Australian Government

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POSITION DESCRIPTION

Position Title:	Process Performance Associate
Cluster / Business Unit / Division	Nuclear Operations and Nuclear Medicine
Section or Unit:	Manufacturing
Classification:	Band 5/6 (Linked Role)
Job Family:	Manufacturing
Position Description Number:	PD-2454
Work Contract Type:	Professional
STEMM/NON-STEMM:	STEMM

POSITION PURPOSE

The primary objective of the Process Performance Associate(s) is to closely monitor and improve process performance within Nuclear Medicine. The Process Performance Associate(s) are responsible for providing technical support for the performance, robustness and continuous improvement of manufacturing processes, in line with the overall manufacturing strategy to support the safe, secure, sustainable supply of Nuclear Medicine.

At the higher level, the Process Performance Lead(s) are specialised professionals who own and manage the process performance activities that underpin and optimise manufacturing operations in Nuclear Medicine. They are responsible for leading the performance, robustness and continuous improvement of each manufacturing process within Nuclear Medicine.

The position focusses on supporting the direct value streams within Nuclear Medicine Manufacturing, ensuring processes are robust, validated, optimised and under effective control, 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

Key Accountabilities

- Drive process performance by developing and maintaining process performance framework deliverables such as risk assessments, control strategies and validation lifecycle documentation in line with safety, quality and regulatory expectations.
  This includes the utilisation of QMS processes such as change control, deviation management, corrective and preventative actions, validation and standard operating procedures.
- Provide validation expertise to operational manufacturing teams to ensure that assurance of the validated state of manufacturing equipment, systems, manufacturing processes and cleaning processes is established and maintained in line with cGMP requirements and using industry best practices.
- Lead investigations into performance, quality, and operational incidents and provide root cause analysis in technical reports.
- Monitoring, trending and reporting of process performance metrics.
- Provide technical support and impact assessments making for process changes, investigations and continuous improvements.
- Champion a supportive environment of communication, consultation and continuous improvement across the Manufacturing team.
- Ensure all work carried out is in accordance with ARPANSA regulations, TGA licensing requirements, Nuclear Medicine procedures, WHS procedures, standards, and regulations.
- Be proactive in encouraging and sharing of knowledge and experience within Nuclear Medicine.
- Undertake additional duties as required and during periods of leave of other staff.

In addition to independently performing all Band 5 key accountabilities, the key accountabilities for a Band 6 position include:

- Design and manage the frameworks by which manufacturing process performance metrics are monitored, trended and reported.
- Mentor and develop other members of the operational manufacturing teams providing process mastery and decision making for process changes, investigations and continuous improvements.
- Initiate and manage process performance projects and lead small teams, ensuring timelines are met, budget is controlled, and risks are managed.
- Lead complex investigations into safety, quality, and operational incidents and provide root cause analysis in technical reports.
- Lead process performance aspects of both internal audits and regulatory inspections, taking a lifecycle approach to inspection readiness, providing manufacturing expertise and responding to any regulatory findings.
- Ensuring end-to-end manufacturing processes are performing within the process performance framework maintaining high levels of safety, quality, and performance.

Decision Making

- 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).
- The position is fully accountable for the accuracy, integrity and quality of the content of advice provided, and is required to ensure that decisions are based on sound evidence, but at times may be required to make effective judgements under pressure or in the absence of complete information or expert advice.

In addition to the above, the Band 6 position will have the following decision making responsibilities:

- Apply independent sound judgement to information received across several different subject matter experts, ensuring that cGMP, safety and regulatory requirements are accurately embedded in manufacturing processes.
- The position at times may be required to make effective judgements under pressure or in the absence of complete information or expert advice.

Key Challenges

- Developing clear and concise documentation where there may be few precedents and which requires close collaboration with subject matter experts to ensure process performance, validation and other manufacturing documentation is fit for purpose and in line with cGMP requirements and regulatory approvals.
- Prioritising work and completing tasks where there are multiple stakeholder requirements, conflicting priorities and unplanned activities that need to be completed within nominated deadlines.
- Identifying risks and addressing safety, quality and compliance issues proactively that mitigate impact in a "no inventory" short life supply chain.
- Communicating effectively and working with a diverse team of subject matter experts with varying levels of technical and regulatory understanding within and outside of Nuclear Medicine.
- Ensuring compliance obligations across TGA, FDA, ARPANSA, ASNO, ANSTO and other agencies are delivered in full every day.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Head of Manufacturing	• Identify emerging process performance issues/risks and their implications and propose solutions.
Process Performance Manager	• Receive broad guidance and direction. • Provide regular updates on key KPIs, challenges and critical priorities. • Escalate issues and propose solutions. • Recommend and gain approvals for operational enhancements, improvements, and process/procedure changes or improvements.
Process Performance, and Manufacturing teams	• Closely collaborate to ensure business objectives are achieved. • Optimise engagement and influence constructively to achieve outcomes. • Communicate effectively to ensure workload is distributed evenly.
Validation Leader	• Closely collaborate to ensure business objectives are achieved.

