Australian Government

ANSTO
Science. Ingenuity. Sustainability.

POSITION DESCRIPTION

Position Title:	Process Technician (Senior Process Technician)
Cluster / Business Unit / Division	Nuclear Operations and Nuclear Medicine
Section or Unit:	Nuclear Medicine
Classification:	Band 4/5 Linked Role
Job Family:	Manufacturing
Position Description Number:	PD-2455
Work Contract Type:	Technical
STEMM/NON-STEMM:	STEMM

POSITION PURPOSE

The primary objective of the Process Technician(s) is to execute the effective and efficient day-to-day operation of the manufacturing facilities within Nuclear Medicine. Process Technicians are responsible for a range of activities inclusive of Nuclear Medicine production, operation of plant and equipment as well as provision of support services that enable manufacturing such as transfer of materials/equipment, maintenance, housekeeping and waste handling.

At the higher level, Senior Process Technicians provide technical mastery as process and facility specialists and supervise production in line with the overall manufacturing strategy to support the safe, secure and sustainable supply of Nuclear Medicine.

The position focuses on ensuring manufacturing reliability and engages with 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. It is also based 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

The Key accountabilities for the Band 4 position include:

- Efficiently carryout manufacturing of Nuclear Medicine in accordance with approved procedures to meet customer and regulatory expectations for safety, quality and performance.
  - Ensure department, productivity and quality goals are achieved.
  - Coordinate production flow in accordance with approved schedules. This includes assisting supervisors with coordination of production start-ups, shutdowns and changeovers and resolving complex or out of policy operational issues.
  - Work within all areas of the facility to fulfill production schedule requirements.
  - Ensure documentation, such as manufacturing and fissile material records, are completed and maintained as per TGA, ARPANSA, ASNO and quality system requirements. This includes raising incident reports (near misses, deviations) and recording corrective actions.
  - Ensure delays, issues and problems are communicated in a timely manner to stakeholders.
  - Maintain compliance with training requirements.
  - Maintain high level of housekeeping and line clearances.
  - Ensure accurate stock locations and holdings, as well as accuracy against bill of materials requirements and production routings.
  - Operate plant and equipment within the production facility, using process and facility knowledge to analyse and develop responses to unforeseen problems.
  - Independently perform regular maintenance and review of equipment. Identify, investigate and troubleshoot routine issues and provide solutions using technical knowledge.
  - Install, commission, and troubleshoot plant and equipment, including assisting with equipment delivery and acceptance.
- Provide support services to enable safe, secure and sustainable Nuclear Medicine manufacturing, these include but are not limited to:
  - Transfer targets from the OPAL reactor to the manufacturing facility.
  - Transfer of equipment and materials between hot cells.
  - Transfer and manage facility waste.
  - Conduct GMP cleaning of GMP and radiologically classified areas and equipment.
- Maintain procedures and instructions to ensure processes are fully documented and are compliant with regulatory requirements.
- Participate in project activities with tasks such as process development, providing input and support to validation, planning and report writing activities associated with continuous improvements to safety, quality and performance.
- Promote and foster safety culture with the aim of continuous improvement to safety and its awareness across site.
- Train and support team members, pro-actively sharing knowledge and experiences to establish productive working relationships and ensure effective knowledge transfer amongst new and existing staff.
- Undertake additional duties as required and during period of leave of other staff.

In addition to performing all Band 4 key accountabilities, the key accountabilities for a band 5 position include:

- Lead, monitor and ensure compliance with safe work practices amongst the team, including the wearing of appropriate PPE, performing selected Radiological Monitoring activities, identifying safety issues (though raising near misses), minor investigations, action close outs & ensure sufficient training of team members.

- Lead, monitor and ensure compliance with quality work practices amongst the team, including the compliance with GMP practices, identifying quality issues (though raising Deviations, participating in audits), minor investigations, action close outs & ensure sufficient training of team members.
- Supervise daily manufacturing activities and resources by planning, scheduling, prioritising and allocating production tasks where there are multiple regulatory and customer requirements and unplanned activities to be completed within tight timeframes.

  This includes acting as Shift Manager in their absence.
- Utilise technical mastery of the process and facility to identify, investigate and perform troubleshooting of complex problems, inclusive of providing appropriate solutions that are implemented in line with safety, quality and regulatory expectations. This includes utilisation of QMS processes such as deviation management, risk assessment and corrective and preventative actions.
- As a multi-skilled subject matter expert, train and assess the competency of team members against approved procedures and training/accreditation requirements.
- Lead project activities associated with continuous improvements to safety, quality and performance such as review of processes, developing new or modified procedures, identifying adverse trends from analysis of process/performance data and leading teams to effect step changes in ways of working. This includes utilisation of QMS processes such as change control, validation, risk assessment and periodic quality review.
- As a leader within the team, champion ANSTO values to improve team behaviours and drive results.
- Contribute to and deliver on the Nuclear Medicine team culture and engagement plans.

