPANS Act [Ref: (3)] and Regulations [Ref: (4)], and ANSTO policies and procedures. The plan describes the methodology and techniques used to address guidance requirements referred to in the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) regulatory guidelines relating to the plans and arrangements for managing safety [Ref: (6)].

The NMMF Safety Management Plan is an integral element of the NMMF Safety Analysis Report NMMP-2040-RT-0001 [Ref: (5)] and supporting Plans and Arrangements.

This document will be adjusted and progressively updated during the development phase of the program and will be used to guide the health and safety strategies and plans of the principal consultant and contractors.

3. Responsibility

The Chief Executive Officer (CEO) of ANSTO is the Applicant for the siting licence from ARPANSA and has overall responsibility for safety in accordance with the ANSTO Act [Ref: (7)], WHS Act [Ref: (1)] and Regulations [Ref: (2)], and ARPANS Act [Ref: (3)] and Regulations [Ref: (4)].

The CEO will delegate responsibility for the NMMF to the Nominee, who is the Group Executive, ANSTO Maintenance and Engineering during the siting and construction phases of the NMMF Program. The Nominee will be assisted by a Facility Officer, Licensing Officer, and Radiation Safety Officer. The details of these responsible officers will be recorded and maintained on the ANSTO intranet.

The ANSTO Senior Leadership Team (including Group Executives and General Managers) are responsible for understanding the scope of operations and processes of their work groups, including the associated hazards and controls. They are responsible for demonstrating safety leadership and implementation of the ANSTO Work Health and Safety Management System (WHS MS), refer AP-2300 ANSTO WHS Management System Overview [Ref: (8)].

The Executive Committee: Workplace Health & Safety and the Environment, is charged with providing oversight and setting direction on behalf of the ANSTO Executive for safety and environment strategies, initiatives, event and incident management processes, targets, and reporting through the delegation of the CEO as per AG-5729 Charter Executive Committee: Workplace Health & Safety and the Environment [Ref: (9)]. A full description of the WHS responsibilities of ANSTO roles is outlined in AP-2362 WHS Accountabilities, Responsibilities and Actions [Ref: (10)].

Roles and responsibilities during the siting and construction phase of the NMMF have been detailed in Table 1.

Role	Responsibility
Program Manager	• Overall responsibility for WHS in areas under their control. • Installing systems, procedures, and technologies in compliance with ANSTO WHS MS. • Ensuring that risk assessments are conducted prior to commencement of any activity and controls and implemented following the hierarchy of controls. • Delegating appropriate workers to undertake WHS roles and responsibilities. • Reviewing reports of all events including incidents, accidents, hazards, and near hits and following up on actions. • Implementing recommendations from investigations and WHS inspections. • Assisting with Safety and Reliability Assurance (SRA) submissions as required. • Ensuring that there is a process for induction of new workers. • Ensuring that workers are trained and accredited to undertake their roles. • Ensuring that all relevant persons are kept informed of WHS issues. • Completing design risk assessments and controlling environmental aspects, including resources used and waste management. • Conducting WHS inspections within areas of control. • Arranging for prompt implementation of Return to Work programs. • Ensuring a WHS (Safety Moment) is an agenda item at all meetings. • Ensuring that all new buildings comply with AG-3219 ANSTO Building Code [Ref: (11)].

Role	Responsibility
Contractor Supervisor	• Selecting contractors in consultation with the Program Manager, considering WHS performance and relevant WHS tickets and licencing requirements. • Conducting weekly site safety inspections with contractors and issuing non-conformances where applicable. • Providing inductions. • Providing appropriate supervision. • Conducting toolbox talks. • Reporting and investigating incidents and near hits involving contractors. • Ensuring the application of ANSTO WHS MS. • Stopping observed or reported unsafe work practices. • Undertake and perform the responsibilities of this role as specified in AP-2303 Safe Management of Contractors [Ref: (12)].
Site Safety Officer	• Bringing WHS issues to the attention of the NMMP team members and their contractors. • Stopping observed or reported unsafe work practices. • Reviewing and commenting on contractor Safe Work Method & Environmental Statements (SWMES). • Reporting and investigating incidents and near hits involving contractors. • Providing inductions. • Ensuring the application of the ANSTO WHS MS. • Ensuring that all contractors working on site are appropriately ticketed or trained to carry out their assigned tasks. • Approving contractor equipment for use on site.
Workers	• Working safely to reduce any risks to themselves or others. • Always using appropriate controls considering the hierarchy of controls. • Reporting unsafe work practices, events, and near hits, and following procedures if events occur. • Participating in investigations, inspections, and risk assessments. • Attending WHS training, refreshers, and toolbox talks specific to their role, task, and work area. • Applying a questioning attitude towards all work activities. • Applying conservative decision making. • Adhering to ANSTO's WHS MS. • Advising their supervisor of any WHS improvements for the area. • Stopping any unsafe work.
WHS Support	• Providing advice on WHS matters as requested. • Undertaking safety audit roles in consultation with the Project Manager and the Contractor Supervisor. • Reviewing site safety plans in conjunction with the Project Manager and the Contractor Supervisor. • Providing feedback on risk assessments for the Program • Providing advice on occupational hygiene monitoring for the Program.