	• Co-ordinate to ensure successful on time completion of validation activities.
Quality Assurance Manager – Operations, Quality Control Manager, as well as Engineering and Maintenance (e.g. system engineer or project engineer)	• Closely collaborate to ensure business objectives are achieved. • Provide feedback on process performance and validation.
Work area team members	• Provide expert advice and analysis on a full range of matters relevant to the production process including compliance with cGMP and safety requirements. • Contribute to group decision making processes, planning and goal setting. • Collaborate and share accountability. • Negotiate and resolve conflicts. • Work closely with and provide support to Business Improvement Projects.
Internal Stakeholders	• ANSTO Service Providers • Monitor KPIs
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	Process Performance Manager
Direct Reports	Nil
Indirect Reports	Nil

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 interstate or internationally from time to time
Physical:	Office based physical requirements (sitting, standing, minimal manual handling, movement around office and site, extended hours working at computer) Public speaking Industrial facility physical requirements (lifting, standing for long periods, operating machinery, equipment and manipulators) Wearing personal protective equipment for the handling of hazardous and/or radioactive materials

Radiation areas:	May be required to work in radiation areas under tightly regulated conditions. Perform duties in an area where radioactive materials are handled under tightly controlled safety 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. After hours work will be required on a regular basis
Clearance requirements:	Satisfy ANSTO Security and Medical clearance requirements. Obtain and maintain appropriate federal government clearance.

Workplace Health & Safety	
Specific role/s as specified in AG-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

KNOWLEDGE, SKILLS AND EXPERIENCE

1. Degree qualification or equivalent experience within an engineering or science discipline.
2. Experience in GMP manufacturing environment (validation preferred), experience in sterile or pharmaceutical manufacturing and/or high reliability environment highly regarded.
3. Demonstrated understanding of relevant regulatory standards and guidelines in the pharmaceutical or manufacturing industry, such as TGA, FDA, PIC/S, ICH or other applicable regulators such as ARPANSA.
4. Proven ability to identify opportunities and implement process improvement to enhance operational efficiency, quality and safety.
5. Ability to work independently and as part of cross-functional teams.
6. High level technical writing skills and highly competent in the use of MS Office Suite.
7. Strong time-management, planning and organisational skills.

In addition to demonstrating strong knowledge, skills and experience at a Band 5 level, the Band 6 position also requires:

1. Strong leadership skills including the ability to effectively manage, motivate, delegate and stimulate achievement in a team within a matrix environment.
2. Proven ability to independently identify and deliver opportunities for process improvement within a manufacturing environment and lead positive change to enhance operational efficiency, quality and safety.
3. Demonstrated expertise in stakeholder engagement and autonomous decision-making, with the ability to integrate insights from multiple subject matter experts to make sound judgements.

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:	Rob Raposio	Name:	Justine Murison
Title:	Process Performance Manager	Title:	Head of Manufacturing
Signature:		Signature:	
Date:		Date:	

Process Performance Associate Linked Role (PD-2454)
Band 5 to Band 6 Transition Checklist

Name:	
Commencement Date:	
Assessment Date:	

Note: Full written submission demonstrating and justifying how the employee meets the requirements must be attached to support the transition. Review, assessment and endorsement of the transition will be achieved via employees presentation of the submission to the senior manufacturing leadership team and requires unanimous agreement. Transition will only be authorised by the General Manager.

Requirements for Transition	Met Criteria
Performing Band 5 accountabilities, as described in this PD (or equivalent experience in a similar highly regulated manufacturing environment) and completion of the Band 5 to Band 6 transition criteria curriculum with 100% metric are completed.	Yes No
Demonstrated ability to independently plan, coordinate and drive continuous improvements in process performance effectively over a sustained period of time.	Yes No
Sustained application of technical mastery across the Process Performance Framework as demonstrated by:	
Champion continuous improvement activities and lead team members in the implementation of solutions to improve safety, quality, productivity, efficiency and capability within the team.	Yes No
Oversee manufacturing programs such as validation, change management, process performance framework, incident/event management.	Yes No
Train and mentor new team members and uplift the technical process understanding of direct value stream team members.	Yes No
	Yes No
Lead complex investigations of process performance events and implement appropriate corrective/preventatives actions in a timely manner.	Yes No
Demonstrated independent decision-making ability to ensure safety, quality and performance is not impacted.	Yes No
Demonstrated ability to engage and influence a wide range of internal and external stakeholders across a variety of different scenarios.	Yes No

Process Performance Manager Assessment

I have assessed the submission and confirm that the employee meets all requirements for transition from Band 5 to Band 6.

Name:	
Signature:	
Date:	

Head of Manufacturing Endorsement

I have assessed the submission and confirm that the employee meets all requirements for transition from Band 5 to Band 6.

Name:	
Signature:	
Date:	

General Manager Nuclear Medicine Authorisation

I have reviewed all information and approve transition from Band 5 to Band 6.

Name:	
Signature:	
Date:	
Effective Date of transition:	