Australian Government

ANSTO
Science. Ingenuity. Sustainability.

POSITION DESCRIPTION

Position Title:	Shift Manager
Cluster / Business Unit / Division	Nuclear Operations and Nuclear Medicine
Section or Unit:	Nuclear Medicine
Classification:	Band 6
Job Family:	Manufacturing
Position Description Number:	PD-2452
Work Contract Type:	Technical/Professional
STEMM/NON-STEMM:	STEMM

POSITION PURPOSE

The primary objective of the Shift Manager(s) is to lead and manage the effective and efficient day-to-day operation of the manufacturing facilities within Nuclear Medicine. The Shift Manager is responsible for providing direct leadership of manufacturing teams on shift and has effective control of activities carried out within the manufacturing facility, in line with the overall manufacturing strategy to support the safe, secure and sustainable supply of Nuclear Medicine.

The position focusses on ensuring manufacturing reliability and pursues improvements in safety, quality, performance and culture in accordance with compliance obligations and the expectations of our business, teams and customers.

ORGANISATIONAL ENVIRONMENT

ANSTO leverages great science to deliver big outcomes. We partner with scientists and engineers and apply new technologies to provide real-world benefits. Our work improves Nuclear Medicine, saves lives, builds our industries, and protects the environment. ANSTO is the home of Australia's most significant landmark and national infrastructure for research. Thousands of scientists from industry and academia benefit from gaining access to state-of-the-art instruments every year.

Nuclear Medicine is engaged in the manufacture and sales of radiopharmaceuticals and radiochemical products. Manufacturing is based upon the GMP Code of Manufacturing, where processes must meet certain standards and Quality Control (QC) is essential and also on just-in-time principles, where all processes are extremely time critical.

Nuclear Medicine has a dominant market share position in Australia and is expanding into the global market. Nuclear Medicine operates under external regulatory requirements such as ISO 9001, ARPANSA and TGA, within ANSTO's procedural framework and is overseen by the ANSTO Board. Over 500,000 Australian patients benefit from Nuclear Medicine radiopharmaceuticals annually.

ACCOUNTABILITIES & RESPONSIBILITIES

Safety

- Lead, monitor and comply with safe work practices through your teams, including the wearing of appropriate PPE, radiological monitoring, housekeeping, identifying safety issues (though raising near misses and incident reports), investigations, action close outs & ensure sufficient training of team members.
- Ensure operations performed in the facility comply with the approved safety case, inclusive of providing this expertise to team members and applying it to normal & non-normal operating scenarios.

Quality

- Lead, monitor and comply with quality work practices through your teams, including the compliance with cGMP procedures, quality checks and manufacturing records, identifying quality issues (though raising Deviations), investigations, action close outs & ensure sufficient training of team members.
- Ensure systemic problem solving are applied to resolve issues and drive improvement. This includes use of QMS processes such as root cause analysis, corrective and preventative actions, as well as change control and validation. Resolve issues at Tier 1 and escalate to Tier 2 if required.

Performance

- Manage production resources through planning, scheduling, prioritising and allocation of production activities to ensure efficient and effective manufacture of Nuclear Medicine according to plan and in line with cGMP, ARPANSA, ISO and ASNO regulations and guidelines.
- Co-ordinate, review and ensure preventative maintenance plans are executed and closed out for plant and equipment to ensure compliance of the facilities at all times to GMP, ARPANSA, ISO and ASNO regulations and guidelines.
- Engage with and support the execution of the process performance framework to drive process robustness and reliability, maintaining key lifecycle document such as risk assessments, control strategies, standard operating procedures and manufacturing instructions.

Leadership

- Champion a safety and quality culture with the team, it's our priority.
- Actively use the ANSTO's HR processes to develop high-performing teams.
- Contribute to and deliver on the Nuclear Medicine team culture and engagement plans.
- Train, coach and mentor staff in order to enhance expertise of the individual and the team.
- Undertake additional duties as required and during periods of leave of other staff.

Decision Making

- Accountable person for safety, quality and performance of the team, manufacturing process and facility whilst on shift.
- Ensure compliance to all regulatory and ANSTO procedures and policies.
- The levels of authority delegated to this position are those approved and issued by the Chief Executive Officer. All delegations will be in line with the ANSTO Delegation Manual AS-1682 (as amended or replaced).

