Australian Government

ANSTO
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POSITION DESCRIPTION

Position Title:	QC Analytical Chemist
Cluster / Business Unit / Division	Nuclear Medicine
Section or Unit:	Quality Control
Job Family:	Compliance & Regulation
Classification:	Band – 4/5 Linked Role
Position Description Number:	PD-2237
STEMM/NON-STEMM:	NON-STEMM
Work Contract Type:	Technical

POSITION PURPOSE

The primary purpose of the QC Analytical Chemist is to test starting materials, intermediates, radio chemicals and radiopharmaceuticals against quality control procedures to ensure products are fit for intended use as described by ANSTO Nuclear Medicine 's Quality Management System.
The position also undertakes Quality Assurance activities, particularly the release of API.

At the higher level the position will also perform and supervise the day-to-day quality control activities as well as providing technical expertise as a product specialist in accordance with ANSTO policies and procedures and regulatory requirements to support the safe, secure, sustainable supply of nuclear medicine.

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 Nuclear Medicine 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 high-level regulatory standards. The Quality Control department plays an integral role in ensuring this standard is met on just-in-time principles, where all processes are extremely time-critical.

ANSTO Nuclear Medicine 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 oversighted by the ANSTO Board. Over 500,000 Australian patients benefit from ANSTO Nuclear Medicine radiopharmaceuticals annually.

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities – Band 4

- Inspection and testing of starting materials, components, intermediates, radio chemicals and radiopharmaceuticals against quality control procedures to ensure products are fit for intended use as described by ANSTO Nuclear Medicine's Quality Management System and meet regulatory requirements.
- Record all QC test results according to regulatory requirements and ensure all documentation meets TGA, ARPANSA and quality system requirements.
    - Complete all test records on finished products and record QC results in SAP and laboratory notebooks

        - Record all non-conformances and corrective actions
        - Compliance to batch control procedures including label checks.
- Perform non-routine chemical analysis on materials and products, e.g. investigations
- Assist in auditing activities and take corrective and preventative actions to always ensure regulatory compliance.
- Using theoretical knowledge to analyse and develop responses to unforeseen problems.
- Assist in the calibration and maintenance activities of QC instruments according to procedures and work instructions to ensure delivery of accurate results.
        - Carry out routine calibration / verifications
        - Use appropriate calibration standards
        - Tag out faulty instruments
        - Record calibration data
        - Escalate faulty instruments for repair
- Assist with project tasks such as method development, validations and other activities associated with corrective/preventative actions, quality notifications, laboratory improvements.
- Review and revise existing work instructions and draft new work instructions to always ensure compliance to regulations.
- Troubleshoot and advise the Team Leader / QC Manager / QA Manager of QC related issues; using theoretical knowledge to analyse and develop resolution to unforeseen problems to always ensure compliance to regulations.
- Provide leadership to individuals or the team; providing direction or advice to other staff on work-related matters to ensure regulatory compliance (quality and safety) is always met.
- Peer review and QC release of materials and products to enable final disposition by QA.
- Although this position has no direct reports, on occasions, the person may be the senior member of the team and expected to lead the shift.
- Undertake additional duties as required and during periods of leave of other staff.

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

- Plan, coordinate and supervise the daily QC activities and contribute to training and coaching the QC staff.
- Ensuring that all quality control activities performed are carried out in a manner that complies with the TGA licensing requirements, Quality Management System and appropriate safety regulations.
- Ensuring that all necessary testing is carried out using analytical methods that are adequately validated; and are approved in accordance with the requirements of GMP and pharmacopoeia.
- Prioritising workload where there are multiple regulatory and customer requirements and unplanned activities requiring to be completed within tight timeframes.
- As a technical expert, train, coach and develop staff to ensure technical knowledge is shared across the wider Quality Team. Provide advice and guidance to staff.
- Perform the analyses of raw materials, intermediate reagents and finished goods and perform Quality Assurance activities, particularly release of finished goods.
- Assist with the maintenance of the Quality Assurance system to ensure compliance with TGA requirements.
- Assist in coordinating all calibration, method development, validation and maintenance activities in the QC laboratories are performed in accordance with the applicable procedures.
- Coordinate and perform stability testing and compile stability protocol and reports.
- Contribute to continuous improvement initiatives by:
    - reviewing processes, developing new or modified procedures and updating relevant documentation;
    - reviewing laboratory records, and identifying adverse trends as part of preventive actions;

- performing statistical analysis;
- assisting with validation requirements for the equipment improvement program and management;
- leading staff in the implementation of solutions to improve productivity and efficiency within the team.

