



POSITION DESCRIPTION

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|-------------------------------------------|-----------------------------------------|
| Position Title: | Technician |
| Cluster / Business Unit / Division | Nuclear Operations and Nuclear Medicine |
| Section or Unit: | Nuclear Medicine |
| Classification: | Band 3 |
| Job Family: | Manufacturing |
| Position Description Number: | PD-2456 |
| Work Contract Type: | Technical |
| STEMM/NON-STEMM: | STEMM |

POSITION PURPOSE

The primary objective of the Technician(s) is to participate in and support the effective and efficient day-to-day operation of the manufacturing facilities within Nuclear Medicine. Technicians are responsible for a range of activities that support Nuclear Medicine manufacturing such as transfer of materials/equipment, preparation of components, intermediate and starting materials used in production, housekeeping, clean-room cleaning/sanitation and waste handling.

The position focusses on supporting manufacturing reliability and participates 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 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

- Efficiently support manufacture 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.
 - 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.
- Transfer targets from the OPAL reactor to the manufacturing facility
- Transfer of equipment and materials between hot cells
- Manufacture of intermediate materials and components
- Perform specialised clean-room cleaning and sanitation
- Transfer and manage facility waste
- Conduct 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.

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.
- 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 supporting the production of medical radioisotopes, working in a fast-paced production environment that involves short lead times and a “no inventory” supply chain.
- Maintaining rigour in chemical, radiation and manual handling safety in a shifting and challenging environment.
- Compliance to all processes and GMP ARPANSA, ISO and ASNO regulations and guidelines.

KEY RELATIONSHIPS

| Who | Purpose |
|-------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Internal | |
| Head of Manufacturing | <ul style="list-style-type: none"> • Receive broad guidance and direction. • Escalate issues and propose solutions. • Recommend and gain approvals for facility modifications, enhancements, improvements, and process/procedure changes or improvements. |
| Manufacturing Manager | <ul style="list-style-type: none"> • Provide expert advice and analysis on range of matters. |
| Leadership Team | <ul style="list-style-type: none"> • Contribute to group decision making processes, planning, and goals. |
| Work area team members | <ul style="list-style-type: none"> • Collaborate and share accountability. • Earn trust and respect through knowledge and performance. • Identify and negotiate solutions to conflicting demands on resources. |
| Key Stakeholders | <ul style="list-style-type: none"> • Provide expert advice on manufacturing area operational support processes. • Optimise engagement and influence constructively to achieve outcomes |
| External | |
| Key Stakeholders | <ul style="list-style-type: none"> • Optimise engagement and influence constructively to achieve outcomes |
| Regulators, licensing authorities and customers | <ul style="list-style-type: none"> • 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 | NIL |

Special / Physical Requirements

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|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Location: | <ul style="list-style-type: none"> • Lucas Heights • Working in different areas of designated site/campus as needed. |
| Travel: | <ul style="list-style-type: none"> • 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: | <ul style="list-style-type: none"> • 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 (includes wearing respiratory equipment) • Ability to work with chemical and radioactive materials • Ability to stand for periods • Ability to work in GMP clean rooms • Ability to operate machinery & equipment (e.g. floor scrubbers) • Frequent movements, labour intensive tasks and manual handling • Ability to lift heavy objects (>16kg) – manual handling |

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|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Radiation areas: | <ul style="list-style-type: none"> 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: | <ul style="list-style-type: none"> 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: | <ul style="list-style-type: none"> Satisfy ANSTO Security and Medical clearance requirements |

Workplace Health & Safety

Specific role/s as specified in AP- All Workers

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| <u>2362</u> of the ANSTO WHS Management System | 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. Tertiary qualification or equivalent experience within an engineering, trade, science or supply chain discipline.
2. Demonstrated experience working as part of a team and operating plant and equipment within a highly regulated environment. *Preferred: pharmaceutical.*
3. 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.
5. Ability to trouble-shoot and problem-solve 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.
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.

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 (Jason Howe Interim) | Name: Justine Murison |
| Title: Shift Manager Nuclear Medicine | Title: Head of Manufacturing Nuclear Medicine |
| Signature: | Signature: |
| Date: | Date: |