



POSITION DESCRIPTION

Position Title:	Periodic Safety Review Coordinator
Cluster / Business Unit / Division	Nuclear Operations Nuclear Medicine
Section or Unit:	Nuclear Medicine
Classification:	Band 6
Job Family:	Compliance & Regulation
Position Description Number:	PD-2274
Work Contract Type:	Professional
STEMM/NON-STEMM:	NON-STEMM

POSITION PURPOSE

The key purpose of the position is to undertake compliance activities as per organisation's ARPANSA licence condition relating to the Periodic Safety Review (PSR).

The position ensures that a review of the periodic safety of the facility is undertaken as per the ARPANSA licence conditions. This involves coordination, work-planning, time-line allocation, regular monitoring, review and finalisation of the reports required for the completion of the review. This role will also monitor, track and ensure that the progress and quality of the reports are to the agreed acceptable requirements, providing feedback on the reports to key stakeholder during the completion of the task assignments and in the preparation of the reports.

The PSR Coordinator ensures that the plans and the reports are prepared, approved and issued in time for submission to ARPANSA as per agreed timeframes.

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 is a business unit within ANSTO engaged in the manufacture and sales of radiopharmaceutical and radiochemical products.

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

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities

- Initiate and develop detailed plans for the conduct of the periodic safety review as per the requirements of the ARPANSA Licence Conditions.
- Seek advice and coordinate with other subject matter experts at ANSTO to manage the completion of the periodic safety review.

- Lead and manage all aspects of the periodic safety review project, including finalising the draft plans, getting the plans approved, identifying and allocating resources and establishing timelines and performance.
- Identify and analyse any PSR process/procedural gaps and/or continuous improvement opportunities and develop and implement solutions to address.
- Coordinate completion of the identified tasks from the periodic safety review work plans with the task owners to meet agreed timeframes, ensure on-going tracking and monitoring of the progress and flagging any issues / delays in a timely manner.
- Review of the periodic safety reports and coordination of the review with key stakeholders and approvers, identification and communication of the issues with the task owners for rectification and revisions.
- Allocate actions identified from the review into GRC and assign resources, organise key-stakeholder consultations.
- Participate in meeting with ARPANSA on the progress of the periodic safety review.
- Finalise the periodic safety plans and reports, issuance in master control for communication to ARPANSA.
- 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 methods and approaches, operations, project planning and allocation of resources.
- The PSR coordinator works within the ANSTO values, organisational corporate plan, business plan, operational excellence program, the Nuclear Medicine strategy and objectives.
- The position is 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 position is to determine key work priorities within the context of agreed periodic safety review work plans and will consult with the key stakeholder on complex, sensitive and major issues that have a significant impact on the timely completion of the periodic safety review.
- 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

- Finalise periodic safety review plans that meet the requirements of the licence conditions, have been agreed with key ANSTO stakeholders and ARPANSA.
- Ensuring the successful completion of plans and the reports through coordination and working with key stakeholders, whilst managing conflicting priorities and deadlines.
- Keeping abreast of challenges in the timely completion of the project, ensuring that key stakeholder feedback (including ARPANSA's) is incorporated in a timely manner to prevent any delays in the completion of the project.
- Maintaining a steady pace of work, considering the variety of stakeholder involvement, with the nuclear medicine business and from within ANSTO.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Manager/Executive	<ul style="list-style-type: none"> • Receive guidance and direction • Provide expert, authoritative and evidence-based advice • Stakeholder engagement • Negotiate and report on timelines and resources consistent with plans and goals of the project • Recommend and gain endorsement for plans, goals and report
Work area team members	<ul style="list-style-type: none"> • Provide expert advice on the project requirements • Coordinate on timelines and project requirements. • Contribute to decision making processes, planning and goals • Collaborate and share accountability • Engage to monitor trends, ensure performance and progress against the SR plan and evaluate further support which may be required to ensure delivery against the plan
ANSTO Systems safety and high reliability, radiation protection, health physics	<ul style="list-style-type: none"> • Discuss and seek advice on aspects of SSCs (Structures, Systems and Components), OLCs (Operating Limits and Conditions), and CCs (Critical controls) • ANSTO enablers, high reliability group to seek advice on radiation protection and health physics areas of the PSR. • Liaison with OPAL who have previous experience of conducting the periodic safety reviews.
External	
ARPANSA	<ul style="list-style-type: none"> • Participate in meetings on the progress of the periodic safety review.

POSITION DIMENSIONS

The PSR Coordinator largely works independently seeking advice from the licensing officer and the regulatory manager for the completion of the periodic safety review as per ARPANSA licence condition.

The PSR coordinator ensure that the project is complete within the project timeframe and budget allocations.

Staff Data	
Reporting Line	Reports to the Regulatory Affairs Manager
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, minimal manual handling, movement around office and site, extended hours working at computer) 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
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) 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

On file

KNOWLEDGE, SKILLS AND EXPERIENCE

1. An engineering or science degree and experience in manufacturing, engineering, safety or regulatory environments or equivalent demonstrated experience.
2. Demonstrated experience in successful management of projects that requires key stakeholder involvement, periodic deliverables, and completion to agreed timelines.
3. Proven experience in setting out project requirements, leading and managing the completion of these activities with key stakeholders to achieve desired organisational outcomes, and optimal work performance.
4. Experience guiding, developing and mentoring staff to deliver review reports against agreed work plan areas identified for the periodic safety review.
5. Demonstrated experience in managing effective relationships with key stakeholders and making sure that project timelines are communicated and monitored over the duration of the project.
6. Ability to identify, analyse and prioritise key tasks required for successful completion of the project, and an ability to identify key resources that may be required for their completion for the most optimal results.
7. Demonstrated ability to initiate and manage change, allocate resources effectively and identify and manage risks in line with and as required per Nuclear Medicine and ANSTO procedures
8. The PSR coordinator will be required to communicate and liaise with various staff within the Nuclear Medicine business and with staff from ANSTO, hence a high level of communication, interpersonal, negotiation, influencing, and strategic planning skills will be required.

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 Affairs Manager	Title:	GM Nuclear Medicine Products
Signature:		Signature:	
Date:		Date:	

Coordinate safety assessment of ANSTO's Nuclear Medicine facility with the purpose of safety, reliability and compliance.

Strong compliance focus with an ability to work with people and guide them through the periodic safety assessment process in order to achieve project milestones as per agreed timeframes.

Plan the tasks required for the completion of the PSR, allocate resources and timeframes. Ability to work with people, provide information succinctly and regular follow ups. Ability to write and review reports for regulatory submissions.