Role	Responsibility
Designated First Aid Officer	• Maintaining first aid accreditation. • Maintaining first aid boxes including those in vehicles. • Providing first aid as appropriate. • Keeping records in Register of Injuries and sending copies to the ANSTO Health Centre. • Encouraging event reporting where appropriate.

Table 1: Roles and responsibilities during siting and construction of the NMMF

The expected roles and responsibilities during the operation of the NMMF are briefly detailed in Table 2. The roles are responsibilities will be formalised and detailed in the licence application to operate the facility.

Role	Responsibilities
Nominee	• Management of plans and arrangements. • Overall control of the proposed facility. • Ensuring that local procedures and instructions relevant to achieving regulatory compliance are in place and appropriately maintained.
Licencing Officer	• Providing general advice to the Responsible/Facility Officers and Line Management 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 the Facility Officer. • Assisting, when required, in the preparation of regulatory submissions for the facility. • Acting as a point of contact for conduct 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	• 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. • Preparing annual reports when required. • Preparing reports for ARPANSA on abnormal operations or breaches in conjunction with the Manager, Regulatory Affairs, and the Licensing Officer. • Assisting with the preparation of regulatory submissions for the facility. • Acting as a point of contact for conduct of inspections of the facility. • Conducting reviews of the plans and arrangements for the facility in accordance with Section 61 of the ARPANS Regulations.
Building Manager	• Providing WHS information in relation to their building e.g., legacy issues, dosimetry data, and environmental discharge data. • Authorising Safe Working Permits (SWP). • Liaising with Area Supervisors in their building to maintain knowledge of operations and hazards.

Role	Responsibilities
	• Ensuring that necessary examination, maintenance, inspection, and testing of plant and equipment is carried out in accordance with statutory and licence schedules and requirements to ensure continued safe performance and compliance. • Ensuring compliance with ANSTO WHS MS. • Addressing any potentially unsafe situations. • Undertake and perform the responsibilities of this role as specified in AP-3212 Role of Building Manager [Ref: (13)].
Area Supervisors	• Addressing any safety concerns in their designated hazardous areas. • Ensuring that all activities have been assessed and hazards and appropriate controls implemented. • Conducting local area inductions for all new workers, contractors, and visitors by addressing all hazards and required controls that must be complied with in the area. • Maintaining WHS information (e.g., Safety Hazard Notice Boards, chemical registers, and Safety Data Sheets). • Ensuring that all required Personal Protective Equipment (PPE) is available and worn. • Ensuring compliance with ANSTO WHS MS.
Workers	• Working safely to reduce risk to self and others. • Using appropriate controls always considering the hierarchy of controls. • Reporting unsafe work practices, events, and near hits, following procedures if events occur. • Participating in investigations, inspections, and risk assessments. • Attending WHS training, refreshers, and toolbox talks specific to role, task, and work area. • Applying a questioning attitude towards work activities. • Applying conservative decision making. • Adhering to ANSTO's WHS MS. • Advising supervisors of WHS improvements for the area. • Stopping any unsafe work.

Table 2: Roles and responsibilities for the NMMF during operation

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4. Safety Policy and Objectives

ANSTO has a holistic approach to health and safety which strives to maintain a culture where safety always remains the top priority, as described in the ANSTO Health, Safety, Community and Environment Policy [Ref: (14)].

The ANSTO Health, Safety, Community and Environment Policy [Ref: (14)] is affirmed and signed by the CEO who commits all personnel to being responsible for safety through demonstrated values, attitudes, beliefs, and behaviours and are encouraged to fully adopt all safety policy objectives. ANSTO is fully aware of its obligations under the Work Health and Safety Act 2011 and all relevant Australian legislation, regulations, and policies and recognises its responsibility to ensure that all workers have access to a safe and healthy workplace, striving to eliminate risks to health and safety as far as reasonably practicable.

The AE-2307 Nuclear Safety Standard [Ref: (15)] underscores ANSTO's commitment to prioritizing safety over production, highlighting the importance of a culture that encourages informed challenges to enhance safety and support continuous improvement. It emphasizes sound management and engineering practices, along with a strong focus on quality assurance, personnel training, and qualifications for both normal operations and foreseeable accidents. Additionally, the standard includes a comprehensive safety assurance system featuring objective assessments by subject matter experts, a robust monitoring and review framework, and the integration of feedback from lessons learned through experience and research.

The Work Health, Safety and Environmental Management Plan Delivery Phase NMMP-0010-PM-0003 [Ref: (16)] describes the Work Health, Safety, and Environment (WHS&E) Management System that the NMMP Management Team will incorporate into the management plans for the Nuclear Medicine Manufacturing Program (NMMP). The WHS&E Management Plan [Ref: (17)] and this Safety Management Plan have been developed based on legislative requirements and associated guidance materials, Australian Standards, and ANSTO internal policies, practices and procedures.

The NMMF Safety Management Plan utilises the defence in depth strategy and has several layers of protection for workers and the environment. The framework for the documentation is accessible to all staff via ANSTO's Atom of Safety, see Figure 1. This framework allows for the unique nature of risks associated with ANSTO's operations and flexibility for the site whilst maintaining compliance with legislative obligations and international best practice based on ISO 45001 [Ref: (17)].

