Australian Government

ANSTO
Science. Ingenuity. Sustainability.

POSITION DESCRIPTION

Position Title:	Microbiology Officer
Cluster / Business Unit / Division	Nuclear Operations & Nuclear Medicine/Nuclear Medicine
Section or Unit:	Quality
Classification:	Band 4/5 Linked
Job Family:	Monitoring & Audit
Position Description Number:	PD-2207
Work Contract Type:	Technical
STEMM/NON-STEMM:	STEMM

POSITION PURPOSE

To maintain a high sterility assurance level for the manufacturing of sterile nuclear medicine and perform testing to ensure ANSTO continues to deliver safe, secure, and sustainable supply of nuclear medicine.

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 human health, 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.

ANSTO, Nuclear Medicine is engaged in the manufacture and sales of sterile and non-sterile radiopharmaceutical and radiochemical products. ANSTO Nuclear Medicine has a dominant market share position in Australia and is expanding into the global market. The manufacture of radiopharmaceuticals and radiochemicals is based upon the current Code of Good Manufacturing Practice.
ANSTO Nuclear Medicine operates under external regulatory requirements; ISO 9001, ARPANSA and TGA and within ANSTO's procedural framework, with oversight by the ANSTO Board.
Due to the short-lived nature of radioactive products ANSTO, Nuclear Medicine products works on just-in-time principles, where all processes are extremely time-critical. Microbiology plays an essential part of the manufacturing and quality control processes; ensuring manufactured and tested product is satisfactory for use by the end-user.

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities – Band 4

- Perform media preparation and autoclaving, equipment calibration, microbiological testing for ANSTO and external stakeholders. This includes starting materials, intermediate materials and finished products.
- Maintain microbiology laboratory inventory and perform daily laboratory duties and housekeeping to ensure the laboratory meets GMP and safety requirements.
- Oversee environmental and operator monitoring program to support current and future operations, including review and trend of data.
- Perform aseptic gowning qualification and maintain personnel qualification as per cleanroom requirements.

- Investigate and lead the monitoring of microbiological deviations and out of specifications for the manufacturing facilities and liaise with the other departments for timely resolution of these events.
- Actively contribute to projects related to microbiology department including:
    - Updating and revising microbiology documentation to ensure regulatory compliance.
    - Qualification of microbiology equipment.
    - Validation of microbiology test methods.
    - Calibration microbiology equipment.
    - Collation of data and report writing for work executed.
- Provide microbiological testing support for validation activities (facility, manufacturing and engineering).
- Undertake additional duties as required and during period of leave of other staff.

Key Accountabilities – Band 5

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

- As SME provide guidance in the area of microbiology, aseptic processing, and contamination control program.
- Coordinate routine laboratory activities including sample tracking, routine testing, results, and reporting.
- Lead investigation for all safety and OOS/OOT incidents related to microbiology department and implement corrective actions as applicable.
- Analyse existing sterility assurance SOP's for content and develop risk assessment for sterility assurance compliance.
- Train new microbiology team members, and coordinate routine laboratory activities, equipment calibration and maintenance.
- Organise environmental monitoring, maintain documentation, trend data at regular interval and plan corrective action if any deviation is observed.
- Train new operators entering the cleanrooms and maintain personnel qualification program as per cleanroom environment.
- Identify opportunities for improvement and contribute effectively to maintain high standard of nuclear medicine PQMS system including, CAPAs, change control, deviations, validation, OOS, etc.
- Undertake additional duties as required and during period of leave of other staff.

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).

Key Challenges

The key challenges for this position include:

- Ensuring that all testing occurs to meet the just-in-time delivery requirements to key significant stakeholders.
- Ensuring all tasks are executed following strict TGA and ARPANSA regulatory compliance requirements.
- Maintaining rigour in chemical, microbiological and radiation safety in a manufacturing environment.
- Ensuring microbiology quality systems are in control, information about status of the system is communicated accurately and actions within them are executed by the stated deadline.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Quality Control Manager	• Receive guidance and direction. • Provide expert, authoritative and evidence-based information. • Recommend and gain endorsement for plans and goals and other initiatives.
QC Microbiology Team Leader	• Receive guidance and direction. • Provide expert, authoritative and evidence-based information. • Recommend and gain endorsement for plans and goals and other initiatives.
Microbiology Team Members	• Collaborate and share accountability. • Contribute to group decision making processes, planning and goals. • Negotiate and resolve conflicts.
Direct Reports	• Nil
Quality Assurance	• Provide expert, authoritative and evidence-based information. • Provide support for investigations.
Production	• Provide support for validation and production changes which impact sterility assurance. • Provide support for the execution of gowning and operator aseptic validations and Media Fill. • Notify gowning and aseptic assembly status.
Validation Leader	• Provide expert, authoritative and evidence-based information. • Provide support for the successful execution and completion of validation activities. • Provide input into the validation of microbiology methods and equipment.
Engineering & Maintenance	• Provide support for gowning validation and upcoming maintenance which impact sterility assurance. • Notify gowning status.
ANSTO e.g. NST, Business Development	• Provide support for microbiology testing of finished product.
External	
Regulators	• Participate in regulatory audits as required.
Suppliers / Contractors	• Liaise with providers of microbiology testing services as required and perform audits as required.

