



POSITION DESCRIPTION

Position Title:	Licencing Officer
Cluster / Business Unit / Division	Nuclear Precinct/Nuclear Medicine
Section or Unit:	Regulatory Affairs
Classification:	Band 6
Position Description Number:	PD-2105
Work Contract Type:	Technical
STEMM/NON-STEMM:	NON-STEMM

POSITION PURPOSE

- The primary objective of the Licensing Officer is to:
- Assess and document compliance with ARPANSA licence conditions and other regulatory requirements, including the collation of information and subsequent preparation of periodic reports (e.g. quarterly reports) to regulatory authorities;
- Facilitate and coordinate the timely responses to regulatory issues and ensure the effective control and integration of safety and licensing activities within ANM and Health Products;
- Contribute to the development, implementation and maintenance of the ANM and Health Products Business Management System (BMS) via participation as an internal auditor and when necessary, the development and/or revision of BMS documentation; and
- Facilitate and coordinate timely responses to WHS activities that occur within ANM and Health Products.

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 Health and ANSTO Nuclear Medicine are sites for the manufacture and testing of radiopharmaceuticals and radiochemical Active Pharmaceutical Ingredients (APIs). Medicines manufactured at these sites are supplied to customers in Australia and overseas. Manufacture of pharmaceutical products at these sites is undertaken in compliance with ARPANSA and TGA GMP licenses and applicable license conditions.

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities

- Ensuring quarterly reports and any other information required under the facility licence is prepared and submitted in accordance with the licence.
- Ensuring the ANM and Health Products safety documentation (SAR and Plans and Arrangements) are maintained consistent with ANSTO safety and licensing requirements and with the appropriate authority and regulatory requirements including reflecting current practices of the facility and industry best practices.
- Providing technical expertise in relation to licensing and regulatory issues in support of ANM and Health Products.
- Ensuring ANM and Health Product works understand the ANM and Health Product Licence Conditions and Licencing Documentation.

- Assisting the interface between ANM and Health Products and the principle regulator, ARPANSA. This includes coordinating appropriate responses to safety and licensing issues raised by ARPANSA and other Commonwealth regulators.
- Contributing to the development, implementation and maintenance of the BMS to ensure that the ANM and Health Products comply with regulatory, organisational and industry safety, quality and environmental standards.
- Coordinating the safety analysis work done by ANSTO and contractor(s) (where applicable) and also the preparation of relevant safety cases. Includes implementation and review of ANM and Health Products documentation (including procedures, instructions, modification submissions) relevant to safety and licensing aspects).
- Coordinating one or more projects, or tasks within projects. Including coordination of the project or tasks, conception and development of project ideas and maintaining visibility of the project with internal and external stakeholders.
- Environmental Co-ordinator for Nuclear Medicine
- Work closely with the Regulatory Affairs Manager on reporting requirements and continuous improvement initiatives in ANM and Health Products.
- Contributing to a safe working environment through the active identification, assessment, control and review of facility risks and incorporation of these into licencing documentation.
- Building strong relationships with clients and regulators to assist with the negotiation of effective outcomes.
- Preparing monthly Safety Performance Indicators (SPIs) reports and the maintenance of the SPI reporting system.
- Support Nuclear Medicine in ensuring emergency, business resilience and business impact plans are in place and up to date. Review and amend these plans in consultation with key stakeholders where required
- Undertaking additional duties as required and during periods of leave of other staff. Fulfilling WHS responsibilities as specified in AG-2362 of the ANSTO WHS system.

Decision Making

- The licensing officer works within the requirements of ARPANSA Act and Regulation framework including ARPANSA Guidance material. Within this framework, the position provides advice on how to achieve objectives of the unit in compliance with ARPANSA requirements, including deciding on methods and approaches to be used to achieve this objective.
- In line with ANSTO's value of Safe and Secure, this position ensures that compliance requirements, as set out in organisational corporate plan, business plan, operational excellence program, and within Health and ANM's strategies, are met.
- The Licensing Officer position is accountable for the accuracy, integrity and quality of the content of regulatory advice provided to Health and ANM, and is required to ensure 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 Licensing Officer determines key work priorities within the context of agreed work plans and will consult with the Regulatory and Medical Affairs Manager on complex, sensitive and major issues that have a significant impact on Health and ANM.
- 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:
- Developing and maintaining knowledge of the ANM and Health Products safety case consistent with ANSTO safety and licensing requirements and with the appropriate regulatory requirements.

