



Australian Government



POSITION DESCRIPTION

Position Title:	Analytical Chemist
Institute / Division / Business Unit:	Nuclear Operations & Nuclear Medicine
Section or Unit:	Quality Control
Classification:	Band 4
Position Description Number:	PD- 0056
Work Contract Type:	Technical

POSITION PURPOSE

The primary objective of the Analytical Chemist is to test starting materials, intermediates, radiochemicals and radiopharmaceuticals against quality control procedures to ensure products are fit for intended use as described by ANSTO Health's Quality Management System.

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.

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 certain standards and 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. 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.

ACCOUNTABILITIES & RESPONSIBILITIES

Key Core Accountabilities

- Inspection and testing of starting materials, components intermediates, radiochemicals and radiopharmaceuticals against quality control procedures to ensure products are fit for intended use as described by ANSTO Health'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 ensure regulatory compliance at all times.
- 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 ensure compliance to regulations at all times.
- 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 ensure compliance to regulations at all times.
- 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 met at all times.
- 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.

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

The major challenges for this position include:

- 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.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Team Leader	<ul style="list-style-type: none"> • Receive guidance and direction • Provide regular updates on key tasks, challenges and critical issues that may impact customers, ANSTO’s reputation • Provide evidence based advice



	<ul style="list-style-type: none"> • Recommend and gain endorsement for plans and goals and other initiatives • Escalate issues and propose solutions
Work area team members	<ul style="list-style-type: none"> • Support team members and work collaboratively to meet objectives • Collaborate and share accountability • Contribute to group decision making processes, planning and goals • Knowledge transfer
Divisions of ANSTO	<ul style="list-style-type: none"> • Provide support to all divisions; primarily QC Manager, Microbiology, QA, Regulatory Compliance, Production, Planning, Validation, Safety, Purchasing, Customer Service and Supply Chain.

POSITION DIMENSIONS

Staff Data	
Reporting Line	Reports to the Analytical Chemist 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:	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 as there is some manual handling.
Radiation areas:	May be 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, flexible and varied hours based on operational requirements. Shift work – which includes Sundays and Public Holidays 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 Obtain and maintain appropriate federal government clearance
Workplace Health & Safety	
	All Workers



Australian Government



Specific role/s as specified in <u>AG-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.

Delegations

The levels of authority delegated to this position are those approved and issued by the CEO. All delegations will be in line with the ANSTO Delegation Manual AS-1682 (as amended or replaced).

Knowledge, Skills and Experience

1. Relevant degree qualifications or equivalent relevant experience in the radiochemical industry
2. Experience in analytical testing preferably in the pharmaceutical industry
3. Sound understanding of and adherence to GMP
4. Training in TGA, ARPANSA, radiation safety and quality systems
5. Knowledge and experience in analytical instrumentation and analytical techniques
6. Proactive attitude with good attention to detail.

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:	Belinda Lehn	Name:	Ian Martin
Title:	Quality Control Laboratory Manager	Title:	ANSTO Health General Manger
Signature:		Signature:	
Date:		Date:	