POSITION DIMENSIONS

Staff Data	
Reporting Line	QC Microbiology Team Leader
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 travel to ANSTO sites from time to time
Physical:	Industrial Laboratory physical requirements; sitting, standing, routine manual handling, lifting, standing for long periods and operating equipment. Some office based physical requirements, sitting, movement around office Wearing personal protective equipment for the handling of hazardous and radioactive materials Wearing sterile clean room garments for working in cleanrooms Ability to work with chemical and testing materials Applicants should be fit, able to lift heavy objects up to 23kg and be able to stand for periods of time Must test free of colour blindness and pass an annual eye examination
Radiation areas:	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 may be required for short and infrequent periods Shift Work
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

Refer to published Organisational Chart

KNOWLEDGE, SKILLS AND EXPERIENCE

Band 4

1. Relevant degree qualification in Microbiology or related field.
2. Extensive experience in microbiology laboratory skills or specific technical experience in Microbiology or equivalent disciplines.
3. Knowledge and understanding of GMP, ISO9001 standards, TGA requirements and International Pharmacopeia(s).
4. Knowledge and understanding of sterile manufacturing techniques, clean room standards and nuclear and pharmaceutical production regulations.
5. Experience working within a highly regulated environment (TGA, FDA and ISO highly regarded).
6. Experience in verification or calibration of instrumentation and analytical methods.
7. Demonstrated ability to effectively communicate to a wide audience including tradespeople, professionals and management.
8. Pro-active, deadline driven, and reliable in following through with actions.
9. Demonstrated ability to work within a team environment.

10. Demonstrated ability to work within a strong quality and safety culture.
11. Ability to work flexible hours to meet operational requirements.
12. Experience performing quality system tasks, including completion of Change Control, CAPA, Deviation Investigations etc.

Band 5

In addition to the knowledge, skills and experience for the Band 4 position, the knowledge, skills and experience requirements for the Band 5 position include:

1. Extensive experience co-ordinating and performing training of new team members in test methods and processes.
2. Demonstrated ability to identify areas for continuous improvement and manage the project through to implementation e.g., new testing methods and/or equipment.
3. Demonstrated time management, planning, organisational and leadership skills, including providing direction and advice to other team members to ensure operational and quality requirements are met.
4. Demonstrated ability to lead investigation for all safety and OOS/OOT incidents related to microbiology department and implement corrective actions as applicable.
5. Demonstrated effective communication and problem-solving skills.

Linked Role Transition

Transition to the higher Band within the linked role is not automatic and ability to perform Band 5 accountabilities will need to be demonstrated and assessed. This can be done by completing the attached form and completing a full written submission demonstrating and justifying how an employee meets the transition requirements.

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:	Micheal Gobrial	Name:	Ian Martin
Title:	Quality Control Manager	Title:	General Manager, Nuclear Medicine
Signature:		Signature:	
Date:		Date:	

[Microbiology Officer] (PD-2207) Band 4 to Band 5 Transition Checklist	
Name:	
Commencement Date:	
Assessment Date:	

Written submission demonstrating and justifying how the employee meets requirements must also be attached.

Requirements for transition	Met Criteria
a) Minimum 5 years working as Microbiology Officer (Band 4) OR b) Minimum 5 years equivalent experience	☐ Yes ☐ No OR ☐ Yes ☐ No
Microbiology Officer or equivalent	☐ Yes ☐ No
Extensive experience working as Microbiology Officer and demonstrate meeting all below requirements	☐ Yes ☐ No

Demonstrated ability to independently and responsibly perform Band 5 accountabilities and apply required knowledge, skills and experience for the Band 5 position including:	
Undertake Band 4 accountabilities at a technical expert level and independently without supervision or guidance	☐ Yes ☐ No
Demonstrated ability to independently and responsibly perform Band 4 accountabilities and apply required knowledge/skills/experience for a Band 5 position by exercising sound individual judgement that will not challenge the safety and reliability of the facilities and meet all regulatory requirements	☐ Yes ☐ No
Demonstrated knowledge of microbiology testing and monitoring practices within ANSTO Health and the ability to coach, support and train new and other Microbiology staff.	☐ Yes ☐ No
Demonstrated proficiency and ability to independently lead, plan and motivate small teams or work independently in the microbiology laboratory environment to deliver daily planned tasks.	☐ Yes ☐ No
Demonstrated proficiency and ability to independently	☐ Yes ☐ No
Attendance commensurate with a level expected to be able to manage weekly testing on a consistent basis.	☐ Yes ☐ No
Establish and exhibit the behaviours and values appropriate to leadership level.	☐ Yes ☐ No
Demonstrated knowledge, experience and ability to independently and competently undertake the following: o Change Control Process and Validation process. o Investigate, update and closeout deviations and out of specifications. o Delivery of CAPA and TGA items to negotiated deadlines.	☐ Yes ☐ No
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, proactively assisting others to meet deadlines or finish tasks in times when there is spare capacity	☐ Yes ☐ No
Coordinate equipment maintenance and calibration as approved schedule.	☐ Yes ☐ No
Demonstrated ability to identify areas for continuous improvement and manage the project through to implementation e.g. new testing methods and/or equipment.	☐ Yes ☐ No
Demonstrated Interpersonal effectiveness in engagement with stakeholders.	☐ Yes ☐ No
Ability to coach others in the principles of the Code of GMP and Safety requirements	☐ Yes ☐ No

Attach written submission demonstrating and justifying how the employee meets <u>each</u> of the above requirements.

Manager Recommendation

I have reviewed the employee's competence in accordance with Linked Role PD-2207 and certify that the employee meets all requirements for transition and recommend transition from Band 4 to Band 5 be endorsed as demonstrated in the attached written submission detailing how the employee meets each of the requirements.

Name & Title:			
Signature:		Date:	

General Manager Nuclear Medicine I have reviewed all information and approve transition from Band 4 to Band 5.

Name & Title:			
Signature:		Date:	
Effective date of transition:			