- Developing and maintaining a relationship with ARPANSA and other Commonwealth regulators in conjunction with the ANSTO Regulatory Affairs Manager.
- Maintaining knowledge of industry best practice and new technology.
- Leveraging influence across key stakeholders in ANM and Health Products.
- Engaging with key stakeholders across ANSTO to prioritise work in a timely manner.
- Prioritising work and completing tasks within deadlines with the resources available.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Manager/Executive	<ul style="list-style-type: none"> • Receive guidance and direction • Provide expert, authoritative and evidence based advice • Staff engagement • Recommend and gain endorsement for plans and goals and other initiatives
Work area team members	<ul style="list-style-type: none"> • Provide expert advice and analysis on a full range of matters • Contribute to group decision making processes, planning and goals • Collaborate and share accountability • Negotiate and resolve conflicts
Direct Reports	<ul style="list-style-type: none"> • N/A
Other departments (name)	<ul style="list-style-type: none"> • Liaise for the purpose of seeking expert advice in a timely manner. • Keep key external stakeholders informed of key developments and issues.
External	
ARAPNSA	<ul style="list-style-type: none"> • Liaise for the purpose of open and honest communication, and developing relations built on trust and respect.

POSITION DIMENSIONS

Licensing Officer reports to Regulatory and Medical Affairs Manager.

Staff Data	
Reporting Line	Reports to the Regulatory and Medical Affairs Manager.
Direct Reports	Nil
Indirect Reports	Nil

Financial Data	
Revenue / Grants	
Operating Budget	
Staffing Budget	
Capital Budget	
Assets	

Special / Physical Requirements	
Location:	Lucas Heights (ANM and Health) Working in different areas of designated site/campus as needed
Travel:	May be required travel to ANSTO sites from time to time Frequent travel to ANSTO sites within Australia Frequent travel both internationally and nationally Field work in remote locations

Physical:	Office based physical requirements (sitting, standing, minimal manual handling, movement around office and site, extended hours working at computer) Standing for long periods Public speaking
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 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

Specific role/s as specified in <u>AP-2362</u> of the ANSTO WHS Management System	All Workers Officer (definitions found in appendix A of AP-2362) Group Executive / General Manager Managers / Leaders / Supervisors 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

attached

KNOWLEDGE, SKILLS AND EXPERIENCE

1. Degree in Engineering or Science or equivalent experience
2. Thorough understanding of analytical, technical and general engineering terms.
3. Familiarity with the Australian nuclear regulatory regime and with the ANM and Health Products safety cases.
4. An understanding of the implementation of safety management systems and safety/risk assessment methodologies and processes.
5. Developed technical writing skills including attention to detail coupled with an understanding of ANSTO's operations to enable contribution to briefs, including responses to Government, ministerial and departmental enquiries.
6. Reliable and deadline driven, to proactively following through, when attending to ANSTO and customer interests within budget.
7. Excellent communication and negotiation skills with the ability to share information and contribute to the team's project planning and activities and interact with staff and stakeholders of varying backgrounds and experiences to establish productive working relationships.
8. Project management skills include setting goals and objectives, leading negotiations and motivating multi-disciplinary or specialist project teams, monitoring and reviewing work.
9. A good understanding of AS 4801 safety management, ISO 9001 quality management and ISO 14001 environmental management principles.
10. Experience using database software for reporting 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:	Aman Sharma	Name:	Ian Martin
Title:	Regulatory and Medical Affairs Manager	Title:	General Manager, Nuclear Medicine
Signature:		Signature:	
Date:		Date:	