



POSITION DESCRIPTION

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| Position Title: | Production Operator |
| Institute / Division / Business Unit: | ANSTO Health |
| Section or Unit: | Operations |
| Classification: | Band 3/4 |
| Position Description Number: | PD-1533 |
| Work Contract Type: | Technical |

Primary Objective

The **primary objective** of the Production Operator is to ensure the safe and efficient production of radiopharmaceuticals and intermediates to ensure ANSTO Health production schedules are achieved at optimum cost while complying with safety regulations, GMP, ARPANSA, ISO and ASNO requirements.

Organisational Environment

ANSTO is the national organisation for nuclear science and technology. We focus on undertaking leading edge research, delivering innovative scientific services and providing specialised advice to government, industry, academia and other research organisations.

ANSTO Health is a business unit within ANSTO engaged in the manufacture and sales of radiopharmaceutical and radiochemical products. Manufacturing is based upon the GMP Code of Manufacturing, where processes must meet certain standards and QC is essential and also on just-in-time principles, where all processes are extremely time-critical.

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

Position Environment

The Production Operator reports to the Production Supervisor and will be required to work day/night shift as production requires to a set roster. While the role does not have any direct reports, those working at the band 4 level are expected to oversee and train new recruits while they are undertaking allocated tasks, which the position is competent to perform, provide coaching and support to other Production staff and oversee the production process.

This position's key internal customers include all staff within ANSTO Health, staff from Reactor Operations, Support Services, Health Physics, WHS and staff involved in the supply chain or enabling groups interacting with ANSTO Health.

As a linked role, it is the intention that this position will be initially recruited into the band 3 level of which the employee will develop and acquire the competence, skills, knowledge and experience, over a period of time, to competently operate at the Band 4 level.

Key Accountabilities

The key accountabilities for the Band 3 position include:

- Perform routine production of the full range of radiopharmaceuticals and radioisotope based products and intermediates in accordance with procedures to meet tight deadlines, quality standards and production schedules. This includes operating hot

cells, undertake aseptic assembly, prepare components and operate other production equipment.

- Comply with production procedures at all times to ensure a safe, incident free work place that complies with GMP, ARPANSA, ISO and ASNO regulations and guidelines.
- Install, commission and troubleshoot new or modified plant and equipment including assisting with equipment delivery and acceptance
- Perform scheduled preventative maintenance of equipment as required in accordance with approved procedures, guidelines and safety instructions
- Perform routine maintenance work for breakdowns in a timely, efficient and safe manner, liaising with other users and process experts to investigate, identify and provide solutions for problems as required
- Expand skills via training and pro-actively share knowledge and experiences to establish productive working relationships. Contribute and participate in team meetings, tool box talks and other relevant meetings. Maintain the training metrics required to fulfil the duties of the production operator role.
- Provide input and support to validation planning, execution and report writing.
- Ensure all documentation meets TGA, ARPANSA and quality system requirements to enable systematic and compliant production. Keep meticulous records in order to comply with GMP and TGA requirements
- Perform production execution functions in ANSTO's ERP (currently SAP) to enable systematic and compliant production
- Undertake additional duties as required and during periods of leave of other staff.

In addition to performing all Band 3 key accountabilities, the key accountabilities for a band 4 position include:

- Independently monitor production processes to ensure production is running to schedule, in line with safety and quality standards
- Independently and without supervision perform accountabilities of band 3
- Oversee and safely operate plant and equipment without supervision. Act as the technical lead in the production of radiopharmaceuticals/intermediates including:
 - Ensure department and productivity and quality goals are achieved.
 - Coordinate production flow in accordance with approved schedules
 - Regular maintenance and review of equipment.
 - Communicate with internal ANSTO stakeholders to ensure optimal production performance in accordance with forecasts.
 - Maintain high level of housekeeping and line clearances
 - Review production and intermediate batch records to completion and sign off.
 - Maintain records and yields for plant and production processes.
 - Ensure accurate stock locations and holdings, Bill of materials and production routings
 - Coordinate Change Control and Validation processes.
 - Prepare and review SWMS, lodge quality notifications and ensure they are investigated according to defined timelines
 - Assist Supervisor to coordinate production start-ups, shutdowns and changeovers and resolve complex or out of policy operational issues.
- Assist Engineers / other experts in the design and development of equipment and plant including modifications, improvements and procedures
- Use independent judgement and liaise with other disciplines to identify and resolve complex production issues as they arise without supervision. Actively engage with

other stakeholders in the supply chain and lead discussions regarding production schedules, production issues, delays and non-conformances.

- Coordinate, train and mentor new production staff and production staff at the band 3 level on production processes, relevant safety and quality procedures. Lead team meetings, tool box talks and safety meetings.
- Apply analytical and diagnostic skills to recommend and implement improvements to production processes, operating procedures, plant and equipment to improve plant reliability and product quality. Develop/review and update procedures, work instructions and specifications.
- Promote and foster the desired ANSTO Health safety and quality culture with the aim of continuous improvement to safety and quality and its awareness across site. Lead 5S process and other continuous improvement activities within the Production Team.
- Provide technical support for project objectives and cross functional activities including working with project team members to plan and complete activities within ANSTO Health and ANSTO.
- Demonstrate a proactive attitude and practical application of ANSTO values including coaching and mentoring other staff, identifying and resolving issues as they arise within skills, knowledge and expertise.

