



POSITION DESCRIPTION

Position Title:	Safety, Regulatory and Quality Officer
Cluster / Business Unit / Division	Nuclear Science and Technology
Section or Unit:	Biosciences / Operations
Classification:	Band 6
Job Family:	Compliance & Regulation
Position Description Number:	PD-2430
Work Contract Type:	Professional
STEMM/NON-STEMM:	STEMM
STEMM CATEGORY:	Research and Sciences

POSITION PURPOSE

The primary objective of the Safety, Regulatory and Quality Officer is to manage the portfolio of compliance activities to ensure the compliance obligations to safely operate Biosciences facilities and laboratories are met. The position is responsible for advising, improving and optimising Biosciences safety practices and quality management system for productive operation of Biosciences facilities. The role also facilitates, interacts, and works closely with ANSTO's High Reliability teams, Enabling Services and ANSTO's Quality teams to ensure Biosciences can effectively fulfil its safety, regulatory, compliance and quality commitments.

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 Science & Technology (NST) incorporates ANSTO's research, innovation, landmark research infrastructure and associated platforms and capabilities. NST conducts research and development in relation to nuclear science and technology and connects people, transfers knowledge, and provides nuclear-based products and services for the benefit of Australia.

The Research Infrastructure portfolio consists of platforms established on scientific infrastructure and capabilities, with a number of the platforms categorised as landmark infrastructure. This includes a range of scientific assets, infrastructure, capability development and delivery for multi-decadal, multi-disciplinary, multi-user platforms for a collaborative user community and for internal research and development endeavours.

Biosciences is a Research Infrastructure platform which includes facilities and capabilities organised into three groups – Radiochemistry, Irradiations, and Biology & Preclinical Imaging. The platform partners with pharmaceutical, biomedical and medical devices companies to bring new products and methods to market. It collaborates with the NST Human Health research theme to develop greater understanding of disease states, diagnosis and treatment, assists in optimising ANSTO Nuclear Business production methods and develops new and improved methods of deploying landmark infrastructure and nuclear methods for the benefit of partners, collaborators and customers.

The Biosciences Operations team manages and guides the effective and efficient operation of the facilities and provides operational support and advice to platform stakeholders. It achieves this through sustainable facility asset management, optimising the quality of operations, ensuring compliance obligations are met and improving safety.

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities

- Management and improvement of the relevant safety documentation and related submission process, to ensure records and documents are current, accurate, meet regulatory requirements and delivered in a timely manner. This includes safety approval forms and documents (e.g. SRA), instructions, risk assessments (e.g. SWMEs) and registers such (e.g. radioisotope and chemical registers)
- Responsible for maintaining and improving the quality management systems (ISO9001, ISO14001 and ISO45001), in the platform. This includes general document management, including upkeep of records, laboratory logbooks, change controls, audit programs, training records and reporting relevant key performance indicators.
- Coordination of tasks and activities to facilitate information exchange and optimise engagement between the platform with High Reliability and Enabling teams to ensure timely delivery of safety approvals.
- Undertake ARPANSA Source officer duties. This includes, ensuring compliance with any licence conditions that platform operates under and providing reports to the relevant ARPANSA licencing officer as required.
- Keep abreast of regulatory updates (WHS, ARPANSA, TGA, OTGR) and provide advice to management and staff, including science subject matter experts on interpretation and application of regulations, standards and guidelines to ensure the platform remains safe, compliant and productive.
- Manage the currency and use of the incident reporting system (GRC) to drive continuous improvement in safety, quality, and compliance performance.
- Undertake additional duties as required and during period of leave of other staff.

Decision Making

The ANSTO values, organisational corporate plan, integrated business planning process, the NST strategic plan and the Biosciences business plan provide the context for the position.

- Determine key work priorities and methods within the context of agreed work plans and consult with the Biosciences Operations Manager and or with Platform Leader on issues that have a significant impact to the platform. The position has some independence in deciding on methods and approaches to achieve performance objectives.
- The position is fully accountable for the accuracy, integrity and quality of advice provided, ensuring that decisions are based on sound evidence, but at times may be required to make effective judgements under pressure or in the absence of complete information or expert advice.
- The position works within a framework of legislation, policies, professional standards, and resource parameters. Within this framework the position has some independence in consultation with the line manager in determining how to achieve operational plans and objectives of the facilities and must always ensure compliance to relevant regulations.
- 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

- Translating and communicating regulatory legislation and licence/permit conditions to enable effective and productive facility operation.
- Balancing the competing demands of safety, compliance, and scientific productivity
- Balancing operational and strategic demands in a complex and dynamic environment to ensure successful delivery of agreed objectives.
- Building professional networks across a diverse range of stakeholders to identify and implement opportunities for improvement in facilities and operations.