Decision Making

- The position operates in structured operating environment that is subject to established policies, procedures and practices underpinned by GMP ARPANSA, ISO and ASNO regulations and guidelines, quality and safety procedures and other statutory requirements. The position has some capacity to adapt operating practices.
- Has some degree of autonomy in respect to their day-to-day work priorities and, in this context is expected to make day-to-day decisions relating to work priorities and workload management, for themselves.
- Utilises judgement to independently assess priorities.
- Consults with management on decisions which will substantially alter the outcomes, timeframe or requirements of work plans, any issues or conflicts arising in the course of undertaking duties, and all matters which require a higher delegated authority for approval.
- 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

- High level of responsibility and accountability producing medical radioisotopes, working in a fast-paced production environment that involves short lead times and a “no inventory” supply chain.
- Maintaining rigour in chemical and radiation safety in a shifting and challenging environment.
- Compliance to all processes and GMP ARPANSA, ISO and ASNO regulations and guidelines.
- Participation in training and sharing of knowledge and experiences with other staff in Production processes and equipment.

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.
Indirect Reports (at the higher level)	• Provide leadership, guidance, direction, and advice. • 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	Shift Manager
Direct Reports	NIL
Indirect Reports	Up to 8 first line / Technicians

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 • Ability to work with chemical and radioactive materials. • Ability to stand for periods. • Ability to use manipulators for hot-cell work. • Ability to work in GMP clean rooms. • Ability to lift heavy objects (>16kg) – some manual handling

Radiation areas:	• 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 which requires work on weekends and public holidays. • 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 – Band 4

1. Tertiary qualification or equivalent experience within an engineering, trade, science or supply chain discipline.
2. Demonstrated experience working within operational teams, operating plant and equipment within a highly regulated environment. *Preferred: pharmaceutical.*
3. Strong understanding of and commitment to continuous improvement and excellence in safety, quality and performance. *Preferred: lean/six sigma practices.*
4. Ability to work as a contributing member of a high performing team as well as proven experience delivering tasks independently and without supervision.
5. Ability to apply technical knowledge and critical thinking to trouble-shoot process issues and use problem solving tools to identify and apply solutions.
6. Working knowledge of and ability to apply regulatory requirements. *Preferred: GxP, PIC/S, ICH, TGA, FDA, ARPANSA, ASNO, IAEA and ISO 9001.*
7. Strong communication (written and verbal) skills with an emphasis on the ability to adapt styles to suit the audience and scenario.
8. Strong computer and digital information literacy, with competency in the use of MS Office Suite. Preferred: *SAP, online collaboration, electronic document management or eQMS platforms.*
9. Established time management, planning and organisational skills.

In addition to the knowledge, skills and experience required at the Band 4 level:

KNOWLEDGE, SKILLS AND EXPERIENCE – Band 5

1. Degree or equivalent experience within an engineering, science or supply chain discipline.
2. Experience supervising operational teams within a highly regulated environment. This includes planning and scheduling tasks to meet time-critical deadlines. *Preferred: pharmaceutical.*
3. Demonstrated ability to ensure the work of others complies with quality and safety standards, using coaching, mentoring and feedback tools to deliver expected performance results.
4. Proven ability to apply technical mastery of process manufacturing and facility operations to a variety of scenarios such as investigation and trouble-shooting as well as continuous improvement.
5. Proven experience training and assessing competency of others.

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:	TBC	Name:	Justine Murison
Title:	Shift Manager Nuclear Medicine	Title:	Head of Manufacturing Nuclear Medicine
Signature:		Signature:	
Date:		Date:	

Manufacturing Technician Linked Role (PD-2455)
Band 4 to Band 5 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 employee's presentation of the submission to the senior manufacturing leadership team (panel) and requires unanimous agreement. Transition will only be authorised by the General Manager.

Requirements for Transition	**Met Criteria**
Full performance of Band 4 accountabilities (Level 5) Inclusive of knowledge, skills and experience described in this PD *and* the Manufacturing Skills defined in the current Capability Matrix for this PD.	☐Yes ☐No
Proven *proficiency* in all Nuclear Medicine Capabilities defined in the current Capability Matrix for this PD.	☐Yes ☐No
Demonstration of pursuing and building Band 5 accountabilities Inclusive of knowledge, skills and experience described in this PD *and* the Manufacturing Skills defined in the current Capability Matrix for this PD.	☐Yes ☐No
Working towards *mastery* in Nuclear Medicine Capabilities defined in the current Capability Matrix for this PD.	☐Yes ☐No

Shift Manager Recommendation:

I have reviewed the employee's competence and capabilities in accordance with Linked Role PD-2455 and certify that the employee meets all requirements for transition and recommend transition from Band 4 to Band 5 be endorsed.

Name:	
Signature:	
Date:	

Manufacturing Manager Assessment

I have assessed the submission and confirm that the employee meets all requirements for transition from Band 4 to Band 5.

Name:	
Signature:	
Date:	

Head of Manufacturing Endorsement

I have assessed the submission and confirm that the employee meets all requirements for transition from Band 4 to Band 5.

Name:	
Signature:	
Date:	

General Manager Nuclear Medicine Authorisation

I have reviewed all information and approve transition from Band 4 to Band 5.

Name:	
Signature:	
Date:	
Effective Date of transition:	