Figure 1: ANSTO's Atom of Safety

All ANSTO safety standards, policies, and practices are fully endorsed by the CEO of ANSTO and are subject to ongoing review and audit to ensure they continue to adequately reflect the safety practices implemented at ANSTO. They are easily accessible through the intranet, learning and development systems, or document management systems. Every document within the WHS MS is required to be formally reviewed at least every 3 years (unless otherwise specified based on risk) or as needed depending on changes to the overarching legislation and regulations, with any updates disseminated to the appropriate stakeholders through the Program Leadership Team as appropriate.

5. Monitoring and Measurement

ANSTO's site-wide Key Performance Indicators (KPIs) include incident reporting and injury metrics as detailed below:

- Incident reporting: positive reporting culture where 70% of incidents will be opportunities for improvement.
- Injuries: No Class 1 Injuries and decreasing year on year incidences of Class 2 and Class 3 injuries.

Safety performance and controls effectiveness monitoring and measurement processes will be implemented during the design and development phase of the NMMF. These have been detailed in the NMMP Design Guide - Safety in Design Strategy NMMP-0710-PM-0001 [Ref: (18)].

Key aspects of performance monitoring include the following safety-related data:

- Hazard Log and verification of safety critical controls (including Human Factors Assessments)
- Risk and ALARP assessments and risk level categorisation.
- Data from incident, accident, or exceedance events.
- Data from tests, observations, reports, assessments, inspections, or audits.
- Radiation data from radiation monitors, stack monitoring, and personnel dosimetry.
- Occupational health and hygiene data.
- Hazardous inventory data, radioactive sources, and hazardous substances.
- Maintenance and performance data for plant and equipment.

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

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- Routine review of safety documentation as required under the ANSTO and/or NMMP Document and Quality Management Systems.
- Management system audits.
- Regular workplace safety comments, suggestions, and housekeeping inspections, as per AG-2432 Workplace Safety & Housekeeping Inspections [Ref: (19)].
- External and independent audits conducted by Subject Matter Experts (SMEs) for the Principal Contractor and ANSTO based risk and activities to ensure contractors are meeting the requirements detailed in AF-1311 Contractor Onsite Inspection Checklist [Ref: (20)].
- Compliance checks through the Smartek Contractor Pre-qualification Compliance System for due diligence monitoring of contractors' relevant insurance/s, safety management systems, licenses, and other compliance criteria assigned by ANSTO, and described in AP-2303 Safe Management of Contractors [Ref: (12)].
- Audits to identify discrepancies in actual conduct of operations compared to procedures.
- Safety surveys.

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

In accordance with the NMMP WHS&E Management Plan [Ref: (16)] and AG-6685 Construction Safety [Ref: (21)], the Site Safety Officer and Contractor Supervisor must complete regular audits to confirm SWMES and Permit to Work compliance. A schedule of inspections and/ or audits will be established and maintained for the site by the Site Safety Officer with particular focus on high-risk activities. Audits must be recorded on AF-1311 Contractor Onsite Inspection Checklist [Ref: (20)]. Reports generated from these processes will be entered into ANSTO's Governance, Risk, and Compliance (GRC) Cloud System [Ref: (22)] with actions assigned as required and will be utilised to ensure learning and continuous improvement.

While there is no plan for radioactive materials to be present during the initial construction phase of the NMMP, any radiation monitoring program, if required will be implemented based on potential risk., to assess radiological conditions both internal and external to the NMMF site.

A1 5.1. Incident Response and Notification

When an incident occurs, including a near miss/ hit, it must be reported immediately to local management and then through the ANSTO Incident Management System.

For incidents requiring support outside of the immediate area i.e., Emergency Response Team (ERT), HPS, or WHS, the ANSTO Security Operations Centre (ASOC) must be called immediately to engage required support.

Incidents which are serious, critical, or dangerous in nature, including death, serious injury, or illness, must be reported to Comcare and safety regulators in-line with AP-2372 Safety Incident Response and Notification [Ref: (23)] procedure and AG-2375 Incident Investigations [Ref: (24)]. These processes address the initial response, reporting, notification, communication, and investigation of incidents that occur at the ANSTO and NMMF site.

The process for reporting an accident involving controlled materials, controlled apparatus or controlled facilities must be reported to ARPANSA as described in AG-5445 Guide on ARPANSA Requirements [Ref: (25)].

5.2. Investigation and Recommendation of Actions

All incidents are to be investigated and actioned by the work area manager commensurate with the nature and severity of the incident based on the following:

- Low significance incidents are notifiable and recorded for trending purposes.
- Minor, moderate, major, or severe incidents require investigation in-line with ANSTO processes.

A suitably trained and competent person must be assigned to lead the incident investigation process. This may include the supervisor, line manager, or appropriate delegate. The investigator is to ensure that the incident investigation is completed, including identifying direct, contributory and root causes in-line with ANSTO procedure AG-2375 Incident Investigations [Ref: (24)]. Where issues and actions are identified, developed, and agreed upon during the investigation, this information is entered into the ANSTO Incident Management System (GRC) which is monitored and updated with progress notes and closed when completed.

Additionally, any potential non-conformance or licence breach under Section 57 of the ARPANS Regulations, must be reported to the Manager, Regulatory Affairs and Compliance, as soon as possible so that the appropriate level of reporting and paperwork can be decided upon.

