Australian Government

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# POSITION DESCRIPTION

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|---|---|
| **Position Title:** | Quality Compliance Associate |
| **Cluster / Business Unit / Division** | Nuclear Operations & Nuclear Medicine |
| **Section or Unit:** | Quality Assurance |
| **Classification:** | Band 4/5 Linked Role |
| **Job Family:** | Compliance and regulation |
| **Position Description Number:** | PD-2239 |
| **Work Contract Type:** | Professional |
| **STEMM/NON-STEMM:** | STEMM |

## POSITION PURPOSE

The primary objective of the Quality Compliance Associate is to co-ordinate and maintain the quality management systems across Nuclear Medicine to ensure compliance with the requirements of the TGA licence to manufacture therapeutic goods, and other regulatory requirements. This includes (but not limited to):

- Coordination and maintenance of the Nuclear Medicine quality system activities for:
  - Documentation Control system
  - Non-conformances/Deviations system
  - OOS/OOT system
  - Management of Change (MOC) system
  - Corrective and Preventative Actions (CAPAs) system
  - Internal and Supplier Audits
  - Supplier management system
  - Customer complaints system
  - PQR system
  - TGA Remediation Programs
- Report metrics for all quality systems and trend monthly data generating detailed monthly reports for management.
- Support continuous improvement initiatives across the quality processes and systems.

## 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 has a dominant market share position in Australia and is expanding into the global market. ANSTO Nuclear Medicine operates under strict external regulatory requirements including TGA, FDA, ISO 9001, ARPANSA and ASNO, within ANSTO's procedural framework and in oversighted by the ANSTO Board. Over 500,000 Australian patients benefit from ANSTO's radiopharmaceuticals annually.

## ACCOUNTABILITIES & RESPONSIBILITIES

### Key Accountabilities Band 4

- Effectively plan and maintain the quality management systems across nuclear medicine to ensure the Code of GMP and other regulatory requirements are met.

- Maintain the Nuclear Medicine quality management systems such as Deviations, OOS/OOT, CAPA, Management of change, Customer Complaints, Audit program and Supplier Qualification.
- Coordinate and maintain the document management systems.
- Coordinate and maintain the supplier and contract manufacturer register.
- Coordinate and maintain the PQR register.
- Coordinate and maintain the nuclear medicine audit program.
- Participate in regulatory audits as a technical SME in the quality management systems.
- Support the co-ordination of the TGA regulatory remediation plans.
- Subject Matter Expert (SME) for the Nuclear Medicine quality System compliance matters impacting Nuclear Medicine.
- Support the implementation of the continuous improvement program of quality processes and systems across nuclear medicine.. Ensure all Continuous improvement activities are carried out in a manner that complies with the TGA licensing requirements, Product Quality System (PQS) and other regulatory requirements.
- Provide quality system support and advice into CI activities undertaken in Nuclear Medicine
- Ensure all work carried out is in accordance with ARPANSA regulations, TGA licensing requirements, Nuclear Medicine procedures, WHS procedures, standards and regulations and ensure quality assurance of all work undertaken
- Participate in on-going GMP training.
- Provide training on the quality systems to personnel across nuclear medicine
- Report quality metrics for the quality systems and trend monthly data generating detailed updated reports for monthly management meetings.
- 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:**

- Effectively plan, coordinate and maintain and drive the quality systems across nuclear medicine to ensure the Code of GMP and other regulatory requirements are met.
- Drive continuous improvement initiatives across eQMS modules associated with the quality systems within nuclear medicine such as Documentation, Deviations, OOS/OOT, CAPA, Management of change, Customer Complaints, Audit program, Supplier Qualification and PQR.
- Drive forward the implementation of the continuous improvement program of quality processes and systems.
- Be a qualified Auditor and identify and record product and service problems, and to initiate, recommend and /or provide solutions, and then to verify those solutions.
- Co-ordinate, maintain and drive the nuclear medicine audit program undertaking both internal and supplier audits.
- Support and contribute in regulatory inspections as a technical SME for the nuclear medicine quality management system Prepare regulatory inspection responses post regulatory Inspections.
- Co-ordinate and drive forward the TGA regulatory remediation plans.
- Identify and implement opportunities for improving the Continuous Improvement processes.
- Develop and establish measurable quality metrics for the quality systems and trend monthly data generating detailed updated reports for management.
- Recommend changes and improvements in quality systems processes following review.
- Undertake additional duties as required and during period of leave of other staff.

**Decision Making**

- The position works within a framework of legislation, policies, professional standards and resource parameters. Within this framework the position has some independence in determining how to achieve objectives of the unit, including deciding on methodologies and approaches, operations, resource allocation and project planning.