Key Challenges

- Establish strong relationships within teams and across the organisation.
- Increasing capability and diversity within the manufacturing teams.
- Ensuring relevant Responsible Officers, Area Supervisors and Facility Officers are kept informed of safety and compliance related issues.
- Ensuring that there is consistent application of practices across Nuclear Medicine Manufacturing.
- Balancing varied operational requirements in a highly complex, heavily regulated, and dynamic environment to ensure successful delivery of agreed objectives.
- Delivering very high customer service levels in a "no inventory" short life supply chain.
- Ensuring compliance obligations across TGA, FDA, ARPANSA, ANSO, ANSTO and other agencies are delivered in full every day.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Head of Manufacturing	• Receive broad guidance and direction. • Provide regular updates on key KPIs, challenges and critical priorities. • Escalate issues and propose solutions. • Provide advice on operational requirements. • Recommend and gain approvals for facility modifications, enhancements, improvements, and process/procedure changes or improvements.
Manufacturing Manager & Leadership Team	• Provide expert advice and analysis on range of mattes. • Contribute to group decision making processes, planning, and goals. • Collaborate and share accountability. • Influence effectively to effect change and improvement. • Earn trust and respect through knowledge and performance. • Identify and negotiate solutions to conflicting demands on resources.
Direct Reports	• Provide leadership, guidance, direction, and advice. • Set performance requirements, manage performance and development, optimise employee experience. • Engage to monitor trends, performance and progress against tactical plans, allocated tasks and priorities to ensure smooth and effective operation of manufacturing area(s). Evaluate further support which may be required to ensure delivery against the plan.
Key Stakeholders	• Provide expert advice on manufacturing area operational processes. • Optimise engagement and influence constructively to achieve outcomes
External	
Key Stakeholders	• Optimise engagement and influence constructively to achieve outcomes
Regulators, licensing authorities and customers	• Ensure compliance within areas of responsibility. • Build and engage positive working relationships that promote trust and credibility and enable effective collaboration (e.g. during inspections).

POSITION DIMENSIONS

Staff Data	
Reporting Line	Manufacturing Manager
Direct Reports	6-20 Technicians / Senior Technicians
Indirect Reports	NIL

Financial Data (2023/2024)	
Revenue / Grants	NA
Operating Budget	NA
Staffing Budget	Circa. $2.5
Capital Budget	NA
Assets	NA

Special / Physical Requirements	
Location:	• Lucas Heights • Working in different areas of designated site/campus as needed.
Travel:	• May be required to travel to ANSTO sites from time to time. • May be required to travel internationally and nationally from time to time.

Physical:	• Office based physical requirements (sitting, standing, minimal manual handling, movement around office and site, extended hours working at computer) • Wearing personal protective equipment for the handling of hazardous and/or radioactive materials • Public speaking
Radiation areas:	• May be required to work in radiation areas and perform duties where radioactive materials are handled under tightly regulated conditions. • Perform duties with and in an area where hazardous chemicals or materials are handled under tightly controlled safety conditions
Hours:	• Willingness to work extended and varied hours based on operational requirements. • Shift Work on Roster System. • After hours works may be required on an as-needs basis.
Clearance requirements:	• Satisfy ANSTO Security and Medical clearance requirements

Workplace Health & Safety	
Specific role/s as specified in AP-2362 of the ANSTO WHS Management System	All Workers Other specialised roles identified within the guideline a position holder may be allocated to in the course of their duties

ORGANISATIONAL CHART

On File

KNOWLEDGE, SKILLS AND EXPERIENCE

1. Degree or equivalent experience/qualifications within an engineering, science or supply chain discipline.
2. Significant experience leading operational teams within a highly regulated environment with the ability to coach and build capability in others. *Preferred: pharmaceutical manufacturing.*
3. High level process improvement skills with analytical ability and strategic problem-solving skills (root cause analysis, process improvements & corrective actions).
4. Proven experience delivering results and ensuring work of others complies with quality and safety standards, ideally gained through working within a highly regulated manufacturing environment. *Preferred: GxP, PIC/S, ICH, TGA, FDA, ARPANSA.*
5. Demonstrated personal commitment to safety, quality and performance culture, including the ability to initiate, manage and deliver significant change and continuous improvement.
6. Proven experience leading and managing staff, including coaching and mentoring skills, providing constructive feedback on performance, as well as giving advice and guidance on development.
7. Demonstrated high level interpersonal, communication and negotiation skills with the capacity to influence key decision-makers.
8. Excellent problem-solving skills with an ability to meet critical deadlines and respond to changing demands, maintaining accuracy and attention to detail.
9. Proficiency using Microsoft Office and proven associated skills (e.g. report writing, data analysis/interpretation, presentations, online collaboration).

VERIFICATION

This section verifies that the line manager and appropriate senior manager/executive confirm that this is a true and accurate reflection of the position.

Line Manager		**Delegated Authority**	
Name:	Warren Brown/Jason Howe	Name:	Justine Murison
Title:	Manufacturing Manager Nuclear Medicine	Title:	Head of Manufacturing Nuclear Medicine
Signature:		Signature:	
Date:		Date:	