In the case of an accident or injury where emergency arrangements described in the NMMF Emergency Plan NMMP-0410-PM-0005 [Ref: (26)] are invoked the ANSTO Incident Controller must be contacted through the ANSTO Site Operations Centre (ASOC). The Incident Controller will engage assistance from subject matter experts from, WHS, Radiation Protection Services (RPS), Security & Safeguards, Regulatory & Compliance, and Environmental Protection teams etc to assist with managing the incident and assist with the incident investigation.

The NMMF site emergency response arrangements during the development phase will be coordinated through the principal consultant site safety officer and ANSTO contractor supervisor. The NMMF Emergency Management Plan [Ref: (26)] has been developed by leveraging AG-5950 ANSTO Emergency Management Plan Lucas Heights Campus Emergency Plan [Ref: (27)].

The ANSTO Business Management System (BMS) is certified to ISO 9001:2008 Quality Management systems and include requirements for maintaining safety system records in accordance with, AR-1477 ANSTO Records Management Process [Ref: (28)] and AR-1041 Business Management System (BMS) Controlled Document Process [Ref: (29)], outlining the storage locations, retention periods, and responsibilities for maintaining records.

A1 6. Risk Management and Mitigation

ANSTO strives to ensure that all potential hazards and risks are eliminated or mitigated, as low as reasonably practicable (ALARP) in line with regulatory expectations. AR-5216 Enterprise Risk Management Process [Ref: (30)] and AP-2301 Work Health and Safety Risk Management Procedure [Ref: (31)] detail the comprehensive hazard identification and risk assessment process followed to safeguard the health, safety and radiation protection of all persons at ANSTO, the public, and the environment. Further documentation on hazard and risk management procedures are found in the WHS MS [Ref: (8)].

Risk assessments are conducted prior to the introduction of a new process, plant, equipment, or hazardous material to the work area. Table 3 describes this process.

Risk assessment for any new or changed activity is conducted using:	Assessment result	Review
AP-1094 Safety and Reliability Assurance procedure [Ref: (32)]	Impact level of moderate or above.	A safety control evaluation must be performed to ensure effective controls are in place to adequately mitigate that risk.
ANSTO's standard criteria for the analysis of risk AG-2395 Risk Analysis Matrix [Ref: (33)]	Inherent level of risk of medium or above.	

Table 3: Risk assessments for new or changed activity

As such, additional risk assessments will be performed prior to each change of a process or modification of a plant or equipment, refer to NMMP Change Management Plan NMMP-0010-PM-0036 [Ref: (34)].

The ANSTO Risk Management process involves the following elements:

- Identification of all hazards after establishing context.
- Assessment of the risks.
- Treatment and control of the risks.
- WHS and environment review and approval.
- Waste management/ minimisation.
- Monitoring and evaluation.

Risk assessments are conducted in compliance with the WHS Act and Regulations 2023 and ARPANS Act 1998 as detailed in AP-2301 Work Health & Safety Risk Management [Ref: (31)]. Risk assessment data is collected as detailed in Section 5 Monitoring and Measurement, as well as the use of tools including:

- Hazard Operability Analysis (HAZOP)
- Preliminary Hazard Analysis (PHA)
- Failure Mode Effects Analysis (FMEA)
- Failure Mode, Effects and Criticality Analysis (FMECA)
- Fault Tree Analysis (FTA)
- Human Factor Hazard identification and Risk Analysis
- Risk Ranking and Filtering

- Supporting Statistical Tools
- ALARP and Optioneering Studies.

The steps for conducting a risk assessment in consultation with stakeholders include:

- Hazard identification – analysed for likelihood and consequence
- Determine inherent risk
- Identify and implement controls
- Determine residual risk
- Review risk assessment
- Accept residual risk
- Close risk assessment.

The level of risk assessment and safety review performed by qualified personnel is commensurate with the nature of the hazards and categorisation based on their impact and likelihood according to AG-2395 Risk Analysis Matrix [Ref: (33)]. Hazard identification, risk assessment, and risk control follow the AG-2397 Explanatory Notes for Safe Work Method and Environmental Statement [Ref: (35)] guide for non-standard/ new tasks or for standard tasks with existing procedures that are undertaken with changed operating circumstances.

Quantitative risk analysis of tasks, new plant or process modifications involving significant radiological hazards, complex WHS hazards, or sophisticated engineering-based analysis requires the support of specialists such as Health Physicists (HP) from RPS, WHS experts, or System Safety and Reliability (SSR) specialists. The process for quantitative risk analysis is documented in AP-2301 Work Health & Safety Risk Management [Ref: (31)]. AF-2398 Quantitative Risk Assessment [Ref: (36)] outlines the methodology for identifying the hazards, developing the scenarios, establishing the defence-in-depth, strategy and conducting the risk assessment to develop risk control measures to prevent occurrence of the incident or accident. Risk study exercises are conducted in consultation with relevant personnel including operators, managers, engineering, safety/ radiation protection advisors, or external contractors. The safety control measures and solutions undertaken must eliminate or mitigate the level of risk.

The hierarchy of control to eliminate or mitigate the likelihood and consequence associated with the hazard is:

- Elimination
- Substitution
- Isolation
- Engineering
- Administration
- PPE.

The NMMF will conduct and prepare a formal risk assessment conducted prior to submission of each licence application to ARPANSA. This process will ensure the appropriate steps have been taken to identify and mitigate all reasonably foreseeable hazards and risks as the project develops. The NMMF Safety and Security Consequence Analysis NMMP-0410-RT-0003 [Ref: (37)] has been conducted and submitted as part of the siting licence application.