- Perform the release of raw materials, intermediates, components and packaging materials for use in the manufacture of API in accordance with the release procedure.
- Perform the release of Mo-99 API when required and in accordance with the release procedure
- Coordinate QMS functions relevant to the Quality Section, such as CAPAs, MOCs, Deviations and OOS/OOT.
- Active engagement in safety initiatives, safety investigations and coordinate implementation of relevant safety-related actions.
- Ensure all staff on the shift comply with safety and regulatory work practices.
- Prepare and maintain documentation such as procedures, work instructions, specifications, quality plans, and other quality and technical documents.
- Provide technical information, specifications, and validation information for submissions to regulating authorities and customers.
- Assist with investigations into product and service quality issues, and to recommend solutions within the quality function.
- Perform technical troubleshooting as a product specialist for a range instrumentation and test methodology.
- Participate in regulatory audits as a technical SME e.g. TGA, FDA and ARPANSA
- Undertake additional duties as required and during periods 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).
- The position will maintain a high level of customer focus in particular identifying potential business impacts to technical issues and will escalate as required.

Key Challenges

- Often short testing lead times to enable prompt delivery of radiopharmaceutical products to customers.
- Pressure from the business for the urgent testing and release of materials and products at times.
- Complying with TGA and ARPANSA regulations, and internal procedures.
- Maintaining rigour in chemical and radiation safety in a shifting and challenging environment.
- Consistent compliance to TGA, GMP and ARPANSA regulations.
- Working safely with chemicals in a radiation environment.
- Working in a fast-paced production environment.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Quality Control Leader	• Receive guidance and direction • Provide regular updates on key tasks, challenges and critical issues that may impact customers and ANSTO's reputation • Immediately notifying of any incidents and escalating any concerns regarding product • Provide evidence-based advice

	• Recommend and gain endorsement for plans and goals and other initiatives • Escalate issues and propose solutions
Work Area Team Members	• Support team members and work collaboratively to meet objectives • Collaborate and share accountability • Contribute to group decision making processes, planning and goals and knowledge transfer
Quality Control Manager	• Coordinating as a Quality Control Leader delegate
Production Team	• Communicating to ensure operations are not interrupted
Microbiology/QA/Regulatory & Compliance/Planning/Validation /Safety/Purchasing/Customer Service/Supply Chain	• Provide support as appropriate
Development Chemist	• Communicating to ensure workflow is not interrupted
Systems Officer	• Coordinating to address quality related issues
External	
Industry Regulators - ARPANSA	• Ensure compliance with ARPANSA licences within areas of responsibility.
Licensing Authority - TGA	• Ensure compliance with TGA and GMP code within areas of responsibility.

POSITION DIMENSIONS

Staff Data	
Reporting Line	Reports to the Quality Control 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 to travel to ANSTO sites from time to time
Physical:	Office based physical requirements (sitting, standing, movement around office and site, extended hours working at computer). Ability to work with chemical and testing materials. Ability to stand for periods. Ability to lift heavy objects up to 23kg - some manual handling. High attention to detail Laboratory environment and working with chemicals and testing materials
Radiation areas:	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:	Shift work may/will be required which includes some Sundays and Public Holidays Willingness to work extended and varied hours based on operational Requirements. Variable start/finish times in accordance with roster to provide coverage

	After hours work may be required for short and infrequent periods.
Clearance requirements:	Satisfy ANSTO Security and Medical clearance requirements
Linked Role:	The Transition from Band 4 to Band 5 is not automatic and requires a full written submission, in addition to the attached checklist, to demonstrate how the employee meets the requirements. Transition will only occur following approvals from the QC Team Leader, QC Manager and the General Manager Nuclear Medicine Products.