Transition Criteria

Requirements for transition from Band 3 to Band 4:

- Performing Band 3 accountabilities, as described in this PD (or equivalent experience in a similar highly regulated manufacturing pharmaceutical environment); and completion of the Band 3 and 4 transition criteria curriculum with >90% metric.
- Significant experience in the manufacture of radiopharmaceuticals and intermediates in accordance to procedures and ability to work without supervision;
- Demonstrated knowledge of production processes across the range of radiopharmaceuticals and intermediates manufactured within ANSTO Health and the ability to coach, support and train new and other Production staff
- Demonstrated proficiency and ability to independently perform the following competencies within ANSTO Health Operations:
 - Lead, plan and motivate small teams in the production environment to deliver daily schedules.
 - Attendance commensurate with a level expected to be able to manage weekly production, processes and operations on a consistent basis.
 - Establish and exhibit the behaviours and values appropriate to leadership level.
- Demonstrated knowledge, experience (within ANSTO Health) and ability to independently and competently undertake the following:
 - Change Control Process and Validation process
 - Investigate, update and closeout Quality Notifications
 - Delivery of CAPA and TGA items to negotiated dead lines.
- Sustained commitment to demonstrating a proactive attitude and practical application of ANSTO values including coaching and mentoring other staff, identifying and resolving issues as they arise within skills, knowledge and expertise, and proactively assisting others to meet deadlines or finish tasks in times when there is spare capacity.
- Demonstrated experience in the resolution of complex production issues across a range of areas including production, plant and equipment and production based waste management of all areas..

- Demonstrated commitment to provide feedback and contribute to the process of continual improvement in safety, efficiency and individual knowledge and competency;
- Demonstration of ability to build and maintain strong stakeholder relationships to ensure customer requirements are met

Transition from Band 3 to Band 4 will occur following a recommendation from the relevant supervisor, assessment by the Production Manager and Operations Manager and approval from the Group Executive Nuclear Business. Transition is not automatic and compliance with transition criteria will need to be demonstrated and assessed.

Challenges

The major challenges for this position include:

- Interact ANSTO Health staff to ensure production occurs in a timely and efficient manner in line with production schedules. Ensure delays, issues, problems are communicated appropriately with relevant stakeholders in the supply chain.
- High level of responsibility and accountability producing medical radioisotopes for human consumption.
- Compliance to all processes, 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.
- Assist Supervisors to determine, plan and coordinate production activities, corrective actions and planned maintenance to ensure operational excellence is achieved.
- Developing working relationships with key ANSTO stakeholders such as Opal, B54 Mo99 processing plant, Supply chain and support services.

Special Requirements/ Physical Requirements

- Working in different areas of ANSTO as needed
- Perform duties in an area where radioactive materials are handled under tightly controlled safety conditions
- Ability to stand for lengthy periods, use hand manipulators and lift up to 23kg.
- Applicants should be fit, able to do all duties and do regular amounts of manual handling.
- Required to wear clean room garments for aseptic manufacturing.
- Willingness to work extended and varied hours based on operational requirements. Shift work is required.
- Satisfy ANSTO Security and Medical clearance requirements.

Delegations

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).

Work, Health & Safety Accountabilities, Responsibilities and Actions

ANSTO is committed to delivering excellence in WHS performance based on ANSTO's core values. All employees are responsible for undertaking their activities in a safe manner and co-operating and complying with WHS requirements and to improve WHS in their workplace by taking a proactive approach to WHS, using appropriate controls, working safely to reduce risk to self and others, and reporting unsafe work practices, equipment, incidents and near misses.

The specific role, as specified in [AG-2362](#) of the ANSTO WHS Management System, which defines the accountabilities, responsibilities and actions allocated to this position is:

- All Workers; and

- other specialised roles identified within the guideline the position holder may be allocated to in the course of their duties.

Knowledge, Skills and Experience

The knowledge, skills and experience requirements for the Band 3 position include:

1. Tertiary qualifications, relevant degree in Science or Industrial Trade qualification
2. Relevant technical experience in a laboratory or radio pharmaceutical production environment.
3. Experience with the operation of plant and equipment and or work within an manufacturing environment
4. Knowledge of regulatory requirements including ARPANSA, TGA, ANSO Safeguards and ISO 9001.
5. Understanding and working knowledge of the Code of GMP.
6. Strong analytical/ problem solving skills.
7. Strong verbal communication skills with emphasis on the ability to adapt communication styles to suit the audience.
8. Understanding of radiation and radiation protection measures.
9. Understanding of importance of Work Health and Safety, Environment, Quality and Regulatory requirements

In addition to the knowledge, skills and experience for the Band 3 position, the knowledge, skills and experience requirements for the Band 4 position include:

1. Significant experience in the manufacture of radiopharmaceuticals and intermediates in accordance to procedures and ability to work without supervision
2. Ability to lead and work in a team or independently.
3. Significant experience in the resolution of complex production issues including process, plant and equipment issues
4. Extensive knowledge of production process across the range of radiopharmaceuticals and intermediates manufactured within ANSTO Health
5. Demonstrated competence in performing preventive maintenance and troubleshooting
6. Demonstrated ability in training new staff, coaching and mentoring other staff
7. Demonstrated ability to investigate quality notifications and drive the completion of actions to resolve root cause controls until close out
8. Demonstrated ability to build and maintain effective and strong relationships with all members of the supply chain
9. Ability to coach others in the principles of the Code of GMP and Safety requirements