Once the facility is operational, the risk assessment will continue to be updated regularly throughout the facility lifecycle in compliance with risk management standards. In addition to scheduled routine updates, the risk assessment will be revised in response to any changes in the facility or in the event of any unplanned deviations from the safety monitoring data collected.

Risk assessments will be subject to ANSTO's SRA process and reviewed to ensure the overall safety approach is adequate and that all risks have been managed sufficiently.

All records of the safety evaluation process are stored centrally by the SRA Manager in electronic format. Records will be stored for the life of the facility at minimum. Records documenting risk management of all WHS hazards must be kept for a minimum of 75 years as per AP-2301 WHS Risk Management [Ref: (31)].

7. Change Management

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

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The NMMP will manage changes during the delivery phase including design, specification/requirement development, construction, commissioning up to the stage of operational readiness using NMMP Change Management Plan [Ref: (34)].

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

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

The Change Management process is managed through a Change Control Request (CCR) Form NMMP-0010-FR-0004 [Ref: (38)]. This form is used to formally register the change proposal, record initial details, articulate justification for the change, commence a preliminary assessment, formally prepare a Configuration Change Management plan and Verification/Validation strategy. A schematic diagram of the NMMP Change Control Process is described at Figure 2.

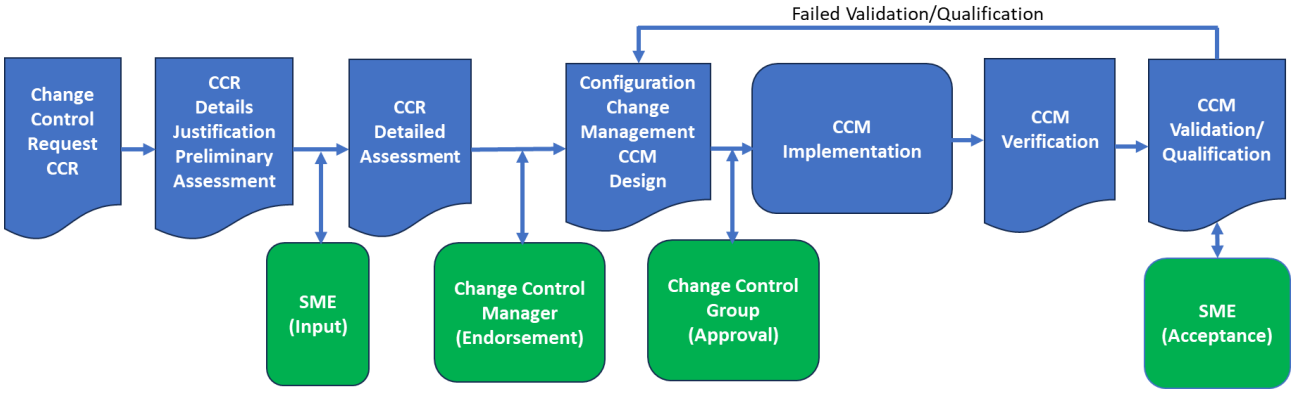

Figure 2: Schematic of the NMMP Change Control Process

7.1. Governance

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The NMMP Change Management Plan [Ref: (34)] is a key part of the overall management of the NMMF Program. A Change Control Group (CCG) is established to ensure compliance with ANSTO policy, processes and procedures. The CCG are tasked with making recommendations to nominated personnel with Delegated Authority on behalf of the ANSTO Board.

7.2. Change Control Assessment

The Change Control Request (CCR) initiates two levels of assessment to identify potential risks, hazards and aspects that may impact upon the program. Initially a preliminary assessment is prepared using the checklist in the CCR Form [Ref: (38)]. The preliminary assessment is used to identify relevant stakeholders and the significance of risk factors including safety hazards and regulatory requirements.

Following the preliminary assessment, a detailed Proposed Controlled Change (PCC) assessment is prepared to assess the significance and impact on personnel, technical risk, operating practices and processes. Relevant Subject Matter Experts (SMEs) are engaged to consider the implications of the PCC on safety, quality, regulatory, technical and process aspects of the change. Input from SMEs is essential for development of a detailed assessment and Change Implementation Plan.

7.3. Configuration Change Management

When the design for the change has been developed a Configuration Change Management (CCM) Form [Ref: (39)] is submitted to the Change Control Group and SMEs for endorsement to ensure that:

- Knowledge of the physical configuration of controlled plant or materials is retained.
- Safety margins are characterised, understood and met.
- Human Factors design aspects are considered.
- Operations remain within the constraints of the Safety Case/SAR.
- Patient safety is not compromised
- Potential for discharge to air, water, soil
- Noise pollution
- Chemical and dangerous materials storage and relocation safety
- Environment protection requirements are identified
- All legislative requirements are incorporated.

During this phase of the change management process, multiple options should be developed to ensure that the best option is selected. Stakeholders and personnel potentially affected by the change are consulted and empowered to provide feedback and voice any concerns or alternate ideas. ANSTO supports the open-door policy with management and staff to create an empowering environment to promote input on proposed changes.