Workplace Health & Safety	
Specific role/s as specified in AP-2362 of the ANSTO WHS Management System	All Workers Managers / Leaders / Supervisors 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. Advanced Diploma in Microbiology and/or Chemistry/similar science supported by demonstrated relevant experience.
2. Demonstrated experience in chemical analysis and TGA, FDA, ISO and NATA audits and regulations.
3. Knowledge and experience using statistical techniques.
4. Experience using and validating analytical instrumentation and analytical techniques, including nuclear instrumental counting techniques.
5. Experience with Good Manufacturing Practices (GMP) and knowledge of relevant nuclear and pharmaceutical production regulations and legislation.
6. Demonstrated ability to communicate effectively with internal and external stakeholders within various departments.
7. Pro-active, deadline driven, and reliable in following through with actions.
8. Strong time management, planning and organisational skills.
9. Strong customer service focus.
10. Demonstrated ability to work within and promote a strong safety culture.
11. Team working spirit and demonstrated respectful workplace behaviour .

In addition to the requirements at Band 4 level the following will be required at the Band 5 level:

KNOWLEDGE, SKILLS AND EXPERIENCE – BAND 5

1. Degree qualifications in Microbiology and/or Chemistry/similar science or equivalent demonstrated experience.
2. Knowledge of analytical instrumentation and analytical techniques, including nuclear instrumental counting techniques.
3. The ability to plan, coordinate and supervise the daily activities, contribute to training and coach and mentor staff.
4. Demonstrated ability to lead investigations on multiple non-compliances/complaints and/or issues reviews.
5. Demonstrated ability to engage and influence a wide range of stakeholders.

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:	Bhawna Sharma
Title:	Quality Control Manager	Title:	Head of Quality
Signature:		Signature:	
Date:		Date:	

QC Analytical Chemist Linked Role (PD-2237)
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 also be attached.

Requirements for transition	Met Criteria
Performing Band 4 accountabilities, as described in this PD (or equivalent experience in a similar highly regulated manufacturing pharmaceutical environment) and completion of the Band 4 to Band 5 transition criteria curriculum with 100% metric are completed	☐Yes ☐No
Demonstrated ability to plan, coordinate and supervise the daily activities, contributed to training, coaching and mentoring staff.	☐ Yes ☐ No
All quality control activities performed on the shift are carried out in a manner that complies with the TGA licensing requirements, Quality Management System and appropriate safety regulations.	☐ Yes ☐ No
Participated as an SME in regulatory audits e.g. TGA, FDA and ARPANSA	☐ Yes ☐ No
Participated in continuous improvement activities by leading CAPAs/MOCs and lead staff in the implementation of solutions to improve productivity and efficiency within the team.	☐ Yes ☐ No
Overseen quality projects such as the stability program, Preventative maintenance schedule and/or involved in validation activities.	☐ Yes ☐ No
Lead investigations on multiple non-compliances/complaints and/or issues reviews.	☐ Yes ☐ No
Completed training in order to authorise the release of API in accordance with the release procedure.	☐ Yes ☐ No
Completed training in order to authorise the release of raw materials, intermediates, components and packaging materials for use in the manufacture of API in accordance with the release procedure.	☐ Yes ☐ No
Demonstrated decision making ability in the absence of the QC leader to ensure operations are not impacted.	☐ Yes ☐ No
Sustained commitment to demonstrating a proactive attitude and practical application of ANSTO values, 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 capacity	☐ Yes ☐ No
Demonstrated an ability to engage and influence a wide range of stakeholders.	☐ Yes ☐ No

Quality Control Team Leader Recommendation:
I have reviewed the employee's competence in accordance with Linked Role PD-2237 and certify that the employee meets all requirements for transition and recommend transition from Band 4 to Band 5 be endorsed.

Team Leader Name:	

Signature:	
Date:	

Quality Control Manager Assessment
I have assessed the submission and confirm that the employee meets all requirements for transition from Band 4 to Band 5

Quality Control Manager Name:	
Signature:	
Date:	

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

GM Nuclear Medicine Products Name:	
Signature:	
Date:	
Effective Date of transition:	