POSITION DESCRIPTION

Position Title:	Principal Radiochemist (Core Product Manager)
Cluster / Business Unit / Division	Nuclear Science & Technology
Section or Unit:	Biosciences
Classification:	Band 8
Job Family:	Research
Position Description Number:	PD-2266
Work Contract Type:	Research and Science
STEMM/NON-STEMM:	STEMM

POSITION PURPOSE

The primary objective of the Principal Radiochemist (Core Product Manager) is to support the translation and improvement of ANSTO's nuclear medicine products. The position will manage and undertake manufacture development and optimisation to improve the reliability, profitability, and agility of ANSTO's Nuclear medicine core products to meet varying and challenging demand. The position also supports late-stage scale-up manufacture to enable the translation of new products for clinical research or commercialisation. The role will also make a significant contribution towards the redevelopment of ANSTO's nuclear medicine manufacturing processes of its core products and design. This will include the commissioning of new infrastructure. The position holder uses expertise and experience to build and utilise internal networks across NST, Nuclear Medicine businesses and international collaborators for the delivery of high impact outcomes, contributing to ANSTO's strategic imperatives.

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 radiochemistry group provides a wide range of capabilities to enable the radiochemistry research and development team to deploy the delivery of radiopharmaceuticals, radioisotopes, advanced manufacturing

methods and radioisotope separations. The radiochemistry core product team supports the renewal and improvement of nuclear medicine products, including process trouble shooting for end stage nuclear medicine manufacturing. The team leads late-stage manufacture development prior to process validation and support data for new products destined for commercialisation or clinical research support. The team utilises automated radiosynthesis modules and custom-built remote handling technologies in GLP or GMP environments, to improve ANSTO's nuclear medicine products or enable the delivery of new radiopharmaceuticals and radioisotopes. The nuclear medicine core product team works in close cooperation and collaboration with the radiopharmaceutical and radioisotopes development and translation teams and the ANSTO's Nuclear Medicine team.

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities

- Provide specialist expertise in reactor produced radioisotopes and or radiopharmaceuticals to improve or renew radiochemical manufacture, leading to product reliability, profitability, and agility.
- Responsible for identifying radiochemical manufacturing solutions, improvements and troubleshooting issues. Researching information, analysing issues, drawing accurate conclusions based on evidence, and provides links between issues to break them down to weigh up options. Explores possibilities to identify solutions and to anticipate problems.
- Lead end stage translation of new radiopharmaceutical and radioisotope manufacture for product commercialisation or clinical research provision. Evaluate, validate, and execute new and improved manufacture methods for routine supply of radiopharmaceuticals and radioisotopes, using sound knowledge of the principles of Good Manufacture Practice (GMP).
- Drive the creation and development of technologies, that supports sustainable manufacture of nuclear medicine products, which includes proposing research or development programs, negotiating resources, development of work plans and ensuring completion of activities.
- Lead the Core Products team through appropriate staff, resource and project management in a manner that reflects and achieves the present and future direction of ANSTO including responsibility for setting objectives, managing performance, and conducting performance assessment and career development.
- Responsible for the management of radiochemistry translation facilities and equipment through an asset management framework and assist with the capital development program to ensure the availability and utilisation of capabilities, meeting operational safety, security, sustainability and compliance requirements within applicable standards, legislation, and regulations.
- Responsible for the development and maintenance of quality, safety, and compliance programs. Write SRA, SWMES, work instructions and procedures for equipment usage and for safe experimental practice, validation records and protocols.
- Ensure equipment is used properly, safely and in accordance with ANSTO policies and procedures.
- Maintain accurate records to meet regulatory and quality requirements, including radioactive sample and chemical registers, to ensure inventory and relevant safety documentation (Materials Safety Data) are kept up to date.
- Develop and maintain extensive national and international networks to represent ANSTO and identify and secure collaborative research opportunities with strategic partners including international government radiochemical research and manufacturing laboratories, universities, and industry.
- Lead the preparation of scientific reports, publish papers, reports, patents, and abstracts, presenting results in national and international forums.
- 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 for the radiochemistry team within the context of agreed work plans and in consultation with the Manager, Radiochemistry and Radiochemistry Capability Managers.
- 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.
- 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