7.4. Changes to Regulated Structures, Systems and Components

Where a PCC will impact on items important for safety including process or fixed plant and equipment listed as structures, systems or components (SSCs) the change must be managed in accordance with the ANSTO Safety and Reliability Assurance procedure AP-1094 [Ref: (32)]. The description of items important for safety is documented under ARPANSA Regulatory Guide - Construction of an item important for safety (ARPANSA-GDE-1760) [Ref: (40)] and listed in the NMMP Structures, Systems and Components Register NMMP -2040-SC-0001 [Ref: (41)].

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Where a proposed change has a safety or regulatory impact on structures, systems or components, or could represent a significant health and safety risk an ANSTO Safety and Regulatory Impact Screening Form AF-2322 [Ref: (42)] will be required. This form assists in determining if the proposed change will require approval from ARPANSA.

During this phase, multiple options should be developed to ensure that the best option is selected. All stakeholders and staff affected by the change should be consulted early in the design to provide feedback and voice any concerns or alternate ideas. ANSTO supports the open-door policy with management and staff to create a welcoming environment to promote input on proposed changes.

7.5. Change Implementation

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Following endorsement of the configuration change by the CCG, the change can be implemented in accordance with the agreed Configuration Change Management process detailed in the NMMP Change Management Plan [Ref: (34)] and an approved Change Implementation Plan if required.

During implementation of the controlled change, a review, inspection or test cycle must be established to ensure the change meets the requirements for the documented configuration change including radiation protection and safety objectives.

Throughout implementation of the controlled change documentation for regulated structures, systems and components SSC's must be secured, including necessary objective quality evidence for review by the regulatory authority, i.e., pressure vessel design certificates, plant/hoist/crane design registration certificates, electrical inspection certificates etc.

The consultation and engagement plan should be executed and any resistance to the change monitored with necessary, strategies implemented to gain an understanding of the core issues for engagement and resolution.

7.6. Reviewing Change

Upon implementation of an approved change a two-stage review process is applied to ensure the change has been effectively implemented. The "**verification"** process is to ensure quality and system requirements have been met. A formal inspection of the change is conducted to confirm key components of the change have been delivered and the system is functional.

Where a system or change has specified performance criteria formal "**validation"** of the change is necessary. A validation test and report is conducted to demonstrate that the change meets the performance criteria and should be overseen by the relevant SME. An example of a formal validation test would be the challenge testing of a safety interlock.

Verification and Validation outcomes are documented in the CCR Form [Ref: (38)].

8. Learning and Continuous Improvement

Learning and continuous improvement are achieved through audit and review of both the safety management system processes and practical implementation of the system in the workplace. The Human Resources (HR), WHS and Radiation Protection teams maintain procedures and conduct regular management reviews and audits of these systems and procedures. The radiation protection arrangements, emergency response plans, and security plans are described in the NMMF Safety Analysis Report and Plans and Arrangements documents for the program. The effectiveness of these plans will be monitored through the NMMF Safety and Radiation Protection Working Group in line with the Risk Management and Mitigation arrangements described at Section 6.

ANSTO's AG-4532 Business Resilience Learning and Improvement Strategy [Ref: (44)] establishes key objectives focused on value-adding activities and initiatives to embed resilience within organisational culture and shape thinking around disruption-related risk. The strategy was introduced to ensure ANSTO's business resilience arrangements and capabilities remain suitable, adequate, and effective. This Learning and Improvement Strategy enhances ANSTO's organisational resilience by:

- Embedding business resilience as part of 'business as usual' across ANSTO by aligning business resilience activities with ANSTO's strategic objectives and culture.
- Establishing and maintaining core business continuity and incident management competencies.
- Ensuring business resilience capabilities are commensurate with ANSTO's current and future requirements.
- Business Resilience Exercise Program that tests and validates plans and trains personnel.
- Training and awareness activities for continuous improvement.

All events and incidents are reported, monitored, and managed through the GRC Cloud following the AR-6350 ANSTO Incident Management Process [Ref: (45)]. The GRC Cloud is a fully integrated system that assists ANSTO in securely managing its assurance activities, by recording all information pertaining to the investigation of the incident including:

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

Records are securely maintained to provide adequate evidence of each investigation and any resulting action. The records are managed in accordance with ANSTO requirements and are readily retrievable for audit purposes. Safety records are maintained in compliance with AR-1477 ANSTO Records Management Process [Ref: (28)] and AR-1041 Business Management System (BMS) Controlled Document Process [Ref: (29)]. These documents outline the appropriate storage locations, approvals, availability, retention periods, and responsibilities for maintaining the records to ensure all regulatory and legal requirements are met.

To encourage reporting and communication of safety data, ANSTO adopts a transparent, no blame but full disclosure safety culture. The GRC reporting system simplifies the reporting process by reducing the number of forms that need to be completed and providing a user-friendly interface to allow easy and accessible reporting to all staff.

Regular planned workplace safety inspections allow General and Line Managers to identify and address hazards and to monitor implemented control measures and potential improvements to local procedures. This is conducted according to the AG-2432 Workplace Safety & Housekeeping Inspections [Ref: (19)] guide. In line with AG-2432 an inspection schedule is prepared with the inspection frequency based on the severity of risk and/or type of hazards involved. In an area of specific hazards, a checklist will be developed. Any areas/ issues found to be unsatisfactory, undergo changes via the Change Management process detailed in Section 7, to bring them to a satisfactory level. In addition to this, AP-7863 Executive Walk Arounds [Ref: (46)] is used to increase the visibility of the Executive across the organisation and allow them to obtain direct information from across all areas of ANSTO, not just in their areas of responsibility. This will provide a holistic view and ownership of the impact of strategic decision making and endorse safety leadership.