- The position is required at times to make effective judgements under pressure and time constraints.
- The position is required to independently develop objectives for Continuous Improvement processes.
- 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 major challenges for this position include:

- Facilitating and fostering an environment of continuous improvement across nuclear medicine including driving change.
- Training Nuclear Medicine staff on quality systems, continuous improvements processes and principles.
- Encouraging teamwork, cooperation, communication, and consultation.
- Encourage sharing of knowledge and experiences within the team and keep up-to-date with current technology whilst being aware of its potential to impact on the work of the group

**KEY RELATIONSHIPS**

| Who | Purpose |
|---|---|
| **Internal** | |
| Manager/Executive: | • Receive guidance and direction.<br>• Promote staff engagement and quality recruitment.<br>• Provide regular updates on key continuous improvement activities, quality system, challenges and critical issues that may impact operations, customers, ANSTO's reputation.<br>• Recommend and gain endorsement for plans and goals and other initiatives.<br>• Escalate issues and propose solutions |
| Work area team members: | • Drive quality culture across nuclear medicine<br>• Provide expert advice and analysis on a full range of matters associated with CI processes and quality systems.<br>• Contribute to group decision making processes, planning and goals.<br>• Support team members and work collaboratively to contribute and meet objectives.<br>• Cross Train across all Quality Systems<br>• Negotiate and resolve conflicts |

**POSITION DIMENSIONS**

**Staff Data**

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| Reporting Line: | Reports to the Quality Systems and Compliance Manager |
| Direct Reports: | Nil |

**Special / Physical Requirements**

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| Location: | Lucas Heights<br>Working in different areas of designated site/campus as needed |
| Travel: | May be required to travel to ANSTO sites from time to time<br>Infrequent travel within NSW or interstate |
| Physical: | Office based physical requirements (sitting, standing, minimal manual handling, movement around office and site, extended hours working at computer) |

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|---|---|
| Radiation areas: | May be required to work in radiation areas under tightly regulated conditions |
| Hours: | Willingness to work extended and varied hours based on operational requirements<br>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 Quality Systems and Compliance Manager, Head of Quality 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<br>Officer (definitions found in appendix A of AP-2362)<br>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. Diploma qualification in Science or other relevant discipline or relevant industry experience.
2. Experience in working in a sterile and non-sterile GMP pharmaceutical manufacturing environment
3. Demonstrated Quality Systems and GMP compliance experience working within the pharmaceutical industry.
4. Experience and knowledge in maintaining quality management systems within the pharmaceutical manufacturing industry such as documentation, deviations, OOS/OOT, customer complaints, Supplier Management, management of change, CAPAs and audit program and PQR.
5. Understanding of and adherence to TGA, FDA, EU and ARPANSA requirements.
6. Sound knowledge and understanding of the GMP requirements, ISO 9001 standard and knowledge of the TGA requirements and International Pharmacopoeia(s).
7. Experience in participating in TGA, FDA and ISO audits.
8. Understanding and experience of master control and SAP electronic systems (preferable).
9. Ability to work effectively in cross functional and multi-disciplinary teams.
10. Excellent organisational, interpersonal and communication skills.
11. Excellent problem-solving skills and flexibility in responding to changing demands.
12. Ability to meet critical deadlines and maintaining accuracy and attention to detail.

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

**KNOWLEDGE, SKILLS AND EXPERIENCE – BAND 5**

1. Degree qualification in science or other relevant discipline or relevant industry experience.
2. Extensive Quality Management Systems and GMP compliance experience within the pharmaceutical industry.
3. The ability to effectively plan, coordinate and maintain and drive quality management systems within the pharmaceutical industry.
4. Experience in regulatory audit participation as a technical SME in quality systems e.g. TGA, FDA and ARPANSA.
5. Demonstrated experience in auditing.

6. Extensive experience in working with quality electronic systems such as Mastercontrol.
7. Ability to mentor and coach staff on quality management systems/processes.
8. Ability to co-ordinate and drive forward TGA regulatory remediation plans.
9. 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: | Margaret Sequeira | Name: | Ian Martin |
| Title: | Quality Systems and Compliance Manager | Title: | General Manager Nuclear Medicine Products |
| Signature: | | Signature: | |
| Date: | | Date: | |

**Quality Compliance Associate Linked Role (PD-2239)**

**Band 4 to Band 5 Transition Checklist**

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|---|---|
| Name: | |
| Commencement Date: | |
| Assessment Date: | |

**Note: Full written submission demonstrating and justifying how the employee meets the requirements must also be attached.**

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| 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 effectively plan, coordinate, maintain at least four quality systems across Nuclear Medicine | ☐ Yes ☐ No |
| Demonstrated ability to drive continuous improvement initiatives across eQMS modules to improve productivity and efficiency.<br><br>Demonstrated ability in mentoring and coaching nuclear medicine staff in quality processes and systems. | ☐ Yes ☐ No<br><br>☐ Yes ☐ No |
| Participated as a Quality system and compliance SME in regulatory audits eg. TGA, FDA and ARPANSA | ☐ Yes ☐ No |
| Demonstrated ability to co-ordinate forward TGA regulatory remediation plans through stakeholder engagement. | ☐ Yes ☐ No |
| Completed audit training to become a qualified auditor for the nuclear medicine audit programme. | ☐ Yes ☐ No |
| All quality assurance activities are carried out in a manner that complies with the TGA licensing requirements, Quality Management System and appropriate safety regulations. | ☐ Yes ☐ No |
| Demonstrated decision making ability with quality system processes in the absence of the Quality Systems and Compliance Manager 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 ability to engage and influence a wide range of stakeholders. | ☐ Yes ☐ No |

**Quality Systems and Compliance Manager Recommendation:**

I have reviewed the employee's competence in accordance with Linked Role PD-2239 and certify that the employee meets all requirements for transition and recommend transition from Band 4 to Band 5 be endorsed.

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|---|---|
| Manager Name: | |
| Signature: | |
| Date: | |

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

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| Head of Quality Name: | |
| Signature: | |
| Date: | |

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

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