- Balancing operational and strategic demands in highly complex, heavily regulated, and dynamic environment to ensure successful delivery of agreed objectives.
- Working in a complex environment on parallel projects and influencing multidisciplinary teams to deliver high impact outcomes.
- Championing the renewal of the high value capital equipment fleet through the Biosciences Asset Management Plan to ensure the sustainability of radiochemical manufacture capabilities, in a competitive and resource-constrained environment.
- Building high quality professional international networks with other radiochemists to share knowledge and experience and build relationships to identify and implement opportunities for improvement in facilities and operations.
- Understanding and balancing the different expectations from a variety of users, collaborators, and partner communities, particularly ANSTO nuclear medicine businesses and the external nuclear medicine community.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Manager, Radiochemistry, Biosciences, NST	• Receive broad guidance and direction. • Receive performance requirements consistent with the business plan and objectives. • Report on compliance of the instrumentation. • Provide advice on operational and capital budgetary requirements. • Recommend and gain approvals for facility modifications, enhancements, improvements, and process/procedure changes or improvements. • Escalate issues and propose solutions. • Provide regular updates on key tasks, issues, and priorities. • Provide expert, authoritative and evidence-based advice.
Radiochemistry and Nuclear Medicine Team Members	• Determine work priorities. • Deliver to the business plan. • Lead team members and work collaboratively to contribute to the delivery of high impact outputs. • Provide expert scientific advice, analysis, and leadership.

	• Influence and shape group decision making processes, planning, and goals. • Collaborate and share accountability. • Identify and negotiate solutions to conflicting demands on resources.
Direct Report	• Provides guidance, direction, and advice. • Provides performance requirements consistent with business plans and objectives. • Monitor and evaluate performance. • Provide regular updates on key tasks, issues, and priorities. • Allocate tasks, set task priorities to ensure smooth and effective operation of laboratory and maximise user experience.
External	
Facility Contractors	• Oversee and direct service technicians and contractors undertaking maintenance or repair works within the facility.
ANSTO Nuclear Medicine and NST Subject Matter Experts	• Collaborate and share knowledge. • Provide expert advice, analysis, and leadership.

POSITION DIMENSIONS

Staff Data	
Reporting Line	Radiochemistry Group Manager
Direct Reports	1 x Principal Radiochemist (Core Product)
Indirect Reports	3 x Radiochemists

Financial Data (2022/2023)	
Revenue / Grants	NA
Operating Budget	NA
Staffing Budget	NA
Capital Budget	NA
Assets	NA

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

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 AP-2362 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

ORGANISATIONAL CHART

Refer to published Organisational Chart.

KNOWLEDGE, SKILLS AND EXPERIENCE

1. PhD in radiochemistry, inorganic, organic or medicinal chemistry, pharmaceutical sciences, or Degree plus equivalent experience.
2. Extensive knowledge and experience with the manufacture of radiopharmaceuticals and or radioisotopes, their development and radioanalytical measurement.
3. Extensive knowledge and experience with [131I]radioiodine, [177Lu]lutetium, [Tc99m]generators development and handling and or with reactor or cyclotron-based radioisotope separations.
4. Good knowledge and demonstrated ability in the manufacture, QC and QA of radiopharmaceuticals and or radioisotopes using GMP standards, PIC/S, ISO, BP, USP standards.
5. Significant experience and knowledge in a senior role within the development of radiopharmaceuticals and or radioisotopes, radiolabelling methods, optimisation, characterisation, and stabilisation.
6. Proven experience in leading and managing staff, including coaching and mentoring skills. Provide constructive feedback on performance, as well as give advice and guidance on ways of developing skills, knowledge, and experience.
7. Strong project management experience, including the co-ordination of the work of other staff, effective deployment of resources, ability to manage multiple tasks, priority management and organisational skills.
8. Proven experience ensuring own, and work of others complies with quality, safety, standards, regulatory and statutory requirements ideally gained through working within a highly regulated manufacturing environment.
9. Demonstrated high level interpersonal, communication and negotiation skills with the capacity to influence key decision-makers.
10. Proven experience to develop and maintain productive working relationship with a wide variety of staff, commercial and academic partners, and regulators.
11. Demonstrated research leadership and publication track record in radiopharmaceutical and or radioisotope manufacturing method development.

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: Ivan Greguric	Name: John Bennett

Title: Group Manager, Radiochemistry	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