To ensure a sustained improvement in housekeeping, inspections are conducted regularly using the Housekeeping Inspection Scorecard. These inspections involve all stages of responsibility such as Supervisors/ Managers, Area Supervisors, and managers from other divisions. The inspection score for each area is reviewed as per AG-2432 Workplace Safety & Housekeeping Inspections [Ref: (19)].

Any site-wide learnings or continuous improvement opportunities will be shared with the organisation through safety messaging via the WHS alerts and lessons learnt page on the intranet. These WHS Alerts are issued to inform staff of emerging issues or events that have occurred on site that may have ramifications for their area. These can be related to health, safety, or environmental issues. Any staff member can raise an WHS Alert to advise staff on site of issues relating to health, safety, or the environment that may require immediate attention by filling out the relevant alert form and emailing it to their WHS Advisor.

9. Training and Education

ANSTO has comprehensive processes which collectively ensure potentially hazardous work is performed and supervised by trained and competent personnel. This process is initiated during recruitment where candidate selection is based on approved selection criteria for the role which includes consideration of the appropriate qualifications, knowledge, and experience for the work to be performed. Position descriptions for the role describe the responsibilities safety requirements to be performed by the role holder. All NMMF position descriptions will be maintained by the HR division.

The ANSTO Learning Framework is described in AG-6189 Training and Development Best Practice Guideline [Ref: (47)] and is monitored through the SAP Learning Management System (LMS) and People Hub. The learning framework is used to assign and facilitate competency training required to support personal development and meet the changing needs of the organisation. Induction training will be provided to all new employees working within the NMMF with completion being tracked through People Hub.

As new employees commence with the NMMP their managers and Area Supervisor will facilitate the learning and development process by:

- Providing constant and appropriate supervision.
- Ensuring that the training is effectively delivered and evaluated.
- Facilitate practical training to implement relevant procedures and work instructions.

Refresher training for procedures, radiation protection, and WHS will be scheduled through the Learning Management System (LMS) at periodic intervals or as a need is identified. The High Reliability team are responsible for developing, managing, and maintaining the ANSTO WHS MS and all WHS-related courses, including inductions. They provide information, advice, assessments, and training to all employees as required.

Task-specific training will be provided for any personnel required to undertake specialised tasks. Requirements for training will be recorded in a training matrix and in the LMS. The training program for each role will be regularly reviewed and updated in line with changes in regulations and job requirements.

Contractors involved in NMMF construction or maintenance work must hold all relevant licences, qualifications, and have undertaken all ANSTO specific training required for site access prior to work commencing. AP-2303 Safe Management of Contractors [Ref: (12)] details the role of an ANSTO Contractor Supervisor. This includes being responsible for all contactors and sub-contractors under their supervision and the compliance with WHS and security requirements associated with work. This includes facilitating the completion of a SWP as detailed in AP-2408 Safe Working Permits [Ref (48)].

Visitors to the LHSTC and NMMF site must be registered, inducted at ANSTO reception, and always escorted by an authorised person. Any visitor entering construction work areas should hold a General Construction Induction Card or must be directly escorted by a representative of the Principal Contractor. The Principal Contractor will provide a local NMMF site induction and outline all required PPE required for entry to the NMMF site. Visitors and contractors working or staying for extended periods of time must undertake comparable induction and training and must be supervised as deemed necessary. A full list of courses and retraining period requirements is provided in AG-2058 WHS Training Handbook [Ref: (49)].

10. Review Process

Under Section 61 of the ARPANS Regulations, ANSTO requires that for licenced facilities the SAR and Plans and Arrangements documents are formally reviewed at least every 3 years to assure ongoing compliance and accuracy.

The ANSTO WHS MS requires that referred policies, procedures and instructions formally reviewed at least every 3 years or as needed depending on changes to the legislative requirements, developments in international best practice and technology and that updates be disseminated to appropriate stakeholders through the NMMP Leadership Group.

The process for Reviewing Plans and Arrangements for ARPANSA Licences is described in form AF-3417 [Ref: (50)]. The details for each plan are recorded and any changes that have been approved are summarised in the relevant section.

In addition to the 3-yearly review requirement, Plans and Arrangements are to be reviewed yearly as part of the Nuclear Safety Review process as per AI-3416 Reviewing Plans and Arrangements for ARPANSA Licences [Ref: (51)].