- Communicating and negotiating with a range of internal and external stakeholders to achieve required outcomes in a complex environment where resources are highly constrained.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Manager, Operations	<ul style="list-style-type: none"> • Receive broad guidance and direction. • Receive performance requirements consistent with the business plan and objectives. • Provide advice on operational requirements. • Report on facility safety, quality and compliance. • Recommend facility modifications and process/procedure to enhance or improve safety, quality or compliance. • Escalate issues and propose solutions. • Provide regular updates on key tasks, issues, and priorities. • Provide expert, authoritative and evidence-based advice.
Work area team members	<ul style="list-style-type: none"> • Determine work priorities. • Deliver to the business plan. • Provide expert regulatory and licencing advice, analysis, and leadership. • Influence and shape group decision making processes, planning and goals. • Collaborate and share information
NST teams, Subject Matter Experts, High Reliability teams, Enabling teams and Quality teams	<ul style="list-style-type: none"> • Collaborate and share information • Provide advice and analysis • Disseminate and facilitate information exchange • Optimise engagement, coordinate tasks and activities
Facility Users - internal	<ul style="list-style-type: none"> • Ensure safety and regulatory compliance • Provide expert advice and analysis • Monitor trends and implement strategies to improve operations. • Provide user training to ensure safety, regulatory and quality compliance.
External	
Facility Users - external	<ul style="list-style-type: none"> • Provide expert advice, analysis, and leadership • Maximise user experience • Ensure safety and regulatory compliance. • Provide training and supervision. • Build and utilise effective and productive networks, nationally.
Regulators and auditors	<ul style="list-style-type: none"> • Establish and maintain effective and collaborative working relationships

POSITION DIMENSIONS

Staff Data	
Reporting Line	Biosciences Operations Manager
Direct Reports	0
Indirect Reports	Facility Manager, Laboratory Coordinator
Financial Data (2023/2024)	
Revenue / Grants	N/A
Operating Budget	N/A

Staffing Budget	N/A
Capital Budget	N/A
Assets	N/A

Special / Physical Requirements

Location:	Lucas Heights Working in different areas of designated site/campus as needed.
Travel:	Operational needs may require temporary and/or periodic assignments at collaborative partner facilities within Australia or training assignments both nationally and internationally.
Physical:	Office based physical requirements (sitting, standing, minimal manual handling, movement around office and site, extended hours working at computer) Labour intensive physical requirements (sitting, standing, frequent manual handling) Standing for long periods Wearing personal protective equipment for the handling of hazardous and/or radioactive materials Working in facilities that house or use small animals
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 and varied hours based on operational requirements
Clearance requirements:	Satisfy ANSTO Security and Medical clearance requirements

Workplace Health & Safety

Specific role/s as specified in <u>AP- 2362</u> 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
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ORGANISATIONAL CHART

Refer to published Organisational Chart.

KNOWLEDGE, SKILLS AND EXPERIENCE

1. Degree in science or other relevant experience or equivalent relevant experience.
2. Demonstrated knowledge, understanding and experience in applying laboratory standards and applicable Work Health and Safety, and Environmental regulatory requirements and ISO standards.
3. Experience with ANSTO's radiation regulatory environment or experience with working in a highly regulated environment.
4. Ability to develop and maintain productive working relationship with a wide variety of staff, facility users, commercial vendors, and regulators.
5. Demonstrated high level communication and interpersonal skills with the capacity to influence key decision-makers.
6. Demonstrated personal qualities that promote a safety first attitude and abilities to develop strong individual and collective safety culture to a team operating in a highly regulated environment.
7. Demonstrated teamworking skills in diverse networks to promote continual improvement.

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: Tien Pham	Name: John Bennett
Title: Manager, Biosciences Operations	Title: Leader, Biosciences
Signature:	Signature:
Date:	Date:

Appendix 1

ANSTO Job Families
Accounting & Finance
Administration
Communications & Marketing
Compliance & Regulation
Engineering and Technical
Human Resources
ICT & Digital Solutions
Information & Knowledge Management
Legal
Manufacturing
Monitoring & Audit
Operations
Organisational Leadership
Project & Program
Research
Science
Security & Intelligence
Senior Executive
Service Delivery
Strategic Policy
Trades & Labour