11. Definitions

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

Term	Definition
ALARP	As Low As Reasonably Practicable
ANSTO	Australian Nuclear Science and Technology Organisation
APEA	Annual Performance Effective Appraisal
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ASOC	ANSTO Security Operations Centre
BMS	Business Management System
CEO	Chief Executive Officer
EPD	Electronic Personal Dosimeters
ERT	Emergency Response Team
FMEA	Failure Mode Effects Analysis
FMECA	Failure Mode, Effects and Criticality Analysis
FTA	Fault Tree Analysis
GRC	Governance, Risk, and Compliance
HAZOP	Hazard Operability Analysis
HHM	Human Health Monitoring
HP	Health Physicists
HPS	Health Physics Surveyors
HR	Human Resources
KPI	Key Performance Indicator
L&D	Learning and Development
LHSTC	Lucas Heights Science and Technology Centre
LMS	Learning Management System
NMMF	Nuclear Medicine Manufacturing Facility
NMMP	Nuclear Medicine Manufacturing Program
PHA	Preliminary Hazard Analysis
PPE	Personal Protective Equipment
RPA	Radiation Protection Advisor
RPS	Radiation Protection Services
SME	Subject Matter Expert
SRA	Safety and Reliability Assurance
SSR	System Safety and Reliability
STAR	Stop, Think, Act, and Review

Term	Definition
SWMES	Safe Work Method & Environmental Statement
SWP	Safe Working Permit
TLD	Thermo-Luminescent Dosimeter
WHS	Work Health & Safety
WHS & E	Work Health and Safety and Environment
WHS MS	Work Health and Safety Management System

12. References

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

1. Work Health and Safety Act 2011.
2. Work Health and Safety Regulation 2017.
3. Australian Radiation Protection and Nuclear Safety (ARPANS) Act. s.l. : Cth, 1998.
4. Australian Radiation Protection and Nuclear Safety (ARPANS) Regulations. Cth, 2018.
5. NMMP-0410-RT-0004 NMMF Safety Analysis Report.
6. ARPANSA-GDE-1735 ARPANSA Regulatory Guide - Plans and Arrangements for Managing Safety. 2023.
7. Australian Nuclear Science and Technology Organisation Act 1987.
8. AP-2300 ANSTO WHS Management System Overivew.
9. AG-5729 Executive Committee - Workplace Health, Safety and Environment Committee Charter.
10. AP-2362 WHS Accountabilities, Responsibilities and Action.
11. AG-3219 ANSTO Building Code Revision 32.
12. AP-2303 Safe Management of Contractors.
13. AP-3212 Role of Building Manager.
14. AB-0002 ANSTO Health Safety Community and Environment Policy.
15. AE-2307 Nuclear Safety Standard. AE-2307.
16. NMMP-0010-PM-0003 Work Health, Safety and Environmental Management Plan Delivery Phase. NMMP-0010-PM-0003.
17. ISO 45001 Occupational health and safety management systems — Requirements with guidance for use. 2018.
18. NMMP-0710-PM-0001 Design Guide - Safety in Design Strategy.
19. AG-2432 Workplace Safety & Housekeeping Inspections.
20. AF-1311 Contractor Onsite Inspection Checklist.
21. AG-6685 Construction Safety.
22. ANSTO Governance, Risk, Compliance (GRC) Cloud.
23. AP-2372 ANSTO Safety Incident and Notification.
24. AG-2375 Incident Investigations.
25. AG-5445 Guide on ARPANSA Requirements.
26. NMMP-0410-PM-0005 NMMF Emergency Response Plan.
27. AG-5950 ANSTO Emergency Management Plan Lucas Heights Campus Emergency Plan.
28. AR-1477 ANSTO Records Management Process.
29. AR-1041 ANSTO Management System (BMS) Controlled Document Process.
30. AR-5216 Enterprise Risk Management Process.
31. AP-2301 Work Health & Safety Risk Management.
32. AP-1094 Safety and Reliability Assurance.
33. AG-2395 ANSTO Risk Analysis Matrix.
34. NMMP Change Management Plan. NMMP-0010-PM-0036.
35. AG-2397 Explanatory Notes to Safe Work Method & Environmental Statements (SWMES).
36. AF-2398 Quantitative Risk Assessment.
37. NMMP-0410-RT-0003 NMMF Safety and Security Consequence Analysis.
38. NMMP Controlled Change Request Form. NMMP-0010-FR-0004.
39. NMMP Configuration Change Management (CCM) Form. NMMP-0010-FR-0005.

40. ARPANSA Regulatory Guide: Construction of an item important for safety. s.l. : ARPANSA, 2021. ARPANSA-GDE-1760.
41. NMMP Structures, Systems and Components Register. NMMP-2040-SC-0001.
42. AF-2322 Safety and Reliability Assurance Screening Form.
43. AF-6948 Consultation and Engagement Plan.
44. AG-4532 Business Resilience Learning and Improvement Strategy.
45. AR-6350 ANSTO Incident Management Process.
46. AP-7863 Executive Walk Arounds.
47. AG-6819 Training and Development Best Practice Guideliine. AG-6189.
48. AP-2408 Safe Working Permits.
49. AG-2058 ANSTO WHS Training Handbook.
50. AF-3417 Reviewing Plans and Arrangements for ARPANSA Licences.
51. AI-3416 Reviewing Plans and Arrangements for ARPANSA Licences.
52. AE-2310 Radiation Safety Standard.
53. AR-1667 ANSTO Customer Satisfaction Process.
54. AR-1006 ANSTO Management System Review .
55. AF-6945 Change Management Risk Assessment.
56. AF-6947 Change Management Plan.
57. AG-2249 Annual Performance Effectiveness Appraisals (APEA) Guidelines.
58. AG-2521 Personal Dosimetry Guide.
59. AP-2363 ANSTO WHS Training Procedure.
60. NMMP-0010-PM-0011 Design Management Plan.
61. NMMP-0410-PM-0003 NMMF Radiation Protection Plan.
62. NMMP-0410-PM-0008 NMMF Security Plan.

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